WILMERHALE

LITIGATION/CONTROVERSY

January 9, 2018

False Claims Act: 2017 Year-in-Review

TABLE OF CONTENTS

INTRODUCTION: HIGHLIGHTS AND TRENDS

False Claims Act (FCA) recoveries topped $3.7 billion in fiscal year 2017, marking the eighth straight year of annual recoveries in excess of $3 billion. Healthcare cases, including ones involving drug and device companies, accounted for most of the total, at roughly $2.47 billion. Recoveries in Defense Department cases increased to approximately $220 million, nearly double the 2016 figure, and the number of government-initiated cases in that sector more than doubled, reflecting in part the results of investigations from the country's long-running military engagements in Iraq and Afghanistan. The value of settlements and judgments in the non-healthcare and non-defense category dropped by half to roughly $1 billion, of which more than $500 million was from the financial services sector. In 2017, 674 new qui tam cases were filed—an average of more than 12 a week—down from the year before but still at historically high levels.[1]

In 2017, the Department of Justice (DOJ) continued to stress its focus on individual accountability, noting a number of substantial awards against individuals in cases also involving corporate entities and more than $60 million in awards against individuals not involving joint-and-several liability with corporate entities.[2]

Division in the Lower Courts Over *Escobar*

The Supreme Court's 2016 decision in *Universal Health Services, Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016), continued to generate debate among the lower courts. In *Escobar*, the Court held that implied certification claims were viable under the FCA but only in certain circumstances. In the year and a half since the Court handed down *Escobar*, dozens of lower courts have addressed issues left uncertain by *Escobar*, above all (i) when does a claim for payment constitute an implied certification of compliance with a regulatory or contractual obligation, and (ii) what establishes or disproves the materiality of an allegedly false representation. As to the first issue, a number of courts have held that the circumstances identified by the Supreme Court as giving rise to an implied certification—"the defendant submits a claim for payment that makes specific representations about the goods or services provided, but knowingly fails to disclose the defendant's noncompliance with a statutory, regulatory, or contractual requirement . . . if the omission renders those representations misleading"—are exclusive, *see, e.g*., *United States ex rel. Campie v. Gilead Sciences, Inc*., 862 F.3d 890, 901 (9th Cir. 2017); *United States ex rel. Forcier v. Computer Sciences Corp*., 12 Civ. 1750 (DAB), 2017 WL 3616665, at *12 (S.D.N.Y. Aug. 10, 2017), while others have ruled that those circumstances are sufficient but not necessary to establish an implied false certification, *see, e.g*., *United States ex rel. Badr v. Triple Canopy, Inc.*, 857 F.3d 174, 178 (4th Cir. 2017); *United States ex rel. Landis v. Tailwind Sports Corp*., 234 F. Supp. 3d 180, 198 (D.D.C. 2017). As to the second issue, a number of courts of appeals have held that if the government continues to pay claims while knowing of the defendant's alleged non-compliance, that suffices to show the non-compliance's lack of materiality to payment, *see, e.g*., *United States ex rel. McBride v. Halliburton Co.*, 848 F.3d 1027 (D.C. Cir. 2017); *Abbott v. BP Exploration & Production, Inc.*, 851 F.3d 384 (5th Cir. 2017), whereas others have refused, at least at the motion to dismiss stage, to find that such government conduct necessarily undercuts the materiality of the alleged

non-compliance, *see, e.g*., *United States ex rel. Campie v. Gilead Sciences, Inc.*, 862 F.3d 890. Many of these decisions are described in greater detail in part II below.

Limiting the Tax Deductibility of Settlements and Judgments

The extent to which Section 162(f) of the Internal Revenue Code limits the deductibility of settlement payment and judgments in government litigation has been a matter of recent controversy, both in FCA and non-FCA matters.[3] The tax legislation enacted on December 22, 2017 (the "Tax Act," Pub. L. No. 115-97), extends the Section 162(f) deduction limitation in a manner that may imperil the deductibility of certain settlement and judgment payments under the FCA, particularly because of the FCA's provision for more than single damages. Under Section 13306 of the Tax Act, except as specifically provided, no deduction shall be allowed "for any amount paid or incurred (whether by suit, agreement, or otherwise) to, or at the direction of, a government or governmental entity in relation to the violation of any law or the investigation or inquiry by such government or entity into the potential violation of any law." The only exceptions are amounts that the taxpayer can establish were paid as restitution (or expended to come into compliance with the law) and that are identified as such in the applicable court order or settlement agreement. An amount paid to reimburse the government for investigation or litigation costs cannot be treated as restitution for this purpose.[4] Generally, the government or governmental entity must report to the Internal Revenue Service and the taxpayer the amount required to be paid that constitutes restitution (or an amount paid to come into compliance with the law).

Continued Debate Over the First-to-File Bar

Courts continue to debate whether a first-to-file bar dismissal can be cured by amendment or only by filing a new action. In *Kellogg Brown & Root Services, Inc. v. United States ex rel. Carter*, 135 S. Ct. 1970 (2015), the Supreme Court held that the first-to-file bar does not apply once the earlier-filed action is no longer pending, but it left open how a relator may proceed after dismissal. This past year, two courts of appeals weighed in, both siding with the defendant. The D.C. Circuit held that a relator must file a new action—not an amended or supplemental complaint in the earlier-filed action—to cure a first-to-file defect. *United States ex rel. Shea v. Cellco Partnership*, 863 F.3d 923, 930 (D.C. Cir. 2017). The Fourth Circuit, in a narrower decision, held that a relator could not cure a first-to-file defect with an amended pleading that failed to affirmatively allege that the earlier-filed actions were no longer pending. *United States ex rel. Carter v. Halliburton Co.*, 866 F.3d 199, 210 (4th Cir. 2017). A number of district courts addressed this issue as well, some holding amendment impermissible, *see United States ex rel. Denis v. Medco Health Solutions, Inc.*, Civ. No. 11-684-RGA, 2017 WL 63006, at *11-12 (D. Del. Jan. 5, 2017), and others permitting amendment, *see United States ex rel. Brown v. Pfizer, Inc.,* No. 05-6795, 2017 WL 1344365, at *2-4 (E.D. Pa. Apr. 12, 2017); *United States ex rel. Wood v. Allergan, Inc*., 246 F.Supp.3d 772, 792–800 (S.D.N.Y. 2017); *see also United States ex rel. Brown v. Pfizer, Inc.,* No. 05-6795, 2017 WL 2691927, at *3 (E.D. Pa. June 22, 2017).

Continued Debate Over Rule 9(b) Particularity Requirements

The courts continue to wrestle with the level of detail required for an FCA complaint to survive a motion to dismiss. In 2017, for example, the Sixth Circuit affirmed the dismissal of a complaint that failed to identify a single fraudulent prescription that was actually submitted to the government for payment as a result of the defendant's alleged misconduct; the court rejected what it had previously described as a "relaxed" pleading standard that might apply where the relevant evidence is beyond a relator's knowledge, insisting that the courts had no more authority to "relax" the Rule 9(b) pleading requirements than they do to tighten them. *United States ex rel. Hirt v. Walgreen Co.,* 846 F.3d 879, 881 (6th Cir. 2017). The Second Circuit, by contrast, reversed dismissal of a case in which the district court had faulted the relator for failing to identify a single false claim that was actually submitted to the government for payment. The court of appeals held instead that a relator can survive a motion to dismiss when the evidence needed to support the missing allegations is uniquely within the defendant's possession and the complaint creates a "strong inference" that such claims were actually submitted. *United States ex rel. Chorches for Bankruptcy Estate of Fabula v. American Medical Response, Inc.*, 865 F.3d 71, 86 (2d Cir. 2017). The Second Circuit addressed the decisions of other Circuits that imposed more exacting pleading requirements, explaining that, in its view, any talk of a circuit split was "greatly exaggerated." *Id.* at 89.

Increased Penalties

Pursuant to the 2015 law that requires annual inflation-based adjustments in federal civil penalties, DOJ in February 2017 increased the FCA penalty range from $10,781 to $21,563 per violation to $10,957 to $21,916 per violation, a 1.6% increase. The increased amounts apply only to penalties assessed after February 3, 2017, whose associated violations occurred after November 2, 2015, the date of enactment of the 2015 authorizing law.[5]

Criticism of DOJ Positions by Some Courts

DOJ came in for unusually harsh criticism from at least two courts this year over what the courts viewed as unreasonable litigating positions. In *United States ex rel. Wall v. Circle C Construction, LLC,* 868 F.3d 466 (6th Cir. 2017), the Sixth Circuit reversed a district court's refusal to grant a contractor attorneys' fees under the Equal Access to Justice Act following the Sixth Circuit's prior rejection of the damages theory DOJ had advanced in an FCA case against the contractor. The court of appeals rebuked DOJ for seeking damages that were "a hundredfold greater than what it was entitled to," and then "press[ing] that demand over nearly a decade of litigation" based on a theory that was "nearly frivolous" as applied in the case at hand. *Id*. at 472. In *United States ex rel. Ribik v. HCR ManorCare Inc.*, No. 1:09-cv-00013 (E.D. Va.), following a hearing on defendants' motion for sanctions for expert discovery violations related to DOJ's belated production of its expert's notes, the magistrate judge struck the expert's report and deposition testimony and precluded the expert from testifying at trial. The magistrate judge stated that DOJ's case was "a 'huge waste of money' and a 'house of cards' that rested on [the expert's] testimony" and that the expert's testimony and notes revealed that the case never should have been brought.[6]

Trump Administration Change in Enforcement Policy?

In an October 2017 speech at a healthcare compliance conference, Michael Granston, director of the Civil Frauds Section of DOJ's Civil Division, made statements that health care industry news and information site RACmonitor interpreted as DOJ's announcing its intent to make more frequent use of its authority to move to dismiss qui tam cases that it believes lack merit.[7] DOJ later told Law360 that Mr. Granston's remarks were simply an affirmation of its existing power to dismiss cases and did not in fact reflect a policy shift.[8] Whether DOJ will change its approach under President Trump and Attorney General Sessions remains to be seen.

I. FEDERAL LEGISLATIVE AND REGULATORY DEVELOPMENTS

A. Congress

Enacted Legislation

- On June 14, 2017, President Trump signed into law H.R. 657, the Follow the Rules Act, which protects employees who refuse to obey employer orders that would require employees to violate a current law, rule or regulation.[9]

- On June 23, 2017, President Trump signed into law S. 1094, the Department of Veterans Affairs Accountability and Whistleblower Protection Act of 2017, which includes a number of measures aimed at protecting whistleblowers within the Department of Veterans Affairs (VA), including establishing the VA Office of Accountability and Whistleblower Protection and requiring the VA to develop criteria to promote supervisory protection of whistleblowers. The Act also requires the Government Accountability Office (GAO) to report to Congress on retaliation against employees.[10]

- On October 26, 2017, President Trump signed into law S. 585, the Dr. Chris Kirkpatrick Whistleblower Protection Act of 2017. The Act provides additional protections to federal employees who are retaliated against for disclosing waste, fraud and abuse; enacts reforms to ensure that managers who retaliate against whistleblowers are held accountable; and provides the Office of Special Counsel with access to information to allow for complete investigations, among other measures. In particular, the Act—named after a VA psychologist who committed suicide after being fired for reporting that veterans were being over-drugged and mistreated—directs the VA to address agency-specific shortcomings in its protection of VA employees.[11]

House of Representatives

- On February 2, 2017, the House passed H.R. 702, the Federal Employee Antidiscrimination Act of 2017. The bill, among other measures, prohibits nondisclosure agreements that seek to prevent federal employees from disclosing to Congress, the Office of Special Counsel, or an inspector general any information that relates to violations of law or instances of waste, fraud or abuse.[12]

- On October 11, 2017, the House passed H.R. 2196, which would amend the Whistleblower Protection Act to expand the number of individuals to whom a whistleblower in the intelligence community may disclose information related to waste, fraud or abuse to include the whistleblower's immediate supervisor or agency head, the Director of National Intelligence, the Inspector General of the Intelligence Community, or an employee designated to receive such disclosures.[13]

- On October 12, 2017, Representatives Rod Blum (R-IA) and Elijah Cummings (D-MD) introduced H.R. 4043, the Whistleblower Protection Extension Act of

2017, which would permanently extend the program requiring each inspector general's office to have a dedicated official focused on empowering and educating whistleblowers. The bill would change the name of these officials from "Ombudsman" to "Whistleblower Protection Coordinator," and would task them with assisting inspectors general in strengthening their roles in investigating reprisal and whistleblower disclosures. Senators Chuck Grassley (R-IA), Ron Johnson (R-WI), Ron Wyden (D-OR), and Claire McCaskill (D-MO) introduced a companion bill in the Senate, S. 1869.[14]

- On October 31, 2017, Representative Eleanor Holmes Norton (D-DC) introduced H.R. 4195, the Congress Leads by Example Act of 2017. The bill would provide whistleblower protections and other antidiscrimination protections for employees of the legislative branch. Senators Chuck Grassley (R-IA), Claire McCaskill (D-MO), and Ron Wyden (D-OR) introduced a related bill in the Senate, S. 633.[15]

Senate

- On March 15, 2017, Senators Chuck Grassley (R-IA), Claire McCaskill (D-MO), and Ron Wyden (D-OR) introduced S. 633, the Congressional Whistleblower Protection Act of 2017. The bill would extend certain whistleblower protections to employees of congressional offices and committees, as well as related offices. (e.g., the Office of Congressional Accessibility Services, the Capitol Police, the Congressional Budget Office). Representative Eleanor Holmes Norton (D-DC) introduced a related bill in the House, H.R. 4195.[16]

- On March 29, 2017, Senators Chuck Grassley (R-IA) and Ron Wyden (D-OR) introduced the IRS Whistleblower Improvements Act of 2017, S. 762, which would increase communication between the IRS and whistleblowers by giving whistleblowers access to more information, and provide legal protections to IRS whistleblowers by extending the anti-retaliation provisions that are currently afforded under other whistleblower laws, such as the False Claims Act. The bill would also subject whistleblowers who receive tax return information to criminal penalties for the unauthorized disclosure of taxpayer information.[17]

- On September 27, 2017, Senators Chuck Grassley (R-IA), Ron Johnson (R-WI), Ron Wyden (D-OR), and Claire McCaskill (D-MO) introduced the Whistleblower Protection Coordination Act, S. 1869, which would permanently extend the program requiring each inspector general's office to have a dedicated official focused on empowering and educating whistleblowers. The bill would change the name of these officials from "Ombudsman" to "Whistleblower Protection Coordinator," and would task them with assisting inspectors general in strengthening their roles in investigating reprisal and whistleblower disclosures. Representatives Rod Blum (R-IA) and Elijah Cummings (D-MD) introduced a companion bill in the House, H.R. 4043.[18]

- On October 24, 2017, Senator Claire McCaskill (D-MO) introduced the Ensuring Protections for Intelligence Community Contractor Whistleblowers Act of 2017, S. 2002, which would expand whistleblower protections to employees of intelligence community contractors.[19]

- On November 15, 2017, the Senate passed S. 807, the Criminal Antitrust Anti-Retaliation Act of 2017. The bill, introduced by Senators Chuck Grassley (R-IA) and Patrick Leahy (D-VT), would extend whistleblower protections to employees who provide information to DOJ related to criminal antitrust violations. The Senate unanimously passed a similar version of the legislation in both 2013 and 2015.[20]

B. Department of Justice

- Pursuant to the 2015 law that requires annual inflation-based adjustments in federal civil penalties, DOJ in February 2017 increased the FCA penalty range from $10,781 to $21,563 per violation to $10,957 to $21,916 per violation, a 1.6% increase. The increased amounts apply only to penalties assessed after February 3, 2017, whose associated violations occurred after November 2, 2015, the date of enactment of the 2015 authorizing law.[21]

- In a speech in April, Attorney General Jeff Sessions noted that DOJ "will continue to emphasize the importance of holding individuals accountable for corporate misconduct" but also emphasized that it would distinguish between honest mistakes and willful misconduct.[22]

- In October, Deputy Attorney General Rod Rosenstein stated in a speech that he "generally agree[d] with the critique that motivated Deputy Attorney General Yates to issue a new policy" on individual accountability, but also confirmed that the Yates memo, like other DOJ enforcement priorities, was under review.[23]

- In an October speech at a healthcare compliance conference, Michael Granston, director of the Civil Frauds Section of DOJ's Civil Division, made statements that health care industry news and information site RACmonitor interpreted as DOJ's announcing its intent to make more frequent use of its authority to move to dismiss qui tam cases that it believes lack merit.[24] DOJ later told Law360 that Mr. Granston's remarks were simply an affirmation of its existing power to dismiss cases and did not in fact reflect a policy shift.[25]

- Also in October, Deputy Attorney General Rosenstein stated that DOJ's corporate monitorship program was under review. Since that time, a number of experts have offered ideas for improving the program.[26]

- In a speech in November, Deputy Attorney General Rosenstein emphasized the importance of robust corporate compliance programs and, in particular, how compliance should permeate the entire culture of an organization.[27]

C. Department of Health and Human Services

- On January 12, 2017, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) issued a final rule codifying its authority to exclude entities and individuals from participation in federal healthcare programs, which was most recently expanded by Congress in the Affordable Care Act. The rule, which took effect on February 13, 2017, states in relevant part that the HHS OIG may exclude entities and individuals for "knowingly making or causing to be

made any false statement, omission, or misrepresentation of material fact in any application, agreement, bid, or contract to participate or enroll as a provider of services or supplier under a Federal health care program. . . ."[28]

- On December 27, 2017, HHS OIG issued its annual notification soliciting proposals for developing new, and modifying existing, safe harbor provisions under the Anti-Kickback Statute (AKS) as well as developing new OIG Special Fraud Alerts. Comments are due by February 26, 2018.[29]

D. Department of Veterans Affairs

- On April 27, 2017, President Trump signed an Executive Order on Improving Accountability and Whistleblower Protection at the Department of Veterans Affairs.[30] The Executive Order directed the VA Secretary to establish an Office of Accountability and Whistleblower Protection, which was made permanent when Congress passed S. 1094, the Department of Veterans Affairs Accountability and Whistleblower Protection Act of 2017, as noted above.

E. Securities and Exchange Commission

- In late October, Jane Norberg, head of the Securities and Exchange Commission's (SEC) whistleblower program, stated that the SEC was seeing fewer companies using separation agreements intended to prevent departing employees from become whistleblowers. Norberg reported that the SEC had brought nine enforcement actions in 2017 related to companies that had allegedly taken steps to impede whistleblowers, but she noted that the SEC has seen some improvement in this area.[31]

F. Commodity Futures Trading Commission

- On May 22, 2017, the Commodity Futures Trading Commission (CFTC) issued final rules to strengthen its whistleblower program. The new rules expand the CFTC's anti-retaliation protections and make a number of structural changes so that the CFTC's whistleblower program is more closely aligned with the SEC's.[32]

II. FEDERAL CASE LAW DEVELOPMENTS

A. Pending Supreme Court Case: Materiality

***Gilead Sciences v. United States ex rel. Campie*, No. 17-936 (petition for certiorari docketed Jan. 3, 2018)**

This petition for certiorari presents the important post-*Escobar* question whether a qui tam complaint should be dismissed when the government continued to pay the defendant's claims after learning of the defendant's alleged noncompliance with governing requirements.

