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2021 Mid-Year False Claims Act Update

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As the United States emerges from the darkest days of the COVID-19 pandemic and the Biden Administration settles in, the U.S. government and *qui tam* relators continue to churn out litigation and investigations under the False Claims Act ("FCA"), the government's primary tool for combatting fraud against the federal fisc.

Six months ago, in our 2020 Year-End FCA Update, we explored what the new Biden Administration's priorities might be and whether they would alter FCA enforcement. To date, there have been no major shifts in overarching policy, but the contours of the Biden Administration's priorities are emerging. And, with nearly $400 million in FCA settlements in the first half of the year, more aggressive and forward-leaning FCA enforcement may well be on the horizon. Indeed, the Biden Administration forecasts that its efforts to root out COVID-19-related fraud will result in "significant cases and recoveries" under the FCA.

Meanwhile, federal courts issued several significant decisions in the first half of 2021, including important decisions exploring the use of statistical evidence in FCA cases, causation in fraudulent inducement cases, alleged "fraud on the FDA," liability based on Anti-Kickback Statute ("AKS") violations, the FCA's materiality requirement, and DOJ's discretion to dismiss *qui tam* cases where the government has not intervened.

Below, we begin by summarizing recent enforcement activity, then provide an overview of notable legislative and policy developments at the federal and state levels, and finally analyze significant court decisions from the past six months. Gibson Dunn's recent publications regarding the FCA may be found on our website, including in-depth discussions of the FCA's framework and operation, industry-specific presentations, and practical guidance to help companies avoid or limit liability under 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 2021

Momentum continued to build on the FCA enforcement front during 2021's first half, as DOJ announced a number of FCA resolutions totaling more than $393 million. Although the number of resolutions demonstrated a continued high level of enforcement activity, these resolutions did not include any blockbuster settlements by historical standards; DOJ did not announce any nine-figure settlements in the first half of the year.

Below, we summarize the most notable settlements thus far in 2021, with a focus on the industries and theories of liability involved. Consistent with historical trends, a majority of FCA recoveries from enforcement actions for the first half of this year have involved health care and life sciences entities, including alleged violations of the AKS, but DOJ also announced several resolutions in the government contracting and procurement space.

A. HEALTH CARE AND LIFE SCIENCE INDUSTRIES

FCA resolutions in the health care and life sciences industries totaled more than $228 million. Consistent with historical trends, this made up the largest share of overall

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recoveries of any industry. Of the 27 resolutions summarized below, at least five included a Corporate Integrity Agreement.

- On January 11, a California laboratory agreed to pay $2.5 million to resolve allegations that it violated the FCA and the AKS by billing Medicare for genetic tests that were induced by kickbacks paid for referrals of the tests. A marketing company purportedly referred its clients to the laboratory for testing, and the laboratory allegedly paid a specified percentage or fixed amount of Medicare's reimbursement for covered tests.[1]
- On February 4, a Florida company and the company's president agreed to pay $20.3 million to settle allegations that they violated the FCA by fraudulently establishing corporations to bill for medically unnecessary durable medical equipment ("DME") and by engaging in improper marketing practices in violation of the According to the government's allegations, the company established dozens of front companies purporting to be DME suppliers, submitted more than $400 million in improper DME claims to Medicare and the Veterans Administration ("VA"), and bribed doctors to approve the claims even when they had not interacted with the purported beneficiaries. In addition to the settlement, the company's president pleaded guilty to conspiracy to commit health care fraud and filing a false tax return for which she faces a maximum penalty of 13 years in federal prison. The share of the whistleblower who originally filed the action was not disclosed at the time of the settlement announcement.[2]
- On February 25, a Pennsylvania pharmacy agreed to pay $2.9 million to resolve allegations that it violated the FCA by filling prescriptions with inexpensive generic medications but billing Medicare for pricier brand-name drugs, and that it violated the Controlled Substances Act by illegally dispensing opioids and other controlled substances to individuals who did not have prescriptions.[3]
- On February 25, a global medical technology company agreed to pay $3.6 million to settle allegations that it violated the FCA by submitting improperly completed certificates of medical necessity ("CMN") for devices that were medically unnecessary. The allegations stemmed from the company's self-disclosure to HHS-OIG that its sales representatives at times filled out a CMN section that, under Medicare rules, must be completed by the treating physician's office.[4]
- On March 2, a North Carolina medical equipment provider agreed to pay $20.1 million, and its individual owner agreed to pay an additional $4 million, to resolve allegations that the company violated the federal and North Carolina FCA The government alleged that the company fraudulently billed Medicaid for DME purportedly provided to individual Medicaid recipients, but the individuals never ordered or received the equipment; in some cases, the supposed recipients allegedly had been deceased for years before the submission of the claims. The U.S. government and the state of North Carolina also obtained a default judgment of $34.7 million against a sales representative of the company. In a related criminal investigation, the company was sentenced to five years of probation and ordered to pay a $2 million fine and over $10 million in restitution to the North Carolina Medicaid Program related to charges of health care fraud. The company self-reported the activity to the North Carolina Medicaid Investigations Division.[5]
- On March 2, a Virginia medical practice agreed to pay $2.1 million to resolve allegations that it violated the FCA by double-billing Medicare for treatments administered to patients. The at-issue treatment is sold in single-use vials, but some patients do not need an entire vial. In such cases, Medicare rules allow the doctor to bill as if the entire vial had been administered while discarding the leftover amount. Allegedly, the medical practice engaged in a scheme whereby it would administer a partial vial to one patient, give the remainder of the vial to a different patient, and then bill Medicare for one full vial per patient. In June 2020, the medical practice pleaded guilty to one count of criminal health care fraud related to the conduct.[6]

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- On March 5, the Florida-based parent of two Ohio psychiatric hospitals and one Ohio substance abuse treatment facility agreed to pay $10.3 million to resolve allegations that they violated the FCA by billing federal health care programs for medical services that were induced by kickbacks improperly provided to patients. According to the government, the company unlawfully provided free long-distance transportation to patients to induce them to seek treatment at the company's facilities and then submitted claims for the services it provided to those patients. The government also alleged that some of the inpatient admissions, for which the company submitted claims, were medically unnecessary. In addition to the financial settlement, the company entered into a Corporate Integrity Agreement with HHS-OIG that requires it to retain an independent reviewer for a five-year period to examine its claims to Medicare and Medicaid. The share of the whistleblower who originally filed the action was not disclosed at the time of the settlement announcement.[7]
- On March 16, two former owners of a telemarketing company agreed to collectively pay at least $4 million to settle allegations that they violated the FCA by scheming to generate referrals to pharmacies in exchange for kickbacks. The government alleged that the former owners solicited prospective patients to accept compounded drugs notwithstanding the medical necessity of such drugs, procured prescriptions for the patients, and then arranged to have those prescriptions filled at compounding pharmacies. In exchange, the former owners received a kickback from the pharmacies equal to half of the amount that TRICARE ultimately reimbursed for each prescription. Under the settlement agreement, the exact resolution amount will be determined based the sale price of certain real property that one of the former owners agreed to sell. A former employee of one pharmacy to which the telemarketing company referred prescriptions initially filed the *qui tam* The share of the whistleblower who originally filed the action was not publicized at the time the settlement was announced.[8]
- On March 18, a Michigan physician and his practice agreed to pay $2 million to resolve allegations that the practice violated the FCA by billing federal programs for diagnostic tests that were unnecessary or never performed. In addition to the financial settlement, the physician and his practice agreed to a Integrity Agreement with HHS-OIG that requires billing practices oversight for a three-year period. The shares of the two whistleblowers who originally filed the actions were not disclosed at the time of the settlement announcement.[9]
- On March 26, a former owner of a North Carolina diagnostic testing laboratory agreed to pay $2 million to settle allegations that he participated in kickback schemes to induce physicians to refer patients to the laboratory for medically unnecessary drug tests, leading to the submission of claims to Medicare in violation of the AKS and the FCA. According to the government, the laboratory provided benefits, including urine drug testing equipment and loans to physicians, as well as volume-based commissions and a salary to an individual for influence over two physician practices, in exchange for referrals to the laboratory for testing. On March 30, another of the laboratory's former owners consented to an entry of final judgement requiring that he pay $4.5 million to resolve allegations that he paid kickbacks to the owner or a medical practice.[10]
- On April 1, a New York-based pharmaceutical company agreed to pay $75 million to resolve allegations that it knowingly underpaid rebates owed pursuant to the Medicaid Drug Rebate Program. The government alleged that the company had underreported the Average Manufacturer Prices ("AMPs") for multiple drugs because it improperly subtracted service fees paid to wholesalers from the reported AMPs and excluded additional value the company received under contractual price-appreciation provisions with the wholesalers. According to the government, the underreported AMPs resulted in underpaid quarterly rebates to states and, relatedly, caused overcharges to the United States for the government's Medicaid program payments to the states.[11] The company will pay approximately $41 million, plus interest, to the United States and the remainder to

