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The False Claims Act in 2017: The Year in Review and What to Watch in 2018

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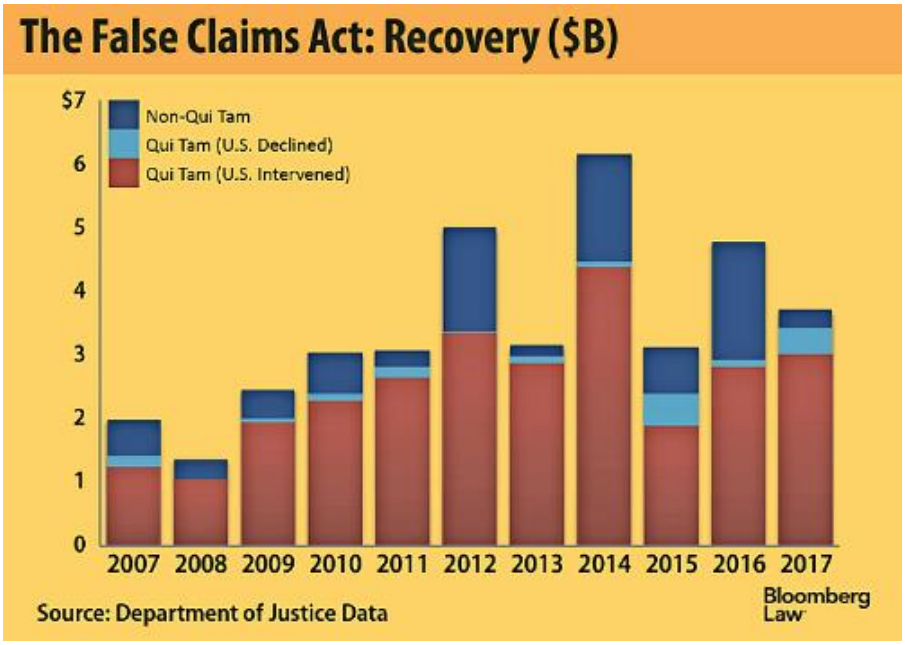
Introduction

The False Claims Act (the "FCA") was heavily litigated in the courts in 2017, resulting in a number of significant rulings and the emergence of important new issues. In light of these new issues and continued active FCA enforcement, it is important for legal practitioners and government contractors to be aware of FCA developments and trends from 2017 and how they may affect business in 2018. Enforcement successes, individual accountability, and FCA decisions and developments regarding, among other issues, materiality, falsity, and knowledge are detailed below. Possible trends in the law and enforcement actions, including the impact of the recently-enacted $1.3 trillion federal spending bill, are also discussed.



FCA Enforcement Remained Robust in 2017

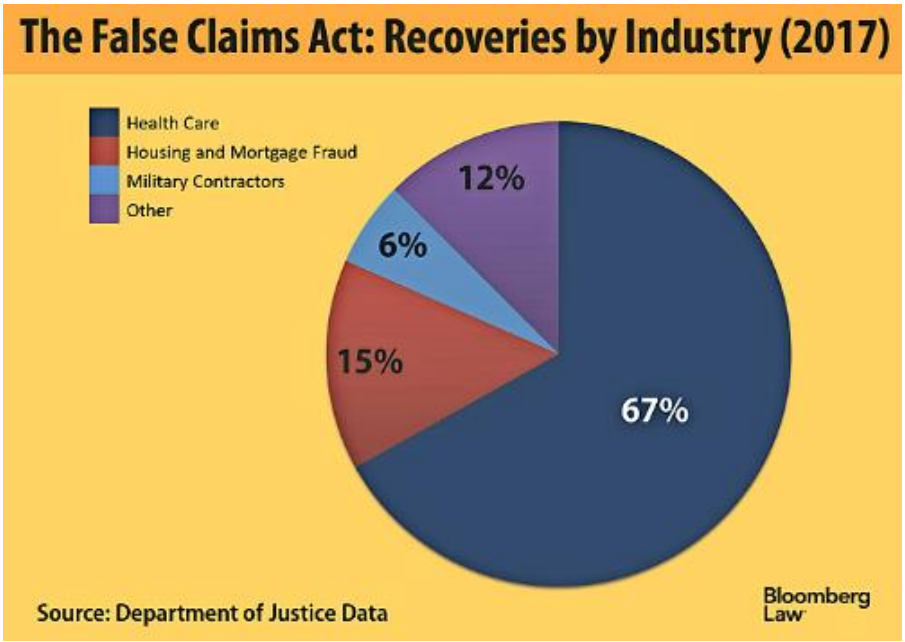
In 2017, the Department of Justice (the "DOJ") continued its robust enforcement of the FCA. In fiscal year 2017, the DOJ obtained $3.7 billion in settlements and judgments in FCA cases. While the government's total recovery dipped slightly from 2016, 2017 was the eighth straight year that recoveries topped $3 billion.

