GIBSON DUNN

2023 Mid-Year False Claims Act Update

Client Alert | August 2, 2023

The False Claims Act ("FCA") has had a somewhat mixed first half of 2023, marked by two Supreme Court decisions, significant decisions in the lower federal courts, and a large jury verdict for the government, but also by lower-than-usual recoveries by the government through settlements.

The June decisions by the Supreme Court settled circuit splits over scienter and the government's dismissal authority in ways that generally aligned with expectations among the FCA bar as far as the core issues went, but that also highlighted key questions for the lower courts to resolve going forward. Meanwhile, the U.S. Department of Justice ("DOJ") reached FCA resolutions totaling more than $485 million during the first half of the year, as well as an FCA judgment that by itself equaled approximately $487 million. Lower federal courts grappled with issues surrounding causation, the FCA's public disclosure bar, and the standard for pleading FCA allegations with particularity under Federal Rule of Civil Procedure 9(b).

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 first half of the year. 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 2023

During the first half of 2023, DOJ announced 36 FCA resolutions totaling more than $485 million. By comparison, in the first half of 2022, there were 29 resolutions totaling over $500 million—but by year end, DOJ had collected over $2.2 billion in FCA recoveries for the year. While 2023 appears to be off to a slower start in dollar terms compared to prior years, the number of resolutions in the first half shows that the government is as active as ever in this space.

Below, we summarize the most notable settlements and judgments from the first half of this year, organized by industry and focused on key theories of liability at issue in the resolutions.[1] As usual, FCA recoveries in the healthcare 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.

In addition to the settlements summarized below, there also was a federal jury trial under the FCA during the first half of the year—a relative rarity given the treble damages and punitive liability the statute imposes. On May 15, a U.S. District Court Judge for the District of Minnesota entered a judgment of approximately $487 million against an ophthalmic supplies company and the company's owner. Previously, on February 27, a jury had concluded that the defendants in the case violated the FCA and the Anti-Kickback Statute ("AKS") by paying kickbacks to ophthalmic surgeons to incentivize them to use the company's products in cataract surgeries for Medicare beneficiaries. The alleged kickbacks included luxury travel and entertainment, some of which was paid for out of what was referred to within the company as a "secret fund" and a "slush fund." The jury

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found that the defendants' conduct led to the submission of 64,575 false claims to Medicare, resulting in approximately $43,695,000 in damages to Medicare. Pursuant to the FCA, the court trebled these damages and imposed approximately $358,446,000 in statutory penalties—a number which may well be decreased under the Eighth Amendment's prohibition on excessive fines, but will still stand as a daunting recovery. The underlying lawsuit was initially brought by a *qui tam* relator, whose share of the judgment was not disclosed in the press release.[2]

A. Healthcare and Life Science Industries

- On January 9, a physicians group agreed to pay approximately $1.85 million to resolve allegations that it violated the FCA by billing the government for medically unnecessary cataract surgeries and diagnostics tests, tests that were incomplete or of no value, and office visits in which the level of service claimed was not provided. As part of the settlement, the physicians' group entered into a five?year Integrity Agreement and Conditional Exclusion Release with the Office of Inspector General for the Department of Health and Human Services ("HHS-OIG"). Under the agreement, HHS-OIG did not release its permissive exclusion authority and will provide such a release only after the physicians group has satisfied its obligations under the agreement. The settlement resolved a *qui tam* suit brought by a former employee; the former employee's share of the recovery was not disclosed.[3]
- On January 12, an orthopedic company and its owner agreed to pay approximately $1.8 million to resolve FCA allegations that between 2008-2015 the company submitted false claims for reimbursement for a particular knee agent when it was using a less expensive knee agent on beneficiaries of federal healthcare programs. The government alleged that the company and its owner profited from the use of the higher-priced products. The settlement resolved a *qui tam* suit brought by a medical device sales representative, whose share of the recovery was not disclosed at the time of the settlement.[4]
- On February 7, a clinical laboratory services provider agreed to pay $19 million to resolve allegations that it caused the submission of false claims to Medicare in violation of the FCA. The government alleged that the company provided phlebotomy services to doctors who ordered laboratory testing from the company and two other third-party providers when it knew the third-party providers paid fees to the doctors to induce referrals. The settlement resolved a *qui tam* suit brought by two relators, who together received approximately $5.6 million of the settlement.[5]
- On February 22, a company operating a long-term care hospital agreed to pay approximately $21.6 million to resolve claims that the company improperly billed Medicare. The government alleged that the company submitted claims for unauthorized services, services not provided, and services considered worthless. The settlement resolved a *qui tam* suit brought by an individual working at the long-term care hospital; the relator will receive $4,327,502 of the settlement amount.[6]
- On February 27, a Pennsylvania physician, a university medical center, and a healthcare practice agreed to pay a total of $8.5 million to resolve allegations that the physician improperly billed for concurrent surgeries. Specifically, the government alleged that the physician regularly performed multiple complex surgical procedures at the same time, failed to participate in all of the "key and critical" portions of the surgeries, and forced patients to endure hours of medically unnecessary anesthesia time, as the physician moved between surgeries. In June 2022, a court had denied the defendants' motion to dismiss the complaint. The settlement requires a corrective action plan for the physician and a third-party audit of the physician's Medicare billings. Under the resolution, the university medical center has the ability to request guidance and/or an advisory opinion from the Centers for Medicare and Medicaid Services (CMS) regarding certain Medicare regulations related to surgical practices.[7]

