2020 Mid-Year False Claims Act Update

Client Alert | July 17, 2020

As the world reels from the COVID-19 pandemic and certain sectors of the economy struggle, False Claims Act ("FCA") enforcement and litigation has largely plodded along during the first six months of 2020—and some areas reflect increasing activity. At the same time, the federal government's stimulus efforts are sowing seeds for potentially significant future enforcement efforts, and the dire economic and employment landscape domestically may well catalyze whistleblower complaints.

As we have explained in prior alerts (available here and here), the federal government has spent record sums as part of COVID-19 stimulus and relief efforts; and whenever the government spends large amounts of money, activity under the FCA—the government's primary tool for combating fraud against the government—is sure to follow. True to form, the government has already announced that FCA enforcement related to COVID-19 funding will be a priority in the months and years ahead, and we have begun to see the first wave of fraud prosecutions and investigations related to the government's stimulus spending.

Meanwhile, enforcement efforts that started before the recent crisis have continued. And the courts, while somewhat slowed by shutdowns that have affected every court in the country, nevertheless produced notable opinions in the last six months that deserve careful attention for any company doing business, directly or indirectly, with the federal or state governments. As detailed below, these opinions address a wide range of issues, including the scope of the FCA's falsity element (including in relation to whether and when differences in clinical judgments can serve as a predicate for liability), the contours of other key elements of the statute (e.g., scienter and materiality), and the public disclosure bar.

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 we 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 2020

The first few months of 2020 featured a fairly typical number of FCA resolutions announced by DOJ. Unsurprisingly, there was a clear slowdown beginning in April as many government offices (and businesses) shuttered. This slowdown has resulted in lower overall recoveries compared to the pace during the first half of prior years. In a significant departure from past years, DOJ has announced only one nine-figure settlement this year (a \$145 million settlement with a health information technology developer that was implicated in an alleged kickback scheme relating to prescriptions of opioid products).

Behind the scenes, however, neither the government nor the private relators' bar seem to have lost focus on FCA enforcement as a result of COVID-19. Ongoing investigations are moving forward. And June has already seen a slight uptick in the number of resolutions

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announced (although the average amounts generally have been lower than in the beginning of 2020).

As usual, the majority of FCA recoveries from enforcement actions this year have involved health care and life sciences entities, including recoveries alleging violations of the Anti-Kickback Statute ("AKS") and the Stark Law, which generally prohibit various types of remunerative arrangements with referring health care providers. Below, we summarize these and some of the other most notable settlements thus far in 2020.

In addition to the settlements summarized below, there was also a (comparatively rare) federal jury trial under the FCA during the first half of the year. In March 2020, a federal jury found after a nine-week trial that several individuals and their affiliated companies were liable for violations of the FCA, and awarded \$10.85 million in single damages (which after statutory trebling and civil penalties resulted in a judgment of more than \$32 million).[1] According to the government, the defendants submitted fraudulent Medicare cost reports when they billed Medicare for compensation paid to owners and executives who did not do reimbursable work for the hospital; the U.S. Attorney for the Southern District of Mississippi called the matter "one of the most egregious cases of Medicare fraud we have litigated in the State of Mississippi."

A. Health Care and Life Science Industries

- On January 15, a California-based manufacturer of durable medical equipment ("DME") agreed to pay more than \$37.5 million to resolve allegations that it violated the FCA by paying kickbacks to equipment suppliers, sleep laboratories, and other health care providers. The government alleged that the DME manufacturer induced patient referrals by, among other things, providing free patient outreach services and below-cost equipment and installation, as well as arranging for, and guaranteeing payments due on, interest-free loans for the purchase of its equipment. The company contemporaneously entered into a Corporate Integrity Agreement with the Department of Health and Human Services Office of Inspector General ("HHS-OIG") that requires the company to implement additional controls around its product pricing and sales and conduct monitoring of its arrangements with referral sources.
- On January 21, a patient co-pay foundation based in Virginia agreed to pay \$3 million to resolve allegations that it coordinated with three pharmaceutical manufacturers to enable them to provide kickbacks to Medicare patients taking the manufacturers' drugs. DOJ alleged that the foundation designed and operated funds that directed money from the pharmaceutical manufacturers to patients to cover co-payments for drugs sold by those companies. The settlement amount was determined based on the foundation's ability to pay. The foundation agreed to a three-year Corporate Integrity Agreement with HHS-OIG that requires the foundation to implement measures to ensure that it operates independently and that its interactions with donors comply with the law. The Integrity Agreement also requires compliance-related certifications from the foundation's Board of Directors, and reviews by an independent review organization. The federal government previously entered into settlements with the three pharmaceutical manufacturers related to the same allegations.[3]
- On January 27, a California-based health information technology developer entered into a deferred prosecution agreement and agreed to pay over \$26 million in criminal fines and forfeit criminal proceeds of nearly \$1 million, to resolve allegations that it obtained unlawful kickbacks from pharmaceutical companies in exchange for implementing clinical decision support alerts in its electronic health record software designed to increase prescriptions of the companies' drug products. This represents the first criminal action against an electronic health records vendor. In a simultaneous civil settlement, the developer agreed to pay approximately \$118.6 million to the federal government and states to resolve

allegations that it accepted kickbacks from pharmaceutical companies and that it caused its users to submit false claims for federal incentive programs by misrepresenting the capabilities of its software. The civil settlement also resolved allegations that the developer obtained false certifications for its electronic health care software.[4]

