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2018 MID-YEAR FALSE CLAIMS ACT UPDATE

To Our Clients and Friends:

Six months ago, we remarked in these pages on the largely unchanged and unrelenting pace of False Claims Act ("FCA") enforcement under the Trump Administration. Now, with another half-year behind us, the Administration has started to put its stamp on FCA enforcement and to signal openness to less draconian FCA enforcement, at least on the margins. In a series of internal guidance memoranda and public speeches, high-ranking Department of Justice ("DOJ") officials have indicated their recognition of the very real costs of overly aggressive and unchecked FCA enforcement by *qui tam* whistle-blowers and DOJ itself, and laid out some steps they plan to take. It is still too early to tell what effect, if any, these announcements will have in practice. But the next six months and beyond are likely to provide telling indications of whether DOJ matches its shift in tone with a real shift in tactics.

For now, however, broader FCA trends appear unaffected by these recent developments. DOJ announced a typically robust, albeit slightly reduced, set of eight- and nine-figure settlements and judgments, including at least two that topped $100 million apiece, over the course of the last six months. Meanwhile the courts continued to explore the important intricacies and nuances of FCA jurisprudence, with nearly a dozen notable circuit court cases released in just the last half-year. The Supreme Court also indicated that it might engage again with the FCA by inviting the views of the Solicitor General on important issues arising from the Court's last seminal decision in *Universal Health Services v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016). And there were also a handful of regulatory and state-law changes that could affect the scope of FCA enforcement going forward.

We address all of these and other developments in greater depth below. We discuss enforcement activity at the federal and state levels first, turn to activity on the legislative front, and then conclude with an analysis of significant court decisions from the past six months. As always, Gibson Dunn's recent publications on 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 2018

The first half of 2018 saw several notable developments in DOJ enforcement activities, including both positive and not-so-positive developments for companies facing FCA exposure. On the one hand, several internal DOJ guidance documents suggested that the current leadership at DOJ is considering a less aggressive approach to FCA enforcement than we have seen develop increasingly over the last 10 years. But on the other hand, DOJ also continued to announce significant settlements and stringent

enforcement programs, aimed at a wide variety of industries, under a wide variety of theories. We explore these developments below.

A. DOJ Releases Important Guidance on FCA Enforcement and Signals More Changes to Come

Though many have advocated for FCA reform as the number of *qui tam* cases and enforcement efforts have exploded in recent years, those efforts have not proven too fruitful. But the new Administration may be a more receptive audience, as recent guidance from DOJ signals the first significant policy changes in recent memory that recognize the burden of FCA exposure. As we reported in our client alerts on these topics (available here and here), there were three major announcements during the last six months that introduced current, and forthcoming, changes from DOJ.

First, on January 10, 2018, Michael Granston, the Director of the Fraud Section of DOJ's Civil Division, issued a memorandum (the "Granston Memo") directing government lawyers evaluating a recommendation to decline intervention in a *qui tam* FCA action to "consider whether the government's interests are served . . . by [also] seeking *dismissal* [of the underlying *qui tam*] pursuant to 31 U.S.C. § 3730(c)(2)(A)."[1] The memorandum notes that DOJ "has seen record increases in qui tam actions" filed under the FCA, and while the "number of filings has increased substantially over time," DOJ's "rate of intervention has remained relatively static." Emphasizing that DOJ "plays an important gatekeeper role in protecting the False Claims Act," the memorandum identifies dismissal of non-intervened cases as "an important tool to advance the government's interests, preserve limited resources, and avoid adverse precedent." The memo then sets forth seven factors that prosecutors should consider when evaluating whether seeking dismissal of a declined *qui tam* action is appropriate. Although those factors all stem from existing precedent in cases where DOJ has previously moved for dismissal, the fact that DOJ issued the Granston Memo indicates that DOJ may be more willing to go beyond merely declining unmeritorious cases. By taking additional steps to dismiss such cases, DOJ may mitigate the extreme burden caused by unbridled *qui tam* plaintiffs..

Second, on January 25, 2018, then-Associate Attorney General Rachel Brand, the Department's third-ranking official, issued a memorandum (the "Brand Memo") that prohibits DOJ from using noncompliance with other agencies' "guidance documents as a basis for proving violations of applicable law in" affirmative civil enforcement cases and from using "its enforcement authority to effectively convert agency guidance documents into binding rules."[2] Agencies commonly issue guidance documents interpreting legislation and regulations, and the government has sometimes employed evidence that a defendant violated such guidance to prove a violation of the underlying statute or regulation—which, in turn, may support a showing that a defendant's claims or statements were "false" under the FCA. The memorandum explicitly prohibits DOJ attorneys from engaging in this practice, although it is careful to note that prosecutors can continue to use such guidance as evidence that a defendant *knew* of its obligations under the law. The Brand Memo builds on an earlier memo from Attorney General Jeff Sessions, from November 2017, that prohibited DOJ from issuing "guidance documents that purport to create rights or obligations binding on persons or entities outside the Executive Branch" without adhering to rulemaking processes as required by the Administrative Procedure Act (the "Sessions Memo").[3] Together, the Brand Memo and Sessions Memo reflect the Administration's

efforts to reign in administrative and regulatory requirements, with the Brand Memo signaling the Administration's determination to extend that broader policy agenda in the FCA space.

Third, DOJ has continued to reinforce its interest in taking measures to promote a more fair and consistent application of the FCA. In a June 14 speech, Acting Associate Attorney General Jesse Panuccio described five policy initiatives being undertaken by DOJ to reform FCA enforcement, including the Brand and Granston memos highlighted above, as well as three additional areas: (i) cooperation credit; (ii) compliance program credit; and (iii) preventing "piling on." As to the latter three, Panuccio noted that DOJ is working on formalizing its practices with regard to cooperation credit and suggested that formal cooperation credit might be expanded to cover situations outside of those in which the defendant makes a self-disclosure. Cooperation credits in FCA cases have traditionally been less well spelled-out than in some other contexts (e.g., under the Foreign Corrupt Practices Act), and Panuccio's speech is a step towards formalizing those processes. He also explained that DOJ will "reward companies that invest in strong compliance measures," and that to prevent piling on, DOJ attorneys will promote coordination within the agency and with other regulatory bodies to ensure that defendants are subject to fair punishment and receive the benefit of finality that should accompany a settlement.

DOJ's continued focus on these efforts, led by officials at the highest levels within DOJ, suggests that FCA enforcement reform is a priority for the Department.

B. Opioid Enforcement Efforts Continue

In our 2017 Year-End FDA and Health Care Compliance and Enforcement Update – Drugs and Devices, we noted the surge in enforcement activities surrounding the opioid epidemic. From public pronouncements to criminal indictments, the current Administration has demonstrated widespread commitment to enforcement efforts around opioid issues. The focus is unlikely to let up soon.

For the time being, many of the enforcement efforts with regard to opioids have been on the criminal side and not directly related to the FCA. But given DOJ's close coordination between its criminal and civil divisions, widespread criminal enforcement efforts against an industry are often correlated with current, or imminent, FCA enforcement.

