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2019 MID-YEAR FALSE CLAIMS ACT UPDATE

To Our Clients and Friends:

As we progress through the Trump Administration's third year, robust False Claims Act ("FCA") enforcement continues. At the same time, the Administration has continued to signal a greater openness to tempering overly aggressive FCA theories. In the past six months, the Department of Justice ("DOJ") issued long-awaited guidance about cooperation credit in FCA cases and also continued to seek dismissal of some declined cases pursued by whistleblowers (albeit with mixed success). Aside from these efforts, however, DOJ has not evidently relaxed its approach to enforcement: the first half of the year saw DOJ announce recoveries of nearly three-quarters of a billion dollars in settlements, largely from entities in the health care and life sciences industries.

The next year should provide insight as to whether the Administration's policy refinements are the vanguard of a more meaningful shift by DOJ away from its historical enforcement efforts. But even if that were the case, enterprising relators and aggressive state enforcers may end up filling any gaps. In just the past half year, several states took steps to enact or strengthen existing FCA statutes.

Regardless of what direction DOJ and the Trump Administration head, federal courts' FCA decisions from the last six months serve as a reminder that FCA litigation remains hard-fought, given the enormous stakes. At the highest level, the U.S. Supreme Court weighed in on the FCA again this year, resolving a circuit split about the FCA's statute of limitation in favor of whistleblowers. This marked the third time in four years the land's highest court interpreted the FCA. Meanwhile, lower courts also remained active in FCA jurisprudence, issuing a number of notable opinions that we have summarized herein.

Below, we begin by addressing enforcement activity at the federal and state levels, turn to legislative developments, and then analyze significant court decisions from the past six months. As always, 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 2019

DOJ has announced more than $750 million in settlements this year, a slight uptick from this point in 2018, but somewhat down from half-year highs set in recent years. The dollar totals tell only part of the story, however, as neither DOJ nor *qui tam* relators have scaled back FCA investigations or whistleblower complaints considerably.

As in recent years, DOJ secured the lion's share of its FCA recoveries from enforcement actions involving health care and life sciences entities. Although DOJ's recoveries came from cases reflecting a wide variety of theories of FCA liability, cases involving alleged violations of the Anti-Kickback Statute ("AKS") and the Stark Law, which generally prohibit various types of remunerative arrangements with referring health care providers, continued to predominate. This year, DOJ's AKS enforcement activity includes several large recoveries, totaling nearly $250 million, from pharmaceutical companies accused of unlawfully covering Medicare copays for their own products through charitable foundations. Further, DOJ backed up its statements regarding its plans to combat the opioid epidemic as it recovered more than $200 million from an opioid manufacturer accused of paying kickbacks.

Below, we summarize these and some of the other most notable settlements thus far in 2019.

A. Health Care and Life Science Industries

- On January 28, a hospital and six of its owners agreed to pay the federal government $8.1 million to settle claims that it violated the FCA by submitting false claims to Medicare and Medicaid programs in violation of the AKS and Stark Law. DOJ alleged that the hospital, its subsidiary, and at least two affiliates recruited a medical director in order to secure his referrals of patients by offering the physician compensation that exceeded fair market value for his services. The whistleblower will receive $1.6 million from the federal government.[1]

- On January 30, a pathology laboratory agreed to pay $63.5 million to settle allegations that it violated the FCA by engaging in improper financial relationships with referring physicians. The settlement resolves allegations that the company violated the AKS and the Stark Law by providing subsidies to referring physicians for electronic health records ("EHR") systems and free or discounted technology consulting services. The allegations stem from three whistleblower lawsuits, and the whistleblowers' share of the settlement had not been determined at the time the settlement was announced.[2]

- On February 6, a Florida-based developer of EHR software agreed to pay $57.25 million to resolve allegations that it caused its users to submit false claims to the government by (1) misrepresenting the capabilities of its EHR product (thereby enabling them to seek meaningful use incentive payments) and (2) violating the AKS (by financially incentivizing its client health care providers to recommend its product to prospective customers).[3]

- On February 6, a Georgia-based hospital agreed to pay $5 million to resolve allegations that it violated the FCA by engaging in improper financial relationships with referring physicians between 2012 and 2016. DOJ alleged that the hospital compensated the physicians in amounts that were above fair market value or in a manner that took into account the volume or value of the physicians' referrals.[4]

- On February 27, a Tennessee-based health care company and its related companies agreed to pay more than $18 million to resolve a lawsuit brought by DOJ and Tennessee alleging they billed the Medicare and Medicaid programs for substandard nursing home services. The settlement also resolves claims brought by DOJ against the company's majority owners and CEO, as well as the LLC's former director of operations, who agreed to pay $250,000 toward the settlement.[5]

- On March 11, a medical technology company agreed to pay more than $17.4 million to resolve allegations that it violated the FCA by providing free or discounted practice development and market development support, allegedly amounting to "in-kind" payments to induce physicians in California and Florida to purchase the company's ablation products. Under the settlement, the company also will pay approximately $1.4 million to California and approximately $1.0 million to Florida for claims paid for by the states' Medicaid programs. The two whistleblowers, former company employees, will receive approximately $3.1 million as their share of the federal recovery.[6]

- On March 21, a Maryland-based health care company and its affiliates agreed to pay $35 million to settle allegations under the FCA that it paid kickbacks to a Maryland cardiology group in exchange for referrals, through a series of contracts with two Maryland hospitals. The settlement resolved two whistleblower lawsuits brought by cardiac surgeons and former patients, who alleged that the company and its affiliates performed medically unnecessary cardiac procedures for which they submitted false claims to Medicare. The whistleblowers' share had not been disclosed yet.[7]

- In April, several pharmaceutical companies reached settlements with DOJ over allegations involving charitable funds. For example:

  - As part of a string of investigations by the U.S. Attorney's Office for the District of Massachusetts, three pharmaceutical companies agreed to pay a total of $122.6 million to resolve allegations that they violated the FCA by illegally paying the Medicare or Civilian Health and Medical Program copays for their own products through purportedly independent foundations that were allegedly used as mere conduits. The government contended that the companies' payments of the copays were kickbacks aimed at inducing patients to use the companies' drugs. In all three matters, the government alleged that the foundations were used to generate revenues from prescriptions for patients who would have otherwise been eligible for the companies' free drug programs. One company agreed to pay $57 million; the second company agreed to pay $52.6 million, and the third company agreed to pay $13 million.[8]

  - On April 30, a Kentucky-based pharmaceutical company agreed to pay $17.5 million to resolve allegations that it violated the FCA and AKS by paying kickbacks to patients and physicians to induce prescriptions of two of its drugs. DOJ alleged that the company increased the drugs' prices in January 2012, which increased Medicare patients' copays. Then, DOJ asserted, the company paid these patients' copays through a third-party Parkinson's Disease fund, thereby providing illegal inducements to patients to purchase the drugs. The allegations underlying the settlement were originally raised by whistleblowers, who will receive $3.15 million as their share of the recovery.[9]

- On April 12, a California-based health care services provider and several affiliated entities agreed to pay $30 million to resolve allegations that the affiliated entities submitted false information about the health status of beneficiaries enrolled in Medicare Advantage plans, which purportedly resulted in overpayments to the provider.[10]

- On May 6, a West Virginia-based health care company agreed to pay $17 million to resolve allegations of a billing scheme that allegedly defrauded Medicaid of $8.5 million. This represented the largest health care fraud settlement in the history of West Virginia, and the state will collect $2.2 million from the settlement. DOJ alleged that the company, acting through a subsidiary and several of its drug treatment centers, sent blood and urine samples to outside laboratories for testing, and then submitted reimbursement claims to West Virginia Medicaid as if the treatment centers had performed the tests themselves. According to the government, since the company paid the outside laboratories a lower rate than its requested reimbursement to Medicaid, the company wrongfully collected $8.5 million.[11]

- On May 30, a Kansas-based cardiologist agreed to pay $5.8 million to resolve allegations that he and his medical group violated the FCA by improperly billing federal health care programs for medically unnecessary cardiac stent procedures. This marked the DOJ's third False Claims settlement with the cardiologist and his medical group, who concurrently agreed with U.S. Department of Health and Human Services ("HHS") to be excluded from participation in federal health programs for three years. The settlement announcement resolves allegations in a whistleblower lawsuit filed by another cardiologist, who will receive approximately $1.16 million from the settlement.[12]

- On May 31, a New Jersey-based pharmaceutical company was charged under the Sherman Act for conspiring with competitors to fix prices, rig bids, and allocate customers. In a separate civil resolution, the company agreed to pay $7.1 million to resolve allegations under the FCA related to the alleged price fixing conspiracy. DOJ asserted that between 2012 and 2015, the company paid and received remuneration through arrangements on price, supply, and allocation of customers with other pharmaceutical manufacturers for certain generic drugs, in violation of the AKS, and that its sale of such drugs resulted in claims submitted to or purchases by federal health care programs.[13]

- On June 5, an opioid manufacturing company agreed to a $225 million global resolution to settle the government's criminal and civil investigations. DOJ alleged that the company paid kickbacks and engaged in other unlawful marketing practices to induce physicians and nurse practitioners to prescribe its opioid to patients. As part of the criminal resolution, the company entered into a deferred prosecution agreement with the government, and its subsidiary pleaded guilty to five counts of mail fraud. The company also agreed to pay a $2 million criminal fine and a $28 million forfeiture. As part of the civil resolution, the company agreed to pay $195 million. The allegations stem from five whistleblower lawsuits, and the whistleblowers' share of the settlement has yet to be determined.[14]

- On June 30, the nation's largest operator of inpatient rehabilitation centers agreed to pay $48 million to resolve allegations that its centers provided medically unnecessary treatment, and also submitted false information to Medicare to achieve higher levels of reimbursement. The settlement involved allegations across multiple facilities and was part of DOJ's broader efforts to target inpatient treatment facilities nationally.