- On February 27, a New York nursing facility, its landlord, and several individuals agreed to collectively pay $7,168,000 to resolve allegations that the parties violated the FCA by submitting claims for payment for services the government claimed were worthless because of the facility's alleged failure to maintain a license and ensure proper staffing and maintenance.[8]
- On March 1, a medical equipment company agreed to pay $7 million to resolve allegations that it violated the FCA by making false statements in reimbursement claims submitted to three states' Medicaid programs. The government alleged that the company failed to disclose all discounts it received from, or actual costs it paid to, manufacturers. As part of the settlement, the company entered into a five-year corporate integrity agreement (CIA) with HHS-OIG, which requires the company to implement a centralized risk assessment program and hire an independent review organization to complete annual reviews of its Medicare and Medicaid claims. The settlement resolved a *qui tam* suit brought by a former employee, who received approximately $1.05 million of the settlement.[9]
- On March 3, a Florida medical center agreed to pay $4 million to resolve allegations that it improperly funded Florida's share of certain Medicaid payments by making donations to a local unit of government that were then returned to the medical center as Medicaid reimbursements. The government alleged that between October 2014 and September 2015, the medical center assumed and paid the Medicaid contribution obligations of a local unit of government under the guise of a donation. These donations were allegedly designed to increase Medicaid payments received by the medical center, by freeing up funds for the local government unit to contribute to the state as part of the state's share of Medicaid payments to the medical center.[10]
- On March 23, a Texas-based provider of ophthalmology services committed to pay approximately $2.9 million to settle allegations that it violated the AKS, and in turn the FCA, by offering and paying kickbacks to optometrists in exchange for referrals of Medicare and Medicaid patients for cataract surgery. The alleged kickbacks included payments as well as free continuing education courses and travel and entertainment. The allegations stem from a *qui tam* lawsuit, but the relator's share of the recovery was not disclosed at the time of the press release.[11]
- On March 27, a clinical laboratory services provider agreed to pay $2.1 million to resolve allegations that it violated the FCA by overbilling the Department of Defense for genetic tests performed for military members by a third-party reference laboratory. The settlement resolved a *qui tam* suit brought by a former employee, who received $357,000 of the settlement.[12]
- On March 29, a regional hospital system and two physicians agreed to pay a total of more than $69 million to resolve allegations under the FCA of improper financial relationships with eight referring physicians and a physician-owned investment group. The settlement resolves claims brought in a *qui tam* suit; the relator will receive a combined $12,384,927.36 from the government's recovery.[13]
- On April 19, a Virginia-headquartered healthcare company agreed to pay $3 million to settle allegations that it violated the FCA through fraudulent billing practices related to pediatric in-home health, personal care, and related services. The allegations include billing Virginia Medicaid for in-home healthcare services for pediatric patients who were actually hospitalized during that time, as well as billing for home health services that were not provided. The settlement also resolves claims brought by a *qui tam* relator. The United States and Virginia intervened in the *qui tam* case and obtained default prior to settlement.[14]
- On April 20, an ophthalmologist agreed to pay approximately $1.17 million to resolve allegations that he violated the FCA by paying kickbacks to optometrists for referrals of Medicare beneficiaries to his practice for cataract surgeries. The settlement agreement resolved a *qui tam* lawsuit brought by two relators, who together will receive approximately $257,000 as a result of the settlement.[15]

- On April 21, a Pennsylvania medical equipment company agreed to pay $5.3 million to resolve allegations that it violated the FCA by submitting false claims to federal healthcare programs for respiratory devices that patients did not need or use. The settlement resolved a *qui tam* suit brought by a former employee, who received approximately $950,000 of the settlement.[16]
- On May 9, two Kentucky companies that perform urine drug tests and related services agreed to collectively pay approximately $1.7 million to resolve allegations that they improperly billed federal and state healthcare programs for urine drug tests that were performed pursuant to court order rather than for medical reasons. The settlement resolves allegations brought in a *qui tam* complaint. The two relators will receive approximately $295,000 of the recovery.[17]
- On May 24, a Massachusetts hospital group agreed to pay over $5.7 million to resolve allegations that seven of its physician compensation plans, involving 44 doctors, violated the Stark Law and the FCA. The settlement resolved a *qui tam* suit brought by a whistleblower, who received 17% of the recovery. The settlement included language that required the hospital group to "admit, acknowledge, and accept responsibility for" certain facts—a requirement that has not become universal in DOJ settlements but that we have seen certain U.S. Attorneys' Offices imposing with increasing frequency.[18]
- On May 25, a Philadelphia-based primary care physician practice and two of its physicians agreed to pay a total of $1.5 million to settle allegations that they misrepresented to Medicare the severity of patients' illnesses and the services provided to them. The practice allegedly submitted unsupported diagnosis codes, including morbid obesity and smoking cessation codes for patients who did not qualify for them. The settlement resolves a *qui tam* lawsuit filed by former employees of the practice.[19]
- On May 25, a vascular surgeon agreed to pay up to $43.42 million to resolve allegations that his fraudulent billings to healthcare programs violated the FCA. The government alleged that the surgeon submitted false claims for procedures that he never performed and improperly used Modifier 59 to "unbundle" services that should have been billed together in a single claim. In a related criminal case, the surgeon was sentenced to 80 months in prison and ordered to pay $19.5 million in restitution. The FCA settlement resolved a *qui tam* suit, whose relator will receive up to $4,341,900 of the recovery.[20]
- On May 31, a Detroit hospital system agreed to pay over $29 million to resolve allegations that it violated the FCA and the AKS by providing kickbacks to certain referring physicians. The settlement resolved a *qui tam* suit brought by a former employee of an affiliated medical school, who received approximately $5.2 million of the settlement.[21]
- On June 15, a South Carolina healthcare system agreed to pay $36.5 million to resolve allegations that it violated the FCA, the Stark Law, and the AKS by tying payments to an orthopedic practice to the volume or value of the practice's referrals. The settlement resolved a *qui tam* suit; the relator received approximately $10.2 million of the settlement.[22]
- On June 15, two Jacksonville pharmacies agreed to pay $7.4 million (and more, in potential contingency amounts) to resolve allegations that they added an antipsychotic drug to topical pain creams to boost reimbursement as well as routinely waived patient copayments. As part of the settlement, the owner of the pharmacies entered into a three-year integrity agreement with HHS-OIG, which includes an annual claims review by an independent review organization. The settlement resolved two *qui tam* suits brought by two former employees; their share of the recovery had not been determined at the time of settlement.[23]
- On June 16, a Maryland-based healthcare information technology company agreed to pay $1.7 million to settle allegations that it violated the FCA by billing the

National Institutes of Health (NIH) for costs that were not eligible for reimbursement, including personal expenses unrelated to work on the contract at issue, in the form of luxury vehicles, housekeeping services, mortgage payments, and wedding costs. The settlement resolves *qui tam* lawsuits filed by multiple relators, of which two will receive $171,294.94, collectively, and the other will receive $171,294.94.[24]