The intense focus on the criminal side can hardly be overstated. In June, the chief executive officer of a health care company and four physicians were charged in a superseding indictment with numerous crimes, including conspiracy to commit wire fraud and money laundering, as part of an ongoing investigation into the defendants' alleged $200 million fraudulent health care scheme involving Michigan- and Ohio-based pain clinics, laboratories, and other providers.[4] This was followed later in June by a DOJ announcement regarding the "National Health Care Fraud and Opioid Takedown."[5] Attorney General Sessions announced that DOJ was "charging 601 people, including 76 doctors, 23 pharmacists, 19 nurses, and other medical personnel with more than $2 billion in medical fraud."[6] DOJ also announced it has a "new data analytics program that focuses specifically on opioid-related health care fraud."[7] DOJ has also made forays into civil litigation by filing a statement of

interest in a high-stakes multi-district action against opioid manufacturers and distributors that is premised on allegedly false, deceptive, or unfair marketing practices for prescription opioid drugs.[8]

FCA enforcement is not far behind. On May 15, 2018, for example, an unsealed complaint revealed that the United States had intervened in five lawsuits accusing an Arizona-based opioid manufacturer of paying kickbacks to induce physicians and nurses to prescribe the company's opioid painkiller for their patients. The lawsuits allege that these kickbacks took the form of payments for sham speaking engagements, jobs for the prescribers' friends and relatives, and extravagant meals and other entertainment. The lawsuits likewise allege that the manufacturer improperly encouraged physicians to prescribe its opioids to patients who did not have cancer—the approved use of the drug—and that company employees also lied to insurers in order to obtain reimbursement under Medicare and TRICARE.[9]

C. Notable Settlements

All told, DOJ has announced more than approximately $600 million in settlements this year. This amount represents a decrease from previous years at the same point, largely because there have been comparatively fewer blockbuster settlements during the last six months. Still, the cadence of enforcement activity has continued to be steady.

1. Health Care and Life Sciences Industries

- On January 10, a dental management company and more than 130 of its affiliated dental clinics agreed to pay $23.9 million, plus interest, to settle allegations that the companies knowingly submitted false claims to state Medicaid programs for unnecessary services on Medicaid-insured youth. DOJ alleged that the companies incentivized and disciplined dentists to meet goals on procedures performed, ignoring when dentists complained about overutilization. DOJ alleged that the companies submitted false Medicaid claims in 17 states, and also submitted false claims to an additional program, the Texas Medicaid Program for First Dental Home. The federal government will receive approximately $14.2 million, plus interest, and states will receive approximately $9.7 million, plus interest. This investigation was initiated by five whistle-blower lawsuits. Three of the whistle-blowers, former employees of the dental clinics, will receive a total of more than $2.4 million from the federal portion of the settlement.[10]

- On March 7, a Pennsylvania hospital and cardiology group agreed to pay approximately $20.8 million combined to resolve claims that the two engaged in improper financial relationships to secure physician referrals. Specifically, the government alleged that the hospital paid the cardiology group up to $2 million per year under physician and administrative service arrangements for services that were duplicative, not performed, or not needed. The whistle-blower, a doctor in the cardiology group, received approximately $6 million of the recovered amount.[11]

- On March 23, a medical device manufacturer and its domestic subsidiary agreed to pay approximately $33.2 million to resolve claims that the subsidiary caused hospitals to submit false claims to government health care programs by knowingly selling materially unreliable point-of-

care diagnostic testing devices. The government claimed that the subsidiary received customer complaints that put it on notice that devices it sold produced erroneous results and failed to take corrective action until FDA inspections prompted a nationwide product recall. The whistle-blower, a former senior quality control analyst at the subsidiary, will receive approximately $5.6 million of the recovered amount.[12]

- On March 28, a Virginia ambulance services provider agreed to pay $9 million to settle allegations that it submitted false or fraudulent claims to Medicare, Medicaid, and TRICARE for ambulance transports that were not medically necessary, that did not qualify as Specialty Care Transports, and that should have been billed to other payers. As part of the settlement, the company entered into a five-year corporate integrity agreement with HHS OIG.[13]

- On March 29, a Texas company operating radiation therapy centers nationwide, along with its acquirer, agreed to pay up to $11.5 million to settle allegations that the Texas company paid kickbacks to physicians for referring patients to its cancer treatment centers. The companies also agreed to enter into a five-year corporate integrity agreement with HHS OIG, which includes internal and external monitoring of relationships between the companies and referring physicians. The Texas company allegedly distributed a share of the profits through a series of leasing companies in which referring physicians were permitted to invest. The whistle-blower will receive up to $1.7 million as part of the settlement.[14]

- On April 12, a Florida respiratory equipment supplier agreed to pay approximately $9.7 million to settle allegations that it knowingly submitted false claims for portable oxygen contents to Medicare between January 2009 and March 2012. Specifically, the government alleged that the company billed Medicare without verifying that beneficiaries used or needed the oxygen, and without obtaining the requisite proof of delivery. The whistle-blower will receive approximately $1.6 million as part of the settlement.[15]

- On April 12, an Arizona company that owns acute-care hospitals agreed to pay over $18 million to resolve allegations that 12 of its hospitals knowingly overcharged Medicare patients for short-stay, inpatient procedures that should have been billed on a less costly outpatient basis. The settlement also resolved claims that the company inflated the number of hours for which patients received outpatient observation in its reports to Medicare. As part of the settlement, the company entered into a five-year corporate integrity agreement with HHS OIG, which includes the requirement to retain an independent review organization to review the accuracy of claims submitted to federal health care programs. The whistle-blower, a former employee of the company, will receive approximately $3.3 million of the recovered amount.[16]

- On April 19, a California diagnostics laboratory agreed to pay $2 million to settle claims that it submitted and caused the submission of false claims to Medicare for Breast Cancer Index tests that were not reasonable and necessary. The government alleged the company promoted and performed the tests for patients who had not been in remission for five years and who had not been taking tamoxifen. The government claimed performing tests under such circumstances is medically unnecessary based on published clinical trial data and clinical practice guidelines.[17]

- On May 10, a Cincinnati-based nonprofit company operating several health care facilities in Ohio and Kentucky agreed to pay $14.25 million to settle allegations that the company provided compensation to six referring physicians in excess of the fair market value for the physicians' services. Per the government's announcement, these issues were self-reported by the nonprofit hospital system.[18]

- On May 24, a large pharmaceutical company agreed to pay $23.85 million to resolve claims that the company illegally paid the co-pays of Medicare patients taking three of the company's drugs. The alleged scheme involved the use of a foundation as a conduit for the remuneration.[19]

- On May 31, two owners of a Philadelphia pharmacy agreed to pay $3.2 million to resolve claims that over the course of roughly seven years the pair fraudulently billed Medicare for prescription medications that their pharmacy did not actually dispense to its patients.[20]

- On June 8, a Kentucky-based health care company that owns and operates roughly 115 skilled nursing facilities in several states agreed to pay more than $30 million to resolve allegations that it knowingly submitted false claims to Medicare for medically unreasonable or unnecessary rehabilitation therapy services. As part of the agreement, the State of Tennessee will receive a portion of the final settlement. The two relators who initially brought the suit will also receive a yet undetermined portion of the eventual settlement.[21]