B. Government Contracting

- On January 28, a corporation that provides information and technology services agreed to pay $5.2 million to resolve allegations that it violated the FCA by falsely billing labor under its contract with the United States Postal Service ("USPS"). Under the contract, the company would bill the USPS for personnel performing services at rates established by certain billing categories. DOJ alleged that the corporation knowingly billed the USPS for certain personnel services at higher category rates, even though the personnel did not have the education and/or experience to be in these categories.[15]

- On March 25, a private university in North Carolina agreed to pay the government $112.5 million to resolve allegations that it violated the FCA by submitting applications and progress reports that contained purportedly falsified research on federal grants to the National Institutes of Health ("NIH") and to the Environmental Protection Agency. Among other allegations, DOJ asserted that the university fabricated research results related to mice to claim millions of grant dollars from the NIH. The allegations stem from a whistleblower lawsuit brought by a former university employee, who will receive $33.75 million from the settlement.[16]

- On May 13, a California-based software development company agreed to pay $21.57 million to resolve allegations that it caused the government to be overcharged by providing misleading information about its commercial sales practices, which was then used in General Services Administration ("GSA") contract negotiations. DOJ alleged that the company knowingly provided false information concerning its commercial discounting practices for its products and services to resellers. These resellers then allegedly used that information in negotiations with GSA for government-wide contracts. DOJ alleged this caused GSA to agree to less favorable pricing, which led the government purchasers to be overcharged. The allegations stemmed from a whistleblower lawsuit filed by a former company employee, who will receive over $4.3 million from the resolution.[17]

II. LEGISLATIVE AND POLICY DEVELOPMENTS

A. Federal Developments

1. Guidance Regarding Cooperation Credit

The first half of 2019 did not witness major legislative developments at the federal level pertaining to the FCA. But DOJ has advanced its recent efforts to more publicly and transparently articulate its approach to FCA cases, as evidenced by the May 2019 release of long-awaited guidance regarding cooperation credit in FCA investigations.[18] We covered this development in detail in our May 14, 2019 alert entitled "Cooperation Credit in False Claims Act Cases: Opportunities and Limitations in DOJ's New Guidance." Several key points regarding the guidance bear mention here.

The guidance is the latest chapter in a broader effort by DOJ to scale back the "all or nothing" approach to cooperation credit set forth in the 2015 Yates Memorandum. This initiative stems from a belief that that approach, in the words of former Deputy Attorney General Rod J. Rosenstein, had been "counterproductive in civil cases" because it deprived DOJ attorneys of the "flexibility" they needed "to accept settlements that remedy the harm and deter future violations."[19] In keeping with Mr. Rosenstein's statements, the new DOJ guidance—codified at Section 4-4.112 of the Justice Manual[20]—provides that defendants may receive varying levels of cooperation credit depending on their efforts across ten non-exhaustive categories of cooperation.[21] These include:

- "[i]dentifying individuals substantially involved in or responsible for the misconduct";
- making individuals available who have "relevant information";
- "[a]dmitting liability or accepting responsibility for the relevant conduct"; and
- "[a]ssisting in the determination or recovery" of losses.[22]

The guidance also notes that cooperation must have value for DOJ, as measured by the "timeliness and voluntariness" of the cooperation, the "truthfulness, completeness, and reliability" of the information provided, the "nature and extent" of the cooperation, and the "significance and usefulness of the cooperation" to DOJ. Under the guidance, DOJ's determination of cooperation credit will consider remediation undertaken by the defendant, including remediation focused on root causes and discipline of relevant individuals.[23]

The guidance states that to receive full credit, entities should "undertake a timely self-disclosure that includes identifying all individuals substantially involved in or responsible for the misconduct, provide full cooperation with the government's investigation, and take remedial steps designed to prevent and detect similar wrongdoing in the future."[24] Unlike DOJ's guidance regarding cooperation in criminal cases, the new FCA guidance does not provide for percentage reductions in penalties (or damages) for various levels of cooperation. Instead, the guidance focuses on DOJ's "discretion . . . [to] reduc[e] the penalties or damages multiple sought by the Department," and provides that no defendant may receive cooperation credit so great as to result in the payment of an amount less than single damages (including relator's share, plus lost interest and costs of investigation).[25]

The new guidance provides a measure of clarity regarding DOJ's overall approach to cooperation credit, and the flexible standards the guidance sets forth provide opportunities for defendants to formulate creative negotiation and litigation strategies. On the other hand, the guidance lacks specificity regarding several critical issues (e.g., what constitutes cooperation and how to assess the value that cooperation provides to DOJ).

2. Application of the Granston Memorandum

As we have previously discussed, DOJ signaled last year that it will increasingly consider moving to dismiss some FCA *qui tam* actions. Specifically, in January 2018, Michael Granston, the Director of the Fraud Section of DOJ's Civil Division, issued a memorandum (the "Granston Memo") stating that "when evaluating a recommendation to decline intervention in a *qui tam* action, attorneys should also consider whether the government's interests are served, in addition, by seeking dismissal pursuant to section 3730(c)(2)(A)."[26]

The Granston Memo established a list of non-exhaustive factors for DOJ to evaluate when considering whether to dismiss a case under section 3730(c)(2)(A), which states that the government may dismiss an FCA "action notwithstanding the objections of the person initiating the action if the person has been notified by the Government of the filing of the motion and the court has provided the person with an opportunity for a hearing on the motion."[27] The Granston Memo's release prompted cautious optimism among FCA observers that DOJ would step in to dismiss unmeritorious cases, but the Memo also left many open questions regarding exactly how DOJ would exercise its discretion.

Since the Memo's release, FCA defendants routinely have pushed DOJ to dismiss cases, and in some cases, DOJ has done just that. But a little more than a year after the Memo's release, there are signs that DOJ is continuing to calibrate its approach, in response both to defendants' insistent entreaties and scrutiny by the courts (which must approve any dismissal).

First, the memorandum's namesake, DOJ Civil Fraud Section Director Michael Granston, recently elaborated on how DOJ will apply the Granston Memo's principles. In remarks at the Federal Bar Association's FCA Conference in March, Mr. Granston explained that DOJ will not be persuaded to dismiss *qui tam* actions "[j]ust because a case may impose substantial discovery obligations on the government."[28] The decision to seek dismissal, he said, will instead be evaluated on a case-by-case basis, with the cost-benefit analysis focusing on the likelihood that the relator can prove the allegations brought on behalf of the government.[29] Mr. Granston cautioned that defendants "should be on notice that pursuing undue or excessive discovery will not constitute a successful strategy for getting the government to exercise its dismissal authority," and that "[t]he government has, and will use, other mechanisms for responding to such discovery tactics."[30] Overall, Mr. Granston stated, "dismissal will remain the exception rather than the rule."[31]

Second, Deputy Associate Attorney General Stephen Cox delivered remarks at the 2019 American Conference Institute's Advanced Forum on False Claims and *Qui Tam* Enforcement that explained DOJ's approach to dismissals.[32] Regarding the Granston Memo, Mr. Cox characterized the relationship between *qui tam* relators and the government as a "partnership," formed on the belief that relators "are often uniquely situated to bring fraudulent practices to light."[33] He emphasized, however, that DOJ plays a "gatekeeping role" in ensuring that when a relator prosecutes a non-intervened FCA case, it does not do so in a way that harms the government's financial interests or creates bad law for the government.[34] Mr. Cox stated that the Granston Memo "is not really a change in the Department's historical position," but he acknowledged that DOJ's use of its dismissal authority has increased since 2017.[35] Mr. Cox told listeners that while DOJ "will remain judicious," it "will use this tool more consistently to preserve our resources for cases that are in the United States' interests."[36] In more recent remarks, Mr. Cox has added that DOJ's "more consistent[]" use of its dismissal authority will aim at "reign[ing] in overreach in whistleblower litigation."[37]

With DOJ's increased use of its statutory dismissal authority has come greater judicial scrutiny of the scope of that authority and the standards to be applied in determining whether dismissal is appropriate. In the wake of the Granston Memo, lower courts have been forced to analyze the standard that courts should apply when the government moves to dismiss *qui tam* cases. These cases have pitted two competing standards against each other, with mixed results.

