

# THE GOVERNMENT CONTRACTOR®

Information and Analysis on Legal Aspects of Procurement



THOMSON  
REUTERS®

Vol. 64, No. 7

February 16, 2022

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### FEATURE COMMENT: The Top FCA Developments Of 2021

While 2021 marked the second year of the global COVID-19 pandemic, it was business as usual with respect to the False Claims Act, with significant recoveries attained and hundreds of new cases filed. In addition to important case law developments involving the Government's dismissal authority, materiality, pleading requirements, scienter, and more, the year was marked by the announcement of a new initiative to use the FCA to enforce cybersecurity protocols as well as the introduction of several potential amendments aimed at strengthening the FCA. As always, this Feature Comment highlights these and other top FCA developments and looks ahead to what's in store in 2022.

**Recovery Statistics and Notable Settlements**—Department of Justice recoveries and settlements in FCA matters in fiscal year 2021 exceeded \$5.6 billion. While this represents the second-highest annual recovery total ever, some \$3.2 billion of that comes from various opioid crisis settlements, including a \$2.8 billion general unsecured bankruptcy claim against Purdue Pharma. With that context, the recovery numbers—though still large—represent more of a typical if not below average year. It is also notable that the lion's share of the recoveries came from healthcare fraud actions, as less than \$600 million was recovered in matters involving Department of Defense and other non-healthcare agencies.

A total of 801 new actions were brought in FY 2021. This does not match the staggering 934 new actions of the prior year, but it is consistent with the trend of past years. That said, the number of relator-initiated cases (598) is the lowest it has been

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since 2010, while the 203 cases brought directly by the Government is the second-highest total in more than 20 years. And because more than half of the new Government-initiated actions involve non-healthcare claims, contractors should not take the lopsided recovery totals as a sign that DOJ's enforcement priorities are solely healthcare-based. Indeed, DOJ touted multiple procurement fraud recoveries, including a \$50 million settlement with Navistar Defense LLC concerning allegations of fraudulent inducement with respect to the pricing of a contract modification for armored vehicles, a \$25 million settlement with Insitu Inc. regarding allegations of false cost and pricing data, and an \$18.9 million settlement with Cognosante LLC concerning unqualified labor and billing allegations on two General Services Administration contracts.

On the whole, the numbers again reinforce that the FCA is DOJ's most powerful civil fraud enforcement and recovery tool. And DOJ is expanding its focus on procurement fraud matters, the latest sign of which is the launch of a new cybersecurity initiative that will likely increase scrutiny on contractors for years to come.

**Pending Amendments to the FCA**—On July 26, 2021, a bipartisan group of senators, led by Sen. Chuck Grassley (R-Iowa), introduced a bill entitled “False Claims Amendments Act of 2021” (S. 2428) aimed at “beef[ing] up the government's most potent tool to fight fraud.” Sen. Grassley has been vocal about his displeasure that the Judiciary, including the Supreme Court, has weakened the FCA in recent years by (1) affording DOJ too much deference with respect to its authority to dismiss qui tam lawsuits; and (2) misapplying the FCA's materiality standard in *Universal Health Servs. v. U.S. ex rel. Escobar*, 579 U.S. 176 (2016); 58 GC ¶ 219, and its progeny. In 2021, Grassley remarked that the FCA should provide the Government with the tools “to come down with a sledgehammer, not a toothpick,” and stated in a press release that one of the primary goals of the proposed Amendments was to resolve “confusion” caused by *Escobar* concerning the required element of materiality.

To accomplish the goal of strengthening the FCA's provisions, the July version of the False Claims Amendments Act of 2021 proposed several new provisions, as follows:

**Materiality:** The amendments would add a new paragraph (e) to 31 USCA § 3729 titled “Proving

Materiality” (1) specifying that the Government or a relator may establish materiality by a preponderance of the evidence and (2) adding that a defendant may only rebut an “argument of materiality” by “clear and convincing evidence.”

**Discovery on the Government in Declined Cases:** The amendments would add a new paragraph (f) to § 3731's procedures that would include non-intervened qui tam cases and direct that “the court shall, upon a motion by the Government, order the requesting party to pay the Government's expenses, including costs and attorney's fees, for responding to a party's discovery requests, unless the party can demonstrate that the information sought is relevant, proportionate to the needs of the case, and not unduly burdensome on the Government.”

**Government Dismissal Authority (§ 3730(c)(2)(A)):** The amendments would add new language to § 3730(c)(2)(A) concerning the hearing to be afforded to a relator facing a Government motion to dismiss in a non-intervened case, specifying that “at [the hearing] the Government shall have the burden of demonstrating reasons for dismissal, and the relator shall have the opportunity to show that the reasons are fraudulent, arbitrary and capricious, or contrary to law.”