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states participating in the settlement. The settlement stemmed from a *qui tam* lawsuit, which the whistleblower pursued after the government declined to intervene. The whistleblower's share was not announced with the settlement.

- On April 8, an urgent-care provider network in South Carolina and its management company agreed to pay $22.5 million to resolve allegations that the management company falsely certified that network health care providers credentialed to bill Medicaid, Medicare, and TRICARE had performed various procedures, when non-credentialed providers actually performed those services. The companies also entered into a five-year Corporate Integrity Agreement with HHS-OIG and DCIS that requires the management company to retain an independent review organization to review its claims.[12] The share of the whistleblowers who originally filed the action was not announced with the settlement.
- On April 20, a network of three specialty health care providers in Massachusetts agreed to pay $2.6 million to resolve allegations that they improperly billed Medicare and Massachusetts' Medicaid program for certain office visits while also billing for procedures performed at the office visits, allowing the providers to obtain reimbursements to which they were not entitled under the circumstances. The whistleblower who originally filed the action will receive 15% of the recovery.[13]
- On April 21, a Tennessee-based network of pain-management clinics, its four majority owners, and a former executive agreed to pay $4.1 million to settle allegations involving the submission of false claims for medically unnecessary or non-reimbursable treatments, testing, and drugs to federal health care programs, as well as for services and testing that were not actually performed. The settlement also resolved common-law claims of fraud, payment by mistake, and unjust enrichment. With the settlement, the government agreed to dismiss its underlying civil action against all the parties except the network's former CEO, who was convicted of health care fraud in 2019. The allegations originally stemmed from *qui tam* lawsuits, pursuant to which the whistleblowers will receive $610,685.[14]
- On April 30, a health care software developer in Florida agreed to pay $3.8 million to resolve allegations that it used its marketing referral program for electronic health records products to pay unlawful kickbacks to generate sales. The government alleged that the referral program financially incentivized existing clients to recommend the developer's products and barred program participants from providing negative product information to prospective clients, without the prospective clients' knowledge of the arrangement. The government also asserted that the kickback payments rendered false the claims the company submitted under Medicare and Medicaid Meaningful Use Programs and the Merit-Based Incentive Payment System. The whistleblower who originally filed the action will receive approximately $800,000 in connection with the settlement.[15]
- On May 3, a neurosurgeon in South Dakota, as well as two affiliated medical device distributors owned by the doctor, agreed to pay $4.4 million to resolve allegations that the doctor accepted illegal payments to use certain medical devices and knowingly submitted claims for medically unnecessary surgeries. The doctor allegedly requested and received kickbacks, in the form of meals and alcohol, from a medical device manufacturer through a restaurant that the doctor owned with his wife. The doctor also allegedly knowingly submitted false claims for medically unnecessary procedures using medical devices in which he had a financial interest. The two medical device distributors agreed to pay an additional $100,000 to resolve claims that they violated the Centers for Medicare & Medicaid Services' ("CMS") Open Payments Program when the distributors failed to report to the CMS the doctor's ownership interests and payments made to him. The settlement precludes each of the defendants from participating in federal health care programs for a period of six years. The whistleblowers who originally filed the action will receive $880,000 in connection with the settlement.[16]
- On May 4, a Delaware-based pharmaceutical manufacturer agreed to pay $12.6 million to resolve allegations that it used a third-party foundation to cover the

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copays of Medicare and TRICARE patients taking its myelofibrosis drug. The government alleged that the manufacturer improperly induced patients to purchase its drugs after pressuring the foundation to use funds donated by the manufacturer for patient copays and help ineligible patients complete financial assistance applications to the fund. The whistleblower who originally filed the action will receive approximately $3.59 million of the recovery.[17]

- On May 5, an Arizona hospital, operated by one of the largest health care systems in the United States, and a neurosurgery provider on the hospital's campus agreed to pay $10 million to resolve allegations that they billed Medicare for concurrent, overlapping surgeries in violation of regulations and reimbursement policies. The neurosurgery provider contemporaneously entered into a five-year Corporate Integrity Agreement with HHS-OIG that requires the provider to maintain compliance and risk-assessment programs and hire an independent review organization to annually review its claims. The share of the recovery the whistleblower who originally filed the action was not announced with the settlement.[18]
- On May 10, a private university in Florida agreed to pay $22 million to resolve claims related to its laboratory and off-campus, hospital-based facilities. The government alleged that the university billed federal health care programs for medically unnecessary laboratory tests for kidney transplant patients, submitted inflated reimbursement claims for pre-transplant laboratory testing in violation of regulations limiting above-cost reimbursements for tests performed by a provider's related entity, and knowingly failed to provide required notice to beneficiaries regarding the cost of receiving services at hospital facilities rather than physician offices. Contemporaneous with the settlement, the university entered into a five-year Corporate Integrity Agreement with HHS-OIG, which requires the university to establish compliance, risk-assessment, and internal-review programs. The share of the whistleblower who originally filed the three underlying *qui tam* lawsuits was not disclosed at the time of settlement.[19]
- On May 11, a national pharmacy-services provider based in Texas agreed to pay $2.8 million to resolve a number of alleged violations under the Controlled Substances Act and FCA. The settlement also resolved allegations that the provider dispensed opioids and other controlled substances without valid prescriptions, submitted false claims for invalid emergency prescriptions to Medicare, and billed Medicare for claims that had already been reimbursed. The share of the whistleblower who originally filed the action was not announced with the settlement.[20]
- On May 14, two Texas-based dentists, as well as their affiliated practices and dental management companies, agreed to pay $3.1 million to resolve allegations that they knowingly billed Medicaid for services not rendered or falsely identified who provided those services. The share of the whistleblowers who originally filed the action was not announced with the settlement.[21]
- On May 19, a French medical device manufacturer and its American affiliate agreed to pay $2 million to resolve allegations that they violated the AKS, FCA, and the Open Payments Program's requirements. The government alleged the manufacturer provided items of value—such as meals, entertainment, and travel expenses—to U.S.-based doctors attending a conference in France to induce purchases of their spinal devices and failed to fully report the physician-entertainment expenses as part of the Open Payments Program. The share of the whistleblower who originally filed the action was not announced with the settlement.[22]
- On May 21, an Atlanta-based chain of nursing facilities agreed to pay $11.2 million to resolve allegations that it billed Medicare for medically unreasonable, unnecessary, and unskilled rehabilitation therapy services, and that it billed both Medicare and Medicaid for substandard or "worthless" skilled-nursing services after allegedly failing to have a sufficient number of skilled nursing staff to care for