- On June 20, a national wound-care provider agreed to pay $22.5 million to settle allegations that it billed the government for unnecessary and unreasonable hyperbaric oxygen therapy, which is a therapy indicated for certain chronic wounds. According to the government, the company billed for these unnecessary treatments for five years, between 2010 and 2015. In addition to the monetary settlement, the company entered into a five-year corporate integrity agreement that subjects the company to independent reviews.[22]

- On June 25, a hospice chain agreed to pay $8.5 million to resolve allegations that it improperly billed the federal government for hospice services. The government alleged that the company provided hospice care to patients who were not terminally ill (and therefore ineligible for the services), despite repeated warnings that ineligible patients were being admitted.[23]

2. Government Contracting and Defense/Procurement

- On March 15, a Japanese fiber manufacturer and its American subsidiary agreed to pay approximately $66 million to resolve claims that they sold defective Zylon fiber used in bulletproof vests, which the United States purchased for law enforcement agencies. The government alleged that between 2001 and 2005, the companies knew that Zylon degraded quickly in normal heat and humidity, rendering it unfit for use in bulletproof vests. Yet, according to the government, the companies published misleading degradation data that understated the defect and engaged in a marketing campaign that advocated for the continued sale of Zylon-containing vests after a body armor manufacturer recalled such vests. The whistle-blower will receive over $5.7 million as part of the settlement.[24] The settlement resolves part

of a long-running series of FCA cases related to allegedly defective bulletproof vests that goes back several decades and involved several companies.[25]

- On April 19, a former professional cyclist agreed to pay $5 million to resolve allegations that he submitted millions of dollars in false claims for sponsorship payments to the U.S. Postal Service ("USPS"), which sponsored his cycling team. The government claimed that the cyclist violated the terms of his team's USPS sponsorship by using performance enhancing drugs ("PEDs"), as well as making numerous false statements—including statements under oath—denying his PED use to induce the USPS to renew and increase its sponsorship. The whistle-blower, a former teammate, will receive $1.1 million as part of the settlement.[26]

- On May 29, a foreign-based federal contractor and several of its subsidiaries agreed to pay $20 million to resolve allegations that the companies knowingly overbilled the United States Navy under contracts to provide ship husbanding services in numerous ports around the world. As part of the resolution, the whistle-blowers in the case, three former employees of the contractor, will receive approximately $4.4 million.[27]

3. Financial Services

- On February 28, an audit firm agreed to pay $149.5 million to resolve potential FCA claims related to the firm's role as the independent outside auditor for a now-defunct originator of mortgage loans that were insured by the Federal Housing Administration ("FHA") under the Department of Housing and Urban Development ("HUD"). As part of a HUD program, the mortgage company was considered to be a Direct Endorsement Lender, and could submit claims to the United States to recover any losses that occurred as a result of a default on a loan insured by the FHA that the company had underwritten and endorsed. To maintain Direct Endorsement Lender status, the mortgage company was required to submit annual audited financial statements in compliance with HUD requirements. The audit firm issued audit reports on the mortgage company's annual financial statements for fiscal years 2002 through 2008. The United States alleged that the mortgage company was engaged in a fraudulent scheme involving the alleged sale of "fictitious or double-pledged" loans, leading to financial statements that failed to accurately reflect that the company was in financial distress. The United States also alleged that the audit firm did not identify the mortgage company's fraudulent conduct and alleged that by continuing to issue audit reports notwithstanding the mortgage company's misconduct, the company was able to continue originating the insured loans until the mortgage company declared bankruptcy in 2009. A number of officials from the mortgage company were criminally convicted in connection with the conduct at issue as well. [28]

4. Other

- On January 16, a home furnishings company agreed to pay $10.5 million to settle claims that it knowingly made false statements on customs declarations forms to avoid paying antidumping duties on imported bedroom furniture from China. The company classified the furniture as non-

bedroom furniture, which was not subject to the antidumping duties. In connection with the FCA settlement, a whistle-blower will receive approximately $1.9 million.[29]

D. Notable Verdicts and Judgments

In addition to the settlements noted above, there were several notable verdicts and judgments in FCA cases during the last six months.

- On January 11, a federal district court in Florida reversed a $350 million FCA jury verdict. The jury reached a verdict that a nursing home operator had submitted false claims by allegedly failing to maintain a comprehensive care plan that was "ostensibly required by Medicaid regulation," alongside other relatively minor infractions. *United States v. Salus Rehab., LLC*, 304 F. Supp. 3d 1258, 1260 (M.D. Fla. 2018). The court overturned the verdict, holding that "[t]he record fatally wants for evidence of materiality and scienter." In so holding, the court took umbrage that "relator won judgments for almost $350 million based" only on the theory that "a handful of paperwork defects" and "failure to maintain care plans made" defendants' claims to Medicare and Medicaid false or fraudulent. *Id.* The court explained that "the relator offered no meaningful and competent proof that the federal or the state government, if either or both had known of the disputed practices (assuming that either or both did not know), would have regarded the disputed practices as material to each government's decision to pay the defendants and, consequently, that each government would have refused to pay the defendants." *Id.* It also disagreed that there was any evidence the defendants acted knowingly. *Id.* In so holding, the court affirmed the importance of the Supreme Court's *Escobar* decision and its role in enforcing the FCA's materiality standard.

- On May 29, the United States District Court in the District of South Carolina entered a judgment totaling approximately $114 million against three individuals found liable under the FCA of paying kickbacks to physicians in exchange for patient referrals. The underlying claims were initially brought as part of three lawsuits filed by four whistle-blowers, alleging that the kickback scheme caused two blood testing laboratories in Virginia and California to bill federal health care programs for medically unnecessary tests. The whistle-blowers' share of the judgment has not yet been determined.[30]

II. LEGISLATIVE ACTIVITY

A. Federal Legislation

As with the latter half of 2017, the first half of 2018 has seen little to no federal legislative activity affecting the FCA. While President Trump's plan to repeal and replace the Affordable Care Act ("ACA") could have affected the ACA's amendments to the FCA—as discussed in our 2017 Mid-Year False Claims Act Update[31]—Congress has not shown any signs that it will pass such a bill in the near future, though some commentators have speculated that Senate Republicans may attempt such a feat in an effort to rally the base for the 2018 elections.[32] Senator Lindsey Graham (R-S.C.) announced in May that he is working on a new repeal-and-replace bill, but no new bills have been introduced in Congress and Senator Graham's "effort appears to have little, if any, chance of passing this year."[33]

In a February speech on the Senate floor, Senator Chuck Grassley laid out his views about problems arising from the Supreme Court's 2016 *Escobar* decision that are "getting some defendants, and judges, tied in knots."[34] In particular, Senator Grassley criticized courts for applying the Supreme Court's instruction regarding so-called "government knowledge"—that continued government payment, in the face of government knowledge of non-compliance with regulatory or contractual requirements, may be strong evidence that the violation is not material. According to Grassley, the Court "did not say that in every case, if the government pays a claim despite the fact that someone, somewhere in the bowels of the bureaucracy might have heard about allegations that the contractor may have done something wrong, the contractor is automatically off the hook."[35] And he set forth his views of how courts should apply *Escobar* without "piling on bogus restrictions that are just not in the law."[36] Notably, the issue of the interplay between government knowledge and materiality is back before the Supreme Court on a petition for certiorari in *United States ex rel. Campie v. Gilead Sciences. Inc.*, 862 F.3d 890 (9th Cir. 2017), as discussed below. If the Court takes that case, and rules in a way that bolsters its *Escobar* decision instead of the viewpoint espoused by Senator Grassley, we will be watching closely to see if the Court's interpretation prompts a Congressional response.