Of the 799 new FCA actions filed in FY 2017, 674 were qui tam actions. Qui tam actions in which the government elected to intervene continued to constitute the lion's share of the recovery in qui tam actions, amounting to $3 billion of the $3.4 billion recovered through qui tam suits.

Government FCA Recovery Was Highest in Health Care but Included Housing, Energy, and Tech

Of the $3.7 billion recovered by the DOJ in FY 2017, $2.4 billion came from the health care industry, the eighth consecutive year health care fraud recoveries have surpassed $2 billion. The DOJ settled or obtained judgments against defendants in a wide variety of sectors of the health care industry, including pharmaceutical companies, hospitals, physicians and physician practice groups, outpatient clinics, hospice and hospice care systems, and pharmacies.

The largest recoveries came from pharmaceutical and medical device manufacturers, which accounted for over $900 million of the $2.4 billion in health care fraud recoveries. The DOJ recovered money from defendants in a wide number of non-health care industries. Housing and mortgage fraud was second to health care fraud with over $543 million in recoveries. The DOJ also recovered from military contractors, energy providers, and technology companies, among others.



In 2017, the Government Continued to Prioritize Individual Accountability

Since the "Yates Memo" in 2015, issued by Salley Quillian Yates when she was a Deputy Attorney General, the DOJ has emphasized individual accountability for corporate misconduct. The DOJ has assessed penalties against individuals for FCA violations through fines, licensure termination, restitution, and imprisonment.

An emerging component of the DOJ's emphasis on individual accountability is holding owners and executives of private companies jointly and severally liable with their companies in FCA settlements. For example, in May 2017, the DOJ reached an agreement to hold three executives of an electronic health records software company, jointly and severally liable as part of a settlement agreement related to alleged FCA violations. The three executives agreed to be jointly and severally liable for a payment of nearly $155 million related to the company's alleged misrepresentation of the capabilities of its

software when obtaining certification from the Department of Health and Human Services ("HHS") as part of an incentive program to encourage health care providers to adopt electronic health record technology.

Significant FCA Decisions and Developments

In 2017, the courts considered a broad range of FCA issues. Several noteworthy decisions addressed the FCA elements of materiality, falsity and knowledge. Particularly significant were decisions regarding the requirements for establishing implied false certification liability and materiality in the wake of the Supreme Court's decision in Universal Health Services v. United States ex rel. Escobar, 2016 BL 192168 (2016) ("Escobar"). The courts also considered issues surrounding reverse false claims, the statutory bars to FCA actions (i.e. public disclosure bar and first-to-file bar), pleading requirements pursuant to FRCP 9(b), and the government's settlement veto authority.

Materiality

In Escobar, the Supreme Court emphasized the "rigorous" and "demanding" nature of the materiality requirement, holding that FCA liability only arises from violation of a statutory, regulatory, or contractual requirement where the requirement actually matters to the government's decision to pay, and the defendant knew that it would. Materiality cases in 2017 primarily considered what evidence was necessary to prove materiality.

The Fourth Circuit, in U.S. ex rel. Badr v. Triple Canopy, Inc., 2017 BL 164046 (4th Cir. 2017), a case involving a military contractor, found omissions were material based on both "common sense and [defendant's] own actions in covering up the noncompliance." The military contractor had agreed to provide guards that had met marksmanship requirements to a U.S. airbase in Iraq, but instead falsified marksmanship qualifications for its guards who failed to meet qualifications, therefore billing the government for unqualified employees. The court considered the marksmanship requirement for guards material based on common sense, analogizing it to an example used by the Escobar court regarding a contract for guns that do not shoot, stating that "[g]uns that do not shoot are as material to the Government's decision to pay as guards that cannot shoot straight." Further, the court determined that the military contractor's actions of falsifying the guards' qualifications was sufficient evidence of "actual knowledge" that the guard's ability to shoot actually mattered to the government's decision to pay.

