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# 2022 Mid-Year False Claims Act Update

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Hundreds of millions of dollars in government recoupments. Supreme Court attention. Potential Congressional legislation. All of this—and more—marked the False Claims Act (FCA) landscape during the first half of 2022, and proved yet again that the FCA is one of the government's most powerful, and most litigated, enforcement tools.

On the enforcement front, the U.S. Department of Justice (DOJ) announced FCA resolutions totaling more than $500 million during the first half of the year, outpacing last year's settlements. Among those resolutions were settlements related to fraud under the COVID stimulus programs and novel settlements from DOJ's nascent "cyber-fraud" initiative, which promises to blur the line between traditional cybersecurity law and traditional FCA claims. DOJ also settled its usual assortment of cases against health care companies and government contractors.

Meanwhile, the Supreme Court agreed to decide yet another FCA case—this time to decide how much control the government retains over FCA litigation pursued by whistleblowers on its behalf—marking the 10th time in the last 15 years that the Supreme Court has decided to clarify aspects of the FCA statutory framework. The Supreme Court's grant of certiorari adds to a host of important circuit court decisions from the last six months, as well as continued rumblings about potential Congressional action to strengthen the FCA.

With all of these developments, Gibson Dunn is pleased to once again present our mid-year round-up of the critical developments that businesses and practitioners must know about under the FCA.

Below, we summarize recent enforcement activity, then provide an overview of notable legislative and policy developments at the federal and state levels, and finally analyze significant court decisions from the past six months. Gibson Dunn's recent publications regarding the FCA may be found on our website, including in-depth discussions of the FCA's framework and operation, industry-specific presentations, and practical guidance to help companies navigate the FCA. And, of course, we would be happy to discuss these developments—and their implications for your business—with you.

## I. NOTEWORTHY DOJ ENFORCEMENT ACTIVITY DURING THE FIRST HALF OF 2022

During the first half of 2022, DOJ announced FCA resolutions totaling more than $500 million. Enforcement activity thus far in 2022 has outpaced that of the first six months of 2021, although many of the resolutions announced this year have been relatively modest in amount. It remains to be seen whether DOJ will match the recoveries obtained during 2021, which included blockbuster settlements stemming from the opioid crisis.

Some of the most notable settlements of the first six months of 2022 came from the continued fallout from COVID and a new DOJ initiative around cyber-fraud.

Specifically, DOJ continues to focus on enforcement actions related to the Paycheck Protection Program (PPP), including actions under the FCA. For example, as detailed below, in February DOJ reached a settlement with a Virginia-based software development company to resolve allegations that the company fraudulently obtained multiple PPP loans

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in the year 2020.[1] In April, DOJ announced a settlement with a medical provider network, and several individuals, of claims that the company billed for unnecessary telehealth visits and instructed physicians to order certain medical tests without assessing for medical necessity.[2] In addition, DOJ claimed that the company submitted false statements in connection with a PPP loan application, by representing in its PPP loan application that the company was not engaged in unlawful activity. Notably, all four of the *qui tam* actions resolved by the settlement pre-dated the creation of the PPP program under the CARES Act. In addition to FCA claims, the settlement resolved a claim under the Financial Institutions Reform, Recovery and Enforcement Act (FIRREA), ostensibly based entirely on the PPP allegations. The addition of this claim follows the approach taken in DOJ's very first PPP-related settlement in January 2021, which we have covered previously.

DOJ also continues to focus on employing the FCA to respond to cybersecurity threats. In March, DOJ announced its first settlement under the "Cyber Fraud Initiative" that it announced late last year.[3] The Cyber Fraud Initiative was set up to encourage the federal government to pursue fraud claims related to cybersecurity, including claims related to data security practices by health care providers. In this particular settlement, a Florida-based medical services provider agreed to pay $930,000 to resolve allegations that it failed to disclose to the State Department that it had not consistently stored patients' medical records in a secure electronic medical record system and that it failed to properly obtain certain controlled substances that were manufactured in accordance with federal quality standards. Given the significance of data security in the health care industry, it is not surprising that DOJ's first settlement under the Cyber Fraud Initiative was with a medical company—but we expect to see DOJ extending the initiative's efforts broadly across industries in the coming months. Indeed, on July 8, DOJ announced another first-of-its-kind FCA settlement with a defense and aerospace contractor who allegedly misrepresented its compliance with cybersecurity requirements in certain federal government contracts.

Below, we summarize the other most notable settlements from the first half of the year, organized by industry and focused on key theories of liability at issue in the resolutions. As is often the case, FCA recoveries in the health care and life sciences industries dominated enforcement activity during the first half of the year in terms of the number and value of settlements. DOJ, however, also announced notable resolutions in the government contracting and procurement space, described below.

## A. Health Care and Life Science Industries

Settlements to resolve liability under the FCA in the health care and life sciences industries totaled more than $400 million in the first half of 2022.

- On January 11, a California health system agreed to pay $3 million to resolve allegations that it violated the FCA by ordering and submitting referrals for unnecessary genetic testing, leading to the submission of false claims to Medicare for those tests.[4]
- On January 12, a specialized footwear company agreed to pay $5.5 million to settle allegations that the company sold shoe inserts to diabetic patients who received a prescription for the inserts from a physician. According to the government, the company billed Medicare and Medicaid as if the inserts provided to patients were customized, but the inserts actually all came from a generic model. In connection with the settlement, the company entered a three-year corporate integrity agreement, requiring the company to update its policies and hire an independent review organization to monitor the company's Medicare and Medicaid claims. The settlement also resolved a *qui tam* suit brought by a former employee; that individual's share of the recovery was not reported with the settlement announcement.[5]
- On January 31, a health care company agreed to pay more than $13 million to

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settle allegations that it violated the FCA and AKS by providing initial discounts on the purchase of drugs to physician practices. The government alleged the company used these discounts to persuade the practices to buy federally reimbursable drugs from the company rather than its competitors. According to the government, the company's upfront discounts ran afoul of the FCA and AKS because they were not tied to any particular sale and were not associated with an earned rebate. The settlement also resolved *qui tam* suits brought against the health care company, for which the relators received approximately $2.8 million of the settlement.[6]

- On February 9, a hospital agreed to pay $3.8 million to resolve allegations that it violated the FCA and AKS by paying its own cardiologists to cover for, and provide services to, another cardiologist's patients when that cardiologist was unavailable. The government alleged that the cardiologist, in turn, referred millions of dollars of medical procedures to the hospital. The government asserts the arrangement constituted an unlawful kickback and resulted in the submission of false claims to the government. The settlement also resolved a *qui tam* suit brought by a former hospital employee; that individual's share of the recovery was not reported with the settlement announcement.[7]
- On February 15, three Ohio-based health care providers agreed to pay more than $3 million to resolve allegations that the providers submitted bills to Medicare for complex surgeries by an orthopedic surgeon who worked out of each of the providers' facilities. The government asserted that the surgeon claimed to have performed numerous procedures that he actually did not perform. Even though none of the parties knowingly submitted false claims based on the surgeons' actions, the government alleged there was sufficient evidence that each provider should have known that the claims were false.[8]
- On March 7, a pharmaceutical company agreed to pay $260 million to resolve allegations that it violated the FCA and AKS by underpaying Medicaid rebates for a particular drug and using a foundation to subsidize patient co-pays. Approximately $234.7 million of the settlement went to resolving the rebate allegations and $26.3 million went toward resolving the kickback claims. In addition to the payment, the pharmaceutical company agreed to a corporate integrity agreement, which includes monitoring provisions focused on Medicaid rebates. The settlement also resolved *qui tam* suits brought by two whistleblowers, who received almost $30 million of the settlement.[9]
- On March 28, a psychiatrist agreed to pay $3 million to resolve allegations that he violated the FCA by billing the Department of Labor Office of Worker's Compensation Programs for psychiatric appointments that never took place and double-billing for other sessions. As part of the settlement, the psychiatrist agreed to be excluded from federal health care programs for 25 years.[10]
- On April 6, a health care system and four affiliated entities agreed to pay $20 million to resolve allegations that they violated the FCA by making donations to a local entity which in turn contributed the money to the state's Medicaid program—the state ultimately paid back the funds to the health care system. The government asserted that, based on this conduct, the government had to make matching Medicaid payments without any actual expenditure by the state. The settlement also resolved a *qui tam* suit brought by a former hospital reimbursement manager, who received $5 million of the settlement.[11]
- On April 12, a pain management company agreed to pay $24.5 million to resolve allegations that it violated the FCA by submitting claims for unnecessary drug, genetic, and psychological testing. As part of the settlement, the company entered into a corporate integrity agreement with the Office of Inspector General for the Department of Health and Human Services (HHS-OIG) that required the company to maintain a compliance department and submit to ongoing reviews by an independent review organization. The settlement resolved *qui tam* suits brought by former employees of the company and its affiliates; the relators' share of the

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recovery was not reported with the settlement announcement.[12]