As in several other recent FCA cases, the relators here alleged that the defendant falsely represented its compliance with regulations for prescription drugs issued by the Food and Drug Administration (FDA). The defendant, Gilead Sciences, makes three HIV drugs—Atripla, Truvada, and Emtriva—of which the government buys large quantities, both as a direct purchaser and through reimbursements under various government healthcare programs.

The relators allege that Gilead misrepresented, in its applications for FDA approval of these drugs, that it would obtain the active ingredient in the drugs from certain registered facilities. Instead, the relators allege, Gilead obtained a portion of the ingredient from a facility in China that was at that point unregistered. They also allege that Gilead concealed the role of the Chinese facility. Even though the government has known of the Chinese facility for years, however, the FDA never rescinded its approval of the three drugs, and the federal government has continued to purchase them without requesting refunds.

As described more fully below, the Ninth Circuit held that the complaint was adequate to survive a motion to dismiss. 862 F.3d 890 (9th Cir. 2017). A unanimous panel held that the relators had pleaded materiality even though the government had taken no action against Gilead after learning of its conduct. *Id.* at 904-07. The court reasoned that it would be improper "to read too much into the FDA's continued approval" for several reasons. *Id.* at 906. "First," the court explained, "to do so would allow Gilead to use the allegedly fraudulently-obtained FDA approval as a shield against liability for fraud." *Id.* "Second," the court opined that "there are many reasons the FDA may choose not to withdraw a drug approval." *Id.* "Third," the court noted that Gilead had "ultimately stopped using" the Chinese facility, and reasoned that "[o]nce the unapproved and contaminated drugs were no longer being used, the government's decision to keep paying for compliant drugs does not have the same significance as if the government continued to pay despite continued noncompliance." *Id.*

In seeking Supreme Court review, Gilead argues that the Ninth Circuit's decision conflicts with decisions of other circuits that have rejected FCA claims when the government continued to pay the defendant after learning of its alleged noncompliance. In particular, Gilead claims that the Ninth Circuit's decision conflicts with *D'Agostino v. ev3, Inc.*, 845 F.3d 1 (1st Cir. 2016); *United States ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29 (1st Cir. 2017); *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481 (3d Cir. 2017); *Coyne v. Amgen, Inc.*, 2017 WL 6459267

(2d Cir. Dec. 18, 2017) (unpublished); *United States v. Sanford-Brown, Ltd.*, 840 F.3d 445 (7th Cir. 2016); *United States ex rel. Marshall v. Woodward, Inc.*, 812 F.3d 556 (7th Cir. 2015); *Abbott v. BP Expl. & Prod., Inc.*, 851 F.3d 384 (5th Cir. 2017); *United States ex rel. Harman v. Trinity Indus., Inc.*, 872 F.3d 645 (5th Cir. 2017); *United States ex rel. Thomas v. Black & Veatch Special Projects Corp.*, 820 F.3d 1162 (10th Cir. 2016); and *United States ex rel. McBride v. Halliburton Co.*, 848 F.3d 1027 (D.C. Cir. 2017).

A grant of certiorari in this case—or even a call for the views of the Solicitor General—could shed light on one of the most frequently litigated issues in the wake of the Supreme Court's path-marking decision in *Universal Health Services, Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016).

B. D.C. Circuit: (1) Materiality; (2) First-to-File Bar; (3) Public-Disclosure Bar; (4) Rule 9(b) Pleading Standard

***United States ex rel. McBride v. Halliburton Co.*, 848 F.3d 1027 (D.C. Cir. 2017)**

The D.C. Circuit affirmed a grant of summary judgment in favor of Kellogg Brown & Root (KBR), finding that the relator had failed to show that the company's alleged misrepresentations regarding headcount in its Iraq recreational facilities were material to the government's decision to pay KBR pursuant to a government contract.

About the Case

The relator alleged that KBR had inflated headcount data to show how many troops frequented recreation centers it maintained for the US Army in Iraq.

The government declined to intervene, and in October 2006, the Defense Contract Audit Agency investigated the relator's allegations concerning the headcount numbers. The agency did not report any findings, but it also did not challenge the amounts KBR had billed for its services. *Id.* at 1029. After three years of discovery, the district court granted KBR's motion for summary judgment, holding that the relator had not presented evidence that the headcount practices in the facilities were material to the government's decision to pay KBR. *Id.* at 1030.

The D.C. Circuit affirmed, reasoning that the relator had failed to show that KBR violated a contractual or regulatory requirement that was material to the government's payment decision. *Id.* at 1028. Quoting *Escobar*, the court emphasized that the materiality standard for implied certification claims is demanding: it noted that courts "need not opine in the abstract when the record offers insight into the Government's actual payment decisions," and that "courts should look beyond the express designation of a requirement as a condition of payment to find it material." *Id.* at 1032 (citation omitted).

Implications for Future FCA Cases

The case underscores the demanding requirements of the materiality requirement for an implied certification case in the wake of the Supreme Court's *Escobar* decision.

***United States ex rel. Shea v. Cellco Partnership*, 863 F.3d 923 (D.C. Cir. 2017)**

The D.C. Circuit upheld a district court's ruling dismissing a relator's action without prejudice because he violated the first-to-file bar in filing his action while a prior action was still pending. The D.C. Circuit held that the relator's claims did not warrant a dismissal with prejudice under the public-disclosure bar. (Note: WilmerHale represented the defendants in the litigation.)

About the Case

The relator brought two actions against a number of Verizon entities, alleging that the company had defrauded the government by billing for taxes and surcharges prohibited under a number of contracts for telephone services. *Id.* at 926, 927. The relator filed his first action in 2007, which eventually settled in 2011 (referred to as *Verizon I*). *Id.* While *Verizon I* was still pending, the relator brought a second action against Verizon, alleging that the company had defrauded the government in additional federal contracts (*Verizon II*). *Id.* at 927. The district court held that the relator had violated the first-to-file bar because *Verizon I* had been pending at the time of filing the complaint in *Verizon II*. *Id.* at 926. Because *Verizon I* had since concluded, the district court dismissed the relator's second action *without* prejudice. *Id.*

The relator then appealed, arguing that the district court should have instead allowed him to *amend* his complaint (and thereby allow him to avoid the six-year statute of limitations that may have run on his claims against Verizon) rather than refile it. *Id.* at 928-929. Verizon cross-appealed, arguing that the district court should have dismissed the relator's complaint with prejudice under the public-disclosure bar and for failing to meet Rule 8 and Rule 9(b) pleading requirements. *Id. at 928.*

The D.C. Circuit upheld the district court's decision. First, it held that the district court had not erred in dismissing the suit under the first-to-file bar. *Id.* at 928. The relator did not dispute that *Verizon II* was filed while *Verizon I* was pending, or that the two cases were related. *Id.* at 928–29. But the relator argued that when *Verizon I* settled, the district court erred in not allowing him to amend his complaint to "cure [his] first-to-file violation[.]" *Id.* at 929. The court of appeals rejected that argument, concluding that amending the *Verizon II* complaint could not "operate to end the action and begin a new one. It thus cannot alter when [the relator] brought his action [in *Verizon II*]—i.e. at a time when a related suit was pending. For purposes of the first-to-file bar, in short, [the relator's] action was incurably flawed from the moment he filed it." *Id.* at 930.

The court next turned to Verizon's argument that the district court erred by failing to dismiss *Verizon II* with prejudice under the public-disclosure bar. *Id.* at 932. Assuming the pre-amendment version of the public-disclosure bar applied, the court upheld the district court's ruling that the relator had not relied on publicly available information in bringing his claims. *Id.* Lastly, the court held that the district court did not abuse its discretion in refusing to dismiss the relator's complaint with prejudice under Rules 8 and 9(b). *Id.* at 935. The court noted that "we generally do not dismiss suits with prejudice for failing to plead fraud with particularity [under Rule 9(b)]," and that it "almost always" allows leave to amend. *Id.* at 936.

Implications for Future Cases

The D.C. Circuit's decision obligated the relator to cure his first-to-file bar by filing a new action. Notably, the D.C. Circuit acknowledged that it "saw things differently" than the First Circuit, which found that "dismissal in the circumstances of [a similar] case would be a 'pointless formality.'" *Id.* at 930 (citing *United States ex rel. Gadbois v. PharMerica Corp.*, 809 F.3d 1, 6 (1st Cir. 2015)). In the court's view, the relator's "preferred rule" allowing him to amend his complaint "not only is difficult to square with the statutory terms, but it also would give rise to anomalous outcomes." *Id.*

C. First Circuit: (1) Rule 9(b) Pleading Standard; (2) Causation; (3) Retaliation; (4) Reverse False Claims

***United States ex rel. Booker v. Pfizer, Inc.*, 847 F.3d 52 (1st Cir. 2017)**

The First Circuit upheld a district court's decisions resolving relators' claims against Pfizer on motions to dismiss and for summary judgment in an off-label promotion case. The court rejected the relators' argument that Pfizer had allegedly violated the FCA's reverse false claims provision by failing to report a violation of a 2009 Corporate Integrity Agreement (CIA) with the government. The court further held that the relators' aggregate data showing government expenditures for an allegedly off-label use of Pfizer's drug failed to provide sufficient evidence of the submission of an "actual false claim."

About the Case

The relators alleged that Pfizer had induced third parties to submit claims for payment by marketing a drug for off-label uses in violation of the Food, Drug, and Cosmetic Act and paying kickbacks for the prescription of two drugs, in violation of the Anti-Kickback Statute (AKS). *Id.* at 54. The relators further alleged that Pfizer had failed to notify the government of violations of a prior 2009 CIA entered into with HHS, thereby denying the government funds owed for such violations and running afoul of the FCA's reverse false claims provision. *Id.* at 55. Finally, the relators alleged that the company had improperly terminated one relator's employment in violation of the FCA's anti-retaliation provisions. *Id.* After dismissing the relator's reverse FCA claim and allowing for discovery on the remaining claims, the district court granted summary judgment in favor of Pfizer. *Id.*

The First Circuit affirmed dismissal of the reverse FCA claim. *Id.* It rejected the relators' argument that Pfizer had improperly avoided penalties under the CIA by failing to report to HHS an internal complaint sent by the relator by email to Pfizer's compliance department. *Id.* at 56. In the email, one of the relators had claimed that his manager instructed him to engage in off-label promotion in violation of the CIA. *Id.* The court held that under the CIA, Pfizer was obligated to report such an event only if the company determined, after investigation, that there was a "probable violation" of a specific set of laws. *Id.* Here, the relator failed to allege that Pfizer determined that a reportable event occurred and affirmed the dismissal on that basis. *Id.* at 57.

The First Circuit also upheld the district court's grant of summary judgment in favor of Pfizer on the off-label promotion and retaliation claims. *Id.* at 57–58. As to the off-label claims, it held that "even when a relator can prove that a defendant engaged in

'fraudulent conduct affecting the government,' FCA liability attaches only if that conduct resulted in the filing of a false claim for payment from the government." *Id.* at 57. Here, the relators, after several years of discovery, had only proffered aggregate expenditure data showing Medicaid expended funds for pediatric off-label prescriptions of a drug over a period of several years. *Id.* at 58. The court held that this evidence, without a further showing of the specific entities that submitted the claims or the "times, amounts, and circumstances" surrounding such claims, is "woefully inadequate" to support the relator's off-label promotion claims. *Id.* at 58–59.

On the retaliation claim, the First Circuit held that the relator's two internal complaints to his supervisor, in which he claimed that the company had continued to promote off-label uses for a drug after entering the CIA with HHS, did not constitute protected activity. *Id.* at 60. It held that "[e]vidence that an employee objected to or reported receipt of instructions to promote a drug's off-label use, absent any evidence that those objections or reports concerned FCA-violating activity such as the submission of false claims, cannot show at the summary judgment stage that the employee engaged in conduct protected by the FCA." *Id. at 59.*

Implications for Future FCA Cases

The case underscores that relators must trace a defendant's allegedly fraudulent course of conduct through the entire causation chain leading to submission of a claim for payment.

***United States ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29 (1st Cir. 2017)**

The First Circuit upheld dismissal of relators' claims against DePuy, in which they alleged that the company had made false statements in connection with securing FDA approval to market a hip replacement device. But the court of appeals reversed the dismissal of relators' remaining claims premised on the theory that DePuy had allegedly caused doctors to seek reimbursement for a device that did not comport with the FDA-approved version of the device, finding that the relators had sufficiently pleaded fraud under the First Circuit's "more flexible" Rule 9(b) analysis. (Note: WilmerHale filed an amicus brief on behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA) in the First Circuit in support of the defendant.)

About the Case

The relators allege that DePuy's marketing of its Pinnacle MoM hip replacement device violated the FCA and its state counterparts in two ways. First, the relators allege that DePuy made false statements regarding the product's safety and effectiveness when seeking clearance from the FDA to market the device. *Id.* at 34. The relators further allege that, but for such statements, the FDA would not have approved the device, and doctors would not have submitted claims for government reimbursement for the device. *Id.* at 32. Second, the relators allege that the company had "palmed off" inferior versions of the hip replacement device, which they claimed had "latent manufacturing defects" and failed to comport with the design specifications of the FDA-approved version of the device. *Id.*

The First Circuit affirmed the dismissal of claims that relied on the allegation that DePuy had falsely made statements in securing FDA approval of the device. *Id.* at 34, 37. It noted that even when the FDA was made aware of the relators' allegations that the design was "substandard," the agency had allowed the device to stay on the market. *Id.* at 35. The court held that "[the FDA's] decision not to employ [its] tools in the wake of Relators' allegations so as to withdraw or even suspend its approval . . . leaves Relators with a break in the causal chain between the alleged misstatements and the payment of any false claim." *Id.* at 34.

The First Circuit reversed dismissal of the claims resting on the relators' allegations that the company sold defective devices that "materially differed" from the FDA-approved device. *Id.* at 37, 41. As an initial matter, the court noted that it applies "a 'more flexible' standard in actions . . . where the defendant allegedly 'induced *third parties* to file false claims with the government"; specifically, a relator can satisfy Rule 9(b) "by providing 'factual or statistical evidence to strengthen the inference of fraud beyond possibility' without necessarily providing details as to each false claim.'" *Id.* at 39.

Here, the relators' complaint included (1) a single allegation that a doctor in New York in 2007 had implanted the hip replacement device, which then failed for the patient as a result of alleged manufacturing defects that became apparent only after the doctor submitted a claim for Medicaid reimbursement, *id.* at 37, and (2) a statistical analysis, which the court viewed as showing to a "statistically certain[ty]" that DePuy caused providers to unknowingly submit false claims for reimbursement, *id.* at 41.

The court noted that the relators properly "allege [that] . . . several thousand Medicare and Medicaid recipients received what their doctors understood to be Pinnacle MoM device implants; that more than half of those implants fell outside the specifications approved by the FDA; and that the latency of the defect was such that doctors would have had no reason not to submit claims for reimbursement for noncompliant devices." *Id.* In this context, Rule 9(b) did not "require Relators to plead false claims with more particularity than they have done here." *Id.*

DePuy sought a stay of the First Circuit's mandate pending its filing of a petition for certiorari with the Supreme Court, which the First Circuit denied. The certiorari petition is due Feb. 5, 2018.

Implications for Future FCA Cases

The *Nargol* case is notable because the relators' claims survived a Rule 9(b) challenge despite reliance on statistical data coupled with a single specific allegation of an actually submitted false claim. The court acknowledged, that "a consensus has yet to develop [in the circuit courts] on whether, when, and to what extent a relator must state the particulars of specific examples of the type of false claims alleged." *Id.* at 38.

D. Second Circuit: (1) First-to-File Bar; (2) Rule 9(b) Pleading Standard

United States ex rel. Hayes v. Allstate Insurance Co., 853 F.3d 80 (2nd Cir. 2017), *cert. denied*, 138 S. Ct. 199 (Oct. 2, 2017)

The Second Circuit affirmed dismissal of a qui tam action, holding that the first-to-file bar is not jurisdictional and instead informs whether relator has properly stated a claim. (Note: WilmerHale represented a defendant in the case.)

About the Case

The relator brought a qui tam action against liability insurance companies, alleging that they have been intentionally noncompliant with requirements under the Medicare Secondary Payer Act—specifically, their obligation to reimburse Medicare for certain payments made for Medicare beneficiaries. 853 F.3d at 84. The relator alleged that he had "personal knowledge" of each defendant's participation in the fraud. The district court concluded that he had no personal knowledge and had acted in bad faith in making that claim. *Id.* The district court dismissed with prejudice. *Id.*

While most defendants urged affirmance on the grounds relied upon by the district court, one set of defendants also argued that the district court lacked subject matter jurisdiction over the action because of the FCA's first-to-file bar. *Id.* at 84. The Second Circuit affirmed dismissal on the grounds relied upon by the district court. *Id*. at 86. With respect to the jurisdictional challenge, the court held that "a district court does not lack subject matter jurisdiction over an action that may be barred on the merits by the first-to-file rule." *Id*. Looking to the D.C. Circuit, the Second Circuit found persuasive the observation that 31 U.S.C. § 3730(b)(5) "'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[.]'" *Id*. (quoting *United States ex rel. Heath v. AT&T, Inc.*, 791 F.3d 112, 120 (D.C. Cir. 2015), *cert. denied*, 136 S. Ct. 2505 (2016)).

Implications for Future FCA Cases

The Second Circuit joined the D.C. Circuit in holding that the first-to-file bar is not jurisdictional. This sets the Second and D.C. Circuits apart from the Fourth, Fifth, and Sixth, all of which have stated or assumed that the rule is jurisdictional. *See, e.g., U.S. ex rel. Carter v. Halliburton Co.*, 710 F.3d 171, 181 (4th Cir. 2013), *aff'd in part, rev'd in part on other grounds sub nom. Kellogg Brown & Root*, 135 S. Ct. at 1979 (2015); *U.S. ex rel. Branch Consultants v. Allstate Ins. Co.*, 560 F.3d 371, 376–77 (5th Cir. 2009); *Walburn v. Lockheed Martin Corp*., 431 F.3d 966, 970 (6th Cir. 2005).

United States ex rel. Chorches for Bankruptcy Estate of Fabula v. American Medical Response, Inc., 865 F.3d 71 (2d Cir. 2017)

The Second Circuit held that a relator may satisfy Rule 9(b)'s pleading requirements without identifying specific false claims that were submitted for payment, if the missing facts are solely within the defendant's possession and the relator's allegations create a "strong inference" that such claims were actually submitted.

About the Case

The relator worked as an emergency medical technician (EMT) for American Medical Response, Inc. (AMR), the largest ambulance company in the United States. In his qui tam complaint, he alleged that AMR had falsely certified certain ambulance transports as being "medically necessary" under applicable Medicare law and that AMR had submitted claims it knew were not actually reimbursable under Medicaid. 865 F.3d at 75. He also alleged that AMR had made EMTs and paramedics alter or recreate reports to include false statements that demonstrated the putative medical necessity required for Medicaid reimbursement. *Id.* at 76. His complaint identified "several general categories of patients who were susceptible to having their [ambulance transport] falsely certified as medically necessary," and "more than ten specific runs for which [he] was ordered to alter" patient care reports to include false information. *Id.* at 76–77. The complaint, however, did not specify "exact billing numbers, dates, or amounts for claims submitted to the government." *Id.* at 82.