- On February 19, an operator of nursing facilities in Pennsylvania, Ohio, and West Virginia agreed to pay more than \$15.4 million to settle allegations that it overbilled Medicare and the Federal Employees Health Benefits Program for medically unnecessary rehabilitation therapy services. The settlement also resolves allegations that the nursing facility operator received payments for ineligible services performed by employees who were excluded from federal health care programs. The relators who filed the case will receive approximately \$2.8 million as their share of the recovery. The nursing facility operator also agreed to enter into a chain?wide Corporate Integrity Agreement.
- On February 28, DOJ announced a second settlement related to the provision of unnecessary rehabilitation therapy services at nursing homes. A Tennessee-based provider of skilled nursing and rehabilitation services agreed to pay \$9.5 million to settle allegations that it knowingly submitted false claims to Medicare for rehabilitation therapy services that were not reasonable, necessary, or provided by appropriately skilled personnel, and that it forged pre?admission evaluations of patient need for skilled nursing services to Tennessee's Medicaid Program. The two relators who filed the case will receive approximately \$1.4 million and \$145,000, respectively, as their share of the recovery.
- On February 28, a pharmaceutical company agreed to pay nearly \$11.9 million to resolve allegations that it paid kickbacks to Medicare patients through a charitable foundation. The government alleged that the company violated the AKS and thus the FCA by making payments to the foundation for the purpose of using the foundation as a conduit to pay Medicare co-pay obligations of patients taking the company's drug. The company also entered into a Corporate Integrity Agreement with HHS-OIG that will require, among other things, reviews by an independent review organization and compliance-related certifications from the company's executives and Board of Directors.
- On March 17, a Pennsylvania doctor agreed to pay \$2.8 million under the FCA and the Controlled Substances Act, as well as in civil forfeiture, relating to alleged distribution to patients of non-medically necessary drugs for which he then submitted claims to federal health care programs.[8]
- On April 6, a New Jersey chiropractor agreed to pay \$2 million to resolve allegations that he billed federal health care programs for unnecessary injections and knee braces and accepted kickbacks. This resolution followed an agreement reached with seven former clinics and their owners, which we discussed in our 2019 Year-End Update.[9]
- On April 6, a Georgia-based biopharmaceutical company agreed to pay \$6.5 million to resolve claims that it charged inflated prices to the U.S. Department of Veterans Affairs for human tissue graft products.[10] The company allegedly misreported its commercial pricing, enabling the company to charge inflated prices to the government.
- On April 10, a rehabilitation services company agreed to pay more than \$4 million
 to resolve allegations that it caused three skilled nursing facilities to submit claims
 for reimbursement for unnecessary or inaccurately recorded time allegedly spent
 on rehabilitation services. The company also entered into a five-year Corporate
 Integrity Agreement that requires training, auditing, and monitoring relating to the
 conduct at issue.[11]
- On April 14, a rehabilitation company and related entities agreed to pay \$10 million to resolve similar allegations that the company submitted claims to Medicare for

- rehabilitation therapy services that were improperly labeled as being for "Ultra High"—or the neediest—patients.[12]
- On April 15, a lab company, an associated pain clinic, and two former executives agreed to pay \$41 million to resolve FCA allegations that they engaged in unnecessary urine drug testing.[13] According to the government, the defendants developed and implemented a practice of automatically ordering expensive and unnecessary testing, without any physician making an individualized determination that the tests were medically necessary for particular patients.
- On April 22, a non-profit hospital operator and affiliated physician group paid nearly \$10 million to resolve allegations that they had engaged in unlawful referral arrangements in violation of the Stark Law, AKS, and FCA.[14] The hospital operator proactively self-disclosed its violations of the FCA to the government and cooperated in the investigation.
- On April 27, a North Carolina-based laboratory agreed to pay \$43 million to resolve FCA allegations that the company submitted claims for tests that were not medically necessary and engaged in other improper billing and compensation methods.[15]
- On June 25, an Atlanta-based hospital system agreed to pay \$16 million to resolve FCA allegations that it inappropriately billed federal health care programs for more costly inpatient care, rather than for outpatient care.[16] The government alleged that case managers overturned the judgment of treating physicians and billed Medicare and Medicaid for inpatient care despite the physicians' recommendation that outpatient care was appropriate. The settlement also resolved allegations that the hospital system paid a commercially unreasonable sum to acquire a cardiology group in violation of the AKS.

B. Government Contracting

- On January 3, a university based in New Jersey agreed to pay more than \$4.8 million to resolve allegations that it submitted false claims for payment to the Department of Veterans Affairs to receive education benefits and funds pursuant to the Post-9/11 Veterans Education Assistance Act to which the university was not entitled. Three individuals previously pleaded guilty to related criminal charges.
- On January 31, two companies agreed to pay a collective \$29 million to resolve FCA allegations that they rigged bidding in an auction to acquire a U.S.
 Department of Energy Loan. The government alleged that the companies pressured competing bidders to suppress bids during a live auction, thereby reducing the amount recovered in the auction and allowing the companies to acquire the loan for less than its fair market value. The relators who filed the case will receive approximately \$5.2 million as their share of the recovery.[18]
- On February 6, the successor to a local redevelopment agency based in Los Angeles, California, agreed to pay \$3.1 million to resolve allegations that its predecessor violated the FCA by allegedly failing to comply with federal accessibility laws when it financed and helped develop affordable housing using federal funds. Since the events underlying the allegations, California has dissolved all redevelopment agencies, and the party to the settlement is working to wind down the affairs of its predecessor.[19]
- On April 27, a Massachusetts university agreed to pay more than \$1.3 million to resolve allegations of overcharging NIH grants.[20] The university self-disclosed concerns that one of its professors had overcharged NIH by overstating time and effort spent on statistical analysis support that the professor and her team provided to other professors on grant-related research.

II. LEGISLATIVE AND POLICY DEVELOPMENTS

A. COVID-19 Enforcement Policy

As we reported previously, DOJ has already confirmed that it will focus resources on COVID-19-related fraud. In a March 16 memorandum to all U.S. Attorneys and a March 20 press release, Attorney General William Barr announced that DOJ will prioritize the investigation and prosecution of coronavirus-related fraud schemes.[21] In addition, Attorney General Barr directed U.S. Attorneys to appoint a "Coronavirus Fraud Coordinator" in each district—responsible for coordinating enforcement and conducting public outreach and awareness—and also established a national system for whistleblowers to report suspected fraud.