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the residents. The settlement also resolved allegations that the chain submitted false claims to Medicaid for coinsurance amounts for beneficiaries eligible for both Medicare and Medicaid. Contemporaneously, the chain entered into a five-year Corporate Integrity Agreement with HHS-OIG that requires an independent organization to annually review patient stays and associated claims as well as an independent monitor to review resident-care quality. The settlement resolves several *qui tam* suits; the whistleblowers' share of the recovery was not announced with the settlement.[23]

- On May 25, a dental-clinic system in New York agreed to pay $2.7 million to resolve allegations that it submitted false claims to Medicaid for dental services performed with improperly sterilized equipment. The share of the whistleblower who originally filed the action was not announced with the settlement.[24]
- On June 8, a Texas-based chiropractor and her medical group agreed to pay $2.6 million to resolve allegations that the chiropractor improperly billed Medicare and TRICARE programs for the implantation of neurostimulator electrodes despite not performing such surgeries. In addition to the settlement, the chiropractor and affiliated medical entities agreed to a 10-year period of exclusion from participation in any federal health care program.[25]
- On June 28, a surgery center and its affiliated outpatient surgery provider agreed to pay $3.4 million to resolve allegations that the companies submitted claims for kidney stone procedures that were not medically justified and also engaged in a kickback scheme. One of the surgery centers allegedly submitted claims for certain kidney stone procedures for Medicare and TRICARE patients that were not medically necessary. Further, a physician and the two companies allegedly engaged in a kickback arrangement in which the physician performed the kidney stone procedures in exchange for per-procedure payments at the surgery center, which the surgery center then billed to Medicare and TRICARE. The settlement resulted from a *qui tam* lawsuit, and the whistleblower will receive $748,000 of the settlement proceeds. In November 2020, the estate of the physician also paid the U.S. government $1.75 million to resolve claims related to his participation in the conduct.[26]

B. GOVERNMENT CONTRACTING AND PROCUREMENT

Settlement amounts to resolve liability under the FCA in the government contracting and procurement space totaled more than $165 million in the first half of 2021.

- On January 8, a Connecticut electrical contractor agreed to pay $3.2 million to settle allegations that it violated the FCA in connection with public construction contracts principally funded by the U.S. Department of Transportation. Under the terms of the contracts, the contractor was required to subcontract a portion of the work to Disadvantaged Business Enterprises ("DBE"). The government alleged that the contractor fraudulently misrepresented that a DBE had performed work as a subcontractor, when in fact the work in question was performed by the electrical contractor's own employees. As part of the settlement, the contractor agreed to enter a monitoring agreement with the Federal Transit Administration.[27]
- On January 12, a Washington aerospace contractor agreed to pay $25 million to resolve allegations that it submitted materially false cost and pricing data in relation to military contracts, in violation of the FCA. The contractor entered into contracts to supply Unmanned Aerial Vehicles ("UAVs") to the military. The proposals submitted by the contractor incorporated cost and pricing data that assumed new parts would be used in building the UAVs, but the government alleged that the contractor instead used recycled, refurbished, reconditioned, or reconfigured parts. The whistleblower who originally filed the *qui tam* lawsuit will receive $4.625 million of the settlement amount.[28]
- On February 17, a subsidiary of a French civil engineering company agreed to pay

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$3.9 million to resolve allegations that it violated the FCA by knowingly using contractually noncompliant concrete in the construction of an overseas U.S. military airfield. In addition to the civil settlement, the company agreed to enter into a separate DPA under which the company admitted to the underlying facts and accepted responsibility for a one-count information for conspiracy to commit wire fraud, and agreed to pay a monetary penalty of more than $12.5 million. The civil settlement credited approximately $1.95 million of the DPA payment.[29]

- On February 19, a Virginia company agreed to pay more than $6 million to settle allegations that its predecessor company, an information technology contractor, violated the FCA by overbilling the Department of Homeland Security ("DHS") for work performed by its employees. The contractor allegedly used underqualified personnel to perform services and knowingly billed DHS at higher rates meant for more qualified personnel.[30]
- On February 26, a U.S.-based airline agreed to pay $49 million to resolve criminal charges and civil claims that it provided fraudulent data to the U.S. Postal Service ("USPS") in connection with a contract to deliver mail internationally on behalf of U.S.P.S. Under the airline's contracts with USPS, it was required to provide bar code scans of mail containers when it took possession of them and again when it delivered them to intended recipients; the airline was entitled to payment only if accurate scans were provided and the mail was timely delivered. According to the government, the airline submitted automated scans that did not correspond to the actual movement of the mail, and thus it was not entitled to payment. The airline admitted that it concealed problems related to mail movement and scanning that would have subjected it to penalties under the contracts. The airline agreed to pay nearly $32.2 million to resolve civil allegations that it violated the FCA, and the airline also entered into a criminal non-prosecution agreement and agreed to pay an additional $17.3 million in criminal penalties and disgorgement. The airline also agreed to continued cooperation with the DOJ Criminal Division's Fraud Section. The airline further agreed to strengthen its compliance program and agreed to reporting requirements, including annual reports to DOJ.[31]
- On March 1, the subsidiary of a multinational software engineering and support company agreed to pay $2.2 million to settle allegations that it violated the FCA by failing to pay required administrative fees pursuant to contracts it signed with the U.S. General Services Administration, and that it violated the FCA by failing to provide contracted discounts and not meeting contractual requirements regarding the educational and experiential qualifications of its staff.[32]
- On March 19, a New York-based nongovernmental organization ("NGO") agreed to pay $6.9 million to settle allegations that it violated the FCA in relation to programming funded by the U.S. Agency for International Development ("USAID"). The NGO received USAID funding to provide humanitarian assistance to refugees in Syria. According to the government, the NGO's staff participated in a collusion and kickback scheme with a foreign supplier to rig bids for goods and services contracts used in its humanitarian relief efforts. The government alleged that this conduct led to the procurement of goods at unreasonably high prices, which were then invoiced to USAID.[33]
- On April 29, a California-based manufacturer agreed to pay $5.6 million to resolve allegations that it falsely certified the origin of materials and the manufacturing location of items produced under a contract with the Government of Israel, which was funded by the U.S. Defense Security Cooperation Agreement Agency. To be eligible for foreign procurement grant funds, the materials must be sourced and manufactured in the United States by domestic companies. As related to items manufactured under the DSCA-funded contract with the Government of Israel, the government alleged that the manufacturer knowingly submitted false certifications that Chinese-sourced materials were produced in the United States and that manufacturing had occurred in the United States, when the company had in fact contracted with a Mexican maquiladora. The whistleblowers who filed the action