In considering materiality, courts also focused on the government's knowledge of the misrepresentation and its subsequent actions based on its knowledge. For example, the D.C. Circuit, in U.S. ex rel. McBride v. Halliburton Co., 2017 BL 48645 (D.C. Cir. 2017), held that the government's investigation into the relator's allegations and subsequent payment of the claims was "very strong" evidence that the misrepresentations were not material. The Third and Fifth Circuits relied on similar evidence in determining materiality in U.S. ex rel. Spay v. CVS Caremark Corp., 2017 BL 411359 (3d Cir. 2017) and Abbot v. BP Exploration & Production, Inc., 2017 BL 78754 (5th Cir. 2017).

Several appeals court decisions in 2017 also based findings of materiality on whether the government chose to intervene in a qui tam action. For example, the Fourth Circuit, in Badr, noted that the fact that the government "immediately intervened in the litigation" was evidence that the defendant's "falsehood affected the Government's decision to pay." In contrast, in U.S. ex rel. Petratos v. Genentech, Inc., 2017 BL 143769 (3d Cir. 2017) the government declined to intervene and the court considered the declination as evidence that the misrepresentation was not material.

In 2017, courts also considered whether materiality is an element in cases involving pre-2009 conduct. Congress added materiality as an explicit requirement to several sections of the FCA in the Fraud Enforcement and Recovery Act of 2009. In 2017, the Third Circuit, in Spay, held for the first time that the materiality requirement applied to pre-2009 conduct. The court relied on the reasoning in Escobar that the materiality requirement is derived from common law, and that the changes in 2009 did not add a new element to FCA claims, but "merely made explicit and consistent that which had previously been a judicially-imposed . . . standard."

Falsity

Escobar also featured prominently in 2017 decisions related to the falsity requirement of the FCA. In Escobar, the Supreme Court held that the "implied false certification theory," can provide the basis for liability under the FCA. The implied false certification theory involves a defendant making a representation when submitting its claim, but omitting violations of statutory, regulatory, or contractual requirements, which render the representations misleading. The Court reasoned that FCA liability is triggered for such half-truths. The Court concluded that such claims meet the falsity requirement and

result in FCA liability, "at least where two conditions are satisfied: first, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths."

In 2017, courts split on whether both conditions articulated in Escobar must be satisfied. Some courts concluded that defendant's claim must make specific representations in order for the falsity requirement to be met. See, e.g., U.S. ex rel. Campie v. Gilead Sciences, Inc., 2017 BL 234508 (9th Cir. 2017) ("[Defendant] must not merely request payment, but also make specific representations about the goods or services provided."). Other courts reasoned that the two conditions articulated it Escobar are only one way to prove the falsity element and that the defendant need not make specific representations for a submitted claim to be a half-truth, and thus meet the falsity element. For example, in Badr the defendants submitted invoices listing only "the number of guards and hours worked and . . . contained no falsities on their face" or specific representations regarding the guards' compliance with contractual marksmanship requirements. The Fourth Circuit concluded that this knowingly deceptive conduct constituted the sort of "half-truth" the Court in Escobar had held met the falsity requirement.

In 2017, the Ninth Circuit took a unique approach to the Escobar falsity conditions. In Campie, relators alleged that a drug manufacturer submitted claims for payment of drugs it manufactured and that those claims violated the FCA under an implied false certification theory because they were manufactured at facilities in China that were not certified by the Food and Drug Administration, as required by statute. The Ninth Circuit held that a specific representation was required under an implied false certification theory. However, the court ruled that the drug names themselves were specific representations of compliance with FDA regulations.

Knowledge

A split in the federal appeals courts developed in 2017 regarding the FCA's knowledge requirement. Beginning in 2015, several courts have held that a defendant's articulation of a reasonable interpretation of an ambiguous regulation precludes the finding of scienter necessary to establish a claim under the FCA. See, e.g., U.S. ex rel. Donegan v. Anesthesia Assoc. of Kansas City, 2016 BL 261452 (8th Cir. 2016); United States ex rel. Purcell v. MWI Corp., 2015 BL 386398 (D.C. Cir. 2015).

However, the Eleventh Circuit, in U.S. ex rel. Phalp v. Lincare Holdings, Inc., 2017 BL 177893 (11th Cir. 2017), took a markedly different approach in 2017, holding that defendants cannot evade FCA liability by articulating a reasonable interpretation to an ambiguous regulation after the fact. The court stated that the proper approach in determining scienter is "whether the defendant actually knew or should have known that its conduct violated a regulation in light of any ambiguity at the time of the alleged violation." The decision was a significant departure from the holdings of other courts and may increase the risk of FCA liability to those companies operating in ambiguous regulatory territory.