After filing his qui tam action, the relator declared personal bankruptcy, and the bankruptcy trustee intervened as relator to preserve standing. *Id.* at 78. The district court dismissed for failure to state a claim, holding that the complaint did not satisfy Rule 9(b)'s heightened pleading requirements. *Id.* The trustee appealed. *Id.*

The Second Circuit held that "a complaint can satisfy Rule 9(b)'s particularity requirement by making plausible allegations creating a strong inference that specific false claims were submitted to the government and that the information that would permit further identification of those claims is peculiarly within the opposing party's knowledge." *Id.* at 86. Pleading actual examples of false claims is thus not necessary, but at the same time, these requirements ensure "that those who *can* identify examples of actual claims *must* do so at the pleading stage." *Id.*

Implications for Future FCA Cases

In reaching this conclusion, the Second Circuit stated that reports of a Circuit split on this issue are "greatly exaggerated," and took the view that some of the circuits that appear to have required pleading actual false claims (such as the First, Fourth, Sixth, Eighth, and Eleventh) have in fact softened those stances in favor of a more nuanced, case-specific assessment. *Id.* at 89.

E. Third Circuit: (1) Falsity; (2) Materiality; (3) Reverse False Claim

***United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481 (3d Cir. 2017)**

The Third Circuit clarified that FDA approval of a drug does not foreclose FCA liability for claims that prescriptions were not "reasonable and necessary" for purposes of Medicare reimbursement, but affirmed dismissal of a claim under a heightened materiality standard adopted in the wake of the Supreme Court's *Escobar* decision.

About the Case

The relator, a former head of healthcare data analytics for Genentech, alleged that Genentech suppressed data, which caused doctors to certify incorrectly that Avastin, a cancer drug, was "reasonable and necessary" for certain at-risk Medicare patients, as required for Medicare reimbursement. 855 F.3d at 485. The district court dismissed the claims as "fatally deficient" because the FDA's approval of the drug and its inclusion in authoritative drug compendia was tantamount to a determination that the drug was "reasonable and necessary" for its indicated uses. *Id.* at 487. The Third Circuit disagreed. It held that the "reasonable and necessary" determination involves both FDA approval *and* prescribing physicians' determination that the drug is reasonable and necessary for the individual patient. *Id.* at 487–88.

The Third Circuit affirmed the district court's judgment, however, on materiality grounds. *Id.* at 489, 494. Noting that the Supreme Court's *Escobar* decision emphasized that the FCA's materiality requirement is "'demanding'" and "'rigorous,'" the Third Circuit joined a number of other Circuits that have adopted "a heightened materiality standard" following *Escobar*. *Id.* at 489, 492. The relator's claims failed under this standard because he offered no factual allegation showing that the government would not have reimbursed the claims at issue had the alleged reporting deficiencies been cured. *Id.* at 490–92. To the contrary, the Third Circuit noted, the relator conceded that government regulators had deemed the alleged violations insubstantial. *Id.* at 490.

Implications for Future FCA Cases

The Third Circuit clarified that legal falsity in the Medicare context is broad enough to include claims relating to drugs that were approved by the FDA. The Third Circuit also signaled, however, that the materiality standard will be strictly enforced, even at the pleading stage, under the demanding standard articulated in *Escobar*.

***United States ex rel. Petras v. Simparel, Inc.*, 857 F.3d 497 (3d Cir. 2017)**

The Third Circuit held that when the Small Business Administration (SBA) acts as receiver of a preferred shareholder, it does not act as the government, and thus no reverse FCA claim can be brought based on fraudulent conduct intended to avoid paying dividends to preferred shareholders. It also held that "obligation" in the reverse-false-claims provision does not include a contingent obligation that did not exist at the time of the alleged conduct.

About the Case

The relator sued his former employer, Simparel, and its founder and executive officers, alleging a reverse false claim under the FCA. L Capital, a venture capital firm licensed by the SBA, was an original investor in Simparel and in return received preferred shares. 857 F.3d at 499. Some years later, the SBA was appointed as receiver of L Capital. *Id.* at 500. The relator contended that, as a result, the SBA became a preferred shareholder in Simparel. *Id.*

Under the operative certificate of incorporation, Simparel was required to pay accrued dividends to preferred shareholders under two conditions: (1) if Simparel's board

exercised its discretion to pay the dividends; and (2) if Simparel underwent a liquidation, dissolution, or windup. *Id.* at 499–500.

The relator did not allege that either of these conditions was met. He instead alleged that Simparel had engaged in certain conduct to avoid paying dividends, including fraudulent tactics to hide from the SBA its deteriorating financial condition, in order to avoid involuntary liquidation. *Id.* at 500. The district court dismissed the FCA claim because Simparel's obligation to pay the government that formed the basis of the claim was "too speculative." *Id.* at 501.

The Third Circuit affirmed. *Id.* at 499, 507. Though the district court did not address the SBA's status, the Third Circuit first examined whether the SBA is the government when acting as receiver of a private entity. *Id.* To assert a reverse FCA claim, a relator must allege that the defendant "knowingly and improperly avoid[ed] or decrease[d] an obligation to pay or transmit money or property *to the Government*." 31 U.S.C. § 3729(a)(1)(G) (emphasis added). The Third Circuit held that the SBA is not the government when acting as receiver of a federally chartered but private entity, because in those circumstances the federal agency "usually 'steps into the private status of the entity' and does not retain any federal authority.'" 857 F.3d at 503–04.

The Third Circuit also held that, even if the SBA could qualify as the government, the relator's claims would still fail for the reasons explained by the district court. *Id.* The FCA defines "obligation" as "an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment." 31 U.S.C. § 3729(b)(3). The Third Circuit held that "an established duty" is one "owed at the time that the alleged improper conduct under the FCA occurred" and does not include a duty that is "dependent on a future discretionary act." *Id.* The court further clarified that the phrase "whether or not fixed" concerns "whether or not the *amount* owed" was fixed at the time of the violation, not "whether an obligation to pay was fixed." *Id.* at 506.

Implications for Future FCA Cases

This decision held that a federal agency acting as receiver of a private entity is not the government and that "obligation" is limited to those duties existing at the time of the alleged violation. The case thus narrows the circumstances in which reverse false claims counts can be brought in two significant respects.

F. Fourth Circuit: (1) Government's Unreviewable Veto; (2) Falsity; (3) Materiality; (4) First-to-File Rule

***United States ex rel. Michaels v. Agape Senior Community, Inc.*, 848 F.3d 330 (4th Cir. 2017)**

The Fourth Circuit joined the Fifth and Sixth Circuits in holding that the government has unreviewable veto authority over qui tam settlements under 31 U.S.C. § 3730(b)(1).

About the Case

The relators alleged that elder-care facilities in South Carolina had fraudulently billed Medicare and other federal health care programs for services that were not actually provided or were provided to ineligible patients. 848 F.3d at 333. The United States declined to intervene but requested that the parties obtain the Attorney General's written consent under 31 U.S.C. § 3730(b)(1) before asking the court to rule on any proposed dismissal. *Id.* at 334.

While the case was pending in district court, the relators and defendants engaged in mediation without the government's knowledge and reached a proposed settlement. *Id.* at 335. The government objected to the proposed settlement, relying on § 3730(b)(1), but did not seek to intervene. The government considered the $25 million proposed settlement to be "appreciably less" than its own estimate of total damages. *Id.* The relators filed a motion to enforce the proposed settlement over the government's objection, arguing that the objection was subject to a reasonableness review because the government had declined to intervene. *Id.* The district court denied the motion on the ground that the government has absolute veto authority over settlements in qui tam cases.

The Fourth Circuit agreed with the district court—and the Fifth and Sixth Circuits—that the government possesses an absolute veto power over voluntary settlements in FCA qui tam actions. *Id.* at 340. The Fourth Circuit rejected the Ninth Circuit's position that § 3730(b)(1) is limited by § 3730(b)(2)-(4), which sets out the default 60-day period during which the government may elect to intervene. *Id.* at 339. The Fourth Circuit explained that the relator's right to conduct the action when the government declines to intervene does not create "an unfettered right to settle on the part of the relator." *Id.* The court noted that "§ 3730(b)(1) does not overtly require that the government satisfy any standard or make any showing reviewable by the court," in contrast to § 3739(c)(2), which requires that the court determine a proposed settlement by the government over the relator's objection is fair, adequate, and reasonable. *Id.* at 339-40.

Implications for Future FCA Cases

The Fourth Circuit joins the Fifth and Sixth Circuits in holding that the government has an unreviewable veto over voluntary qui tam settlements by relators in declined cases. *See Searcy v. Philips Electronics North America Corp*., 117 F.3d 154 (5th Cir. 1997); *United States v. Health Possibilities*, P.S.C., 207 F.3d 335 (6th Cir. 2000).

***United States v. Triple Canopy, Inc.*, 857 F.3d 174 (4th Cir. 2017), *petition for cert. dismissed*, 199 L. Ed. 2d 275 (Oct. 24, 2017)**

On remand following the Supreme Court's *Escobar* decision, the Fourth Circuit reaffirmed its prior decision that the government had adequately pled falsity and materiality.

About the Case

The relator alleged that Triple Canopy had failed to hire security guards that met marksmanship standards required in its contract to provide security services in Iraq and

had falsified marksmanship scorecards for the guards. 857 F.3d at 175. The government intervened, alleging that Triple Canopy had knowingly presented false claims because it had billed the government for unqualified security guards. *Id.* at 176. The district court dismissed the government's complaint, declining to recognize the implied certification theory of liability. *Id.* The Fourth Circuit reversed, holding that the implied certification theory was valid in certain circumstances. *Id.* Triple Canopy petitioned for certiorari.

The Supreme Court granted certiorari, vacated the Fourth Circuit's prior opinion, and remanded for further consideration in light of *Escobar*. *Id.* at 177. On remand, the Fourth Circuit concluded that *Escobar* did not alter its earlier decision and again reversed the district court's dismissal of the government's complaint. *Id.*

The Fourth Circuit rejected Triple Canopy's argument that *Escobar* had adopted a narrower view of falsity, explaining that invoices requesting payment for guards Triple Canopy knew had failed to meet a contractual requirement were exactly the kind of "half-truths" recognized by the Supreme Court as potentially actionable misrepresentations. *Id.* at 178. The Fourth Circuit also concluded that *Escobar* supported its earlier determination that the falsity was material because of "common sense and Triple Canopy's own actions in covering up the noncompliance." *Id.*

Implications for Future FCA Cases

Triple Canopy clarifies the Fourth Circuit's analysis of falsity and materiality following the Supreme Court's *Escobar* decision.

***United States ex rel. Carter v. Halliburton Co.*, 866 F.3d 199 (4th Cir. 2017)**

The Fourth Circuit reaffirmed its prior holding that the first-to-file bar turns on whether other actions are pending when a qui tam action is filed, and held that, on the facts of the case, the relator did not overcome the first-to-file bar by filing an amended pleading after dismissal of the other pending cases.

About the Case

The relator filed a qui tam action in June 2011 alleging fraudulent billing for services provided to the US military in Iraq. 866 F.3d at 203. At the time the relator filed his case in Virginia, two related actions were pending in Maryland and Texas. *Id.* The Maryland and Texas actions were dismissed in October 2011 and March 2012, respectively. *Id.* The district court dismissed the Virginia action under the first-to-file bar with prejudice in November 2011. *Id.* The Fourth Circuit agreed that the first-to-file bar applied, but ruled the dismissal should have been without prejudice because some of the relator's claims were not time-barred and the related actions were no longer pending. *Id.* at 204. The Supreme Court granted review; it held that the first-to-file bar applies only while the first-filed actions are pending and agreed that dismissal with prejudice of any timely claims was therefore improper. *Id.* at 205.

On remand to the district court, the relator sought leave to amend his complaint to overcome the first-to-file bar. *Id.* The relator's proposed amendments would have expanded his damages theories but did not address the dismissals of the Maryland and

Texas actions. *Id.* The district court held that relator could not cure the first-to-file defect through amendment. *Id.*

The Fourth Circuit applied its prior holding "that a court must look at the facts as they existed when the claim was brought to determine whether an action is barred by the first-to-file bar," rejecting the relator's argument that it was overruled by the Supreme Court's intervening decision in the case. *Id.* at 207 (internal quotations and citations omitted). The Fourth Circuit then held that the district court had properly denied the relator's proposed amendments, which only added detail to his damages theories and did not "address any matters potentially relevant to the first-to-file rule, such as the dismissals of the Maryland and Texas Actions." *Id.* at 210.

Judge Wynn wrote a concurring opinion to clarify "the narrow scope" of the majority's decision, which, in his view, "simply holds that a proposed amendment or supplement to a complaint cannot cure a first-to-file defect when the amendment or supplement does not reference the dismissal of publicly disclosed, earlier-filed related actions." *Id.* at 212.

Implications for Future FCA Cases

The Fourth Circuit reaffirmed its prior holding that the first-to-file bar prohibits actions filed at the time an earlier-filed, related action was pending, even after the earlier action has concluded. How a relator is to proceed after conclusion of the earlier-filed action remains uncertain. On the facts of the case, the Fourth Circuit distinguished the First Circuit's decision in *United States ex rel. Gadbois v. PharMerica Corp.*, 809 F.3d 1 (1st Cir. 2015), which held that a relator could cure a first-to-file defect with a supplemental pleading clarifying that the first-filed action had been dismissed, and did not expressly go as far as the D.C. Circuit's decision in *United States ex rel. Shea v. Cellco Partnership*, 863 F.3d 923 (D.C. Cir. 2017), which held that amendment cannot, as a matter of law, cure a first-to-file defect.

G. Fifth Circuit: (1) Relation Back of Government's non-FCA Claims; (2) Materiality; (3) Public-Disclosure Bar; (4) Rule 9(b) Pleading Standard; (5) Government-Knowledge Defense; (6) Pre-2010 Public-Disclosure Bar; (7) Causation

***United States ex rel. Vavra v. Kellogg Brown & Root, Inc.*, 848 F.3d 366 (5th Cir. 2017)**

The Fifth Circuit held that the FCA permits the government to add non-FCA claims when it intervenes in a qui tam action, and that the added claims relate back to the filing date of the original qui tam complaint.

About the Case

The relators alleged that KBR had violated the FCA in connection with a government contract to provide logistical support to the Army. 848 F.3d at 370. More than six years later, the government intervened and filed its own complaint, which asserted FCA claims and added allegations that KBR, through actions by its employees, had violated that Anti-Kickback Statute (AKS). *Id.* The district court dismissed the government's AKS claim because the allegations were insufficient to establish vicarious liability. *Id.* at

370–71. The Fifth Circuit reversed and remanded on the ground that the district court had applied the wrong vicarious-liability standard. *Id.* at 371. After a bench trial, the district court found KBR vicariously liable for accepting kickbacks. *Id.* KBR appealed, arguing that the government's AKS claim did not relate back to the relators' qui tam complaint under 31 U.S.C. § 3731(c), requiring the verdict to be set aside as outside the statute of limitations. *Id.*

Section 3731(c) states, in relevant part: "If the Government elects to intervene . . . the Government may file its own complaint . . . to clarify or add detail to the claims in which the Government is intervening and to add any additional *claims* with respect to which the Government contends it is entitled to relief."

KBR argued that "claims" as used throughout § 3731(c) means "FCA claims" and therefore limits the government to adding FCA claims when intervening in a qui tam action. 848 F.3d at 381. The Fifth Circuit disagreed. The court of appeals agreed that the first use of "claims" in § 3731(c) means FCA claims because § 3731(c) provides that the government can only clarify or add detail to the claims in which it is intervening, which are necessarily FCA claims. *Id.* at 382. By contrast, the court held, the second use of "claims" is not limited to FCA claims because the context does not limit the term—that part of § 3731(c) "permits the Government 'to add *any additional* claims." *Id.* However, the additional claims must still arise from the same "conduct, transactions, or occurrences" in the prior complaint for the government to take advantage of § 3731(c)'s relation-back provision. *Id.*

The Fifth Circuit also rejected KBR's argument that the government's claims did not relate back because the government did not continue to pursue the FCA claims after they were dismissed. *Id.* at 383. The court reasoned that the government did proceed with the FCA claims when it intervened, making § 3731(c) operative and permitting the additional claims to relate back to the original complaint. *Id.* The subsequent dismissal of the FCA claims by the district court did not affect the applicability of the relation-back doctrine. *Id.*

Implications for Future FCA Cases

The Fifth Circuit's decision establishes that the government may bring non-FCA claims if it intervenes in a qui tam action, and that those claims will relate back to the original complaint if they arise out of the same conduct, transaction, or occurrence as the original claims.

***Abbott v. BP Exploration & Production, Inc.*, 851 F.3d 384 (5th Cir. 2017)**

The Fifth Circuit upheld the district court's grant of summary judgment in favor of BP on a relator's FCA claims, finding that the relator has failed to create a genuine dispute of material fact as to materiality.

About the Case

The relator alleged that BP had falsely certified compliance with regulatory requirements for the Atlantis Platform, an oil rig in the Gulf of Mexico. 851 F.3d at 385–86. The relator's allegations led Congress to request an investigation by the Department of the

Interior (DOI). *Id.* at 386. DOI's investigation found that the allegations were without merit. *Id.*

The district court granted summary judgment in favor of BP on the FCA claims. *Id.* The Fifth Circuit affirmed, applying the materiality standard set forth by the Supreme Court in *Escobar*. *Id.* at 387. The Fifth Circuit noted that "when the DOI decided to allow the Atlantis to continue drilling after a substantial investigation into [the] allegations, that decision represents 'strong evidence' that the requirements in th[e] regulations [at issue] are not material." *Id.* at 388. The court found that the relator had failed to rebut "these 'strong facts'" and therefore had not created a genuine dispute of material fact as to materiality. *Id.*

BP also moved for summary judgment on the basis that the court lacked jurisdiction over the amended complaint under the public-disclosure bar. *Id.* at 387 n.2. In a footnote, the Fifth Circuit held that it did not have to consider BP's public-disclosure-bar argument because the post-2010 version of the public-disclosure bar, which was in effect by the time the relator amended the complaint and BP moved for summary judgment, is not jurisdictional, *id.*, joining the Third, Fourth and Eleventh Circuits in finding the post-2010 bar non-jurisdictional. *See United States ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294 (3d Cir. 2016); *United States ex rel. May v. Purdue Pharm. L.P.*, 737 F.3d 908 (4th Cir. 2013); *United States ex rel. Osheroff v. Humana, Inc.*, 776 F.3d 805 (11th Cir. 2015)

Implications for Future FCA Cases

The case illustrates how the Fifth Circuit will analyze materiality under the Supreme Court's *Escobar* decision and clarifies that the Fifth Circuit does considers the post-2010 public-disclosure bar non-jurisdictional.

***United States ex rel. Colquitt v. Abbott Laboratories*, 858 F.3d 365 (5th Cir. 2017)**

The Fifth Circuit affirmed dismissal of certain claims under the public-disclosure bar and Rule 9(b), and upheld a verdict in favor of the defendant regarding allegations of off-label marketing of a medical device.

About the Case

The relator alleged that Abbott: 1) had made misrepresentations in its application for FDA approval of medical stents (fraudulent inducement claim); 2) had violated the AKS and caused false compliance certifications on hospital claims (AKS claim); and 3) had caused the presentment of false claims by marketing the stents for off-label use (false presentment claim). 858 F.3d at 370. The district court dismissed all claims.

First, the Fifth Circuit affirmed dismissal of the AKS claim under Rule 9(b), concluding that the relator had failed to provide details to "show that the unidentified doctors who received the ill-defined benefits caused the hospital to use Abbott stents" and that "the complaint never link[ed] the alleged carrots to the purchase and use of the stents[.]" *Id.* at 372.