**FCA Retaliation (§ 3730(h)(1)):** The amendments would add the words “current or former” to § 3730(h)(1) to make the FCA's anti-retaliation provision applicable to acts taken against “[a]ny current or former employee, contractor, or agent.”

**Retroactivity:** The amendments would apply prospectively to any case filed on or after the date of enactment as well as retroactively to any case “pending on the date of enactment of this Act.”

After much discussion and criticism, this version of the amendments stalled in Congress. Then, in August 2021, a version of the proposed amendments appeared, and then disappeared, from the Bipartisan Infrastructure Deal (Infrastructure Investment and Jobs Act), and was not included in the version of the bill that passed in November 2021 as P.L. 117-58. This signaled that the controversial changes were not going to be passed by Congress as a late addition to a broad and significant piece of legislation.

A significantly pared down version of the legislation was introduced on Oct. 26, 2021, and cleared the Senate Judiciary Committee by a 15–7 vote on Nov. 9, 2021. The diluted version dropped the dis-

covery fee-shifting provision, the burden-shifting materiality standard, and the proviso that the amendments would apply retroactively. It retained the expansion of the retaliation clause to “former” employees, and offered new changes on materiality and the Government’s dismissal authority. On materiality, the revised version would add “(e) PROVING MATERIALITY.—In determining materiality, the decision of the Government to forego a refund or to pay a claim despite actual knowledge of fraud or falsity shall not be considered dispositive **if other reasons exist** for the decision of the Government with respect to such refund or payment.” (emphasis added). This change, if passed, would feed a debate already occurring in some cases as to what factual predicate should be required for allegations by a relator of such “other reasons.” Were courts to interpret this provision to mean that a relator need only posit his own ideas as to why the Government continued to pay in the face of purportedly material noncompliance, the “rigorous” materiality standard espoused by the Supreme Court in *Escobar* would be significantly weakened.

As for the Government’s dismissal authority, the Committee version of the proposed amendments to § 3730(c)(2) would require the Government to “identify a valid government purpose and a rational relation between dismissal and accomplishment of the purpose, and the person initiating the action shall have the burden of demonstrating that the dismissal is fraudulent, arbitrary and capricious, or illegal,” essentially codifying the Ninth Circuit’s standard set forth in *Sequoia Orange Co. v. Baird-Neece Packing Corp.*, 151 F.3d 1139 (9th Cir. 1998).

Even with the recent passage out of the Senate Judiciary Committee, there is still a long road before any amendments to the FCA are codified and effective. Proposed amendments to the FCA remain a key issue to watch in 2022.

**COVID-19 Fraud and Enforcement**—During 2021, DOJ maintained its focus on COVID-19 related fraud. Since the COVID-19 outbreak in March 2020, Congress has passed several measures to provide trillions of dollars in financial relief to individuals and businesses and created new oversight bodies to investigate and root out potential fraud and abuse. These bodies include the Office of the Special Inspector General for Pandemic Recovery (SIGPR), responsible for conducting investigations and making reports related to loans made under

the CARES Act; and the Pandemic Response Accountability Committee (PRAC), composed of 21 existing agency inspectors general whose mission is to prevent and detect fraud, waste, abuse and mismanagement in connection with funds distributed pursuant to the CARES Act.

On Feb. 3, 2021, the PRAC issued an update to its first report issued in June 2020. The PRAC identified four key challenges with respect to the administration of relief funds: (1) preventing and detecting fraud against Government programs; (2) informing and protecting the public from pandemic-related fraud; (3) data transparency and completeness; and (4) federal workplace safety. Notably, the report lists two primary contributing factors to the challenge of preventing and detecting fraud: (1) self-certification of compliance with the threshold requirements by funding applicants; and (2) lack of due diligence into applicants by Government agencies as well as lenders. Two days before the release of the PRAC update, SIGPR issued its quarterly report to Congress summarizing its efforts to “aggressively” identify fraud, waste, and abuse. So far, those efforts have (1) identified investigative leads for suspected CARES Act fraud, 69 of which have been referred to law enforcement; (2) initiated five investigations, three of which are being handled with U.S. attorneys’ offices; (3) vetted 27 complaints and referred two to law enforcement; and (4) developed “risk scores” for the Main Street Lending Program to help identify potentially fraudulent activities.

