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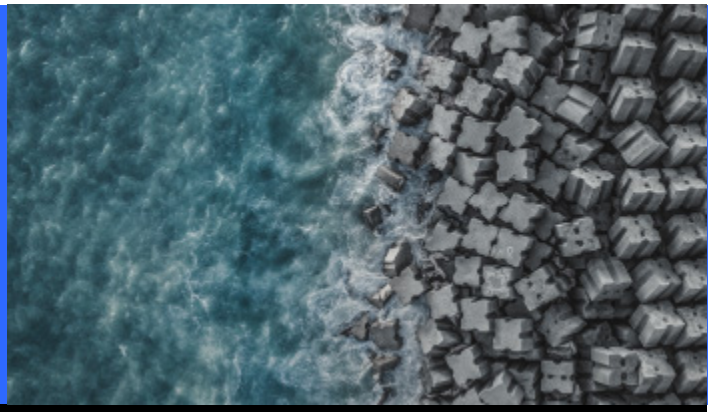

False Claims Act / Qui Tam Defense Update July 30, 2024

False Claims Act 2024 Mid-Year Update

This update summarizes recent enforcement activity, provides an overview of notable legislative and policy developments at the federal and state levels, and analyzes significant court decisions from the first half of the year.

I. Introduction

When the False Claims Act ("FCA") is not making headlines on the Supreme Court's docket, the flow of enforcement developments nonetheless remains constant. The first half of 2024 is a reminder that that flow can surge at any moment, bringing with it massive settlements for the government—over $1 billion over six months, in the case of 2024. Meanwhile, as the first half of 2024 also makes clear, there is never a dull moment when it comes to caselaw developments in the lower federal courts, and even when the U.S. Department of Justice ("DOJ") is not being particularly vocal about its FCA enforcement priorities in speeches and publications, it often is taking steps in other enforcement contexts that have implications for the FCA.

In the first half of 2024, DOJ has continued its focus on FCA matters related to cybersecurity; has initiated pilot programs in criminal enforcement that have implications for *qui tam* whistleblower incentives; and has concluded settlements across a range of industries and legal theories, with the primacy of settlements in the healthcare industry continuing. Courts have grappled with issues such as FCA causation and the scienter required in FCA cases premised on violations of the Anti-Kickback Statute ("AKS"), and the Supreme Court granted certiorari in a case involving the definition of "claim" 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 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.

II. Noteworthy DOJ Enforcement Activity During the First Half of 2024

2024 has been a notable half-year for FCA settlements by DOJ: during the first six months of the year, the government announced resolutions totaling over $1 billion.[1] That dollar figure is the highest for the first half of a calendar year—by a significant margin—in recent memory. It also includes two nine-figure settlements, whereas the first half of 2023 included none and the first half of 2022 included only one. While both of those nine-figure settlements grant DOJ claims in the bankruptcy cases of the settling counterparties and the government thus stands to recover significantly less than the settlements' face values, the fact of resolutions valued at those figures remains a significant development.

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. 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.

A. Healthcare and Life Science Industries

As usual, the vast majority of FCA recoveries in the first half of 2024 involved entities and individuals in the healthcare and life sciences industries.

- On January 4, a healthcare facility operator in Delaware agreed to pay $42.5 million to resolve allegations that the company provided ancillary service providers—including nurse practitioners and physician assistants—to assist with patients as an inducement to non-employee doctors to refer patients to the company's hospitals. The complaint alleged that these arrangements violated the AKS and the Stark Law. The allegations underlying the settlement agreement stemmed from a *qui tam* suit brought by the company's former chief compliance officer, who will receive an unspecified portion of the recovery.[2]
- On January 4, a Florida non-profit agreed to pay approximately $19.5 million to resolve allegations that it billed federal healthcare programs for items and services used in clinical trial research that it should have billed to non-government sponsors. The organization itself initiated an independent investigation into the alleged behavior and disclosed its findings to the government. The federal government will receive $18.2 million from the settlement, and Florida Medicaid will receive $1.3 million.[3]
- On January 4, a Memphis hospital system agreed to pay $7.25 million to resolve claims that it submitted false claims to Medicare that arose out of improper financial arrangements. Specifically, the government alleged the hospital system had a multi-agreement relationship with a medical clinic, and the hospital system used these various

business contracts as a vehicle to pay kickbacks to the clinic to induce it to refer Medicare beneficiaries to the hospital system. The suit resolves a *qui tam* suit brought by a former president of a hospital within the system and a medical school dean, who will each receive an unspecified portion of the settlement.[4]

- On January 5, an Arizona home health agency agreed to pay nearly $10 million to resolve allegations that it submitted false claims to a healthcare program serving Department of Energy employees and contractors with occupational illness. The government alleged that the agency billed the program for nursing and care services when its employees were not physically present in the patients' homes. It further alleged that the agency's "friends and family" program violated the AKS by paying cash and in-kind payments for food, travel, and other expenses in exchange for patient referrals. The agency made a voluntary disclosure to the government regarding its friends and family program and in-kind remuneration, and the settlement agreement acknowledges the agency's cooperation in this regard. The settlement resolves a *qui tam* suit brought by a former Corporate Administrator and Director of Human Resource Administration and Management at the agency and its predecessor, who will receive approximately $1.7 million from the settlement.[5]

- On January 10, a New Jersey clinical laboratory and its CEO agreed to pay $13.2 million to resolve allegations that it billed federal healthcare programs for laboratory tests procured through illegal kickbacks. The government alleged that the laboratory obtained referrals through five different kinds of kickbacks, including: (1) commissions paid based on volume and value of referrals to the laboratory through independent contractors; (2) payments disguised as management services organization fees that were actually incentives for laboratory referrals; (3) payments to healthcare providers disguised as consulting or medical director fees in exchange for ordering lab tests; (4) payments to substance abuse recover centers to induce referrals for lab testing; and (5) specimen collection fees to healthcare providers to induce referrals to the laboratory. In addition, the government alleged that the laboratory and CEO submitted claims for tests that were not medically necessary or not otherwise covered by Medicare and Medicaid.[6]

- On January 11, a long-term care hospital agreed to an ability-to-pay settlement requiring it to pay over $18.6 million plus 4.5% interest per year to resolve allegations that the hospital impermissibly claimed excessive cost outlier payments from Medicare. Specifically, the government alleged that the hospital manipulated the cost outlier payment system for supplemental reimbursement by increasing its charges in excess of its costs and beyond what the hospital would be able to repay once Medicare cost reports were reconciled to its charges. In addition to the FCA claim, the settlement involved a $12 million penalty resolving Federal Debt Collection Procedures Act allegations against certain hospital investors for their role in the hospital's alleged fraudulent transfer of money without equivalence value exchange to its investment management company.[7]

- On January 17, a healthcare company and its owners consented to a $2 million judgment, admitting to FCA violations for using medical staff to submit claims for medically unnecessary care to federal healthcare programs. The government alleged that the company hired vulnerable or inexperienced medical staff and then pressured those staff members to provide unnecessary care, and to submit the claims for that care to federal payors. The government further alleged that the company falsified information to obtain Paycheck Protection Program (PPP) loan forgiveness. The consent agreement resolves allegations under the FCA, AKS, and Controlled Substances Act.[8]

- On January 23, a Philadelphia pharmacy and its current and former owners agreed jointly to pay approximately $3.9 million to resolve allegations that they billed Medicare and