Second, the Fifth Circuit affirmed dismissal of the fraudulent inducement claim based on the public-disclosure bar, agreeing with the district court that the public documents submitted to the FDA provided all the information necessary to discover the alleged fraud. *Id.* at 373–74. The Fifth Circuit concluded that the relator's knowledge from working at Abbott was not related to the FDA approval process and that he therefore did not qualify as an original source. *Id.* at 374.

Third, the Fifth Circuit affirmed the district court's decision on summary judgment to limit the time frame of relator's false presentment theory based on the public-disclosure bar. *Id.* at 377. Although the facts about Abbott's promotion of the stents had been publicly disclosed, the relator's false presentment theory had survived a motion to dismiss because the district court had found that the relator was an original source of those allegations. *Id.* at 375. At summary judgment, however, the district court accepted Abbott's argument that the relator was an original source only for the period of his employment at Abbott. *Id.* The Fifth Circuit agreed, concluding that the relator did not have direct, independent knowledge of the alleged fraud prior to or after his employment. *Id.* at 377.

At trial, Abbott defended against the time-limited false presentment claim using what the Fifth Circuit described as an "open secret" defense—i.e., that everyone involved, including the government, knew how the stents were being used—and the jury ultimately found against the relator. *Id.* at 371. The relator later disputed several trial rulings, including the district court's rejection of his proposed jury instruction on the government knowledge defense. *Id.* at 379–80. The Fifth Circuit agreed with the district court that the relator's proposed instruction misstated the law, explaining that "government knowledge can negate liability when the defendant knew not only that the statements at issue were false, but that the government knew it as well." *Id.* at 380.

Implications for Future FCA Cases

This case provides guidance on key defenses in the Fifth Circuit, including the requirement to plead causation with sufficient particularity, the public-disclosure bar, and the government-knowledge defense.

***United States ex rel. King v. Solvay Pharmaceuticals, Inc.*, 871 F.3d 318 (5th Cir. 2017)**

The Fifth Circuit affirmed the district court's grant of summary judgment to the defendant, holding that 1) the relators did not qualify for the original-source exception under the pre-2010 version of the public-disclosure bar; and 2) the relators had not presented sufficient evidence of causation regarding their off-label marketing claims.

About the Case

The relators, former Solvay sales and marketing employees, claimed that Solvay had induced the submission of false claims through a nationwide off-label marketing and kickback scheme to promote three drugs. 871 F.3d at 323. The relators asserted, among other claims, that Solvay had caused the filing of false claims by marketing the drugs for off-label uses to physicians, lobbying members of state pharmaceutical and therapeutic committees to add the drugs to preferred drug lists, and lobbying a drug

compendium publisher to include off-label uses in the compendium using misleading scientific literature. *Id.* at 324. The district court dismissed all claims.

The Fifth Circuit upheld the district court's dismissal of claims with respect to one of the drugs under the public-disclosure bar. *Id.* at 327. The Fifth Circuit held that to meet the voluntary disclosure requirement of the original-source exception to the pre-2010 public-disclosure bar, a relator's pre-suit disclosure must "connect direct and independent knowledge of information about [a defendant's] conduct to false claims submitted to the government, i.e., suggest an *FCA violation*." *Id.* The Fifth Circuit concluded that the the relators' evidence did not suggest that any FCA claims were submitted to the government and therefore could not meet their summary judgment burden. *Id.*

The Fifth Circuit also held that the evidence presented by the relators regarding the other two drugs was insufficient to create a genuine issue of material fact as to whether Solvay had caused the submission of false claims. The Fifth Circuit rejected the relators' evidence, which included an expert report attempting to link off-label marketing with increased off-label sales and sales representative call notes, as based on conjecture and speculation and thus insufficient to indicate that Solvay's off-label marketing had actually caused submission of false claims. *Id.* at 328–29. The opinion emphasized the difficulty of establishing causation when it is common and permissible for doctors to prescribe medicines for off-label uses. *Id.* at 328. The Fifth Circuit similarly found that the relators had failed to provide sufficient evidence of causation to survive summary judgment on their claims of improper lobbying activities. *Id.* at 330–31.

Implications for Future FCA Cases

This decision clarifies the requirements in the Fifth Circuit for relators to meet the original-source exception to the pre-2010 public-disclosure bar, which continues to be relevant given the long periods during which FCA claims may remain under seal. It also provides a useful framework for disputing causation in off-label marketing cases.

***United States ex rel. Harman v. Trinity Industries, Inc.*, 872 F.3d 645 (5th Cir. 2017)**

The Fifth Circuit reversed a $663 million jury verdict for lack of materiality and rendered judgment as a matter of law for the defendant.

About the Case

The relator alleged that Trinity had made changes to guardrails it manufactures after receiving approval for the guardrails from the Federal Highway Administration (FHWA), and had failed to disclose those changes. 872 F.3d at 650. The relator alleged that Trinity therefore had falsely certified compliance with FHWA testing requirements, causing the submission of false claims for federal subsidies. Trinity argued that FHWA regulations required retesting only for changes deemed significant under a standard of "good engineering judgment." *Id.* at 656.

Throughout the case, the FHWA indicated that it did not believe it had been defrauded. Prior to trial, the FHWA, with knowledge of the changes made to the guardrails and the relator's allegations, issued a memorandum stating that "there was an unbroken chain of eligibility for Federal-aid reimbursement" for the guardrails. *Id.* at 651. After the jury

returned a verdict in favor of the relator, the FHWA ordered independent testing of the guardrails and again concluded that the guardrails installed across the country had been tested and approved. *Id.* The FHWA never rescinded its approval for the guardrails and continued to make payments for the guardrails.

On appeal, Trinity argued that the relator could not establish falsity, scienter, or materiality. *Id.* at 653–54. While the Fifth Circuit indicated that there may not have been sufficient evidence to establish the elements of falsity and scienter because of the ambiguity of the FHWA testing requirement, it based its decision on lack of materiality. *Id.* at 657, 660.

Applying the materiality standard outlined by the Supreme Court in *Escobar*, the Fifth Circuit held that the relator had not established materiality "given FHWA's unwavering position that the [guardrail] was and remains eligible for federal reimbursement." *Id.* at 668. The court noted that, "though not dispositive, continued payment by the federal government after it learns of the alleged fraud substantially increases the burden on the relator in establishing materiality," *id.* at 663, and found that the "FHWA continued to reimburse the [guardrail] units with full knowledge of [relator's] claims about the product's purported deficiencies," *id.* at 668. The Fifth Circuit also highlighted that eight of nine states had declined to intervene in the action and eleven states had filed an amicus brief in support of Trinity. *Id.* at 665. The Fifth Circuit emphasized the importance of the government's repeated determination that it was not defrauded, noting that the jury's "determination of materiality cannot defy the contrary decision of the government . . . absent some reason to doubt the government's decision as genuine." *Id.* at 669.

Implications for Future FCA Cases

This decision highlights the strength of the materiality requirement in the Fifth Circuit following *Escobar*, particularly when there is evidence of continued payment by the government after it learns of a relator's allegations.

H. Sixth Circuit: (1) Rule 9(b) Pleading Standard; (2) Government Liability for Defendants' Attorney's Fees

***United States ex rel. Hirt v. Walgreen Co.,* 846 F.3d 879 (6th Cir. 2017)**

The Sixth Circuit affirmed dismissal of a complaint that failed to identify a single specific false claim submitted to the government, rejecting the relator's contention that his allegations survived under the Sixth Circuit's "relaxed" Rule 9(b) pleading standard.

About the Case

The relator, Andrew Hirt, owns two local pharmacies. He alleged that Walgreen had offered $25 gift cards to Medicare and Medicaid recipients to induce them to transfer their prescriptions to Walgreen in violation of the AKS and that the resulting prescription drug claims to Medicare and Medicaid thus violated the FCA. The government declined to intervene, and the district court dismissed the action under Rule 9(b) for failure to state the claims with particularity.

The Sixth Circuit affirmed because Hirt's complaint failed to identify any of the affected customers, the dates on which their prescriptions were filled, or the dates on which Walgreen had submitted claims to the government. 846 F.3d at 881. In *United States ex rel. Bledsoe v. Community Health Systems, Inc.*, 501 F.3d 493 (6th Cir. 2007), the court had previously suggested that it may relax the requirement that a plaintiff identify at least one fraudulent claim with particularity if the plaintiff "cannot allege the specifics of actual false claims that in all likelihood exist." 846 F.3d at 881. The Sixth Circuit acknowledged that its use of the term "relax" in *Bledsoe* and later decisions "runs the risk of misleading lawyers and their clients," but said that the court has "no more authority to 'relax' the pleading standard established by Civil Rule 9(b) than [it] do[es] to increase [it]." 846 F.3d at 881.

Without knowledge of Walgreen's billing practices or any allegation that customers had used the gift cards to fill prescriptions, Hirt "was not the right plaintiff to bring this qui tam claim." *Id.* at 882. The court also rejected HIPAA privacy considerations as an impediment because Hirt had not even alleged specific fraudulent claims using customer initials. *Id.*

Implications for Future FCA Cases

The Sixth Circuit narrowed the extent to which courts may "relax" the Rule 9(b) standard, requiring that relators alleging fraudulent schemes or billing practices to plead facts showing at least one specific, representative example of an FCA violation, or, at least, a sufficient factual predicate from which to infer that false claims "in all likelihood exist." *Id.* at 882.

***United States ex rel. Wall v. Circle C Construction, LLC,* 868 F.3d 466 (6th Cir. 2017)**

The Sixth Circuit held that the government was liable for the defendant's attorneys' fees under the Equal Access to Justice Act because it had pursued an unreasonable theory of damages.

About the Case

Circle C, a general contractor, constructed 42 warehouses for the Army; a subcontractor paid two of its electricians $9,916 less than what was required by the Davis-Bacon Act. The government asserted that as a result of the underpayments, Circle C's compliance statements submitted with its invoices had violated the FCA and sought $1.66 million in treble damages (on the theory that all $544,000 of electrical work was tainted by the underpayment and thus worthless). 868 F.3d 470. The year before, the Sixth Circuit had rejected that theory of damages, noting that "in all of these warehouses, the government turns on the lights every day," and had reduced damages to an award of under $15,000, which was less than 1% of the government's demand. *Id*. at 468 (citing *United States ex rel. Wall v. Circle C Constr. LLC*, 813 F.3d 616, 617 (6th Cir. 2016)).

On remand, Circle C moved to recover over $468,000 for attorneys' fees accrued over the past decade pursuant to a 1996 amendment to the Equal Access to Justice Act. *Id.* at 469. Under that provision, subject to two exceptions, if the damages originally sought by the government are both "substantially in excess of the judgment finally obtained and

unreasonable when compared with such judgment," the defendant is entitled to recover "fees and other expenses related to defending against the excessive demand." *Id.* at 468–469 (citing 28 U.S.C. § 2412(d)(1)(D)). The district court denied the motion.

On appeal, Circle C pointed to the text of the FCA—31 U.S.C. § 3730(g)—which states that 28 U.S.C. § 2412(d) "shall apply" in civil actions brought by the United States under this section. The government countered that the fee-shifting provision does not apply because subsection 3730(g) is entitled "Fees and expenses to prevailing defendant;" because the court dramatically reduced, but did not reverse, the damages award against Circle C, the government argued that Circle C was not a "prevailing defendant." *Id.* at 469. The court rejected that reading, citing the canon of statutory interpretation "that a provision's title cannot limit the plain meaning of the text." *Id.* (citing *Penn. Dep't of Corr. v. Yeskey*, 524 U.S. 206, 212 (1998)).

After summarily holding that the $1.66 million in treble damages sought were "substantially in excess" of the $14,748 award, the court held that the government's demand was also "unreasonable" within the meaning of Section 2412(d)(1)(D). 868 F.3d at 468. As the court had previously held in its remand order, actual damages were limited to the shortfall of $9,916 in wages which did not diminish the underlying value of the work performed. *Id.* at 470 (citing *Wall*, 813 F.3d at 617–18). In the court's view, no reasonable person could conclude that the underpayments tainted the value of over $550,000 of electrical work. 868 F.3d at 471.

Finally, the court found that neither exception to recovery of attorneys' fees in subsection 2412(d)(1)(D) applied. First, there was no evidence that Circle C had acted in "bad faith." To the contrary, Circle C presented evidence that the certifications were submitted on the sincere belief that they were true. And the court rejected the government's argument that a defendant who is liable under the FCA by definition "knowingly" submitted false claims, because the district court had found that Circle C had acted with only "reckless disregard." 868 F.3d at 472. Second, the court did not believe that "special circumstances" would make an award of attorneys' fees "unjust." *Id.*

Addressing the government's contention that a fee award would have a "chilling effect" on vigorous enforcement of the FCA, the court fired back that "[o]ne should hope so" in circumstances where the government demanded "damages a hundredfold greater than what it was entitled to, and then pressed that demand over nearly a decade of litigation, all based on a theory that as applied here was nearly frivolous." 868 F.3d at 472.

Implications for Future FCA Cases

The court's scathing criticism of the government's pursuit of excessive damages, which it described as "fairyland, rather than actual," 868 F.3d at 470 (citing *Wall*, 813 F.3d at 618), will provide strong support for defendants litigating or negotiating with the government over potentially excessive damages.

***United States ex rel. Ibanez v. Bristol-Myers Squibb Co.*, 874 F.3d 905 (6th Cir. 2017)**

The Sixth Circuit affirmed the dismissal of a complaint where the relators had failed to allege facts to support the entire chain of events for any representative claim—i.e., one beginning with alleged misconduct by the defendants in marketing their pharmaceuticals and culminating in the submission of an allegedly tainted prescription to the government for reimbursement.

About the Case

The relators were Bristol-Meyers Squibb (BMS) sales representatives who marketed the antipsychotic drug Abilify from 2005 to 2010. 874 F.3d at 912. BMS and Otsuka American Pharmaceutical, Inc. have marketed and sold the drug since 1999. *Id.* The FDA has approved use of Abilify for three conditions for adults (schizophrenia in 2002, bipolar disorder in 2004, and depression in 2007) as well as for three pediatric uses in specific age groups. *Id.* The relators' allegations consisted of two theories: that the defendants (1) had encouraged providers to prescribe Abilify for off-label uses; and (2) had induced providers to prescribe Abilify through remunerations in violation of the AKS. *Id.* In 2007 and 2008, respectively, BMS and Otsuka entered into five-year CIAs to settle separate qui tam actions alleging substantially these same practices.[33] The government declined to intervene, and the district court dismissed all of the relators' claims except for their retaliation claims. *Id.* at 912–13.

The Sixth Circuit held that the relators had failed to satisfy Rule 9(b) because they had failed to allege "a representative claim that describes each step with particularity: a prescription reimbursement submitted to the government for a tainted prescription of Abilify." 874 F.3d at 915. The court distinguished its prior decision, *United States ex. rel. Prather v. Brookdale Senior Living Communities*, 838 F.3d 750, 768 (6th Cir. 2016), in which the Sixth Circuit had applied a "relaxed" standard when the relator was employed specifically for the purpose of reviewing documentation to be submitted to Medicare. In contrast, the relators here, as sales representatives, had no such interaction with any claims. The relators pointed to documentation of Medicaid reimbursements for pediatric Abilify prescriptions before the FDA had approved Abilify for pediatric patients, without connecting the prescribing physicians to the defendants. *Id.* at 920. Likewise, documentation of Medicaid reimbursements for prescriptions by physicians connected to the defendants—without allegations of specific kickbacks—lacked sufficient particularity. *Id.* at 921.

The court proceeded to dismiss relators' claims asserted under additional sections of the FCA. *Id.*

Judge Stranch, in dissent, would have held that the relators had satisfied the Sixth Circuit's "relaxed" test articulated in *Prather*. She argued that by presenting personal knowledge of corporate strategies with statistical evidence, the relators had presented facts supporting a "strong inference" that fraudulent claims were submitted. 874 F.3d at 923–25 (citing *Prather*, 838 F.3d at 769).

Implications for Future FCA Cases

For the second time in 2017, the Sixth Circuit minimized its prior holding in *Prather* to emphasize the limited application of the "relaxed" pleading standard. In the Sixth Circuit, "Rule 9(b) requires relators to adequately allege the entire chain—from start to finish—to fairly show defendants caused false claims to be filed." 874 F.3d at 914.

I. Seventh Circuit: (1) Public-Disclosure Bar; (2) Causation

Bellevue v. Universal Health Services of Hartgrove, Inc., 867 F.3d 712 (7th Cir. 2017)

The Seventh Circuit affirmed the dismissal of a qui tam action on public-disclosure grounds, where state and federal audit reports had disclosed the underlying non-compliance without identifying any fraudulent intent by the defendant.

About the Case

The relator brought federal and Illinois FCA claims against a children's psychiatric hospital receiving Medicaid payments, alleging that (1) Hartgrove had admitted patients in excess of its permit from the Illinois Department of Public Health (IDPH) to maintain 150 beds; and (2) Hartgrove had claimed inpatient expenses for patients actually sleeping in rollout beds waiting for available rooms. 857 F.3d at 715.

DOJ and the State of Illinois declined to intervene, and the district court granted Hartgrove's motion to dismiss for failure to state a claim with particularity in December 2014, but rejected Hartgrove's argument that the public-disclosure bar applied. *Id.* The district court dismissed the relator's amended complaint in October 2015. *Id.* at 715–16.

On appeal, Hartgrove argued that the claims had been publicly disclosed by IDPH audits showing that Hartgrove's patient count exceeded the number of patients it was permitted to house on 52 separate occasions. 867 F.3d at 715 n.1, 718. The Seventh Circuit agreed. It first explained that, even though the audits did not allege fraud and merely stated that Hartgrove was over capacity, the government had sufficient information in the public domain from which to infer scienter. *Id.* at 718–19. The court distinguished precedent involving public information that a provider had failed to meet a patient's standard of care because such conduct necessarily involves judgment, from which a non-fraudulent mistake could also be inferred. *Id.* at 719. Second, the court found that the relator's allegations were substantially similar to those made public by CMS and IDPH, including allegations of fraud taking place after the release of the audit reports. The Seventh Circuit explained that the relator's allegations "pertain to the same entity and describe the same contested conduct as the publicly disclosed information." *Id.* at 720. It declined to decide whether the relator qualified as an original source because he had failed to "materially add" to the public allegations. *Id.* at 720–21 (citing 31 U.S.C. § 3730(e)(4)(B).

Implications for Future FCA Cases

The decision clarifies the Seventh Circuit's approach to the public-disclosure bar. It also contains an interesting footnote, explaining that the 2010 amendments to the FCA

added a qualification that audit reports constituting public disclosures must be "Federal," while the Illinois False Claims Act limited public disclosures to "State" audits. *Id.* at 719 n.5 (citing § 3730(e)(4)(A); 740 Ill. Comp. Stat. 175/4 (2010)). Thus, depending on the circumstances of the public disclosure, state FCA claims may be barred while federal FCA claims are not, and vice versa.

***United States v. Luce,* 873 F.3d 999 (7th Cir. 2017)**

The Seventh Circuit overruled Circuit precedent and adopted a proximate-causation standard for FCA claims, joining other Circuits in doing so.

About the Case

The government brought an FCA action alleging that Luce had falsely certified that he had no criminal history so that his mortgage company could participate in the a government-backed insurance program. The district court granted summary judgment in favor of the government, concluding both that the certifications were material and that they had caused the submission of false claims.