- On June 16, a diagnostic laboratories billing company based in Maryland agreed to pay $300,479.58 to resolve FCA allegations relating to billing for unnecessary respiratory pathogen panels run on seniors who received COVID-19 tests. According to the government, a diagnostics laboratory that tested senior living community residents for COVID-19 directed the billing company to bill Medicare for respiratory pathogen panels; the government alleged that the physician who purportedly ordered the tests was ineligible to treat Medicare beneficiaries and had not actually ordered the respiratory tests. Allegedly, the billing company used a different physician's medical credentials and, without authorization, billed Medicare.[25]
- On June 20, DOJ announced a $1.6 million settlement with two Georgia companies that own and operate a number of clinics and COVID-19 rapid testing sites. The settlement resolves allegations that the companies upcoded when billing Medicare for Evaluation and Management services for testing and treatment of patients with COVID-19 symptoms. Several relators filed complaints making these allegations; the settlement resolves all of those cases. As part of this resolution, the relators will receive $320,000.[26]
- On June 21, DOJ announced that Alta Vista Healthcare & Wellness Centre, LLC ("Alta Vista") and its management company agreed to pay $3.23 million to the United States and $596,700 to California to resolve allegations that Alta Vista had submitted false claims based on violations of the AKS. Alta Vista allegedly paid several physicians monthly stipends and provided them with travel and entertainment, in return for their referral of patients to Alta Vista. In parallel with the DOJ settlement, Alta Vista agreed to enter into a five-year CIA with HHS-OIG. The settlement resolves case filed in 2015 by a former Alta Vista employee, who received a $581,094 share of the total recovery.[27]
- On June 29, a California county organized health system and three healthcare providers agreed to pay a combined $68 million to resolve allegations that they violated the FCA and the California False Claims Act. The settlements resolve allegations that the four defendants knowingly submitted or caused the submission of false claims to California's Medicaid program (Medi-Cal) for "Enhanced Services" that were purportedly provided to Adult Expansion Medi-Cal members under the Affordable Care Act. The United States and California alleged that the payments were not "allowed medical expenses" permissible under the relevant contract; were pre-determined amounts that did not reflect the fair market value of any Enhanced Services provided; and/or were duplicative of services already required to be rendered. The United States and California further alleged that the payments were unlawful gifts of public funds in violation of the California Constitution. The relator in the case will receive approximately $12.56 million as his share of the federal recovery.[28]

B. Government Contracting and Procurement

- On February 27, a South Carolina-based 3D printing company holding contracts with the National Aeronautics & Space Administration (NASA) and the Department of Defense (DOD) agreed to pay up to $4.54 million to resolve allegations that it violated the FCA by improperly transmitting controlled technical data to China. Between January 2012 and December 2017, and in connection with its NASA and DOD contracts, the company allegedly transmitted certain items and/or intellectual property to China without the appropriate license or authorization. The company also reached parallel settlements with the Department of State (DOS) and the

Department of Commerce (DOC) over the alleged export control violations underlying the FCA case, worth $20 million and $2.77 million, respectively. The agreement with DOJ permits crediting of amounts paid to DOS and DOC against penalties owed to DOJ.[29]

- On March 2, a paint manufacturer agreed to pay $1 million to resolve allegations that it participated in a scheme to defraud the federal Disadvantaged Business Enterprise (DBE) program in connection with a contract to paint a bridge in Philadelphia. The government alleged that the joint venture that was awarded the contract for the project worked with the paint manufacturer, rather than a qualified DBE as required by the contract—while nominally subcontracting with a DBE in what the government alleged was a sham arrangement.[30]
- On April 24, a manufacturer of military communications equipment agreed to pay $21.8 million to resolve allegations that it violated the FCA by knowingly submitting and causing the submission of false claims to DOD by including in contract proposals the cost of certain parts twice. The government alleged that the manufacturer submitted contract proposals that double-counted the cost of low-cost common-stock items, such as nuts and bolts. In conjunction with the resolution, DOJ agreed to settle for just under $8 million a breach of contract lawsuit by the manufacturer against the United States alleging that in its effort to prevent the manufacturer from continuing to double-charge for common-stock items, DOD improperly prohibited the manufacturer from charging certain other costs.[31]
- On May 30, a U.S. Postal Service (USPS) contractor and its parent company agreed to pay $2.75 million to settle allegations that they knowingly withheld funds owed to USPS and related to the agency's change of address process, by allegedly deducting the contractor's own costs before sharing revenue with USPS. Additionally, the contractor allegedly improperly allocated labor costs from one contract to another, increasing its profits and passing off a portion of its labor costs to USPS. The settlement resolves claims in a *qui tam* lawsuit brought by a former employee of the contractor.[32]
- On June 20, DOJ announced the resolution of two cases involving alleged false statements by a project superintendent and a construction company in connection with the federal Route 6/10 Interchange Project. The company paid $1 million to resolve the FCA portion of the cases. The company's construction contract for the project prohibited the removal, use, and transport of contaminated soil in the course of construction. DOJ alleged that the superintendent, a former employee of the company, misled state inspectors into believing that stone for the Route 6/10 Interchange Project had been tested as required by the construction contract and environmental standards, when in fact no tests had been performed. In parallel with DOJ's civil settlement with the company, the company entered a non-prosecution agreement with DOJ, and the superintendent pled guilty to making false statements and was sentenced to one year of probation and a $40,000 fine.[33]
- On June 29, a space and defense company based in Florida, its owner, and an Ohio-based affiliate agreed to pay $7,759,693.32 to resolve allegations that the company knowingly provided false information to the SBA to gain access to contracts set aside for small businesses. The government alleged that the company failed to accurately report distributions and payments the company had made to the owner's family members and misreported the owner's assets. According to the government, had the company provided correct information, it and its affiliate would not have been eligible for contracts it obtained with NASA, the U.S. Army, and the U.S. Air Force. The settlement resolves claims in a *qui tam* lawsuit brought by another space and defense company, which will receive $1,357,964 of the settlement amount.[34]
- On June 30, a government contractor agreed to pay $80,944 to settle a civil fraud case alleging that it violated the Trade Agreements Act (TAA) and the FCA by

fraudulently misrepresenting the country of origin for over a dozen printer toner products and offering them for sale, as TAA compliant, through a General Services Administration (GSA) Multiple Award Schedule (MAS) contract and an Air Force Blanket Purchase Agreement.[35]

C. Other

- On April 10, a company that provides engineering services and staffing services agreed to pay approximately $9.9 million to resolve "reverse" FCA allegations that it underpaid visa fees owed to the federal government by seeking less expensive B-1 visas for foreign national employees, rather than more expensive H-1B visas. The settlement resolves claims brought in a *qui tam* suit; the relator's share of the recovery was not disclosed at the time of the settlement.[36]