- On April 13, a company, its co-founders, and 18 affiliated anesthesia entities agreed to pay $7.2 million to resolve allegations that they violated the FCA and AKS by sharing revenue received from the company's anesthesia services with the physicians running outpatient surgery centers in order to obtain exclusive anesthesia agreements with the surgery centers. The settlement also resolved a *qui tam* suit brought by a whistleblower, who received $1.3 million of the settlement.[13]
- On April 29, a hearing aid company agreed to pay $34.4 million to resolve allegations that it violated the FCA by submitting inaccurate claims for reimbursements to the federal government. Some Federal Employees Health Benefits Program plans elect to offer a benefit for hearing aids but require submission of a hearing-loss related diagnosis code supported by a hearing exam by a physician. The government alleged that the company submitted claims for hearing aids containing unsupported diagnosis codes to the Benefits Program.[14]
- On May 9, a home health company agreed to pay $2.1 million to resolve allegations that it violated the FCA by submitting claims for Medicare beneficiaries who were not homebound and did not require certain skilled care. The government also alleged the company submitted claims for services that otherwise did not have a valid or appropriate plan of care and/or did not have requisite in-person encounters to qualify for home health service certification. The settlement resolved allegations brought in a *qui tam* and a HHS-OIG complaint; the whistleblower's share of the recovery was not disclosed at the time of the settlement.[15]
- On June 1, a behavioral health care provider agreed to pay $2.1 million to settle claims that it improperly billed claims to Medicaid that were ineligible for reimbursement under the state's medical clinical coverage policy. The allegations stemmed from a *qui tam* lawsuit; the whistleblower's share was not disclosed at the time of the settlement announcement.[16]
- On June 1, a molecular science company agreed to pay over $2.8 million to resolve allegations that it billed Medicare for laboratory tests in violation of Medicare's 14-Day Rule, which prohibits laboratories from separately billing for certain tests ordered within 14 days of a patient's discharge from an inpatient or outpatient hospital setting. In addition to submitting purportedly improper claims, the government alleged that the company failed to discourage providers who ordered testing within 14 days after a discharge from canceling the order and placing a new order for testing after the 14-day period had elapsed. The settlement partially resolves one *qui tam* lawsuit and fully resolves another.[17]
- On June 6, a diagnostics company that provides home sleep testing agreed to pay $3.5 million to resolve FCA and AKS allegations that it billed Medicare and four other federal health care companies for unnecessary home sleep testing. The government alleged that the company's founder directed employees to submit claims for additional nights of home sleep testing when only one night was necessary to effectively diagnose sleep apnea. The government further alleged that the company improperly multiplied copays received from Medicare beneficiaries and incentivized physicians to refer all home sleep testing services to the company. The settlement agreement requires the company's founder and vice president to pay $300,000 and $125,000, respectively, and the company and its founder agreed to a corporate integrity agreement. The allegations in the settlement were part of two *qui tam* [18]
- On June 10, a Los Angeles doctor agreed to pay $9.5 million to resolve FCA allegations that he submitted claims to Medicare for procedures and tests that he never performed and admitted that he intentionally submitted false claims for payment. The settlement amount includes nearly $5.5 million paid as criminal restitution following a guilty plea to health care fraud in a separate criminal matter. The allegations originally stemmed from a *qui tam* lawsuit filed by a former medical

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assistant and former IT consultant. The two whistleblowers will receive more than $1.75 million as their share of the recovery.[19]

- On June 21, a managed care health services company and its previously-owned subsidiary agreed to pay $4.6 million to resolve allegations that it billed a joint federal and state Medicaid program for care provided by unlicensed and unsupervised staff. The settlement also resolved allegations that the companies failed to provide and timely document the provision of adequate clinical supervision for clinicians. The settlement resolves a *qui tam* suit filed by four former employees; the whistleblowers were awarded $810,000 as their share of the recovery.[20]

## B. Government Contracting and Procurement

Settlements to resolve liability under the FCA in the government contracting and procurement space totaled more than $90 million in the first half of 2022.

- On February 23, a kitchen and food service equipment company agreed to pay $48.5 million to resolve allegations that it provided inaccurate information to the government regarding contracts awarded to small businesses. The federal government may set aside certain contracts for various categories of small businesses; and, in some instances, only eligible small businesses may bid on and receive contracts. The government alleged that the company caused federal agencies to award contracts to small businesses that claimed to be run by service-disabled veterans when, in reality, the small businesses served as the face of the contracts, and the company actually provided all of the services. The settlement resolved a *qui tam* suit brought by a competing company, which received $10.9 million of the settlement.[21]
- On March 7, a construction contractor agreed to pay $10 million to resolve allegations it overbilled the government. The government asserted that the contractor—which was performing work for the Department of Energy—presented false invoices for non-existent materials submitted by a subcontractor to the contractor. According to the government, the contractor's employees received kickbacks from the subcontractor to submit the claims.[22]
- On March 14, two freight carrier companies agreed to pay $6.9 million to resolve allegations they violated the FCA by inflating bills submitted to the Department of Defense. The government alleged the companies each claimed to have hauled greater weights than they actually carried, which served as the basis for payment under the contract. The settlement resolved a *qui tam* suit brought by a former employee of one of the companies who received $1.3 million of the settlement.[23]
- On March 21, a package delivery company agreed to pay $5.3 million to resolve allegations that it violated the FCA by submitting inaccurate information regarding time and proof of delivery. Under the company's contract for mail pick-up and delivery at various Department of Defense and State Department locations domestically and abroad, the company received penalties for mail delivered late or to the wrong location. The government alleged that the company submitted scans of proof of mail and package deliveries that did not accurately reflect when the company actually delivered the packages.[24]
- On May 12, a construction company agreed to pay $2.8 million to settle FCA allegations that the company improperly manipulated a subcontract reserved for service-disabled, veteran-owned small businesses (SDVOSBs). The government awarded the company a contract to develop retirement communities and residential facilities for veterans, a condition of which was to provide subcontracting opportunities to SDVOSBs. The company admitted that it negotiated with a non-SDVOSB for the subcontract and then entered into a subcontract with an SDVOSB for the same work, but with an additional 1.5% fee. The company further admitted that it should have known the SDVOSB was a pass-

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through for the non-SDVOSB, which provided all of the work under the subcontract. The settlement resolves allegations originally brought in a *qui tam* lawsuit; the whistleblower received approximately $630,000 for its share of the recovery.[25]

- On May 18, seven South Korean companies agreed to pay $3.1 million to settle FCA and other allegations that they conspired to rig the bidding process for contracts for construction and engineering work on United States military bases in South Korea. The government alleged that, as a result of the anticompetitive behavior, the government paid more for services performed under the contracts than it otherwise would have.[26]
- On May 25, a manufacturing company agreed to pay $3 million to settle allegations that it violated the FCA by knowingly selling technical fabrics to the military that failed to meet required specifications. The company allegedly falsified test results and falsely certified that its military-grade fabrics met all requisite performance specifications set by the military. The company also entered into an agreement with the Defense Logistics Agency to ensure that it remains in compliance with testing requirements going forward. The settlement resolves allegations brought under a *qui tam* lawsuit; the whistleblower's share was not disclosed at the time of the settlement announcement.[27]
- On June 2, a manufacturing company and two related entities agreed to pay $5.2 million to resolve allegations that the company violated the FCA by improperly obtaining a contract reserved for small businesses that it was ineligible to receive. The manufacturing company allegedly falsely certified that it was a "small business concern" within the meaning of the Small Business Administration's regulations so as to receive 22 small business set-aside contracts, even though the company ceased to qualify after its acquisition by a larger company. The company also allegedly falsely certified that it was a "women-owned small business concern." As part of the settlement agreement, the entities received credit for the company's voluntary disclosure and cooperation with the government during the investigation.[28]
- On June 14, four companies agreed to pay $13.7 million to resolve FCA and AKS allegations that the companies rigged the bidding process for subcontracts to perform logistics support services for the military in Iraq and that employees entered into arrangements with a foreign contractor under which the companies would receive a kickback for every subcontract awarded to the foreign entity. The government alleged that the employees influenced the federal government to award two subcontracts to the foreign contractor at prices higher than necessary to fulfill the military's contract requirements, and the government alleged that the companies extended the duration of subcontracts at inflated prices and sought reimbursement of these inflated costs from the U.S. military. The settlement resolves allegations originally brought in a *qui tam* lawsuit; the whistleblower's share was not disclosed at the time of the settlement announcement.[29]

## C. Other

Settlements to resolve other types of FCA cases totaled nearly $25 million in the first half of 2022.

