GIBSON DUNN

2020 Year-End False Claims Act Update

Client Alert | January 27, 2021

Looking back on the incredible year that was 2020, some observers of the False Claims Act ("FCA") enforcement space may note that the year's FCA recoveries were the lowest they have been in twelve years, but the most important takeaway for those who deal in government funds is this: the government opened the most new FCA investigations ever in 2020. Despite the global pandemic, closed courts, and the realities of remote work (including remote investigations and litigation), the government and *qui tam* relators still opened 922 new FCA cases last year. This is the largest single-year total ever by a substantial margin and brings the total number of new FCA cases opened in the last 5 years to more than 4,100.

If the government's enforcement activity around past economic crises and resulting government stimulus programs is any indication, the stage is set for FCA cases to surge further still in the next few years. Last year, the government enacted legislative stimulus packages totaling nearly $4 trillion in COVID-relief funds, and anytime the government spends money, FCA cases follow. A huge portion of that spending, moreover, has been in health care and health care-adjacent fields, areas which have accounted for more than 80% of all FCA recoveries over the last four years. Further, the Department of Justice ("DOJ") swiftly prioritized rooting out COVID-related fraud in 2020—a focus that we expect to continue and likely intensify under the Biden administration. As the incoming administration's enforcement priorities solidify, we also will monitor any efforts to change course from steps previously taken by the Trump administration toward reining in FCA enforcement through various policy changes, such as the Brand Memorandum's prohibition of DOJ enforcement actions predicated on violations of non-binding agency guidance.[1]

Meanwhile, 2020 saw no major legislative developments relating to the FCA at the federal level. But states continue to enact or amend false claims statutes that enable states to receive a higher percentage share of recoveries and expand potential liability. On the judicial front, courts issued a number of significant decisions in 2020, including important decisions exploring the FCA's materiality and scienter requirements, and several decisions regarding DOJ's discretion to dismiss *qui tam* cases where the government has not intervened.

As always, Gibson Dunn's recent publications on the FCA may be found on our website, including industry-specific articles, webcasts, 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. FCA ENFORCEMENT ACTIVITY

A. New FCA Activity

The government and *qui tam* relators filed ***more FCA cases in 2020 (922) than in any other year since Congress enacted the FCA during the Civil War***.[2] Although that figure is staggering in and of itself, equally surprising is ***who*** drove the increase in cases.[3]

During the last five years, there has been an average of approximately 800 new FCA

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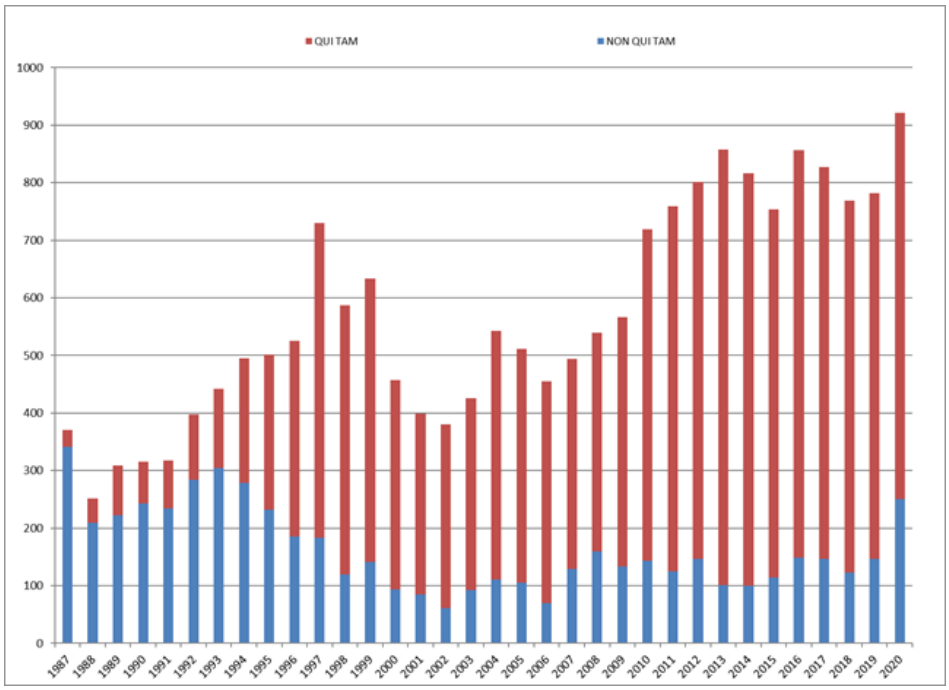
cases a year, with *qui tam* relators filing approximately 660 cases on average and the government filing approximately 135 cases on average. But in 2020, the ***federal government*** was the impetus behind the increase to more than 900 new cases. These non-*qui tam* cases may arise from a variety of sources, including referrals from government agencies based on their program oversight activities or from mining government spending data for leads. With 250 cases last year, federal enforcement attorneys filed 120 more cases than in an average year, a mark last seen in 1994 when the modern *qui tam* provisions were still relatively new. As discussed below in the following section, cases where the government is involved—either because the government brought the case, or later intervened—typically account for 90% of all FCA cases with a recovery. The fact that the government brought so many new cases in 2020 suggests that recoveries in years to come will be robust.

Some of the government's new cases stem from COVID relief efforts and a desire to police fraud in the government's massive spending programs during the last year. But it does not appear that COVID-related cases account for the entirety of the nearly 100% increase in cases by the government. As more details are released about those cases, we will be watching carefully to identify where the government's actions are focused.

Number of FCA New Matters, Including Qui Tam Actions



Source: DOJ "Fraud Statistics – Overview" (Jan. 14, 2021)

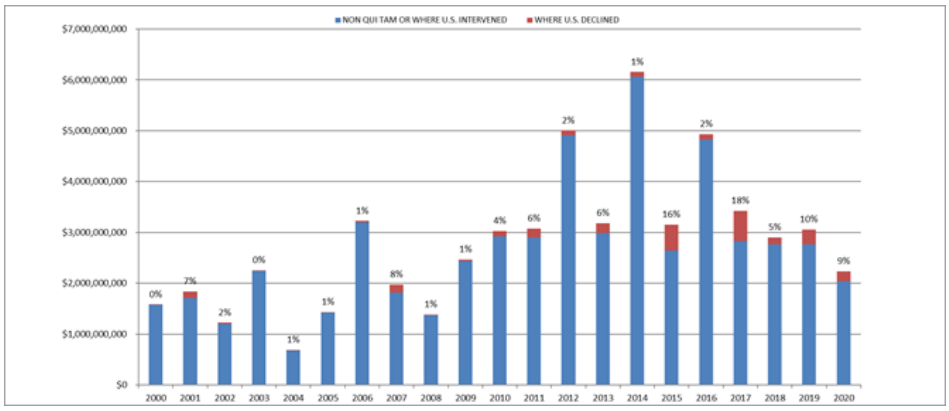
B. Total Recovery Amounts: 2020 Recoveries Exceed $2 Billion

The federal government also recovered more than $2.2 billion during fiscal year 2020, which ended September 30, 2020. Of this amount, more than 90% was recovered in intervened cases, underscoring that companies face more significant exposure in cases in which the government initiated the case or intervened.

The total of $2.2 billion is down from recent years, as shown in the chart below. Given the continued high number of new investigations being opened, this is likely a reflection of

disruptions caused by the COVID-19 pandemic. Although COVID never resulted in a total work stoppage, investigations were delayed as were court proceedings in the middle of 2020. As noted, however, the overall pace of FCA litigation has not slowed whatsoever, and the pipeline of new cases is as full as ever. Significant settlements entered into after the close of fiscal year 2020, such as the $2.8 billion settlement entered into with an opioid manufacturer discussed below, are likewise poised to boost next fiscal year's figures drastically.