Consistent with the Trump administration's agenda, Federal regulatory activity implicating the FCA has also remained stagnant. As noted in our 2017 Year-End False Claims Act Update,[37] the FDA proposed a regulation in January 2017 that would amend and expand the agency's definition of "intended use" for drugs and devices codified in 21 C.F.R. § 201.128 and 21 C.F.R. § 801.4, but that rule's effective date was delayed until March 19, 2018 after opposition from industry.[38] On March 16, the FDA delayed indefinitely the effective date of the portions of the rule relating to intended use "to allow further consideration of the substantive issues raised in the comments received regarding the amendments."[39]

On March 23, 2018, President Trump signed an omnibus appropriations bill authorizing $1.3 trillion in spending, $654.6 billion of which was designated for the Department of Defense—a $60 billion increase from 2017 defense spending.[40] The bill also includes a $21.2 billion appropriation for infrastructure spending. This law does not amend the FCA or substantively alter enforcement, but the increase in spending may invite greater FCA enforcement scrutiny or relator actions for the defense and construction contractors who work with the federal government.

B. State Legislation

In 2005, Congress created financial incentives for states to enact their own False Claims Acts and make them as effective as the federal FCA in facilitating *qui tam* lawsuits. If a state meets this standard, it may be eligible to "receive a 10-percentage-point increase in [its] share of any amounts recovered under such laws."[41] The Department of Health and Human Services Office of Inspector General ("HHS OIG") is tasked with assessing whether a state's law qualifies. As reported in our last Mid-Year update,[42] HHS OIG notified 15 states at the end of 2016 that their laws required amendment to meet the federal standard, and it set a "grace period" through the end of 2018 to bring state law into compliance or risk losing the 10% financial incentive.[43] Since our Year-End update:

- A **Michigan** bill that would amend the civil penalties in the Michigan Medicaid False Claims Act to mirror penalties allowed under the federal FCA has not progressed beyond its November 28, 2017 referral to the Senate Judiciary Committee.[44]

- A similar **New York** bill died in the Senate and was returned to the Assembly on January 3, 2018.[45]

- A similar **North Carolina** bill has not progressed since it was re-referred to the Committee on Rules and Operations of the Senate in April 2017.[46]

- Other notable state legislative developments include:

- A **Florida** bill to exempt information from disclosure under the state's public records law that is related to an "investigation of violation of Florida False Claims Act" was approved by the governor on March 21, 2018.[47] As noted in our 2017 Year-End Update, this bill exempts the Florida FCA's under seal requirements from review and potential repeal under the Sunset Review Act.[48]

- There has been no action on a **Michigan** bill that would create a general Michigan False Claims Act since it was referred to the state's Senate Committee on the Judiciary in January 2017.[49] The bill would expand Michigan's current Medicaid False Claims Act beyond the Medicaid context.

- No action has been taken on a **Pennsylvania** bill that would create a state False Claims Act; the bill has been in the House Judiciary Committee since March 2017.[50]

We expect to see additional state legislative activity in the second half of 2018, as the HHS OIG "grace period" draws to an end. To date, HHS OIG has informed 12 states that their laws meet the federal standard (Colorado, Connecticut, Illinois, Indiana, Iowa, Massachusetts, Montana, Nevada, Oklahoma, Tennessee, Texas, and Vermont) and has informed 14 states that their laws do *not* meet the federal standard (California, Delaware, Florida, Georgia, Hawaii, Michigan, Minnesota, New Hampshire, New York, North Carolina, Rhode Island, Virginia, Washington, and Wisconsin).[51] Three other states were informed prior to recent federal amendments that their state laws did not meet the old federal standard (Louisiana, New Jersey, and New Mexico).[52]

III. NOTABLE CASE LAW DEVELOPMENTS

Thus far in 2018, courts have continued to advance the body of FCA case law. The appellate courts have issued nearly a dozen notable cases in the first part of the year, including decisions that explored the meaning of the Supreme Court's decision in *Universal Health Services, v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016), the FCA's statute of limitations, and the public disclosure bar. These decisions clarified some areas of the law, yet deepened splits in others. As always, we have closely monitored these developments and summarize the most notable decisions below.

A. Post-*Escobar* Developments

Now two years since it was decided, courts continue to grapple with the Supreme Court's landmark decision in *Escobar*. As we have previously discussed in depth (including here), in *Escobar*, the Supreme Court held that an implied false certification theory of liability under the FCA is actionable when: (1) a claim "does not merely request payment, but also makes specific representations about the goods or services provided" and (2) the defendant's failure to disclose noncompliance with some "material statutory, regulatory, or contractual requirement[] makes those representations misleading half-truths." *Id.* at 2001. The *Escobar* Court further instructed courts to apply a "rigorous" and "demanding" materiality standard, necessitating the plaintiff show something akin to that the government actually refused payment, or would have refused payment had it known of the alleged misrepresentations regarding compliance. *Id.* at 2002–03.

Since *Escobar*, lower courts have worked to determine the precise requirements for establishing materiality at the pleading stage. The fact-intensive analysis involved with materiality has produced some useful guidance for FCA defendants. For example, conclusory statements by a plaintiff that the government would not have paid had it known of the alleged false statement are insufficient to survive a pleadings challenge, *United States ex rel. Mateski v. Raytheon Co.*, No. 2:06-cv-03614, 2017 WL 3326452, at *7 (C.D. Cal. Aug. 3, 2017), yet, pleading that the government has previously terminated eligibility for similar falsities may be sufficient, depending upon the other allegations asserted, *see United States ex rel. Lacey v. Visiting Nurse Serv. of N.Y.*, No. 14-cv-5739, 2017 WL 5515860, at *10 (S.D.N.Y. Sept. 26, 2017).

As in prior years, the appellate courts continued to grapple with the application of *Escobar's* "rigorous" and "demanding" materiality requirement in the first half of 2018.

1. Sixth Circuit Considers Government Payment Practices

In *Escobar*, the Supreme Court explained that "proof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement." *Escobar*, 136 S. Ct. at 2003. The Sixth Circuit recently weighed in on the question of what is required to adequately allege materiality at the pleading stage in such cases.

United States ex rel. Prather v. Brookdale Senior Living Communities, Inc., 892 F.3d 822 (6th Cir. 2018) involved alleged false claims for home health services. Specifically, the relator alleged that the defendant home health provider failed to timely obtain provider physician certifications in violation of a regulation requiring such certifications to "be obtained at the time the plan of care is established or as soon thereafter as possible." *Id.* at 825. Despite concluding that compliance with the timing regulation was an express condition of payment, the district court had dismissed the claim for failure to adequately allege materiality under the standards articulated in *Escobar*. *Id.* at 826, 832. The district court reasoned that the complaint failed to identify any instance in which the government denied reimbursement for a similar violation in the entire 50-plus year history of the regulation, which suggested the government did not view violations of the certification regulation as material. *Id.* at 834. In addition, the relator cited

materials suggesting the government's concern focused on ensuring the services were medically necessary, not that the certification was made at a particular time. *Id.* 847–48 (J. McKeague, dissenting).