Medicaid for medications that were never dispensed from January 2018 through September 2020. The government also alleged that in some cases the pharmacy dispensed low-cost formulations to beneficiaries but billed Medicare for the high-cost versions of the formulations. The pharmacy and its principal pharmacist entered into an integrity agreement requiring them to undertake significant compliance obligations and conduct third-party audits of their Medicare claims and drug inventory through an Independent Review Organization.[9]

- On January 26, a group of durable medical equipment companies agreed to pay $2.1 million to resolve allegations that they submitted false claims to federal healthcare programs by selling used hospital beds as if they were new. The government also alleged the companies upcoded support products and mischaracterized non-reimbursable travel time as repair time in claims for payment made to federal programs and contractors. This settlement resolved a related *qui tam* suit brought by a former employee, who will receive an undisclosed portion of the settlement amount.[10]

- On January 30, a drug rehabilitation facility and a clinical laboratory agreed to resolve liability for submitting false claims for urine drug testing services to the federal Medicare and Kentucky state Medicaid programs by paying $2.2 million and $4.9 million respectively. The government alleged that the drug rehabilitation facility used the same complex panel of urine drug tests for all patients on a weekly basis, despite the results often not being used for diagnosis or treatment and without considering whether individual patients needed the panel. The clinical laboratory performed the urine tests and billed them to federal and state healthcare programs despite knowing that the tests were not typically used for diagnosis or treatment and also performed additional urine drug screens without proper medical orders requesting the screens. As a part of the settlement, the drug rehabilitation facility entered into a corporate integrity agreement with HHS-OIG, which requires the facility to appoint a compliance officer and retain an independent expert for its compliance program. The clinical laboratory's share of the settlement will require it to cease operations and pay the United States 100% of the net proceeds of the sale of its assets, along with 70% of reimbursements from healthcare payors for one year and any employee retention tax credit funds received. The settlement resolves a related *qui tam* suit, with the relator receiving an undisclosed portion of the recovery.[11]

- On February 7, a Pennsylvania multi-hospital system agreed to pay $11.7 million to resolve allegations that it submitted claims to Medicare for services relating to annual wellness visits. The hospital system voluntarily disclosed that it submitted claims that were not supported by the medical record between December 2015 and November 2022. Following its self-disclosure, the government noted, the hospital system took corrective action, although in resolving the case the government did not specify what that action was.[12]

- On February 14, a medical equipment company that rented non-invasive ventilators agreed to pay $25.5 million to resolve allegations that it continued to bill federal health care programs after patients ceased using their devices. Additionally, DOJ alleged that the company failed to confirm that the devices it rented were medically necessary, impermissibly waived coinsurance payments to get more patients to rent their equipment, and paid kickbacks to induce Medicare beneficiaries to rent its equipment. The company admitted it received reimbursement for claims it submitted to federal healthcare programs that did not comply with Medicare billing guidelines. This resolved a related *qui tam* suit for which the relator will receive an unspecified portion of the proceeds.[13]

- On February 16, a Kentucky toxicology lab and its owner agreed to a nearly $5.6 million judgment for violating the FCA by charging court-ordered urine tests to Medicare and Medicaid, even though the tests were not medically necessary. The lab's compliance officer also agreed to a $4.87 million judgment against her for a related scheme in which she solicited urine drug tests from non-medical homeless shelters and charged those tests to Medicare and Medicaid. Both the owner and the compliance officer received prison sentences of 46 months and six months respectively for related criminal charges. Furthermore, the lab, the owner, and the compliance officer will be excluded from federal health care program participation for 20 years. The consent agreements resolve a *qui tam* suit for which the relator will receive an unspecified portion of the proceeds.[14]

- On February 28, a pharmaceutical manufacturer, DOJ and an ad hoc group of first lien creditors reached a comprehensive settlement of all federal government claims against the manufacturer. The settlement included resolution of FCA claims asserted by DOJ, which were resolved by granting DOJ a $475.6 million general unsecured claim in the manufacturer's chapter 11 bankruptcy cases. DOJ alleged that the company marketed its opioid drug to providers the company knew prescribed the drug for non-medically accepted indications, and that the company incentivized such targeting through sales goals, employee incentive compensation plans, and employee performance reviews. In resolution of a parallel criminal investigation, the comprehensive settlement also required a debtor affiliate of the manufacturer to plead guilty to a misdemeanor violation of the Food, Drug and Cosmetic Act ("FDCA") based on allegations that it introduced misbranded drugs into interstate commerce. Altogether the comprehensive settlement encompassed approximately $8 billion of alleged claims asserted by the IRS, the civil and criminal branches of DOJ, and several federal healthcare agencies. Under the terms of the comprehensive settlement, the company made a single $200 million payment in satisfaction of all the government's claims upon the effective date of its chapter 11 plan of reorganization in April 2024, and the settlement allowed the company's pharmaceutical business to emerge under such plan.[15] Gibson Dunn represented the first lien ad hoc group, which negotiated the foregoing economic settlement with DOJ, and was intimately involved in all aspects of this comprehensive resolution and its implementation.

- On February 28, a Georgia laboratory and its owner agreed to pay $14.3 million to partially resolve allegations that it submitted false claims to government healthcare programs. In particular, the government alleged that the owner paid independent contractors to recommend that senior living communities order expensive and unnecessary respiratory pathogen panels (RPPs), rather than the COVID-19 tests that the communities initially requested. The contractors also, with the owner's alleged knowledge, performed COVID-19 tests in senior living communities, but then arranged for the laboratory to submit claims to federal health plans using sham Medicaid diagnosis codes that did not reflect the medical conditions of those receiving the tests. The contractors also allegedly forged physician signatures on RPP order forms. The owner, along with four other people, pleaded guilty to criminal charges connected to the scheme. The federal government will receive $13.9 million from the civil settlement, and Georgia will receive $400,000. The settlement also resolves a *qui tam* suit for which the relator will receive $2.86 million.[16]

- On March 6, a hospital system in New York agreed to pay $17.3 million to resolve allegations that it paid unlawful kickbacks to doctors at the hospital's chemotherapy infusion center. The government alleged that the hospital entered into contracts with the physicians that linked the physicians' compensation to the number of referrals made for services at the chemotherapy center. The settlement agreement also resolves claims that the physicians failed to adequately supervise these services as required by Medicare and

Medicaid regulations, in addition to claims under New York's state FCA statute. The hospital voluntarily disclosed the information to the United States.[17]

- On March 6, a generic pharmaceutical manufacturer agreed to pay $2 million to resolve allegations that it submitted false claims to TRICARE, the VA, the Federal Employees Health Benefits Program, and the Department of Labor Office of Works Compensation Programs. The government alleged that the company sold adulterated pharmaceuticals after failing to follow controls required by manufacturing regulations, which resulted in the submission of false claims. This settlement resolved the civil liability component of a criminal investigation related to the introduction of adulterated drugs into interstate commerce. The company also entered into a plea agreement to resolve the related criminal indictment, pursuant to which it agreed to a three-year deferred prosecution agreement and to pay an additional $1.5 million fine.[18]