Settlements or Judgments in Cases Where the Government Declined Intervention as a Percentage of Total FCA Recoveries



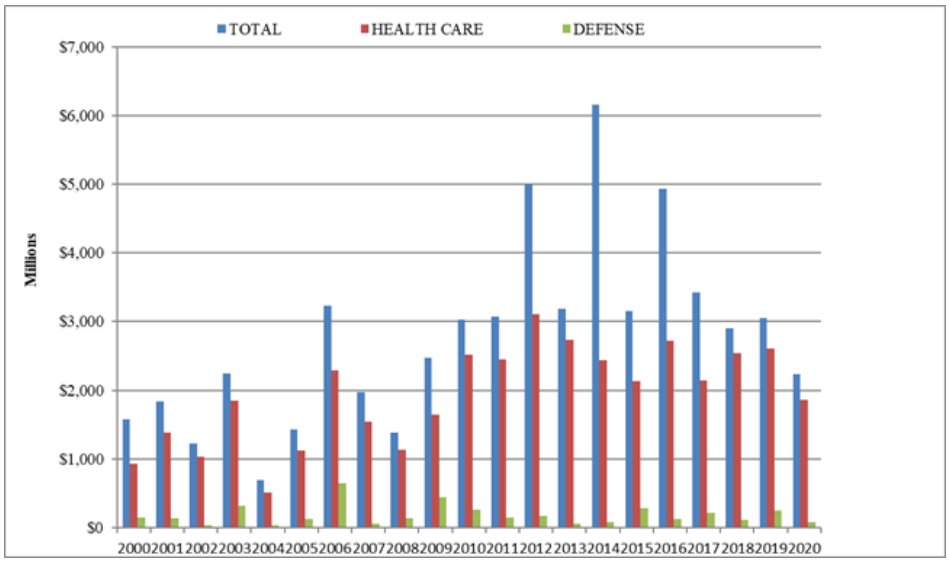
Source: DOJ "Fraud Statistics – Overview" (Jan. 14, 2021)

C. Industry Breakdown

While filings are up and recoveries are (perhaps temporarily) down, the industry breakdown of recoveries remains largely unchanged. As Assistant Attorney General Michael D. Granston recently remarked at the ABA Civil False Claims Act and Qui Tam Enforcement Institute, "[o]f the $11.4 billion recovered over the last four years, approximately 80 percent, or $9 billion, was recovered in health care fraud matters," while "procurement fraud and mortgage fraud" marked the next two largest categories.[4]

2020 was no exception: Health care cases comprised 83% of total recoveries, Department of Defense procurement issues made up 3%, and the remaining 14% was split among other areas.[5]

FCA Recoveries by Industry



Source: DOJ "Fraud Statistics – Overview" (Jan. 14, 2021)

II. NOTEWORTHY DOJ ENFORCEMENT ACTIVITY DURING THE SECOND HALF OF 2020

We summarize below some of the notable FCA settlements announced since July 2020 (we covered notable settlements and judgments from the first half of 2020 in our 2020 Mid-Year False Claims Act Update). These summaries provide insight into the theories of liability and industries that have been a focus of government (and relator) enforcement efforts during the last year.

A. Health Care and Life Science Industries

- On July 1, a molecular diagnostics testing company agreed to pay $8.25 million to settle allegations that it violated the FCA by conspiring with hospitals to artificially delay orders for the company's genetic test. The company allegedly sought to circumvent Medicare's 14-Day Rule, which prohibited laboratories from separately billing for certain tests ordered within 14 days of a patient's discharge from an inpatient or outpatient hospital setting. The government previously alleged in a separate settlement in 2017 that a Kentucky hospital also participated in the scheme in which the company separately billed Medicare instead of the hospital for the tests. A former employee initially filed the *qui tam* lawsuit, and the whistleblower's share was not disclosed at the time of the settlement announcement.[6]
- On July 1, a pharmaceutical company agreed to pay $678 million to resolve claims that it violated the FCA. As part of the settlement, the company agreed to pay $51.25 million to resolve allegations that it improperly used three foundations as conduits to pay copayments of Medicare patients taking its drugs in a manner that resulted in disproportionate assistance for those patients. The company also agreed to pay $591.44 million to resolve allegations that it paid kickbacks through speaker programs and related events. As purported inducement to prescribe its products, the company's managers allegedly instructed sales representatives to select high-volume prescribers as paid speakers. The company further agreed to forfeit $38.4 million, to pay approximately $48 million to resolve state claims, and to abide by strict limitations on future speaker programs and other events under a five-

year Corporate Integrity Agreement.[7]

- On July 8, a hospice care company agreed to pay $3.2 million to settle claims that it violated the FCA by knowingly submitting false claims to Medicare, Medicaid, and TRICARE for hospice care provided to purportedly non-terminally-ill beneficiaries who did not qualify for those services. The settlement also resolves allegations that the company submitted false claims for a medically unnecessary level of hospice care. The company agreed to enter into a Corporate Integrity Agreement as part of the settlement, and the whistleblower, a former employee, will receive 19% of the recovery.[8]
- On July 8, an Oklahoma City-based specialty hospital, its part-owner and management company, a physician group, and two physicians agreed to pay $72.3 million to resolve allegations that they violated the FCA and the Oklahoma Medicaid False Claims Act. The government alleged that improper relationships between the specialty hospital and physician group resulted in the submission of false claims to Medicare, Medicaid and TRICARE, and that the specialty hospital and its management company provided improper remuneration to the physician group and certain physicians in exchange for referrals. The settlement also resolves claims related to the management company's purportedly preferential offering of investment opportunities to physicians at four surgery facilities in Texas. The specialty hospital agreed to pay $60.86 million to the United States, $5 million to Oklahoma, and $206,000 to Texas. The physician group and two of its physicians, agreed to pay $5.7 million to the United States and $495,619 to Oklahoma. The specialty hospital and the physician group also agreed to enter five-year Corporate Integrity Agreements. The whistleblower's share had not yet been determined at the time of the settlement announcement.[9]
- On July 10, a hospital management company, its subsidiary, and one of its facilities agreed to pay a total of $122 million to resolve alleged violations of the FCA. The management company and its subsidiary agreed to pay a total of $117 million, split between the United States and participating states, to resolve allegations that they submitted false claims to Medicare, Medicaid, TRICARE, Department of Veterans Affairs, and Federal Employee Health Benefit programs for billing for medically unnecessary inpatient behavior health services and failing to provide appropriate and adequate services to patients. The company expressly denied the allegations. In a separate settlement, the facility agreed to pay the United States and the State of Georgia $5 million to resolve allegations that it provided free or discounted transportation services to induce Medicare and Medicaid beneficiaries to seek treatment at certain of the facility's programs. The management company, on behalf of its inpatient acute and residential behavioral health facilities, also agreed to enter into a five-year corporate integrity agreement. The settlement with the management company resolves 18 *qui tam* lawsuits, and the whistleblowers will receive a total of $15.86 million of the federal recovery. The settlement with the facility stemmed from a separate *qui tam* lawsuit, and the whistleblower will receive $861,853 from the recovery.[10]
- On July 13, a management corporation and 27 affiliated skilled nursing facilities agreed to pay $16.7 million to settle allegations that they violated the FCA by submitting false claims to Medicare for unnecessary or unreasonable rehabilitation therapy services. The facilities allegedly pressured therapists to increase the amount of patient therapy to meet pre-planned Medicare revenue targets, purportedly set without regard to patients' needs and at an amount achievable only by billing high percentages of patients at the highest Medicare reimbursement level. The company entered into a five-year Corporate Integrity Agreement, and the whistleblowers collectively will receive approximately $3 million of the recovery.[11]
- On July 20, a health care company agreed to pay $11.94 million to resolve allegations that the company violated the FCA and Anti-Kickback Statute ("AKS") by paying kickbacks to two companies in exchange for referrals of urine drug tests

paid for by federal healthcare programs. The company agreed to fully cooperate and enter a five-year Corporate Integrity Agreement, under which the company must routinely report to the Office of Inspector General for the United States Department of Health and Human Services ("HHS-OIG") and retain an Independent Review Organization to monitor its arrangements with other individuals and entities. One of the companies receiving the kickbacks and three of its executives also were indicted for conspiracy to pay and solicit kickbacks. The trial is set to take place in 2021.[12]