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will receive 17% of the settlement.[34]

- On May 27, an Illinois-based military manufacturer agreed to pay $50 million to resolve allegations that it fraudulently induced the U.S. Marine Corps to enter into a contract modification at inflated prices for components of armored vehicles. The government alleged that the manufacturer knowingly created and submitted fraudulent sales invoices for sales that never occurred to justify the contract's inflated prices. The whistleblower who filed the action will receive approximately $11.1 million of the settlement.[35]
- On June 3, a Washington subsidiary of a Colorado-based environmental cleanup and remediation company paid approximately $3 million to resolve allegations that it submitted fraudulent small-business subcontractor reports. The company had entered into a government contract that required it to make efforts to award small businesses a percentage of its subcontracts and regularly report its progress; the contract provided fee-based incentives for its subcontracting successes and imposed monetary penalties if these goals were missed in bad faith. The government alleged that the company falsely represented the status of two businesses awarded subcontracts to claim credit for small-business subcontractors under the contract. The whistleblowers who originally filed the action will receive approximately $865,900 of the settlement.[36]
- On June 10, a national car-rental group headquartered in New Jersey agreed to pay $10.1 million to resolve allegations that it submitted false claims under an agreement managed by the Department of Defense Travel Management Office for unallowable supplemental charges to car rentals, such as collision-damage waiver insurance, supplemental liability coverage, personal-effects coverage, and late turn-in fees. Additionally, the government alleged that some of the fees charged were already included in the government rental rate.[37]
- On June 25, a multinational telecommunications and Internet service provider company agreed to pay more than $12.7 million to resolve allegations that the company violated the FCA in numerous ways. Former officials of the company allegedly accepted kickbacks in return for favorable treatment for subcontractors related to government contracts. The company also allegedly improperly obtained protected competitor bid information related to a government contract to gain a bidding advantage. Further, the company allegedly misstated its compliance with woman-owned small business subcontracting requirements under a contract with the Department of Homeland Security. The settlement resolves claims under the FCA, the Anti-Kickback Act, and the Procurement Integrity Act. The share of the whistleblower who originally filed the action was not disclosed at the time of the settlement announcement.[38]
- On June 30, a government contractor agreed to pay $4.3 million to settle allegations that three of its former executives accepted kickbacks from a subcontractor in exchange for awarding subcontracts for government contracts. A former executive allegedly instructed a subcontractor to mark up the cost of the subcontractor's services provided to the contractor, and instructed the subcontractor to divide the proceeds between the subcontractor, the former executive, and two other former executives in exchange for awarding the subcontracts to the subcontractor.[39]

II. POLICY AND LEGISLATIVE DEVELOPMENTS

A. COVID-19-RELATED DEVELOPMENTS

During the first half of 2021, DOJ has maintained its focus on COVID-19-related fraud. In a February 17, 2021 speech at the Federal Bar Association *Qui Tam* Conference, Acting Assistant Attorney General Brian M. Boynton outlined the Civil Division's key enforcement priorities and placed pandemic-related fraud at the top of the list.[40] Acting AAG Boynton described ongoing efforts by DOJ and its agency partners to "identify, monitor, and

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investigate the misuse of critical pandemic relief monies," and also expressed confidence that DOJ's devotion of resources to this effort will be worthwhile: "The vast majority of the funds distributed under [pandemic relief] programs have gone to eligible recipients. Unfortunately, however, some individuals an1 businesses applied for—and received—payments to which they were not entitled."[42]

In his remarks, Acting AAG Boynton highlighted DOJ's first civil settlement under the PPP.[42] The settlement was small (only $100,000), but marked the first such settlement related to COVID PPP funds and resolved claims a company had violated the FCA and the Financial Institutions Reform, Recovery and Enforcement Act (FIRREA) based on allegations the company "made false statements to federally insured banks that [it] was not in bankruptcy in order to influence those banks to approve, and the Small Business Administration (SBA) to guarantee" a PPP loan.[43] And while the PPP-related settlement did not involve a *qui tam* relator, in March, DOJ confirmed what many in the defense bar have long known or suspected—namely that "whistleblower complaints have been on the rise" during the COVID-19 pandemic.[44]

The other priorities Acting AAG Boynton outlined in his February speech also reveal that DOJ views pandemic-related fraud as extending beyond relief programs implemented during the pandemic. For example, in discussing DOJ's continued focus on the opioid crisis, Acting AAG Boynton characterized the crisis as "not new, but . . . exacerbated by the pandemic."[45] Similarly, he attributed DOJ's "continued focus on telehealth schemes" in part to "the expansion of telehealth during the pandemic."[46] These remarks make clear that DOJ has not lost sight of pre-pandemic enforcement priorities, in addition to focusing on fraud tied to government programs that are themselves creatures of the pandemic.

B. CONTENDING WITH THE LEGACY OF THE GRANSTON MEMO

Under the Trump administration, DOJ took prominent steps to assert DOJ's control of FCA lawsuits. Specifically, on January 10, 2018, Michael Granston, the then-Director of the Fraud Section of DOJ's Civil Division, issued a memorandum directing government lawyers evaluating a recommendation to decline intervention in a *qui tam* FCA action to "consider whether the government's interests are served . . . by seeking dismissal pursuant to 31 U.S.C. § 3730(c)(2)(A)."[47] That policy was then formally incorporated into the Justice Manual. After that, DOJ became noticeably more willing to seek dismissal of certain FCA cases.

Thus far in 2021, the Biden Administration has not signaled whether it plans to scale back DOJ's efforts to dismiss certain *qui tam* suits. Nor has the Administration disavowed the principles outlined in the Granston Memo or Justice Manual. However, statements by DOJ officials in the last six months suggest that DOJ may be adapting its approach to *qui tam* enforcement by enhancing the government's own ability to identify and pursue FCA violations without prompting from relators. In his February speech, Acting AAG Boynton stated explicitly that observers can "expect the Civil Division to continue to expand its own efforts to identify potential fraudsters, including its reliance on various types of data analysis."[48] He went on to discuss "sophisticated analyses of Medicare data" by DOJ "to uncover potential fraud schemes that have not been identified by whistleblower suits, as well as to help analyze and support the allegations that we do receive from such suits."[49]

While the Biden Administration DOJ explores its options, there has been continued criticism by Senator Chuck Grassley (R-IA) of DOJ's use of its dismissal authority under the FCA. A week after Acting AAG Boynton's remarks, Senator Grassley wrote to then-Attorney General Nominee Merrick Garland that "it is up to the courts, through a hearing, to determine whether or not a [*qui tam*] case lacks merit."[50] According to Senator Grassley, "[t]he Justice Department is not, and cannot be, the judge, jury, and executioner of a relator's claim."[51] Senator Grassley asserted that he is "working with a cadre of

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bipartisan Senate colleagues to draft legislation that will further strengthen and improve the False Claims Act."[52]

While the degree of DOJ involvement in this legislative effort—and the extent to which it addresses DOJ's dismissal authority—remains to be seen, the balance between DOJ-pursued FCA cases and relator-driven matters may shift. On one level, increased leveraging of data analytics could result in less reliance on relators overall, and therefore fewer situations in which DOJ attempts to exercise its dismissal authority and risks making bad law. On another, an increase in the volume and sophistication of DOJ's data analyses of cases that *do* involve relators could better position DOJ to make merits-based arguments in favor of dismissal in the event that judicial scrutiny of those decisions ratchets up.