The PRAC update and SIGPR report confirmed the rising tide of civil enforcement activity with respect to pandemic relief funds that occurred in 2021, especially as it relates to funds dispersed under the CARES Act, and in particular the Paycheck Protection Program (PPP). DOJ announced several settlements related to PPP fraud last year beginning in January 2021. In the first settlement, announced Jan. 12, 2021, SlideBelts Inc., an internet retail company, and Brigham Taylor, the company’s president and CEO, agreed to pay \$100,000 to resolve claims that the company had violated the FCA and the Financial Institutions Reform, Recovery and Enforcement Act by making false statements regarding whether the company was presently involved in any bankruptcy, which induced banks to approve, and the Small Business Administration to guarantee, PPP loans. On April 21, 2021,

DOJ announced a second settlement for \$70,000 in damages and penalties with Sandeep S. Walia, M.D., a Professional Medical Corp. (Walia PMC), and its owner, Dr. Walia, to resolve allegations that it falsely certified in a second loan application that it had not previously received a PPP loan, although it had already received one from a different lender. Walia PMC also agreed to repay the second PPP loan for \$430,000.

Notably, in late August DOJ announced the first FCA settlement to arise out of a *qui tam* action in *U.S. ex rel. Hablitzel v. All in Jets, LLC & Seth A. Bernstein*. The owner of the defendant jet charter company agreed to pay \$287,055 to resolve allegations that he misappropriated PPP loan proceeds for his personal expenses. The claims were brought by a former employee who served as a senior accountant and assistant controller for the company. In the midst of these settlements, on May 27, 2021, Attorney General Merrick Garland announced the creation of the COVID-19 Fraud Enforcement Task Force, charged with “bring[ing] together the full power of the federal government to bolster” DOJ’s enforcement efforts against the various kinds of fraud associated with the pandemic.

The recent settlements, creation of the Task Force, and continued flow of whistleblower complaints made to the national hotline dedicated to COVID-19 fraud reinforce that pandemic-related fraud was at the top of the Civil Division’s enforcement priorities for 2021. While the number of civil actions and amount of recoveries to date have been anything but staggering, anecdotal evidence suggests that more significant actions are currently under seal or being investigated, and 2022 may see some of those come to light publicly.

**Cybersecurity Initiative Launch**—In 2021, the Government continued to increase its focus on strengthening its cybersecurity defense posture and commitment to pursue contractors for failing to meet or falsely certifying compliance with new and developing cybersecurity standards. In May 2021, the Biden Administration issued a detailed Executive Order on Improving the Nation’s Cybersecurity, calling for the creation of new cybersecurity standards, as well as updates to Federal Acquisition Regulation and Defense FAR Supplement-based contract requirements, affecting both information and operational technology. To complement and supplement these efforts, on Oct. 7, 2021, DOJ

announced its new Civil Cyber-Fraud Initiative, focused on civil enforcement against Government contractors that fail to follow cybersecurity contract requirements. The initiative, led by the Civil Division’s Commercial Litigation Branch and Fraud Section, will use the FCA to combat cyber threats to sensitive information and critical systems by enforcing the Government’s contractual cybersecurity standards. The initiative will hold accountable contractors that knowingly (1) provide deficient cybersecurity products or services, (2) misrepresent cybersecurity compliance, or (3) fail to monitor and report cybersecurity incidents in accordance with contract requirements.

Acting Assistant Attorney General Brian Boynton confirmed DOJ’s intent to aggressively enforce cybersecurity compliance during a Cybersecurity and Infrastructure Security Agency event on Oct. 13, 2021, and stated that DOJ “expect[s] whistleblowers to play a significant role in bringing to light knowing failures and misconduct in the cyber arena.” He emphasized three common cybersecurity failures that are prime candidates for enforcement: (1) knowing failure to meet specific contract terms, such as standards that require contractor measures to protect Government data, restrict non-U.S. citizen employees from accessing systems, or avoid using components from certain foreign countries; (2) knowing misrepresentation of security controls and practices, such as representations about a system security plan detailing the security controls it has in place, the company’s practices for monitoring its systems for breaches, or password and access requirements; and (3) knowing failure to timely report suspected breaches.

Importantly, Boynton asserted that the FCA was a “natural fit” for pursuing the knowing failure to comply with cybersecurity requirements because it “deprives the government of what it bargained for,” and that a contractor’s knowing misrepresentation of security controls and practices “may cause the government to choose a contractor who should not have received the contract in the first place.” These remarks suggest that the Government may pursue some types of cybersecurity shortcomings under a fraud-in-the-inducement theory, which carries the threat of potentially massive damages. Under this theory, the Government would assert that a contractor’s misrepresentation of compliance with cybersecurity requirements at the outset

fraudulently induced the Government to enter the contract, which entitles it to recover civil penalties on every single claim for payment submitted over the life of the contract, in addition to treble damages the Government suffered as a result of the fraud.

The benefits of the initiative articulated in DOJ's announcement and in Boynton's remarks include (1) improving overall cybersecurity practices and helping to prevent cybersecurity intrusions across the Government, the public sector and key industry partners; (2) holding contractors and grantees to their commitments to protect Government information and infrastructure; (3) ensuring a level playing field; (4) supporting the work of Government experts to timely identify, create, and publicize patches for vulnerabilities in commonly used information technology products and services; and (5) reimbursing the taxpayers for the losses incurred when entities or individuals fail to satisfy their cybersecurity obligations.