Previously, in *United States ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp.*, 151 F.3d 1139 (9th Cir. 1998), the Ninth Circuit held that the government's dismissal is first examined for: (1) an identification of a valid government purpose by the government; and (2) a rational relation between the dismissal and accomplishment of the government's purpose. *Id.* at 1145. If the government's dismissal meets the two-step test, the burden shifts to the relator to show that the "dismissal is fraudulent, arbitrary and capricious, or illegal." *Id*. (quoting *United States ex rel. Sequoia Orange Co. v. Sunland Packing House Co.*, 912 F. Supp. 1325, 1353 (E.D. Cal. 1995)). The Tenth Circuit adopted the *Sequoia* standard and also applies the above test. *Ridenour v. Kaiser-Hill Co.*, 397 F.3d 925, 936, 940 (10th Cir. 2005).

In contrast, in *Swift v. United States*, 318 F.3d 250, 253 (D.C. Cir. 2003), the D.C. Circuit rejected the Ninth Circuit's *Sequoia* standard, holding that nothing in section 3730(c)(2)(A) "purports to deprive the Executive Branch of its historical prerogative to decide which cases should go forward in the name of the United States." The court observed that the purpose of the hearing provided for in section 3730(c)(2)(A) "is simply to give the relator a formal opportunity to convince the government not to end the case." *Id.* Therefore, the D.C. Circuit held that the government has "an unfettered right to dismiss" FCA actions, and so government dismissals are basically "unreviewable" (with a possible exception for dismissals constituting "fraud on the court"). *Id.* at 252-53.

However, the remainder of the federal circuit courts have not weighed in on the standard for government dismissals of *qui tam* actions thus far. In the meantime, several district courts have confronted this issue, with some following *Sequoia*, while others followed *Swift*. Among the courts following *Sequoia* were the following:

- In *United States v. EMD Serono, Inc.*, 370 F. Supp. 3d 483 (E.D. Pa. 2019), the U.S. District Court for the Eastern District of Pennsylvania adopted the Ninth Circuit's *Sequoia* standard after critiquing the D.C. Circuit's approach in *Swift*. The court then held that the government's dismissal had met the *Sequoia* standard because the government had "articulated a legitimate interest" when it argued that the "allegations lack merit, and continuing to monitor, investigate, and prosecute the case will be too costly and contrary to the public interest." at 489. *Id*. at 489.
- In *United States ex rel. CIMZNHCA, LLC v. UCB, Inc.*, No. 17-CV-765-SMY-MAB, 2019 WL 1598109 (S.D. Ill. Apr. 15, 2019), the U.S. District Court for the Southern District of Illinois adopted the Ninth Circuit's *Sequoia* standard and rejected the D.C. Circuit's approach in *Swift*. Applying the *Sequoia* standard, the court found that the government's "decision to dismiss this

action is arbitrary and capricious, and as such, not rationally related to a valid governmental purpose." *Id*. at *4. Although the government had identified a valid interest of avoiding litigation costs, the court found the government had failed to conduct the requisite "minimally adequate investigation" because it collectively investigated the eleven claims that the relator's group filed without specifically investigating the relator's claim against the defendants in this case. *Id.* at *3.

Other district courts have been persuaded by *Swift's* "unfettered" dismissal standard.

- In *United States ex rel. Davis v. Hennepin County*, No. 18-CV-01551 (ECT/HB), 2019 WL 608848 (D. Minn. Feb. 13, 2019), the U.S. District Court for the District of Minnesota stated that the *Swift* standard was more consistent with section 3730(c)(2)(A)'s text and with the Constitution, but did not decide the issue because the government was entitled to dismissal under both the *Swift* and *Sequoia* standards. According to the court, the government could dismiss because "the Relators were notified of the motion and received the opportunity for a hearing." *Id.* at *7. However, the court then observed that the government would still be entitled to dismissal even under *Sequoia*. *Id.* The court credited the government's rationale of avoiding the cost and burden of a case that would likely result in no recovery, and also noted that the relators had put forth no factual evidence that the government was acting capriciously by ignoring evidence. *Id.*

- In *United States ex rel. Sibley v. Delta Reg'l Med. Ctr.*, No. 17-CV-000053-GHDRP, 2019 WL 1305069 (N.D. Miss. Mar. 21, 2019), the U.S. District Court for the Northern District of Mississippi indicated its agreement with the *Swift* standard, but then observed that the government was entitled to dismissal under either standard. There, the government declined to intervene, then moved to dismiss her action, arguing that the action would interfere with the government's efforts to enforce the Emergency Medical Treatment Act, would use scarce government resources, and that the complaint did not allege any viable claims. *Id.* at *2-*3. Aligning with *Swift*, the court explained that the government "possesses the unfettered discretion to dismiss a *qui tam* [FCA] action" and therefore that the court must grant the government's motion. *Id.* at *7. Regardless, the government was entitled to dismissal even under *Sequoia*, as the government had stated a "valid reason for dismissal" that the relator could not refute. *Id.* at *8.

- In *United States ex rel. De Sessa v. Dallas Cty. Hosp. Dist.*, No. 3:17-CV-1782-K, 2019 WL 2225072 (N.D. Tex. May 23, 2019), the U.S. District Court for the Northern District of Texas also echoed *Swift's* reasoning, while concluding that the government was entitled to dismissal under either standard. In a short decision, the court cited to *Swift* and granted the government's motion to dismiss the relator's FCA fraud claim. *Id.* at *2. The court then explicitly noted that its holding did not dismiss the relator's FCA *retaliation* claim, as that claim was *not* brought on behalf of the U.S. government. *Id.*

B. State Developments

As detailed in our 2018 Mid-Year and Year-End False Claims Act Updates, Congress created financial incentives in 2005 for states to enact their own false claims statutes that are as effective as the federal FCA in facilitating *qui tam* lawsuits, and that impose penalties at least as high as those imposed by the federal FCA.[38] States passing review by HHS's Office of Inspector General ("OIG") may be eligible to "receive a 10-percentage-point increase in [their] share of any amounts recovered under such laws" in actions filed under state FCAs.[39] As of June 2019, HHS OIG has approved laws in twenty states (California, Colorado, Connecticut, Delaware, Georgia, Illinois, Indiana, Iowa, Massachusetts, Montana, Nevada, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, Virginia and Washington), while nine states are still working towards FCA statutes that meet the federal standards (Florida, Hawaii, Louisiana, Michigan, Minnesota, New Hampshire, New Jersey, New Mexico, and Wisconsin).[40] Five approvals have occurred in 2019 to date (California, Delaware, Georgia, New York, and Rhode Island).[41] While HHS OIG did not publicly state the reasons for these approvals, they likely stemmed at least in part from the fact that all five states recently amended their false claims statutes to peg their civil penalties to those imposed by the federal FCA, including as adjusted for inflation under the Federal Civil Penalties Inflation Adjustment Act of 1990.[42]

Some states have continued to consider (or implement) revisions to their false claims acts after federal approval. Most notably, in May 2019, the California Assembly passed Assembly Bill No. 1270, which would amend the California False Claims Act's definition of materiality, for purposes of the "false record or statement" prong of the statute, to consider only "the potential effect of the false record or statement when it is made, not . . . the actual effect of the false record or statement when it is discovered."[43] This change could mark a significant pro-plaintiff limiting of the concept of materiality in the wake of *Escobar*, which held that materiality is a matter of the "effect on the likely *or actual* behavior of the recipient of an alleged misrepresentation."[44]

The California bill also would expand the state false claims act to apply to certain claims, records, or statements made under the California Revenue and Taxation Code. Specifically, the bill extends the California false claims act to tax-related cases where the damages pleaded exceed $200,000, and where the state-taxable income or sales of any person or corporation against whom the action is brought exceeds $500,000.[45] The new law would require the state Attorney General or prosecuting authority, prior to filing or intervening in any false claims act case related to taxes, to consult with the relevant tax authority.[46] Under the bill, the state Attorney General or prosecuting authority, but not a *qui tam* relator, would be authorized to obtain from state government agencies otherwise confidential records relating to taxes, fees, or other obligations under California's Revenue and Taxation Code.[47] The amendment would prohibit the state government authorities from disclosing federal taxation information to the state Attorney General or prosecuting authority without IRS authorization. The amendment would also prohibit disclosure by the state Attorney General or prosecuting authority of any taxation information it does receive, "except as necessary to investigate and prosecute suspected violations" of the California false claims act.[48] The bill is currently being considered by committees in the California Senate.[49]

Other states lack false claims statutes and have moved in fits and starts towards enacting them. For example, as of June 2019, a bill to enact the South Carolina False Claims Act remained pending in the state's legislature after being referred to the state senate's judiciary committee in January.[50] The bill is nearly identical to the last false claims act bill introduced in South Carolina's Senate, which died in that body's judiciary committee after being referred in January 2015.[51]

Other states that lack broad false claims acts have nonetheless moved incrementally towards endowing themselves with robust enforcement powers. West Virginia, for example, lacks a false claims statute broadly defined, but does prohibit Medicaid fraud through a statute that in some ways resembles the FCA.[52] Until early 2019, the state's Medicaid Fraud Control Unit ("MFCU"), which holds the power to investigate possible violations of the statute, sat within the state department of health and human services. However, a bill was passed on March 7, 2019, which will relocate the MFCU to the Office of the Attorney General.[53] Once effective on October 1, 2019, the new law will give primary prosecution authority to the Office of the Attorney General; only if that office declines prosecution will attorneys employed or contracted by the state department of health and human services have authority to take the case forward.[54] This consolidation of power in the Office of the Attorney General could be the first step in a push for enactment of broader false claims enforcement powers.