- On January 14, a loan servicer agreed to pay $7.9 million to resolve allegations that it violated the FCA by submitting inaccurate claims to the Department of Education. The government alleged that the loan service failed to make required financial adjustments to borrower accounts and improperly treated some ineligible borrowers as eligible for military deferments.[30]
- On April 4, a telecommunications carrier agreed to pay $13.4 million to resolve allegations that it enrolled 175,000 ineligible customers for free cell phones and service under a federal program. The federal government runs the Lifeline

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Program, which assists low-income individuals with telecommunications needs. According to the government, the carrier failed to monitor subscriptions obtained by a third-party marketing firm who actually enrolled the ineligible customers. The settlement also resolved a *qui tam* suit brought by a former employee of the marketing firm, who received roughly $450,000 of the settlement.[31]

- On May 27, a for-profit school and its owner agreed to pay over $1 million to settle allegations that they improperly concealed financial information to influence the school's student loan default rate, which affects an institution's ability to participate in Title IV programs. The for-profit school and its owner allegedly mailed 154 direct payments to loan servicers on behalf of 102 students to prevent those students from defaulting on their loans and, therefore, counting towards the school's student loan default rate. The school and its owner allegedly failed to disclose the actual student loan default rate to the Department of Education. The school and its founder also entered into an administrative agreement with the Department of Education.[32]

## II. LEGISLATIVE AND POLICY DEVELOPMENTS

### A. Federal Legislative Developments

As we previously reported, last summer, Senator Chuck Grassley (R-IA), along with a bipartisan group of Senators, introduced a bill to amend the FCA which he subsequently amended last November. Senator Grassley's proposed amendments were targeted at limiting the implications of the Supreme Court's decision in *Escobar* and limiting the government's ability to dismiss claims brought by relators. Since being reported out of the Senate Judiciary Committee, there has been no indication regarding whether the bill will receive a floor vote.

Time will tell whether the Supreme Court's decision to take up the *Polansky* case (which relates to the government's ability to dismiss claims brought by relators, as covered below in this Alert) has the effect of further delaying or killing the bill's progress. In the meantime, Senator Grassley filed an *amicus curiae* brief in support of a *certiorari* petition in the *United States ex rel. Schutte v. SuperValue Inc.*, which deals with the relevance of a defendant's subjective beliefs for FCA scienter.[33] Consistent with his statements in the past, Sen. Grassley's brief focuses on what he sees as the importance of a defendant's contemporaneous subjective intent, in a professed effort to prevent the same defendant's "post-hoc" (albeit objectively correct) interpretations of the law from hobbling the government's efforts to establish scienter.

### B. State Legislative Developments

The first half of 2022 has witnessed significant developments in state-level FCA legislation. Most notably, Colorado expanded its false claims law beyond the realm of Medicaid fraud. The Colorado False Claims Act (CFCA), which became law on June 7, 2022, largely tracks the federal FCA, but with several significant features not found in the federal statute.

First, the CFCA expressly states that "[a] person who acts merely negligently with respect to information is not deemed to have acted knowingly, unless the person acts with reckless disregard of the truth or falsity of the information."[34] The federal FCA contains neither an express carve-out for negligence (although courts routinely find that it does not satisfy the Act's scienter requirement), nor any sort of caveat regarding situations in which negligence could still be actionable.

Second, the CFCA contains a distinct framework for assessing reduced damages and penalties for cooperating defendants. The federal FCA grants courts discretion to impose only double damages when a defendant reports information within 30 days of obtaining it, cooperates fully with the government, and discloses the information prior to the

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commencement of any action under the FCA and without actual knowledge of any FCA investigation. The CFCA, by contrast, requires the imposition of double damages for any defendant who reports information within 30 days of learning it, does so without actual knowledge of the existence of an FCA investigation, and does so while an FCA action is under seal.[35] In the event that a similarly situated defendant reports the information prior to any action being filed under seal, the court is required to impose one-and-one-half the amount of damages.[36] In this way, the CFCA places a premium on companies enhancing their compliance programs to affirmatively identify fraudulent conduct, but arguably incentivizes *qui tam* relators to act hastily in filing complaints in an effort to lock even cooperating defendants into at least double damages. On another level, the apparently mandatory nature of the reduced damages provisions in cases where defendants make voluntarily self-disclosures could have the effect of making settlement discussions in such cases more efficient by vesting the government with less discretion to negotiate damages multipliers where the other requirements for cooperation credit are otherwise met.

Third, and notably in light of *Polansky* and the longer history of disputes at the federal level regarding DOJ's dismissal authority, the CFCA explicitly requires the Colorado Attorney General to consider certain enumerated factors when determining whether to voluntarily dismiss a CFCA action.[37] Those factors are "the severity of the false claim, program or population impacted by the false claim, duration of the fraud, weight and materiality of the evidence, other means to make the program whole, and other factors that the Attorney General deems relevant."[38] The statute also expressly provides that "[t]he Attorney General's decision-making process concerning a motion to dismiss and any records related to the decision?making process are not discoverable in any action."[39]

Fourth, unlike the federal FCA, the CFCA expressly prohibits a *qui tam* relator from disclosing—as part of its mandatory disclosure statement served on the State along with a copy of the complaint—"any evidence or information that the person reasonably believes is protected by the defendant's attorney-client privilege unless the privilege was waived, inadvertently or otherwise, by the person who holds the privilege; an exception to the privilege applies; or disclosure of the information is permitted by an attorney pursuant to [the SEC's standards of professional conduct], the applicable Colorado Rules of Professional Conduct, or otherwise."[40]

Elsewhere, other states have been actively considering steps to expand or revise their false claims laws. In Connecticut and Michigan, bills are pending that would—like Colorado's new law—expand false claims liability beyond Medicaid, although without nearly as much variation on matters of FCA procedure and practice compared to the federal statute as is reflected in the CFCA.[41] New York's legislature, for its part, on June 3 passed an amendment to the state's FCA that would expand liability for tax-related claims to include fraudulent failures to file tax returns. As currently written, the New York FCA covers tax-related actions but limits them to the knowing use of false records and statements material to tax obligations.[42] The new bill is now awaiting the governor's signature.

HHS-OIG provides incentives for states to enact false claims statutes in keeping with the federal FCA. HHS-OIG approval for a state's FCA confers an increase of 10 percentage points in that state's share of any recoveries in cases involving Medicaid.[43] Such approval requires, among other things, that the state FCA in question "contain provisions that are at least as effective in rewarding and facilitating *qui tam* actions for false or fraudulent claims" as are the federal FCA's provisions.[44] Approval also requires a 60-day sealing provision and civil penalties that match those available under the federal FCA.[45] Consistent with our reporting in prior alerts, the lists of "approved" and "not approved" state statutes remain at 22 and 7, respectively.[46] Michigan is on the "not approved" list, and could remain there even if its FCA amendment passes: the bill entitles *qui tam* relators to a maximum of 20% of recoveries in intervened cases, whereas the federal FCA caps that amount at 25%.[47] HHS-OIG could well determine that this discrepancy means the Michigan law (if it passes in its current form) is not "at least as effective" as the federal

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FCA is in rewarding *qui tam* relators.

## III. CASE LAW DEVELOPMENTS

The big news of the last six months was the Supreme Court's decision to wade into the FCA waters once more. But the first half of 2022 also saw a number of notable federal appellate court decisions. We cover all of these developments below.

### A. Supreme Court and Multiple Courts of Appeal Consider DOJ's Dismissal Authority

#### 1. Supreme Court Grant of Cert

The Supreme Court granted certiorari in *United States ex rel. Polansky v. Executive Health Resources, Inc.*, 17 F.4th 376, 385 (3d Cir. 2021), *cert. granted*, 142 S. Ct. 2834 (2022), to decide the question of whether the government can dismiss a *qui tam* realtor lawsuit after declining to litigate, and if it can, what the government must show in order to persuade the district court to dismiss the case. 21-1052, *United States, Ex Rel. Polansky v. Executive Health Resources, Inc*., https://www.supremecourt.gov/qp/21-01052qp.pdf (last visited July 14, 2022).

The FCA generally provides that the government may dismiss a *qui tam*, over the objection of a relator, at any time, subject to certain procedures. 31 U.S.C. § 3730. This provision is an important check on runaway whistleblower suits, *United States ex rel. Campos v. Johns Hopkins Health Sys. Corp.*, 2018 WL 1932680, at *8 (D. Md. April 24, 2018), and is a critical feature that courts have relied upon to uphold the constitutionality of the *qui tam* provisions against constitutional challenges under the delegation clause, *United States ex rel. Stilwell v. Hughes Helicopters, Inc.*, 714 F.Supp. 1084, 1086–93 (C.D. Cal. 1989).

Currently, however, there is a circuit split as to the standard under which a district court may evaluate the government's decision to dismiss relators' cases.[48] Some courts have concluded that the government may dismiss virtually any action brought on behalf of the government, with very little scrutiny. *Polansky*, 17 F.4th at 384–88. Other courts have decided that if the government does not intervene in a relator's case, the government must first intervene in the lawsuit before seeking to dismiss it under Federal Rule of Civil Procedure 41(a)'s standard. *Id.* Still other courts have indicated that the government must have some reasonable basis for the decision to dismiss, and ostensibly apply a degree of scrutiny to dismissal decisions. *Id.*

In *Polansky*, appellant Jesse Polansky argues that the Supreme Court must adjudicate the "intractable split" on the issue, urging the Court to hold the government to a heightened standard. *Id.*, Pet. at I. Unsurprisingly, respondent Executive Health Resources—seeking to preserve DOJ's decision to dismiss—contends that the standards are just "slightly different" and that appellant would lose under all of them. *Id.*, Opp. at 1.