- On May 11, an Alaska telecommunications company agreed to pay $40.24 million to settle allegations that it violated the FCA by inflating its prices in connection with the Federal Communications Commission's (FCC) Rural Health Care Program. This program provides subsidies to rural healthcare providers for telecommunications services, awarded through a mandatory competitive bidding process. The government alleged that between 2013 and 2020, the company received more subsidy payments than it was entitled to by inflating its prices and failing to comply with FCC regulations. The company entered into a corporate compliance agreement with the FCC and resolved a pending administrative investigation with the FCC. The settlement resolved claims brought in a *qui tam* suit filed by a former director of business administration at the company, who will receive $6.4 million of the settlement amount.[37]
- On May 12, a South Korean company agreed to pay $2.05 million plus interest to resolve its potential liability under the FCA in connection with an alleged customs avoidance scheme. The company also pled guilty to the scheme and was sentenced to a criminal fine of $250,000 and restitution in the amount of $2.05 million. The resolutions resolved allegations that from 2012 to 2019, the company evaded customs duties on clothing and apparel that it manufactured abroad and imported into the United States, by preparing an accurate invoice for U.S. purchasers and a false invoice for U.S. Customs that undervalued the goods. Accordingly, the government alleged that the company underpaid customs duties that it owed based on the true value of the goods. The FCA settlement resolves a *qui tam* suit whose relator will receive 18 percent of the settlement amount.[38]
- On June 27, a think tank agreed to pay $501,161 to resolve allegations that it falsely certified that it was eligible to receive a Second Draw Paycheck Protection Program (PPP) Loan from the SBA. The Coronavirus Aid, Relief, and Economic Security Act (CARES Act) authorized forgivable loans to small businesses for job retention and certain approved expenses, through the PPP. Entities that applied for Second Draw PPP loans were required to certify that they were not primarily engaged in political or lobbying activities. According to the settlement, the think tank certified to the SBA that it was not a think tank primarily engaged in political or lobbying activities, when it had publicly stated otherwise on LinkedIn, in various sections of its website, and in press releases. The settlement resolves a *qui tam* suit filed by a relator, who will receive 10 percent of the recovery.[39]
- On June 29, a mortgage company agreed to pay $23.75 million to resolve allegations that it violated the FCA by failing to comply with material program requirements when it originated and underwrote mortgages insured by the Department of Housing and Urban Development's (HUD) Federal Housing Administration (FHA) or guaranteed by the Department of Veterans Affairs (VA). According to the settlement, the company falsely certified for FHA mortgage insurance and VA home loan guarantees a material percentage of loans that did not meet applicable requirements and, therefore, were not eligible under those programs, and HUD and the VA would not have insured or guaranteed the loans

but for the company's submission of false certifications. The relators in this case, two former employees of the company, will receive a total of $4,037,566 of the settlement proceeds.[40]

II. Legislative and Policy Developments

A. Senate Passes Amendments to the Program Fraud Civil Remedies Act

On March 30, 2023, the Senate passed the Administrative False Claims Act of 2023 (AFCA), which was co-sponsored by Senators Chuck Grassley and Dick Durbin. The bill would expand the scope of the existing Program Fraud Civil Remedies Act of 1986, a law that targets lower dollar?value frauds against the government, provides for an administrative process for government agencies to use in pursuing such claims when DOJ declines to do so, and establishes conditions for judicial review.[41] The AFCA would raise the statutory ceiling for these smaller claims from $150,000 to $1 million, and would mandate the adjustment of the statutory ceiling for inflation. It also would allow the government to recover costs for investigating and pursuing cases within the scope of the statute.[42] The legislation has now moved to the House of Representatives for further action.[43]

B. Tax-Related Claims at the State Level

The first half of 2023 has witnessed notable developments related to the efforts of certain states to expand their false claims laws to cover claims predicated on non-payment of taxes. Such claims are unique to the state context, because the federal FCA expressly excludes them. Granted, most state FCAs do as well. Virginia's Fraud Against Taxpayers Act, for example, tracks the federal statute's language closely and provides that the law "shall not apply to claims, records, or statements relating to state or local taxes."[44] But a small minority of states do allow for tax-related claims to be brought under the False Claims Act—the most notable among them being New York, the District of Columbia, Illinois, and Indiana. Until recently, all of these states' FCAs required affirmative false statements to the government as a condition of liability; they did not cover scenarios in which the defendant simply failed to file required taxes with the state altogether. In at least one jurisdiction, this principle was recently affirmed in a decision granting a motion to dismiss for failure to allege a false claim, record, or statement pursuant to the jurisdiction's tax laws.[45] In May of this year, New York became the first state to depart from this norm by amending its FCA to cover persons who improperly fail to file a tax return in New York. On May 3, 2023, 2023-S. 4009-C was signed into law by Governor Hochul.[46] With that amendment, the statute now applies to those who commit "tax law violations" rather than only those who submit false "claims, records, or statements made under the tax law."[47] With this change, New York's False Claims Act has become the most aggressive amongst the state Acts that address tax law violations. The New York amendment follows two prior unsuccessful attempts by the state's lawmakers to enact even more expansive changes. On December 31, 2021, Governor Hochul vetoed Senate Bill 4730, which had proposed expanding the application of the statute to tax-related "claims, records, or statements" to "claims, records, or statements, *and obligations*."[48] In her veto statement, the Governor explained that the use of the word "obligations" was too broad and could encompass more than only non-filers.[49] Just over a year later, on January 30, 2023, Governor Hochul vetoed Senate Bill 8815, which added some limiting language related to scienter but still contained the vague "obligations" language, and provided "an undefined retroactive lookback period" that would not provide filers with sufficient notice of how the amendment would be applied.[50] The amendment that was eventually signed into law, in addition to eliminating the "obligations" language, also specified that the amendment would only be applied to future actions filed against "tax obligations knowingly concealed or knowingly avoided after May 1, 2020," thereby eliminating the "undefined retroactive lookback period" contained in the previously proposed amendment.[51] Notwithstanding the shortening of the lookback period, the New York amendment still has significant implications for companies and individuals with New York touchpoints. The statute covers both income taxes and

other types of taxes as well—and, critically, it does not carve tax-based claims out of the provisions permitting suits by *qui tam* relators.[52] As a result, we can expect to see increased efforts by the plaintiffs' bar to bring cases grounded in alleged technical non?compliances with New York tax law, including mere failures to file tax returns. And while the amendment has faced its fair share of criticism from trade associations and other groups,[53] it remains possible that legislatures in other states that allow tax-based FCA liability will attempt similar expansions of their laws. The New York amendment also could serve to re-invigorate attempts in states with no tax-based FCA liability to enshrine such liability in their statutes. Ohio will be one state to watch in that regard. In January 2022, Ohio House Bill 533 proposed extending the state's FCA to cover claims brought under the state's tax laws.[54] The bill was referred to the Committee on Civil Justice in February 2022, but has not made any progress since then.[55] Elsewhere, New York's approach could continue to prove an outlier. After New York passed its amendment, Connecticut passed HB 6826, which expands the state's FCA to cover most state programs and benefits, rather than only state-administered health and human services programs, but expressly carves out tax-based liability.[56] Connecticut lawmakers had—before New York's amendment—unsuccessfully attempted an that would have allowed tax-based claims.[57]

C. HHS-OIG Incentives for States

HHS-OIG provides an incentive for states to enact false claims statutes in keeping with the federal FCA. If HHS?OIG approves a state's FCA, the state receives an increase of 10 percentage points in its share of any recoveries in cases involving Medicaid. Consistent with our reporting in prior alerts, the lists of "approved" and "not approved" state false claims statutes remain at 22 and 7, respectively.[58] **III. CASE LAW DEVELOPMENTS**