By a 2 to 1 vote, the Sixth Circuit reversed. *Id.* at 825. The court faulted the lower court for drawing "a negative inference from the absence of any allegations about past government action." *Id.* at 834. The majority explained that a relator is "not required to make allegations regarding past government action," and so absent the government's actual knowledge of the alleged fraud being pled, its past payment practices were irrelevant to whether an FCA plaintiff has adequately pled materiality in their complaint. *Id.* The court went on to find that the relator adequately alleged materiality, including based on the fact that the timing requirement was an express condition of payment. *Id.* at 836. The majority also concluded that the relator had adequately alleged scienter. *Id.* at 838.

In contrast, a vigorous dissent took the majority to task for failing to faithfully apply *Escobar* and for not requiring materiality to be alleged with particularity under Federal Rule of Civil Procedure 9(b) despite the fact that "every [other] Circuit to address this question agrees that Rule 9(b) governs materiality allegations." *Id.* at 845. As the dissent pointed out, the relator failed to allege that the government routinely refuses to pay claims based on the alleged violations, or that it would have refused to pay particular claims under the circumstances, which ran afoul of *Escobar's* guidance that "[t]he government's payment habits are, by far, the best evidence of materiality." *Id.* Moreover, the dissent faulted the court for "equating negligence with fraud"; as the dissent pointed out, the complaint alleged facts that were, at best, "only consistent with recklessness" and therefore did not adequately allege scienter. *Id.* at 852–53.

2. Eleventh Circuit Revives an Implied False Certification Claim

The Eleventh Circuit similarly revived an FCA claim predicated on an implied false certification theory in *Marsteller ex rel. United States v. Tilton*, 880 F.3d 1302 (11th Cir. 2018). *Marsteller* involved allegations that a defense contractor had certified compliance with code of business ethics and conduct requirements applicable to government contractors, but that the company did not comply with those requirements because it failed to disclose evidence of purportedly unethical acts of bribery, and that it provided the government with incomplete pricing data in violation of the Truth in Negotiations Act, 10 U.S.C. § 2306a. *Id.* In a pre-*Escobar* decision, the district court had dismissed the complaint, after declining the government's suggestion in a statement of interest "to limit the restrictive reading of the implied certification theory found in" prior precedent, and instead ruling that the theory only encompassed claims for payment made "despite a knowing failure to comply" with an express condition of payment. *Id.* at 1309–10.

On appeal, the Eleventh Circuit held that the line of cases relied upon by the district court was no longer good law in light of *Escobar* and remanded the case for the lower court to consider whether "in fairness to the relators, they should have an opportunity to replead their allegations in light of the Supreme Court's guidance" in *Escobar*. *Id.* at 1312–14. As the court emphasized, *Escobar* directs the materiality inquiry towards "whether [the] Government would have attached importance to the violation in determining whether to pay the claim" at issue. *Id.* at 1313.

In both *Marsteller* and *Prather*, the government filed a statement of interest regarding the district court's materiality analysis, despite having declined to intervene. In *Marsteller*, although the Government took no position on the viability of the complaint itself, it nevertheless "respectfully urge[d]" the district court "not to adopt the atextual position that implied certification False Claims Act liability for non-compliance with a contract provision (including regulatory or statutory provisions incorporated therein) necessarily hinges on the presence of an express statement within that provision that payment is conditioned on its compliance." 880 F.3d at 1309 n.15. Likewise in *Prather*, although the government took no position on the complaint at issue in the case, it argued that an express condition of payment is not required under *Escobar*, and further argued that *Escobar* does not require an FCA plaintiff to plead prior government denials of payments for similar violations. United States' Statement of Interest Regarding Defendants' Motion To Dismiss Third Amended Complaint at 2–3, 6, *Prather*, 892 F.3d 822 (No. 17-5826). If these cases are any indication, FCA defendants can expect to face the government's opposition in future cases that turn on allegations of materiality.

3. The Supreme Court Invites the Government's Views on *Gilead*

In our 2017 Mid-Year False Claims Act Update, we addressed the Ninth Circuit's materiality analysis in *United States ex rel. Campie v. Gilead Sciences. Inc.*, 862 F.3d 890 (9th Cir. 2017). As a reminder, in *Gilead*, the Ninth Circuit reversed dismissal of an implied certification claim. *Id.* at 895. In doing so, the court rejected the argument that the alleged violation was immaterial because the FDA was aware of the falsity and yet did not withdraw product approval. *Id.* at 906. This decision was appealed and the petition for certiorari is currently pending. *See* Petition for Writ of Certiorari, *Gilead*, 862 F.3d 890 (No. 17-936).

In April, the Supreme Court invited the U.S. Solicitor General to file a brief expressing the government's views on the case. This may signal the Court's interest in reviewing the matter to provide more guidance on the impact of government acquiescence. Clarification here would be welcomed, as we have previously noted that a circuit split is developing in this area. However, in recent years the Supreme Court has asked for the Solicitor General's views on key FCA issues only to go on to deny *certiorari* anyway. *See, e.g.*, *United States ex rel. Nathan v. Takeda Pharm.*, 707 F.3d 451 (4th Cir. 2013), *cert. denied* 81 U.S.L.W. 3650 (U.S. Mar. 31, 2014) (No. 12-1349).

B. The Eleventh Circuit Deepens a Circuit Split Regarding When the FCA's Extended Statute of Limitations Applies

For most FCA relators, the statute of limitations requires a suit be brought within six years of the underlying alleged violation. 31 U.S.C. § 3731(b)(1). However, an extended limitations period of up to ten years applies in select cases. 31 U.S.C. § 3731(b)(2) (permitting actions for "3 years after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances, but in no event more than 10 years after the date on which the violation is committed"). Circuits are split in determining whether this greater, up to ten-year period is only available when the government files or intervenes in the FCA suit, as opposed to being pursued only by the relator after the government declines intervention. Currently, most courts only apply the extended statute of limitations to suits brought by

the government itself, as well as *qui tam* actions in which the government chooses to intervene. *See United States ex rel. Sanders v. North American Bus Indus. Inc.*, 546 F.3d 288, 295 (4th Cir. 2008) (holding that "only a subset of civil actions may benefit from the extended limitations period in Section 3731(b)(2)—those in which the government is a party"); *United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 725–26 (10th Cir. 2006) ("[W]e hold that § 3731(b)(2) was not intended to apply to private *qui tam* relators at all."); *but see United States ex rel. Hyatt v. Northrop Corp.*, 91 F.3d 1211, 1214 (9th Cir. 1996) ("[T]here is nothing in the entire statute of limitations subsection which differentiates between private and government plaintiffs at all.").