C. A PIVOT AWAY FROM THE BRAND MEMO?

In January 2018, then-Associate Attorney General (the third-ranking position at DOJ) Rachel Brand issued a memorandum titled "Limiting Use of Agency Guidance Documents In Affirmative Civil Enforcement Cases."[53] The so-called "Brand Memo" expressly asserted that "[g]uidance documents" issued without notice-and-comment rulemaking "cannot create binding requirements that do not already exist by statute or regulation."[54] Therefore, the Brand Memo stated that DOJ "may not use compliance with guidance documents as a basis for proving violations of applicable law in [affirmative civil enforcement] cases."[55] The Brand Memo also explained that DOJ "should not treat a party's noncompliance with an agency guidance document as presumptively or conclusively establishing that the party violated the applicable statute or regulation."[56] Despite its brevity—under two pages—the Brand Memo represented a substantial policy change for civil enforcement, especially for the FCA. In December 2018, DOJ issued new section 1-20.000 of the Justice Manual, "Limitation on Use of Guidance Documents in Litigation," which incorporated the Brand Memo and explained that, with some important caveats—such as the use of "awareness of [a] guidance document" as evidence of scienter—DOJ "should not treat a party's noncompliance with a guidance document as itself a violation of applicable statutes or regulations."[57]

Under the Biden Administration, DOJ may marginalize the Brand Memo. On the day he was inaugurated, President Biden issued an executive order that signaled an expected shift from the Trump Administration's skepticism of agencies toward greater deference to agency expertise and guidance. Executive Order 13992 revoked six Trump executive orders relating to agency regulation.[58] This included revoking Trump's Executive Order 13891 ("Promoting the Rule of Law Through Improved Agency Guidance Documents"), which required that "agencies treat guidance documents as non-binding both in law and in practice, except as incorporated into a contract" and stated as a matter of executive policy that "[a]gencies may impose legally binding requirements on the public only through regulations and on parties on a case-by-case basis through adjudications."[59]

President Biden's order noted that "executive departments and agencies . . . must be equipped with *the flexibility to use robust regulatory action* to address national priorities," which include addressing the "coronavirus disease 2019 (COVID-19) pandemic, economic recovery, racial justice, and climate change" (emphasis added).[60] Although Executive Order 13992 does not expressly refer to DOJ's civil enforcement or the FCA, the Order may foster a climate in which DOJ is more willing to use sub-regulatory guidance as the basis for FCA allegations. Such a change would both allow for broader FCA enforcement and signal support for the expertise of agencies in promulgating external-facing guidance. Likewise, as companies continue to adapt to DOJ's efforts to root out fraud in government programs, a renewed focus on agency guidance could change the risk calculus built into corporate compliance programs and internal investigation efforts.

D. STATE LEGISLATIVE DEVELOPMENTS

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The federal government provides incentives for states to conform their false claims statutes to the federal FCA. In particular, HHS-OIG grants "a 10-percentage-point increase" in a state's share of any recoveries under the relevant laws to any state that obtains HHS-OIG approval for its false claims statute.[61] Such approval requires that the statute in question, among other requirements, "contain provisions that are at least as effective in rewarding and facilitating qui tam actions for false or fraudulent claims as those described in the [federal] FCA."[62] The statute is also required to contain a 60-day sealing provision and "a civil penalty that is not less than the amount of the civil penalty authorized under the [federal] FCA."[63] The total number of states with approved statutes is now twenty-two, with Minnesota having obtained approval on May 27, 2021.[64] That leaves seven states—Florida, Louisiana, Michigan, New Hampshire, New Jersey, New Mexico, and Wisconsin—with false claims statutes listed by HHS-OIG as "not approved."[65]

There have been several other notable developments in state-level false claims legislation in the first half of this year.

- In **Montana**, the legislature passed a law in April that changes the order of priority according to which damages and penalties not paid to *qui tam* relators are to be disbursed to affected government entities.[66] The statute previously provided that the affected government entity's general fund would receive the balance of such monies; under the new law, the monies "must be distributed first to fully reimburse any losses suffered by the governmental entity as a result of the defendant's actions," with the remainder then going to the entity's general fund.[67]
- In **Arkansas**, which has a false claims statute specific to its Medicaid program, the General Assembly recently approved a bill granting the state's Attorney General the ability to intervene in cases brought in federal court under the federal FCA that implicate Arkansas Medicaid funds.[68]
- In **California**, the legislature introduced a bill that would (among other things) levy a 1% annual "wealth tax" on any resident with a net worth of over $50 million (or $25 million in the case of a married taxpayer who files a separate return).[69] The bill contains a provision subjecting false claims and records concerning the wealth tax to liability under California's false claims statute.[70]

III. CASE LAW DEVELOPMENTS

The first half of 2021 saw a number of notable federal appellate court decisions, which we have summarized below.

A. D.C. CIRCUIT EXPLORES CAUSATION IN FCA CASES PREMISED ON "FRAUDULENT INDUCEMENT" THEORY

In *United States ex rel. Cimino v. International Business Machines Corp.*, the D.C. Circuit issued an important opinion exploring the contours of the "fraudulent inducement" theory of FCA liability, under which an initial fraud during procurement of a contract allegedly results in liability for all claims submitted to the federal government under that contract. No. 19-7139, 2021 WL 2799946 (D.C. Cir. July 6, 2021). In its decision, the D.C. Circuit imposed important limits on the fraudulent inducement theory by requiring a relator to plead (and ultimately prove) but-for causation.

The *Cimino* case involved allegations that IBM had "violated the FCA by (1) using a false audit to fraudulently induce the IRS to enter into a $265 million license agreement for software the IRS did not want or need, and (2) presenting false claims for payment for software that the IRS never received." *Id.* at *1. In evaluating what it deemed an issue of first impression, the D.C. Circuit undertook an in-depth review of fraudulent inducement cases under the FCA, and the Supreme Court's most recent opinions in FCA cases, to conclude that "a successful claim for fraudulent inducement requires demonstrating that a defendant's fraud caused the government to enter a contract that later results in a request

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for payment." *Id.* at *4. The court explained that the critical question for "liability under the FCA for fraudulent inducement must turn on whether the fraud caused the government to contract." *Id.* Turning to what standard of causation applied, the court rejected a lesser standard urged by the Relator and instead held that the FCA requires the relator or government "to allege actual cause under the but-for test," which required the relator in *Cimino* to "provide sufficient facts for the court to draw a reasonable inference that IBM's false audit *caused* the IRS to enter the license agreement." *Id.* at *6 (emphasis added). Notably, the court also rejected relator's argument that causation was encompassed within the FCA's materiality requirement, and did not need to be pled separately. The court instead recognized that "a plaintiff must plead both causation and materiality," *id.* at *7, and that those are "separate elements that we cannot conflate," *id.* at *5.

Applying these standards, the D.C. Circuit concluded that the Relator had met his pleading burden in this particular case. But by setting forth this rigorous analysis of the causation and materiality requirements under the FCA in fraudulent inducement cases, the court also charted a course for defendants facing liability under similar circumstances. Where a relator does not plead that a defendants conduct *actually caused* the government to enter into the underlying contract, a fraudulent inducement theory should not be able to move forward.