Deputy Attorney General Lisa O. Monaco also highlighted the Government's increased focus on protecting the country's national and economic security by strengthening its cybersecurity and holding contractors accountable in her opening remarks at DOJ's Criminal Division cybersecurity roundtable on Oct. 25, 2021. Monaco outlined DOJ's maturing approach to fighting cybercrime, which included a specific focus on the heightened responsibility of Government contractors. She stressed that a contractor's failure to "follow required cybersecurity standards, or misrepresent their cybersecurity practices or capabilities" is unacceptable, and vowed to "go after that behavior." Monaco also made a direct appeal to work cooperatively with private industries.

The developments should come as little surprise to defense contractors and information technology companies that maintain protected Government information, as the Government has previously noted this was a priority area and has used the FCA to prosecute cybersecurity breaches in the past. As just one example, in August 2019, Cisco Systems Inc. agreed to pay more than \$8.6 million to settle allegations in *U.S. ex rel. Glenn v. Cisco Sys. Inc.*, No. 1:11-cv-0400 (W.D.N.Y.), that it violated the FCA by selling video surveillance systems to state and federal agencies that contained software flaws that exposed those agencies to potential cyber intruders and failed to inform Government agencies that the

software did not comply with Federal Information Security Management Act standards.

Nevertheless, the launch of the new initiative signals that DOJ is putting more resources and attention on such matters, which will undoubtedly incentivize would-be relators as well. Many unsuspecting entities may find themselves in the crosshairs as new cybersecurity requirements are implemented as part of the DOD Cybersecurity Maturity Model Certification program and in response to the Executive Order on Improving the Nation's Cybersecurity. Accordingly, we expect to see an uptick in FCA investigations, settlements, and litigation concerning cybersecurity issues, increased coordination among Government agencies, and increased interest in the relator's bar for such *qui tam* actions.

**The Ongoing Circuit Split on Government Dismissal Authority**—While Grassley's proposal to amend § 3730(c)(2)(A) remains at bay, two more circuits last year weighed in on the Government's power to dismiss non-intervened *qui tam* actions. At the end of 2020, there were three competing standards under which circuits review the Government's FCA dismissal authority: (1) the "unfettered discretion" standard from *Swift v. U.S.*, 318 F.3d 250 (D.C. Cir. 2003); (2) the "valid purpose" test from *U.S. ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp.*, 151 F.3d 1139 (9th Cir. 1998), which requires the Government to demonstrate that the dismissal has a rational relation to a valid Government purpose, and which has been adopted by the Tenth Circuit as well; and (3) the most recent standard enumerated in *U.S. ex rel. CIMZNHCA v. UCB, Inc.*, 970 F.3d 835 (7th Cir. 2020); 62 GC ¶ 254, under which the Government has an absolute right to dismiss a *qui tam* action under Fed. R. Civ. P. 41.

In 2021, the Third and Eleventh Circuits entered the fray and cemented the Seventh Circuit's *UCB* test as the third position in the ongoing circuit split. First, in *Polansky v. Exec. Health Res. Inc.*, 17 F.4th 376 (3d Cir. 2021); 63 GC ¶ 348, the Third Circuit affirmed the grant of the Government's motion to dismiss alleged violations of the FCA based upon over-admission for in-patient services. On appeal, the Third Circuit held that the Government must meet only the standard articulated in Fed. R. Civ. P. 41(a) to exercise its dismissal power, as articulated by the Seventh Circuit in *UCB*. Rule 41(a) articulates different standards for a dismissal

by a plaintiff depending on the procedural posture of the case: (1) if the motion is filed before the defendant files an answer or motion for summary judgment, the plaintiff is entitled to an automatic and immediate dismissal upon filing notice with the court; and (2) in contrast, once a defendant has filed a responsive pleading, the case is considered past the “point of no return,” and a plaintiff may move to dismiss only with leave of the court “on terms that the court considers proper.” While a district court has wide discretion, the Third Circuit suggested that dismissal will generally be granted upon the Government’s showing of “good cause,” which it found easily satisfied in the case before it, in spite of how far the case had progressed.

On the penultimate day of the year, in *U.S. v. Republic of Honduras*, 21 F.4th 1353 (11th Cir. 2021), the Eleventh Circuit held similarly in affirming a district court’s decision to grant the Government’s motion to dismiss. The Eleventh Circuit held that the Government does not have to formally intervene before moving to dismiss a qui tam action, even if it has already declined to intervene. And “decisions to dismiss are within the province of the Executive Branch subject only to limits imposed by the Federal Rules of Civil Procedure, a statute, or the Constitution.” Citing *UCB*, the Court noted that “these are generous limits that would be breached rarely if ever.”