Recent public remarks by DOJ Civil Division Principal Deputy Assistant Attorney General Ethan Davis—delivered in a June 28, 2020 speech—reaffirmed that the Civil Division's Fraud Section has prioritized FCA actions involving fraud relating to COVID-19.[22] These remarks highlighted, in particular, intent to focus scrutiny under the FCA on several aspects of the stimulus funding under the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"), such as in connection with certifications of compliance with loan program requirements.

And DOJ has already begun taking action against COVID-19 related fraud, as promised. In one instance, DOJ filed criminal healthcare fraud charges against an officer of a medical technology company alleging in part that the defendant paid unlawful kickbacks and bundled medically unnecessary COVID-19 testing with other services billed to the government and thereby allegedly caused submission of false claims that were kickbacktainted, medically unnecessary, and/or otherwise not provided as represented.[23] Although the case involves only criminal charges, the underlying health care fraud allegations regarding unlawful billing and alleged kickbacks are what would likely form core FCA issues in a civil fraud action, and may be an indicator of what is to come.

B. Federal Legislative Developments

1. COVID-19 Legislation

There also have been several federal legislative developments thus far in 2020 that may spur FCA enforcement activities for years to come. We have covered these developments in detail in updates throughout the COVID-19 crisis (available here and here), and we summarize the key provisions here for ease of reference.

The most notable legislation is the CARES Act. The CARES Act, which is the largest emergency stimulus package in history, devotes \$2.2 trillion worth of government funds to mitigate the effects of COVID-19.[24] 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, as well as economic stabilization programs to provide loans, loan guarantees, and funding for eligible industries, businesses, states, and municipalities.

DOJ has repeatedly signaled that it will devote significant resources to combating fraud related to COVID-19, including fraud involving CARES Act funds. [25] DOJ's efforts will be complemented by the CARES Act's creation of a new oversight committee called the Pandemic Response Accountability Committee ("PRAC") to promote transparency and oversight of CARES Act appropriated funds. [26] The Act's emergency appropriations included \$80 million for the PRAC, which will be comprised of various agency Inspectors General to "(1) prevent and detect fraud, waste, abuse, and mismanagement; and (2) mitigate major risks that cut across program and agency boundaries." [27]

2. Public Pronouncements Regarding DOJ's Dismissal Authority

As in the past several years, public debate has continued in the first half of 2020 regarding DOJ's use of its authority to dismiss FCA actions brought by *qui tam* relators. In a May 4, 2020 letter to Attorney General Barr, Senator Chuck Grassley (R-IA) stated that he could "confidently say," as "the original author" of the 1986 amendments to the FCA, that the text of the FCA subjects DOJ's dismissal decisions to judicial review.[28] As such, Senator Grassley stated, he "vehemently" disagreed with DOJ's view, contained in a brief the Solicitor General recently filed in the Supreme Court, that DOJ's dismissal decisions are "an unreviewable exercise of prosecutorial authority."[29] DOJ has increasingly moved to dismiss FCA cases since January 10, 2018, when Michael Granston, then Director of the Civil Fraud Section, issued guidance on when DOJ should exercise its dismissal authority, a development we have discussed in prior updates (available here and here). It remains to be seen whether Senator Grassley's letter will prompt any shift in DOJ's approach.

DOJ itself has continued to make its dismissal authority a focal point of the Department's public pronouncements. In January 2020, at the 2020 Advanced Forum on False Claims and Qui Tam Enforcement, then? Deputy Associate Attorney General Stephen Cox emphasized that the FCA continues to be one of DOJ's "most important tools" to fight health care, grant, financial, and government-contracting fraud.[30] He also discussed DOJ's 31 U.S.C. § 3730(c)(2)(A) dismissal authority, noting that "if we see a qui tam action raising frivolous or non-meritorious allegations that the Department of Justice disagrees with or could not make in good faith, we should not let a plaintiff try the case on behalf of the United States."[31] He further stated that DOJ's "exercise of this authority will remain judicious, but we will use this tool more consistently to preserve our resources for cases that are in the United States' interests and to rein in overreach in whistleblower litigation."[32] This may be a signal that DOJ will become more aggressive in exercising its dismissal authority. However, it is also worth noting that Cox was recently confirmed as U.S. Attorney for the Eastern District of Texas, and another senior DOJ official, Jody Hunt, resigned from his position as Assistant Attorney General for the Civil Division effective July 3. It remains unclear whether these changes in senior DOJ personnel will beget a shift in DOJ's approach to the exercise of its dismissal authority. We will continue to monitor and report on any such developments.

3. Final DOJ Rule Increasing Per-Claim Penalties

In late June, DOJ issued a final rule increasing FCA per?claim penalties for the first time since 2018.[33] DOJ is required by law to adjust penalties to keep pace with inflation, and this change effectuates that mandate. Under the new penalty framework, for FCA penalties assessed after June 19, 2020 (and applicable to violations occurring after November 2, 2015), the minimum per?claim penalty is now \$11,665 (up from \$11,181) and the maximum penalty is now \$23,331 (up from \$22,363).[34]

C. State Legislative Developments

We detailed HHS-OIG's review and approval of state false claims statutes and other developments in state laws in our <u>2019 Mid-Year FCA Update</u> and <u>2019 Year-End FCA Update</u>.