- On July 23, a biotech testing company agreed to pay $49 million to resolve allegations that the company fraudulently overbilled Medicaid and the Department of Veterans Affairs by miscoding its prenatal tests and that it provided illegal kickbacks to physicians in the form of excessive "draw fees," meals and happy hours, and improperly reduced or waived patient coinsurance and deductible payments to induce orders for the company's tests. The company agreed to pay $19.45 million to the United States and $13.15 million to various states to resolve the kickback and fraudulent billing claims and agreed to enter a five-year Corporate Integrity Agreement. The allegations stemmed from a *qui tam* lawsuit; the whistleblower's share in the recovery had not been announced at the time of settlement. In a separate settlement, the company agreed to pay $16.4 million to resolve similar fraudulent billing claims related to TRICARE and the Federal Employees Health Benefits Program with the U.S. Attorney's Office for the Southern District of California, and the company entered into a Non-Prosecution Agreement with that office.[13]
- On July 24, a pharmaceutical company's two parent companies agreed to pay $300 million to resolve allegations that they caused the submission of false claims to government health care programs in violation of the FCA. The government alleged that the companies improperly promoted the sale and use of an opioid-addiction-treatment drug to physicians for indications that were not medically accepted, among other allegations. The government also alleged that the companies promoted the drug to physicians and state Medicaid agencies using false and misleading claims regarding the diversion, abuse, and safety risks of the drug, and that they took steps to improperly control the pricing of the drug by seeking to delay the entry of generic competitors, including through a petition to the U.S. Food and Drug Administration ("FDA") claiming safety issues with the drug's tablet version. Approximately $209.3 million of the civil settlement will go to the federal government and $90.7 million will go to states opting in to the agreement. The civil settlement stemmed from six *qui tam* lawsuits, and the whistleblowers' share in the recovery had not been announced at the time of settlement. Separately, the pharmaceutical company agreed to pay another $289 in a criminal fine, forfeiture, and restitution in connection with pleading guilty to a one-count felony charge for making false statements relating to health care matters in connection with marketing and promoting the safety of its products, and the former CEO of its parent pleaded guilty to a one-count misdemeanor information related to the company's alleged false and misleading representations to the Massachusetts Medicaid program. The pharmaceutical company also entered into a five-year Corporate Integrity Agreement that includes numerous accountability and auditing provisions as part of the resolution, and the company separately agreed to pay $10 million to the FTC to resolve unfair competition claims. The settlements come on the heels of a $1.4 billion resolution with the pharmaceutical company's former parent, announced in 2019, which also related to the marketing of the company's opioid drug.[14]
- On July 28, a pharmaceutical company agreed to pay $3.5 million to resolve claims that it violated the FCA by paying kickbacks to physicians through sham research grants as inducement to prescribe the company's newly-launched analgesic drug. Among other allegations, the pharmaceutical company purportedly required placement of its drug on the formulary of the physicians' institution before agreeing to award research grants and subsequently expressed little interest in the

physicians' proposed research. The whistleblower, a pharmacist, will receive approximately $520,000 of the federal recovery and approximately $118,000 of the state recovery.[15]

- On August 19, a nonprofit hospice provider agreed to pay $5.2 million to settle allegations that it improperly billed Medicare and Medicaid for services provided to hospice patients at unnecessarily heightened levels of care for which the patients did not qualify. The provider agreed to pay $4.85 million to the United States and agreed to pay $375,000 to New York. The allegations stem from a *qui tam* lawsuit, and the whistleblower's share in the recovery was not disclosed at the time of the settlement announcement.[16]
- On August 24, a Massachusetts-based pharmaceuticals company agreed to pay $20.75 million to settle claims that it knowingly promoted a drug administration process that contradicted the FDA-approved instructions and was unsupported by sufficient clinical evidence, thereby causing physicians to submit false claims to Medicare and the Federal Employee Health Benefit Program. The company allegedly encouraged physicians to use a less effective drug administration process through paid speaker programs and physician peer-to-peer discussions, promotion by the company's sales personnel, and dissemination of incomplete or misleading responses to questions asked by physicians, among other means. The company also allegedly failed to inform physicians that the administration process resulted in significantly lower clearance rates for the condition and, at times, falsely stated that the clearance rates were the same. The company and its parent company agreed to enter a Corporate Integrity Agreement, and the whistleblower, a former sales representative, will receive approximately $3.5 million of the recovery.[17]
- On September 9, a West Virginia-based acute care hospital agreed to pay $50 million to resolve allegations that it paid illegal kickbacks under the FCA to referring physicians. The government alleged that, over thirteen years, the hospital improperly paid the physicians based on the volume or value of their referrals, or otherwise paid them above-fair-market-value rates. The whistleblower will receive $10 million of the recovery.[18]
- Also on September 9, two companies that operate eleven radiology facilities in California agreed to pay $5 million to resolve allegations that they knowingly submitted claims for improperly supervised CT scans and MRIs in violation of the FCA. The companies also agreed to enter into a three-year Integrity Agreement with HHS-OIG. The whistleblower will receive approximately $925,000 of the recovery.[19]
- On September 11, a research institute agreed to pay $10 million to settle allegations that for a period of eight years it improperly charged research grants funded by the National Institutes of Health for activities unrelated to the grants, such as faculty time spent writing new grant applications, teaching, administrative activities, and committee tasks. The whistleblower will receive $1.75 million of the recovery.[20]
- On September 22, a biotechnology company that provides molecular and diagnostic tests agreed to pay $11.5 million to resolve claims that it knowingly billed government healthcare programs for inpatient testing for which the hospitals should have paid, and that it paid a percentage of the cost of electronic medical records transition software for sixty-nine physicians' offices that the company calculated would generate revenue for the company equal to three times its payment.[21] The company made several admissions related to the purported conduct as part of the settlement.
- On September 23, a pharmaceutical company joined the growing list of companies to face FCA liability for allegedly setting up a fund within a charitable foundation to pay the co-pays of Medicare patients using the company's pulmonary arterial hypertension drug. The government alleged that the company used spend data

from the foundation to assess the amount patients were paying for its drug, then made charitable donations to the foundation sufficient to cover only those payments while simultaneously referring patients to the foundation. The company entered into a $97 million settlement to resolve the matter, without admitting any wrongdoing.[22]