III. NOTABLE CASE LAW DEVELOPMENTS

With a U.S. Supreme Court decision, more than a dozen notable circuit court decisions, and a handful of important district court decisions too, the first half of 2019 was an active period on the case law front (as detailed below).

A. U.S. Supreme Court Extends the Statute of Limitations in Cases Where the Government Does Not Intervene

The FCA provides two different limitations periods for "civil action[s] under section 3730"—(1) six years after the statutory violation occurs, or (2) three years "after the United States official charged with the responsibility to act knew or should have known the relevant facts, but not more than [ten] years after the violation." 31 U.S.C. § 3731(b). Whichever period is longer applies. In *Cochise Consultancy, Inc. v. United States ex rel. Hunt*, 139 S. Ct. 1507 (2019), the Supreme Court resolved a circuit split regarding the FCA's statute of limitations for *qui tam* actions pursued only by a whistleblower, without government participation. Specifically, the question that had split the circuit courts is whether a relator—pursuing a case where the government has declined to intervene—can take advantage of the longer statute of limitations period of up to ten years.

In *Cochise*, the relator conceded that more than six years had elapsed before he filed his suit from when the alleged FCA violations occurred. *Id.* at 1511. However, the relator argued that fewer than three years had elapsed between when the relator had revealed the alleged FCA violations to federal agents and when the relator filed his suit. *Id.* Thus, the relator argued that he should be able to take advantage of the longer statute of limitations period, triggered from when he had disclosed his allegations to the government. *Id.* The district court initially dismissed the suit, holding that section 3731(b)(2)'s three-year period does not apply to relator-initiated suits in which the government declines to intervene. *Id.*

But the Eleventh Circuit reversed, and held that the longer period could apply to relator-initiated suits in which the government declines to intervene. *Id.*

The Supreme Court, looking to resolve a circuit split, unanimously affirmed the Eleventh Circuit's ruling. *Id.* at 1510. The Court reasoned that, because section 3731(b)'s two statute of limitations periods apply to "civil action[s] under section 3730" and because both government and relator-initiated FCA suits constitute "civil action[s] under section 3730," the statute's plain text made both of the limitations periods applicable to both types of suits. *Id.* at 1511-12 (quoting section 3731(b)). The Court also held that private relators in non-intervened suits do not constitute "the official of the United States charged with responsibility to act in the circumstances" under section 3731(b)(2). *Id.* at 1514. In other words, section 3731(b)(2)'s three-year period does not begin when a *private relator* who initiates the suit knows or should have known about the fraud. *Id.* Thus, because section 3731(b)(2)'s three-year period is available in relator-initiated non-intervened suits and because the private relator's learning of the facts does not begin this three-year period, dismissal of the relator's suit was not warranted on statute-of-limitations grounds. *Id.*

B. Courts Continue to Interpret the FCA's Materiality Requirement Post-*Escobar*

As we have previously discussed, courts continue to wrestle with the implications of the Supreme Court's decision in *Universal Health Services v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016), the landmark decision that addressed the implied certification theory of liability, and in the process gave renewed emphasis to the concepts of materiality and government knowledge under the FCA.

1. The Fifth Circuit Applies *Escobar* in Analyzing Materiality

In *United States ex rel. Lemon v. Nurses To Go, Inc.*, 924 F.3d 155 (5th Cir. 2019), the Fifth Circuit, reviewing a district court's dismissal of claims, engaged in a thorough application of *Escobar*, articulating three non-exhaustive "factors" for determining materiality. First, the court asked whether the government expressly conditioned payment on meeting the statutory or regulatory requirements at issue. Second, the court considered whether the government would have denied payment if it had known of the violations, a factor which the court referred to as "government enforcement." And third, the court asked whether the defendant's noncompliance was substantial or minor. In *Lemon*, the relators alleged that a hospice provider submitted claims affirming it had complied with various Medicare statutory and regulatory requirements, despite allegedly violating several requirements related to certifications, face-to-face physician patient encounters, and writing plans of care. *Id.* at 157. They also alleged that the hospital billed for ineligible services and patients, such as billing for already deceased patients. *Id.* at 157-58.

Applying each of its articulated *Escobar* factors in turn, the Fifth Circuit began by addressing conditions of payment. The court acknowledged that *Escobar* held that violating a requirement which is labeled a condition of payment does not alone "conclusively establish materiality." *Id.* at 161. Nevertheless, conditioning payment on a requirement is "certainly probative evidence of materiality." *Id.* (quoting *United States ex rel. Rose v. Stephens Institute*, 909 F.3d 1012, 1020 (9th Cir. 2018)). Because the Medicare statute expressly noted that payment can only be made if the certification, face-to-face encounter, and plan-of-care requirements that the defendants allegedly violated were met, the court held that the defendants' allegedly fraudulent certifications that they had complied with the statutory and regulatory requirements violated the government's express conditions of payment. *Id.*

Second, the court turned to government enforcement. *Id.* at 161-62. Here, the relators alleged in their complaint that HHS OIG had previously pursued enforcement actions against other hospice providers that had committed violations similar to the defendants' alleged violations—namely submitting bills for ineligible services and patients and failing to conduct the required certifications. *Id.* at 162. Because of these past enforcement actions, the Court held that the relators here had created a reasonable inference that the government would have denied payment had it known of the defendants' violations. *Id.* The Court found additional support for this conclusion in the Sixth Circuit's holding in *United States ex rel. Prather v. Brookdale Senior Living Communities, Inc.*, 892 F.3d 822 (6th Cir. 2018) (previously discussed here and here). There, the Sixth Circuit concluded that *Escobar* does not require relators to allege specific previous government prosecutions for claims similar to the relator's. *Id.*

Third, the Fifth Circuit analyzed whether the noncompliance was substantial or minor. *Id.* at 163. Citing *Escobar*, the court noted that a violation is material either when a reasonable person would "attach importance" to the noncompliance or when the defendant knew or had reason to know that the false representation's recipient would attach importance to it, even though a reasonable person would not. *Id.* Because the court had determined in its government enforcement analysis that the government would have denied payment had it known of the defendants' violations, the court therefore held that government would have attached importance to the violations. *Id.* Thus, the relators had also satisfied the third factor, showing that the noncompliance was substantial. *Id.* Given that all three factors were satisfied, the court held that the relators had sufficiently alleged material violations to survive the motion to dismiss. *Id.*

2. The Third Circuit Analyzes Post-*Escobar* Materiality Standards on Summary Judgment

In *United States ex rel. Doe v. Heart Solutions, PC*, 923 F.3d 308 (3d Cir. 2019), the Third Circuit explored materiality and causation in light of *Escobar*. There, the government filed an FCA claim alleging that the defendants, an individual and her health care company, had violated Medicare regulations requiring all diagnostic testing to be performed under the proper level of physician supervision. *Id.* at 311. Specifically, the government alleged that the defendants had falsely represented that a licensed neurologist performed all their company's neurological testing as required by regulation, when their testing allegedly was not supervised by a neurologist in reality. *Id.*

Applying *Escobar* to the government's motion for summary judgment, the Third Circuit found that the government met its initial summary judgment burden to show materiality by submitting evidence that Medicare would not have paid the testing claims without a supervising neurologist's certification, per regulation. *Id.* 318. When the defendants failed to introduce any evidence to rebut this, the court held that the government had met its materiality burden. *Id.*

Notably, the court also held that by establishing materiality, the government also had adequately demonstrated causation. *Id.* According to the court, "because these misrepresentations were material, they caused damage to Medicare," and therefore "but for the misrepresentations, Medicare would never have paid the claims." *Id.* This ruling, which appears to conflate the separate elements of causation and materiality by hinging causation entirely on materiality, will be one to watch in future decisions.

C. Courts Continue to Analyze Rule 9(b)'s Particularity Requirement in FCA Claims

In last year's year-end update, we noted that the circuit courts continue to struggle with how to apply Rule 9(b)'s particularity requirement in FCA cases. Rule 9(b) heightens the pleading standard required in fraud claims, stating that a party alleging fraud "must state with particularity the circumstances constituting fraud or mistake." This year, several circuits further analyzed Rule 9(b)'s application to FCA cases.