A. Supreme Court Rules in Two Long-Awaited False Claims Act Cases

i. Supreme Court Rules that Subjective Standard Governs Scienter

Our 2022 Year-End False Claims Act Update also highlighted the Court's decision to grant certiorari in *United States ex rel. Schutte v. SuperValu Inc.*, 143 S. Ct. 1391 (2023), the consolidation of two decisions of the Seventh Circuit: *United States ex rel. Schutte v. SuperValu Inc*., 9 F.4th 455 (7th Cir. 2021), *cert. granted*, 143 S. Ct. 644 (Jan. 13, 2023), and *United States ex rel. Proctor v. Safeway, Inc*., 30 F.4th 649 (7th Cir. 2022), *cert. granted*, 143 S. Ct. 643 (Jan. 13, 2023). On June 1, 2023, the Court reversed the Seventh Circuit's rulings in those cases, holding that knowledge under the FCA turns on a subjective standard—what the defendant actually knew and believed at the time of the alleged false claim—not on an objectively reasonable interpretation the defendant may have had after the fact. *Schutte*, 143 S. Ct. at 1399, 1401. Defendants SuperValu and Safeway operated retail drug pharmacies nationwide. *Id.* at 1396. In both cases, Relators alleged that defendants misrepresented their "usual and customary" drug prices in the process of seeking reimbursement from Medicare and Medicaid over the course of several years. *Id.* at 1397. Rather than reporting the "usual and customary charges [for the drug] to the general public," as CMS instructs, *see* 42 C.F.R. § 447.512(b)(2), which the Relators alleged were the heavily discounted prices the defendants provided to patients through cost-matching programs, the defendants allegedly submitted retail drug costs. *Id.* The district court agreed with Relators that the discounted drug prices the defendants charged customers were the companies' usual and customary prices, and that by failing to disclose the lower prices, the defendants had submitted false claims to the government. *Id.* at 1398. Ultimately, however, the district court granted summary judgment in favor of the defendants, finding that the defendants had not submitted false claims knowingly. *Id.* The Seventh Circuit affirmed, applying *Safeco Insurance Co. of America v. Burr*, 551 U.S. 47 (2007), to conclude that "[b]ecause SuperValu had an objectively reasonable understanding of the regulatory definition of U&C price and no authoritative guidance placed it on notice of its error, the Relators have not shown that SuperValu acted knowingly." *Schutte*, 9 F.4th at 472. The Supreme Court reversed,

holding that "[w]hat matters for an FCA case is whether the defendant knew the claim was false." 136 S. Ct. at 1396. Looking first to the text of the FCA and noting that "either actual knowledge, deliberate ignorance, or recklessness will suffice" to satisfy the "knowingly" element, the Court explained that "[t]hat three-part test largely tracks the traditional common-law scienter requirement for claims of fraud." 143 S. Ct. at 1400. The Court explained its reliance on the common law by reference to its incorporation of common?law concepts into the 2016 *Escobar* decision. *Id.* On the basis of this textual and common?law analysis, the Court articulated the meaning of each of the FCA's three alternatives for scienter, notably characterizing reckless disregard as occurring when a defendant is "conscious of a substantial and unjustifiable risk that [its] claims are false, but submit[s] the claims anyway"—but caveating this discussion by saying that it was not considering whether recklessness exists when a defendant submits claims despite "an unjustifiably high risk of illegality that was so obvious that it *should* have been known, even if the defendant was not actually conscious of that risk." *Id.* at 1401 & n.5. As noted in Gibson Dunn's alert immediately following the Court's decision, this decision will potentially make it harder for courts to resolve FCA cases at the pleading stage because measuring scienter according to contemporaneous subjective knowledge may be an inquiry that some courts deem to be too fact-intensive. And while the decision was unsurprising given the significant majority of federal appellate courts that had already held that a *post hoc* legal interpretation cannot vitiate a defendant's contemporaneous, subjective belief, the decision also articulated a standard for "reckless disregard" under the FCA without much guidance for lower courts on when the standard is satisfied. We can expect that question to become a battleground in FCA cases now that the Court has foreclosed the so-called "*Safeco*" defense.

ii. Following *SuperValu*, Supreme Court Sends *Sheldon* Back to the Fourth Circuit and *Olhausen* to the Eleventh

In an order list, the Supreme Court sent two major wins for FCA defendants—the Fourth Circuit's *Sheldon v. Allergan* decision and the Eleventh Circuit's decision in *Olhausen v. Arriva Medical*—back to the appellate courts "for further consideration in light of *United States ex rel. Schutte v. SuperValu*." *Sheldon v. Allergan Sales, LLC*, No. 20-2330, Dkt. No. 105 (4th Cir.); *Olhausen v. Arriva Med., LLC*, No. 22-374, Dkt No. 46 (11th Cir.). Now, both Circuits must further consider their rulings in light of *SuperValu*'s holding that scienter under the FCA turns on a defendant's "subjective beliefs" about its conduct, even when those practices are "objectively reasonable." In April 2022, the Eleventh Circuit held in *Olhausen* that a provider of mail-order diabetic testing supplies and other medical products had not acted with the requisite scienter to defraud Medicaid because "the Medicare rules that [the relator] alleged the Defendants violated are susceptible to multiple reasonable interpretations." *Olhausen v. Arriva Med., LLC*, No. 21-10366, 2022 WL 1203023, at *2 (11th Cir. Apr. 22, 2022), cert. granted, judgment vacated sub nom. *Olhausen v. Arriva Med., LLC*, No. 22-374, 2023 WL 4278438 (U.S. June 30, 2023). In September 2022, an en banc Fourth Circuit examined the FCA's scienter element in *Sheldon*, joining the then-growing number of circuits to incorporate the so-called "*Safeco*" defense into FCA cases. The Fourth Circuit had held that "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"—an "objective standard" that "precludes inquiry into a defendant's subjective intent." *Sheldon*, 24 F.4th at 348. Shortly thereafter, in a per curiam order on rehearing en banc, the full Fourth Circuit reached an impasse and vacated the panel opinion and affirmed the district court. *United States ex rel. Sheldon v. Allergan Sales, LLC*, 49 F.4th 873 (4th Cir. 2022).

iii. Supreme Court Clarifies When the Government May Dismiss *Qui Tam* Cases Over the Objections of Relators