As an incentive for seeking HHS-OIG approval, states can receive "a 10-percentage-point increase in their share of any amounts" recovered under the relevant laws. [35] 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. [36] 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. [37] 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), while 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).[38]

Several states also have proposed false claims act legislation in the first half of 2020. In the District of Columbia, the D.C. Council is considering a bill that would amend 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."[39] The bill would authorize 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.[40] Because D.C.'s current false claims statute excludes tax?related claims from false claims liability, this bill, if passed, would represent a major policy shift.[41] The D.C. Council Committee of the Whole reported favorably on the bill on January 21, 2020, and recommended approval of the bill by the Council.[42]

The Pennsylvania legislature also is considering 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."[43] The bill would also require the Attorney General to make recommendations to state agencies on how to prevent false claims violations from occurring.[44] The new law would empower the Pennsylvania Office of the Attorney General to enforce its provisions, including via civil investigative demands.[45] The bill largely mirrors the federal FCA and was first referred to the House Human Services Committee on May 21, 2020.[46] As of this update, it is pending review by the House Rules Committee, as the Pennsylvania General Assembly continues its 2019-2020 session.[47]

We also reported in our 2019 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 <code>Escobar[48]</code>—of "the actual effect of the false record or statement when it is discovered."[49] 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.[50] 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.[51] The bill remains pending in the State Senate, which was scheduled to return from its summer recess on July 13 but on July 9 announced that the return would be delayed until July 27.[52] We will continue to monitor state legislation in these states and others for signs of further movement or revisions.

III. NOTABLE CASE LAW DEVELOPMENTS

The first half of 2020 saw a number of notable circuit court decisions, including several touching on the FCA's reach, exploring Rule 9(b)'s heightened pleading requirements, and addressing notable topics such as litigation funding arrangements.

A. Third and Ninth Circuits Hold That Differences in Clinical Judgments May Satisfy "Falsity" Element under the FCA

One key area of developing FCA jurisprudence in recent years has been whether and when differences in medical opinions may satisfy the falsity element of FCA liability. Last year, the Eleventh Circuit held in *United States v. AseraCare, Inc.* that claims cannot be "deemed false" under the FCA based solely on "a reasonable difference of opinion

among physicians" as to a medical provider's clinical judgment, although the court left open the door for FCA claims where there is a showing of facts "inconsistent with the proper exercise of a physician's clinical judgment." 938 F.3d 1278, 1293 (11th Cir. 2019). Earlier decisions by the Tenth and Sixth Circuits, on the other hand, suggested that a mere difference of medical opinion between physicians may be sufficient in certain circumstances to show that a statement is "false" for purposes of FCA liability. *United States ex rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730 (10th Cir. 2018); *United States v. Paulus*, 894 F.3d 267 (6th Cir. 2018).

The Third and Ninth Circuits entered the fray this year in a pair of similar decisions. First, the Third Circuit, in *United States ex rel. Druding v. Care Alternatives*, stated 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 (3d Cir. 2020). There, relators argued that defendants provided medically unnecessary hospice care to ineligible patients even though defendants maintained written certifications of necessity of care from a physician for each patient who was admitted to the hospice program. To prove the alleged "falsity" of the certifications, relators relied on expert testimony that the patients at issue did not, in fact, need hospice care—a conclusion disputed by defendants' own experts. *Id.* at 91. The district court granted summary judgment to the defendants; because there was no evidence that any physician had certified hospice treatment was appropriate for any patient that the physician actually "believed was not hospice eligible," the court reasoned that a mere disagreement among experts as to necessity of care could not establish that the admitting physicians' clinical judgments were false. *Id.*

On appeal, the Third Circuit reversed, faulting the district court for conflating the elements of falsity and scienter, and concluding that "falsity" *can* be shown by mere differences in medical judgments. The court explained that a claim based on a medical conclusion regarding a patient's care could be deemed "legally false,"—i.e., a claim that does not conform to certain regulatory requirements such as a requirement that any certification as to necessity of care be supported by a clinical diagnosis—and that in such circumstances, expert testimony would be relevant to determining falsity. *Id.* at 98.

Importantly, however, the Third Circuit recognized that the scienter element still serves as a "limit[to] the possibility . . . [of] expos[ure] to liability under the FCA any time the Government could find an expert who disagreed with the certifying physician's medical prognosis." *Id.* at 96. Thus, even showing that opinions are "false" cannot serve to establish FCA liability absent evidence "that Defendant's certifying doctor was making a *knowingly* false determination." *Id.*

The Ninth Circuit reached a similar conclusion 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 be sufficient to survive a motion to dismiss. 953 F.3d 1108, 1117 (9th Cir. 2020). In *Winter*, the relator (a nurse) alleged that the defendant, a hospital provider, had "falsely certif[ied] that patients' inpatient hospitalizations were medically necessary," based on the relator's opinion and on other evidence allegedly in the patients' medical files. *Id.* at 1112. The district court granted defendants' motion to dismiss, holding that because a relator "must show that a defendant knowingly made an 'objectively false' representation," "a doctor's clinical judgment cannot form the basis of an FCA suit" because "subjective medical opinions . . . cannot be proven to be objectively false." *Id.*

The Ninth Circuit reversed, holding that differences in opinion may satisfy the falsity element. Like the Third Circuit, the Ninth Circuit faulted the district court for conflating scienter and falsity. Citing *Druding* and relying on the statutory text, the court explained that medical judgements can be "false" under the statute's plain language, which does not "carve out an exception for clinical judgments and opinions." *Id.* at 1117. The court explained that an opinion as to medical necessity may be "false," for example, if the opinion is "dishonestly held" or is shown to be untrue by other evidence of a diagnosis in

accordance with "standards of medical practice." *Id.* The Ninth Circuit also disclaimed any conflict with the Eleventh Circuit's *AseraCare* opinion, which it read as recognizing that clinical judgments can be false in some circumstances.