FCA practitioners know that the "split" may be more of an illusion than a reality. In practice, district courts almost *always* agree to dismiss cases where DOJ seeks dismissal, regardless of what jurisdiction they are in and what standard they apply. Indeed, in every Circuit Court case making up the split, the court upheld the government's dismissal. It is therefore unclear why the Supreme Court decided to hear the case, given the lack of practical differences in the standards. But we will be watching carefully to see whether the Supreme Court strengthens—or weakens—DOJ's ability to reign-in *qui tam* lawsuits.

#### 2. First and Eleventh Circuits Consider the Government's Dismissal Authority

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While the Supreme Court's grant of cert in *Polansky* was the big news with regard to the government's dismissal authority, several circuit courts also issues decisions that bear on DOJ's control over *qui tams*.

The FCA provides for a hearing when the Government moves to dismiss a relator's *qui tam* action over the relator's objection. But the statute is silent as to the standards governing that hearing and the courts of appeals have developed different tests for assessing the propriety of such a motion to dismiss. Weighing in on the issue for the first time, the First Circuit held in *Borzilleri v. Bayer Healthcare Pharmaceuticals, Inc.*, 24 F.4th 32 (1st Cir. 2022), that the Government must "always provide its reasons for seeking dismissal" and that the "court's role is to apply commonly recognized principles for assessing government conduct—the well-established 'background constraints on executive action.'" *Id.* at 42. The motion to dismiss should be granted unless the relator can establish that the government's decision to seek dismissal "transgresses constitutional limitations" or that the government "is perpetrating a fraud on the court." *Id.* Further, if the relator seeks discovery to establish the government's "improprieties" the relator must make a "substantial threshold showing" to support her claims. *Id.* at 44.

In so holding, the First Circuit, disagreed with the approaches taken by other circuits. For example, the *Borzilleri* Court held that the Ninth Circuit's approach, which requires the government to identify a "valid government purpose" for dismissal and to establish a "rational relation between dismissal and accomplishment of the purpose" erred in placing too weighty a burden on the government. *Id.* at 37, 40 (quoting *United States ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp.*, 151 F.3d 1139, 1145 (9th Cir. 1998)). The *Borzilleri* Court likewise rejected the approach taken by the Seventh and Third Circuits, which look to Federal Rule of Civil Procedure 41 for guidance. The First Circuit concluded that Rule 41 was not an "appropriate guide" for the FCA because its primary aim is to protect the defendant from being prejudiced by a plaintiff's voluntary dismissal, while § 3730(c)(2)(A) hearings are intended to protect the relator's "unique" interests as an "objecting co-plaintiff." *Id.* at 41.

In *United States ex rel. Farmer v. Republic of Honduras*, 21 F.4th 1353 (11th Cir. 2021), meanwhile, the Eleventh Circuit took up the issue of whether the Government must formally intervene in a *qui tam* action to move for dismissal, where it has initially declined to intervene. *Id*. at 1355. There, when relators filed their initial complaint in the *qui tam* action, the United States declined to intervene. *Id*. Later, however, after the relators filed an amended complaint adding defendants, the United States—without first filing a motion to intervene in the case—motioned to dismiss the action. *Id*. The relators challenged the dismissal motion on the ground that the Government was not a party to the suit because it had not formally intervened "*for* good cause" under 31 U.S.C. § 3730(c)(3), and thereby lacked standing to motion for dismissal. Section 3730 asserts that Courts may allow the Government to later intervene—in a case for which it initially declined intervention—upon a showing of "good cause." *Id*. at § 3730(c)(3). However, the Court held that the Government was not required to show "good cause" for late interventions that strictly seek dismissal, explaining that the good-cause subsection "applies only when the [G]overnment intervenes for the purpose of actually proceeding with the litigation," rather than intervening "for the purpose of settling and ending the case." *Id*. at 1356. "[W]hen the Government moves to dismiss an action after having declined to intervene," the Court continued, "it need provide the Relator only notice and a hearing." *Id*. at 1357. Notably, the Eleventh Circuit subsequently voted to rehear the case *en banc*, and accordingly vacated the initial panel's opinion.

## B. Public Disclosure Bar and First-to-File

The FCA employs two related rules barring relators from bringing actions in situations where the underlying, alleged wrongdoing has already been disclosed or addressed by someone else. First, the public disclosure bar requires dismissal of FCA cases brought by private litigants where "substantially the same allegations or transactions" underlying the

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action have already been publicly disclosed, including "in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party," unless the relator is an "original source of the information." 31 U.S.C. § 3730(e)(4). Relatedly, the first-to-file rule prevents private litigants from bringing an action that is "based on the facts underlying" any other action that was pending at the time and brought by a separate litigant. *Id*. at § 3730(b)(5). There were a number of notable decisions under these bars in the first half of the year.

## 1. Eleventh Circuit Considers Public Disclosure and First-to-File Bars

In *Cho on behalf of States v. Surgery Partners, Inc.*, 30 F.4th 1035 (11th Cir. 2022), the Eleventh Circuit considered questions related to both the first-to-file rule and the public disclosure bar.

First, it considered whether an amended complaint filed *after* a related action was resolved can overcome the first-to-file rule's applicability to an earlier compliant that was filed while a related case was still pending. *Id*. at 1038, 1040. In April 2017, relators filed a *qui tam* action against a private equity firm and its subsidiary for allegedly leading a fraudulent enterprise to submit false claims for reimbursement under Medicare. *Id*. at 1037, 1039. However, in August 2016, approximately six months before the relators filed their complaint, a different group of relators had filed a *related* action against one of the same parties—the subsidiary—but not against the parent, private equity firm. *Id*. at 1039. After the August 2016 action settled and became public, the relators for the April 2017 action filed an amended complaint, which focused the allegations solely on the private equity firm that had not been a party in the separate, but related, action brought by the different relators in the August 2016 action. *Id*. However, the district court dismissed the second amended complaint, finding that though the amended complaint was filed after the August 2016 case was resolved, the first-to-file rule rendered the entire action dismissible because the initial, April 2017 complaint was filed when the August 2016 suit was still pending. *Id*.

Under *de novo* review, the Eleventh Circuit affirmed the district court's dismissal under the first-to-file rule on appeal. Focusing on the key words "bring" and "action" within section 3730(b)(5) (establishing that "no person . . . may intervene to bring a related action based on the facts underlying [a] pending action"), the Court asserted that the first-to-file rule "turns on the moment the Relators *initiated* legal proceedings." *Id*. at 1040 (emphasis in original). The Court accordingly concluded that the plain text of the FCA "tethers" the first-to-file analysis on the "moment a *qui tam* action is filed." *Id*. at 1042.

The Eleventh Circuit also considered a nuance to the public disclosure bar: what test it should apply when determining whether a pending action is "related" to a later-filed *qui tam* action. *Id*. Adopting the same approach used by its sister circuits and the district court below, the Court decided to use the "same material elements" test to assess relatedness. *Id*. Under this test, two actions are deemed to be related if they "rely on the same 'essential facts.'" *Id*. (quoting *United States ex rel. Wood v. Allergan, Inc.*, 899 F.3d 163, 169 (2d Cir. 2018)). Applying this test to the facts at hand, the Court found that the relators' April 2017 action was adequately "related" to the separate relators' August 2016 action for the purposes of dismissal, explaining that though the April 2017 complaint named an additional defendant not included in the August 2016 action, the suits were related because the first-to-file bar does not "require[] a necessarily defendant-specific approach[,] . . . particularly where the new defendant is a corporate relative or affiliate of the earlier-named defendants." *Id*. at 1043.

## 2. Ninth Circuit Considers What Counts as a Public Disclosure

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In a pair of cases, the Ninth Circuit considered what public disclosures can trigger the public disclosure bar.

First, the Ninth Circuit addressed whether materials released by a government agency under FOIA can trigger the public disclosure bar in *Roe v. Stanford Health Care*, No. 20-55874, 2022 WL 796798 (9th Cir. Mar. 15, 2022). In that case, appellant brought a FCA suit alleging that Stanford Health Care engaged in fraudulent Medicare billing. The Ninth Circuit affirmed the district court's dismissal of appellant's claims on the basis of the FCA's public disclosure bar. Appellant's claims were barred because the "second amended complaint is almost entirely premised on publicly disclosed Medicare data [appellant] obtained through Freedom of Information Act requests," and because "[t]he other information [appellant] identifies . . . is either irrelevant or already revealed in the data." *Id*., at *1. In so holding, the Ninth Circuit joined the vast majority of courts to consider the issue in holding that FOIA disclosures do trigger the public disclosure bar.