- On September 28, a Texas-based hospital and co-defendants agreed to pay more than $15.3 million to resolve allegations that they overstated support and understated risks of construction of the hospital in order to obtain a federal mortgage loan, including by delaying refunds for cancelled investments, resulting in a loss for the U.S. Department of Housing and Urban Development, which had purchased the mortgage note.[23]
- On October 14, a medical device maker settled allegations that for a period of six years it paid kickbacks in the form of free advertising and practice support to physicians and hospitals in exchange for referrals of its embolization devices. DOJ alleged that the device maker ignored numerous warnings that its conduct may violate the AKS, including from its own Chief Compliance Officer. To settle the allegations, the device maker agreed to pay $18 million and enter into a five-year Corporate Integrity Agreement with HHS-OIG, pursuant to which it must hire a compliance expert and undergo review by an independent review organization. The whistleblower will receive $2.65 million.[24]
- On October 21, an opioid manufacturer agreed to pay $2.8 billion to resolve allegations that it promoted opioids for uses that were unsafe and medically unnecessary and engaged in kickback schemes to induce physicians to prescribe its drugs. With respect to the AKS, DOJ alleged that the manufacturer paid physicians to prescribe its opioids under the guise of payments for educational talks and consultant agreements; paid an electronic health records company to facilitate referrals, recommendations, and orders of its opioids; and contracted with specialty pharmacies to fill prescriptions other pharmacies had rejected. The manufacturer's settlement is part of a broader global resolution, pursuant to which the manufacturer agreed to pay $8.3 billion to settle the FCA allegations and related criminal charges.[25]
- On October 29, a medical device maker agreed to pay $8.1 million to resolve allegations that, in order to induce a neurosurgeon to use the device maker's implantable pumps, it paid for meals and drinks at more than one hundred social events hosted at a restaurant owned by the neurosurgeon and his wife and attended by the neurosurgeon's acquaintances, colleagues, and existing and potential referral sources.[26]
- On November 16, a Medicare Advantage provider agreed to pay over $6.3 million to settle allegations that it violated the FCA by knowingly submitting invalid diagnoses to Medicare that were not supported by Medicare Advantage beneficiaries' medical records. These submissions allegedly resulted in inflated payments from Medicare. The allegations stem from a *qui tam* lawsuit brought by a former employee. The whistleblower will receive approximately $1.5 million of the recovery.[27]
- On November 19, the former owners of a drug and device subsidiary agreed to pay $10 million to resolve allegations that the subsidiary violated the FCA by promoting two systems for unapproved uses for pediatric patients between 2006 and 2012. A private equity company that also formerly owned the subsidiary agreed to pay an additional $1.5 million to settle allegations that the subsidiary continued the allegedly improper practices after that owner acquired the company in 2012. The allegations stem from a *qui tam* lawsuit, and the whistleblowers' share of the settlement was not announced at the time of the settlement announcement.[28]
- On November 20, a Florida-based home health agency and two former executives agreed to pay $5.8 million in total to settle allegations that the home health agency provided improper financial inducements to referring physicians in violation of the

FCA. The home health agency paid just over $3.85 million and each executive paid $647,000. The government alleged that the home health agency violated the AKS and the Stark Law by entering into fake medical director agreements as a way of providing remuneration for referrals. The government also alleged that the home health agency violated the Stark Law by providing bonuses to employees based on referrals made by their physician spouses. The home health agency also agreed to pay an additional $675,000 to settle separate allegations that its employees pressured clinical personnel to increase the number of home visits to Medicare patients to avoid a Medicare adjustment that would have decreased the home health agency's Medicare reimbursement. The government alleged that these services were medically unnecessary. The allegations stem from two *qui tam* lawsuits. The relators in one lawsuit received approximately $145,000 of the proceeds related to the Medicare adjustment allegations, and the relator's share in the other lawsuit had yet to be determined at the time of the settlement announcement.[29]

- On December 17, a Massachusetts-based pharmaceutical company agreed to pay $22 million to resolve allegations that it violated the FCA by illegally using two foundations as a conduit to pay copays for Medicare patients to induce the patients to fill certain Medicare-reimbursed prescriptions. The pharmaceutical company allegedly identified certain patients in its free drug program for its vendor, and purportedly worked with the vendor to transfer the patients to the foundations, which received payments from the pharmaceutical company and then paid the copays for the Medicare patients. The allegations stem from a *qui tam* lawsuit, and the whistleblower will receive approximately $3.96 million of the recovery.[30]

B. Government Contracting and Procurement

- On July 22, a holding company agreed to pay $8 million to settle allegations that it violated the FCA by knowingly avoiding tariffs on imported brake parts. The government alleged that the holding company falsely improperly identified the brake parts as a type exempt from the tariffs. The whistleblowers, two former employees, will receive $1.48 million of the recovery.[31]
- On August 31, an engineering and construction firm and related entity agreed to pay approximately $5.6 million to resolve allegations that they violated the FCA and other civil claims by submitting inaccurate cost and labor hour estimates and certifications related to certain task orders for a federal contract with the U.S. Navy. The allegations stem from a *qui tam* lawsuit brought by a former employee, and the whistleblower's share in the recovery was not disclosed at the time of the settlement announcement.[32]
- On September 10, an asphalt contractor agreed to pay more than $4.25 million over four years to resolve allegations that it misrepresented the materials it would use to pave federally-funded roads by falsely claiming that its asphalt mix contained a sufficient amount of binder to hold together and last a reasonable amount of time, in violation of the FCA.[33]
- On September 15, a software engineering firm that provides training systems to the Department of Defense agreed to pay more than $37 million in restitution to resolve allegations that the firm bribed an Air Force contracting official in exchange for procurement information. According to the government, the firm leveraged that information to secure government contracts for training simulators, causing a prime contractor to submit false invoices to the government. The firm paid the restitution as part of a broader plea agreement based on the same conduct, pursuant to which the firm pleaded guilty to conspiracy to commit wire fraud, but the civil settlement did not require admissions of liability. The majority owner, president and CEO of the firm separately agreed to pay $500,000 to resolve FCA allegations regarding his personal conduct.[34]
- On September 22, major federal construction contractors and a subsidiary

admitted to improperly billing the Department of Energy for unreasonable and unallowable idle time in connection with a waste treatment plant project over a period of ten years, in violation of the FCA. Pursuant to the settlement, the companies agreed to pay $57.75 million and enter into a three-year corporate monitorship. Four whistleblowers will split $13.75 million.[35]

- On November 3, an Illinois-based charter school management company agreed to pay $4.5 million to settle allegations that it engaged in non-competitive bidding practices related to the Federal Communications Commission's ("FCC") E-Rate Program, thereby violating the FCA. The company allegedly rigged the bidding for E-Rate contracts between 2009 and 2012 so that its charter schools selected chosen technology vendors. The company's chosen vendors also allegedly provided equipment at higher prices than FCC-approved prices for equipment with the same functionality. Finally, the company allegedly failed to maintain sufficient control over the FCC-reimbursed equipment, such that some of the equipment was missing. The company agreed to enter into a corporate compliance plan with the FCC.[36]
- On November 20, a federal contractor providing health care and IT services and solutions to federal agencies agreed to pay $18.98 million to settle allegations that it violated the FCA by using labor that did not meet requisite contractual qualifications and overcharging government agencies in connection with services provided under two General Services Administration ("GSA") Multiple Award Schedule contracts. The federal contractor allegedly provided false information regarding its commercial discounting practices during contract negotiations with the government. The federal contractor investigated and disclosed the contractual violations to the United States, and received disclosure and cooperation credit.[37]
- On December 3, an ergonomic office furniture maker and its parent company agreed to pay $7.1 million to settle claims that they violated the FCA by overcharging the government for office furniture under a GSA contract. The government alleged that the company did not fulfill contractual obligations to provide GSA with accurate information about its sales practices during the contract negotiations, and the company also did not offer lower prices to government customers as required under the GSA contract. The allegations stem from a *qui tam* lawsuit brought by a former employee. The whistleblower will receive approximately $1.27 million of the recovery.[38]
- On December 17, a nationwide provider of electricity solutions for buildings and data centers agreed to pay $11 million to settle criminal and civil allegations relating to kickbacks and overcharges on federally-funded energy savings performance contracts. The provider agreed to pay $9.3 million to resolve allegations that it violated the FCA and AKS by soliciting and receiving over $2.5 million in kickbacks from subcontractors working on the contracts; including inflated estimates and improper costs in contract proposals; and overcharging federal agencies under the contracts. In a separate criminal settlement announced on the same day, the company admitted that it committed wire fraud when it fraudulently charged the government for design costs that it disguised and spread across various line items and also admitted that it violated the AKS when its former convicted employee solicited and received kickbacks from the subcontractors.[39]

III. LEGISLATIVE AND POLICY DEVELOPMENTS

A. Federal Legislative Developments

As we have reported previously, several COVID-19 related federal legislative developments in 2020—economic spending and stimulus packages—are likely to spur FCA enforcement. We have covered these developments in detail in updates throughout the COVID?19 crisis (available here and here). The most notable legislation, the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"), marked the largest emergency

stimulus package in history, providing $2.2 trillion worth of government funds to mitigate the effects of COVID-19.[40] The Act provides relief for businesses, industries, individuals, employers, and states in a number of ways, including a Small Business Administration ("SBA") loan program offering up to $350 billion in relief, the Paycheck Protection Program ("PPP"), as well as economic stabilization programs to provide loans, loan guarantees, and funding for eligible industries, businesses, states, and municipalities.