Furthermore, just weeks into 2022, another circuit decision has issued that provides yet another deferential standard for dismissal by the Government. In *Borzilleri v. Bayer Healthcare Pharms., Inc.*, 2022 WL 190264, at \*1 (1st Cir. Jan. 21, 2022), the First Circuit affirmed the lower court’s dismissal of the relator’s qui tam over the relator’s objections. The First Circuit held that a Government motion to dismiss a non-intervened qui tam should be denied only when a relator can show (1) that the Government’s decision to seek dismissal of the qui tam action “transgresses constitutional limitations” or (2) that, in moving to dismiss, the Government is “perpetrating a fraud on the court.”

While the tests do not all look exactly the same, the trendline is clearly toward affording near absolute deference to the Government’s ability to determine, as the real party in interest, whether a qui tam action that the Government is not interested in pursuing should be permitted to proceed. That said, that trend could be upset if Grassley’s proposed

amendment passes and codifies the Ninth Circuit’s *Sequoia Orange* standard, or if the Supreme Court takes up the issue, which the relator in *Polanksy* has asked it to do. Even if the rational relation / valid purpose test becomes law, even that standard hardly creates a difficult burden for the Government to meet.

**Materiality**—Materiality remains a key area of focus in FCA litigation, now in the fifth year since the Supreme Court’s landmark decision in *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 579 U.S. 176 (2016). Whether at the pleading stage, summary judgment, trial or on appeal, this element—as its name suggests—is now regularly the essential factor upon which the viability or merits of an FCA case turns. In a notable case this past year, *U.S. ex rel. Foreman v. AECOM*, 19 F.4th 85 (2d Cir. 2021), the Second Circuit applied *Escobar* and its own 2020 decision in *U.S. v. Strock*, 982 F.3d 51 (2d Cir. 2020); 63 GC ¶ 19, to uphold the dismissal of certain claims for failure to meet the FCA’s materiality requirement in a case alleging improper billing and noncompliance with respect to utilization rates and property tracking. The Second Circuit first rejected the relator’s argument that *Escobar*’s materiality analysis applies only to implied certification claims, holding instead that it sets forth the standard for all FCA claims. Second, the Court ruled that a provision denoting compliance with “all terms of the contract” as a condition of payment did not weigh in favor of materiality because it failed to put the contractor on notice of the importance of the particular requirements at issue.

Continuing its analysis, the Second Circuit found that the Government’s continued payment and extensions of the contract in spite of its knowledge of the contractor’s noncompliance, based on the complaint’s allegations and Defense Contract Management Agency corrective action reports integral to the complaint, undermined materiality. While the Court acknowledged the possibility of circumstances under which the Government might continue to pay in spite of such knowledge, it noted that it was the relator’s burden to plead them. Last, the Second Circuit expanded upon its analysis from *Strock* of the requirement that the alleged violation be substantial. The Court explained that substantiality requires a showing that there are sufficiently widespread deficiencies in the contractor’s performance that go to the heart of the bargain, such that

any regulatory, statutory, or contractual violations would likely affect the Government's payment decision. Although this factor weighed "modestly" in favor of materiality for the property tracking allegations, the Second Circuit found that was not enough to adequately plead materiality. It reversed dismissal only as to the labor billing allegations because the lower court had improperly relied upon evidence outside the complaint in dismissing those parts of the relator's claim. *Foreman* has multiple important and helpful takeaways for defendants in challenging materiality at the pleading stage, not the least of which is its recognition that it is the relator's burden to plead factual allegations to support materiality.

In contrast, in *U.S. ex rel. Bibby v. Mortgage Investors Corp.*, 987 F.3d 1340 (11th Cir. 2021); 63 GC ¶ 63, the Eleventh Circuit reversed a grant of summary judgment where genuine issues of material fact existed as to materiality of an allegedly false certification to the Department of Veterans Affairs. Under a VA mortgage loan program, the defendants were required to certify that they only charged proper fees under the program, which was a condition of payment by the VA in the event of a loan default. The relator alleged that the fees were not proper and therefore the defendants' certification to the VA was false. While the lower court found this certification to be immaterial because the VA was aware of the alleged improper fees and still continued to pay on the loans, the Eleventh Circuit reversed based on a "holistic" materiality analysis. In doing so, the Court noted that there was evidence that the VA took corrective measures against defendants, even while continuing to pay the loans and that the VA was required by statute to continue to pay in spite of its knowledge of the noncompliance. This evidence was sufficient to find that the VA's continued payment did not preclude a finding of materiality. While *Bibby* will likely be the subject of further debate in continued payment cases, its factual circumstances make it unique and, for that reason, readily distinguishable.