- On March 20, two former Philadelphia-based pharmacy employees agreed to pay over $4.1 million to resolve liability under the FCA and Controlled Substances Act for illegally dispensing and distributing controlled substances and engaging in fraudulent billing. Specifically, the government alleged that the former employees dispensed opioids and other "cocktail" drugs in extreme doses and combinations under highly suspicious circumstances, including excessive cash payments and clearly forged prescriptions. The employees also engaged in a scheme using a "BBDF" ("Bill But Don't Fill") code to falsely claim to Medicare and other insurers that drugs had been dispensed to patients. The former employees also pled guilty to related criminal charges and were sentenced to several months imprisonment along with receiving permanent bans on dispensing controlled substances. The civil settlement and criminal convictions marked the end of a multi-year investigation into related fraudulent activity at the pharmacy, including activities by its owner and other employees.[19]

- On March 25, a clinical laboratory and its owners agreed to pay approximately $13.6 million and to be excluded from federal health care programs for 15 years to resolve allegations that they submitted Medicare claims for tests that were neither medically necessary nor ordered by healthcare providers. Specifically, the government alleged that the laboratory performed and submitted claims for medically unnecessary urinary tract infection panel of tests by PCR when physicians only ordered a less extensive urinalysis tests as part of an illegal kickback scheme. The laboratory allegedly did so because Medicare reimbursements for the PCR tests were significantly higher than reimbursements for the tests the physicians had ordered. This settlement resolved a related *qui tam* action brought by a physician who owned health care facilities and served patients for whom the laboratory ran tests. The physician relator will receive approximately $2.3 million of the settlement amount.[20]

- On March 25, a healthcare staffing company agreed to pay approximately $9.3 million to resolve FCA and criminal liability regarding its visa sponsorship program. Specifically, the government alleged the staffing company submitted false visa immigrant applications, provided false job placement letters, and made false statements to government officials while recruiting healthcare professionals into the United States. Along with undertaking extensive remedial efforts in its compliance, the company also pledged an additional $8 million to healthcare projects in an effort to address harms caused by its prior practices. The pledge will be distributed to various NGOs and non-profits involved with ethical recruitment, strengthening healthcare access and infrastructure in certain developing countries and in rural/underserved U.S. communities.[21]

- On March 27, a Georgia teleradiology company and its CEO agreed to pay $3.1 million to settle liability for violations of the FCA and comparable state laws for fraudulently billing

federal health care programs. The government alleged that the company's U.S.-based radiologists failed to adequately review interpretation reports prepared by overseas contractors who were not permitted to practice medicine in the U.S. or bill U.S. federal healthcare programs. The company also misrepresented which medical professionals actually rendered radiology services, and improperly sought reimbursement for services provided by medical professionals outside of the United States. Approximately $2.68 million of the settlement will be paid to the U.S., and the remaining $420,000 will be distributed to various states. The settlement additionally resolves a *qui tam* suit, but it was not disclosed whether the relators would receive a share of the settlement.[22]

- On April 2, a Texas oncology practice and diagnostic reference laboratory agreed to pay approximately $4 million to resolve allegations that they violated the AKS. The government alleged that the laboratory offered illegal kickbacks in exchange for bone marrow biopsy exams, which induced physicians to order the tests. Furthermore, the government contended that one of the practice's physicians billed federal and state healthcare programs for medically unnecessary tests and services. This settlement resolved a *qui tam* suit brought by a former physician at the practice who will receive an unspecified amount. The oncology practice also entered into an integrity agreement for a period of three-years as part of the settlement.[23]

- On April 9, a California-based nursing home chain agreed to pay approximately $7 million to resolve allegations that it submitted claims to Medicare and Medicaid for reimbursement for skilled care that it did not actually provide. The government alleged that the company misused a COVID-19 emergency waiver that removed the three-day hospital stay requirement to receive reimbursement for skilled care for nursing home residents. The company allegedly submitted claims for skilled care reimbursement when residents at the home were merely exposed to COVID-19, rather than infected, and as a result did not actually receive skilled care in the nursing home. The company will pay the federal government approximately $6.8 million and the state of California approximately $242,000, plus interest. The company will also enter a Corporate Integrity Agreement (CIA) with the Department of Health and Human Services, Office of Inspector General (HHS-OIG). The settlement resolves a *qui tam* suit for which the relators will receive approximately $1.2 million, plus interest.[24]

- On April 24, an Atlanta-based company agreed to pay $2.7 million to resolve allegations that it violated the False Claims Act by failing to implement adequate cybersecurity measures to protect health information obtained through a contract with the Pennsylvania Department of Health to provide staffing for COVID-19 contact tracing. The government alleged that the company transmitted confidential and/or personally identifiable information in unencrypted emails, that it stored and transmitted information through Google files that were not password protected, and that staff used shared passwords to access the information. The government also alleged that the company received complaints for at least five months before the company started remediating the issue. The settlement resolves a *qui tam* lawsuit brought by a former staff member at the company, who will receive a $499,500 share of the lawsuit.[25]

- On April 25, a healthcare management company and its subsidiaries agreed to pay $4.2 million to resolve allegations that it knowingly submitted false Medicare claims. In particular, the government alleged that the company retained overpayments for hospice care claims when the patients were not terminally ill and therefore ineligible for hospice care. This settlement resolved a *qui tam* suit brought by a former employee, who received $672,000 of the settlement.[26]

- On May 6, the owner and operator of multiple medical diagnostic and laboratory-related LLCs agreed to pay $27 million to resolve allegations that he and his companies conspired to violate the FCA by submitting false claims to federal healthcare programs for medically unnecessary cancer genomic tests (CGx) procured through illegal kickbacks. In particular, the government alleged that he and his companies conspired with telemarketers to solicit Medicare beneficiaries for CGx tests and conspired with telemedicine providers to prescribe medically unnecessary CGx tests. The government further claimed that he and his companies conspired with reference laboratories that would perform the CGx tests, and with billing laboratories and a hospital to submit claims to Medicare and Medicaid. The Floridian owner and operator previously pled guilty to criminal healthcare fraud related to this same conduct in 2022. As part of this settlement agreement, his companies agreed to be excluded from all federal health care programs. This settlement resolves three related *qui tam* actions, including one action brought by a minority owner of one of the LLCs, who will receive approximately $4.7 million of the settlement amount.[27] The portion of the settlement that the other relators will receive is not specified.

- On May 8, a Michigan healthcare practice agreed to pay approximately $2 million to resolve allegations that it submitted claims for improperly supervised medical care to Medicare and Medicaid. In particular, the government alleged that the company submitted claims to Medicare and Medicaid for procedures performed by physician assistants in nursing home facilities without the required doctor supervision. The state of Michigan will receive approximately $66,000 from the settlement.[28]

- On May 16, a Massachusetts hospital agreed to pay $24.3 million to resolve allegations that it submitted claims to Medicare for medical treatments that did not comply with Medicare rules about evaluating patient suitability for the prescribed medical treatment. Specifically, the government alleged that the hospital knowingly submitted claims for transcatheter aortic valve replacement (TAVR) procedures without the required number of physicians either examining the patient or documenting their judgment regarding the patient's suitability for the procedure. As part of the settlement, the hospital will enter into a five-year CIA with HHS-OIG under which an Independent Review Organization will annually review the hospital's Medicare charges. Because the hospital voluntarily assisted the government during its investigation, the hospital received cooperation credit pursuant to DOJ guidelines. The settlement resolves a *qui tam* suit for which the relator will receive approximately $4.36 million.[29]