In another noteworthy decision, the Third Circuit joined six other circuits in recognizing the "government knowledge inference" defense, which precludes a finding of scienter under the FCA if the government has knowledge of facts underlying the allegedly false record or statement. See U.S. ex rel. Spay v. CVS Caremark Corp., 2017 BL 411359 (3d Cir. 2017).

Reverse False Claims

A "reverse false claim" under the FCA occurs where a defendant knowingly makes or uses a false record or statement for the purpose of avoiding or decreasing an "obligation" owed to the United States.

In U.S. ex rel. Kasowitz v. BASF Corp., 2017 BL 378811 (D.D.C., Oct. 23, 2017), the D.C. district court held that unassessed contingent penalties are not an "obligation" under the FCA. In the complaint, the relator alleged several chemical manufacturers failed to report certain health and environmental information to the Environmental Protection Agency ("EPA") as required by the Toxic Substances Control Act ("TSCA"). The relator argued that the penalties the EPA could have assessed against the chemical companies for failing to report the TSCA information constituted an "obligation" that the companies knowingly avoided, thus triggering FCA liability. In finding FCA liability did not apply, the court focused on the EPA's broad discretion to assess penalties under the TSCA and concluded that "an FCA 'obligation' 'does not include a duty that is dependent on a future discretionary act.'"

Public Disclosure Bar

The public disclosure bar requires a qui tam action to be dismissed if substantially the same allegations or facts in the complaint were publicly disclosed in a prior case, a government report, or in the news media. An exception exists if the relator is an "original source" of the information, meaning the relator either conveyed the information to the government before public disclosure or the relator had independent knowledge that materially adds to the disclosed allegations, and provides the information to the government before filing an FCA action. The public disclosure bar is a frequent source of litigation.

In 2017, several courts examined what must be publicly disclosed to trigger the public disclosure bar. In one such case, Amphastar Pharmaceuticals, Inc. v. Aventis Pharma SA, 2017 BL 157523 (9th Cir. 2017), the Ninth Circuit considered the claims of a relator who alleged a drug manufacturer falsified a patent application submitted to the Patent and Trademark Office, and thus obtained an unlawful monopoly. The court affirmed the lower court's dismissal on the grounds that sufficient detail of the fraud was publically disclosed in a prior patent infringement lawsuit between the parties even though that suit made no express reference to false claims or the FCA.

In U.S. ex rel. Lager v. CSL Behring, L.L.C., 2017 BL 150509 (8th Cir. 2017), the Eighth Circuit held that a public disclosure need not explicitly identify the perpetrator of the alleged fraud or the specific fraud itself for the bar to apply. The relator alleged that a drug manufacturer conspired with pharmacies to inflate the price of its drug in reimbursement claims. The district court dismissed the claim pursuant to the public disclosure bar, pointing to news media and government reports regarding an inflated-price scheme regarding this type of drug. The relator appealed, arguing that he had provided added value by identifying the drug manufacturer as the perpetrator and the specifics of the fraud. The Eighth Circuit affirmed dismissal finding that the government and media reports had given "enough information about the participants in the scheme to directly identify the defendants and the subject drugs."

In U.S. ex rel. Ibanez v. Bristol-Myers Squibb Co., 2017 BL 385870 (6th Cir. 2017), the Sixth Circuit addressed the issue of whether conduct that continues or restarts after public disclosure triggers the public disclosure bar. The court held the public disclosure bar did not apply to preclude a qui tam action related to an improper promotion scheme even though the government had previously pursued a FCA action against the defendant pharmaceutical company for nearly identical conduct. The previous promotion scheme had concluded after a settlement agreement with the government. The court held that the fact that the scheme continued or restarted after the agreement was an "essential element of the alleged fraud" which was not in the public domain prior to the qui tam action. Accordingly, the public disclosure bar could not preclude the action.