1. The Ninth Circuit Discusses the Relationship between Rule 9(b)'s Particularity Standard and the FCA's Materiality Requirement

In *United States ex rel. Mateski v. Raytheon Co.*, 745 F. App'x 49 (9th Cir. 2018), *cert. denied sub nom. Mateski v. Raytheon Co.*, No. 18-1312, 2019 WL 1643040 (U.S. May 13, 2019), the Ninth Circuit elaborated on Rule 9(b)'s particularity standard and, in particular, the effect of a lack of particularity on meeting the materiality requirement. In *Mateski*, the relator filed a *qui tam* action against his employer, a defense contractor, alleging that it falsely claimed compliance with contract requirements for a satellite system sensor. *Id.* at *50. The case had been to the Ninth Circuit once before, under the public disclosure bar, at which point the Ninth Circuit reversed the district court's dismissal of the complaint. *Id.*

This time, however, the Ninth Circuit affirmed dismissal of the case. *Id.* First, the court held that the complaint failed to meet Rule 9(b)'s particularity requirement with regard "to the 'what,' 'when,' and 'how' of the allegedly false claims." *Id*. For example, the relator alleged the defendant failed to comply with its contractual requirements to complete tests and retests on component parts, but never specified which parts, which tests, whether the tests were never done or whether they were instead done incompletely, as well as failing to name approximate dates of these tests. *Id.* Without these details, the court held that the defendant did not have enough information to defend against the claims, and so the complaint failed to meet Rule 9(b)'s particularity requirement. *Id.*

The Ninth Circuit also concluded that because of this lack of particularity regarding the false claims, the complaint also inadequately pleaded the materiality requirement. *Id.* Noting that the materiality requirement is a "demanding" standard pursuant to *Escobar*, the court found itself unable to assess whether the noncompliance was material or minor because of the lack of particularity regarding the false claims. *Id.*

2. The Eighth Circuit Provides Further Guidance on Rule 9(b)'s Particularity Requirement

In *United States ex rel. Strubbe v. Crawford County Memorial Hospital*, 915 F.3d 1158 (8th Cir. 2019), the Eighth Circuit elaborated on its prior holding in *United States ex rel. Thayer v. Planned Parenthood of the Heartland*, 765 F.3d 914, 918 (8th Cir. 2014), in which the court concluded that relators in FCA cases can meet Rule 9(b)'s particularity requirement either by: (1) pleading representative examples of false claims; or (2) pleading 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." *Strubbe,* 915 F.3d at 1163 (quoting *Thayer,* 765 F.3d at 918).

In *Strubbe*, the relators, emergency medical technicians and paramedics, filed an FCA *qui tam* action against a hospital, alleging that it submitted false claims for Medicare reimbursement, made false statements to get false claims paid, and conspired to violate the AKS. *Id.* at 1162. The district court dismissed the claims for failure to plead with the required particularity, finding that the complaint did not allege facts showing any false claims were submitted or show how the relators acquired their information. *Id.*

Over a dissent, the Eighth Circuit affirmed, holding that the complaint did not plead the fraud with the particularity required by Rule 9(b). *Id.* at 1166. First addressing the relator's allegation that the hospital submitted false claims, the court found that the relators had not met *Thayer's* first prong of submitting representative examples of false claims. *Id.* at 1164. For example, while they had alleged that the hospital made a false claim for an unnecessary treatment, they failed to include the requisite particularity because they did not identify the date of this incident, the provider, any specific information about the patient, what money was obtained, and crucially, whether the hospital actually submitted a claim for this specific patient. *Id.*

Nor had relators met *Thayer's* second prong, according to the court. *Id.* The court held that the complaint lacked sufficient indicia of reliability to create a strong inference that claims were actually submitted, because the complaint did not provide any details about the hospital's billing practices. *Id.* at 1164-65. Moreover, the relators did not identify the basis for their allegations regarding billing; this was especially problematic given the relators lack of personal knowledge about the hospital's billing due to their lack of access to the hospital's billing department as EMTs and paramedics. *Id.* at 1165-66.

The relators' second claim that the hospital made false statements failed to meet Rule 9(b)'s particularity requirement for similar reasons as their first—namely, the complaint did not connect the false statements to claims submitted to the government and did not provide the basis on which the relators' assertions were founded. *Id.* at 1166. Finally, their third claim, that the hospital conspired to violate the AKS, failed because they did not provide any details about the conspiracy, and so failed to plead with particularity. *Id.* Therefore, the court affirmed the complaint's dismissal. *Id.* at 1170.

3. Under Rule 9(b), the Fourth Circuit Requires Allegations Regarding a Sub-Contractor's Billing and Payment Structure

In *United States ex rel. Grant v. United Airlines Inc.*, 912 F.3d 190 (4th Cir. 2018), the Fourth Circuit held that a relator failed to meet Rule 9(b)'s particularity requirement where his complaint alleged a fraudulent scheme without detailing the billing and payment structure. Because of this omission, the court found that relator's allegations did not foreclose the possibility that the government was never billed or that the alleged fraud was remedied before billing or payment. The case involved allegations by a relator against his former employer, an airline, alleging that the airline violated the FCA by certifying airplane repairs that did not comply with various aviation regulations and contract requirements in the airline's work as a sub-sub-contractor for the U.S. Air Force. *Id.* at 194. Specifically, the relator alleged that the defendant: (1) certified uncompleted work as completed; (2) certified repairs performed by uncalibrated and uncertified tools, in violation of the subcontract's requirements; and (3) allowed inspectors to continue certifying repairs after their training and eye exams had expired. *Id.* at 194-95.

Affirming dismissal of the claims, the Fourth Circuit held that Rule 9(b)'s "stringent" pleading standard requires the complaint to "provide 'some indicia of reliability' to support the allegation that an actual false claim was presented to the government." *Id.* (quoting *United States ex rel. Nathan v. Takeda Pharm. N. Am., Inc.*, 707 F.3d 451, 457 (4th Cir. 2013)). Relators can meet this standard either by: (1) alleging with particularity that specific false claims were actually submitted to the government or (2) alleging "a pattern of conduct that would 'necessarily have led[ ] to submission of false claims' to the government for payment." *Id.* (quoting *Nathan*, 707 F.3d at 457). Over a dissent, the court concluded that the relator had not pleaded specific claims, and also failed to allege a pattern of conduct that would necessarily have led to the submission of false claims, because he had only particularly alleged that the defendant engaged in fraudulent conduct without connecting the fraudulent conduct to the *necessary* presentment of false claims to the government. *Id.* The court reasoned that the complaint failed "to allege how, or even whether, the bills for these fraudulent services were presented to the government and how or even whether the government paid [the defendant] for the services." *Id.* at 198. Because the complaint alleged only an umbrella payment without describing the billing or payment structure, the court held that the complaint left open the possibility that no payments were ever made. The court held that alleging a link between the false claims and government payment is especially necessary to meet Rule 9(b)'s requirements where, as here, the defendant is several levels removed from the government because it is a sub-sub-contractor. *Id.* at 199.

D. Estoppel and the FCA

As DOJ increasingly pursues parallel criminal and civil investigations in cases involving fraud on the government, the interplay between criminal and FCA charges becomes increasingly important. Several decisions during the first half of the year discussed issues relevant to this interplay.

1. The Third Circuit Finds That a Company Is Not Estopped by an Individual Employee's Criminal Conviction

In *United States ex rel. Doe v. Heart Solution, PC*, 923 F.3d 308 (3d Cir. 2019) (discussed previously in relation to materiality), the Third Circuit held that, although an individual defendant was collaterally estopped from denying the falsity and knowledge elements of a civil FCA claim by her criminal conviction and plea colloquy regarding the same conduct, her employer was not. *Id.* at 316-17. The case involved an individual defendant who was convicted criminally of defrauding Medicare after having admitted at her plea colloquy that Medicare paid her company for diagnostic neurological testing that she falsely represented was supervised by a licensed neurologist. *Id.* at 312. After her conviction, the government intervened in a civil *qui tam* FCA case against her and her health care company regarding the same fraudulent neurologist certifications. *Id.*

In granting summary judgment against the defendant *company*, the district court had relied on the *individual* defendant's criminal conviction and plea colloquy. *Id.* at 313. But the Third Circuit held that the district court erred in finding that the health care *company* had conceded all of the essential elements of the FCA claim through the *individual* defendant's plea. *Id.* at 316-17. In so holding, the court relied on the fact that collateral estoppel does not apply unless the party against whom the earlier decision is asserted previously had a "full and fair opportunity to litigate that issue." *Id.* at 316 (internal quotation marks omitted) (quoting *Allen v. McCurry*, 449 U.S. 90, 95 (1980)). Here, the defendant company did not have any opportunity, let alone a "full and fair opportunity," to contest the fraud claim at the individual's separate criminal proceedings. *Heart Sol.*, 923 F.3d at 317. Additionally, some of the elements of the FCA claim against the company, as opposed to the individual, were neither actually litigated nor determined by a final judgment in the individual's criminal case, both of which are required for collateral estoppel to apply. *Id.* at 317.

2. The Fourth Circuit Holds That Non-Intervened *Qui Tam* Actions Decided in Favor of the Defendant Do Not Collaterally Estop the Government from Pursuing Criminal Proceedings

In *United States v. Whyte*, 918 F.3d 339 (4th Cir. 2019), the Fourth Circuit considered whether the government is collaterally estopped from pursuing its own criminal case by a prior *qui tam* FCA action in which it did not intervene. *See id.* at 344. There, the defendant, the owner of a company that supplied armored vehicles to multinational forces in Iraq, was indicted for criminal fraud in July 2012. *Id.* at 342-43. Then, in October 2012, a relator filed a civil FCA suit, in which the government declined to intervene, against the defendant. *Id.* at 343. The defendant ultimately prevailed at trial in his FCA civil suit, but then, over two years later, a jury convicted the defendant in the criminal case. *Id.* at 344.