- On May 17, a medical clinic agreed to pay $7.6 million to resolve allegations that it violated the FCA in connection with three federal grant awards for its research. In particular, the government alleged the clinic failed to disclose that the Principal Investigator on each grant was an employee with pending or active grants from foreign institutions who supported that employee's research and obligated the employee's time, which violated the National Institute of Health (NIH)'s transparency requirements. The settlement also resolved allegations that the clinic impermissibly allowed its employees to share passwords for access to the NIH grant reporting platform, which resulted in other employees making false submissions in the name of the Principal Investigator without their knowledge. The HHS-OIG, FBI, and two assistant U.S. attorneys collaborated with the U.S. Attorney's Office for the Northern District of Ohio to resolve these allegations. The clinic agreed to implement a Corrective Action Plan, and NIH imposed specific award conditions for future grants for at least a one-year period or until completion of the Corrective Action Plan.[30]

- On May 20, two New York not-for-profit corporations agreed to pay approximately $10 million to resolve allegations that they submitted false claims to Medicaid for certain long-term care services. The companies administered a Managed Long Term Care Plan ("MLTCP") for Medicaid beneficiaries, under which they arranged for health and long-term care services and were reimbursed by Medicaid through per-member payments on a monthly basis. As part of the settlement, the companies admitted to collecting payments for the services under the MLTCP that they did not provide or did not adequately document the provision of. The settlement also resolves a *qui tam* suit brought by a relator. The portion of the settlement that relator will receive is not specified.[31]

- On May 22, a medical device manufacturer and two senior executives agreed to pay $12 million to resolve allegations that they violated the False Claims Act by paying kickbacks to spine surgeons to induce the surgeons to use the company's spinal devices. According to the government's allegations, the company provided improper renumeration to spinal surgeons in the form of consulting and other fees, registry payments, performance shares, and travel and lavish dinners. The settlement also resolves a *qui tam* action brought by a former regional sales director for the company, who will receive an approximately $2.2 million share of the recovery.[32]

- On May 28, three affiliated healthcare companies operating in Florida, Minnesota, and Wisconsin agreed to pay approximately $14.9 million to resolve allegations that they improperly billed Medicare, Medicaid, and TRICARE by knowingly submitting claims for two Evaluation and Management codes that did not support the level of service that the companies actually provided. Under the settlement, the federal government will receive approximately $13.8 million, and the state governments of Florida and Minnesota will receive approximately $1 million. The company must also enter into a five-year CIA with HHS-OIG, which will require the company to establish and maintain a compliance program and submit to an Independent Review Organization's review of its Medicare claims to ensure that they are medically necessary. The settlement also resolves a *qui tam* suit for which the relator will receive approximately $2.8 million.[33]

- On June 6, defendants in a New-York ophthalmologist practice agreed to pay approximately $2.5 million to resolve claims that, over a three-year period, they billed federal healthcare programs for medically unnecessary tests and procedures, and services that could not have been performed because the doctor was not in the office at the time the services were purportedly rendered. The government further alleged that the scheme exploited residents in Brooklyn and Queens, many of whom were non-native English speakers or elderly. The settlement agreement resolves two *qui tam* actions but does not specify the relators' shares of the recovery.[34]

- On June 11, a Chicago-based nurse practitioner group and its former owners agreed to pay approximately $2 million to resolve allegations that it submitted false claims to Medicare and Medicaid. The government alleged that the company and its owners developed patient charting software that generated false, upcoded claims for Medicare and Medicaid. According to the government's allegations, the company and its owners required its nurse practitioners to use the software, despite knowing that it resulted in fraudulently upcoded claims being submitted to and paid by Medicare and Medicaid. The settlement also resolves a *qui tam* lawsuit brought by a former employee, which receive approximately $358,647 as part of the settlement.[35]

- On June 24, medical centers and a medical college in Texas agreed to pay $15 million to resolve claims they billed for concurrent heart surgeries in violation of Medicare teaching physician and informed consent regulations. According to the government's allegations, three heart surgeons at the medical center ran a regular practice of running two operating

rooms at once, delegating key aspects of the surgeries to unqualified medical assistants. The $15 million recovery is the largest settlement to date involving concurrent surgeries. Under the settlement, the *qui tam* relator will receive approximately $3.1 million.[36]

B. Government Contracting and Procurement

- On January 19, an oil and gas company agreed to pay $34.6 million to resolve allegations it knowingly underpaid royalties owed on oil and gas produced from federal lands. Specifically, the government alleged that the company submitted royalty payments to the federal government based on estimates and subsequently failed to make follow-up payments based on actual volumes and values as required by its agreements with the government. The company received credit under the settlement for cooperation by assisting with the determination of losses.[37]

- On January 30, a technology company agreed to pay $5 million to resolve allegations that it falsely overstated cost and pricing data in a subcontract proposal to the U.S. Army. Specifically, the government alleged that the company overstated its costs to a primary contractor who was negotiating with the Army, and that the primary contractor then relied on those estimated costs when negotiating its contract, leading to significant overcharges. The settlement resolves a related *qui tam* suit for which the relator will receive $900,000.[38]

- On January 30, a Virginia-based consulting agency and its parent company agreed to pay $3.9 million to resolve allegations that it made false statements about its status as a women-owned small business (WOSB) to obtain a Defense Health Agency contract regarding providing doctors to an Air Force treatment facility that had been set aside for WOSBs. In particular, the government alleged that the consulting company forfeited its WOSBs status when it failed to update its size certifications post-acquisition as required, and when asked by the government's contracting official. The company was awarded the contract based on the allegedly false representation when it would not have been eligible had it provided correct information. This settlement resolved a *qui tam* action brought by an entity healthcare and support services provider, which purportedly discovered the misrepresentations through a report it developed to analyze Defense Health Agency contracts.[39] The settlement amount reflects cooperation from the companies during the government's investigation.[40]

- On March 12, an information and advisory services company agreed to pay $37 million to settle allegations that it violated the FCA and the Financial Institutions Reform, Recovery and Enforcement Act it used data in violation of its government contracts. The government alleged that over a month-long period, the company improperly accessed, retained, and anonymized credit card data it received under various government contracts, which it subsequently used to create proxy data that was incorporated into products and services sold to commercial customers. The company failed to disclose this behavior both to the government and to the commercial clients to whom it sold the products.[41]

- On April 23, a company responsible for managing and operating a National Nuclear Security Administration site agreed to pay $18.4 million to settle liability for overpayments that resulted from production technicians submitting falsified timesheets over a six-year period. The company received credit under the settlement for self-disclosing the misconduct, cooperating with the government's investigation, and for undertaking remediation efforts (including terminating the personnel who engaged in the misconduct).[42]

- On June 6, a Canadian manufacturer of protective head gear for U.S. military and law enforcement use agreed to pay approximately $2.5 million to resolve claims that it used foreign-sourced materials in its production of helmet inserts in violation of the Berry Amendment. The company sold its products to the U.S. military under the Defense Logistics Agency's Special Operational Equipment Tailored Logistic Support Program, which requires that textiles be sourced from the United States in compliance with the Berry Amendment. The government initiated an investigation involving the US Department of Defense, the Defense Criminal Investigative Service, and the Department of the Army Criminal Investigation Division after receiving a complaint from the DLA hotline. The settlement amount reflected that the company accepted responsibility, cooperated with the government's investigation, and implemented compliance measures.[43]