The Seventh Circuit agreed with the district court that Luce's false certifications were material, but it reversed on causation, overruling its prior precedent, *United States v. First National Bank of Cicero*, 957 F.2d 1362 (7th Cir. 1992), and adopting the proximate-causation standard for FCA causes in light of the Supreme Court's decision in *Escobar*.

Materiality

The Seventh Circuit held that the false certifications met the heightened materiality standard articulated in *Escobar* because the certification "concerns an eligibility requirement that flatly prohibits the Government from doing business with individuals who have a criminal record." 873. F.3d at 1007 (internal quotations omitted). The Department of Housing and Urban Development's (HUD) actions to terminate Luce's participation in the program demonstrated that "the false [] certifications simply were not minor or insubstantial violations," but rather were "lies that addressed a foundational part of the Government's mortgage insurance regime, which was designed to avoid the systemic risk posed by unscrupulous loan originators." *Id.* (internal quotations omitted). The court rejected Luce's argument that the certification was not tied to any particular loan, reasoning that it was a threshold requirement applicable to *every* loan. *Id.* at 1009.

Causation

In light of *Escobar*'s application of common-law fraud principles in the FCA context, Luce urged the Seventh Circuit to abandon its but-for causation test. In particular, the Supreme Court in *Escobar* stated that "absent other indication, Congress intends to incorporate the well-settled meaning of the common-law terms it uses and that the term fraudulent is a paradigmatic example of a statutory term that incorporates the common-law meaning of fraud." *Id. at 1011* (citing *United States ex rel. Escobar*, 136 S. Ct. 1989, 1999 (2016)).

The Seventh Circuit proceeded to overrule *Cicero*, in which it had held that the FCA requires only a but-for causation test. The panel recognized that its decision in *Cicero* had created a split with the Third Circuit, and that in the intervening 25 years, the Fifth and D.C. Circuits had adopted a proximate-causation standard, while none had adopted a but-for causation standard. *Id.* at 1010-11. Even though the FCA's text allows the government to recover for damages sustained "because of" the person's actions, "nothing in the FCA contains any indication of an intent to depart from the common-law understanding of causation in fraud cases." *Id.* at 1012.

The Seventh Circuit remanded for a determination as to whether the government can establish Luce's false certifications were the proximate cause of the government's harm. *Id.* at 1014.

Implications for Future FCA Cases

The effects of *Escobar* continue to be felt with respect to the materiality analysis under the FCA. In addition, the Seventh Circuit took an important step to bring its FCA causation doctrine in line with the approach adopted by other Circuits.

J. Eighth Circuit: (1) Public-Disclosure Bar; (2) Sovereign Immunity

In re Baycol Prods. Litig., 870 F.3d 960 (8th Cir. 2017)

The Eighth Circuit held that, to qualify as an original source, a relator need only have direct knowledge of the "true state of facts"—not necessarily first-hand knowledge of specific misstatements made by a defendant.

About the Case

The relator alleged that Bayer misrepresented the safety and efficacy of its cholesterol drug, Baycol, while negotiating a contract for its purchase with the Department of Defense (DoD). 870 F.3d at 961. Bayer asserted that the suit was barred by the public-disclosure bar because news articles, other lawsuits, public filings and medical literature disclosed that Bayer had allegedly concealed Baycol's risks. *Id.* at 962. The relator claimed to be an original source because she had obtained information through Freedom of Information Act requests indicating that Baycol was more dangerous than other cholesterol drugs. She had also directly participated in developing and refining a marketing strategy for Baycol, which had guided Bayer's discussions with DoD. *See In Re Baycol Prods. Litig.*, No. 08-5758, 2015 WL 12803777, at *5 (D. Minn. Mar. 31, 2015).

In holding that a relator is not required to have "direct and independent knowledge" of all elements of an FCA claim to qualify as an original source, the Eighth Circuit relaxed the requirements of the original-source exception to the public-disclosure bar. 870 F.3d at 962. The court held that, "[a]s long as the relator has 'direct knowledge of the true state of the facts,' she can be an original source even though her 'knowledge of the misrepresentation is not first-hand.'" 870 F.3d at 962. Specifically, the court concluded that the relator did not need first-hand knowledge of Bayer's specific, fraudulent communications with particular individuals at DoD, but rather only that Bayer had allegedly misrepresented the benefits and risks of the drug to win DoD contracts. *Id.*

Implications for Future FCA Cases

This decision relaxes the original-source requirements in the Eighth Circuit by relieving relators from having to demonstrate first-hand knowledge of specific misrepresentations made by a defendant. It is sufficient for a relator to have direct knowledge of the concealed "true state of facts" but only derivative knowledge of a defendant's false statements.

***United States ex rel. Fields v. Bi-State Development Agency*, 872 F.3d 872 (8th Cir. 2017), *cert. denied* (Jan. 8, 2018) (17-657)**

The Eighth Circuit held that an agency created by two states pursuant to an interstate compact that operated public transportation services was not an arm of the compacting states and, like a local governmental entity, was not entitled to Eleventh Amendment immunity from a federal FCA suit.

About the Case

The relator alleged that the transportation agency had falsely certified that it had complied with laws restricting political campaign activities, when in fact the agency had allegedly raised funds for a St. Louis county executive's re-election campaign and had ordered its employees to volunteer for the campaign. 872 F.3d at 876. The agency moved for summary judgment, arguing that it did not qualify as a "person" under the FCA. *Id.* The district court denied the motion, and the agency appealed. After the Eighth Circuit dismissed the appeal for lack of jurisdiction, 829 F.3d 598, 600 (8th Cir. 2016), the agency moved for summary judgment on Eleventh Amendment immunity grounds. The district court denied that motion, and this appealed followed.

The Eighth Circuit had long ago held that the agency was not an arm of the state. *See Barket, Levy & Fine, Inc. v. St. Louis Thermal Energy*, 948 F.2d 1084, 1086 (8th Cir. 1991). The panel thus reconsidered in detail various factors that affect a determination of sovereign immunity and found that evidence supporting several of the factors was inconclusive. For example, Missouri had recently deleted "the statutory waiver of sovereign immunity for multistate entities" while Illinois "recently characterized [the agency] as a local public entity under its tort immunity act." 872 F.3d at 878.

The court ultimately concluded that the agency was not an arm of the state entitled to sovereign immunity. 872 F.3d at 883. The court found especially significant that the agency received less than two percent of its funds from a state and was thus not likely to draw from a state's treasury to satisfy unfavorable judgments against it. 872 F.3d at 883.

Implications for Future FCA Cases

This is a decision that has implications for many transit authorities, which can be funded through a mix of sources including federal monies, state monies, fees and bond issues, all potentially subject to FCA liability. The decision demonstrates how the multi-factor test used to determine whether an entity is an arm of the state entitled to sovereign immunity can yield unpredictable results, which affects the ability of relators to bring FCA actions against transportation agencies across various jurisdictions.

K. Ninth Circuit: (1) Materiality; (2) Public-Disclosure Bar

United States ex rel. Kelly v. Serco, Inc., 846 F.3d 325 (9th Cir. 2017)

The Ninth Circuit held, in recognition of the demanding materiality standards under *Escobar*, that the government's acceptance of cost reports, which did not meet formatting requirements and which were incorporated into the alleged false claims, undercut the materiality of the alleged false statements.

About the Case

The relator, a former employee of Serco (a project management, engineering design, and installation support services provider to DoD) alleged that Serco had submitted fraudulent claims for payment for work done under a government contract. 846 F.3d at 328. The relator alleged that the pertinent cost management reports were "unreliable" because they tracked costs manually in a format that was not supported by federal regulation; the defendant, according to the relator, was falsely implying certification of compliance with these regulations when it submitted the reports. *Id.* at 329. The district court granted summary judgment to the defendant, concluding that such compliance was not material to payment. *Id.* at 329–30.

The Supreme Court decided *Escobar* during the pendency of the relator's appeal. The Ninth Circuit acknowledged that the district court had based its pre-*Escobar* decision on the understanding that payment must be explicitly conditioned on a specific obligation for that obligation to be the basis of FCA liability, a position explicitly overruled by *Escobar*. 846 F.3d at 331–32. However, the Ninth Circuit concluded that, even if compliance with a specific obligation were a condition of the contract, the relator still had failed to establish liability because the defendant had never made specific representations about its performance on its vouchers submitted to the DoD, as required by *Escobar*. *Id.* at 332–33 (citing *Escobar*, 136 S. Ct. at 2001). Moreover, there was no evidence that the vouchers themselves contained any false or misleading statements. *Id.* at 333. Finally, the relator had not met the "demanding" test for materiality under *Escobar* both because the government had accepted the relevant cost management reports, despite their non-compliance with the regulation, and because the government did not consider the required format of the reports to be "helpful" and did not use them to manage the project. *Id.* at 334.

Implications for Future FCA Cases

This case illustrates the limits of the implied certification theory in the wake of *Escobar*, as well as the stringent materiality assessment that courts must now undertake, including how the government responds to allegedly fraudulent claims at the time of their submission.

Amphastar Pharm. Inc. v. Aventis Pharma SA, 856 F.3d 696 (9th Cir. 2017)

The Ninth Circuit held that disclosures may qualify as "public disclosures" even when they fail to explicitly identify particular false claims or lack specific details of the alleged fraud.

About the Case

The relator, a generic pharmaceutical firm, brought a qui tam action alleging that Aventis had made fraudulent representations to the Patent and Trademark Office (PTO), obtained an illegal monopoly over a generic blood-thinning drug, and overcharged the United States. 856 F.3d at 700-01. After the government declined to intervene, the district court dismissed the action for lack of subject-matter jurisdiction, holding that the claims were barred by the public-disclosure bar since they were based on claims that Amphastar had already made as part of counterclaims filed in an earlier patent infringement case. *Id.* at 701–02. The earlier counterclaims had alleged that Aventis had obtained an invalid patent due to misrepresentations and that Aventis had knowingly gained a monopoly as a result of these misrepresentations. *Id.* Additionally, the district court held that the relator was not an original source because it had no pre-litigation information relating to the fraud. *Id.*

The Ninth Circuit agreed with the district court that the relator's claims were "nearly identical" to its earlier counterclaims, although those counterclaims never mentioned any false claims submitted to the federal government, because a disclosed allegation need not "contain every specific detail to constitute a disclosure." *Id.* at 704. The allegations of fraud pertinent to FCA liability were "obvious inference[s]" based on the allegations concerning the illegal monopoly, which were publicly disclosed in the counterclaims in the prior suit. *Id.*

Implications for Future FCA Cases

In a decision favorable to defendants, the Ninth Circuit here underscored the breadth of the public-disclosure bar: prior public disclosures need not explicitly mention actual false claims, nor do they need to contain every detail of the alleged fraud to constitute qualifying disclosures.

***United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890 (9th Cir. 2017)**

In an apparent break with other Circuits, the Ninth Circuit held that FDA approval does not preclude FCA liability where false claims may have procured approval in the first instance.

About this Case

The relators allege that in its application for FDA approval for an anti-retroviral drug, Gilead represented that it would source a particular ingredient from registered facilities in Canada, Germany and the United States, but instead bought it from a supplier in China, which contaminated some batches. 862 F.3d at 895–96. They allege that Gilead never informed the FDA of either the swap or the contamination and subsequently obtained approval for the drug. *Id.* at 896. They allege that Gilead then sold its anti-retroviral drug to the government, for which it received federal funds. *Id.* at 895.

The relators alleged that, because FDA approval is the "*sine qua non*" of federal funding, each of Gilead's claims for reimbursement was false or fraudulent because Gilead made either factually false or impliedly false certifications to the FDA during the approval process. 862 F.3d at 905. Gilead argued that "because the government

continued to pay for the medications after it knew of the FDA violations, those violations were not material to its payment decision." 862 F.3d at 906.

The Ninth Circuit held that the complaint was adequate to survive a motion to dismiss. It held that the relators had adequately alleged falsity under factual-falsity, implied-false-certification, and promissory-fraud theories, and that they had adequately alleged scienter. Most importantly for future cases, the Ninth Circuit held that the relators had adequately alleged materiality even though the government had not rescinded its approval of the drugs in question after learning about Gilead's conduct. The court reasoned that it would be improper "to read too much into the FDA's continued approval" for several reasons. *Id.* at 906. First, the court explained, "to do so would allow Gilead to use the allegedly fraudulently-obtained FDA approval as a shield against liability for fraud." *Id.* Second, the court opined that "there are many reasons the FDA may choose not to withdraw a drug approval." *Id.* Third, the court noted that Gilead had "ultimately stopped using" the Chinese facility, and reasoned that "[o]nce the unapproved and contaminated drugs were no longer being used, the government's decision to keep paying for compliant drugs does not have the same significance as if the government continued to pay despite continued noncompliance." *Id.* The court concluded that the issues of materiality were "matters of proof, not legal grounds to dismiss relators' complaint." 862 F.3d at 907.

Implications for Future FCA Cases

Gilead has petitioned the Supreme Court for a writ of certiorari, citing an apparent split with the First and Third Circuits. *Cf. D'Agostino v. ev3 Inc.*, 845 F.3d 1 (1st Cir. 2016); *U.S. ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 490 (3d Cir. 2017). The petition is discussed supra at pp. 11–12.

L. Tenth Circuit: First-to-File Bar

United States ex rel. Little v. Triumph Gear Sys., Inc., 870 F.3d 1242 (10th Cir. 2017)

The Tenth Circuit held that the first-to-file bar is triggered when the original relator is replaced by a person who was not originally a party to the action

About the Case

The original relator brought a qui tam action against a government contractor and manufacturer of aerospace gear systems, alleging that he had witnessed instances of fraud in the contractor's submissions. 870 F.3d at 1245. The initial complaint named Joe Blyn and three John Does as relators. Months later, Blyn and the John Does "vanished from the action," but Blyn's counsel named himself and another person as the new relators. *Id.* The defendant moved to dismiss, asserting that the substitution of relators triggered the first-to-file bar. *Id.* at 1245–46. The district court denied the motion, holding that the new relators had not "intervened" for the purposes of 31 U.S.C. § 3730(b)(5). *Id.*at 1246.

The Tenth Circuit reversed, holding that when an original relator is replaced by other persons via amendment to the complaint by someone other than the original relator, the

first-to-file bar is triggered. *Id.* at 1247–48. Had the original relator amended the complaint while remaining as a party, this would not have triggered the first-to-file bar, since the amendment would have been permissible under Federal Rule of Civil Procedure 15. *Id.*

Implications for Future FCA Cases

The Tenth Circuit made clear that the right to amend to add a new relator belongs solely to the original relator and cannot be invoked by a stranger to the complaint without running afoul of the first-to-file bar.

M. Eleventh Circuit: (1) Government Intervention To Settle; (2) Scienter in the Face of Ambiguous Regulations

***United States v. Everglades College, Inc*., 855 F.3d 1279 (11th Cir. 2017)**

The Eleventh Circuit held that the FCA's "good-cause" intervention provision does not apply when the government intervenes to *end* litigation; it applies only when the government intervenes to *proceed with* the litigation.

About the Case

The relators alleged that the defendant college had falsely certified compliance with the Higher Education Act's ban on incentive payments to admission counselors. 855 F.3d 1282–83. The government originally declined to intervene, and following a bench trial, the relators prevailed on two claims. *Id.* The district court then granted the government's motion to intervene to enter a proposed settlement between the government and the defendant. *Id.* The relators appealed, asserting that under 31 U.S.C. § 3730(c)(3), the government must show "good cause" to intervene after declination. *Id.* at 1285.

The Eleventh Circuit upheld the settlement, despite that (1) the government had originally declined to intervene, (2) the government had intervened solely for the purpose of settlement, and (3) the relators had prevailed at trial without the government's assistance. *Id.* at 1283. Consistent with the holdings of other Circuits, the Eleventh Circuit rejected the relators' argument that the government must show "good cause" to intervene after declining, instead holding that the good-cause intervention provision does not apply when the government intervenes to *end* litigation; it applies only when the government intervenes to *proceed with* the litigation. *Id.* at 1285–86.

Implications for Future FCA Cases

This case has procedural ramifications for the government's role in both intervention and settlement of FCA cases. The Eleventh Circuit held that the government does not need to show good cause to intervene to settle a case. Rather, the validity of such a settlement by the government is determined only by whether it is fair and reasonable.

United States ex rel. Phalp v. Lincare Holdings, Inc., 857 F.3d 1148 (11th Cir. 2017)

The Eleventh Circuit held that a defendant cannot rebut the knowledge element of an FCA claim simply by asserting that it had a reasonable interpretation of an ambiguous regulation.

About the Case

The relators alleged that suppliers of diabetic testing supplies submitted claims to Medicare without adequate authorization from beneficiaries. 857 F.3d at 1151–52. The defendants moved for summary judgment, arguing that ambiguity inherent in the applicable regulations negated the scienter necessary to establish a claim. *Id.* at 1152. The district court granted the motion, holding that, as a matter of law, no reasonable jury could find that the defendants had submitted false claims with the requisite knowledge because the applicable regulations were ambiguous. *Id.* at 1152–53.

The Eleventh Circuit reversed, holding that a defendant cannot rebut the knowledge element of an FCA claim by simply asserting that it had a reasonable interpretation of an ambiguous regulation. *Id.* at 1155–56. The court of appeals rejected the district court's application of an "erroneous scienter standard" that, in its view, would allow defendants to avoid liability merely by identifying a "reasonable interpretation of any ambiguity inherent in the [allegedly violated] regulations." *Id.* at 1151–52. The Eleventh Circuit held that the standard should be "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." *Id.* at 1155. Thus, although ambiguity is still relevant to the scienter analysis, the mere ambiguity of governing regulations will not alone shield defendants from FCA liability. *Id*

The Eleventh Circuit did not discuss the Supreme Court's decision in *Safeco Ins. Co. of Am. v. Burr,* 551 U.S. 47 (2007), in which it held that when "the statutory text and relevant court and agency guidance allow for more than one reasonable interpretation, it would defy history and current thinking to treat a defendant who merely adopts one such interpretation as a knowing or reckless violator." *Id*. at 70 n.20.

Implications for Future FCA Cases

The decision clarifies that in the Eleventh Circuit mere ambiguity in a regulation will not suffice to undercut the knowledge element of an FCA claim. A defendant must be able to show that it had adopted a reasonable interpretation of the regulation in light of that ambiguity at the relevant time.

III. FEDERAL SETTLEMENTS, INTERVENTIONS AND COMPLAINTS

A. Healthcare and Pharmaceuticals

Healthcare and Pharmaceuticals Settlements

- **AmerisourceBergen Corporation:** In November, AmerisourceBergen announced in an SEC filing that following "advanced settlement discussions" with the US Attorney's Office for the Eastern District of New York it had accrued a $625 million reserve with respect to FCA allegations that a subsidiary had improperly repackaged excess drug amounts in nonsterile environments. In September, an AmerisourceBergen subsidiary pleaded guilty to one count of misdemeanor misbranding, paid $208 million in fines, and forfeited $52 million.[34] Except for conduct that was admitted as part of the criminal guilty plea, the claims resolved by the settlement were allegations only, and there was no determination of liability.