The Eleventh Circuit recently went the other way, however, in an opinion holding that relators can utilize the extended statute of limitations period even in *qui tam* cases where the government has declined to intervene. In *United States ex rel. Hunt v. Cochise Consultancy Inc.*, 887 F.3d 1081 (11th Cir. 2018), the court considered this issue as a matter of first impression in the circuit. *Id.* at 1083. First, the court emphasized that "nothing in § 3731(b)(2) says that its limitations period is unavailable to relators when the government declines to intervene." *Id.* at 1089. The court also found that "the legislative history provides no convincing support for [the defendant's] position" that the greater limitations period is only available where the government files suit or intervenes. *Id.* at 1097. The court recognized its decision "is at odds with the published decisions of two other circuits," but found those opinions unpersuasive because those cases "reflexively applied the general rule that a limitations period is triggered by the knowledge of a party" while failing to consider "the unique role that the United States plays even in a non-intervened *qui tam* case." *Id.* at 1092.

In reaching this decision, the Eleventh Circuit departs from the Fourth and Tenth circuits but largely aligns with the Ninth Circuit. *See Hyatt*, 91 F.3d at 1214. However, on the question of the knowledge required to trigger the limitations period, the Eleventh Circuit concluded, contrary to the Ninth Circuit, that "it is the knowledge of a government official, not the relator, that triggers the limitations period," further complicating the circuit split. *Hunt*, 887 F.3d at 1096.

C. The Third Circuit Examines the Public Disclosure Bar

The FCA's public disclosure bar instructs courts to dismiss a relator's FCA action if "substantially the same allegations or transactions" were previously publicly disclosed in certain enumerated sources. 31 U.S.C. § 3730(e)(4). The "original source" exception to this rule, which allows relators to proceed on publicly disclosed allegations if they have "knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions," 31 U.S.C. § 3730(e)(4)(B), was the subject of a recent Third Circuit decision.

In *United States ex rel. Freedom Unlimited, Inc. v. City of Pittsburgh*, No. 17-1987, 2018 WL 1517159 (3d Cir. Mar. 28, 2018), the district court had dismissed the case at the pleading stage under the public disclosure bar, concluding that the relator "filed a qui tam suit based on information that the city revealed" publicly. *Id.* at *3. The Third Circuit reversed, and in doing so, emphasized the sometimes factual nature of whether there "has been a public disclosure within the meaning of the FCA and whether a relator qualifies as an original source." *Id.* (internal quotations omitted). In particular, the court noted that the relator claimed to have "directly observed" the defendant's alleged conduct and had "independent

knowledge" of the falsity. *Id.* While taking care to avoid suggesting that dismissal would never be appropriate at the pleading stage, the Third Circuit concluded the lower court "should have given the parties an opportunity to develop the facts in discovery inasmuch as appellants claim that they did not rely on public disclosures." *Id.* Additionally, because the district court's opinion pre-dated *Escobar*, the Third Circuit directed the district court to "rely on the factors set forth in *Escobar* in making a materiality decision," to the extent the complaint survived the public disclosure bar. *Id.* at *4.

D. Updates to the Causation Standard in Retaliation Claims

The FCA's anti-retaliation provision provides remedies to employees if "discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of lawful acts" conducted in furtherance of an FCA claim. 31 U.S.C. § 3730(h)(1). In a series of recent decisions, several courts have addressed the question of what an employee must show to demonstrate that an adverse action was "because of" the employee's activity protected under the FCA.

In *DiFiore v. CSL Behring, LLC*, 879 F.3d 71 (3d Cir. 2018), the Third Circuit provided guidance on the causation standard. There, the district court had required the plaintiff to show "protected activity was the 'but-for' cause of an adverse action." *Id.* at 76. On appeal, the plaintiff argued that the FCA only requires proof that "protected activity was a 'motivating factor' in the adverse action[]." *Id.* Rejecting this argument, the Third Circuit affirmed, relying on the Supreme Court's analysis in a pair of decisions regarding the causation standard in age discrimination and Title VII claims respectively. *Id.* (citing *Gross v. FBL Financial Services, Inc.*, 129 S.Ct 2343 (2009) and *University of Texas Southwestern Medical Center v. Nassar*, 133 S.Ct 2517 (2013)). As the court noted, the FCA used the "same 'because of' language" found in both the Age Discrimination in Employment Act and Title VII that had "compelled the Supreme Court to require 'but-for' causation." *Id.* at 78. As a result, in the Third Circuit, a plaintiff must show that he would not have faced the relevant adverse employment action "but for" his alleged protected activity.

The Sixth and Seventh Circuits similarly recently indicated a willingness to adopt a "but-for" causation standard in FCA retaliation claims. In *Heath v. Indianapolis Fire Dept.*, 889 F.3d 872 (7th Cir. 2018), the Seventh Circuit affirmed the district court's grant of summary judgment for the defendant. *Id.* at 874. The opinion was more notable, however, because—even though the Seventh Circuit had previously adopted a "motivating factor" standard—the *Heath* court nevertheless raised the question of whether that is the proper standard. *Id.* The court discussed the Supreme Court's opinion in *Nassar* and hinted that the similarity between the statutory language in Title VII and the FCA compels the conclusion that a plaintiff must show the adverse employment action was the "but for" result of activity protected under the FCA. *Id.*

Meanwhile, in *Smith v. LHC Group Inc.*, No. 17-5850, 2018 WL 1136072 (6th Cir. Mar. 2, 2018), the Sixth Circuit reversed dismissal of an FCA retaliation claim and concluded an employer's subjective intent need not be established to prevail on a theory of constructive discharge. *Id.* at *2. Although the panel's majority did not address causation, a concurring opinion expressed the view that causation

requires a showing of "but-for" causation under Supreme Court's *Nassar* and *Gross* decisions. *Id.* at *9 (citing *DiFiore*).

E. The Third Circuit Explores the Link Between the FCA and the Anti-Kickback Statute

The AKS prohibits companies and individuals from offering, paying, soliciting, or receiving "remuneration" to induce or reward referrals of business that will be paid for by Medicare, Medicaid, or other federal health care programs. 42 U.S.C. § 1320a-7b(b). By submitting a claim resulting from a violation of the AKS, an entity or individual also violates the FCA. *See* 42 U.S.C. § 1320a-7b(g) ("[A] claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA].")

The Third Circuit recently addressed the evidentiary requirement to link FCA claims with violations of the Anti-Kickback Statute. *United States ex rel. Greenfield v. Medco Health Sol's, Inc.*, 880 F.3d 89 (3d Cir. 2018). In *Greenfield*, a relator claimed a pharmacy (Accredo Health Group) illegally donated to specific charities in order to exclusively receive patient referrals in return. *Id.* at 91. The pharmacy then allegedly violated the FCA by falsely certifying that it complied with the Anti-Kickback statute when seeking reimbursement for the care provided to referred patients. *Id.* at 92.

The district court entered summary judgment for the defendant-pharmacy, finding the relator "failed to provide evidence of even a single federal claim for reimbursement . . . that was linked to the alleged kickback scheme." *Id.* at 91. In reaching its conclusion, the district court assumed that even if there was an Anti-Kickback Statute violation, there was an insufficient link to establish an FCA violation. *Id.* at 93 Specifically, the district court stated the relator needed to establish a causal link between the pharmacy's donations and a patient's subsequent decision to patron the pharmacy. *Id.* at 95.