- On June 7, a conglomerate of three medical practice and management groups operating urgent care practices in New Jersey and New York agreed to pay over $12 million to resolve allegations that they submitted false claims for reimbursement of COVID-19 tests to a program that funds COVID-19 testing for uninsured individuals. The government alleged that operators did not adequately confirm whether test recipients had health insurance coverage before submitting their claims to the program, resulting in the erroneous submission of claims for insured persons. It also alleged that the operators caused laboratories to submit false claims for those COVID-19 tests by providing requisition forms that inaccurately indicated the test recipients were uninsured. The operators received credit in the settlement for their voluntary disclosure, cooperation, and remediation efforts. The settlement also resolves a *qui tam* suit brought by a patient, who will receive approximately $2 million of the settlement.[44]

- On June 17, two consulting companies agreed to settle allegations that they violated the False Claims by failing to meet cyber security requirements as part of the administration of the application system for the Emergency Rental Assistance Program. As part of the settlement, both companies admitted that they failed to satisfy their obligation to complete required cybersecurity testing for the systems. One company agreed to pay $7.6 million and the second agreed to pay $3.7 million as part of the settlement. The settlement also resolves a *qui tam* lawsuit brought by an entity owned by a former employee of one of the companies, which will receive a share of approximately $1.9 million of the settlement.[45]

- On June 21, two Wisconsin and Connecticut-based aerospace and parts companies agreed to pay $70 million to resolve False Claims Act allegations that they overcharged the Navy for spare parts and materials needed to repair and maintain Navy aircrafts. According to the government's allegations, the two companies, which were both wholly-owned subsidiaries of the same parent company, knowingly entered into a contract under which one would purchase parts from the other at a markup. The purchasing company then submitted cost vouchers to the Navy for reimbursement. The settlement also resolves a *qui tam* suit but does not specify the relator's share of the recovery.[46]

C. Other

- On January 31, an automobile accessory company agreed to pay $3 million to resolve allegations that it knowingly failed to pay antidumping and countervailing duties on materials it imported from China. In particular, the government alleged that the company failed to take any action after being informed that it was not paying the appropriate duties on extruded aluminum components from January 2012 through July 2021. This resolved a *qui tam* action brought by a former employee who will receive $510,000 plus $75,000 in legal fees as part of the settlement.[47]

- On February 29, two individuals in Colorado agreed to pay $3.5 million to resolve allegations that they defrauded the federal government by tampering with rain gauges. The government alleged that the two individuals were part of a conspiracy to tamper with the rain gauges by various means in order to make it appear as though there was below-average rainfall. Doing so would allow them to take advantage of a federal program that pays indemnities to farmers when there is below-average precipitation. In addition to civil penalties, the two individuals pled guilty to criminal charges for which they received prison sentences and were ordered to pay an additional $3.1 million in restitution. The settlement also resolves a *qui tam* suit for which the relator's estate will receive approximately $500,000.[48]

- On March 13, a construction company agreed to pay $2.5 million plus interest to resolve allegations that it violated FCA by taking out EIDL and PPP loans that it was not entitled to. Specifically, the government alleged that the company's owner falsely certified in loan applications that he had not been convicted of a felony involving fraud within the last five years even though he had pled guilty and was convicted of a fraud-related felony charge less than three years before the first loan application. This settlement also resolves a *qui tam* suit for which the relator will receive approximately $250,000.[49]

- On March 21, a New Jersey chemical importer and its owner agreed to pay $3.1 million to resolve claims that it fraudulently underpaid customs duties. In particular, the government alleged that the importer conspired with a Chinese vendor to mislabel imported chemicals, including hazardous chemicals, and submitted falsified documents to customs brokers. This settlement also resolves a *qui tam* suit for which the relator will receive $600,000. The company's owner additionally pled guilty to wire fraud.[50]

- On May 2, a German airline and its Minneapolis-based subsidiary agreed to pay $26.8 million to resolve allegations that it failed to remit to the federal government mandatory travel fees that the airline collected from passengers. In particular, the government alleged that from 2012 to 2018, the company collected fees such as those owed to U.S. Customs and TSA but did not pay those fees to the appropriate government entities. The settlement resolved a *qui tam* lawsuit for which the relator will receive approximately $4.8 million.[51]

- On May 7, a now-bankrupt lender agreed to pay up to $120 million over two settlements to resolve allegations that it submitted false claims for loan forgiveness, loan guarantees, and processing fees to the government under PPP. Under the first settlement, the company agreed to pay up to $63.2 million to resolve allegations that the company inflated PPP loans, causing the Small Business Administration to guarantee and forgive greater loan amounts than borrowers were entitled to receive. And, under the second settlement, the company agreed to pay up to $56.7 million to resolve allegations that the company knowingly failed to implement adequate fraud controls to comply with its regulatory obligations to prevent fraudulent borrowers from seeking PPP benefits. Because the settlement gives the government an unsecured bankruptcy claim, the ultimate settlement amount will depend on the lender's overall assets. The settlement resolves two *qui tam* actions for which the relators will receive a portion of the proceeds.[52]

- On June 12, multiple nonprofit organizations, including two private country clubs and two homeowners associations, paid approximately $5.8 million to settle allegations that they violated the False Claims Act by knowingly submitting false claims and obtaining PPP loans for which they were not eligible. The settlements also resolved a *qui tam* action for which the relator will receive approximately $700,000 of the total recovery.[53]

- On June 20, four restaurants, two fur apparel distributors, and five individuals agreed to pay approximately $4.6 million to settle allegations that they inflated payroll figures in their PPP loan and forgiveness applications. According to the government, the defendants misrepresented that family members and acquaintances were employed by the businesses, listed the same individuals as "full-time employees" of multiple businesses, inflated payroll figures, and improperly sought loan forgiveness for payroll costs that exceeded the maximum allowed. The settlement also resolved a *qui tam* lawsuit brought by a former manager at two of the restaurants, but does not specify what, if any, portion of the recovery he will receive.[54]

III. Cyber-Fraud Initiative Updates

The first half of 2024 witnessed notable developments in DOJ's Civil Cyber-Fraud Initiative, an effort we reported on in our 2023 Year-End Update. The Initiative, launched on October 6, 2021, aims to use the FCA to pursue cybersecurity-related fraud by government contractors and grant recipients that are "knowingly providing deficient cybersecurity products or services, knowingly misrepresenting their cybersecurity practices or protocols, or knowingly violating obligations to monitor and report cybersecurity incidents and breaches."[55] In February 2024, Principal Deputy Assistant Attorney General Brian Boynton emphasized that DOJ "will continue to dedicate resources to investigating companies that fail to comply with their cybersecurity obligations."[56]

A. DOJ Intervenes in First-Of-Its-Kind Cybersecurity Suit Since Launch of Civil Cyber-Fraud Initiative

In the same month in which DOJ re-emphasized its commitment to cybersecurity enforcement, DOJ intervened in a first-of-its-kind *qui tam* lawsuit, alleging that the Georgia Institute of Technology and Georgia Tech Research Corporation failed to comply with mandatory cybersecurity controls in their Department of Defense (DOD) contracts. In *United States ex rel. Craig v. Georgia Tech Research Corporation, et al.*, the Associate Director of Cybersecurity at Georgia Tech and Principal Information Security Engineer brought the suit in July 2022 against research organizations for allegedly failing to secure and interact with government information and data under standards by the National Institute of Standards and Technology (NIST).

DOD contractors must comply with DFARS 252.204-7012 ("Safeguarding Covered Defense Information and Cyber Incident Reporting"), which requires contractors provide "adequate security" to safeguard the defense information they handle during the course of their work for the DOD. In turn, "adequate security" is defined, at a minimum, as implementation of NIST Special Publication 800-171 (NIST SP 800-171), which has 110 security requirements relating to, among other things, identification and authentication measures; audit and accountability; and system and communications protection measures. The lawsuit alleges that defendants' internal assessors assigned to determine compliance with NIST were not qualified, and they were pressured interpret the NIST controls to justify certain actions taken in labs as compliant.