- **Mylan Inc. and Mylan Specialty L.P. (collectively, Mylan):** In August, DOJ announced that Mylan had agreed to pay $465 million to resolve FCA allegations that it had avoided paying certain rebates to state Medicaid programs by misclassifying EpiPen as a generic drug despite the absence of a therapeutically equivalent drug. Mylan also entered into a five-year CIA with the HHS OIG. The settlement resolves a qui tam action filed by Sanofi in the District of Massachusetts.[35] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **Shire Pharmaceuticals LLC:** In January, DOJ announced that Shire and its subsidiaries had agreed to pay $350 million to resolve FCA allegations that Shire and a subsidiary had provided kickbacks to induce hospitals and physicians to use its skin substitute Dermagraft. The settlement, which resolved six qui tam suits pending in the Middle District of Florida, also resolved allegations that Shire and a subsidiary had unlawfully marketed Dermagraft for non-approved uses, made false statements to raise Dermagraft's price, and caused incorrect coding, verification, or certification of Dermagraft claims. Three high-level executives were previously convicted for their supervisory roles in implementing the kickback program. In a press release, DOJ noted that the settlement represented the largest FCA recovery in a kickback case involving a medical device.[36] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **Celgene Corp.:** In July, Celgene agreed to pay $280 million to resolve FCA allegations that it had promoted two cancer drugs for unapproved uses, made false and misleading statements about the drugs, and paid kickbacks to physicians to induce prescriptions of the drugs. The settlement resolved a qui tam action filed in the Central District of California in which DOJ had declined to intervene.[37] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **United Therapeutics Corporation (UT):** In December, DOJ announced that UT had agreed to pay $210 million to resolve allegations that the company had used a foundation claiming tax-exempt status as a conduit to pay the co-pays of Medicare patients taking UT's pulmonary arterial hypertension drugs. UT allegedly made donations to the foundation, which then used the donations to pay co-pays for certain UT drugs to induce patients to purchase these drugs in violation of the AKS. As part of the settlement, UT entered into a five-year CIA with the HHS OIG.[38] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **eClinicalWorks:** In May, DOJ announced that eClinicalWorks had agreed to pay $155 million to resolve FCA allegations that the company had fraudulently obtained certification of its software by concealing that its software did not meet certification requirements and allegations that the company had paid kickbacks to customers in exchange for promoting its software. Under the settlement, eClinicalWorks, its Chief Executive Officer, Chief Medical Officer, and Chief Operating Officer, were jointly and severally liable for the $155 million payment. The settlement resolved a qui tam action filed in the District of Vermont. The company also entered into a five-year CIA with the HHS OIG.[39] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **Chemed Corporation and Vitas Hospice Services LLC:** In October, DOJ announced that Chemed Corporation and several of its wholly owned subsidiaries, including Vitas, the country's largest for-profit hospice chain, had agreed to pay $75 million to resolve FCA allegations that they had submitted claims to Medicare for hospice services provided to patients who did not qualify for such services and had submitted claims to Medicare for continuous home care services that were not necessary, not rendered, or not delivered in accordance with Medicare requirements. As part of the settlement, Vitas entered into a five-year CIA with HHS OIG. The settlement resolved a suit filed by the United States, as well as three qui tam actions, consolidated in the Western District of Missouri. In its press release, DOJ noted that this settlement was the largest FCA settlement with a provider of hospice services.[40] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **DaVita Rx LLC**: In December, DOJ announced that DaVita Rx LLC, a national pharmacy primarily serving patients with severe kidney disease, had agreed to pay $63.7 million to resolve FCA allegations, based on a self-disclosure and a subsequently filed qui tam suit, that it had billed federal healthcare programs for prescriptions that were never shipped, shipped but later returned, and did not comply with documentation requirements for proof of delivery, refill requests or patient consent. The settlement also resolved allegations that DaVita had accepted manufacturer copayment discount cards in place of obtaining payments from Medicare beneficiaries, had written off unpaid beneficiary debt, and had provided discounts to beneficiaries who paid with credit cards, all allegedly in violation of the AKS. The settlement resolves a qui tam action filed by two former

DaVita employees in the Northern District of Texas.[41] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **TeamHealth Holdings:** In February, DOJ announced that TeamHealth Holdings, as successor in interest to IPC Healthcare Inc., had agreed to pay $60 million to resolve FCA allegations that IPC had systematically encouraged billing federal healthcare programs for more expensive hospitalist services than the services actually rendered. As part of the settlement, TeamHealth entered into a five-year CIA with the HHS OIG. The settlement resolved a qui tam action filed by a former IPC employee in the Northern District of Illinois.[42] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **Novo Nordisk Inc.:** In September, DOJ announced that Novo Nordisk had agreed to pay $58.7 million to resolve allegations under the Food, Drug, and Cosmetic Act (FDCA) and the FCA. The FDCA settlement, which included $12.2 million in disgorgement, resolves allegations that Novo Nordisk failed to comply with the FDA-mandated Risk Evaluation and Mitigation Strategy (REMS) for its diabetes medication Victoza, which required the company to notify physicians about certain risks associated with Victoza. The FCA settlement, $46.5 million, resolved allegations that Novo Nordisk's sales representatives had created false or misleading impressions with physicians that the REMS-required messages about Victoza's risks were unimportant, and had promoted Victoza for an unapproved use. The FCA settlement resolved seven qui tam actions filed in the District for the District of Columbia.[43] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **CareCore National LLC:** In May, DOJ announced that CareCore had agreed to pay $54 million to resolve FCA allegations that CareCore, which insurers use to provide prior authorization reviews, had approved prior authorization requests for Medicare and Medicaid managed-care organizations without proper review. The settlement resolved a qui tam action filed in the Southern District of New York.[44]

- **Genesis Healthcare Inc.:** In June, DOJ announced that Genesis Healthcare had agreed to pay $53.6 million to resolve allegations that the company's subsidiaries had submitted claims to federal healthcare programs for ineligible or medically unnecessary hospice and therapy services and substandard nursing home services. The settlement resolved six qui tam actions brought by former employees of the subsidiaries in the District of Nevada, Northern District of Georgia, Northern District of California and Western District of Missouri.[45] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **Walgreen Co.:** In January, DOJ announced that Walgreen had agreed to pay $50 million to resolve kickback allegations under the FCA that it had registered beneficiaries of government healthcare programs in its Prescription Savings Club program and provided them with discounts to induce such beneficiaries to use Walgreen's pharmacies. The settlement resolved a qui tam action filed in the Southern District of New York.[46]

- **PAMC Ltd. and Pacific Alliance Medical Center Inc. (collectively, Pacific Alliance Medical Center):** In June, DOJ announced that Pacific Alliance Medical Center had agreed to pay $42 million to resolve FCA allegations that the hospital had rented office space from referring physicians at above-market rates and had entered into marketing arrangements that provided undue benefits to referring physicians, in violation of both the AKS and the Stark Law. The settlement resolved a qui tam action filed by a former employee in the Central District of California.[47] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **Aegerion Pharmaceuticals Inc:** In September, DOJ announced that Aegerion Pharmaceuticals had agreed to enter into a consent decree with the FDA, to plead guilty to misdemeanor misbranding, to enter into a deferred prosecution agreement, and to pay $36 million to resolve criminal and civil allegations associated with the promotion of Aegerion's drug Juxtapid. In November, a federal district court judge rejected Aegerion's guilty plea, which had included a fine and forfeiture of $7.2 million, and was related to allegations that the company failed to provide physicians with required information pursuant to FDA-mandated REMS and promoted Juxtapid for an unapproved use. The FCA settlement, totaling $28.8 million, resolved allegations in a qui tam action filed by former Aegerion employees in the District of Massachusetts that Aegerion had promoted Juxtapid for an unapproved use, altered statements of medical necessity and prior authorizations, and violated the AKS through a patient assistance program. However, the court's rejection of the guilty plea triggered a provision in the civil settlement agreement, which as amended in December 2017, allows either Aegerion or the government to void the settlement through January 2018. Aegerion also entered into a deferred prosecution agreement to resolve allegations that it conspired to violate HIPAA by obtaining patient information without authorization, entered into a consent decree with the FDA regarding compliance with Juxtapid's REMS requirements, and entered into a five-year CIA with the HHS OIG.[48] Except as to conduct admitted as part of the guilty plea and deferred prosecution agreement, the claims resolved by the civil settlement are allegations only and there has been no determination of liability.

- **EmCare Inc. and Physician's Alliance Ltd.:** In December, DOJ announced that two physician groups, EmCare Inc. and Physician's Alliance Ltd., had agreed to pay $33.6 million to resolve allegations that they had received illegal payments in exchange for referring patients to hospitals owned by the now-defunct Health Management Associates (HMA). EmCare allegedly received payments from HMA to recommend patients be admitted to HMA hospitals on an inpatient basis, for which Medicare pays more, when patients should have been admitted on an outpatient basis. Under the terms of the settlement, EmCare will pay $29.6 million. Also, as part of the settlement, EmCare's parent company, Envision Healthcare Corporation, entered into a five-year CIA with the HHS OIG. Physician's Alliance allegedly received payments from HMA in exchange for referring patients to two HMA hospitals in Pennsylvania. Under a separate settlement, Physician's Alliance and its executives will pay $4 million plus a percentage of the proceeds from a sale of Physician's Alliance's interest in a joint venture with HMA. The settlements resolved two qui tam actions filed in the

District of Columbia.[49] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **Kmart Corporation:** In December, DOJ announced that Kmart Corporation, a subsidiary of Sears Holdings Corporation, had agreed to pay $32.3 million to resolve allegations that pharmacies in Kmart stores had provided discounts on generic drug prices to customers who paid cash via various club programs, but knowingly failed to disclose these discounted prices when reporting to federal health programs. Instead, Kmart allegedly reported its regular prices, which federal health programs usually use to establish reimbursement rates. The settlement agreement with the federal government is part of a global $59 million settlement, which also resolves state Medicaid and insurance claims against Kmart. The settlement resolved a qui tam action filed in the Southern District of Illinois in which DOJ had declined to intervene.[50] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **Mercy Hospital Springfield and Mercy Clinic Springfield Communities:** In May, DOJ announced that Mercy Hospital Springfield and its affiliate Mercy Clinic Springfield Communities, the operators of a hospital, clinic, and infusion center in Springfield, Missouri, had agreed to pay $34 million to resolve FCA allegations that they had billed Medicare for services referred by physicians whose compensation improperly took into account the value of referrals to a related infusion center, in violation of the Stark Law. The settlement resolved a qui tam action in the Western District of Missouri filed by a physician formerly employed by the hospital.[51] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **Freedom Health Inc.:** In May, DOJ announced that Freedom Health had agreed to pay $31.7 million to resolve FCA allegations that it had submitted or caused others to submit unsubstantiated diagnosis codes to CMS in connection with two Medicare Advantage plans in Florida and that Freedom Health had made material misrepresentations to CMS about its provider network when it had applied for permission to expand into new geographic areas. Freedom Health's former Chief Operating Officer agreed to pay $750,000 to resolve allegations related to his participation in the misrepresentations to CMS. As part of the settlement, Freedom Health entered into a five-year CIA with the HHS OIG. The settlement resolved a qui tam action brought by a former Freedom Health employee in the Middle District of Florida.[52] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **21st Century Oncology Inc.:** In December, DOJ announced that 21st Century Oncology and certain of its subsidiaries and affiliates agreed to pay $26 million to resolve FCA allegations that they submitted or caused the submission of claims for services provided pursuant to referrals from physicians with whom they had improper financial relationships in violation of the Stark Law. The settlement also resolves conduct 21st Century self-disclosed that it submitted or caused the submission of false attestations to CMS regarding employed physicians' use of electronic health records (EHR) software, and to support these attestations, its employees falsified data regarding the company's use of EHR software, falsified

software utilization reports, and placed EHR vendor logos on the reports to make them appear legitimate. In addition to the settlement, 21st Century entered into a five-year CIA with the HHS OIG. The settlement resolves a qui tam action filed by a former 21st Century employee in the Middle District of Florida.[53]

- **Omnicare, Inc.:** In May, CVS Health Corp.'s subsidiary, Omnicare, Inc., agreed to pay $23 million to resolve FCA allegations that Omnicare had received kickbacks from drug manufacturer Organon in exchange for promoting two antidepressants. DOJ had declined to intervene in April 2010. The settlement resolved a qui tam action filed by two former employees of Organon that had been transferred to the District of Massachusetts.[54] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **Baxter Healthcare Corporation:** In January, DOJ announced that Baxter Healthcare Corporation had agreed to pay $18.2 million to resolve FCA and criminal allegations that Baxter had failed to comply with current Good Manufacturing Practices (cGMP) by using moldy air filters in its manufacture of sterile intravenous solution. The FCA portion of the settlement totaled $2.2 million and resolved a qui tam action filed by a Baxter employee in the Western District of North Carolina. The criminal portion totaled $16 million. Baxter also entered into a deferred prosecution agreement with DOJ.[55] Except as to conduct admitted in connection with the deferred prosecution agreement, the claims settled by the civil agreement are allegations only and there has been no determination of civil liability.

- **Narco Freedom, Inc.:** In May, the US Bankruptcy Court for the Southern District of New York approved an agreement under which the trustee of Narco Freedom, a bankrupt substance-abuse treatment center, allowed the United States and the State of New York to submit a combined general unsecured claim of $118.4 million and a combined subordinated claim of $467.7 million to resolve federal and state FCA allegations that the company had provided subsidized housing to patients as an inducement to participate in the company's programs, entered into sham agreements under which certain housing operators required patients to attend the company's programs, and falsified patient records, among other allegations. The company had pled guilty to multiple felony charges in New York State Supreme Court.[56]

Healthcare and Pharmaceuticals Interventions and Judgments

- **UnitedHealth Group Inc. (UHG):** In May, DOJ filed complaints in intervention against UHG in two qui tam actions pending in the Central District of California. Both complaints allege that UHG obtained inflated risk adjustment payments based on inaccurate information about the health status of beneficiaries enrolled in UHG's Medicare Advantage plans. In October, the court granted UHG's motion to dismiss one of the cases without prejudice and DOJ subsequently voluntarily dismissed its claims with prejudice. The other suit is still pending.[57] The complaint contains allegations only, and there has been no determination of liability.

- **Consulate Health Care:** In March, the US District Court for the Middle District of Florida entered a $347 million judgment against Consulate Health Care in a qui tam action in which DOJ had declined to intervene. The judgment followed a 20-day trial in which the jury found Consulate Health Care had violated the FCA by upcoding and falsifying records. On March 15, the court stayed execution of the judgment following Consulate Health Care's contentions that paying the judgment would result in the closure of many of its facilities. The matter remains stayed.[58]

B. Procurement and Grants

Procurement and Grants Settlements

- **Agility Public Warehousing Co. KSC:** In May, DOJ announced that Agility, a Kuwaiti company, had agreed to pay $95 million to resolve civil and criminal allegations that the company had overcharged the DoD to supply food for US troops by charging the government full price despite agreeing to pay its supplier 10% less than the amount billed. The government also alleged that Agility had failed to disclose and pass through discounts it had obtained from US-based suppliers, as required by its contracts. In addition to making the settlement payment, Agility forwent $249 million in administrative claims against the United States under its military food contracts and pleaded guilty to a misdemeanor offense of theft of government funds. In return, the DoD's Defense Logistics Agency (DLA) released a $27.9 million claim against Agility and lifted Agility's seven-year suspension from federal government contracting, which had been put in place after Agility was indicted in November 2009. The agreement between DLA and Agility mandates oversight of Agility by an independent monitor and requires Agility to maintain a robust ethics and compliance program. The allegations arose from a qui tam lawsuit filed by a former vendor to Agility. The relator received $38.85 million as part of the settlement.[59] Except for conduct that was admitted as part of the criminal guilty plea, the claims resolved by the settlement were allegations only, and there was no determination of liability.

- **CA Inc.:** In March, DOJ announced that CA Inc. had agreed to pay $45 million to settle allegations that it had submitted false information about discounts it gave commercial customers for its software licenses and maintenance services when negotiating a software contract with the General Services Administration. The government also alleged that CA had failed to provide the government with additional discounts when commercial discounts improved, as required by its contract. The settlement resolved a lawsuit brought by a qui tam relator formerly employed by CA Software Israel Ltd. The relator received $10.195 million as part of the settlement.[60] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **SolarCity Corporation:** DOJ announced in September that SolarCity had agreed to pay $29.5 million to resolve allegations that the company had overstated the cost bases of its solar energy properties when submitting claims under Section 1603 of the American Recovery and Reinvestment Act of 2009, which caused SolarCity and its affiliated investment funds to receive inflated

grant payments from the US Department of the Treasury. As part of the settlement, SolarCity also agreed to release all pending and future claims against the United States for additional Section 1603 payments.[61] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **ADS Inc.:** DOJ announced in August that ADS and several businesses that it controlled had agreed to pay $16 million to resolve allegations that the company had fraudulently induced the government to award certain small business set-aside contracts by concealing the businesses' relationship with ADS and misrepresenting the size of the businesses and their eligibility as service-disabled veteran-owned businesses or socially- or economically-disadvantaged businesses. The government also alleged that ADS had engaged in bid-rigging schemes that distorted prices charged to the government under certain contracts. The settlement resolved a qui tam lawsuit brought by Ameliorate Partners LLP. The relator received $2.9 million as part of the settlement.[62] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **Sierra Nevada Corporation:** In February, the US Attorney for the Eastern District of California announced that Sierra Nevada had agreed to pay $14.9 million to settle allegations that the company had inflated the overhead rates it received under various defense and space contracts with the government by misclassifying certain contract costs as research and development costs.[63] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **Thomas and John Buckner:** The US Attorney for the Western District of Pennsylvania announced in October that two brothers from Pennsylvania had agreed to pay over $12 million to resolve allegations that they had inflated manufacturing costs under a DoD contract to provide Vehicle Emergency Escape Window Kits for Humvees by using false invoices to make it appear that they had paid more for aluminum parts than they actually had. The brothers also pleaded guilty to fraud and tax evasion charges.[64] Except for conduct that was admitted as part of the guilty pleas, the claims resolved by the settlement were allegations only, and there was no determination of liability.