The defendant argued that the government was collaterally estopped in its criminal case by the defendant's victory in the prior *qui tam* civil case, but the courts were not convinced. The Fourth Circuit affirmed the district court, holding as a matter of first impression that "the Government is not a party to an FCA action in which it has declined to intervene," and so is not collaterally estopped by a prior FCA action in which it did not intervene. *Id.* at 345, 350. In so holding, the court first reasoned that collateral estoppel cannot bar a criminal prosecution when the government did not "have a full and fair opportunity to litigate the issue in the prior proceeding." *Id.* at 345 (citation and internal quotation marks removed). Whether the government had that opportunity in turn depends on whether the government was a party to that prior proceeding. *Id.* Citing precedent, the FCA's language and structure, and the government's different interests in intervened versus non-intervened cases, the court held that the government is *not* a party to an FCA action in which it has not intervened. *Id.* at 345-49. Therefore, the court concluded that "the Government cannot be considered to have been a party with a full and fair opportunity to litigate" in a prior FCA action in which it declined to intervene, and so the government's criminal prosecution was not collaterally estopped by a prior, nonintervened FCA *qui tam* action. *Id.* at 349-50.

E. The First Circuit Holds That Unsealing an FCA Complaint Begins the Statute of Limitations for Related Claims

As we previously discussed, RICO suits mirroring FCA suits that challenge off-label drug marketing continue to appear. A recent First Circuit case held that the unsealing of an FCA complaint regarding off-label drug marketing begins the running of RICO's four-year statute of limitations in these kinds of cases.

In *In re Celexa & Lexapro Marketing & Sales Practices Litigation*, 915 F.3d 1 (1st Cir. 2019), the First Circuit addressed the relationship between FCA claims and the statute of limitations for RICO claims (as well as state consumer fraud claims). There, the government intervened in a *qui tam* FCA claim alleging that the defendant pharmaceutical companies engaged in illegal off-label drug marketing schemes intended to fraudulently induce doctors to prescribe their drugs for off-label uses. *Id.* at 5-6. The unsealing of the complaint led to more than a dozen consumers and entities that had paid for these drugs filing suit, including the suits in this case, alleging RICO and state consumer fraud violations related to the defendant's alleged illegal off-label marketing schemes. *Id.* at 7. The First Circuit held that, as a matter of law, the unsealing of the government's FCA complaint put the plaintiffs on notice that the defendants allegedly had been promoting off-label uses of their products. *Id.* at 15. Therefore, the unsealing of the government's FCA complaint began the running of the four-year statute of limitations on the plaintiffs' RICO claims related to the off-label marketing schemes alleged in the FCA complaint. *Id.* at 15-16.

F. The Ninth Circuit Upholds an FCA Settlement Agreement's Confidentiality Provisions

For companies involved in negotiations with DOJ about the terms of settlement agreements under the FCA, there was a bit of good news from the Ninth Circuit. In *Brunson v. Lambert Firm PLC*, 757 F. App'x 563 (9th Cir. 2018), the Ninth Circuit upheld the confidentiality provisions of an FCA settlement agreement, over objection from the relator. *See id.* at 566. In that case, the relator entered into an FCA settlement agreement with the defendants and the government, but later filed several post-settlement motions that put at issue the settlement agreement's confidentiality provisions. *See id.* at 565. The Ninth Circuit held that the settlement agreement's confidentiality provisions were not void on public policy grounds, because the settlement did not impede any whistleblower's ability to bring information to the government, and so did not violate the public interest underlying the FCA's provisions encouraging disclosures of fraud. *Id.* at 566. Additionally, the court held that the confidentiality provisions did not interfere with the public's right to information, given that the entire *qui tam* complaint was still publicly available. *Id.* Finally, the Ninth Circuit held that the district court had not abused its discretion in maintaining the seal over the settlement agreement, because the settlement agreement was a "private agreement reached without court assistance" and was only in the judicial record through the relator's efforts to void its confidentiality provisions. *Id.*

G. The Public Disclosure Bar and Its Original Source Exception

The public disclosure bar, as amended in 2010 by the Affordable Care Act, requires courts to dismiss a relator's FCA claims "if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed," unless that relator "is an original source of the information." § 3730(e)(4)(A). One of the statute's definitions of an original source is an individual "who has knowledge that is independent of and *materially adds* to the publicly disclosed allegations or transactions." § 3730(e)(4)(B) (emphasis added). Although the "materially adds" language has been in effect for nearly a decade, the new language did not apply retroactively, and due to the long timeframe for many FCA cases, it is therefore just in recent years getting serious attention from the appellate courts. In April of this year, the Tenth Circuit became the latest court to opine on the meaning of the original source exception's "materially adds" language.

In *United States ex rel. Reed v. KeyPoint Government Solutions*, 923 F.3d 729 (10th Cir. 2019), the Tenth Circuit explored what a relator must allege to meet the original source exception by materially adding to publicly disclosed information. In defining the "materially adds" language in the original source exception, the Tenth Circuit cited *United States ex rel. Winkelman v. CVS Caremark Corp.*, 827 F.3d 201 (1st Cir. 2016), and held that a relator satisfies the materially-adds requirement when she "discloses new information that is sufficiently significant or important that it would be capable of" influencing the government's behavior, as contrasted with a relator who provides only background information or details about a previously disclosed fraud. *Reed*, 923 F.3d at 757. Under this standard, the court noted that a relator who merely identifies a new specific actor engaged in fraud usually would *not* materially add to public disclosures of alleged widespread fraud in an industry with only a few companies. *Id.* at 758. Ultimately, however, the court concluded that the relator here had materially added to the public disclosures about a specific program at her company. *Id.* at 760-63. Thus, the court held she met the original source exception's materially-adds requirement, but remanded on whether her knowledge was "independent" and whether her claims should otherwise survive scrutiny under Rule 12(b)(6) and Rule 9(b). *Id.* at 763.

H. The First Circuit Holds That the First-to-File Bar Is Not Jurisdictional

The First Circuit joined the D.C. and Second Circuits in holding that the FCA's first-to-file bar is not jurisdictional, such that arguments under the first-to-file bar do not implicate the court's subject matter jurisdiction, even if they are a cause for dismissal. This distinction can affect how, and when, arguments under the first-to-file bar may be made, and also the standard of review a court applies.

In *United States v. Millennium Laboratories, Inc.*, 923 F.3d 240 (1st Cir. 2019), Relator A, who filed first, alleged that the defendant used inexpensive *point-of-care* tests to induce physicians into excessive testing, including confirmatory testing, which was then billed to the government. *Id.* at 245-46. Another relator, Relator B, later filed a complaint against the same defendant related to *confirmatory* testing, not point-of-care testing, allegedly induced through improper custom profiles and standing orders. *Id.* at 246-47. The government intervened in Relator B's action (but not Relator A's) and pursued an FCA case focused on excessive *confirmatory* testing induced through improper custom profiles and standing orders. *Id.* at 247-48. The government and the defendant eventually settled for $227 million plus interest, without resolving which relator was entitled to the relator's share. *Id.* at 247.

The district court dismissed Relator B's crossclaim for the relator's share of the settlement, holding that Relator A was the first to file. *Id.* at 248. As Relator A was the first to file, the district court therefore held that it did not have subject matter jurisdiction over Relator B's crossclaim, because the first-to-file bar was jurisdictional. *Id.*

On appeal, the First Circuit reversed, and held that the first-to-file bar is not jurisdictional, overturning its prior precedent, for three reasons. *Id.* at 248-49. First, the First Circuit pointed to *Kellogg Brown & Root Services, Inc. v. United States ex rel. Carter*, 135 S. Ct. 1970 (2015), in which the Supreme Court addressed a first-to-file issue in an FCA *qui tam* action on "decidedly non-jurisdictional terms," implying that the Supreme Court did not consider the first-to-file rule a jurisdictional one. *Millennium Labs.*, 923 F.3d at 249 (internal quotation marks removed) (quoting *United States ex rel. Heath v. AT&T, Inc.*, 791 F.3d 112, 121 n.4 (D.C. Cir. 2015)). Second, the First Circuit noted that its prior cases all predated *Carter* and also did not *substantively* analyze whether the first-to-file rule was jurisdictional, but rather assumed it was. *Millennium Labs.*, 923 F.3d at 250. Third, applying the Supreme Court's "bright line rule" in *Arbaugh v. Y & H Corp.*, 546 U.S. 500 (2006), which held that provisions are only jurisdictional when Congress clearly states that they are, the First Circuit held that the first-to-file bar's statutory text, context, and legislative history did not describe the bar in jurisdictional terms. *Millennium Labs.*, 923 F.3d at 250-51. For these reasons, the First Circuit held that the first-to-file bar is not jurisdictional. *Id.* at 251. Therefore, the court held that it had jurisdiction over Relator B's crossclaim. *Id.*