The government's deadline to serve defendants with a complaint-in-intervention is August 22, 2024.

B. Potential Civil Cyber-Fraud Initiative Case on Stay

Similarly, in our 2023 Year-End Update we also reported on an unsealed *qui tam* complaint against Penn State by a relator who alleged that the university submitted false cybersecurity certifications to DOD. Following a 90-day stay to allow the government additional time to determine whether it will intervene, the parties' joint written status report updating the court on any developments is due by August 5, 2024.[57]

IV. Legislative and Policy Developments

A. Federal Policy and Legislative Developments

1. Proposed Revisions to Medicare Overpayment Rules

On July 10, 2024, the Centers for Medicare and Medicaid Services ("CMS") issued a proposed rule regarding the Physician Fee Schedule ("PFS"), which governs Medicare payments for the services of physicians and other healthcare professionals.[58] While changes to the PFS were the headline purpose of the proposed rule, the rule also would bring about significant changes to existing provisions governing healthcare providers' return of overpayments under Medicare Parts A and B. By way of context, the Affordable Care Act ("ACA") requires providers to return overpayments to the government within 60 days of the date on which the overpayments are "identified," and specifies that an overpayment not returned by the appropriate deadline counts as an "obligation" for purposes of the reverse FCA, which prohibits knowing and improper avoidance of an obligation to pay money to the government.[59]

The ACA does not specify what it means to "identify" an overpayment.[60] As originally promulgated, regulations governing the return of overpayments by the Medicare program stated that a provider "identifies" an overpayment when it "has determined, or should have determined through the exercise of reasonable diligence, that [it] has received an overpayment."[61] In a proposed rule issued in late 2022, CMS proposed to replace this looser standard of knowledge with the relatively more stringent definition of "knowing" and "knowingly" contained in the FCA.[62] This change came in direct response to a district court decision that struck down the "reasonable diligence" standard as permitting the government to premise FCA liability on nothing more than negligence, when the FCA requires a minimum of reckless disregard.[63] That decision and CMS's response to it, however, left unaddressed a core problem confronting large organizations that face overpayment risks—namely, that it can take much longer than 60 days to determine whether an overpayment has occurred, and the running of that clock without any action to return monies to the government is very often a sign that a good-faith investigation into potential overpayments remains underway, not that overpayments were quickly identified and are being concealed. CMS had previously acknowledged that internal investigations into potential overpayments could take around 180 days, but there was neither a requirement that such investigations be completed in that timeframe nor an explicit provision tolling the deadline for return of overpayments pending such investigations.[64]

The new proposed rule would permit the suspension of the 60-day clock to allow companies to conduct internal investigations, but the devil remains in the details. In particular, in order for the deadline to be suspended, a company would have to have already identified at least one

overpayment and be in the midst of a "good-faith investigation to determine the existence of related overpayments," and would have to actually conduct such a good-faith investigation.[65] And the deadline for returning overpayments would only be suspended until, at the latest, 180 days after the date on which the company identified the initial overpayment that triggered the broader investigation.[66] While these changes enhance incentives for companies to conduct investigations into potential overpayments by extending the reporting deadline pending the completion of such investigations, the reality is that even 180 days may prove an insufficient amount of time for such investigations to fully run their course in large companies. The 180-day cutoff risks being weaponized by *qui tam* relators claiming that any investigation that takes longer than 180 days must not have been conducted in "good faith" under the new rule, and that thus any overpayments not returned after the expiration of the 180-day window should form the basis for reverse FCA liability.

CMS is accepting comments on the proposed rule until September 9, 2024.

2. DOJ Whistleblower Reward Program and Voluntary Self-Disclosures Pilot Program for Individuals

Qui tam cases account for the majority of FCA cases initiated in any given year, as well as for the bulk of the monies the government recovers from FCA matters through settlement or judgment. In 2023, *qui tam* cases represented about 59% of the new FCA cases filed, and about 87% of the recoveries obtained. The FCA *qui tam* framework has no counterpart in U.S. criminal statutes, but DOJ recently has taken steps to develop a more formal policy for whistleblower awards in the criminal context. In March 2024, DOJ announced the creation of a pilot program that would reward a whistleblower with a portion of the resulting forfeiture if he or she helps DOJ discover significant corporate or financial misconduct.[67] In announcing this program, DOJ noted the successes of similar programs created at the SEC, CFTC, IRS, and FinCEN but acknowledged that those programs were limited to misconduct within those agencies' jurisdictions. DOJ also noted that *qui tam* whistleblower initiatives are limited to those actions where fraud against the government is alleged. Thus, DOJ's new initiative would "fill[] these gaps" to "address the full range of corporate and financial misconduct that the Department prosecutes."[68]

While details on this pilot program are still forthcoming, the announcement identified important "guardrails."[69] Payments would be made (1) only after all victims have been properly compensated; (2) only to those who submit truthful information not already known to the government; (3) only to those not involved in the criminal activity itself; and (4) only in cases where there is not an existing financial disclosure incentive—including *qui tam* awards or an award under another federal whistleblower program.[70] Deputy Attorney General Monaco also told potential future whistleblowers that DOJ was especially interested in information regarding "[c]riminal abuses of the U.S. financial system; [f]oreign corruption cases outside the jurisdiction of the SEC, including FCPA violations by non-issuers and violations of the recently enacted Foreign Extortion Prevention Act; and [d]omestic corruption cases, especially involving illegal corporate payments to government officials."[71]

Relatedly, in April 2024, DOJ's Criminal Division announced a pilot program that would extend the benefits of voluntary self-disclosure to individuals who (1) voluntarily, (2) truthfully, and (3) completely self-disclose original information regarding misconduct that was unknown to the

department in certain high-priority enforcement areas, (4) fully cooperate and are able to provide substantial assistance against those equally or more culpable, and (5) forfeit any ill-gotten gains and compensate victims.[72] To qualify, a disclosure must relate to at least one of six areas of DOJ focus:

- Schemes involving financial institutions (*g.*, money laundering, criminal compliance-related schemes);
- Schemes relating to the integrity of financial markets involving financial institutions, investment advisors or funds, or public or large private companies;
- Foreign corruption schemes (e.g., violations of the Foreign Corrupt Practices Act, Foreign Extortion Prevention Act, and associated money laundering);
- Health care fraud and kickback schemes;
- Federal contract fraud schemes; or
- Domestic corruption schemes involving bribes or kickbacks paid by or through public or private companies.

Deputy Attorney General Lisa Monaco noted that at least two U.S. Attorney's offices—in the Southern District of New York and the Northern District of California—established similar programs earlier in the year.[73]

Beyond their significance for DOJ's criminal enforcement efforts, these developments have important implications for FCA practice as well. Because the FCA penalizes fraud, the conduct at issue in an FCA investigation can sometimes be of interest to criminal authorities too. Yet the risks for a would-be whistleblower in coming forward are magnified when the alleged conduct carries potential criminal, in addition to civil, liability. In such a scenario, the possibility that DOJ will decide the relator has unclean hands carries not just the potential for criminal liability, but also the prospect of outright denial of a *qui tam* award. The FCA explicitly provides that a relator who is "convicted of criminal conduct arising from his or her role in the [FCA] violation . . . shall be dismissed from the civil action and shall not receive any share of the proceeds of the action."[74] The new criminal whistleblower pilot program creates an additional financial incentive for reporting misconduct that operates independently of the *qui tam* mechanism. Alongside that pilot program, the individual voluntary self-disclosure pilot program stands to remove the disincentive that otherwise exists in the form of *qui tam* award denial in the event of a criminal conviction. Relators may prove more forthcoming about alleged conduct and their own roles in it, if both non-prosecution and financial gain remain on the table. And the carve-out in the pilot whistleblower program for individuals already covered by another whistleblower regime will likely do little to stop relators from making simultaneous reports to both civil and criminal authorities in the hope of maximizing their chances of a recovery.