In late December 2020, then President Trump signed a second massive stimulus bill, providing $900 billion of additional relief. Among other things, this new legislation renewed the PPP program, providing an additional $285 billion for additional loans for small businesses.[41] The new economic relief program tightened the funding terms and conditions in some respects, an effort apparently aimed at correcting some of the elements of the original program that were subject to criticism. The legislation caps new loans at $2 million, for example, and makes them available only to borrowers with fewer than 300 employees that experienced at least a 25% drop in sales from a year earlier in at least one quarter. In addition, publicly traded companies will not be eligible to apply for loans.

Before taking office on January 20, 2021, President Biden also announced a $1.9 trillion COVID relief plan that he aims to pass during his first 100 days in office.[42] Among other things, the plan provides $416 billion to launch a national vaccination program, $35 billion to make low-interest loans available to certain businesses, and sets aside another $1 trillion in additional stimulus checks for Americans.

There were no major developments with respect to federal FCA legislation in 2020. This may change soon, however. For example, in July, Senator Chuck Grassley (R-IA)—the original author of the FCA's 1986 amendments—announced he is drafting legislation that would "clarify[y]" purported "ambiguities created by the courts" regarding the proper interpretation of the FCA.[43] In particular, Senator Grassley's remarks highlighted his concerns about DOJ's authority to dismiss FCA cases despite relators' objections, as well as DOJ's practice of increasingly exercising that authority following DOJ's issuance of the Granston Memo, on which we have reported previously. We will closely monitor this and other developments at the federal level in the coming year.

B. COVID-19 Enforcement Policy

Under the outgoing administration, DOJ focused on preventing and punishing COVID-19-related fraud. To date, DOJ has scrutinized several aspects of the stimulus funding under the CARES Act, in particular, such as in connection with certifications of compliance with loan program requirements, as well as submission of false claims allegedly kickback-tainted, medically unnecessary, and/or otherwise not provided as represented.[44]

This policy played out in 2020, with DOJ officials announcing plans to "deploy the [FCA] against those who commit fraud related to the various COVID-19 stimulus programs," particularly the Provider Relief Fund ("PRF") and the Paycheck Protection Program—funding programs put into place by the CARES Act. These programs, which impose numerous requirements on funding recipients, make available significant sums of money that DOJ considers may provide "a number of opportunities for fraud."[45]

The Biden administration will almost certainly continue to focus on COVID-19 enforcement. What other enforcement changes or priorities come from the Biden administration remain to be seen.

C. State Legislative Developments

As an incentive for seeking HHS-OIG approval of their false claims act statutes, states can receive "a 10-percentage-point increase in their share of any amounts" recovered under

the relevant laws.[46] To receive approval, state statutes must (among other requirements) contain provisions that are "at least as effective in rewarding and facilitating qui tam actions" as those in the federal FCA, and must contain civil penalties at least equivalent to those imposed by the federal FCA.[47] A similar requirement is that a given state's statute must provide for civil penalty increases "at the same rate and time as those authorized under the [federal] FCA" pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015.[48]

Currently, the total number of states with approved statutes stands at twenty-one (California, Colorado, Connecticut, Delaware, Georgia, Hawaii, Illinois, Indiana, Iowa, Massachusetts, Montana, Nevada, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, Virginia, and Washington). Eight states have laws that have not yet been deemed to meet the federal standards (Florida, Louisiana, Michigan, Minnesota, New Hampshire, New Jersey, New Mexico, and Wisconsin).[49] Thirty-one states have enacted some version of the False Claims Act.[50

Several jurisdictions also enacted or advanced false claims act legislation in 2020. In the District of Columbia, the D.C. Council enacted legislation amending the District's existing false claims act (D.C. Code Ann. § 2-381.01 *et seq.*) to expressly authorize tax-related false claims actions against persons who "reported net income, sales, or revenue totaling $1 million or more in a tax filing to which [the relevant] claim, record, or statement pertained, and the damages pleaded in the action total $350,000 or more."[51] The bill authorizes treble damages for tax-related violations, meaning District taxpayers could be liable for three times the amount not only of any taxes, but also of any interest and tax penalties.[52] Because the District's existing false claims statute excluded tax-related claims from false claims liability, the new legislation represents a major policy shift.[53] In amending its false claims statute in this fashion, the District joins Illinois and New York as jurisdictions that provide for tax-related FCA liability.[54]

In Pennsylvania, which has no statute analogous to the FCA, the legislature advanced a false claims act bill that would enable private citizens to bring lawsuits on behalf of the state against anyone who "[k]nowingly presents or causes to be presented a false or fraudulent claim for payment or approval" or "[k]nowingly makes, uses or causes to be made or used, a false record or statement material to a false or fraudulent claim."[55] The bill would also require the Attorney General to make recommendations to state agencies on how to prevent false claims violations from occurring.[56] The new law would empower the Pennsylvania Office of the Attorney General to enforce its provisions, including via civil investigative demands.[57] The bill largely mirrors the FCA and was first referred to the House Human Services Committee on May 21, 2020.[58] In September 2020, the House committee approved an amended bill to include limited civil liability protections for entities that follow all state and federal directives regarding COVID-19, along with civil fraud provisions matching federal law.[59] To date, the bill is awaiting a vote in the Pennsylvania General Assembly.

We also reported in our 2020 Mid-Year Update on a bill passed by the California Assembly, Assembly Bill No. 1270, which would alter the state's false claim act considerably, including by amending the act to limit the definition of materiality to include only "the potential effect" of an alleged false record or statement "when it is made," without consideration—contrary to the U.S. Supreme Court's 2016 decision in *Universal Health Services v. United States ex rel. Escobar*[60]—of "the actual effect of the false record or statement when it is discovered."[61] The amendments would also extend the act to tax-related cases where the damages pleaded exceed $200,000 and a defendant's state-taxable income or sales exceed $500,000.[62] After the bill stalled in the State Senate, a California Assembly member (Mark Stone, D-Monterey Bay) introduced a substantially similar bill, Assembly Bill No. 2570.[63] As with its predecessor, AB-2570 stalled in the State Senate in 2020.

IV. NOTABLE CASE LAW DEVELOPMENTS

The second half of 2020 saw a number of important case law developments, including with respect to falsity, materiality, and the FCA's important threshold bars. We cover the most notable cases below.

A. A Circuit Split Over "Objective Falsity" Progresses to the Supreme Court

As discussed in our Mid-Year Update, the issue of whether and when differences in physician medical opinions may satisfy the FCA's "falsity" element is driving critical developments in FCA jurisprudence. In particular, a circuit split emerged after the Eleventh Circuit's decision in *United States v. AseraCare, Inc*., in which the court held that claims cannot be "deemed false" under the FCA based solely on "a reasonable disagreement between medical experts" as to a medical provider's clinical judgment. 938 F.3d 1278, 1281 (11th Cir. 2019). By contrast, the Third Circuit held in *United States ex rel. Druding v. Care Alternatives* that a "physician's judgment may be scrutinized and considered 'false'" and that a "difference of medical opinion is enough evidence to create a triable dispute of fact regarding FCA falsity." 952 F.3d 89, 100–01 (3d Cir. 2020). The Ninth Circuit reached a similar result in *Winter ex rel. United States v. Gardens Regional Hospital and Medical Center*, holding that an FCA claim based on an alleged lack of medical necessity may suffice to survive a motion to dismiss. 953 F.3d 1108, 1117 (9th Cir. 2020).