The Ninth Circuit emphasized that "falsity is a necessary, but not sufficient, requirement for FCA liability"—and that "after alleging a false statement, a plaintiff must still establish scienter" (i.e., that it was made with the requisite intent) for the statement to be actionable under the FCA. *Id.* at 1118. The court also cautioned, however, that at least at the pleadings stage, scienter may be "alleged generally" under Rule 9(b) and that "specific intent" to defraud is not required under the FCA. *Id.*

The decisions in *Winter* and *Druding* suggest that in cases premised on allegations regarding medical necessity, courts—at least in certain circuits—may allow claims based upon differences in opinions to proceed on the "falsity" element, at least under certain circumstances; but other elements (such as scienter, and materiality) still provide strong defenses. Unfortunately, this may limit defendants' ability to secure dismissal of spurious suits at the pleading stage.

B. Fourth Circuit Rejects Qualified Immunity as a Defense to FCA Liability for Government Officials

When applicable, the doctrine of qualified immunity shields federal and state officials from damages for violating statutory or constitutional rights. The Fourth Circuit, in *United States ex rel. Citynet, LLC v. Gianato*, rejected qualified immunity as a defense to FCA claims under any circumstances. 962 F.3d 154, 160 (4th Cir. 2020). In *Citynet*, the relator alleged that certain state officials in West Virginia had defrauded the United States when obtaining federal funding to improve broadband connectivity for state residents. Defendants moved to dismiss based on qualified immunity, and although the district court deferred ruling on the merits of the defense, its decision nevertheless implicitly recognized that the doctrine "could [be] invoke[d] as a defense to claims of fraud brought under the FCA." *Id.* at 156.

In an interlocutory appeal, the Fourth Circuit reversed, concluding that qualified immunity "may not be invoked as a defense to liability under the FCA." As the court explained, the doctrine of qualified immunity is fundamentally "inconsistent" with "the FCA's scienter requirement," which is explicit that FCA liability "attaches only where a person has acted intentionally or recklessly." *Id.* at 159. Because qualified immunity protects a government official only when the official acts "reasonably, but mistakenly," and not when "acting intentionally or recklessly," qualified immunity does not apply in the FCA context. *Id.* The court also relied on policy concerns behind application of the doctrine—namely that it is intended to protect the public interest—in rejecting its application in cases where the United States is defrauded. *Id.*

C. Seventh Circuit on AKS Liability

The Seventh Circuit's recent ruling on what may constitute a "referral" subject to the AKS might have FCA implications. In *Stop Illinois Health Care Fraud, LLC v. Sayeed*, the relator alleged that in-home health care services providers and associated entities engaged in an illegal patient referral scheme. Under the alleged scheme, the provider purportedly purchased access to patient files from a non-profit senior care organization, in violation of the AKS and, by extension, the FCA. 957 F.3d 743, 745 (7th Cir. 2020). After a bench trial, the district court entered judgment for the defendants, concluding that there was no evidence that any remuneration was paid with the intent to induce "referrals." *Id.* at 745. Among other arguments, relator argued at trial that the provider had violated the AKS when it entered into a contract with the non-profit under which it paid a monthly fee that was "intended to secure access to client information" in the non-profit's files, which was then used by the provider to solicit business. *Id.*

On appeal, the Seventh Circuit held that the district court had not adequately addressed

whether this "file-access theory" of liability could "constitute a prohibited referral under the Anti-Kickback Statute." *Id.* at 746. The Seventh Circuit outlined that the term "referral" does not require "explicit direction of a patient to a provider" in a direct manner but rather, is to be understood as a "more inclusive" notion, to include "subtle" arrangements that involve even an "indirect means of connecting a patient with a provider." *Id.* The court recognized that where a provider allegedly has provided something of value in exchange for access to files with patient information and then used that information to solicit clients, this set of facts "would allow, but perhaps not compel, a finding that [the arrangement] qualifies as a referral." Ultimately, the Seventh Circuit remanded this "close question" for the district court to consider initially. *Id.*

The Seventh Circuit's description of what could potentially constitute a "referral" subject to the AKS, and, by turn, implicate the FCA if billed to the government, may invite further theories of AKS and FCA liability in this arena.

D. Courts Continue to Interpret the FCA's Materiality And Scienter Requirements Post-Escobar

Courts this year have continued to develop and refine jurisprudence regarding materiality, government knowledge, and scienter under the FCA in the wake the Supreme Court's landmark decision on the implied certification theory of liability in *Universal Health Services v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016). Consistent with the Supreme Court's directive in *Escobar*, courts have examined whether FCA plaintiffs have adequately alleged facts to satisfy the rigorous and demanding materiality standard at the pleadings stage.

Earlier this year, the Eleventh Circuit weighed in on both materiality and scienter—as well as a challenge to a relator's status based on a litigation funding agreement. In *Ruckh v. Salus Rehabilitation, LLC*, the relator alleged that a nursing home facility and related entities were misrepresenting the services they provided and also failed to comply with Medicaid requirements (e.g., by upcoding claims). No. 18-10500, --- F.3d ----, 2020 WL 3467393, at *4 (11th Cir. June 25, 2020). After a jury found the defendants liable for alleged FCA violations and awarded more than \$100 million in damages before trebling, the district court granted a motion to set aside the verdict, finding relators had failed to provide sufficient evidence of materiality and scienter at trial.

On appeal, the Eleventh Circuit reversed and reinstated the verdict in part. As to materiality, while the defendants argued that instances of "upcoding" and similar practices were "recordkeeping mistakes the FCA does not punish," the court held that "the jury was not required to believe the defendants' position" and reasonably could have found this an "implausible explanation." *Id.* at 12. As to scienter, despite the district court's observation there was no evidence of a "massive, authorized, cohesive, concerted, enduring, top-down corporate scheme," the court of appeals held that relator's evidence showing company management was allegedly aware of and approved the practices at issue supported the jury's finding that the defendants acted with scienter. *Id.* at 12-16.