B. State Legislative Developments

There were no major developments with respect to state FCA legislation in the second half of 2022. 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. The lists of

"approved" state false claims statutes increased to 23 with the approval of Connecticut's statute this year; while six states remain on the "not approved" list.[75] The other 21 states have either not enacted a state analogue or have not submitted the statue for approval.

V. Case Law Developments

A. U.S. Supreme Court Grants Certiorari in E-Rate Fraud Claims Case

In June, the Supreme Court granted a petition for a writ of certiorari filed by Wisconsin Bell on the question whether reimbursement requests submitted to the Federal Communications Commission's E-rate program are "claims" under the FCA. *See United States ex rel. Heath v. Wis. Bell*, 92 F.4th 654, 657 (7th Cir. 2024), *cert. granted*, 2024 WL 3014477 (U.S. June 17, 2024). The $4.5 billion E-rate program, established under the Telecommunications Act of 1996, provides discounted services to eligible schools and libraries for which service providers competitively bid on pricing and subsidize cost of service. It is funded by private money and administered by a non-profit company. (Note: Gibson Dunn represents Wisconsin Bell in this matter.)

After relator Todd Heath alleged in 2008 that Wisconsin Bell violated the FCA by over-charging schools and libraries, causing the federal government to pay more than it should have, *id.* at 658, Wisconsin Bell argued that the relator could not satisfy the FCA because, among other things, the E-rate program does not involve government funds, and reimbursement requests are not "claims" within the meaning of the FCA. The district court granted summary judgment for Wisconsin Bell, holding that the relator had not established falsity, scienter, or harm to the government fisc. *Id.* The Seventh Circuit reversed the district court's grant of summary judgment. *Id.* at 671. By reinstating the relator's claims, the Seventh Circuit created a circuit split with the Fifth Circuit, which had previously held that the FCA does not apply to E-Rate reimbursement requests because the government lacks a financial stake in the allegedly lost funds. *See generally United States ex rel. Shupe v. Cisco Sys., Inc.*, 759 F.3d 379, 388 (5th Cir. 2014).

The certiorari petition was granted on June 17, and oral argument is set for November 4, 2024.

B. The Seventh Circuit Remands on Causation and Upholds Damages Award Against Eighth Amendment Challenge

The Seventh Circuit heard argument in *Stop Ill. Health Care Fraud, LLC v. Sayeed*, 100 F.4th 899 (7th Cir. 2024) on the FCA causation issue but declined to take a position and remanded to the district court for further argument.

In *Stop Ill. Health Care Fraud*, Management Principles Inc. ("Management Principles"), a healthcare management company which provided home-based medical services to Medicare recipients, as well as its two subsidiaries and owner, faced AKS allegations for paying Healthcare Consortium of Illinois ("Healthcare Consortium") $5,000 monthly in exchange for patient referrals. *Id*. at 902–03. The company allegedly relied on referrals from Healthcare Consortium, a healthcare diagnostic organization, that would refer seniors to local in-home healthcare providers. *Id*. Management Principles allegedly paid this organization $90,000 for referrals and access to client data, and allegedly billed the federal government over $700,000 for services provided to

clients referred by Healthcare Consortium. *Id.* at 903. Following a bench trial, the district court found that this scheme violated the AKS by paying to induce referrals for medical services. *Id*. at 904. The district court also found the defendants liable under the FCA for submitting claims for payments stemming from an unlawful referral arrangement. *Id*. The district court imposed a judgment of nearly $6,000,000, comprised of the sum of per-claim penalties of $5,500 per claim and treble the value of the Medicare claims at issue. *Id*. The defendants appealed, challenging causation and the award of damages and penalties, "arguing that it [was] constitutionally excessive under the Eighth Amendment and improperly divorced form the actual loss incurred by the government." *Id.* at 906.

The Seventh Circuit held the "resulting from" language in the AKS means "at a minimum, every claim that forms the basis of FCA liability must be false *by virtue* of the fact that the claims are for services that were referred in violation of the Anti-Kickback Statute." *Id.* at 908. The court explained that it was "not able to determine with confidence whether any of the services represented in the plaintiff's loss spreadsheet were provided to patients lawfully referred to the defendants by the [Healthcare] Consortium." *Id.* at 909. The court remanded the case back to the district court for the limited task of determining which claims, if any, were the result of a referral process outside the kickback scheme. *Id.* at 909–10. Thus, in doing so, the Seventh Circuit declined to weigh in conclusively on the proper causation standard for AKS-predicated FCA claims, *id.* at 909, leaving the Seventh Circuit without a definitive position on either side of the deepening circuit split on this issue, which we covered in our 2023 Mid-Year and End-Year Updates. In declining to take a position, however, the Seventh Circuit signaled that, if it does take a side in the debate, it is unlikely to hold that the existence of a kickback "taints" all subsequent claims for payment, regardless of any causal connection between the kickback and the claims. The court made clear that "[t]hat broad suggestion . . . is inconsistent with [the FCA's] directive that a false claim must 'result[] from' an unlawful kickback." *Id.* (second alteration in original). We will continue to closely monitor developments around this issue, including as the related *Regeneron* case in the First Circuit proceeds to oral argument this summer.

Additionally, the Seventh Circuit also addressed whether the nearly $6 million judgment was unconstitutionally excessive under the Eight Amendment. The court held that the judgment did not violate the Eighth Amendment's Excessive Fines Clause, but that the district court still erred by calculating those damages based on Medicare claims that might not have been related to the kickback scheme. *Id*. at 906–07. The court explained that while the Seventh Circuit has not explicitly held whether the Excessive Fines Clause applies to civil penalties under the FCA, the judgment in this particular case would not violate the clause even if it were to apply. *Id*. The Seventh Circuit held that because the defendants established an extensive scheme that defrauded the government, exploited the private health information of seniors, and undermined the public's faith in government programs, the judgment was not "grossly disproportional to the gravity of the defendant's offense," thereby passing Eighth Amendment scrutiny. *Id*..

C. The Sixth Circuit Holds Courts Can Require Plaintiffs Take All Reasonable Steps to Dismiss an FCA Suit, Including Seek Government Consent

A relator cannot unilaterally settle FCA claims without the government's consent. *See* 31 U.S.C. § 3730 (requiring the government's consent to any voluntary dismissal of a *qui tam* case). In *State*

Farm Mut. Auto. Ins. Co. v. Angelo, the Sixth Circuit clarified what steps a court can require a party take to dismiss a FCA suit. 95 F.4th 419 (6th Cir. 2024).