As discussed in Gibson Dunn's 2022 Year-End False Claims Act Update, the Supreme Court heard oral argument in *United States ex. rel. Polansky v. Executive Health Resources, Inc.*, 143 S. Ct. 1720 (2023) in December 2022. In June 2023, the Court

issued its opinion in *Polansky*, clarifying when the government could dismiss an FCA suit over a relator's objection, as long as it intervened sometime in the litigation. 143 S. Ct. at 1727. The FCA provides that "the Government may dismiss the action notwithstanding the objections of the person initiating the action if the person has been notified by the Government of the filing of the motion and the court has provided the person with an opportunity for a hearing on the motion." 31 U.S.C. § 3730(c)(2)(A). In *Polansky*, the government initially declined to intervene in the relator's suit during the investigative "seal period" after the relator had filed the complaint. *Polansky*, 143 S. Ct. at 1729. The government, however, later moved to dismiss without formally intervening. *Id.* The district court granted the request and dismissed the case. The Third Circuit affirmed, determining that although the government had declined to intervene during the seal period, the government's motion to dismiss was reasonably construed as an intervention in the case. *Id.* The Third Circuit further determined that the district court had not abused its discretion in concluding that dismissal was warranted under Federal Rule of Civil Procedure 41(a), which governs voluntary dismissals. *Id.* at 1730. The Supreme Court affirmed by a vote of 8-1. In an opinion authored by Justice Kagan, the Court held that "the Government may seek dismissal of an FCA action over a relator's objection so long as it intervened sometime in the litigation, whether at the outset or afterward" and that, in resolving such motions, district courts "should apply the rule generally governing voluntary dismissal of suits: Federal Rule of Civil Procedure 41(a)." *Id.* at 1727. The Court explained that the government need not intervene during the seal period of the case to have the right to later dismiss it. The Court also made clear that the government cannot move to dismiss unless it intervenes *at some point*, which the Third Circuit deemed the government had done here through its motion to dismiss. The Supreme Court then explained that any motion for dismissal by the government is to be evaluated under Federal Rule of Civil Procedure 41(a), whose "standard varies with the case's procedural posture." *Id.* at 1733. The Court added two caveats, namely: (1) unlike Rule 41(a), the FCA requires notice and an opportunity for a hearing before the government's motion to dismiss may be granted; and (2) a court's analysis of such a motion to dismiss under Rule 41(a) must "consider the[] interests" of the relator, and not only the defendant as in non?FCA cases. *Id.* at 1734. According to the Court, a government motion to dismiss "will satisfy Rule 41 in all but the most exceptional cases." *Id.* Thus, the district court had not abused its discretion in determining that the government had met this standard by "enumerat[ing] the significant costs of future discovery in the suit, including the possible disclosure of privileged documents," and by "explain[ing] in detail why [the government] had come to believe that the suit had little chance of success on the merits." *Id.* at 1735. Notably, the Court agreed with the district court's assessment that the "billions of dollars of potential recovery" the government was foregoing "could not outweigh the Government's reasonable view of the suit's costs and benefits." *Id.* (internal quotation marks removed). Justice Thomas, in dissent, would have held that the government must intervene during the seal period in order to later dismiss the case. Perhaps more significantly, Justice Thomas also stated that "[t]here are substantial arguments that the *qui tam* device is inconsistent with Article II and that private relators may not represent the interests of the United States in litigation." *Id.* at 1741 (Thomas, J., dissenting). According to Justice Thomas, the *qui tam* provisions of the FCA improperly "authorize a private relator to wield executive authority to represent the United States' interests in civil litigation." *Id.* Justice Kavanaugh, joined by Justice Barrett, authored a short concurrence suggesting agreement with Justice Thomas on this point and adding that "the Court should consider the competing arguments on the Article II issue in an appropriate case." *Id.* at 1737 (Kavanaugh, J., concurring). Going forward, we will be watching closely to see whether this skepticism of the constitutionality of the *qui tam* provisions of the FCA takes root more deeply and broadly among the Justices. *Polansky* should clarify the standard lower courts must apply in considering government motions to dismiss *qui tam* actions after years of divergent approaches. While this issue was previously the subject of a circuit split, the split was not so dramatic as to meaningfully deprive DOJ of dismissal power writ large; instead, the devil was in the details, as some courts purported to apply some level of scrutiny to government dismissal motions and thus created less predictability for defendants seeking to persuade the government to exercise its dismissal authority. While time will tell what exactly the lower courts deem to be the "extraordinary circumstance" justifying denial of a dismissal motion, *id.* at 1735, we are

cautiously optimistic that U.S. Attorneys' Offices around the country that previously had been more reluctant than others to exercise dismissal authority will see fewer risks in doing so when the considerations animating such a step are already present.

B. Circuit Split Deepens Over Proper Causation Standard for AKS-Predicated FCA Claims

The Anti-Kickback Statute imposes criminal liability on a person who knowingly and willfully pays, offers, solicits, or receives remuneration in return for referrals or orders of items or services reimbursed by federal health programs. In 2010, Congress amended the AKS to provide that "a claim that includes items or services *resulting from* a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C. 1320a-7b(g) (emphasis added). Notwithstanding the statute's use of language sounding in causation, the government and relators routinely take the position that *all* claims submitted by the recipient of an alleged kickback are false claims because they were "tainted" by the kickback, and that a greater showing of causation is not required. In March, the Sixth Circuit weighed in on a growing circuit split regarding what causation standard a plaintiff must satisfy to show that a false claim "resulted from" a violation of the AKS. In *United States ex rel. Martin v. Hathaway*, the Sixth Circuit joined the Eighth Circuit in concluding that the AKS imposes a "but-for" causation standard. 63 F.4th 1043, 1052–53 (6th Cir. 2023) (Sutton, J.) (citing *United States ex rel. Cairns v. D.S. Medical L.L.C.*, 42 F.4th 828 (8th Cir. 2022)). As the Sixth Circuit explained, "the ordinary meaning of 'resulting from' is but-for causation" and this understanding applies absent strong textual or contextual indications to the contrary. *Id.* at 1052. This interpretation of the AKS's causation standard is the same one reached by the Eight Circuit in the *Cairns* case, which we covered in our 2022 Year-End Update. *See Cairns*, 42 F.4th at 836. The court in *Hathaway* relied both on that case and on the Supreme Court precedent interpreting similar language in the criminal context on which *Cairns* itself had relied. *See* 63 F.4th at 1052 (citing *Burrage v. United States*, 571 U.S. 204, 210–11); 42 F.4th at 834. Applying a but-for causation standard, the Sixth Circuit in *Hathaway* concluded there is no violation of the FCA if "the alleged scheme did not change anything." *Id.* at 1053. This is different than the position taken by the Third Circuit several years ago, which rejected a "but?for" causation standard and instead determined that the FCA and AKS "require[] something less than proof that the underlying medical care would not have been provided but for a kickback." *United States ex rel. Greenfield v. Medco Health Solutions, Inc.*, 880 F.3d 89, 96 (3d Cir. 2018). In *Hathaway*, one ophthalmologist (Dr. Shannon Martin) claimed that another ophthalmologist (Dr. Darren Hathaway) and a local hospital had violated the FCA by submitting claims for reimbursement that had been caused by kickbacks. According to the allegations, Hathaway was the owner of the sole ophthalmology business in a small town in Michigan that made its surgery referrals to the local hospital that also made its eye check-up referrals to Hathaway's ophthalmology business. *Hathaway*, 63 F.4th at 1046. Martin was made a tentative offer of employment at the hospital. *Id.* According to Martin, Hathaway told the hospital that if it hired Martin, he would be forced to direct his surgical referrals elsewhere. *Id.* at 1046–47. The hospital responded by deciding not to hire Martin—allegedly "in return for Dr. Hathaway's commitment to continue sending local surgery referrals," thus "violat[ing] the Anti-Kickback Statute." *Id.* at 1047. The government declined to intervene and the district court granted the defendants' motion to dismiss. *Id.* Martin appealed. *Id.* The Sixth Circuit affirmed the district court for two separate reasons. First, the Sixth Circuit concluded the complaint did not allege remuneration under the AKS. The complaint alleged that the hospital's "refusal to hire Dr. Martin in return for Dr. Hathaway's general commitment to continue sending surgery referrals for his patients" to the hospital constituted remuneration. *Id.* at 1051. The Sixth Circuit rejected this theory of remuneration because it did "not entail a payment or transfer of value to Dr. Hathaway," which the Court deemed necessary for remuneration. *Id.* Because Hathaway had already been sending his surgery referrals to the hospital, "refusing to hire Dr. Martin . . . simply left things where they were." *Id.* at 1052. Second, the Sixth Circuit concluded the complaint failed to allege but-for causation. Because Hathaway already made his referrals to the local hospital, the Sixth Circuit concluded that "[t]here's not one claim for reimbursement identified with