In U.S. ex rel. King v. Solvay Pharmaceuticals, Inc., 871 F.3d 318 (5th Cir. 2017), the Fifth Circuit considered what must be disclosed for a relator to be an "original source" for purposes of the exception to the public disclosure bar. The relator had given information to the FDA regarding a pharmaceutical company's off-label marketing and kickbacks scheme, which had been publically disclosed in magazine article. The Fifth Circuit held that the relator did not qualify as an "original source" because his pre-suit disclosure to the FDA did not connect the fraudulent scheme with any false claims or certification to the government. Accordingly, the court affirmed dismissal pursuant to the public disclosure bar, stating that a "disclosure must—at minimum—connect direct and independent knowledge of information about the pharmaceutical company's conduct to false claims submitted to the government, i.e., suggest an FCA violation."

First-to-File Bar

The first-to-file bar prevents a second relator from bringing a separate qui tam action based on the same facts underlying a pending FCA action. Federal appeals courts have been split on whether the first-to-file bar is jurisdictional, that is, whether the application of the bar deprives the court of subject matter jurisdiction. The First, Fourth, Fifth, Sixth, and Tenth Circuits have held the first-to-file bar is jurisdictional. The D.C. Circuit has held that the rule is non-jurisdictional.

In U.S. ex rel. Hayes v. Allstate Ins. Co., 2017 BL 109607 (2d Cir. 2017), the Second Circuit joined the D.C. Circuit in holding that the first-to-file bar is not jurisdictional. The Second Circuit relied on the Supreme Court's ruling that Congress must clearly state that a rule is jurisdictional; otherwise, the restriction should be treated as non-jurisdictional. The language of the FCA provides that "no person other than the Government" may bring a claim that is "related" to a claim already "pending." The Second Circuit agreed with the D.C. Circuit that "this language 'speaks only to who may bring a private

action and when,' but 'does not speak in jurisdictional terms or refer in any way to the jurisdiction of the district courts." Accordingly, the court held the first-to-file rule is non-jurisdiction, and "instead bears only on the merits of whether a [relator] has stated a claim."

The Second Circuit's decision widens a circuit split that has significant effect on litigants. In jurisdictions where the first-to-file bar is jurisdictional, a defendant can assert the bar through a Rule 12(b)(1) motion to dismiss for lack of subject matter jurisdiction, after which the burden is on the relator to show the court has subject matter jurisdiction and the court may consider information outside of the pleadings. In courts where the rule is non-jurisdictional, the defendant must assert the first-to-file bar in a 12(b)(6) motion for failure to state a claim, after which the burden is on the defendant and where the relator's well-pleaded allegations are treated as true for purposes of the motion.

FRCP 9(b)

Rule 9(b) of the Federal Rules of Civil Procedure provides for dismissal where a complaint fails to plead fraud with sufficient particularity. A circuit split exists between circuits requiring a heightened pleading standard pursuant to FRCP 9(b), requiring pleading of fact such as time, place, and content of fraudulent representation in FCA cases, and those that apply a more lenient standard. There is a trend among those circuits that apply a strict pleading standard to acknowledge flexibility in the standard. See, e.g., U.S. ex rel. Nathan v. Takeda Pharm. N. Am., Inc., 2013 BL 8145 (4th Cir. 2013) (requiring only "some indicia of reliability" that a false claim had been presented to the government); Chesbrough v. Visiting Physicians Ass'n, 2011 BL 216129 (6th Cir. 2011) ("[W]e do not foreclose the possibility that this court may apply a 'relaxed' version of Rule 9(b) in certain situations[.]").

In 2016, the Sixth Circuit, recognized flexibility in its strict interpretation of FCRP 9(b), where a relator has personal knowledge "that support[s] a strong inference that specific false claims were submitted." United States ex rel. Prather v. Brookdale Senior Living Cmtys., Inc., 2016 BL 324660 (6th Cir 2016). However, in 2017, the Sixth Circuit showed that its willingness to be flexible on FRCP 9(b) is limited. In U.S. ex rel. Hirt v. Walgreen Co., 2017 BL 20881 (6th Cir. 2017), a relator alleged a pharmacy violated anti-kickback statutes by using gift cards to incentivize customers to fill prescriptions at its stores, and thus violated the FCA by submitting resultant claims to Medicare and Medicaid. The court upheld dismissal, concluding that the relator's complaint failed to identify a single false claim submitted by the pharmacy and failed to identify a customer who switched to the pharmacy because of their incentive program. The court acknowledged the potentially misleading nature of prior decisions relaxing the standards of FCRP 9(b), but distinguished the case before it because the relator did not have sufficient personal knowledge of claims submission and billing practices, as other relators had.