In September 2020, Care Alternatives petitioned the Supreme Court for a writ of certiorari to challenge the Third Circuit's rejection of the *AseraCare* "objective falsity" standard. Specifically, Care Alternatives asked the Court to decide "[w]hether a physician's honestly held clinical judgment regarding hospice certification can be 'false' under the False Claims Act based solely on a reasonable difference of opinion among physicians." Pet. for Writ of Cert., *Care Alternatives v. United States, et al*., No. 20-371 (U.S. Sept. 16, 2020).

In its petition, Care Alternatives contended that the Third Circuit's recent decision created a "square split" with the Eleventh Circuit's *AseraCare* decision "on an issue of critical importance to the millions of Americans who require hospice care annually and the thousands of hospices and physicians who provide that care." *Id.* at 1–2. Care Alternatives also argued that the Third Circuit's rejection of an objective falsity standard "opens up hospices and physicians to crushing financial liability and reputational harm, notwithstanding near universal acknowledgment that determinations about life expectancy are notoriously difficult and inexact." *Id.* at 2. Further, it highlighted the "untenable prospect . . . that hospices in New Jersey [because of the Third Circuit's decision] will face treble damages for the same difficult medical judgments that cannot be second-guessed in Florida," in light of the Eleventh Circuit's *AseraCare* case. *Id.* at 3.

Given the stakes, the case has attracted attention from industry participants. After Care Alternatives filed its petition, two groups submitted amicus briefs: one by a group of Hospice, Health Care, and Physician Organizations, and the other from the Chamber of Commerce of the United States of America and the Pharmaceutical Research and Manufacturers of America ("PhRMA"). *See* Br. for the Hospice, Health Care, and Physician Organizations as Amici Curiae, *Care Alternatives v. United States, et al*., No. 20-371 (U.S. Oct. 23, 2020) ("Hospice Brief"); Br. of Chamber of Commerce of the United States et al. as Amici Curiae, *Care Alternatives v. United States, et al*., No. 20-371 (U.S. Oct. 23, 2020) ("Chamber of Commerce Brief"). The briefs highlighted the risks the Third Circuit's decision poses for providers and for recipients of government benefits more broadly (such as government contractors). *See generally* Hospice Brief; Chamber of Commerce Brief. The *amici* likewise cited the broader developing circuit split over "objective falsity" as another reason why the Court should grant Care Alternatives' petition. Chamber of Commerce Brief at 8–10.

B. Courts Continue to Grapple with the FCA's Materiality and Scienter Requirements Post-*Escobar*

In the latter half of 2020, federal appellate courts continued to weigh in on the critical issues of materiality and scienter under the FCA in the wake of the Supreme Court's seminal decision in *Universal Health Services v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016). The Court's clear directive in *Escobar* was that courts should scrutinize whether plaintiffs have alleged facts sufficient to satisfy the "rigorous" and demanding materiality standard the FCA imposes. *See id.* at 2004 n.6 (rejecting the notion that materiality cannot be decided at the pleadings stage). Two Circuit Courts of Appeals took up this task in notable ways in the latter half of 2020.

First, in *United States v. Strock*, the Second Circuit considered what counts as a "payment decision" for purposes of assessing materiality under a fraudulent inducement theory of FCA liability. 982 F.3d 51 (2d Cir. Dec. 3, 2020). Under a fraudulent inducement theory, "FCA liability attaches not because a defendant has submitted any claim for payment that is 'literally false,' but instead because 'the contract under which payment [is] made is procured by fraud.'" *Id*. at 60 (quoting *United States ex rel. Longhi v. United States*, 575 F.3d 458, 467–68 (5th Cir. 2009)). In *Strock*, the court evaluated whether *Escobar* materiality analysis applied to the government's initial decision to award the contract, the government's subsequent decision to pay claims under the contract, or both. The government alleged that a putatively service-disabled veteran-owned small business ("SDVOSB") was used "as a front to funnel [government] contract work" to another contractor. *Id.* at 56. The U.S. District Court for the Western District of New York granted the defendants' motion to dismiss and concluded that *Escobar* only required a showing of materiality in connection with the government's initial awarding of the contract. *Id.* at 58–60.

On appeal, the Second Circuit reversed the district court's dismissal of the FCA claims against one individual defendant and vacated the district court's dismissal of the FCA claims against the corporate defendant under a vicarious liability theory. The Second Circuit reasoned that the nature of fraudulent inducement cases required it to assign the meaning of "payment decisions" subject to *Escobar* analysis a "broader scope" than the lower court had. *Id.* at 60. The Second Circuit interpreted *both* the government's initial contract award *and* subsequent payments of claims as "payment decisions" requiring a materiality analysis under *Escobar*. *Id.* at 59–60.

Earlier in 2020, the Fifth Circuit in *United States ex rel. Porter v. Magnolia Health Plan, Inc*. also applied *Escobar*'s materiality standard to a case decided at the pleadings stage. 810 F. App'x 237 (5th Cir. 2020). There, a registered nurse alleged that her former employer violated the FCA by staffing care and case manager positions with licensed practical nurses in contravention of contractual requirements. The district court dismissed the FCA claims, concluding that "broad boilerplate language generally requiring a contractor to follow all laws" was "too general to support a FCA claim." *Id.* at 242. In affirming, the Fifth Circuit agreed that the applicable contracts did not require the defendant to staff relevant positions with registered nurses and that the boilerplate language was not sufficient to establish an FCA claim. The Fifth Circuit also explained that the "continued payments to and contracts with" the defendant "substantially increase the burden . . . in establishing materiality," which the plaintiff did not meet. *Id.* Specifically, the Fifth Circuit noted that "the Mississippi Division of Medicaid took no action after Plaintiff-Appellant informed the Division" of this alleged misconduct but rather "continued payment and renewed its contract with [the former employer] several times." *Id.* Even after the plaintiff's suit was unsealed, the third-party Medicaid contractor awarded the plaintiff's former employer "a contract for the fourth time." *Id.* The Fifth Circuit also affirmed the district court's dismissal with prejudice, finding "no reasonable basis to predict that [the plaintiff] c[ould] recover on her claims" and that any amendment of the nurse's complaint thus would be futile, in part, because of the government's continued payments and contracting arrangements with the nurse's former employer. *Id.* at 243.

On December 9, 2020, after the Fifth Circuit refused to rehear the case, the relator petitioned for a writ of certiorari, asking the Supreme Court to clarify to what extent

Escobar altered the Rule 12(b)(6) plausibility standard the Court imposed in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007) and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009). Pet. for Writ of Cert., *United States ex rel. Porter v. Magnolia Health Plan, Inc*., No. 20-786 (U.S. Dec. 9, 2020). Specifically, the petition asked the Court to decide "whether the Supreme Court ruling in *Escobar* overruled or modified the standard of review to be used in ruling upon Rule 12(b)(6) motions to dismiss in cases involving the False Claims Act so as to require 'proof' or 'evidence' at the initial pleading stage above and beyond the plausibility standard set forth in *Twombly* and *Iqbal*." *Id.* at iii. The Court denied the *qui tam* plaintiff's petition on January 19, 2021.