Second, in *Mark ex rel. United States v. Shamir USA, Inc.*, No. 20-56280, 2022 WL 327475 (9th Cir. Feb. 3, 2022), the Ninth Circuit considered whether an eyeglass lens manufacturer's description of its customer rewards program in public promotional materials triggered the FCA's public disclosure bar. The *qui tam* relator in this case alleged that Shamir's customer rewards program violated the AKS and FCA by exploiting the Government's practice of reimbursing lenses based on the invoice price. *Id.* at *1. According to the relator, Shamir persuaded eyecare professionals (ECPs) to prescribe Shamir's lenses by offering discounts and rebates on lenses and subsequently providing the ECPs with invoices purporting to charge full price so that government insurance programs, "rather than Shamir, pa[id] for the ECP discounts." *Id.* The district court granted Shamir's motion to dismiss the relator's claim, holding that his allegations were precluded by the FCA's public disclosure bar because they were "substantially similar" to statements Shamir made about its rewards program in promotional materials. *Id.* For example, in several industry journals, Shamir encouraged ECPs to participate in its rewards program by stating that "they automatically receive rewards back, making it a win-win for everyone," and offering to develop "personalized YouTube channels" for ECPs to showcase Shamir-manufactured lenses. *Id.* at *2. According to the district court, these "publicly disclosed facts" announced that the discounts and rebates ECPs received from Shamir "were not deducted from any insurance reimbursement," thereby foreclosing the relator's claim. *Id.* The Ninth Circuit overruled the district court, holding that application of the public disclosure bar was not warranted because the information in the promotional materials "was so innocuous" that no "transaction or allegation of fraud" was publicly disclosed by Shamir in the first place. *Id.*

## C. Sixth Circuit Finds Inflated Fixed-Price Proposals Sufficient to Satisfy FCA's Pleading Standard

In *United States ex rel. USN4U, LLC v. Wolf Creek Federal Services, Inc.*, 34 F.4th 507 (6th Cir. 2022), the Sixth Circuit issued a detailed and probing decision that addressed pleading standards for FCA suits. In that case, the relator, USN4U, LLC (USN4U) alleged that Wolf Creek Federal Services, Inc. (Wolf Creek), a federal contractor, "falsely inflated project estimates to the National Aeronautics and Space Administration (NASA) for facilities maintenance projects to be performed by Wolf Creek, resulting in the negotiation of fraudulently induced, exorbitant contract prices," thereby violating the FCA. *Id.* at 510.

Wolf Creek provided facilities management maintenance services to the National Aeronautics and Space Administration (NASA) under the terms of an indefinite-delivery indefinite-quantity (IDIQ) contract awarded in 2013 (the NASA Contract). *Id.* at 510–11. Pursuant to the terms of the NASA Contract, NASA would approve specific projects for Wolf Creek to perform on a firm-fixed price basis. *Id.* at 511. After Wolf Creek received a work order for the subject task, it was required to submit a proposal for schedule of completion and the total cost of labor and materials, which NASA would evaluate for purposes of negotiating a final firm-fixed price amount. *Id.* As the Court noted, once the

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firm-fixed price was established, Wolf Creek's invoices were required to align with the agreed-upon amount. *Id.*

Wolf Creek filed a motion to dismiss USN4U's complaint for failure to state a valid claim, taking the position that "the estimates and project proposals [it submitted] were not 'claims' for FCA purposes" and generally contesting the sufficiency of USN4U's fraud claims more generally. *Id.* at 512. After USN4U amended its complaint, Wolf Creek filed a second motion to dismiss, "repeating their argument that quotes were not 'claims' for purposes of the FCA and further arguing that invoices were not 'false' if they matched the quoted amount." *Id.* The Court noted that USN4U's amended complaint included further examples supporting the FCA allegations, including providing a list of employees who admitted to reporting more hours worked than actually completed, as well as "a transcript of a recorded conversation in which several Wolf Creek employees allegedly discussed the fraudulent scheme." *Id.*

The district court nevertheless granted Wolf Creek's second motion to dismiss and denied USN4U's motion to file a second amended complaint. By the district court's read, notwithstanding that the work order proposals Wolf Creek submitted to NASA contained quoted prices, the proposals did not constitute "claims" under the FCA, serving only as estimates rather than demands or invoices. *Id.* at 512–13. Additionally, the district court held that USN4U did not satisfy its burden to plead falsity under the FCA as USN4U's allegations merely compared the labor costs with industry standards to support its claims of false inflation. *Id.* at 513. Finally, the district court held that USN4U failed to satisfy its burden to plead fraud in the inducement, citing Wolf Creek's continued performance under the NASA Contract even after the fraud allegations materialized. *Id.*

The Sixth Circuit reversed, holding USN4U sufficiently alleged a claim of fraudulent inducement, which is a viable legal theory under the FCA, noting that "FCA liability can be based on a fraudulent premise that caused the United States to enter into a contract," and finding that USN4U adequately pled its fraudulent inducement claim based on its assertions that "Wolf Creek falsely inflated cost estimates in its work order proposals and thus induced NASA to agree to contracts at that price point." *Id.* (internal citation omitted).

Turning next to the elements of an FCA claim, the Court first addressed falsity, finding that reliance on industry standards as the basis for a fraud claim is not presumptively insufficient. *See id.* at 515. The Court also noted that USN4U provided additional support beyond a comparison with industry standards when it offered evidence of a disparity in billing activity between the employees participating in the scheme and those who did not, an incident where a plumber billed to a project where no plumbing work was required, and a recording transcript in which Wolf Creek employees discussed the practice of using false estimates. *Id.*

Regarding scienter, the Court found USN4U satisfied the pleading standard through, in addition to the examples discussed herein, USN4U's submission of a "recorded conversation in which Wolf Creek employees allegedly discussed their knowledge of the falsely inflated cost estimates and labor hours," noting that an employee stated: "[t]he original estimate that they gave me for hours, they told me they needed about 130 hours of overtime. I upped it like I always do to 164 hrs." *Id.* at 516. The employee further stated:

I came back and we started chewing up what you guys had. It was going away so I got nervous and had no intentions of working 40 hrs when I came back. So then I got crazy and started pumping out estimates. And now it[']s, if I stay at the rate that I am at right now we will never run out. So the key is to just have it flooded. Inundate the customer with the quotes.

*Id.* With respect to materiality, the Court found that "Wolf Creek's falsely inflated estimates could have had the tendency to influence NASA's contracting decisions," given that NASA relied on Wolf Creek's contractual estimate rather than conduct its own research into costs. *Id.* The Court noted that "[w]hile it is possible, as Wolf Creek

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suggests, that NASA's faith in Wolf Creek's estimates came from its own careful research and consideration of Wolf Cree's proposals, it is also plausible that NASA trusted and relied exclusively upon Wolf Creek's estimates, and that NASA ultimately paid Wolf Creek based on its induced belief that the quoted prices were reasonably accurate." *Id.* Finally, the Court stated that NASA's decision to allow Wolf Creek to continue with contract performance after the fraud allegations surfaced was not dispositive or indicative of "actual knowledge" of fraud, and noted that various factors could influence the decision to continue performance, including the desire to avoid prematurely ending a contractual relationship prior to an investigation into the alleged fraud. *Id.* at 517. The court also noted that the government's decision not to intervene in a particular case is not considered for purposes of assessing materiality. *Id.*

Lastly, the Court found that USN4U satisfied the pleading requirements for causation, stating that "NASA asked Wolf Creek for estimates and when it awarded Wolf Creek the contracts, NASA always awarded the contracts for the quoted amount, which could indicate that NASA trusted and relied upon the purported accuracy of Wolf Creek's estimates when it entered into the contracts at the quoted prices." *Id.* at 518. The Court also noted that "NASA plausibly would not have agreed to pay Wolf Creek the quoted amount if NASA knew that it was being grossly overcharged." *Id.* The Court accordingly reversed the judgment of the district court and remanded for further proceedings.

### D. Falsity

## 1. Ninth Circuit Holds Disagreement in Clinical Judgment Is Insufficient to Establish Falsity

**In *Holzner v. DaVita Inc.*, No. 21-55261, 2022 WL 726929 (9th Cir. Mar. 10, 2022), appellant alleged that DaVita Inc. (appellee) provided medically unnecessary products and services and/or unreasonably expensive medications in violation of the FCA.**

The Ninth Circuit affirmed the district court's dismissal of appellant's claims on the grounds that appellant had not plausibly alleged a false statement in order to establish FCA liability. *Id*. at *2. The court explained that the complaint "does not contain sufficient facts . . . to state a plausible claim of false or fraudulent billing related to the appellees' provision of dialysis treatments" and prescription drugs, because the allegations instead "show no more than a disagreement in clinical judgment," as "[t]he medical literature on which Holzner relies . . . does not establish new guidelines for practitioners or otherwise compel a change of practice among nephrologists." *Id*. at *1. As a result, "Holzner has not raised a plausible inference that the nephrologists' certifications that these interventions are medically necessary—or appellees' reliance on those certifications—were false or fraudulent." *Id*.

In so holding, the Ninth Circuit joins a growing number of appeals courts to consider these issues in recent years. In *United States v. AseraCare, Inc.*, 938 F.3d 1278 (11th Cir. 2019), the Eleventh Circuit similarly held that clinical disagreement is insufficient to establish falsity because the FCA requires the alleged falsehood to be objectively false. Yet the Third Circuit, in *United States ex rel. Druding v. Care Alternatives*, 952 F.3d 89 (3d Cir. 2020), and the Sixth Circuit, in *United States v. Paulus*, 894 F.3d 267 (6th Cir. 2018), have rejected the Eleventh and Ninth Circuits' conclusion that the FCA requires proof of "objective falsity," and held instead that a difference of medical opinion can be sufficient to show that a statement is false.