On appeal, the Third Circuit affirmed. The panel first rejected the District Court's reasoning and concluded that a relator need not provide "proof that the underlying medical care would not have been provided but for a kickback." *Id.* at 100. Reviewing the legislative history of the FCA and Anti-Kickback Statute, the court concluded that "Congress intended both statutes to reach a broad swath of 'fraud and abuse' in the federal healthcare system" and "neither requires a plaintiff to show that a kickback directly influenced a patient's decision to use a particular medical provider." *Id.* at 96–97.

However, the court also rejected the notion that "the taint" of the alleged kickbacks automatically "renders every reimbursement claim false" and concluded that to prevail on summary judgment, it is not enough for a relator to show merely that the defendant "submitted federal claims while allegedly paying kickbacks." *Id.* at 99–100. In the court's view, "[a] kickback does not morph into a false claim unless a particular patient is exposed to an illegal recommendation or referral and a provider submits a claim for reimbursement pertaining to that patient." *Id.* at 100. Instead, the court held, a relator must therefore demonstrate at least one false claim, i.e., "at least one claim that covered a patient who was recommended or referred" in violation of the Anti-Kickback Statute. *Id.* Absent "evidence . . . link[ing the] alleged kickback scheme to any particular claim" in this manner, an FCA defendant is entitled to summary judgment. *Id.*

IV. CONCLUSION

The first half of 2018 saw developments that could portend important changes on the horizon. We will monitor these developments, along with other FCA legislative activity, settlements, and jurisprudence throughout the year. You can look forward to a comprehensive summary in our 2018 False Claims Act Year-End Update, which we will publish in January 2018.

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[1] *See* Memo, 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 (emphasis added).

[2] *See* Memo, U.S. Dep't of Justice, Limiting Use of Agency Guidance Documents In Affirmative Civil Enforcement Cases (Jan. 25, 2018), https://www.justice.gov/file/1028756/download.

[3] *See* Memo, U.S. Dep't of Justice, Prohibition on Improper Guidance Documents (Nov. 16, 2017), https://www.justice.gov/opa/press-release/file/1012271/download.

[4] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Health Care CEO and Four Physicians Charged in Superseding Indictment in Connection with $200 Million Health Care Fraud Scheme Involving Unnecessary Prescription of Controlled Substances and Harmful Injections (June 6, 2018), https://www.justice.gov/opa/pr/health-care-ceo-and-four-physicians-charged-superseding-indictment-connection-200-million.

[5] *See* Speech, U.S. Dep't of Justice, Attorney General Sessions Delivers Remarks Announcing National Health Care Fraud and Opioid Takedown (June 28, 2018), https://www.justice.gov/opa/speech/attorney-general-sessions-delivers-remarks-announcing-national-health-care-fraud-and.

[6] *Id.*

[7] *Id.*

[8] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Justice Department to File Statement of Interest in Opioid Case (Feb. 27, 2018), https://www.justice.gov/opa/pr/justice-department-file-statement-interest-opioid-case.

[9] *See* Press Release, Office of Pub. Affairs, United States Intervenes in False Claims Act Lawsuits Accusing Insys Therapeutics of Paying Kickbacks and Engaging in Other Unlawful Practices to Promote Subsys, A Powerful Opioid Painkiller (May 15, 2018), https://www.justice.gov/opa/pr/united-states-intervenes-false-claims-act-lawsuits-accusing-insys-therapeutics-paying.

[10] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Dental Management Company Benevis and Its Affiliated Kool Smiles Dental Clinics to Pay $23.9 Million to Settle False Claims Act Allegations Relating to Medically Unnecessary Pediatric Dental Services (Jan. 10, 2018),

https://www.justice.gov/opa/pr/dental-management-company-benevis-and-its-affiliated-kool-smiles-dental-clinics-pay-239.

[11] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Pennsylvania Hospital and Cardiology Group Agree to Pay $20.75 Million to Settle Allegations of Kickbacks and Improper Financial Relationships (Mar. 7, 2018), https://www.justice.gov/opa/pr/pennsylvania-hospital-and-cardiology-group-agree-pay-2075-million-settle-allegations.

[12] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Alere to Pay U.S. $33.2 Million to Settle False Claims Act Allegations Relating to Unreliable Diagnostic Testing Devices (Mar. 23, 2018), https://www.justice.gov/opa/pr/alere-pay-us-332-million-settle-false-claims-act-allegations-relating-unreliable-diagnostic.

[13] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Ambulance Company to Pay $9 Million to Settle False Claims Act Allegations (Mar. 28, 2018), https://www.justice.gov/opa/pr/ambulance-company-pay-9-million-settle-false-claims-act-allegations.

[14] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Radiation Therapy Company Agrees to Pay Up to $11.5 Million to Settle Allegations of False Claims and Kickbacks (Mar. 29, 2018), https://www.justice.gov/opa/pr/radiation-therapy-company-agrees-pay-115-million-settle-allegations-false-claims-and.

[15] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Rotech Agrees to Pay $9.68 Million to Settle False Claims Act Liability Related to Improper Billing for Portable Oxygen (Apr. 12, 2018), https://www.justice.gov/opa/pr/rotech-agrees-pay-968-million-settle-false-claims-act-liability-related-improper-billing.

[16] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Banner Health Agrees to Pay Over $18 Million to Settle False Claims Act Allegations (Apr. 12, 2018), https://www.justice.gov/opa/pr/banner-health-agrees-pay-over-18-million-settle-false-claims-act-allegations.

[17] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, San Diego Laboratory Agrees to Pay $2 Million to Settle False Claims Act Allegations Related to Unnecessary Breast Cancer Testing (Apr. 19, 2018), https://www.justice.gov/opa/pr/san-diego-laboratory-agrees-pay-2-million-settle-false-claims-act-allegations-related.

[18] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Ohio Hospital Operator Agrees to Pay United States $14.25 Million to Settle Alleged False Claims Act Violations Arising From Improper Payments to Physicians (May 10, 2018), https://www.justice.gov/opa/pr/ohio-hospital-operator-agrees-pay-united-states-1425-million-settle-alleged-false-claims-act.

[19] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Drug Maker Pfizer Agrees to Pay $23.85 Million to Resolve False Claims Act Liability for Paying Kickbacks (May 24, 2018), https://www.justice.gov/opa/pr/drug-maker-pfizer-agrees-pay-2385-million-resolve-false-claims-act-liability-paying-kickbacks.

[20] *See* Press Release, U.S. Atty's Office for the Eastern Dist. of Pa., U.S. Dep't of Justice, Pharmacy owners agree to pay $3.2 million to resolve False Claims case (May 31, 2018), https://www.justice.gov/usao-edpa/pr/pharmacy-owners-agree-pay-32-million-resolve-false-claims-case.

[21] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Signature HealthCARE to Pay More Than $30 Million to Resolve False Claims Act Allegations Related to Rehabilitation Therapy (June 8, 2018), https://www.justice.gov/opa/pr/signature-healthcare-pay-more-30-million-resolve-false-claims-act-allegations-related.