- **Huntington Ingalls Industries Inc.:** In August, DOJ announced that Huntington Ingalls had agreed to pay $9.2 million to settle allegations that the company had overbilled the US Navy and the Coast Guard for dive operations to support ship hull construction at shipyards in Pascagoula, Mississippi, by charging for work that had not actually occurred. Three individuals pleaded guilty to related criminal charges and were sentenced in 2015 and 2016. The settlement resolved a qui tam lawsuit brought by a former Huntington Ingalls employee. The relator received $1.59 million as part of the settlement.[65] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **Virginia Department of Social Services (VDSS):** In April, DOJ announced that VDSS had agreed to pay $7.15 million to resolve allegations that it had submitted false claims through its administration of the Supplemental Nutrition Assistance

Program (SNAP). VDSS admitted that in 2010 it had retained Julie Osnes Consulting, a quality control consultant, to reduce its SNAP benefits determination error rate by training VDSS employees to "use whatever means necessary" to find benefits decisions to be correct. If those employees could not find a way to make a benefits decision correct, they were instructed to remove the case from the quality control sample. Those methods caused VDSS to receive unwarranted performance bonuses from the US Department of Agriculture (USDA) for 2011, 2012 and 2013. VDSS also admitted that Julie Osnes Consulting had pressured and intimated VDSS employees who resisted using the improper methods.[66]

- **Wisconsin Department of Health Services (WDHS):** DOJ announced in April that WDHS had agreed to pay $6.99 million to settle allegations that it submitted false claims through its administration of SNAP. WDHS admitted that it had retained Julie Osnes Consulting to review the cases identified by its quality control employees. Based on instructions from that consultant, WDHS had implemented several improper and biased quality control practices, including dropping cases involving errors from the review by discouraging beneficiaries from cooperating with information requests, selectively applying requirements and policies to overturn and reduce errors, and subjecting cases with apparent errors to additional scrutiny with the goal of overturning an error or dropping a case. Those practices improperly decreased WDHS's reported error rate and caused it to receive unwarranted performance bonuses for 2009, 2010, and 2011.[67]

- **SRCTec, LLC:** In January, the US Attorney for the Northern District of New York announced that SRCTec had agreed to pay $6.3 million to resolve allegations that the company, after becoming aware of a flaw with the radar systems it provided the US Army, had failed to sufficiently notify the Army about those flaws, or correct them for two years. During that time, SRTec supplied the Army with tens of millions of dollars' worth of the defective radar systems.[68] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **Washington River Protection Solutions LLC (WRPS):** In January, DOJ announced that WRPS had agreed to pay $5.275 million to resolve allegations that the company had submitted false claims to the Department of Energy (DoE) for overtime and premium pay and had also failed to comply with the contract's internal audit requirements. The government alleged that WRPS had failed to correct fraudulent timekeeping practices implemented by the previous contractor when it was awarded a contract in October 2008 to perform environmental cleanup at DoE's Hanford nuclear site in Richland, Washington. The government also alleged that WRPS had billed the government for auditing work that was not performed because it had installed its general counsel, who had no auditing experience and failed to provide meaningful oversight of the audit process, as the head of the contractually required Internal Audit Department.[69] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **Pacific Architects and Engineers, LLC:** In September, the US Attorney for the District of Columbia announced that Pacific Architects had agreed to pay $5 million to settle allegations that the company had failed to follow vetting requirements under its contract with the State Department for personnel hired to provide training and mentoring to counter-narcotics and drug-interdiction police and investigators in Afghanistan. As a result, the government alleged, the company had submitted false invoices for the labor services of the improperly vetted personnel. The relator, a former Pacific Architects manager, received $875,000 million as part of the settlement.[70] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **Energy & Process Corp. (E&P):** In April, DOJ announced that E&P had agreed to pay $4.6 million to resolve allegations that it had failed to perform required quality assurance procedures and had supplied defective steel reinforcing bars (rebar) in connection with a contract to construct a DoE nuclear waste treatment facility. In addition to paying the settlement amount, E&P agreed to pay the replacement costs for the defective rebar. The allegations arose from a qui tam lawsuit filed by a former employee of the prime contractor for E&P.[71] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **Mercer Transportation Company, Inc.:** The US Attorney for the Middle District of Georgia announced in November that Mercer Transportation had agreed to pay $4.4 million to resolve allegations that it had bribed two government employees to secure contracts to ship government freight out of the Marine Corps Logistics Base in Albany, Georgia. The relator, a Mercer Transportation employee, received $814,000 as part of the settlement.[72] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **Zoladz Construction Company Inc. (ZCC), Arsenal Contracting LLC (Arsenal), and Alliance Contracting LLC (Alliance):** DOJ announced in October that ZCC, Arsenal and Alliance, along with the companies' two owners, had agreed to pay more than $3 million to settle allegations that they had caused false statements to be made to the VA regarding Arsenal's eligibility to participate in the service-disabled veteran-owned small business (SDVOSB) contracting program. The owners allegedly recruited a service-disabled veteran to serve as a figurehead for Arsenal, which then purported to be a legitimate SDVOSB when it was actually managed and controlled by the owners. The government further alleged that Arsenal had subcontracted its work to Alliance and ZCC after receiving SDVOSB contracts. The relator, Western New York Foundation for Fair Contracting, Inc., received $450,000 as part of the settlement.[73] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **Triple Canopy, Inc.:** The US Attorney for the Eastern District of Virginia announced in October that Triple Canopy had agreed to pay $2.6 million to resolve allegations that the company had improperly billed the government for security guards stationed at Al Asad Airbase in Iraq who could not pass contractually required firearms proficiency tests and had created false test

scorecards to conceal the guards' inability to pass those tests. The relator, a former Triple Canopy employee, received approximately $500,000 as part of the settlement.[74] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **Alaska Department of Health and Social Services (ADHSS):** In September, DOJ announced that ADHSS had agreed to pay nearly $2.5 million to resolve allegations that in 2009 it had retained Julie Osnes Consulting to provide advice and recommendations designed to lower its SNAP quality control error rate. The government alleged that Julie Osnes' recommendations, as implemented by ADHSS, had injected bias into its quality control process and had resulted in the submission of inaccurate quality control data to USDA, causing ADHSS to receive unwarranted performance bonuses in 2010, 2011, 2012 and 2013.[75] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **Integrated Medical Solutions Inc. (IMS):** In June, DOJ announced that IMS and its former president had agreed to pay $2.475 million to settle allegations that the company paid a Bureau of Prisons (BoP) employee to assist IMS in obtaining BoP contracts to serve as a third-party administrator responsible for developing managed healthcare networks that provide medical care to federal inmates. The government alleged that the BoP employee had provided IMS with confidential, non-public information that gave IMS an unfair competitive advantage in the bidding process and later improperly assisted IMS in its performance of the contracts while continuing to serve as a BoP financial administrator. In October 2014, the BoP employee had pleaded guilty to a felony for failing to disclose the payments he had received from IMS as part of his obligation to report any potential conflicts of interest.[76] Except for conduct that was admitted as part of the guilty plea, the claims resolved by the settlement were allegations only, and there was no determination of liability.

- **Federal Engineers & Constructors (FE&C):** In September, the US Attorney for the Eastern District of Washington announced that FE&C had agreed to pay $2 million to resolve allegations that the company, along with prime contractor Washington Closure Hanford, LLC (WCH), had misrepresented that subcontractor Sage Tec LLC was a small, disadvantaged business in order to satisfy the requirements of WCH's River Corridor Closure Contract at DoE's Hanford nuclear site. WCH's contract required that it award a certain percentage of subcontracts to small and disadvantaged businesses. The government alleged that WCH, FE&C, Sage Tec and Sage Tec's owner had misrepresented that Sage Tec was a qualified disadvantaged small business in order to be eligible for two multimillion-dollar subcontracts. It further alleged that Sage Tec was actually a pass-through front company for FE&C, which had performed substantially all of the work on WHC's improperly awarded subcontracts. The allegations arose from a qui tam lawsuit filed by Savage Logistics LLC, a Hanford-area small business, and its owner. The relator received approximately $470,000 as part of the settlement.[77] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **Charles River Laboratories International Inc.:** DOJ announced in March that Charles River had agreed to pay $1.8 million to resolve allegations that the company had improperly charged for labor and other costs under contracts with the National Institutes of Health (NIH) that were not actually provided. The fraudulent charges related to the development, maintenance and distribution of colonies of animals as well as the provision of laboratory animals to NIH.[78] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **Para-Plus Translations, Inc.:** In February, the US Attorney for the Western District of Pennsylvania announced that Para-Plus Translations and its owners had agreed to pay the United States, Delaware and New Jersey a total of $1.5 million to resolve allegations that the company had submitted invoices to federal and state governmental clients that purposefully overstated the travel time and mileage incurred by the company's interpreters. The Para-Plus employee who filed the qui tam lawsuit received approximately $330,000 as part of the settlement.[79] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **CH2M Hill, Inc.:** The US Attorney for the Eastern District of Pennsylvania announced in February that CH2M Hill had agreed to pay $1.5 million to settle allegations that it had overbilled the government for overhead costs related to project management functions for several Amtrak construction projects.[80] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **Jackson State University:** In February, the US Attorney for the Southern District of Mississippi announced that Jackson State University had agreed to pay $1.17 million to settle allegations that the university had misused National Science Foundation (NSF) grants and had failed to keep adequate records of its grant expenditures. The government also alleged that university employees had fabricated time-and-effort reports provided to NSF auditors. As part of the settlement, Jackson State agreed to implement a compliance program to prevent future misconduct.[81] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **Misr Sons Development S.A.E.:** In June, DOJ announced that Misr Sons (also known as Hassan Allam Sons, or HAS), a construction company with its principal place of business in Egypt, had agreed to pay $1.1 million to resolve allegations that the company had concealed its improper participation in a joint venture that had received US Agency for International Development (USAID) contracts to construct water and wastewater infrastructure projects in Egypt in the 1990s. The government had previously settled with the other joint-venture participants.[82] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **Sistemas Globales S.A.:** In April, the US Attorney for the Northern District of Texas announced that Sistemas Globales had agreed to pay $1 million to resolve allegations that the company and its corporate affiliates, including US affiliate

Globant LLC, had caused its foreign-national employees to obtain B-1 visas to travel to the United States for the stated purpose of "training" or "knowledge transfer," when in fact they were travelling to perform information technology work that was impermissible on B-1 visas. Those misrepresentations allowed Sistemas Globales to avoid paying the higher costs associated with the proper work visas.[83] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **Notations, Inc.:** The US Attorney for the Southern District of New York announced in October that Notations, a garment wholesaler, had agreed to pay $1 million to settle allegations that the company had ignored warning signs that its business partner, which imported garments from China, had engaged in a scheme to underpay customs duties owed on the imported garments later sold to Notations. As part of the settlement, Notations accepted responsibility for failing to act in response to those red flags and agreed to implement measures designed to prevent recurrences. The allegations arose from a qui tam lawsuit filed by the mother of a former employee of the garment importer. The government's claims against the garment importer remain pending.[84]

Procurement and Grants Interventions

- **City of Los Angeles and CRA/LA:** In August, DOJ announced that it had filed a complaint in intervention against the City of Los Angeles and CRA/LA (formerly the Community Redevelopment Agency of the City of Los Angeles), alleging that they had obtained millions of dollars from HUD by falsely certifying compliance with federal accessibility laws, including Section 504 of the Rehabilitation Act, the Americans with Disabilities Act, and the Fair Housing Act. The government alleged, among other violations, that the city and CRA/LA had failed to ensure that new apartment buildings met minimal accessibility requirements by constructing slopes and ramps that are too steep for safe passage, door thresholds that are too tall for wheelchairs to roll over, steps that prohibit access to common areas, and shelves and surfaces that are outside the reach of persons who use wheelchairs. The qui tam suit was originally filed by a resident of Los Angeles who uses a wheelchair and the Fair Housing Council of San Fernando Valley, a nonprofit civil rights advocacy group.[85] The complaint contains allegations only, and there has been no determination of liability.

Procurement and Grants Complaints

- **Shubhada Industries, Metcon Aerospace & Defense, NRI Capital Corporation, and The Innovation Technology & Enterprise Development Center, Inc.**: In September, the US Attorney for the Eastern District of Pennsylvania announced that the government had filed a lawsuit against four companies and two individuals alleging that they had engaged in a scheme to overcharge the military for spare vehicle parts by purchasing parts they had agreed to manufacture and then reselling those parts to the government with a substantial markup.[86] The complaint contains allegations only, and there has been no determination of liability.

C. Financial Institutions

Financial Institutions Settlements

- **Wells Fargo & Co.:** On August 4, Wells Fargo & Co. announced that it had agreed to pay $108 million to resolve allegations that it had violated the FCA by charging impermissible fees to borrowers under a VA loan guarantee program.[87] The settlement arose from a complaint filed by two Georgia mortgage brokers; the government declined to intervene.[88] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **Financial Freedom:** On May 16, DOJ announced that Financial Freedom, a division of CIT Bank, N.A., and affiliates (collectively Financial Freedom) had agreed to pay $89 million to resolve allegations that they had violated FIRREA and the FCA in connection with their servicing of Home Equity Conversion Mortgages (also known as reverse mortgages). The government alleged that Financial Freedom had sought to obtain insurance payments for debenture interest from HUD despite having failed to disclose that it was not eligible for such interest payments because it had failed to meet various deadlines relating to appraisal of properties, submission of claims to HUD, and pursuit of foreclosure proceedings. The investigation was conducted by the Civil Division's Commercial Litigation Branch, the US Attorney's Office for the Middle District of Florida, the HUD Office of General Counsel and the HUD OIG. The investigation arose from a declaration filed by a whistleblower pursuant to FIRREA; the whistleblower received $1.6 million from the settlement. The claims resolved by the settlement were allegations only, and there was no determination of liability.[89]

- **PHH Corp., PHH Mortgage Corp., and PHH Home Loans (collectively, PHH):** On August 8, DOJ announced that PHH had agreed to pay $74 million to resolve allegations that it had violated the FCA as a direct endorsement lender. The settlement arose from a complaint filed by a relator, a former PHH employee, in the Eastern District of New York; the government intervened contemporaneously with the settlement. As part of the settlement, PHH admitted that between 2006 and 2011, it had certified for Federal Housing Administration (FHA) insurance mortgage loans that did not meet HUD underwriting requirements. PHH admitted that it had not adhered to FHA's and HUD's self-reporting requirements. PHH also admitted that it had originated and sold loans to the VA, Freddie Mac and Fannie Mae that did not meet their respective requirements. The investigation was conducted by HUD, the HUD OIG, the VA OIG, the Federal Housing Finance Agency OIG, DOJ's Civil Division and the US Attorney's Offices for the District of Minnesota, District of New Jersey, Southern District of Florida and Eastern District of New York.[90]

- **IBERIABANK Corporation, IBERIABANK, and IBERIABANK Mortgage Company (collectively, IBERIABANK):** On December 8, DOJ announced that IBERIABANK had agreed to pay $11.6 million to resolve allegations that it had violated the FCA as a direct endorsement lender. The settlement arose from a complaint filed by two former IBERIABANK employees in the Eastern District of Arkansas; the government declined to intervene. As part of the settlement,

IBERIABANK admitted that between 2005 and 2014, it had certified for FHA insurance mortgage loans that did not meet HUD underwriting and origination requirements and were therefore ineligible for FHA mortgage insurance. IBERIABANK admitted that it had paid incentives to underwriters and others who performed underwriting activities, in violation of a prohibition on underwriting commissions. IBERIABANK further admitted that it had failed to timely self-report material violations of HUD requirements. The investigation was conducted by DOJ's Civil Division, the US Attorney's Office for the Eastern District of Arkansas and HUD, including the HUD OIG.[91]

- **Prospect Mortgage Company, LLC:** On July 3, DOJ announced that Prospect had agreed to pay $4.2 million to resolve allegations that it had violated the FCA as a direct endorsement lender. As part of the settlement, Prospect admitted that it had endorsed for FHA insurance loans that had not been originated in accordance with HUD requirements, that it had falsely certified that the non-compliant loans had been underwritten in accordance with HUD underwriting requirements, and that it had failed to adhere to HUD quality control guidelines. The investigation was conducted by the US Attorney's Office for the Northern District of California, the US Attorney's Office for the Northern District of Georgia, and HUD, including the HUD OIG.[92]

- **HSBC Bank USA, N.A.:** On April 14, DOJ announced that HSBC had agreed to pay $2.1 million to resolve allegations that it had violated the FCA for misconduct in connection with HSBC's participation in the SBA Express loan program. A relator initially brought a case against HSBC in 2011; the government partially intervened in that suit and filed its complaint-in-intervention contemporaneous with the settlement. As part of the settlement, HSBC admitted that it had identified a number of loans in which borrowers may have submitted false information to HSBC in obtaining the loans, and that it later sought from the SBA the full guaranteed amounts of those loans after they defaulted, without informing the SBA of all facts indicating that the loans were potentially fraudulent. The case was brought by the US Attorney's Office for the Southern District of New York, in cooperation with the SBA.[93]

- **Residential Home Funding Corp.:** On September 28, the US Attorney's Office for the Southern District of New York announced that Residential Home had agreed to pay $1.67 million to resolve a lawsuit filed by the United States, which alleged that Residential Home violated the FCA as a direct endorsement lender. As part of the settlement, Residential Home admitted that between 2006 and 2012, it failed to maintain a compliant quality control program, falsely certified that it had a quality control program that complied with HUD and FHA regulations, endorsed for FHA mortgage insurance loans that did not meet all underwriting requirements contained in HUD handbooks and mortgagee letters, and submitted to HUD and FHA loan-level certifications stating that loans were eligible for FHA mortgage insurance when in fact they were not. The case was brought by the Civil Frauds Unit of the US Attorney's Office for the Southern District of New York.[94]

- **Alexander Olympus Zarris:** On July 20, the US Attorney's Office for the Middle District of Florida announced that Alexander Olympus Zarris had agreed to pay $475,000 to resolve allegations that he had violated the FCA and FIRREA through his involvement in reverse mortgage transactions at a condominium complex. The government claimed that Zarris had recruited elderly buyers to purchase condominium units at inflated values and required those buyers to apply for reverse mortgages in the maximum amount possible. The government alleged that Zarris, or others working with him, had assisted elderly buyers in applying for reverse mortgages, including filling out their loan applications. The government further alleged that the applications submitted on behalf of these elderly buyers had failed to disclose information that was material to the bank's decision to underwrite. The proceeds of the mortgages were then wired to a company owned by Zarris at the reverse mortgage closing. The investigation was conducted by the US Attorney's Office for the Middle District of Florida and the HUD OIG. The claims resolved by the settlement were allegations only, and there was no determination of liability.[95]

Financial Institutions Complaints

- **Flagstar Bank, FSB:** On November 7, a qui tam complaint against Flagstar was unsealed in the Eastern District of Michigan after the government declined to intervene. The relators, real estate appraisers, allege that Flagstar caused submission of false claims to Fannie Mae and Freddie Mac through its origination and sale of residential mortgage loans and to HUD through its direct endorsement lending. In particular, Flagstar allegedly violated appraiser independence requirements by allowing mortgage brokers to select their preferred appraisal management company, failed to properly ensure that its correspondent lenders complied with appraiser independence requirements, and failed to pay appraisers customary and reasonable fees as required by law.[96] The complaint contains allegations only, and there has been no determination of liability.

- **Wells Fargo Bank, N.A.:** On November 15, a qui tam complaint against Wells Fargo was unsealed in the District of Idaho after the government declined to intervene. The relator, an individual with an interest in property subject to a SBA guarantee, alleges that Wells Fargo violated the FCA and FIRREA by falsely stating that it was the recorded beneficiary, the relator, was in default, and it had complied with reporting requirements, thereby causing the SBA to pay pre-liquidation guarantees it otherwise would not have.[97] The complaint contains allegations only, and there has been no determination of liability.

Financial Institutions Judgments

- **Allied Home Mortgage Capital Corporation and Allied Home Mortgage Corporation (collectively, Allied) and Jim Hodge:** On September 19, DOJ announced a judgment totaling $296 million against Allied and a judgment of $25 million against Allied president and CEO Jim Hodge. The judgments followed a five-week trial in November 2016, in which a jury found that Allied and Hodge

had violated the FCA and FIRREA and caused over $92 million in damages to the United States by falsely certifying that thousands of high-risk, low-quality loans were eligible for FHA insurance and then submitting insurance claims to FHA when any of those loans defaulted. The case was handled by the US Attorney's Office for the Southern District of New York.[98]

IV. STATE AND LOCAL DEVELOPMENTS

State Legislative Activity

- In 2005, Congress enacted the Deficit Reduction Act (DRA), which encourages states to fight Medicaid fraud by allowing a state to keep 10% of what would otherwise be the federal share of Medicaid funds recovered, if the state has enacted a false claims statute that is "at least as effective" as the federal FCA.[99] Following amendments in 2009 and 2010 that strengthened the federal FCA, many states were given until March or August of 2013 to update their false claims laws to bring them back into alignment with the federal statute. Several states have since amended their false claims statutes, and the HHS OIG has issued determinations on whether the state laws are DRA-compliant.