In another appellate ruling on materiality pleading, the D.C. Circuit weighed in on the Rule 12(b)(6) and 9(b) pleading standards in *U.S. ex rel. Cimino v. Int'l Bus. Machines Corp.*, 3 F.4th 412 (D.C. Cir. 2021); 63 GC ¶ 254, reversing the dismissal of a fraudulent inducement claim while upholding the dismissal of a presentment claim. The

Court first held, as a matter of first impression, that but-for causation—rather than merely proximate causation—is an element of fraudulent inducement under the FCA. Therefore, to make out a claim for fraudulent inducement under the FCA, a relator must plead both causation and materiality. The D.C. Circuit held that the complaint stated a fraudulent inducement claim because it contained factual allegations supporting an inference that the IRS would not have entered into the agreement at issue but for IBM's conduct. The Court ruled that the fact that the IRS continued to pay for and extend its licensing agreement with the defendant despite knowledge of the "alleged fraud" was not sufficient at the pleading stage to undermine materiality in light of the complaint's factual allegations supporting materiality. With respect to the presentment claim, however, the Court affirmed dismissal because the complaint failed to plead details adequate to meet Rule 9(b), including when the false claims were presented and who presented those claims. Also of note, the concurrence by Judge Rao—citing an article published in the May 13, 2020 issue of *THE GOVERNMENT CONTRACTOR* (C. Kevin Marshall, Feature Comment, "Fraudulent-Inducement Actions And The FCA's Statute Of Limitations," 62 GC ¶ 133)—questioned whether fraudulent inducement is even a viable FCA theory, given that the FCA statute speaks only of fraudulent claims and says nothing about contracts.

**Scienter**—There were also some notable developments with respect to the FCA's scienter requirement. In *U.S. v. Supervalu Inc.*, 9 F.4th 455 (7th Cir. 2021), the Seventh Circuit joined four other circuits in applying *Safeco Ins. Co. of Am. v. Burr*, 551 U.S. 47 (2007), to the FCA in affirming a grant of summary judgment for the defendant in a qui tam action concerning usual and customary drug pricing. The FCA's scienter standard is satisfied when a defendant acts with "actual knowledge," "deliberate ignorance," or "reckless disregard" as to the truth or falsity of the information. In *Safeco*, the Supreme Court interpreted the similar standard of the Fair Credit Reporting Act and held that a defendant's conduct is not reckless when (1) it acts under an objectively reasonable, albeit erroneous, interpretation, and (2) no authoritative guidance warned it away from that reading. The Seventh Circuit held that *Safeco's* reasoning applies with equal force to the FCA, noting "we do not see how it

would be possible for defendants to actually know that they submitted a false claim if relators cannot establish the *Safeco* scienter standard.” Even if the defendant “might suspect, believe, or intend to file a false claim,” it could not know the claim was false “if the requirements for that claim are unknown.” As to “authoritative guidance” that should have warned a defendant away from its erroneous interpretation, the Court held that such guidance “must come from a governmental source—either circuit court precedent or guidance from the relevant agency.”

And just a few weeks ago, the Fourth Circuit applied *Safeco*’s scienter analysis to the FCA in *U.S. ex rel. Sheldon v. Allergan Sales, LLC*, 2022 WL 211172 (4th Cir. Jan. 25, 2022); 64 GC ¶ 48, affirming the dismissal of a complaint for failure to adequately allege scienter where the defendant held an objectively reasonable interpretation of the relevant statute and no authoritative guidance warned it away from that reading. These decisions align the Seventh and Fourth Circuits with the Third, Eighth, Ninth, and D.C. Circuits in extending the *Safeco* scienter analysis to the FCA and provide important support to defendants faced with alleged violations of ambiguous or vague requirements.

Previewing its recent adoption of *Safeco*, albeit in a case that provides a cautionary tale of one of the key limitations of that standard, the Fourth Circuit’s decision last year in *U.S. v. Mallory*, 988 F.3d 730 (4th Cir. 2021), held that the FCA’s scienter requirement is met when a defendant is repeatedly warned away from its incorrect interpretation of a purportedly ambiguous term, including by legal counsel. In *Mallory*, the defendant entered into contracts that paid sales representatives a percentage of the company’s revenue from offering blood tests. Defendant also paid physicians fees such as process and handling fees payable when they drew blood for the tests. Defendant’s in-house attorneys and outside counsel had warned that this compensation arrangement might violate the Anti-Kickback Statute (AKS), which prohibits “knowingly and willfully” exchanging (or offering to exchange) anything of value, in an effort to induce (or reward) the referral of business reimbursable by federal health care programs. See 42 USCA § 1320a-7b(b) (1). Counsel’s warnings included the transmission of relevant legal precedent. In light of these warnings, defendant’s claim that the AKS was ambiguous was insufficient to reverse a jury verdict finding a

knowing violation. Additionally, the *Mallory* Court explained that the defendant could not rely on the fact that its attorneys drafted the contracts because its attorneys subsequently warned the defendant about potential AKS issues. *Mallory* highlights the risk contractors expose themselves to by failing to heed warnings of counsel and other guidance on issues that may implicate FCA liability.