## 2. District Court Holds That Relator Failed to Satisfy

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## Falsity Element of an FCA Claim Based on Alleged Failure to Comply with State Law

In *United States ex rel. Jehl v. GGNSC Southaven LLC*, 3:19-CV-091-NBB-JMV, 2022 WL 983644 (N.D. Miss. Mar. 30, 2022), the district court held, *inter alia*, that the relator failed to satisfy the falsity element of an FCA claim based on the Defendants' alleged false certification of compliance with state licensure laws. In the complaint, the *qui tam* relator alleged that the Defendants, who operated a nursing facility in Southaven, Mississippi, violated the FCA by billing Medicare and Medicaid for health care services while certifying that the company complied with Mississippi's licensure laws for nurses even though its Director of Nursing Services (Director) was not licensed to work as a nurse in the state. *Id.* at *1. Shortly before she began working for the defendants in Mississippi, the Director obtained a valid multistate nursing license from Virginia based in part on a declaration she submitted averring that Virginia was her primary state of residence (PSOR). *Id.* at *2. The Virginia multistate license permitted the Director to practice nursing in Mississippi, and the day after the Director began her employment at the Southaven facility, an employee for one of the Defendants confirmed that she held an active Virginia nursing license with a multistate privilege. *Id.* However, according to the relator, the Director's multistate license was actually invalid because her claiming of Virginia as her PSOR was false; in fact, the relator continued, the Director's PSOR was actually Tennessee, as evidenced by her Tennessee driver's license. *Id.* The relator argued that because the Director lacked a valid license to practice nursing in Mississippi while employed by the Defendants, their "certifications of compliance with applicable licensure laws in their Medicare and Medicaid reimbursement requests were false within the meaning of the FCA." *Id.*

The district court granted the Defendants' motion for summary judgment, holding that the relator did not possess evidence establishing the FCA's falsity, knowledge, or materiality elements. *Id.* at *6. The Centers for Medicare & Medicaid Services' (CMS) regulations for nursing facilities require such facilities to comply "with all applicable Federal, State, and local laws, regulations, and codes." 42 C.F.R. § 483.70(b). In CMS's *State Operations Manual*, which provides interpretive guidance on CMS's nursing facility regulations, CMS explains that noncompliance "with Federal, State, and local laws, regulations [and] codes" occurs "only when a final adverse action has been taken by the authority having jurisdiction regarding noncompliance with its applicable laws, regulations, codes and/or standards." *Id.* at *4. In this case, undisputed facts showed that during the period when the Director worked at the Southaven facility, neither the Virginia Nursing Board nor any other nursing board had "taken any action, let alone a final adverse action, against [the Director's] professional license, meaning that under CMS's clear rules, her nursing license was . . . valid during the entire period of her employment." *Id.* at *5. Therefore, as a matter of law, the FCA's falsity element could not be satisfied because the Defendants' certifications of compliance with CMS regulations were "demonstrably true and accurate, not false." *Id.* at *6. Similarly, the district court concluded that the relator could not satisfy the knowledge element of an FCA claim because the Defendants' certifications were proper. *Id.* Further, the district court ruled that the relator could not satisfy the FCA's materiality element because the CMS regulations that the Defendants allegedly breached, 42 C.F.R. Part 483, contained only "broad certification language" that, under established precedent, cannot support an FCA claim, and the evidence available at summary judgment "show[ed] no linkage between nurse licensure" and government payment of submitted claims. *Id.*

### E. Materiality

## 1. D.C. Circuit Holds That the FCA's Materiality Inquiry Focuses on the Potential Effect of False Statement When Made

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In *United States ex rel. Vermont National Telephone Co. v. Northstar Wireless, LLC, et al.*, 34 F.4th 29, 31 (D.C. Cir. 2022), Vermont National Telephone Company (Vermont Telephone) alleged that several telecommunications companies, including Northstar, SNR, DISH, and affiliated companies (collectively, Defendants), violated the FCA and defrauded the U.S. government of $3.3 billion by manipulating Federal Communications Commission (FCC) rules and falsely certifying their eligibility for discounts on spectrum licenses. The district court dismissed Vermont Telephone's *qui tam* suit, relying on the FCA's "government-action bar" and the FCA's "demanding materiality standard." *Id*. The D.C. Circuit reversed on both grounds.

To apportion licenses allowing companies to use portions of the electromagnetic spectrum to provide television, cell phone, and wireless internet service, the FCC holds auctions that involve a two-step license application process. *Id.* at 31. The FCC officers allocate "bidding credits" (discounts to cover part of the cost of licenses won at auction) to very small businesses, those with less than $15 million in revenue. *Id.* at 31, 32. As part of the application process, companies must provide information concerning their eligibility to bid in the auction and certify their eligibility for bidding credits. *Id.* at 32.

Vermont Telephone alleged that Defendants failed to disclose resale agreements with DISH, which would have increased their attributable revenues beyond the allowable cap for the very small business credits. *Id*. at 36. Defendants argued that the alleged undisclosed agreements would not have changed the FCC's ultimate decision to deny bidding credits because the FCC found the Defendants ineligible for the discounts even without disclosure of any resale agreements. *Id*. at 37.

The D.C. Circuit rejected Defendants' argument to focus on the "ultimate decision." *Id.* Instead, the Court's materiality analysis focused on the "potential effect of the false statement when it is made," not on "the false statement's actual effect after it is discovered." *Id*. (internal citation omitted). The Court held that Defendants' failure to disclose agreements central to their eligibility for discounts was certainly "capable of influencing" the FCC's eligibility determination and, thus, Vermont Telephone plausibly pleaded materiality. *Id*. at 36–38. This appears to conflict with language from *Escobar* that if the Government pays a particular claim in full despite its *actual* knowledge that certain requirements were violated then "that is very strong evidence" of the immateriality of those requirements*. Universal Health Servs., Inc. ex rel. Escobar v. United States*, 579 U.S. 176, 195 (2016).

## 2. Ninth Circuit Enforces False Certification and Materiality Pleading Requirements

In *McElligott v. McKesson Corp.*, No. 21-15477, 2022 WL 728903, at *1 (9th Cir. Mar. 10, 2022), appellant relators alleged that McKesson "knowingly present[ed], or cause[d] to be presented, a false or fraudulent claim for payment or approval" by making false certifications in violation of the FCA. The Ninth Circuit affirmed the district court's dismissal of relators' claims without leave to amend because the complaint failed to plead a claim for express false certification, as there were no allegations that "defendant submitted a claim for payment to the government in which it expressly certified that it had complied with a specific law or provision of the contract with which it knew it had not complied." *Id*.

Nor did the relators sufficiently allege that Defendant made implied false certifications. "[T]he second amended complaint does not allege that, in its claims for payment, McKesson made specific representations about the medical supplies it provided that were rendered misleading half-truths by its failure to disclose noncompliance with material statutory, regulatory, or contractual requirements." *Id*. Instead, "[a]s far as the complaint reveals, McKesson represented nothing more in its claims for payment than that it delivered certain medical supplies on certain dates," and "[t]he complaint does not allege that those representations were false." *Id.*

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The Court also ruled that the relators failed to allege materiality, as "nothing in the complaint gives rise to a reasonable inference that the security of McKesson's supply chain was material to the government's decision to pay for medical supplies that McKesson actually delivered." *Id*. at *2.

### F. Scienter

## 1. Fourth Circuit Struggles in Determining When a Defendant's Alleged Mistakes of Law Can Establish Scienter

In two recent cases, Fourth Circuit panels divided as to whether a defendant's alleged misinterpretation of a complex regulation could establish scienter under the FCA.

In the first case, *United States ex rel. Sheldon v. Allergan Sales, LLC*, 24 F.4th 340 (4th Cir. 2022), Judge Wilkinson, joined by Judge Richardson, affirmed the district court's dismissal of an FDCA case and imported the scienter standard from the Supreme Court's Fair Credit Reporting Act decision in *Safeco Ins. Co. of America v. Burr*, 551 U.S. 57 (2007), into the FCA context. *Safeco* "set forth a two-step analysis" in determining whether a defendant has acted in reckless disregard of the law. *Sheldon*, 24 F.4th at 347. First, a court asks "whether defendant's interpretation was objectively reasonable." *Id.* The second step is "determining whether authoritative guidance might have warned defendant away from that reading." *Id.* This test is appropriate in FCA cases, reasoned the majority, because the "FCA defines 'knowingly' as including actual knowledge, deliberate ignorance, and reckless disregard. . . . [and] *Safeco* interpreted 'willfully' to include both knowledge and recklessness." *Id.* at 348.

The court then applied *Safeco* to the facts. This case concerned the Medicaid Drug Rebate Statute, which requires "manufacturers seeking to have their drugs covered by Medicaid [to] enter into Rebate Agreements with the Secretary of Health and Human Services and provide quarterly rebates to states on Medicaid sales of covered drugs. . . . For covered drugs, the rebate amount is the greater of two numbers: (1) the statutory minimum rebate percentage, or (2) the difference between the Average Manufacturer Price and the Best Price," the latter of which is essentially "the lowest price available from the manufacture." *Id.* at 345.