Next, the First Circuit turned to the issue of whether Relator A or B was the first to file for purposes of the relator's share of the government's settlement. *Id.* at 252-53. To determine whether Relator A was the first to file in the action in which the government intervened, the court analyzed whether Relator A's complaint contained "all the essential facts" of the fraud that Relator B alleged, on a claim-by-claim basis, looking at the specific mechanisms of fraud alleged. *Id.* at 252-53. Because Relator A's complaint never alleged the specific mechanisms of fraud that Relator B alleged—custom profiles and standing orders in the confirmatory, not point-of-care, stage—Relator A's complaint did not cover the essential facts of the fraud that Relator B and the government alleged. *Id.* at 254. Thus, as Relator A alleged a different fraud than the fraud that the government pursued, he was not the first to file in this case; Relator B was. *Id.*

I. The Second Circuit Holds That a Relator Who Previously Voluntarily Dismissed His FCA Action Is Not Entitled to the Relator's Share of the Government's Subsequent Action

In *United States v. L-3 Communications EOTech, Inc.*, 921 F.3d 11 (2d Cir. 2019), the Second Circuit joined several other circuits in holding that a relator who previously voluntarily dismissed his *qui tam* action and had no other *qui tam* actions pending at the time the government pursued its own FCA claim is not entitled to the relator's share of a later government settlement. Specifically, the court examined the FCA's provision in section 3730(c)(5), which states that, notwithstanding the section of the FCA allowing *qui tam* actions, the government may pursue an "alternative remedy," but if the government pursues an alternative remedy, then "the person initiating the action shall have the same rights in such proceeding as such person would have had if the action had continued under this section." *Id.* at 24 (quoting § 3730(c)(5)). The court held that section 3730(c)(5) only applied if that relator had a pending *qui tam* action in which the government could intervene when the government initiated its own FCA action. *Id.* at 26. Thus, where, as here, the relator had no FCA action pending because the relator had voluntarily dismissed his FCA suit fourteen months before the government commenced its own FCA suit, the relator is not entitled to the relator's share of the government's action. *Id.*

J. FCA Retaliation Claims

There were also a number of decisions from the courts of appeal that addressed issues under the FCA's anti-retaliation provision, which protects would-be whistleblowers from retaliation based on certain protected activity undertaken in furtherance of a potential FCA claim. We very briefly summarize these decisions below.

In *United States ex rel. Reed v. KeyPoint Government Solutions*, 923 F.3d 729 (10th Cir. 2019) (previously discussed regarding the public disclosure bar), the Tenth Circuit affirmed the district court's dismissal of the relator's retaliation claim, holding that the facts she pleaded were inadequate to show that the defendant was on notice that she was engaged in FCA-protected activity. *Id.* at 741, 764. Because the relator was a compliance officer, the court explained that she must plead facts to overcome the presumption that she was just doing her job in reporting fraud internally to her employer. That is, she must plead that the actions she took to report the alleged fraud internally went beyond what was required to fulfill her compliance job duties. *Id.* at 768-69. In that case, the relator did not adequately allege that her employer was on notice she was trying to stop FCA violations, and so the court affirmed the dismissal of her retaliation claim. *Id.* at 772.

In *United States ex rel. Strubbe v. Crawford County Memorial Hospital*, 915 F.3d 1158 (8th Cir. 2019) (previously discussed regarding Rule 9(b)), the Eighth Circuit limited liability for FCA retaliation claims by affirming the district court's ruling that relators' retaliation claim was barred because the complaint did not allege that relators ever told their employer (a hospital) that its practices were fraudulent or potentially violated the FCA. *Id.* The court found that complaining about the hospital's finances and changes the hospital made to certain treatments does not provide the hospital notice that the relators are taking action to stop an FCA violation or in furtherance of a *qui tam* action. *Id.* In addition, as a matter of first impression for FCA retaliation claims before the Eighth Circuit (but not whistleblower claims more generally), the court held that when there is no direct evidence of retaliation, the *McDonnell Douglas* framework—from *McDonnell Douglas Corp. v. Green*, 411 U.S. 792 (1973)—applies to FCA retaliation claims. *Id.* at 1168. Thus, for FCA retaliation claims, the plaintiff must show that: "(1) she engaged in protected conduct, (2) [her employer] knew she engaged in protected conduct, (3) [her employer] retaliated against her, and (4) 'the retaliation was motivated solely by [the plaintiff's] protected activity.'" *Id.* at 1167-68 (quoting *Schuhardt v. Washington University*, 390 F.3d 563, 566 (8th Cir. 2004)). If the plaintiff establishes a prima facie retaliation claim, then the burden shifts to the employer to "articulate a legitimate reason for the adverse action." *Id.* at 1168 (quoting *Elkharwily v. Mayo Holding Co.*, 823 F.3d 462, 470 (8th Cir. 2016)). Then, the burden again shifts back to the plaintiff to show that the employer's reason was "merely a pretext and that retaliatory animus motivated the adverse action." *Id.* (quoting *Elkharwily*, 823 F.3d at 470).

In *Guilfoile v. Shields*, 913 F.3d 178 (1st Cir. 2019), the First Circuit explored the link between FCA retaliation claims and the AKS. The relator alleged that he was fired in retaliation for internally reporting that his employer, which provides specialty pharmacy services to chronically ill patients, was violating the AKS and making false representations in its contracts with hospitals. *Id.* at 182-83. The First Circuit affirmed dismissal with respect to his contract violation-based retaliation claim, but vacated the district court's holding dismissing the plaintiff's AKS-based retaliation claim, over a dissent. *Id.* at 195. In so doing, the First Circuit held that for FCA retaliation claims, plaintiffs do not need to meet Rule 9(b)'s particularity requirement, plead the submission of false claims, or plead that compliance with the AKS was material. *Id.* at 190. Instead, FCA retaliation plaintiffs "need only plead that their actions in reporting or raising concerns about their employer's conduct 'reasonably could lead to an FCA action.'" *Id.* at 189 (quoting *United States ex rel. Booker v. Pfizer, Inc.*, 847 F.3d 52, 59 (1st Cir. 2017)). Under this standard, the court held that the plaintiff had plausibly pleaded that he was engaged in FCA-protected conduct, because by reporting his concerns about paying a consultant to secure contracts at hospitals at which the consultant worked, he was engaging in conduct that could reasonably lead to an FCA action based on the submission of claims resulting from an AKS violation. *Id.* at 193.

Finally, in *United States ex rel. Grant v. United Airlines Inc.*, 912 F.3d 190 (4th Cir. 2018) (discussed previously regarding Rule 9(b)), the Fourth Circuit held that an objective reasonableness standard applies to FCA retaliation claims' new protected activity category, added in 2010, of "other efforts to stop 1 or more" FCA violations. Prior Fourth Circuit precedent applied a "distinct possibility" standard to evaluate protected activity under § 3730(h), which related to retaliation for actions taken "in furtherance" of an FCA action, meaning employees engage "in protected activity when 'litigation is a *distinct possibility*, when the conduct reasonably could lead to a viable FCA action, or when . . . litigation is a reasonable possibility.'" *Id.* at 200 (quoting *Mann v. Heckler & Koch Def., Inc.*, 630 F.3d 338, 344 (4th Cir. 2010)) (emphasis added). However, the court rejected the "distinct possibility" standard for "other efforts to stop 1 or more" FCA violations, and instead adopted an "objective reasonableness" standard. *Id.* at 201. Under the second category's "objective reasonableness" standard, "an act constitutes protected activity where it is motivated by an *objectively reasonable* belief that the employer is violating, or soon will violate, the FCA." *Id.* (emphasis added).

IV. CONCLUSION

We will monitor these developments, along with other FCA legislative activity, settlements, and jurisprudence throughout the year and report back in our 2019 False Claims Act Year-End Update, which we will publish in January 2020.

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[1] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Avanti Hospitals LLC, and Its Owners Agree to Pay $8.1 Million to Settle Allegations of Making Illegal Payments in Exchange for Referrals (Jan. 28, 2019), https://www.justice.gov/opa/pr/avanti-hospitals-llc-and-its-owners-agree-pay-81-million-settle-allegations-making-illegal.

[2] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Pathology Laboratory Agrees to Pay $63.5 Million for Providing Illegal Inducements to Referring Physicians (Jan. 30, 2019), https://www.justice.gov/opa/pr/pathology-laboratory-agrees-pay-635-million-providing-illegal-inducements-referring.

[3] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Electronic Health Records Vendor to Pay $57.25 Million to Settle False Claims Act Allegations Charges (Feb. 6, 2019), https://www.justice.gov/opa/pr/electronic-health-records-vendor-pay-5725-million-settle-false-claims-act-allegations.

[4] *See* Press Release, U.S. Atty's Office for the N. Dist. of GA., Union General Hospital to Pay $5 Million to Resolve Alleged False Claims Act Violations (Feb. 6, 2019), https://www.justice.gov/usao-ndga/pr/union-general-hospital-pay-5-million-resolve-alleged-false-claims-act-violations.

[5] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Vanguard Healthcare Agrees to Resolve Federal and State False Claims Act Liability (Feb. 27, 2019), https://www.justice.gov/opa/pr/vanguard-healthcare-agrees-resolve-federal-and-state-false-claims-act-liability.