In U.S. ex rel. Nargol v. DePuy Orthopedics, Inc., 2017 BL 258966 (1st Cir. 2017), the First Circuit reaffirmed its more lenient FCRP 9(b) standard, under which a relator need only provide "factual or statistical evidence to strengthen the inference of fraud beyond possibility without necessarily providing details as to each false claim." The relator had alleged a medical device company submitted falsified safety information of its hip replacement device when seeking clearance from the FDA to market the device, and as a result the product was marketed to doctors who submitted claims to the government for reimbursement. The court pointed to a statistical analysis contained in the complaint to conclude that the inference of fraud was strengthened "beyond possibility" and, thus, the relator need not "provid[e] details as to each false claim."

The Government's Settlement Veto Authority

Under the FCA, a relator seeking to settle a qui tam action must obtain the consent of the government. In U.S. ex rel. Michaels v. Agape Senior Community, Inc., 2017 BL 43959 (4th Cir. 2017), the Fourth Circuit joined the Fifth and Sixth Circuits in holding that the government has absolute veto authority over settlements in qui tam actions, even where the government declines to intervene. The Ninth Circuit is the only circuit that has limited the government's veto power, reasoning that the FCA only grants the government absolute veto power in the initial 60-day period after a qui tam action is filed, during which the government must decide whether or not to intervene.

What to Watch in 2018

Increases in Defense and Infrastructure Spending

One result of the recently-enacted $1.3 trillion federal spending bill may be an increase in FCA exposure for defense contractors and construction firms. The 2018 omnibus bill signed into law by President Trump on March 23, authorized $654.6 billion for the Defense Department, reflecting an increase of

$60 billion from 2017 spending. The law provides $144.3 billion—a $25.4 billion increase from 2017—for procurement of equipment ranging from an aircraft carrier to communication systems. Additionally, military research and development allocations increased 22 percent from FY 2017. The same week the omnibus bill was enacted, the White House released its proposed budget for FY 2019, which includes a request for $686 billion for the Defense Department, reflecting an additional $30 billion in spending.

Similarly, President Trump has pushed for greater spending on infrastructure projects. The 2018 omnibus bill included $21.2 billion in infrastructure spending including appropriations for highways, airports, railways, broadband development, energy research, IT modernization, and cyber security. This appropriation appears to be only the beginning to the Trump administration's push to invest in infrastructure. In February, the White House released a plan to generate $1.5 trillion in broad-based infrastructure investment, including $200 billion of federal funding. If approved by Congress, the appropriations would be used to procure goods and services from private businesses in a variety of sectors, particularly construction. Those businesses contracting with the government on infrastructure projects should be attuned to the risks of FCA liability.

Continued Decisions in the Wake of Escobar

In 2018, courts will continue to analyze the landmark 2016 Escobar decision, particularly the issues of materiality and whether a defendant must make specific representations to be held liable in implied false certification cases. Several courts have ruled on these issues already in 2018. Clarity in this area will help companies that contract with the government, particularly those in highly regulated industries such as health care, to better understand how to defend implied false certification claims.

DOJ Dismissal of Qui Tam Suits

Additionally, the DOJ's approach to qui tam suit dismissals may begin to change in 2018. A recently authored memorandum by the Director of the Commercial Litigation Branch of the DOJ's Fraud Section, Michael Granston, asks government attorneys to consider several factors in deciding whether to seek dismissal of "meritless" qui tam actions, pursuant to 31 U.S.C. § 3730(c)(2)(A). The Granston memorandum indicates a potential shift in DOJ policy and may provide defendants an opportunity to petition the U.S. Attorney to seek dismissal of a qui tam action when the government declines to intervene. A comprehensive analysis of the guidance is available here.

FCA Liability Related to the Opioid Crisis

Another DOJ initiative likely to impact FCA enforcement in 2018 involves the opioid crisis. On February 27, 2018, Attorney General Jeff Sessions announced the creation of the DOJ's Prescription Interdiction & Litigation (PIL) Task Force. Part of the PIL Task Force's mandate will include pursuing FCA actions against those in the opioid manufacturing and distribution chain for false claims stemming from improper prescribing, violations of FDA regulations, and other opioid-related health care fraud. The PIL Task Force will specifically focus on pharmacies, pain-management clinics, drug testing facilities, and physicians who prescribe opioids.

Conclusion

Heightened FCA enforcement and the rapid development of FCA case law requires companies that contract with the government, especially those in the health care industry to closely monitor FCA events in 2018 and take steps to update and ensure proper function of compliance programs to head off potentially costly litigation.

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