Plaintiff employee filed a *qui tam* suit against Forest Laboratories, LLC under the FCA, alleging that Forest gave discounts to customers but failed to account for these discounts in calculating Best Price, resulting in false reports to the government. *Id.* at 343–44. Forest argued that it correctly, or at least reasonably, interpreted the meaning of "Best Price" and therefore did not knowingly defraud the government.

The majority agreed. Pursuant to the *Safeco* standard, "[u]nder the FCA, a defendant cannot act 'knowingly' if it bases its actions on an objectively reasonable interpretation of the relevant statute when it has not been warned away from that interpretation by authoritative guidance. This objective standard precludes inquiry into a defendant's subjective intent." *Id.* at 348. Forest did not "act knowingly under the FCA" because "Forest's reading of the Rebate Statute was at the very least objectively reasonable and because it was not warned away from that reading by authoritative guidance." *Id.* at 343–44, 347.

Judge Wynn dissented. He accused the majority of "effectively neuter[ing] the False Claims Act . . . by eliminating … two of its three scienter standards (actual knowledge and deliberate ignorance) and replacing the remaining standard with a test (objective recklessness) that only the dimmest of fraudsters could fail to take advantage of." *Id.* at 357 (Wynn, J., dissenting). Judge Wynn would not have "imported" *Safeco* into the FCA, a "vastly different statutory context." *Id.* at 361. The Fourth Circuit subsequently granted

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rehearing en banc, 2022 WL 1467710, but did not vacate the panel opinion.

The second case, *United States ex rel. Gugenheim v. Meridian Senior Living, LLC*, 36 F.4th 173 (4th Cir. 2022), concerned reimbursement for "personal care services," including assisting with activities such as eating, dressing, and bathing, that are provided to elderly or disabled adults under North Carolina's Medicaid program. The program authorizes a certain number of daily "personal care services" for elderly or disabled patients based on a patient's personal needs. *Id.* at 175–76. Defendant adult-care homes billed for the authorized hours of personal care services rather than the actual amount of services provided. *Id.* at 177–78.

Plaintiff attorney filed a *qui tam* suit against the nursing homes under the FCA, alleging that the homes' billing schemes violated the rules of the state Medicaid program. The district court granted summary judgment to the home, holding that the plaintiff failed to show that the home's claims "were materially false or made with the requisite scienter." *Id.* at 178.

A divided panel of the Fourth Circuit affirmed. At issue was whether the defendants knowingly submitted false claims to Medicaid. Judge Rushing, joined by Judge Wilkinson, concluded that the defendants did not. *Id.* at 175. They emphasized that state regulations defining billing for personal care services were unclear and that the defendants plausibly interpreted the regulations as allowing their billing practices. They then held that courts cannot infer scienter when defendants reasonably interpret ambiguous regulations:

We need not determine whether Defendants' interpretation of [state regulations] is correct. The policy and related guidance from NC Medicaid are sufficiently ambiguous to foreclose the possibility of proving scienter based solely on the clarity of the regulation. We cannot infer scienter from an alleged regulatory violation itself, and we especially will not do so where there is regulatory ambiguity as to whether Defendants' conduct even violated the policy.

*Id.* at 181 (quotation marks removed). The court then rejected plaintiff's alternate argument that the home should "have sought more guidance about an ambiguous regulation" because there was no evidence that the home "knew, or even suspected, that [its] interpretation of [the regulation] was incorrect." *Id.* Plaintiff failed to submit "any evidence that Defendants knew, or even suspected, that their interpretation of [the regulation] and the related guidance from NC Medicaid was incorrect (indeed, it may be right)." *Id.*

Senior Judge Traxler dissented and would have allowed the case to proceed to trial. The plaintiff submitted plausible evidence of overbilling and "that Defendants did next to nothing to educate themselves" about the regulation. *Id.* at 183 (Traxler, J., dissenting). Thus, "a reasonable jury could find that Defendants failed to make a reasonable and prudent inquiry into how [the regulation] affected their billing method and, instead, buried their heads in the sand to maximize their billings." *Id.* at 190.

## 2. Fifth Circuit Reiterates Need to Allege Scienter

In *United States ex rel. Jacobs v. Walgreen Company*, 2022 WL 613160 (5th Cir. March 2, 2022), plaintiff pharmacist filed a *qui tam* suit against her employer Walgreens under the FCA, alleging that Walgreens submitted false claims for reimbursement to Medicare and Medicaid. The district court dismissed the case for failure to plead fraud with particularity. The Fifth Circuit affirmed in a short opinion.

The court began by describing the pleading requirements of the Act. A plaintiff must plead: "(1) a false statement or fraudulent course of conduct; (2) that was made or carried out with the requisite scienter; (3) that was material; and (4) that caused the government to pay out money (i.e., that involved a claim)." *Id.* at *1. But the plaintiff did not "plead[] facts

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supporting an inference that the allegedly fraudulent conduct amounted to anything more than innocent mistake or neglect." *Id.* The complaint accordingly failed to state a claim because the FCA does not confer liability "for innocent mistakes or neglect." *Id.* Indeed, the allegation that "Walgreens failed to correct certain billing mistakes once it discovered them" was an impermissibly "conclusory allegation[] that [did] not provide specifics as to the 'who, what, when, where, and how of the alleged fraud.'" *Id.*

### 3. Seventh Circuit Reaffirms Objective Scienter Standard

In *United States ex rel. Proctor v. Safeway, Inc.*, the relator alleged that between 2006 and 2015, Safeway knowingly submitted false claims to government health programs when it reported its "retail" price for certain drugs as its "usual and customary" price, even though many customers paid much less than the retail price due to discount programs. 30 F.4th 649, 652–54 (7th Cir. 2022). The allegations were almost identical to the allegations in *United States ex rel. Schutte v. SuperValu, Inc.*, 9 F.4th 455 (7th Cir. 2021), which we covered in our 2021 Year End False Claims Act Update.

The Seventh Circuit decided *SuperValu* while *Safeway* was pending. *Safeway*, 30 F.4th at 657. In *SuperValu*, the Seventh Circuit held that the Supreme Court's decision in *Safeco Ins. Co. of America v. Burr*, 551 U.S. 47 (2007) applied to the FCA's scienter provision, meaning that a defendant does not act with "reckless disregard" as long as (1) its interpretation of the relevant statute or regulation is "objectively reasonable" and (2) no "authoritative guidance" warned it away from that interpretation. *Id*.

The court reached the same conclusion in *Safeway*, and further explained when guidance is "authoritative." *Id*. at 660. In order for guidance to be "authoritative," it must "come from a source with authority to interpret the relevant text." *Id*. In addition to the source, the Seventh Circuit also considers whether that guidance was sufficiently specific to put a defendant on notice that its conduct is unlawful. *Id*. Accordingly, the court held that a single footnote in a lengthy manual that can be revised at any time is not authoritative guidance. *Id*. at 663

## G. Sixth Circuit Holds that the Limitations Period for FCA Claims Begins to Run When Retaliation Occurs, Not When Relator Receives Notice

The Sixth Circuit recently reaffirmed that there is "no notice requirement" in the FCA statute of limitations for retaliation claims. *El-Khalil v. Oakwood Healthcare, Inc.*, 23 F.4th 633 (6th Cir. 2022). The statute sets forth a three-year limitations period that begins to run when "the retaliation occurred." *Id.* at 635 (quoting 31 U.S.C. § 3730(h)). The Court noted this conclusion is "hardly groundbreaking," it merely codifies the "standard rule" that the "limitation period begins when the plaintiff 'can file suit and obtain relief.'" *Id.* The *El-Khalil* Court did note, however, that equitable doctrines may toll the limitations period if an employer purposely delays its provision of notice in order to let the limitations period run and deprive the relator of a fair opportunity to bring suit. *Id.* at 636.

## IV. CONCLUSION

We will monitor these developments, along with other FCA legislative activity, settlements, and jurisprudence throughout the year and report back in our 2022 False Claims Act Year-End Update, which we will publish in January 2023.

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[1] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Northern Virginia Company Settles False Claims Act Allegations of Improper Paycheck Protection Program Loan (Feb. 11, 2022), https://www.justice.gov/opa/pr/northern-virginia-company-settles-

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false-claims-act-allegations-improper-paycheck-protection.

[2] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Physician Partners of America to Pay $24.5 Million to Settle Allegations of Unnecessary Testing, Improper Remuneration to Physicians and a False Statement in Connection with COVID-19 Relief Funds (April 12, 2022), https://www.justice.gov/opa/pr/physician-partners-america-pay-245-million-settle-allegations-unnecessary-testing-improper.

[3] *See* Press Release, U.S. Atty's Office for the Eastern Dist. of NY, Contractor Pays $930,000 to Settle False Claims Act Allegations Relating to Medical Services Contracts at State Department and Air Force Facilities in Iraq and Afghanistan (March 8, 2022), https://*www*.justice.gov/usao-edny/pr/contractor-pays-930000-settle-false-claims-act-allegations-relating-medical-services.

[4] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, UC San Diego Health Pays $2.98 Million to Resolve Allegations of Ordering Unnecessary Genetic Testing (Jan. 11, 2022), https://www.justice.gov/opa/pr/uc-san-diego-health-pays-298-million-resolve-allegations-ordering-unnecessary-genetic-testing.