Turning to relator's second theory, the court did dismiss certain claims under Federal Rule of Civil Procedure 9(b) (which requires pleading fraud claims with particularity). Applying a strict form of Rule 9(b), the court concluded that the relator failed to plead certain claims with sufficient particularity because he did not plead "when the false claims were presented and who presented those claims." *Id.* at *9.

Finally, in a concurrence, Circuit Judge Rao went a step further and questioned whether fraudulent inducement is even a valid theory under the FCA. Applying a textualist framework, he argued that "[t]he text of the FCA does not readily suggest liability for fraudulent inducement as a separate cause of action." *Id.* at *9 (Rao, J., concurring). The concurrence explained that courts across the country have long accepted fraudulent inducement theories based largely on an eighty-year-old Supreme Court FCA decision in *United States ex rel. Marcus v. Hess*, 317 U.S. 537 (1943), *superseded by statute on other grounds*, Act of Dec. 23, 1943, ch. 377, 57 Stat. 608, 609. *See Cimino*, 2021 WL 2799946, at *10. But Judge Rao said that decision is "hardly a model of clarity regarding the existence of a fraudulent inducement cause of action," and suggested that a "reconsideration of a fraudulent inducement cause of action may be warranted because it exists in some tension with recent Supreme Court decisions" that emphasize the text of the statute over its purpose. *Id.* at *11. We will be watching carefully to see if other courts take up this project of reconsideration.

B. ELEVENTH CIRCUIT DECIDES THAT *QUI TAM* CHALLENGE MIGHT SURVIVE SUMMARY JUDGMENT DESPITE GOVERNMENT'S CONTINUED PAYMENT

In *Universal Health Services v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016), the Supreme Court directed the district courts to scrutinize whether plaintiffs have alleged facts sufficient to satisfy the "rigorous" and "demanding" materiality standard the FCA imposes. The Supreme Court also emphasized that the government's decision to continue paying claims, despite knowledge of an alleged deficiency with those claims, is "very strong evidence" that those issues are not material for purposes of the FCA. Since then, the federal courts have grappled with the impact of these instructions.

Earlier this year, the Eleventh Circuit addressed this issue in *United States ex. rel. Bibby v. Mortgage Investors Corp.,* 987 F.3d 1340 (11th Cir. 2021), *cert. denied sub nom. Mortg. Invs. Corp. v. United States ex rel. Bibby*, No. 20-1463, 2021 WL 1951877, at *1 (U.S. May 17, 2021). In *Bibby*, the relators alleged that lenders were charging fees prohibited by

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the U.S. Department of Veterans Affairs ("VA") regulations (attorneys' fees) while certifying that they charged only permissible fees (title examination and insurance fees) by bundling them together. *Id.* at 1343-45. The district court granted summary judgment for the lender defendants on materiality grounds in light of the fact that the government continued to pay the claims after being on notice of the alleged issue. *See id.* at 1346

The Eleventh Circuit reversed, holding that genuine issues of material fact precluded summary judgment. *Id.* There was no dispute that the VA was aware of the lenders' noncompliance with fee requirements, so the issue of material fact was how the VA reacted to the knowledge that the lenders were charging prohibited fees. *Id.* at 1349-50. The court acknowledged that the government's payment decision is typically relevant to the materiality inquiry, but asserted that the relevance of that fact "var[ies] depending on the circumstances." *Id.* at 1350. In this case, the Eleventh Circuit found it significant that "[o]nce the VA issues guaranties, it is required by law to honor those guaranties" and pay holders in due course, "regardless of any fraud by the original lender." *Id.*

Having decided to "divorce [its] analysis from a strict focus on the government's payment decision," the court "s[aw] no reason to limit [its] view only to the VA's issuance of guaranties." *Id.* at 1351. Instead, the court reviewed "the VA's behavior holistically" and found evidence of materiality in a VA circular sent to lenders reminding them of the applicable fee regulations, as well as the VA's implementation of "more frequent and more rigorous audits." *Id.* Although the VA neither revoked payment on guaranties of loans with purportedly fraudulent fees nor prohibited those lenders from participating in the program, the court determined that those facts did not answer the materiality question on their own. *See id.* at 1352. In ultimately concluding that the question of materiality in this case was one for the fact finder, the panel again emphasized that "the materiality test is holistic, with no single element—including the government's knowledge and its enforcement action—being dispositive." *Id.*

The Supreme Court denied the petition for writ of certiorari on May 17, 2021. *Bibby*, 2021 WL 1951877, at *1. The Eleventh Circuit court's decision in *Bibby* stands as an indicator that the meaning of *Escobar* continues to evolve.

C. NINTH AND ELEVENTH CIRCUITS LIMIT USE OF STATISTICAL EVIDENCE AS SUFFICIENT TO MEET BOTH PLAUSIBILITY AND PARTICULARITY REQUIREMENTS OF FCA PLEADINGS

Courts have continued to clarify pleading requirements for FCA claims under Federal Rules of Civil Procedure 8(a) and 9(b).

In *Integra Med Analytics LLC v. Providence Health & Services*, No. 19-56367, 2021 WL 1233378, at *1 (9th Cir. Mar. 31, 2021), a Ninth Circuit panel held that Integra's statistical analysis of publicly available data—allegedly demonstrating that Providence Health submitted Medicare claims "with higher-paying diagnosis codes" than other comparable institutions—was not enough to plead falsity when Integra had failed to rule out an "obvious alternative explanation" and therefore failed to meet the Rule 8(a) requirement for pleading a plausible claim for relief. *Id.* at *1, *3 (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557 (2007)).

The court noted that Integra, in its pleading, had not ruled out an alternative explanation for why Providence Health's claim submissions included more Medicare reimbursement codes—in this case, major complication or comorbidity ("MCC") codes—than other institutions: namely that Providence, with the assistance of third-party billing consultant JATA aimed at improving its Medicare billing practices, was "at the forefront of a national trend toward coding these relevant MCCs at a higher rate." *Id*. at *4. Absent any insider information alleging otherwise, the court found that Integra offered only a "*possible* explanation" for the results of its statistical analysis (*i.e.*, that Providence was directing its doctors to falsify claims) and ignored that the statistical analysis could also support a

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"plausible alternative (and legal) explanation." *Id*. (emphasis in original). Thus, the court stated "[w]e need not accept the conclusion that the defendant engaged in unlawful conduct when its actions are in line with lawful 'rational and competitive business strategy.'" *Id.* (citation omitted).

Although the Ninth Circuit's decision should reduce the weight courts are willing to attribute to the findings of statistical analyses at the pleading stage FCA cases, the court expressly noted in a footnote that its decision was not "categorically preclud[ing]" the use of statistical data to meet the FRCP 8(a) and 9(b) pleading requirements. *Id.* at *4 n.5.

Similarly, in *Estate of Helmly v. Bethany Hospice and Palliative Care of Coastal Georgia, LLC*, the Eleventh Circuit upheld the dismissal with prejudice of a *qui tam* suit brought by two former employees against Bethany Hospice, reasoning that allegations based on numerical probability are mere inferences that do not suffice to plead fraud with particularity under Rule 9(b). No. 20-11624, 2021 WL 1609823, at *6 (11th Cir. Apr. 26, 2021).