particularity in this case that would not have occurred anyway, no matter whether the underlying business dispute occurred or not." *Id.* at 1053. The mere fact that surgeons at the hospital had submitted claims for reimbursement from the government after Martin's tentative offer of employment was retracted was not enough to plead causation. *Id.* ("Temporal proximity by itself does not show causation.").

C. Courts Continue to Grapple with Sufficiency of Pleading Under Rule 9(b)

DOJ's or a relator's FCA allegations must be pled with particularity under Federal Rule of Civil Procedure 9(b). Courts differ over what an FCA plaintiff alleging that false claims were presented to the government must do to allege presentment with particularity. The first half of 2023 witnessed the Second Circuit reaffirming a relatively stringent standard in this regard, in a case concerning alleged billing for unnecessary medical services.

i. Second Circuit Finds Blanket Allegations Insufficient to Satisfy Pleading Standard

In *Doe 1 v. eviCore Healthcare MSI, LLC*, No. 22-530-CV, 2023 WL 2249577, at *2 (2d Cir. Feb. 28, 2023), the U.S. Court of Appeals for the Second Circuit affirmed the district court's denial of the Plaintiff's claim for failure to plead fraud with sufficient particularity. Relators Jane Doe 1, Jane Doe 2—both former employees—and SW Challenger, LLC, brought 22 claims against eviCore Healthcare MSI, LLC ("eviCore"), including under the FCA. Relators alleged that eviCore contracted with private health insurance companies that cover Medicare and Medicaid beneficiaries to provide reimbursement determinations for medical services. Relators alleged that eviCore undertook a scheme to auto-approve requests related to certain providers, therapies, and populations, irrespective of the patient, and utilized an artificial intelligence program to approve certain requests based on flawed criteria and without manual review. As a result, Relators alleged, eviCore provided "worthless services" which caused those insurance companies to bill the government for unnecessary and fraudulently approved medical services. 2023 WL 2249577, at *1. The district court granted eviCore's motion to dismiss, including for failure to plead with sufficient particularity under Rule 9(b). The Second Circuit agreed with the district court's determination that Relators "failed to identify even a single instance of a medical procedure, involving any particular patient on a specific date, that was fraudulent or unnecessary but that was nevertheless approved by eviCore," and instead merely alleged that "the volume of eviCore's approvals made it inevitable that fraudulent claims were approved." *Id.* at *2. While the court's analysis thus seems to align in principle with that of courts that require plaintiffs to plead "representative examples" of false claims, the court did not explicitly rely on that standard. In fact, the court stated that "Relators' argument that their allegations created a strong inference of fraud is unpersuasive," *id.* at *3—language seemingly more aligned with the majority rule that an FCA plaintiff need only plead details of a fraudulent scheme along with "reliable indicia" that false claims were submitted. Ultimately, the court did not make any definitive statements as to which standard it preferred, as it seemingly deemed the Relators' allegations insufficient regardless of the exact level of detail required in the pleading.

D. Second Circuit Holds that FCA's Public Disclosure Bar Prohibits Suit Even Where Defendant Is Named by Implication

The FCA bars *qui tam* suits with allegations similar to information already in the public domain, in an effort to incentivize relators to alert the government to potential cases to which it has not already been alerted. A relator may overcome this public disclosure bar by establishing that she is the "original source" of the information notwithstanding its public nature. 31 U.S.C. § 3730(e)(4). The statute defines "original source" as "an individual who either (i) prior to a public disclosure . . . has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (2) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action" under the statute. *Id.* at § 3730(e)(4)(B). The Second Circuit in *Piacentile v. U.S. Oncology, Inc*., No. 22-18, 2023 WL 2661579, at *3 (2d Cir.

Mar. 28, 2023), denied Relators' appeal under the original source doctrine. In *Piacentile*, Relators alleged that U.S. Oncology, Inc. was involved in a kickback scheme carried out by pharmaceutical companies that resulted in the submission of false Medicare and Medicaid reimbursement claims. The district court found that three previously filed lawsuits had disclosed the existence of the kickback scheme at issue, naming one of the pharmaceutical companies later sued in the *Piacentile* case and "describ[ing] U.S. Oncology's involvement in the scheme by implication." 2023 WL 2661579, at *2. Applying the public disclosure bar, the district court dismissed the case. The Second Circuit affirmed, holding that the public disclosure bar applies "even if the prior disclosure does not identify a defendant by name," so long as it "set[s] the government squarely on the trail of a specific and identifiable defendant's participation in the fraud." *Id.* "'[O]nce the government knows the essential facts of a fraudulent scheme, it has enough information to discover related frauds.'" *Id.* (citations omitted). The Second Circuit held that the previously filed complaints met this standard: they "provided notice to the government of the essential elements of the kickback scheme such that it would have been able to discover that U.S. Oncology—which the relators repeatedly described throughout this litigation as 'one of [the defendant pharmaceutical company's] major customers,'… participated in it." *Id.* (citations omitted).