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[7] *See* Press Release, U.S. Atty's Office for the Dist. of NH, Catholic Medical Center Agrees to Pay $3.8 Million to Resolve Kickback-Related False Claims Act Allegations (Feb. 9, 2022), https://www.justice.gov/usao-nh/pr/catholic-medical-center-agrees-pay-38-million-resolve-kickback-related-false-claims-act.

[8] *See* Press Release, U.S. Atty's Office for the Southern Dist. of OH, 3 Central Ohio health providers to pay more than $3 million for improper claims submitted to Medicare and Ohio Bureau of Workers' Compensation (Feb. 15, 2022), https://www.justice.gov/usao-sdoh/pr/3-central-ohio-health-providers-pay-more-3-million-improper-claims-submitted-medicare-0.

[9] *See* Press Release, Office of Public Affairs, U.S. Dep't of Justice, Mallinckrodt Agrees to Pay $260 Million to Settle Lawsuits Alleging Underpayments of Medicaid Drug Rebates and Payment of Illegal Kickbacks (Mar. 7, 2022), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-260-million-settle-lawsuits-alleging-underpayments-medicaid-drug.

[10] *See* Press Release, U.S. Atty's Office for the Eastern Dist. of PA, Philadelphia Psychiatrist to Pay $3 Million to Resolve Allegations of False Workers' Compensation Claims (Mar. 28, 2022), https://www.justice.gov/usao-edpa/pr/philadelphia-psychiatrist-pay-3-million-resolve-allegations-false-workers-compensation.

[11] *See* Press Release, Office of Public Affairs, U.S. Dep't of Justice, Florida's BayCare Health System and Hospital Affiliates Agree to Pay $20 Million to Settle False Claims Act Allegations Relating to Impermissible Medicaid Donations (Apr. 6, 2022), https://www.justice.gov/opa/pr/florida-s-baycare-health-system-and-hospital-affiliates-agree-pay-20-million-settle-false.

[12] *See* Press Release, Office of Public Affairs, U.S. Dep't of Justice, Physician Partners of America to Pay $24.5 Million to Settle Allegations of Unnecessary Testing,

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Improper Remuneration to Physicians and a False Statement in Connection with COVID-19 Relief Funds (Apr. 12, 2022), https://www.justice.gov/opa/pr/physician-partners-america-pay-245-million-settle-allegations-unnecessary-testing-improper.

[13] *See* Press Release, U.S. Atty's Office for the Northern Dist. of GA, Paul D. Weir, John R. Morgan, M.D., Care Plus Management, LLC, and Anesthesia Entities pay $7.2 million to Resolve Kickback and False Claims Act Allegations (Apr. 13, 2022), https://www.justice.gov/usao-ndga/pr/paul-d-weir-john-r-morgan-md-care-plus-management-llc-and-anesthesia-entities-pay-72.

[14] *See* Press Release, Office of Public Affairs, U.S. Dep't of Justice, Hearing Aid Company Eargo Inc. Agrees to Pay $34.37 Million to Settle Common Law and False Claims Act Allegations for Unsupported Diagnosis Codes (Apr. 29, 2022), https://www.justice.gov/opa/pr/hearing-aid-company-eargo-inc-agrees-pay-3437-million-settle-common-law-and-false-claims-act.

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[16] *See* Press Release, U.S. Atty's Office for the Western Dist. of NC, Healthkeeperz, Inc. To Pay $2.1 Million To Resolve False Claims Act Allegations (June 1, 2022), https://www.justice.gov/usao-wdnc/pr/healthkeeperz-inc-pay-21-million-resolve-false-claims-act-allegations.

[17] *See* Press Release, U.S. Atty's Office for the Eastern Dist. of NY, Caris Life Sciences Pays over $2.8 Million to Settle False Claims Act Allegations from Delay in Submission of Genetic Cancer Screening Tests (June 1, 2022), https://www.justice.gov/usao-edny/pr/caris-life-sciences-pays-over-28-million-settle-false-claims-act-allegations-delay.

[18] *See* Press Release, U.S. Atty's Office for the Northern Dist. of IL, Suburban Chicago Home Sleep Testing Company To Pay $3.5 Million To Settle Federal Health Care Fraud Suit (June 6, 2022), https://www.justice.gov/usao-ndil/pr/suburban-chicago-home-sleep-testing-company-pay-35-million-settle-federal-health-care#:~:text=CHICAGO%20%E2%80%94%20A%20suburban%20Chicago%20diagnostics,and%20unnecessary%20home%20sleep%20testing.

[19] *See* Press Release, Los Angeles Doctor to Pay $9.5 Million to Resolve Allegations of Fraud Against Medicare and Medi-Cal (June 10, 2022), https://www.justice.gov/usao-edca/pr/los-angeles-doctor-pay-95-million-resolve-allegations-fraud-against-medicare-and-medi.

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[23] *See* Press Release, Office of Public Affairs, U.S. Dep't of Justice, Freight Carriers Agree to Pay $6.85 Million to Resolve Allegations of Knowingly Presenting False Claims to the Department of Defense (Mar. 14, 2022), https://www.justice.gov/opa/pr/freight-carriers-agree-pay-685-million-resolve-allegations-knowingly-presenting-false-claims.

[24] *See* Press Release, Office of Public Affairs, U.S. Dep't of Justice, UPS to Pay $5.3 Million to Settle False Claims Act Allegations for Falsely Reporting Delivery Times of U.S. Mail Carried Internationally (Mar. 21, 2022), https://www.justice.gov/opa/pr/ups-pay-53-million-settle-false-claims-act-allegations-falsely-reporting-delivery-times-us-0.

[25] *See* Press Release, U.S. Atty's Office for the Northern Dist. of NY, Construction Company Agrees to Pay $2.8 Million to Resolve Allegations of Small Business Subcontracting Fraud (May 12, 2022), https://www.justice.gov/usao-ndny/pr/construction-company-agrees-pay-28-million-resolve-allegations-small-business.

[26] *See* Press Release, Office of Public Affairs, U.S. Dep't of Justice, Seven South Korean Companies Agree to Pay Approximately $3.1 Million to Settle Civil False Claims Act Allegations for Bid Rigging on U.S. Department of Defense Contracts (May 18, 2022), https://www.justice.gov/opa/pr/seven-south-korean-companies-agree-pay-approximately-31-million-settle-civil-false-claims-act.

[27] *See* Press Release, U.S. Atty's Office for the Dist. of WV, United States Attorney Chris Kavanaugh Announces $3,000,000 Settlement in False Claims Act Case Against HEYtex USA (May 25, 2022), https://www.justice.gov/usao-wdva/pr/united-states-attorney-chris-kavanaugh-announces-3000000-settlement-false-claims-act.

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[29] *See* Press Release, Office of Public Affairs, U.S. Dep't of Justice, KBR Defendants Agree to Settle Kickback and False Claims Allegations (June 14, 2022), https://www.justice.gov/opa/pr/kbr-defendants-agree-settle-kickback-and-false-claims-allegations.

[30] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Loan Servicer Agrees to Pay Nearly $8 Million to Resolve Alleged False Claims in Connection with Federal Education Loans (Jan. 14, 2022), https://www.justice.gov/opa/pr/loan-servicer-agrees-pay-nearly-8-million-resolve-alleged-false-claims-connection-federal.

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[33] Brief for *Amicus Curiae* Senator Charles E. Grassley In Support of Petitioners, *United States ex rel. Tracy Schutte, et al. v. Supervalu Inc., et al.*, https://www.supremecourt.gov/DocketPDF/21/21-1326/225832/20220519154806836_21-1326%20Amicus%20Brief.pdf.

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[34] Colorado False Claims Act, House Bill 22-1119, https://leg.colorado.gov/sites/default/files/2022a_1119_signed.pdf.

[35] *Id.*

[36] *Id.*

[37] *Id.* at § 24-31-1204(1)(b).

[38] *Id.*

[39] *Id.*

[40] *Id.*

[41] https://www.cga.ct.gov/2022/TOB/S/PDF/2022SB-00426-R02-SB.PDF; http://www.legislature.mi.gov/documents/2021-2022/billintroduced/House/htm/2022-HIB-6032.htm.

[42] *See* N.Y. State Fin. L. § 189(1)(g), (4)(a); https://legislation.nysenate.gov/pdf/bills/2021/S8815.

[43] *See* https://oig.hhs.gov/fraud/state-false-claims-act-reviews/; 42 U.S.C. § 1396h(a).

[44] *Id.*

[45] *Id.*

[46] *Id.*

[47] *Compare* http://www.legislature.mi.gov/documents/2021-2022/billintroduced/House/htm/2022-HIB-6032.htm *with* 31 U.S.C. § 3730(d)(1).

[48] *See* John Elwood, Dismissing False Claims Act cases, promoting prescription fentanyl, and a capital case, SCOTUSBLOG (June 7, 2022, 8:25 PM), https://www.scotusblog.com/2022/06/dismissing-false-claims-act-cases-promoting-prescription-fentanyl-and-a-capital-case/.

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