In *Helmly*, the relators alleged that the defendant hospice violated the FCA by submitting false claims when it billed the government for services provided to patients obtained through a kickback scheme. *Id.* at *1. They argued that because a significant number of Medicare recipients were referred to the hospice, and because "all or nearly all" of the patients at the hospice received coverage from Medicare, it was mathematically plausible that the hospice had submitted to the government claims for patients obtained under kickback agreements. *Id.* at *4-6.

The Eleventh Circuit rejected this argument as the basis for an FCA claim, holding that relators failed to plead the submission of an actual false claim. *Id.* at *6. In order to meet Rule 9(b)'s particularity requirement, a complaint "must allege actual submission of a false claim" and must do so with "some indicia of reliability." *Id.*, at *5 (citing *Carrel v. AIDS Healthcare Found., Inc.*, 898 F.3d 1267, 1275 (11th Cir. 2018)) (internal quotation marks omitted). The *Helmly* court held that "numerical probability is not an indicium of reliability" sufficient to "meet Rule 9(b)'s particularity requirement." *Id.* at *6. "[R]elators cannot 'rely on mathematical probability to conclude that [a defendant] surely must have submitted a false claim at some point.'" *Id.* (quoting *Carrel*, 898 F.3d at 1277) (second alteration in original).

These decisions demonstrate that the pleading stage of an FCA claim requires greater specificity than many relators have typically supplied. Regardless of what the alleged core FCA claim may entail, courts are likely to require plaintiffs to clearly connect the dots and provide more concrete evidence of falsity to survive a motion to dismiss.

D. NINTH CIRCUIT AFFIRMS THE "FRAUD-ON-THE-FDA" THEORY

This past spring, the Ninth Circuit reaffirmed that "fraud-on-the-FDA" theories may state a valid FCA claim sufficient to survive a motion to dismiss in certain circumstances. *United States ex rel. Dan Abrams Co. LLC v. Medtronic Inc.*, 850 Fed. App'x 508 (9th Cir. 2021). In *Medtronic*, the relator alleged, among other claims, that the defendant fraudulently obtained FDA 510(k) clearance for several devices used in spinal fusion surgeries. *Id.* at 510. According to the relator, some of these devices could only be used for a contraindicated use, and could not be used as indicated in defendant's 510(k) submissions at all (the "Contraindicated-only Devices"). *Id.* As such, the relator alleged that these devices were not properly approved or cleared by the FDA and thus would have been ineligible for reimbursement under Medicare but for the defendant's alleged fraud. *Id.* The district court dismissed these fraud-on-the-FDA allegations for failure to state a claim because the allegations were offered "solely as a predicate for the claim that the [devices] were intended for off-label use" and "the federal government allows reimbursement for off-label and even contraindicated uses." *Id.* at 511.

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The Ninth Circuit affirmed most of the district court's dismissal of relators' claims, but reversed the district court's holding as to the Contraindicated-only Devices, holding that the FCA may serve as a vehicle to bring a fraud-on-the-FDA claim here. Citing *United States ex rel. Campie v. Gilead Sciences, Inc.*, 862 F.3d 890, 899 (9th Cir. 2017), the court concluded that for the Contraindicated-only Devices, the relator did not merely allege off-label use; rather, the relator alleged that the devices were not properly cleared for *any* use by the FDA. Because the Contraindicated-only Devices could "*only* be used for their contraindicated use," and disclosures about that intended use are "precisely those that the FDA considers in granting Class II certification," the court held that Medtronic's alleged fraud went "to the very essence of the bargain" and therefore could proceed as a fraud-on-the-FDA claim. *Medtronic*, 850 Fed. App'x at 511. Although the Ninth Circuit recognized that other jurisdictions had previously "cautioned against allowing claims under the [FCA] to wade into the FDA's regulatory regime[,]" citing *Campie*, 862 F.3d. at 905, Ninth Circuit precedent allowed a relator's fraud-on-the-FDA theory to move forward. *Id.*

Relator's other claims—such as the allegation that the defendant promoted off-label and contraindicated uses of certain devices—were dismissed because the devices included those that *could* be used for their stated intended use but were contraindicated for use elsewhere. *Id.* *3. The panel affirmed dismissal of the relator's claim that defendant violated the AKS by entering into improper rebate agreements with hospitals and offering kickbacks to physicians for certain business development events. *Id.* at *511–12. The Ninth Circuit stated that the AKS does not include discounts offered to providers if they are properly disclosed and reflected in charges to the federal program. Moreover, the relator failed to explain how defendant's rebate agreement violated the statute or to state sufficiently specific allegations related to physician kickbacks. *Id.*

E. FOURTH CIRCUIT AFFIRMS THE BROAD REACH OF THE AKS AS A BASIS FOR FCA LIABILITY

The Fourth Circuit's ruling earlier this year in *United States v. Mallory*, 988 F.3d 730 (4th Cir. 2021), serves as a reminder of the risk of compensating independent contractors for marketing activities in light of HHS-OIG guidance on whether such compensation falls within an AKS safe harbor. In *Mallory*, a laboratory that provided blood testing for cardiovascular disease and diabetes contracted with a consulting company to market and sell the blood tests. The consulting company received a base payment and a percentage of revenue based on the number of blood tests ordered. Based on the evidence presented at trial, the jury found that the laboratory's revenue-based commission payments to its sales agents constituted improper remuneration that was intended to induce the sales agents to sell as many laboratory tests as possible. *See United States ex rel. Lutz v. BlueWave Healthcare Consultants, Inc.*, No. 9:11-CV-1593-RMG, 2018 WL 11282049, at *1 (D.S.C. May 23, 2018), *aff'd sub nom*. *United States v. Mallory*, 988 F.3d 730 (4th Cir. 2021).

Defendants argued on appeal that the government failed to prove that the defendants "knowingly and willfully" violated the AKS and that, accordingly, the defendants could not have "knowingly" violated the FCA. *Mallory*, 988 F.3d at 736. The Fourth Circuit found those arguments unconvincing given that, in the course of attempting to assert an advice-of-counsel defense, the defendants were unable to "identify any specific legal opinion" that could support a "good-faith belief that their conduct . . . did not violate the Anti-Kickback Statute." *Id.* at 739. To the contrary, the Government offered evidence that several attorneys had expressed concerns to the defendants regarding possible AKS violations in the arrangements. *Id*. at 736–37.

The defendants also argued on appeal that commissions to independent contractor salespeople do not constitute kickbacks under the AKS. Although the court noted that the AKS does contain a safe harbor for bona fide employment relationships, it explained that HHS-OIG "has expressly recognized that this safe harbor does not cover independent contractors." *Id.* at 738. The court discussed the history of the statutory safe harbor for

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commissions paid to salespeople who are "employee[s]" that have a "bona fide employment relationship" with their employer, 42 U.S.C. § 1320a-7b(b)(3)(B), and HHS's reasoning that if employers "desire to pay [ ] salesperson[s] on the basis of the amount of business they generate," they "should make these salespersons employees" to avoid "civil or criminal prosecution." 54 Fed. Reg. 3088, 3093 (Jan. 23, 1989). Because the amount of compensation in *Mallory* varied with the volume of the referrals, the court found that it fit squarely outside the bounds of the salesperson commission safe harbor. *Mallory*, 988 F.3d at 738.