The court upheld, however, a reduction of approximately \$20 million in the jury verdict relating to a subset of the claims at issue. Those claims stemmed from patient files that lacked care plans allegedly in violation of applicable regulations. *Id.* at 16. The Eleventh Circuit reasoned that there was "no evidence" that the government sought reimbursement for these violations once it was made aware of them; nor was there evidence it ever "declines payment for, or otherwise enforces these types of violations." *Id.* Moreover, the court held that *Escobar* compelled a finding in defendants' favor because there was no evidence linking the absence of care plans to any "specific representations regarding the services provided" as is required by the Supreme Court's opinion. *Id.* at 16-17.

On appeal, defendants sought to disqualify the relator based on a litigation financing agreement between the relator and a litigation funding entity that required the relator to

assign 4% of her interest in any potential recovery to the entity. Defendants argued that the arrangement violated the FCA. *Id.* at 7-9. The court rejected this argument, concluding that while the FCA "does not expressly authorize relators to reassign their right to represent the interests of the United States in *qui tam* actions" neither did it "proscribe[] such assignment." *Id.* at 9. The court reasoned that the FCA expressly "includes a number of restrictions, including on the conduct of *qui tam* actions and who may serve as a relator," and noted that prohibition on entry into a litigation funding agreement was not among those enumerated restrictions. On this basis, the court declined to "engraft[] any further limitations onto the statute." *Id.* at 12.

The Tenth Circuit also addressed the issue of materiality in *United States ex rel. Janssen v. Lawrence Memorial Hospital*, 949 F.3d 533 (10th Cir. 2020). There, the relator alleged a hospital violated the FCA by allegedly falsely certifying (1) the accuracy of data regarding patient arrival times required to be reported by Medicare and (2) compliance with a statutory requirement to provide FCA compliance information in an employee handbook. *Id.* at 546. The district court granted summary judgment to the defendants on materiality, finding there was no evidence that the alleged falsehoods influenced the government's payment decisions. *Id.*

The Tenth Circuit affirmed, explaining that *Escobar* requires materiality to be assessed by looking "to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation," rather than the objective behavior of a reasonable person. *Id.* at 541. In cases alleging regulatory noncompliance, this requires looking to whether the government refused to pay in past similar instances, whether the noncompliance is minor or insubstantial, and whether compliance with the regulations at issue is a condition of payment. *Id.*

In rejecting the theory that recording inaccurate patient arrival times was material, the court relied on the fact that CMS was made aware of the data issue in 2014 through detailed allegations from a former employee, and "has done nothing in response and continues to pay [the] Medicare claims." *Id.* at 542. The court also held that while there were "inaccuracies in [data] reporting" there were not "sufficiently widespread deficiencies" likely to affect the government's payment decision. Moreover, the court noted that imposing FCA liability would "undermine" the separate CMS administrative program intended to handle such noncompliance. *Id.* at 543. As to the allegedly noncompliant employee handbooks, the court found that these were "precisely the type of garden-variety compliance issues that the demanding materiality standards of the FCA are meant to forestall." *Id.* at 545. This issue, at best, was "limited" and did not represent a "wholesale failure" of the company's compliance function (noting the defendant provided FCA training elsewhere). *Id.* Moreover, as with the reporting issues, the relator failed to show any likely effect of the noncompliance on the government's payment decision. *Id.*

The *Janssen* opinion underscores that defendants can and should urge courts to rigorously enforce the FCA's materiality requirement, lest the FCA become the "general antifraud statute and tool for policing minor regulatory compliance issues" that *Escobar* warned against.

By contrast, in *United States ex rel. Drummond v. BestCare Laboratory Services, L.L.C.*, the Fifth Circuit rejected defendants' scienter and falsity challenges. 950 F.3d 277 (5th Cir. 2020). There, a competitor-relator alleged that a clinical testing laboratory obtained millions in reimbursement for miles that its technicians never traveled. *Id.* at 277. The government intervened and argued, in relevant part, that the defendants sought payment for mileage driven by technicians purportedly to collect samples that were, in reality, shipped, and that the defendant counted a single shipment of multiple samples as separate mileage for each sample. *Id.* at 280.

On appeal, defendants argued the reimbursement practices at issue were lawful, relying on sub?regulatory guidance in a CMS billing manual, or in the alternative, that there was a triable issue of fact as to scienter, because they had a "good faith" belief the practices

were lawful based on their interpretation of the manual. *Id.* at 281. The Fifth Circuit rebuffed both arguments. As to the first, the court concluded that even if defendants had complied with the CMS manual, any "sub-regulatory guidance" in the manual would at best be a "policy statement" that has "no binding legal effect." *Id.* at 281. As to scienter, the court held that the sub-regulatory guidance at issue—which expressly stated contractors could not bill "for miles not actually traveled by the laboratory technician"—made it clear there was "no way to read the Manual to suggest" defendants' practices of billing for miles "not actually traveled by anyone" were lawful. *Id.*

E. Fifth and Eighth Circuits Explore Rule 9(b)'s Particularity Requirements in Affirming Dismissal of FCA Claims

While the Supreme Court has rejected multiple petitions to clarify the interplay of Rule 9(b) and the FCA, circuit courts have grappled with precisely how to apply Rule 9(b)'s particularity requirement in FCA cases. Rule 9(b) heightens the pleading standard for fraud claims, stating that a party "must state with particularity the circumstances constituting fraud or mistake." Courts generally have recognized that an FCA plaintiff can satisfy Rule 9(b) either by pleading (1) representative examples of the false claims, or (2) the particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.