**Rule 9(b) Pleading**—Among the circuits, varying approaches to the particularity that a relator must plead in order to meet Rule 9(b)’s requirements can make the choice of forum a significant one. In *U.S. ex rel. Owsley v. Fazzi Assocs., Inc.*, 16 F.4th 192 (6th Cir. 2021), the Sixth Circuit reinforced its strict application of Rule 9(b) in requiring the identification “of at least one false claim with specificity [as] an indispensable element” of an FCA complaint. The district court in *Owsley* dismissed the complaint, finding that the relator’s allegations detailing an upcoding scheme merely related to potential internal fraudulent conduct but did not demonstrate the submission of an actual false claim for payment. Affirming the ruling, the Sixth Circuit held that the relator’s detailed allegations describing a fraudulent scheme—including upcoded data that was submitted as inflated requests for payment to the Government—fell short of “identify[ing] any specific claims” that defendants submitted pursuant to the alleged scheme. Without “particular identified claims” that would provide the defendant with “notice of a specific representative claim that plaintiff thinks was fraudulent,” relator’s claims could not proceed.

In contrast, the Seventh Circuit in *U.S. v. Molina Healthcare of Ill., Inc.*, 17 F.4th 732 (7th Cir. 2021); 63 GC ¶ 365, declined to require the identification of a specific false claim in reversing the district court’s dismissal of a complaint alleging violations of the FCA under three theories: factual falsity, fraud in the inducement, and implied false certification. Applying a more relaxed approach to Rule 9(b), the Seventh Circuit found that relator’s “detailed allegations support a strong inference that Molina was making false claims” while acknowledging that one or more of relator’s theories may “lack support” later in the litigation. The Seventh Circuit found that the relator provided numerous details indicating “when, where, how, and to whom allegedly false representations were made,” but the relator cannot “be blamed for not having information that

exists only in [the defendant's] files." In particular, the Seventh Circuit rejected the district court's conclusion that the complaint fell short for failure to include details about the defendant's contract-renewal negotiations with the Government, given that the relator could not have had access to those documents or conversations. With respect to knowledge and materiality, the Seventh Circuit ruled that the district court failed to properly weigh the complaint's description of the defendant "as a highly sophisticated member of the medical-services industry" in finding that the complaint insufficiently alleged that it knew that the provision of skilled nursing facility services was material to a contract for delivery of Medicaid benefits. The Court also dismissed the import of the Government continuing to contract with the defendant after learning of the qui tam allegations, holding that such an argument was better saved for a "later stage" after discovery, because the defendant appeared to be offering only part of the story. In dissent, Chief Judge Sykes accused the majority of deviating from the Seventh Circuit's precedent and improperly "loosen[ing] pleading standards under circumstances where a specific false statement is hard to identify."

**Retaliation**—In *U.S. ex rel. Felten v. William Beaumont Hosp.*, 993 F.3d 428 (6th Cir. 2021); 63 GC ¶ 113, the Sixth Circuit held that the FCA's anti-retaliation provision protects former employees alleging post-termination retaliation, thereby splitting with the Tenth Circuit's holding in *Potts v. Ctr. for Excellence in Higher Educ., Inc.*, 908 F.3d 610 (10th Cir. 2018), that § 3730(h) unambiguously excludes relief for retaliatory acts occurring after an individual's employment with the defendant has ended.

In *Felten*, the relator claimed that—post-termination—his prior employer "blacklisted" him after he filed a qui tam action claiming that defendant was paying kickbacks to doctors. The district court dismissed the retaliation count, ruling that § 3730(h) did not cover post-termination conduct, but granted interlocutory appeal on that question. The Sixth Circuit disagreed with the district court's ruling and diverged from the Tenth Circuit's holding in *Potts* that the FCA's anti-retaliation provision includes a temporal qualifier and that other FCA provisions do not envision application to both current and former employees. Instead, the Sixth Circuit construed § 3730(h) to effectuate the stat-

ute's broader context and purpose by not limiting its protection to only current employees. The Sixth Circuit also remanded for the district court to consider whether "blacklisting" is a form of retaliatory action. The defendant filed a petition for a writ of certiorari, which is currently pending. Notably, the Sixth Circuit's holding could become law should the current version of the proposed amendments to the FCA, discussed above, be passed.