The Fourth Circuit affirmed the jury's findings and assessment of actual damages totaling more than $16 million for violations of FCA. *Id.* at 742; *Lutz*, 2018 WL 11282049, at *2–3. The court also affirmed the district court's judgment, which totaled more than $100 million after the district court trebled the actual damages and added civil monetary penalties as required by the FCA. *Lutz*, 2018 WL 11282049, at *8.

F. SUPREME COURT DECLINES TO REVIEW SEVERAL IMPORTANT ISSUES UNDER THE FCA

1. SUPREME COURT REJECTS OPPORTUNITY TO REVIEW A SEVENTH CIRCUIT DECISION UPHOLDING DOJ AUTHORITY TO DISMISS CASES OVER OBJECTION OF RELATORS

In the final week of June, the Supreme Court denied a petition to review a Seventh Circuit decision regarding the proper standard to evaluate a government motion to dismiss a relator's claim. *See Cimznhca, LLC v. United States*, No. 20-1138, 2021 WL 2637991 (U.S. June 28, 2021). Cimznhca's appeal argued that the Seventh Circuit improperly expanded its jurisdiction by treating the government's motion to dismiss also as a motion to intervene for purposes of dismissal, even though the government never sought to intervene.

As explained in Gibson Dunn's 2020 Year-End Update and discussed above, DOJ has more regularly invoked its dismissal authority under 31 U.S.C. § 3730(c)(2)(A) since the Granston Memo was issued. In evaluating DOJ's requests to dismiss, courts historically have split based on whether they followed the Ninth Circuit's *Sequoia Orange* test or the D.C. Circuit's *Swift* test in deciding whether the government may dismiss a *qui tam* case. Under the *Sequoia Orange* approach, the government may dismiss a *qui tam* case if: (1) it identifies a valid government purpose; (2) a rational relation exists between the dismissal and the accomplishment of that purpose; and (3) dismissal is not fraudulent, arbitrary and capricious, or illegal. *United States ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp.*, 151 F.3d 1139, 1145 (9th Cir. 1998). The *Swift* test, by contrast, affords the government an "unfettered" right to dismiss a case such that the decision is "unreviewable" except in instances of "fraud on the court." *Swift v. United States*, 318 F.3d 250, 252-53 (D.C. Cir. 2003). Both standards generally favor the government's discretion, albeit to different degrees, and DOJ regularly argues in its motions to dismiss that it has sufficient discretion to dismiss a case under either standard.

In *Cimznhca*, the Seventh Circuit called the choice between the *Sequoia Orange* and *Swift* standards "a false one, based on a misunderstanding of the government's rights and obligations under the False Claims Act." *United States v. UCB, Inc.*, 970 F.3d 835, 839 (7th Cir. 2020). Although it recognized the value of a *Sequoia Orange*-type standard focused on the outer constitutional limits on the exercise of the government's prosecutorial discretion, the court stated that it believes the limit lies closer to the more-deferential *Swift* standard.

When moving for dismissal in the district court, the government argued that the allegations

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"lack[ed] sufficient merit to justify the cost of investigation and prosecution and [were] otherwise . . . contrary to the public interest." *Id.* at 840. In reversing the district court's denial of the government's motion, the Seventh Circuit viewed the government's motion as a motion to intervene and dismiss and held that Federal Rule of Civil Procedure 41 (which governs voluntary dismissal by plaintiffs generally) supplied "the beginning and end of [the court's] analysis." *Id.* at 849. Turning to the *Sequoia Orange* and *Swift* standards, the court held that *Sequoia Orange* simply means that dismissal "may not violate the substantive component of the Due Process Clause," *id.* at 851, which the court characterized as a "bare rationality standard" targeting "only the most egregious official conduct" that "shocks the conscience" or "offend[s] even hardened sensibilities," *id.* at 852 (internal quotation marks omitted) (alteration in original). The court rejected the idea that the relatively formal nature of Section 3730(c)(2)(A) hearings "justif[ies] imposing on the government in each case the burden of satisfying *Sequoia Orange*'s 'two-step test' before the burden is put back on the relator to show unlawful executive conduct." *Id.* at 853.

By declining to review the *Cimznhca* appeal, the Supreme Court left unresolved a growing circuit split over DOJ dismissals of whistleblower lawsuits. Accordingly, we may see other circuits apply either *Sequoia Orange* or *Swift*—or take the Seventh Circuit's position in *Cimznhca* that the standard lies somewhere between the two and should primarily be informed by Federal Rule of Civil Procedure 41.

2. SUPREME COURT DECLINES TO RESOLVE DEBATE OVER "OBJECTIVELY FALSE"

In February, the United States Supreme Court also declined to resolve a prominent split between federal courts of appeal regarding the FCA's falsity standard. In denying petitions for writs of certiorari in *Care Alternatives v. United States*, — S. Ct. —, 2021 WL 666386 (Feb. 22, 2021), and *RollinsNelson LTC Corp. v. U.S. ex rel. Winters*, — S. Ct. —, 2021 WL 666435 (Feb. 22, 2021), the Court left unresolved whether FCA liability must be predicated on a claim that is objectively false based on verifiable facts, or whether a post hoc expert opinion can suffice to establish falsity (at least at the pleading stage). As we have written about here, this objective falsity issue joins a host of other FCA-related questions as to which the federal courts have been unable to provide uniform answers.

IV. CONCLUSION

We will monitor these developments, along with other FCA legislative activity, settlements, and jurisprudence throughout the year and report back in our 2021 False Claims Act Year-End Update, which we will publish in January 2022.

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[1] *See* Press Release, U.S. Atty's Office for the Western Dist. of WI, AutoGenomics, Inc. Agrees to Pay Over $2.5 Million for Allegedly Paying Kickbacks (Jan. 11, 2021), https://www.justice.gov/usao-wdwi/pr/autogenomics-inc-agrees-pay-over-25-million-allegedly-paying-kickbacks.

[2] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Florida Businesswoman Pleads Guilty to Criminal Health Care and Tax Fraud Charges and Agrees to $20.3 Million Civil False Claims Act Settlement (Feb. 4, 2021), https://www.justice.gov/opa/pr/florida-businesswoman-pleads-guilty-criminal-health-care-and-tax-fraud-charges-and-agrees-203.

[3] *See* Press Release, U.S. Atty's Office for the Eastern Dist. of PA, Lancaster County Pharmacy and Pharmacist Agree to Resolve Civil Allegations of Dispensing Controlled Substances Without a Prescription and Falsely Billing Medicare for $2.9 Million

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(Feb. 25, 2021), https://www.justice.gov/usao-edpa/pr/lancaster-county-pharmacy-and-pharmacist-agree-resolve-civil-allegations-dispensing.

[4] *See* Press Release, U.S. Atty's Office for the Middle Dist. of NC, Bioventus Agrees to Pay More Than $3.6 Million to Resolve False Claims Act Violations (Feb. 25, 2021), https://www.justice.gov/usao-mdnc/pr/bioventus-agrees-pay-more-36-million-resolve-false-claims-act-violations.

[5] *See* Press Release, U.S. Atty's Office for the Eastern Dist. of N.C., North Carolina Durable Medical Equipment Corporation Sentenced for $10 Million Healthcare Fraud Scheme, and the Company and Its Owner Agree to Pay Millions to Resolve Related Civil Claims (Mar. 2, 2021), https://www.justice.gov/usao-ednc/pr/north-carolina-durable-medical-equipment-corporation-sentenced-10-million-healthcare.

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