After State Farm sued Michael Angelo, alleging RICO violations, the parties entered into a settlement agreement. *Id*. at 424. In the agreement, Angelo agreed to take "all steps necessary" to release claims against State Farm. *Id*. Before the agreement was signed, Angelo filed an FCA suit against State Farm. *Id*. Because *qui tam* suits are required to be filed under seal, State Farm was unaware of the case until after the RICO settlement agreement was signed and the complaint was unsealed and served on State Farm. *Id*. In the ensuing litigation over State Farm's motion to dismiss the FCA claims, Angelo argued that he could not dismiss the claims because the FCA prohibits relators from dismissing *qui tam* cases without the government's consent. *Id*. at 425. The district court granted State Farm's motion, ordering Angelo to take all steps necessary to dismiss his FCA claims, including seeking the necessary government consent. *Id*.

On appeal, the Sixth Circuit upheld the district court's orders enforcing the RICO settlement agreement. The court explained that while "the FCA statute demands government consent before a *qui tam* relator can dismiss an FCA claim[,]" the law does not "prevent[] a relator from *seeking* the required consent or prohibit[] a district court from ordering a relator to seek such consent." *Id*. at 429–30 (emphasis in original). The Sixth Circuit rejected Angelo's argument that under this interpretation, the settlement agreement violates the public policy rationale behind the FCA. *Id.* at 430. The court held that the "primary goals of the FCA are to incentivize private individuals to bring suit and to alert the government to potential fraud," goals which the RICO settlement did not undermine. *Id*. Because Angelo had filed the FCA suit two years before the settlement was signed, both Angelo and the government had ample time to investigate the claims. *Id*. at 431. The court further explained that even if there had not been ample time, the government still had the opportunity to deny consent to dismiss or to file its own FCA claims, as it was not a party to the RICO settlement and thus was not bound by agreement requiring Angelo to take steps to effectuate dismissal of the *qui tam* case. *Id*. at 432.

D. The Second Circuit Clarifies When a Worker Engages in "Protected Activity"

The FCA prohibits retaliation against employees who report potential FCA violations. *See* 31 U.S.C. § 3730(h)(1). In *Pilat v. Amedisys, Inc.*, workers claimed they were fired in retaliation for raising concerns about certain practices of Amedisys, a home health and hospice company. No. 23-566, 2024 WL 177990 (2d Cir. Jan. 17, 2024). The workers alleged that they disclosed to superiors that Amedisys falsely certified unqualified patients for home care, provided unnecessary and improper treatment, falsified time records, and manipulated patient records. *Id.* at *1. These schemes allegedly resulted in fraudulent bills to the government for reimbursement under the Medicare and Medicaid programs. *Id.* The workers alleged that after they expressed concerns over the unethical nature of these practices and their effects on the health of patients and refused to comply with instructions to carry out these practices, Amedisys fired them. *Id.* at *1–2. The district court held that the Plaintiffs did not have a valid retaliation claim since they did not "engage in protected activity under the statute." *Id*. at *1. The court explained that the complaints were "more appropriately characterized as concerns about patient care[,]" and "did

'not have anything to do with potential false claims.'" *Id.* at *9 (citing *United States v. Amedisys*, No. 17-CV-136, 2023 WL 2481144, at *9 (W.D.N.Y. Mar. 13, 2023)).

The Second Circuit reversed and explained that "relators engage in protected activity if they engage in 'efforts to stop 1 or more violations of' the FCA." *Pilat*, 2024 WL 177990 at *2 (quoting 31 U.S.C. § 3730(h)(1)). Such efforts can include raising concerns to supervisors or refusing to engage in violative practices. *Id*. Because in this case the workers refused to comply with instructions to engage in conduct that would have violated the FCA, they made "efforts to stop 1 or more violations," even if their main concern was the safety of patients. *Id*. The court further rejected the district court reasoning that the Plaintiffs only raised concerns of patient care, not fraud. Even if the complaints were based on concerns of patient care, the Plaintiffs still raised concerns that the amounts billed to the government did not match the actual time spent treating patients, a concern which clearly implicated potential fraud. *Id*.

E. The Second Circuit Affirms Heightened Scienter Under the Anti-Kickback Statute

While the FCA is a civil statute, DOJ and relators often allege that violations of the AKS—a criminal statute—are what made certain claims for payment false. The two statutes contain different scienter requirements. The FCA imposes liability on any person who "knowingly presents . . . a false or fraudulent claim [to the government] for payment or approval." 31 U.S.C. § 3729(a)(1)(A). The FCA defines "knowingly" to mean that a person (1) "has actual knowledge of the information," (2) "acts in deliberate ignorance of the truth or falsity of the information," or (3) "acts in reckless disregard of the truth or falsity of the information," and "require[s] no proof of a specific intent to defraud." 31 U.S.C. § 3729(b)(1)(A-B). The Supreme Court recently clarified that the FCA's "knowingly" standard refers to the defendant's knowledge and subjective beliefs, not what an objectively reasonable person might have known or believed. *United States ex rel. Schutte v. SuperValu Inc.*, 143 S. Ct. 1391, 1404 (2023). The AKS, on the other hand, imposes liability on any person who "knowingly and willfully makes or causes to be made any false statement or representation of a material fact in any application for any benefit or payment under a Federal health care program." 42 U.S.C. § § 1320a–7b. In *United States ex rel. Hart v. McKesson Corp.*, the Second Circuit affirmed a key decision interpreting the willfulness requirement in cases where an FCA violation is premised on a violation of the AKS. 96 F.4th 145 (2d Cir. 2024).

Plaintiffs alleged that Defendants operated an illegal kickback scheme in violation of the AKS and the FCA. *Id.* at 150. According to the complaint, McKesson offered business management tools for free to customers who agreed to solely purchase drugs from McKesson. *Id*. at 151–52. Plaintiffs alleged that this scheme violated the AKS and thus the FCA. *Id*. The district court granted McKesson's motion to dismiss, holding that to act "willfully" as required by the AKS, "a defendant must act knowing that its conduct is, in some way, unlawful," a standard Hart failed to plead. *Id*. at 150. The district court held that because the FCA claim was premised on the AKS claims alone, the defendant failed to plausibly allege an FCA claim. *Id*.

The Second Circuit affirmed and interpreted the AKS's "willful" requirement to mean that "a defendant must act with a 'bad purpose'" and "'with knowledge that his conduct was unlawful.'" *Id.* at 157 (quoting *Bryan v. United States*, 524 U.S. 184, 191 (1998)). The court held that "to violate

the AKS, a defendant must act knowing that his conduct is unlawful, even if the defendant is not aware that his conduct is unlawful under the AKS specifically." *Id*. at 154 (citing *Pfizer v. U.S. Dep't of Health & Hum. Servs.*, 42 F.4th 67, 77 (2d Cir. 2022)). The court held that "a defendant's knowledge of his general legal obligations is not enough if he does not also know that his actions violate those obligations," *id*. at 158, and affirmed the dismissal of Hart's claim for failure to plead willfulness adequately, *id.* at 157–59. Notably, the Second Circuit looked to the specific knowledge of individuals other than the relator when determining whether the Plaintiff adequately pleaded willfulness. *Id*. at 160–62 (rejecting relator's argument that he sufficiently alleged scienter because he pleaded that he told a supervisor that he thought certain conduct violated company policies).

VI. Conclusion

We will monitor these developments, along with other FCA legislative activity, settlements, and jurisprudence throughout the year and report back in our 2024 False Claims Act Year-End Update, which we will publish in early 2025.

The footnotes referenced in this update are available on Gibson Dunn's website at the following link. Please click on a particular footnote above to view details. The complete update is available on this page:

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