In *United States ex rel. Benaissa v. Trinity Health*, the Eighth Circuit addressed the contours of what constitutes "reliable indicia" sufficient to support a strong inference that claims were actually submitted. No. 19-1207, --- F.3d. ----, 2020 WL 3455795, at *4 (8th Cir. June 25, 2020). In *Trinity*, the relator—a trauma surgeon who operated at the defendants' regional hospital system—alleged that the defendants compensated five physicians for referrals in violation of the Stark Law and AKS, rather than for their skills or credentials. After the district court dismissed the claims under Rule 9(b), the relator argued on appeal that he had pleaded the particular details of a scheme paired with "reliable indicia" supporting an inference that claims were submitted. Specifically, relator pointed to his allegation that defendant derived nearly 30% of its annual revenue from Medicare reimbursements and it was likely that at least some of the claims submitted would be for services provided by those particular physicians. *Id.* at *3.

The Eighth Circuit disagreed, and affirmed dismissal under Rule 9(b), holding that the relator lacked "firsthand knowledge of [defendant's] billing practices" and had not pleaded any details about those billing indicating a reliable "basis for knowledge" that fraudulent claims were submitted, such as dates and descriptions of particular services coupled with "a description of the billing system that the records were likely entered into." *Id.* at *4. The court rejected the notion that its ruling constricts would-be relators to a narrow class of only those "members of the billing department or the financial services department of a hospital." *Id.* Acknowledging that such "an insider might have an easier time obtaining information about billing practices," the court observed that it and other courts have held many other types of individuals can serve as relators—including physicians, EMTs, and nurse practitioners—so long as they plead "particular and reliable indicia that false bills were actually submitted as a result of the scheme"—such as "dates that services were fraudulently provided or recorded," and "by whom." *Id.*

The Eighth Circuit's decision makes clear that mere generalized allegations—e.g., that a company is in receipt of a large amount of Medicare reimbursement and that every submitted claim by that company relating to certain physicians was false or fraudulent—do not satisfy Rule 9(b).

In *United States ex rel. Integra Med Analytics, L.L.C. v. Baylor Scott & White Health*, the Fifth Circuit explored whether and when statistical evidence can satisfy pleading requirements in an FCA case. No. 19-50818, --- Fed. App'x ----, 2020 WL 2787652, at *4 (5th Cir. May 28, 2020). There, the relator alleged that a short-term care hospital system and its affiliates billed Medicare for medically unnecessary treatments and engaged in

upcoding. The latter theory relied primarily on allegations regarding a statistical analysis of inpatient claims data that purportedly showed that the defendant coded for certain conditions at a higher rate than other hospitals, as well as alleged statements by a former employee that he was directed to fraudulently bill. *Id.* at *1-2. The Fifth Circuit affirmed the district court's dismissal, holding that the allegations failed to satisfy either the plausibility requirement of Rule 8(a) or the particularity requirement of Rule 9(b). *Id.* at *4.

The court held that the relator's "statistical analysis" did not satisfy either Rule 8(a)'s or Rule 9(b)'s pleading requirements, alone or in conjunction with other allegations. The court explained that the same statistical data showed that the rate of coding for the same procedures by other hospitals increased every year until the average was "within a few percentage points" of the defendants, which was due to an industry wide trend resulting from CMS guidance encouraging hospitals to "tak[e] full advantage of coding opportunities to maximize" Medicare payments as long as supported by documentation in the medical record. *Id.* at *3-4. Thus, the court held, while defendant's higher than average billing rates were "consistent with" the submission of "fraudulent Medicare reimbursement claims to the government," they were also consistent with the defendant simply "being ahead of most [other] healthcare providers in following new guidelines from CMS." *Id.* at *3. The Fifth Circuit held that the relator's allegations regarding medically unnecessary treatments and statements by former coding employees all failed to satisfy Rule 9(b) because the allegations were conclusory and "fail[ed] to state the content of" any allegedly fraudulent directives or guidance. *Id.* at *5.

The Fifth Circuit cautioned that its "conclusion does not exclude statistical data from being used to meet the pleading requirements of Federal Rule of Civil Procedure 8(a) and, when paired with particular details, Rule 9(b)." *Id.* at *4.

F. First and Sixth Circuits Explore Application of the Public Disclosure Bar and Original Source Exception

The FCA's public disclosure bar requires dismissal of an FCA case "if substantially the same allegations or transactions" forming the basis of the action have been publicly disclosed, including "in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party," unless the relator is an "original source of the information." 31 U.S.C. § 3730(e)(4).

In *United States ex rel. Holloway v. Heartland Hospice, Inc.*, the Sixth Circuit unanimously held that relators are "agents" of the government for purposes of the above language of the public disclosure bar, such that disclosure to a relator in a federal civil case may trigger the bar. The court therefore affirmed the district court's dismissal of a case alleging substantially the same scheme as three prior *qui tam* suits involving the defendant's parent company. 960 F.3d 836 (6th Cir. 2020). In that case, the relator—a former consultant for Heartland—alleged that the defendants certified patients as eligible for hospice under Medicare regulations even when the patients were not terminally ill, thereby "leech[ing] millions of dollars from the federal government in payments for unnecessary hospice care." *Id.* at 839.

The court rejected three of the four categories of potential public disclosures identified by the defendant. *Id.* at 841. It explained that a DOJ settlement of FCA claims and a *qui tam* complaint filed against other entities, both of which involved similar schemes, did not constitute public disclosures because courts do not infer industry-wide disclosure from allegations against a particular company. The court also concluded that a report by HHS-OIG finding that 4% of claims "did not meet certification of terminal illness requirements" did not constitute a prior disclosure because the report contained "no insinuation of fraud, but at most noncompliance." *Id.* at 844.

But the Sixth Circuit concluded that three *qui tam* complaints filed against defendants' parent company and related entities triggered the public disclosure bar. The court rejected

the relator's contention that these cases were not "public" because the government did not intervene. As the Sixth Circuit observed, a *qui tam* relator is the government's agent for purposes of the public disclosure bar because the government is the real party in interest and exerts a fair amount of control over *qui tam* litigation. Further, the complaints "disclosed" the fraud alleged in the complaint because they "depict[ed] essentially the same scheme."