[22] *See* Press Release, U.S. Atty's Office for the Middle Dist. Of Fla., U.S. Dep't of Justice, Healogics Agrees To Pay Up To $22.51 Million To Settle False Claims Act Liability For Improper Billing Of Hyperbaric Oxygen Therapy (June 20, 2018), https://www.justice.gov/usao-mdfl/pr/healogics-agrees-pay-2251-million-settle-false-claims-act-liability-improper-billing.

[23] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Caris Agrees to Pay $8.5 Million to Settle False Claims Act Lawsuit Alleging That it Billed for Ineligible Hospice Patients (June 25, 2018), https://www.justice.gov/opa/pr/caris-agrees-pay-85-million-settle-false-claims-act-lawsuit-alleging-it-billed-ineligible.

[24] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Japanese Fiber Manufacturer to Pay $66 Million for Alleged False Claims Related to Defective Bullet Proof Vests (Mar. 15, 2018), https://www.justice.gov/opa/pr/japanese-fiber-manufacturer-pay-66-million-alleged-false-claims-related-defective-bullet.

[25] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Point Blank Pays U.S. $1 Million for the Sale of Defective Zylon Bulletproof Vests (Nov. 7, 2011), https://www.justice.gov/opa/pr/point-blank-pays-us-1-million-sale-defective-zylon-bulletproof-vests; Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, U.S. Sues First Choice Armor & Equipment for Providing Defective Bullet-Proof Vests to Law Enforcement Agencies (Aug. 3, 2009), https://www.justice.gov/opa/pr/us-sues-first-choice-armor-equipment-providing-defective-bullet-proof-vests-law-enforcement.

[26] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Lance Armstrong Agrees to Pay $5 Million to Settle False Claims Allegations Arising From Violation of Anti-Doping Provisions of U.S. Postal Service Sponsorship Agreement (Apr. 19, 2018), https://www.justice.gov/opa/pr/lance-armstrong-agrees-pay-5-million-settle-false-claims-allegations-arising-violation-anti.

[27] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, United States Settles Lawsuit Alleging That Contractor Falsely Overcharged the U.S. Navy for Ship Husbanding Services (May 29, 2018), https://www.justice.gov/opa/pr/united-states-settles-lawsuit-alleging-contractor-falsely-overcharged-us-navy-ship-husbanding.

[28] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Deloitte & Touche Agrees to Pay $149.5 Million to Settle Claims Arising From Its Audits of Failed Mortgage Lender Taylor, Bean & Whitaker (Feb. 28, 2018), https://www.justice.gov/opa/pr/deloitte-touche-agrees-pay-1495-million-settle-claims-arising-its-audits-failed-mortgage.

[29] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Bassett Mirror Company Agrees to Pay $10.5 Million to Settle False Claims Act Allegations Relating to Evaded Customs Duties (Jan. 16, 2018), https://www.justice.gov/opa/pr/bassett-mirror-company-agrees-pay-105-million-settle-false-claims-act-allegations-relating.

[30] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, United States Obtains $114 Million Judgment Against Three Individuals for Paying Kickbacks for Laboratory Referrals and Causing Claims for Medically Unnecessary Tests (May 29, 2018), https://www.justice.gov/opa/pr/united-states-obtains-114-million-judgment-against-three-individuals-paying-kickbacks.

[31] *2017 Mid-Year False Claims Act Update*, Gibson Dunn (July 12, 2017), https://www.gibsondunn.com/2017-mid-year-false-claims-act-update/.

[32] *See, e.g.*, Quin Hillyer, *Obamacare Repeal May Be Closer Than You Think*, Wash. Examiner (Apr. 26, 2018), https://www.washingtonexaminer.com/opinion/obamacare-repeal-may-be-closer-than-you-think.

[33] Peter Sullivan, *Graham Working on New ObamaCare Repeal Bill*, The Hill (May 16, 2018), http://thehill.com/policy/healthcare/388000-graham-working-on-new-obamacare-repeal-bill.

[34] *Prepared Senate Floor Statement by Senator Chuck Grassley of Iowa, Interpreting the False Claims Act; S. Comm. on the Judiciary* (Feb. 13, 2018), https://www.grassley.senate.gov/news/news-releases/interpreting-false-claims-act.

[35] *Id.*

[36] *Id.*

[37] *2017 Year-End False Claims Act Update*, Gibson Dunn (Jan. 5, 2018), https://www.gibsondunn.com/2017-year-end-false-claims-act-update/.

[38] Industry opponents worried that expanding the definition of "intended use" could "spawn[] a flurry of unwarranted FCA lawsuits." *Id.*

[39] *See Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding "Intended Uses"; Partial Delay of Effective Date*, U.S. Dep't of Health & Human Servs.—Food and Drug Admin. (Mar. 16, 2018), https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-05347.pdf. The portions of the rule relating to the regulation of tobacco products went into effect on March 19, 2018.

[40] Mark A. Rush, David I. Kelch & Isaac T. Smith, *The False Claims Act in 2017: The Year in Review and What to Watch in 2018*, BNA (Apr. 25, 2018), https://www.bna.com/false-claims-act-n57982091498/; *see also* Pub. L. No. 115-141 (2018) (final law).

[41] *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.

[42] *See supra* note 37.

[43] *See supra* note 41 (collecting letters to states).

[44] S.B. 0669, 2017 Reg. Sess. (Mich. 2017), http://www.legislature.mi.gov/(S(y01pr1bmjos4hv4bgw5wcuid))/mileg.aspx?page=getobject&objectname=2017-SB-0669&query=on.

[45] A.B. A07989, 2017-2018 Leg. Sess. (N.Y. 2017), http://nyassembly.gov/leg/?default_fld=&leg_video=&bn=A07989&term=2017&Summary=Y&Actions=Y.

[46] S.B. 378, 2017-2018 Reg. Sess. (N.C. 2017), https://www2.ncleg.net/BillLookup/2017/s378.

[47] H.B. 7013, 2017 Reg. Sess. (Fla. 2017), https://www.flsenate.gov/Session/Bill/2018/7013.

[48] *See supra* note 37.

[49] S.B. 0065, 2017 Reg. Sess. (Mich. 2017), http://www.legislature.mi.gov/(S(2eethmzh3ynmq4revoals1xd))/mileg.aspx?page=GetObject&objectname=2017-SB-0065.

[50] H.B. 1027, 2017-2018 Reg. Sess. (Penn. 2017), http://www.legis.state.pa.us/cfdocs/billInfo/billInfo.cfm?sYear=2017&sInd=0&body=H&type=B&bn=1027.

[51] *See supra* note 41.

[52] *See id.*

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Gibson Dunn's lawyers have handled hundreds of FCA investigations and have a long track record of litigation success. Among other significant victories, Gibson Dunn successfully argued the landmark Allison Engine case in the Supreme Court, a unanimous decision that prompted Congressional action. See Allison Engine Co. v. United States ex rel. Sanders, 128 S. Ct. 2123 (2008). Our win rate

and immersion in FCA issues gives us the ability to frame strategies to quickly dispose of FCA cases. The firm has more than 30 attorneys with substantive FCA expertise and more than 30 former 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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