**The Eighth Amendment Excessive Fines Clause**—In an issue of first impression, the Eleventh Circuit in *Yates v. Pinellas Hematology & Oncology, P.A.*, 21 F.4th 1288 (11th Cir. 2021), held that the Excessive Fines Clause of the Eighth Amendment applies in non-intervened FCA qui tam lawsuits. In *Yates*, the defendant owned a clinic with multiple locations, each of which had a laboratory that conducted testing on human specimens, but one of which did not have the proper certification to do so. The jury found the defendant liable for 214 false claims for Medicare reimbursement for tests conducted at the non-certified facility, but awarded actual damages of just \$755.54. The district court then assessed a statutory penalty of \$5,500 to each false claim, for a total of \$1,177,000 in penalties. The defendant filed a motion for judgment as a matter of law, or, in the alternative, for remittitur, arguing that the more than \$1.1 million in penalties in a case with actual damages of less than \$1,000 violated the Excessive Fines Clause. The district court denied the motion and concluded that the penalties did not violate the Eighth Amendment because the calculation was based on the low end of the statutory penalty range of \$5,500 to \$11,000 per false claim.

The Eleventh Circuit affirmed. It first determined that, in a non-intervened qui tam, an award to a relator is subject to the limitations of the Eighth Amendment. Relying on the fact that the Supreme Court "left open" the question of whether the Eighth Amendment applied to non-intervened qui tams, the Eleventh Circuit concluded that because a relator stands in the shoes of the Federal Government, the Eighth Amendment applies to FCA judgments. The Eleventh Circuit further explained that the FCA's penalties (1) constitute a "fine" under the Excessive Fines Clause because they are "essentially punitive" in nature under the case law; and (2) are imposed by the Government in that they are statutorily required irrespective

of whether the Government intervenes, with the Government receiving 70–75 percent of the penalty amounts in a non-intervened *qui tam*.

Turning to the case before it, the Eleventh Circuit held that the \$1.1 million in penalties did not violate the Excessive Fines Clause. While noting that penalties of more than \$1,100,000 in a case with a single damages amount of \$755.54 “may raise an eyebrow,” the Court concluded that those potentially bad “optics” were negated because the penalties were imposed as a result of the defendant’s “repeated (214) instances of fraud against the United States.” The Eleventh Circuit also deferred to Congress’ judgment in imposing mandatory statutory penalties and noted that the harm caused by fraud against the U.S. is “considerable,” regardless of the “ultimate value of the payment.” Finally, the Eleventh Circuit agreed with the district court’s reasoning that because the penalties were based on multiples of the low end of the statutory penalty range, the award did not violate the Excessive Fines Clause.

**2022 Vision: The Year Ahead for the FCA**—Our look back at 2021 gives us a preview of what’s in store in 2022 for the FCA. Over the past two years, there has been a marked increase in Government-initiated matters involving procurement fraud. Many of these new matters are likely investigations yet to hit the public domain, but the coming year may see more come to light as they are resolved or move to litigation. While this increase undoubtedly involves COVID-19 actions, other signs indicate that the Government is more generally increasing FCA enforcement with respect to Government contractors. A prime indicator of this is DOJ’s recent launch of the Civil Cyber-Fraud Initiative, a development that came as little surprise to us after we predicted an increase in Government focus on cybersecurity last year. Further, the pending amendments to the FCA, if passed, would bring several changes of note, including for issues that have seen increased activity among the courts. Whether they would reduce disputes and litigation, however, is another question. Overall, we expect that 2022 will be yet another active year for FCA enforcement.



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## Developments

### ¶ 44

#### DOD IG Questions DHA Oversight Of TRICARE Telehealth Spending

The Defense Health Agency improperly paid claims for telehealth services provided in fiscal year 2020, the Department of Defense inspector general has reported. The funds “could have been used for other critical health care services” within DOD, the IG suggested.

TRICARE supports 9.6 million active duty, retired, and other DOD beneficiaries. Two regional managed care support contractors administer a network of medical providers supporting DOD beneficiaries and “receive, process, and pay claims for authorized medical services on behalf of the DHA,” the IG explained. Telehealth, also known as telemedicine, “involves a patient at an ‘originating site’ receiving care from a provider at a ‘distant site.’”

DHA spent \$2.9 million and \$4 million in FYs 2018–2019, and \$2.3 million through February 2020 in FY 2020 for TRICARE services coded as telehealth, the IG found. “However, use of telehealth by TRICARE beneficiaries increased in March 2020 as a result of the [covid-19] pandemic,” and as of September 2020, TRICARE telehealth payments had exceeded \$150 million. DHA modified its telehealth requirements in May 2020 to ensure access to services during the pandemic, including allowing audio-only visits, allowing providers to administer services to patients in states where the providers are not licensed, and temporarily waiving cost-sharing for covered services.