C. Courts Continue to Scrutinize DOJ's Discretion to Dismiss *Qui Tam* Claims

1. A Third Standard for DOJ's Dismissal Authority?

In the wake of the 2018 Granston Memo, which instructed DOJ attorneys to consider dismissal of a *qui tam* case when recommending declination, DOJ has more regularly invoked its dismissal authority under 31 U.S.C. § 3730(c)(2)(A) than it did in for decades previously. Historically, courts have split based on whether they follow the Ninth Circuit's *Sequoia Orange* test or the D.C. Circuit's *Swift* test. 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.

This past August, the Seventh Circuit suggested that the split may have little practical significance. In *United States ex rel. CIMZNHCA, LLC v. UCB, Inc.*, 970 F.3d 835 (7th Cir. 2020), the court reviewed a district court's denial of the government's attempt to dismiss the case, which concerned the alleged provision of kickbacks to physicians for prescriptions of a drug used to treat Crohn's disease. *Id.* at 839. In moving for dismissal, the government argued that the allegations "lack[ed] sufficient merit to justify the cost of investigation and prosecution and [were] otherwise . . . contrary to the public interest." *Id.* at 840. But the district court, applying the *Sequoia Orange* standard, deemed the government's decision "arbitrary and capricious" and "not rationally related to a valid governmental purpose." *Id.* (internal quotation marks omitted).

The Seventh Circuit reversed, calling 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." *Id.* at 839. Instead, the court 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. While Rule 41(a)(1)(A) states that the voluntary dismissal right is "[s]ubject to . . . any applicable federal statute," the "only authorized statutory deviation from Rule 41" in the FCA itself is the requirement that a relator be given notice and an opportunity to be heard in the event that the government seeks to dismiss the case over the relator's objection. *See id.* at 850. The court acknowledged that such a hearing may amount to little more than formality in cases where there are no questions about the propriety of the government's exercise of its dismissal authority; but the court noted that Rule 41's conditions on the timing of voluntary dismissal motions could arise in Section 3730(c)(2)(A) hearings in cases where "the government's chance to serve notice of dismissal has passed . . . and the relator . . . refuses to agree to dismissal." *Id.* at 850–51.

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 found that the government's dismissal decision, based as it was on the fact that agency guidance and rules had repeatedly "held that the conduct complained of is probably lawful," did not rise to this level. *See id.* At the same time, 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.

In sum, while the court 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's holding suggested that it believes that limit lies closer to the even?more?forgiving *Swift* standard than to the "two-step" approach set forth in *Sequoia Orange*. The Seventh Circuit seems to have believed that the district court lost sight of the constitutional underpinnings of the "rational basis" test—and that a focus on the procedural parameters of Rule 41 can help avoid this error, insofar as they are consistent with a very forgiving approach to the government's exercise of its dismissal authority. Accordingly, going forward we may well see DOJ intervene for the purposes of dismissal to exercise its (c)(2)(A) dismissal authority more often, at least in Seventh Circuit courts.

2. The Ninth Circuit Explores Limits on the Appealability of Denials of the Government's Motions to Dismiss Under Section 3730(C)(2)(A)

In another notable case regarding DOJ's dismissal authority, the Ninth Circuit issued a decision that could create more pressure for DOJ, when it wishes to dismiss a case, to intervene in the action first. In *United States v. Academy Mortgage Corp.*, 968 F.3d 996 (9th Cir. 2020), the district court denied DOJ's motion to dismiss on the ground that the government's cost-benefit justification was insufficient to satisfy the *Sequoia Orange* standard. *Id.* at 1001. The government had claimed that discovery would be burdensome, but the court believed that the government had an incomplete understanding of the potential monetary recovery in the case given the limited nature of the government's investigation. *Id.* The government appealed the denial of its motion under the collateral order doctrine, rather than seek to have the issue certified for interlocutory review. *See id.*

The Ninth Circuit dismissed the appeal for lack of jurisdiction, holding that the collateral order doctrine does not apply to denials of motions to dismiss under Section 3730(c)(2)(A), "at least in cases where the Government has not exercised its right to intervene." *Id.* at 1005. Citing the government's professed concern regarding discovery burdens, the court reasoned that, when the government has not intervened in a *qui tam* action, it is not a party to the action and its discovery obligations accordingly are the same as those of any other non?party under Federal Rule of Civil Procedure 45. *Id.* at 1006. The court noted that the path to appellate review of a question of discovery burdens on a third party typically is to defy a subpoena and appeal the resulting contempt citation; orders merely denying motions to quash under Rule 45 "generally cannot be immediately appealed under the collateral order doctrine." *Id.* at 1006–07. The court stated the core of its concern as follows: "It would be incongruous to hold, as we are asked to do here, that the Government's interest in dismissing the case to avoid the *possibility* of future onerous discovery requests is important enough to merit an immediate appeal, when third parties *actually faced* with burdensome subpoenas have no such right." *Id.* at 1007 (emphases in original). Although the court stated that the government could pursue interlocutory review, the court's opinion could be read to suggest that the case does not present a "controlling question of law as to which there is substantial ground for difference of opinion" where the

government's rationale for dismissal is a mere "run-of-the-mill litigation burden[]." *Id.* at 1009.

The courts in both *Academy Mortgage* and *UCB* treated the question of DOJ's intervention as affecting which legal framework should apply to the analysis of DOJ's dismissal authority. Practically speaking, that reasoning may encourage DOJ to intervene in cases in which it otherwise would not seek to do so, for the limited purpose of strengthening its posture in moving to dismiss the case.

D. Developments on the First-to-File Bar and *Res Judicata*

Under Section 3730(b)(5) of the FCA, "[w]hen a person brings an [FCA] action . . . no person other than the Government may intervene or bring a related action based on the facts underlying the pending action." 31 U.S.C. § 3730(b)(5). The Circuits have split over whether this "first-to-file bar" is jurisdictional. The First, Second, and D.C. Circuits have held that the bar is not jurisdictional, whereas the Fourth, Fifth, Sixth, Ninth, and Tenth Circuits have concluded that the bar is a matter of courts' subject?matter jurisdiction. *See In re Plavix Marketing, Sales Practices & Products Liability Litig.*, 974 F.3d 228, 232 (3d Cir. 2020) (collecting cases).

In a September 1, 2020 opinion, the Third Circuit joined the former camp, relying primarily on the "clear statement rule": "As the Supreme Court has recently instructed, unless Congress states clearly that a rule is jurisdictional, we will treat it as nonjurisdictional. . . . [Defendants] point to no language in § 3730(b)(5), nor do we see any, that 'plainly show[s] that Congress imbued [the first-to-file] bar with jurisdictional consequences.'" *Id.* at 232 (second and third alterations in original) (citation omitted). The court also rejected the defendants' argument that the bar is a matter of constitutional standing, concluding instead that it "asks only 'whether [the relator] falls within the class of plaintiffs whom Congress has authorized to sue,' which is another way to ask whether the statute gives it a cause of action." *Id.* (alteration in original) (citation omitted). Accordingly, a motion to dismiss under the first?to?file bar "falls under Rule 12(b)(6) for failure to state a claim." *Id.* at 233.

In a separate case, the State of New Mexico filed a complaint in state court while the *Plavix* litigation was pending but after the State declined to intervene in that litigation. *See State ex rel. Balderas v. Bristol-Myers Squibb Co.*, 436 P.3d 724, 727 (N.M. Ct. App. 2018). The state trial and appellate courts held that the dismissal of the *Plavix* relator's claims with prejudice did not act as dismissal with prejudice as to the government. *Id.* at 734. The court cited favorably to other decisions reasoning that a non-intervention decision does not automatically mean the government does not see merit in the case in question, and that "perverse incentives" would arise if dismissal with prejudice as to a relator also precluded claims by the government. *Id.* at 731. For example, the government essentially would have to intervene in every case simply to protect its ability to sue a defendant later, *id.*, which would defeat the purpose of statutory provisions granting the government discretion to intervene.