E. Fifth Circuit Finds No Retaliation Without Employer Knowledge of Protected Activity

The FCA prohibits retaliation against individuals for actions taken "in furtherance of an action under [the FCA] or other efforts to stop 1 or more violations of [the FCA]." 31 U.S.C. § 3730(h)(1). Courts typically apply this standard by requiring a showing, as part of a plaintiff's prima facie case, that her employer knew of her FCA?protected activity and retaliated against her because of it. In April, the Fifth Circuit reaffirmed this standard, particularly the knowledge requirement. In *United States ex rel. Toledo v. HCA Holdings, Inc.*, No. 21-20620, 2023 WL 2823899, (5th Cir. Apr. 7, 2023), the Fifth Circuit affirmed the district court's grant of summary judgment to Bayshore, an inpatient rehabilitation facility in Texas, in an administrator's suit alleging she was fired for making complaints about alleged fraudulent claims. The administrator had served as Bayshore's prospective payment system coordinator, and was responsible for sending information about the facility's rehabilitation patients to CMS. Bayshore terminated the administrator when her new supervisor discovered that she had made coding errors on Inpatient Rehabilitation Facility Patient Assessment Instruments (IRF-PAIs) submitted to CMS. Even after Bayshore required the administrator to undergo one-on-one training, provided access to webinar trainings, and sent her to a three-day certification and training course, her supervisor discovered that she had continued to enter non-compliant codes, and she was terminated. The next day, she called an internal ethics hotline, alleging that Bayshore was engaging in fraudulent practices and insisting she was wrongfully terminated. *Id.* at *2. An internal investigation found these claims were unsubstantiated. *Id.* In examining the administrator's retaliation claim, the Fifth Circuit panel determined that even if the administrator had engaged in protected activity, (1) the relevant decisionmakers were unaware of any protected conduct and (2) such conduct did not contribute to her termination. *Id.* at *3. Neither the administrator's single email addressing the use of group therapy to meet CMS therapy minute requirements, nor her single question about using data from late discharge paperwork on CMS forms, alerted her supervisor to allegedly protected activity. *Id.* A third communication, in which the administrator claimed she found a few patients admitted without a physician admit order, could have constituted protected conduct sufficient to alert her supervisor, but she still had not shown that the conduct contributed to her termination. *Id.*

F. Seventh Circuits Interprets Agreement with Insurer About When FCA Settlement Payments Are Covered

The first half of 2023 has seen the Seventh Circuit address a significant but infrequently?examined issue related to the aftermath of FCA cases—insurance coverage for FCA settlements. In *Astellas US Holding, Inc. v. Federal Insurance Co.*, 66 F.4th 1055

(7th Cir. 2023), the Seventh Circuit determined that Illinois public policy did not forbid insurance coverage of a settlement between the federal government and a company being investigated for potential FCA liability. The government had investigated Astellas for contributions made to patient assistance programs which aided in covering the cost for patients of a drug used to treat metastatic prostate cancer. *Id.* at 1059–60. Astellas and the government eventually settled the potential claims for $100 million, $50 million of which was labeled in the settlement agreement as "restitution to the United States" for tax purposes. *Id.* at 1060. Astellas sought coverage of the settlement amount through its liability insurance carriers, including Federal. Federal denied coverage, pointing to a provision of the insurance agreement between the parties that indicated a claim could not be based on a loss "for matters which may be deemed uninsurable under the applicable law." *Id.* at 1061. Under Illinois law, compensatory payments are insurable, but "insurance coverage for losses incurred from settlement payments that are restitutionary in character" are not. *Id.* at 1063 (internal quotation marks omitted). The parties filed cross-motions for summary judgment and the district court granted summary judgment for Astellas. The Seventh Circuit affirmed. The Seventh Circuit acknowledged that the "settlement payment here could be deemed uninsurable restitution if Federal could show that the payment disgorged either something that belonged of right . . . to the federal government or profit that Astellas made from the alleged scheme." *Id.* at 1064 (internal citation and quotation marks omitted; alterations incorporated). But the Seventh Circuit ultimately determined that the settlement payment was not "restitutionary." The Seventh Circuit concluded that it was Federal's burden to show that the settlement was restitutionary in nature, but that it did not do so. As the Court explained, the "fact that a party has been accused of (let alone just investigated for) violating the False Claims Act or the Anti-Kickback Statute falls well short of establishing that its payment to settle such an accusation or investigation is uninsurable." *Id.* at 1069. The Court further explained that it did not believe that the settlement was restitutionary in nature here given that "no court has ever interpreted the False Claims Act as allowing restitutionary remedies." *Id.* at 1076. This decision could prove significant for FCA defendants facing similar insurability rules in the jurisdictions governing their insurance policies, particularly as it has become increasingly common for FCA settlement agreements to explicitly categorize a portion of the settlement amount as restitution to the government. **IV. CONCLUSION** We will monitor these developments, along with other FCA legislative activity, settlements, and jurisprudence throughout the year and report back in our 2023 False Claims Act Year-End Update, which we will publish in January 2024. _____ [1] These summaries cover the period from January 1, 2023 through July 11, 2023. [2] *See* Press Release, U.S. Atty's Office for the Dist. of Minn., Court Enters $487 Million Judgment Against Precision Lens and Owner Paul Ehlen for Paying Kickbacks to Doctors in Violation of the False Claims Act (May 15, 2023), https://www.justice.gov/usao-mn/pr/court-enters-487-million-judgment-against-precision-lens-and-owner-paul-ehlen-paying. [3] *See* Press Release, U.S. Atty's Office for the Northern Dist. of Ga., Conyers doctor pays $1,850,000 to resolve allegations that she performed and billed for medically unnecessary cataract surgeries and diagnostic tests (Jan. 9, 2023), https://www.justice.gov/usao-ndga/pr/conyers-doctor-pays-1850000-resolve-allegations-she-performed-and-billed-medically. [4] *See* Press Release, U.S. Atty's Office for the Northern Dist. of Miss., Mitias to Pay $1.87 Million to Settle False Claims Act Allegations of Medicare and Medicaid Overbilling (Jan. 12, 2023), https://www.justice.gov/usao-ndms/pr/mitias-pay-187-million-settle-false-claims-act-allegations-medicare-and-medicaid. [5] *See* Press Release, U.S. Atty's Office for the Dist. of S.C., Labcorp to Pay the United States $19 Million to Settle Allegations Under the False Claims Act (Feb. 7, 2023), https://www.justice.gov/usao-sc/pr/labcorp-pay-united-states-19-million-settle-allegations-under-false-claims-act. [6] *See* Press Release, U.S. Atty's Office for the Southern Dist. of Tex., Medical center pays over $21M to settle alleged false claims (Feb. 22, 2023), https://www.justice.gov/usao-sdtx/pr/medical-center-pays-over-21m-settle-alleged-false-claims. [7] *See* Press Release, U.S. Atty's Office for the Western Dist. of Pa., James L. Luketich, M.D., University of Pittsburgh Medical Center, and University of Pittsburgh Physicians Agree to Pay $8.5 Million and Implement Monitoring Actions to Resolve False Claims Allegations (Feb. 27, 2023), https://www.justice.gov/usao-wdpa/pr/james-l-luketich-md-university-pittsburgh-medical-

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