[6] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Covidien to Pay Over $17 Million to The United States for Allegedly Providing Illegal Remuneration in the Form of Practice and Market Development Support to Physicians (Mar. 11, 2019), https://www.justice.gov/opa/pr/covidien-pay-over-17-million-united-states-allegedly-providing-illegal-remuneration-form.

[7] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, MedStar Health to Pay U.S. $35 Million to Resolve Allegations that it Paid Kickbacks to a Cardiology Group in Exchange for Referrals (Mar. 21, 2019), https://www.justice.gov/opa/pr/medstar-health-pay-us-35-million-resolve-allegations-it-paid-kickbacks-cardiology-group.

[8] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Three Pharmaceutical Companies Agree to Pay a Total of Over $122 Million to Resolve Allegations That They Paid Kickbacks Through Co-Pay Assistance Foundations (Apr. 4, 2019), https://www.justice.gov/opa/pr/three-pharmaceutical-companies-agree-pay-total-over-122-million-resolve-allegations-they-paid.

[9] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Pharmaceutical Company Agrees to Pay $17.5 Million to Resolve Allegations of Kickbacks to Medicare Patients and Physicians (Apr. 30, 2019), https://www.justice.gov/opa/pr/pharmaceutical-company-agrees-pay-175-million-resolve-allegations-kickbacks-medicare-patients.

[10] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Medicare Advantage Provider to Pay $30 Million to Settle Alleged Overpayment of Medicare Advantage Funds (Apr. 12, 2019), https://www.justice.gov/opa/pr/medicare-advantage-provider-pay-30-million-settle-alleged-overpayment-medicare-advantage.

[11] *See* Press Release, U.S. Atty's Office for the S. Dist. of W.V., United States Attorney Announces $17 Million Healthcare Fraud Settlement (May 6, 2019), https://www.justice.gov/usao-sdwv/pr/united-states-attorney-announces-17-million-healthcare-fraud-settlement.

[12] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Kansas Cardiologist and His Practice Pay $5.8 Million to Resolve Alleged False Billings for Unnecessary Cardiac Procedures (May

30, 2019), https://www.justice.gov/opa/pr/kansas-cardiologist-and-his-practice-pay-58-million-resolve-alleged-false-billings.

[13] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Pharmaceutical Company Admits to Price Fixing in Violation of Antitrust Law, Resolves Related False Claims Act Violations (May 31, 2019), https://www.justice.gov/opa/pr/pharmaceutical-company-admits-price-fixing-violation-antitrust-law-resolves-related-false.

[14] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Opioid Manufacturer Insys Therapeutics Agrees to Enter $225 Million Global Resolution of Criminal and Civil Investigations (Jun. 5, 2019), https://www.justice.gov/opa/pr/opioid-manufacturer-insys-therapeutics-agrees-enter-225-million-global-resolution-criminal.

[15] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Northrop Grumman Systems Corporation Agrees to Pay $5.2 Million to Settle Allegations of False Labor Charges (Jan. 28, 2019), https://www.justice.gov/opa/pr/northrop-grumman-systems-corporation-agrees-pay-52-million-settle-allegations-false-labor.

[16] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Duke University Agrees to Pay U.S. $112.5 Million to Settle False Claims Act Allegations Related to Scientific Research Misconduct (Mar. 25, 2019), https://www.justice.gov/opa/pr/duke-university-agrees-pay-us-1125-million-settle-false-claims-act-allegations-related.

[17] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Informatica Agrees to Pay $21.57 Million for Alleged False Claims Caused by Its Commercial Pricing Disclosures (May 13, 2019), https://www.justice.gov/opa/pr/informatica-agrees-pay-2157-million-alleged-false-claims-caused-its-commercial-pricing.

[18] S*ee* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Department of Justice Issues Guidance on False Claims Act Matters and Updates Justice Manual (May 7, 2019), https://www.justice.gov/opa/pr/department-justice-issues-guidance-false-claims-act-matters-and-updates-justice-manual.

[19] Deputy Attorney General Rod J. Rosenstein Delivers Remarks at the American Conference Institute's 35th International Conference on the Foreign Corrupt Practices Act (Nov. 29, 2018), https://www.justice.gov/opa/speech/deputy-attorney-general-rod-j-rosenstein-delivers-remarks-american-conference-institute-0.

[20] *See* U.S. Dep't of Justice, *Justice Manual*, Section 4-4.112.

[21] *Id*.

[22] *Id.*

[23] *Id*.

[24] *Id.*

[25] *Id.*

[26] *See* Memorandum, U.S. Dep't of Justice, Factors for Evaluating Dismissal Pursuant to 31 U.S.C. 3730(c)(2)(A) (Jan. 10, 2018), https://assets.documentcloud.org/documents/4358602/Memo-for-Evaluating-Dismissal-Pursuant-to-31-U-S.pdf.

[27] *Id.* at 2–3.

[28] *See* Jeff Overly, *DOJ Warns FCA Targets On Discovery Tactics*, Law360 (Mar. 2, 2019), https://www.law360.com/articles/1134479/doj-atty-warns-fca-targets-on-discovery-tactics.

[29] *Id*.

[30] *Id*.

[31] *Id.*

[32] Press Release, U.S. Dep't of Justice, Deputy Associate Attorney General Stephen Cox Delivers Remarks at the 2019 Advanced Forum on False Claims and Qui Tam Enforcement (Jan. 28, 2019), https://www.justice.gov/opa/speech/deputy-associate-attorney-general-stephen-cox-delivers-remarks-2019-advanced-forum-false.

[33] *Id.*

[34] *Id.*

[35] *Id.*

[36] *Id.*

[37] Press Release, U.S. Dep't of Justice, Deputy Associate Attorney General Stephen Cox Gives Remarks to the Cleveland, Tennessee, Rotary Club (Mar. 12, 2019), https://www.justice.gov/opa/speech/deputy-associate-attorney-general-stephen-cox-gives-remarks-cleveland-tennessee-rotary.

[38] State False Claims Act Reviews, Dep't of Health & Human Servs.—Office of Inspector Gen., https://oig.hhs.gov/fraud/state-false-claims-act-reviews/index.asp.

[39] *Id*.

[40] *Id*. Wisconsin repealed its false claims act in 2015. Assembly Bill 1021 would have reinstated the statute, but failed to pass in March 2018. *See* Wisconsin State Legislature, Assembly Bill 1021, http://docs.legis.wisconsin.gov/2017/proposals/reg/asm/bill/ab1021.

[41] *Id.*

[42] *See* Cal. Gov't Code § 12651 (West 2018); Ga. Code Ann. § 49-4-168.1 (2018); Del. Code Ann. tit. 6, § 1201 (2018); N.Y. State Fin. Law §§ 189-190-b; 2018 R.I. Gen. Laws § 9-1.1-3 (2018).

[43] Cal. AB-1270, 2019 Leg. Reg. Sess. (Cal. 2019).

[44] *Escobar*, 136 S. Ct. at 2002 (emphasis added) (citation and internal quotation marks removed).

[45] Cal. AB-1270, 2019 Leg. Reg. Sess. (Cal. 2019).

[46] *Id.*

[47] *Id.*

[48] *Id.*

[49] *AB-1270 False Claims Act*, California Legislative Information (July 9, 2019), http://leginfo.legislature.ca.gov/faces/billStatusClient.xhtml?bill_id=201920200AB1270.

[50] *See* S. 40, A Bill to Amend Title 15 of the 1976 Code, by Adding Chapter 85, to Enact the "South Carolina False Claims Act" (123d Session), https://www.scstatehouse.gov/sess123_2019-2020/bills/40.htm.

[51] *See* S. 223, A Bill to Amend the South Carolina Code of Laws, 1976, by Adding Chapter 85 to Title 15, so as to Enact the "South Carolina False Claims Act" (121st Session), https://www.scstatehouse.gov/sess121_2015-2016/bills/223.htm.

[52] Notably, though, the statute covers claims a defendant "reasonably should have known" were false, thereby creating potential liability for mere negligence (unlike the federal FCA, which requires at least reckless disregard). The West Virginia law also lacks a *qui tam* provision. *See* W.Va. Code § 9-7-6 (2018).

[53] *See* 2019 W.Va. Laws S.B. 318 (2019 Regular Session).

[54] *See id.* at § 9-7-6.

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Gibson Dunn's lawyers have handled hundreds of FCA investigations and have a long track record of litigation success. From U.S. Supreme Court victories, to appellate court wins, to complete success in district courts around the United States, Gibson Dunn believes it is the premier firm in FCA defense. Among other notable recent victories, Gibson Dunn successfully overturned one of the largest FCA judgments in history in United States ex rel. Harman v. Trinity Indus. Inc., 872 F.3d 645 (5th Cir. 2017), and the Daily Journal recognized Gibson Dunn's work in U.S. ex rel. Winter v. Gardens Regional Hospital and Medical Center Inc. as a Top Defense Verdict in its annual feature on the top verdicts for 2017. Our win rate and immersion in FCA issues gives us the ability to frame strategies to quickly dispose of FCA cases. The firm has dozens of attorneys with substantive FCA experience, including nearly 30 Assistant U.S. Attorneys and DOJ attorneys. For more information, please feel free to contact the Gibson Dunn attorney with whom you work or the following attorneys.

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