The defendants filed a petition in the Supreme Court for a writ of certiorari in early September, a request which remains pending. *See generally* Pet. for Writ of Cert., *State ex rel. Balderas v. Bristol-Myers Squibb Co.*, No. 20-293 (U.S. Sept. 3, 2020). If the Court takes the case, it will be an opportunity to resolve a Circuit split over whether the government is bound by with-prejudice dismissals of *qui tam* complaints. The Fifth and Eleventh Circuits have answered that question in the negative, the Seventh and Ninth Circuits in the affirmative. *See id.* at 13–19.

E. The D.C. Circuit Affirms an Award of Summary Judgment Where Defendant Failed to Adequately Address Government's Legal Theories

It is difficult for any plaintiff to prevail on a motion for summary judgment. This is particularly so in FCA actions, which demand that plaintiffs prove various rigorously construed and fact?intensive elements, including materiality and scienter.

In August 2016, however, the U.S. District Court for the District of Columbia granted the government's motion for summary judgment in a case against a home health care company alleged to have submitted claims for reimbursement to the District of Columbia Medicaid Program for services that purportedly lacked adequate documentation. *United States v. Dynamic Visions Inc*., 220 F. Supp. 3d 16, 22 (D.D.C. 2016).

The district court's opinion is notable given how rarely these motions are granted. Just as noteworthy is the fact that, in August 2020, the D.C. Circuit largely affirmed the lower court's award of summary judgment in the government's favor. *United States v. Dynamic Visions Inc*, 971 F.3d 330, 338–40 (D.C. Cir. 2020). The D.C. Circuit highlighted that, on appeal, the defendant-appellant had failed to meaningfully address the government's theory that patients had inadequate "plan of care" documentation in several different regards, having chosen instead to "respond[] only with highly generalized statements to the effect that they submitted plans of care for Medicaid recipients signed by their physicians, . . . that they maintained a policy and procedure manual that was compliant with [Department of Health Care Finance] regulations[,] and [that they] followed the policy and procedures stated in the manual." *Id.* at 337 (internal quotation marks omitted). Because the defendant-appellant failed to provide supporting evidence for those assertions—namely, the manual in question—the court held that "[t]hose statements are too conclusory to create a genuine issue." *Id.*

V. CONCLUSION

As always, Gibson Dunn will continue to monitor these developments and others in the FCA space and stands ready to answer any questions you may have. We will report back to you on the latest news mid-year, in July 2021.

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[1] *See* U.S. Dep't of Justice, Memorandum from Rachel Brand, Associate Attorney General (Nov. 16, 2017), https://www.justice.gov/opa/press-release/file/1012271/download .

[2] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Justice Department Recovers Over $2.2 Billion from False Claims Act Cases in Fiscal Year 2020 (Jan. 14, 2021), https://www.justice.gov/opa/pr/justice-department-recovers-over-22-billion-false-claims-act-cases-fiscal-year-2020 [hereinafter DOJ FY 2020 Recoveries Press Release].

[3] *See* U.S. Dep't of Justice, Fraud Statistics Overview (Jan. 14, 2021), https://www.justice.gov/opa/press-release/file/1354316/download [hereinafter DOJ FY 2020 Stats].

[4] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Remarks of Deputy Assistant Attorney General Michael D. Granston at the ABA Civil False Claims Act and Qui Tam Enforcement Institute (Dec. 2, 2020), https://www.justice.gov/opa/speech/remarks-deputy-assistant-attorney-general-michael-d-granston-aba-civil-false-claims-act.

[5] *See* DOJ FY 2020 Stats.

[6] *See* Press Release, U.S. Atty's Office for the W. Dist. Of Ky., California Genetic Testing Company Agrees To Pay $8.25 Million To Resolve False Claims Allegations; Paducah, Ky, Area Hospital Also Settles (July 1, 2020), https://www.justice.gov/usao-wdky/pr/california-genetic-testing-company-agrees-pay-825-million-resolve-false-claims.

[7] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Novartis Pays Over $642 Million to Settle Allegations of Improper Payments to Patients and Physicians (July 1, 2020), https://www.justice.gov/opa/pr/novartis-pays-over-642-million-settle-allegations-improper-payments-patients-and-physicians; Press Release, U.S. Atty's Office for the S. Dist. of N.Y., Acting Manhattan U.S. Attorney Announces $678 Million Settlement Of Fraud Lawsuit Against Novartis Pharmaceuticals For Operating Sham Speaker Programs Through Which It Paid Over $100 Million To Doctors To Unlawfully Induce Them To Prescribe Novartis Drugs (July 1, 2020), https://www.justice.gov/usao-sdny/pr/acting-manhattan-us-attorney-announces-678-million-settlement-fraud-lawsuit-against.

[8] *See* Press Release, U.S. Atty's Office for the Middle Dist. of Fla., Hope Hospice Agrees To Pay $3.2 Million To Settle False Claims Act Liability (July 8, 2020), https://www.justice.gov/usao-mdfl/pr/hope-hospice-agrees-pay-32-million-settle-false-claims-act-liability.

[9] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Oklahoma City Hospital, Management Company, And Physician Group To Pay $72.3 Million To Settle Federal And State False Claims Act Allegations Arising From Improper Payments To Referring Physicians (July 8, 2020), https://www.justice.gov/opa/pr/oklahoma-city-hospital-management-company-and-physician-group-pay-723-million-settle-federal.

[10] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Universal Health Services, Inc. And Related Entities To Pay $122 Million To Settle False Claims Act Allegations Relating To Medically Unnecessary Inpatient Behavioral Health Services And Illegal Kickbacks (July 10, 2020), https://www.justice.gov/opa/pr/universal-health-services-inc-and-related-entities-pay-122-million-settle-false-claims-act.

[11] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Twenty-Seven Skilled Nursing Facilities Controlled By Longwood Management Corporation To Pay $16.7 Million To Resolve False Claims Act Allegations (July 13, 2020), https://www.justice.gov/opa/pr/twenty-seven-skilled-nursing-facilities-controlled-longwood-management-corporation-pay-167.

[12] *See* Press Release, U.S. Atty's Office for the W. Dist. of Wash., DOJ settles False Claims Act allegations against drug testing lab with operations in Tacoma and Denver (July 20, 2020), https://www.justice.gov/usao-wdwa/pr/doj-settles-false-claims-act-allegations-against-drug-testing-lab-operations-tacoma-and.

[13] *See* Press Release, U.S. Atty's Office for the S. Dist. of N.Y., Acting Manhattan U.S. Attorney Announces $49 Million Settlement With Biotech Testing Company For Fraudulent Billing And Kickback Practices (July 23, 2020), https://www.justice.gov/usao-sdny/pr/acting-manhattan-us-attorney-announces-49-million-settlement-biotech-testing-company.

[14] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Indivior Solutions Pleads Guilty To Felony Charge And Indivior Entities Agree To Pay $600 Million To Resolve Criminal And Civil Investigations As Part Of DOJ's Largest Opioid Resolution (July 24, 2020), https://www.justice.gov/opa/pr/indivior-solutions-pleads-guilty-felony-charge-and-indivior-entities-agree-pay-600-million.

[15] *See* Press Release, U.S. Atty's Office for the Dist. of N.J., Pharmaceutical Company Agrees to Pay $3.5 Million to Resolve Allegations of Violating False Claims Act (July 28, 2020), https://www.justice.gov/usao-nj/pr/pharmaceutical-company-agrees-pay-35-million-resolve-allegations-violating-false-claims.

[16] *See* Press Release, U.S. Atty's Office for the E. Dist. of N.Y., New York Hospice Provider Settles Civil Healthcare Fraud Allegations (Aug. 19, 2020),

https://www.justice.gov/usao-edny/pr/new-york-hospice-provider-settles-civil-healthcare-fraud-allegations.

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