In *United States ex rel. Banigan v. PharMerica Inc.*, meanwhile, the First Circuit clarified the meaning of the term "original source." 950 F.3d 134 (1st Cir. 2020). There, the plaintiffs alleged that the defendant, one of the largest long-term care pharmacy companies in the United States, provided kickbacks to incentivize nursing homes to switch residents' prescriptions from other manufacturers' drugs to its own antidepressants. The purported kickbacks included contractual discounts, rebates, and bonuses. The district court dismissed the case, applying the public disclosure bar.

But the First Circuit reversed. Although the circuit court agreed with the district court that an earlier FCA action involving the same scheme triggered the public disclosure bar, it concluded that the relator was an "original source of the information," and that dismissal was therefore inappropriate. *Id.* at 137.

As the circuit court explained, under the version of the public disclosure bar in effect prior to the 2010 amendments to the FCA, an "original source" must have both direct and independent knowledge of the information on which his allegations are based. *Id.* at 136 n.1, 138. The First Circuit rejected the argument that the relator's knowledge was not "direct" because he had learned about the scheme from others, through email and word of mouth, rather than being someone who had participated in or observed the scheme in operation directly. The court also held that the relator could still qualify as an original source, despite first learning of the scheme only as it was winding down. *Id.* at 140. Focusing on the statutory text, the court stated that the statute requires direct and independent knowledge only of the *information* on which allegations are based, not direct and independent knowledge of the fraudulent acts themselves. Similarly, the court rejected any requirement that an original source have contemporaneous knowledge of the fraud. According to the court, that position lacks textual support, and such a requirement would discourage reports of fraud. *Id.*

IV. CONCLUSION

We will monitor these developments, along with other FCA legislative activity, settlements, and jurisprudence throughout the year and report back in our 2020 False Claims Act Year-End Update, which we will publish in January 2021.

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- [8] See Press Release, U.S. Atty's Office for the Eastern Dist. of PA, Doctor Who Pleaded Guilty to Health Care Fraud for "Goodie Bags" Agrees to Resolve Civil Fraud and Controlled Substance Liability for \$2.8 Million (Mar. 17, 2020), https://www.justice.gov/usao-edpa/pr/doctor-who-pleaded-guilty-health-care-fraud-goodie-bags-agrees-resolve-civil-fraud-and.
- [9] See Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, New Jersey Chiropractor Agrees to Pay \$2 Million to Resolve Allegations of Unnecessary Knee Injections and Knee Braces and Related Kickbacks (Apr. 6, 2020), https://www.justice.gov/opa/pr/new-jersey-chiropractor-agrees-pay-2-million-resolve-allegations-unnecessary-knee-injections.
- [10] See Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, MiMedx Group Inc. Agrees to Pay \$6.5 Million to Resolve False Claims Act Allegations of False Commercial Pricing Disclosures (Apr. 6, 2020), https://www.justice.gov/opa/pr/mimedx-group-inc-agrees-pay-65-million-resolve-false-claims-act-allegations-false-commercial.
- [11] See Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Contract Rehab Provider to Pay \$4 Million to Resolve False Claims Act Allegations Relating to the Provision of Medically Unnecessary Rehabilitation Therapy Services (Apr. 10, 2020), https://www.justice.gov/opa/pr/contract-rehab-provider-pay-4-million-resolve-false-claims-act-allegations-relating-provision.
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- [21] U.S. Dep't of Justice, Memorandum from Attorney General William P. Barr (Mar. 16, 2020), https://www.justice.gov/ag/page/file/1258676/download; Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Attorney General William P. Barr Urges American Public to Report COVID-19 Fraud (Mar. 20, 2020), https://www.justice.gov/opa/pr/attorney-general-william-p-barr-urges-american-public-report-covid-19-fraud.
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- [25] See, e.g., U.S. Dep't of Justice, Memorandum from Attorney General William P. Barr (Mar. 16, 2020), https://www.justice.gov/ag/page/file/1258676/download.
- [26] See Gibson, Dunn & Crutcher LLP, Senate Advances the CARES Act, the Largest Stimulus Package in History, to Stabilize the Economic Sector During the Coronavirus Pandemic (Mar. 26, 2020) ("CARES Alert"), https://www.gibsondunn.com/senate-advances-the-cares-act-to-stabilize-economic-sector-during-coronavirus-pandemic/.

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[31] Id.
[32] Id.
[33] 85 Fed. Reg. 37004 (June 19, 2020).
[34] Id. at 37006.
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[37] Id.
[38] Id.
[39] DC B23-0035, 23d Council (2019-2020),
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[40] See D.C. Code § 2-381.02(a) (2013).
[41] See D.C. Code § 2-381.02(d) (2013) (stating that "[t]his section shall not apply to
claims, records, or statements made pursuant to those portions of Title 47 of the District of
Columbia Official Code that refer or relate to taxation").
[42] See Council of the District of Columbia, Committee of the Whole Committee Report
on Bill 23-35, "False Claims Act of
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http://chairmanmendelson.com/wp-content/uploads/2020/01/B23-35-False-Claims-
Committee-Packet.pdf.
[43] See HB 2352 Pennsylvania General Assembly Bill Information (2019-2020), here.
[44] Id.
[45] Id.
[46] Id.
[47] Id.
[48] Universal Health Servs. v. United States ex rel. Escobar, 136 S. Ct. 1989, 2002
(2016).
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[49] See AB-1270 False Claims Act, California Legislative Information (2019-2020), https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201920200AB1270.

[50] Id.

[51] See AB-2570 False Claims Act, California Legislative Information (2019-2020) http://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201920200AB2570.

[52] Id.; see also Patrick McGreevy, California legislators delay return to Capitol as a lawmaker is hospitalized with COVID-19, L.A. Times (July 8, 2020), here.

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