- In late 2016 and 2017, the OIG certified or re-certified the following states as DRA-compliant: Colorado, Connecticut, Illinois, Indiana, Iowa, Massachusetts, Montana, Nevada, Oklahoma, Tennessee, Texas and Vermont.[100]

- In late 2016 and 2017, the OIG determined that the following states are not DRA-compliant: California, Delaware, Florida, Georgia, Hawaii, Michigan, Minnesota, New Hampshire, New York, North Carolina, Rhode Island, Virginia, Washington and Wisconsin. The most frequent deficiency cited was that the state statute did not reflect the increased penalties mandated under the Federal Civil Penalties Inflation Adjustment Improvements Act of 2015, which increased the civil penalties authorized under the federal False Claims Act.[101] The OIG granted most of these states a grace period to amend their statutes by the end of 2018 (and thus the states continue to receive incentive funding until then).[102]

- On April 5, 2017, **Arkansas** Governor Asa Hutchinson signed into law a bill conforming the civil penalty provisions of the Medicaid Fraud False Claims Act with the federal False Claims Act.[103]

- On April 24, 2017, **Oklahoma** Governor Mary Fallin signed a law modifying the Oklahoma Medicaid False Claims Act to make its penalty provisions consistent with the federal act's and modifying the public-disclosure bar's definition of "proceeding" to include only those in which the state or its agent was a party.[104]

- On May 25, 2017, **Maryland** Governor Larry Hogan signed into law a bill amending the Maryland False Claims Act to alter the definition of "governmental entity" to include municipal corporations.[105]

- On July 24, 2017, **California** Governor Jerry Brown signed into law an amendment aligning the California False Claims Act's civil penalties provisions with those in the federal act.[106]

- On August 25, 2017, **Illinois** Governor Bruce Rauner signed into law an amendment to the Illinois False Claims Act which provides for civil penalties not less than the minimum or greater than the maximum amounts allowed in the federal act.[107]

- Bills that would align the current state false claims act with the federal act remain pending in **North Carolina**, **Michigan** and **Kansas**.[108]

- In **Illinois**, a bill is pending that would provide the Department of Revenue and the Attorney General, but not private parties, with authority to bring an administrative action or judicial action, respectively, for false claims relating to certain taxes.[109]

- In **Florida**, a bill remains pending that would continue to exempt from public record requirements (under the Open Government Sunset Review Act) the complaint and information held by the Department of Legal Affairs pursuant to an investigation of a violation of the Florida False Claims Act.[110]

- Bills that would establish a state false claims statute (or add an additional false claims act) remain pending in **Pennsylvania** and **Michigan**;[111] similar bills failed or were postponed in **Alabama** and **Arkansas**.[112]

Noteworthy State Settlements or Judgments

As in prior years, the most significant state false claims settlements in 2017 concerned alleged Medicaid fraud, typically involving allegations of inflated pricing, kickback schemes or deceptive marketing. States have also continued to join forces with the federal government, either individually or in multi-state efforts.

Some of the more significant state false claims settlements in 2017, in chronological order, included:

- **Several states settled with Shire Pharmaceuticals LLC for $350 million.** In January, Shire Pharmaceuticals LLC and other subsidiaries of Shire PLC agreed to pay $350 million to the federal government, 37 states and the District of Columbia to settle allegations that Shire and a company it acquired in 2011, Advanced BioHealing, had employed kickbacks and other unlawful methods to improperly promote Dermagraft, a bioengineered human skin substitute approved by the FDA for the treatment of diabetic foot ulcers.[113] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **New York settled with Harbert Management Corporation and top executives at the firm for $40 million.** In April, Harbert Management Corporation, the fund sponsor for a $26-billion hedge fund based in New York City, as well as top executives at the firm, agreed to pay New York $40 million to settle whistleblower allegations that members of the investment manager had failed to pay millions of dollars in state tax for several years.[114] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **Indiana settled with Indiana University Health Inc. and HealthNet Inc. for $7.78 million.** In April, Indiana University Health Inc. and HealthNet Inc. agreed to pay Indiana $7.78 million and the federal government $10.22 million to settle allegations that they had improperly billed for services involving high-risk pregnancies that were provided by certified nurse midwives rather than

physicians.[115] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **Several states settled with CareCore National LLC for $54 million.** In May, CareCore National LLC agreed to pay $54 million to the federal government and 21 states to settle allegations that CareCore had instituted a scheme to auto-approve hundreds of radiology service requests on a daily basis, deeming those diagnostic services reasonable and medically necessary, even though there had been no evaluation by the appropriate medical personnel.[116] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **New York settled with Visiting Nurse Service of New York for $2.63 million.** In July, Visiting Nurse Service of New York and its Managed Long-Term Care Plan, VNS Choice, agreed to pay New York $2.63 million and the federal government $1.77 million to settle allegations that VNS Choice had improperly obtained public funds and knowingly retained over $1.6 million in Medicaid overpayments.[117] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **Several states settled with U.S. Bioservices Corporation for $13.4 million.** In September, U.S. Bioservices Corporation agreed to pay $13.4 million to the federal government and more than 30 states to settle allegations that it had knowingly recommended the drug Exjade to Medicaid patients in exchange for kickbacks.[118] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **All fifty states and the District of Columbia settled with Mylan Inc. and Mylan Specialty L.P. for $465 million.** In October, Mylan Inc. and its wholly-owned subsidiary, Mylan Specialty L.P., agreed to pay $465 million to the federal government, all fifty states, and the District of Columbia to settle allegations that they had underpaid rebates owed to the Medicaid program for EpiPens dispensed to Medicaid beneficiaries.[119] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **New York settled with Yankee Clipper Food Services I Corporation for $13 million.** In October, Yankee Clipper Food Services I Corporation agreed to pay New York $13 million to settle allegations that it had intentionally underpaid state taxes by more than $5 million and had underpaid by approximately $350,000 fees owed to the Port Authority of New York and New Jersey for operating at Kennedy Airport.[120] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **Massachusetts settled with Centrus Premier Home Care Inc. d/b/a Maxim Healthcare Services, Inc. for $14.26 million.** In December, Centrus Premier Home Care Inc. d/b/a Maxim Healthcare Services, Inc., a nationwide provider of home health and other healthcare services, agreed to pay Massachusetts $14,264,803 to settle allegations that it had improperly received overpayments for services from the state's Medicaid program, known as MassHealth.[121] The

claims resolved by the settlement were allegations only, and there was no determination of liability.

Noteworthy State Supreme Court Decision

- ***Matter of Enforcement of New Jersey False Claims Act Subpoenas*, 162 A.3d 262 (N.J. 2017):** The New Jersey Supreme Court held that the New Jersey False Claims Act does not authorize the New Jersey Attorney General to invoke his or her administrative subpoena power after declining to intervene in a qui tam action.

ABOUT WILMERHALE'S FALSE CLAIMS ACT PRACTICE

With a team of veteran litigators and former lawyers from across the federal government, WilmerHale brings unparalleled experience to defending against allegations of fraud, and in particular FCA matters. We regularly represent clients in sectors of the economy facing the greatest FCA activity, including pharmaceutical and healthcare, defense, government procurement, financial services, energy and information technology. Our team includes lawyers who, when in government service, were directly responsible for the management, litigation and settlement of major FCA investigations and cases. We thus approach each matter with a deep understanding of the government's objectives, and we have obtained favorable resolutions of numerous matters without a formal action being filed. We have been able to obtain early dismissal or resolution of suits brought by qui tam relators and the government by focusing on precedent-setting legal defenses, including innovative uses of the public-disclosure and first-to-file bars. By conducting credible internal investigations and negotiating with DOJ, we have also helped clients avoid criminal prosecution and accomplish appropriate civil resolutions of parallel criminal, civil and administrative proceedings. If a case goes to trial, we have experienced courtroom advocates prepared to take the case to a jury.

Our FCA Group includes:

- A former Deputy Attorney General of the United States in the Obama Administration, who supervised all of DOJ's litigating and law enforcement components (including DOJ's Civil Frauds Unit and the US Attorneys' Offices) and co-led (with the Deputy Secretary of HHS) the Administration's "HEAT" initiative against health care fraud. He also served in earlier administration as Assistant Attorney General for the Civil Division, where he directly supervised FCA enforcement for the United States; and as Deputy General Counsel for DoD, where he supervised all litigation at DoD, including FCA and government-contracts litigation.

- A former Deputy Attorney General of the United States in the Clinton Administration, who in that capacity had ultimate oversight over DOJ's Civil Frauds Unit and considered major interventions and settlements. She also had served as General Counsel of DoD, responsible for overseeing all litigation, including FCA litigation.

- A former General Counsel of DoD in the Obama Administration, responsible for overseeing all litigation, including FCA and other procurement-related legal work.

- Four former US Attorneys for the District of Colorado, the District of Columbia, and the Central District of California.

- A former Deputy US Attorney for the Southern District of New York, who participated in the creation of the S.D.N.Y.'s Civil Frauds Unit in March 2010 and oversaw that unit's civil fraud actions in the financial services and healthcare sectors, including actions under the FCA.

- A former Deputy Assistant Attorney General and Principal Deputy Associate Attorney General of DOJ, who in those capacities worked closely with the Civil Frauds Unit on several high-profile matters, and who in the latter capacity considered major interventions and settlements proposed by that unit.

- A former Chief of Staff and Assistant Secretary for the United States Department of the Interior, who, in response to the Deepwater Horizon incident, acted as lead negotiator of the Natural Resource Damage Assessment team.

- Numerous lawyers with jury trial experience, as well as litigators who specialize in handling government contracts litigation, including bid protests, disputes concerning performance or payment, and suspension and debarment proceedings.

For more information on False Claims Act matters, please contact:

Washington DC

Christopher E. Babbitt	+1 202 663 6681	christopher.babbitt@wilmerhale.com
Jonathan G. Cedarbaum	+1 202 663 6315	jonathan.cedarbaum@wilmerhale.com
Jamie Gorelick	+1 202 663 6500	jamie.gorelick@wilmerhale.com
Ronald C. Machen	+1 202 663 6881	ronald.machen@wilmerhale.com
Alejandro N. Mayorkas	+1 202 663 6221	alejandro.mayorkas@wilmerhale.com
Carl J. Nichols	+1 202 663 6226	carl.nichols@wilmerhale.com
David W. Ogden	+1 202 663 6440	david.ogden@wilmerhale.com
Jonathan E. Paikin	+1 202 663 6703	jonathan.paikin@wilmerhale.com
Stephen W. Preston	+1 202 663 6900	stephen.preston@wilmerhale.com
Charles C. Speth	+1 202 663 6133	charles.speth@wilmerhale.com

New York

Debo P. Adegbile	+1 212 295 6717	debo.adegbile@wilmerhale.com
Boyd M. Johnson III	+1 212 230 8862	boyd.johnson@wilmerhale.com

Boston

Stephen A. Jonas	+1 617 526 6144	stephen.jonas@wilmerhale.com
Emily R. Schulman	+1 617 526 6077	emily.schulman@wilmerhale.com

Los Angeles

David C. Marcus	+1 213 443 5312	david.marcus@wilmerhale.com

Denver

Thomas L. Strickland	+1 720 274 3148	thomas.strickland@wilmerhale.com
John F. Walsh	+1 720 274 3154	john.walsh@wilmerhale.com

The overall editors of this report were Jonathan Cedarbaum and Christopher Babbitt. The contributors were Debo Adegbile, Stephen Jonas, Carl Nichols, Jonathan Paikin, Emily Schulman, Charles Speth, Rama Attreya, Matthew Benedetto, David Beraka, Claire Chung, Tania Faransso, Kevin Gallagher, Kevin Holt, Webb Lyons, Lauren Moore, Michael Morillo, Cadene Russell, Saurabh Sanghvi, Joshua Sharp, Stephanie Simon, Anuradha Sivaram, Jordan Smith, Ariel Warner, Jason Wilson, Daniel Winik, and Derek Woodman.

---

[1] The figures in this paragraph come from the following Justice Department documents: Civil Division, US Dep't of Justice, Fraud Statistics--Overview (Dec. 19, 2017), https://www.justice.gov/opa/press-release/file/1020126/download; Civil Division, US Dep't of Justice, Fraud Statistics—Health and Human Services (Dec. 19, 2017), https://www.justice.gov/opa/press-release/file/1020116/download; Civil Division, US Dep't of Justice, Fraud Statistics—Department of Defense (Dec. 19, 2017), https://www.justice.gov/opa/press-release/file/1020111/download; Civil Division, US Dep't of Justice, Fraud Statistics—Other (Non-HHS, Non-DOD) (Dec. 19, 2017), https://www.justice.gov/opa/press-release/file/1020121/download (Dec. 21, 2017); and Press Release, Off. of Public Affairs, US Dep't of Justice, *Justice Department Recovers Over $3.7 Billion from False Claims Act Cases in Fiscal Year 2017* (Dec. 21, 2017), https://www.justice.gov/opa/pr/justice-department-recovers-over-37-billion-false-claims-act-cases-fiscal-year-2017.

[2] Press Release, Off. of Public Affairs, US Dep't of Justice, *Justice Department Recovers Over $3.7 Billion from False Claims Act Cases in Fiscal Year 2017* (Dec. 21, 2017), https://www.justice.gov/opa/pr/justice-department-recovers-over-37-billion-false-claims-act-cases-fiscal-year-2017.

[3] *See, e.g., Fresenius Medical Care Holdings, Inc. v. U.S.*, 763 F.3d 64 (1st Cir. 2014).

[4] Tax Act, Pub. L. 115-97, § 13306(a), ___Stat. ____ (2017), https://legiscan.com/US/text/HB1/2017.

[5] Dep't of Justice, Civil Monetary Penalties Inflation Adjustment for 2017, 82 Fed. Reg. 9131, 9133 (Feb. 3, 2017), https://www.gpo.gov/fdsys/pkg/FR-2017-02-03/pdf/2017-01306.pdf.

[6] C. Ryan Barber, *Judge Excoriates US Justice Dept. for a 'House of Cards' False Claims Case*, Nat'l L. J. (Nov. 3, 2017), https://www.law.com/nationallawjournal/sites/nationallawjournal/2017/11/03/judge-excoriates-u-s-justice-dept-for-a-house-of-cards-false-claims-case/?slreturn=20180005164831.

[7] David Glaser, *Developing Story: DOJ Will Dismiss Qui Tam Cases Lacking Merit*, RACmonitor (Nov. 2, 2017), https://www.racmonitor.com/developing-story-doj-will-dismiss-qui-tam-cases-lacking-merit.

[8] Daniel Wilson, *DOJ Denies Claims of Change to FCA Dismissal Policy*, Law360 (Nov. 17, 2017), https://www.law360.com/articles/986650/doj-denies-claims-of-change-to-fca-dismissal-policy.

[9] Matthew Beddingfield & Colleen Murphy, *IRS Whistleblower Office Faces Test with Trump Administration*, Bloomberg BNA, Daily Tax Report (Apr. 3, 2017), https://www.bna.com/irs-whistleblower-office-n57982086147/; Pub. L. No. 115-40, 131 Stat. 861 (2017), https://www.congress.gov/115/plaws/publ40/PLAW-115publ40.pdf.

[10] *See* Department of Veterans Affairs Accountability and Whistleblower Protection Act of 2017, Pub. L. No. 115-41, 131 Stat. 862, https://www.gpo.gov/fdsys/pkg/PLAW-115publ41/pdf/PLAW-115publ41.pdf. Geoff Bennett, *Congress Passes Bill to Increase Accountability Among VA Employees*, NPR (June 13, 2017), https://www.npr.org/2017/06/13/531810565/congress-passes-bill-to-increase-accountability-among-va-employees.

[11] *See* Dr. Chris Kirkpatrick Whistleblower Protection Act of 2017, Pub. L. No. 115-73, 131 Stat. 1235, https://www.gpo.gov/fdsys/pkg/PLAW-115publ73/pdf/PLAW-115publ73.pdf.

[12] *See* Press Release, H. Comm. on Oversight & Government Reform, *Cummings Applauds the Passage of Bill to Strengthen Protections for Federal Employees* (Feb. 2, 2017), https://democrats-oversight.house.gov/news/press-releases/cummings-applauds-passage-of-bill-to-strengthen-protections-for-federal.

[13] H.R. 2196, 115th Cong. (2017), https://www.congress.gov/bill/115th-congress/house-bill/2196?q=%7B%22search%22%3A%5B%22whistleblowers%22%5D%7D&r=5.

[14] H.R. 4043, 115th Cong. (2017), https://www.congress.gov/bill/115th-congress/house-bill/4043/text?q=%7B%22search%22%3A%5B%22whistleblowers%22%5D%7D&r=6; Press Release, Off. of Rep. Rod Blum, *Rep. Rod Blum and Ranking Member Elijah Cummings Introduce Bipartisan Bill to Increase Support for Whistleblowers* (Oct. 16, 2017), https://blum.house.gov/news/documentsingle.aspx?DocumentID=583.

[15] H.R. 4195, 115th Cong. (2017), https://www.congress.gov/bill/115th-congress/house-bill/4195/titles?q=%7B%22search%22%3A%5B%22whistleblowers%22%5D%7D&r=2.

[16] S. 633, 115th Cong. (2017), https://www.congress.gov/bill/115th-congress/senate-bill/633?q=%7B%22search%22%3A%5B%22whistleblowers%22%5D%7D&r=12s.

[17] *See* Press Release, Off. of Sen. Chuck Grassley, *Grassley, Wyden Introduce IRS Whistleblower Improvements Act of 2017* (Mar. 29, 2017), https://www.grassley.senate.gov/news/news-releases/grassley-wyden-introduce-irs-whistleblower-improvements-act-2017; S. 762, 115th Cong. (2017); https://www.congress.gov/bill/115th-congress/senate-bill/762?q=%7B%22search%22%3A%5B%22whistleblowers%22%5D%7D&r=11.

[18] Press Release, Off. of Sen. Chuck Grassley, *Senators Introduce Bill to Make Protections Work Better for Whistleblowers* (Sept. 27, 2017), https://www.grassley.senate.gov/news/news-releases/senators-introduce-bill-make-protections-work-better-whistleblowers; S. 1869, 115th Cong. (2017), https://www.congress.gov/bill/115th-congress/senate-bill/1869/text.

[19] S. 2002, 115th Cong. (2017), https://www.congress.gov/bill/115th-congress/senate-bill/2002/text?q=%7B%22search%22%3A%5B%22whistleblowers%22%5D%7D&r=4.

[20] S. 807, 115th Cong. (2017), https://www.congress.gov/bill/115th-congress/senate-bill/807/actions?r=1. *See* Press Release, Off. of Sen. Chuck Grassley, *Grassley, Leahy Reintroduce Legislation to Protect Whistleblowers in Criminal Antitrust Cases* (Apr. 4, 2017), https://www.grassley.senate.gov/news/news-releases/grassley-leahy-reintroduce-legislation-protect-whistleblowers-criminal-antitrust.

[21] Dep't of Justice, Civil Monetary Penalties Inflation Adjustment for 2017, 82 Fed. Reg. 9131, 9133 (Feb. 3, 2017), https://www.gpo.gov/fdsys/pkg/FR-2017-02-03/pdf/2017-01306.pdf.

[22] Jeff Sessions, Att'y Gen., Remarks at Ethics and Compliance Initiative Annual Conference, Washington, DC (Apr. 24, 2017), https://www.justice.gov/opa/speech/attorney-general-jeff-sessions-delivers-remarks-ethics-and-compliance-initiative-annual.

[23] Rod Rosenstein, Deputy Att'y Gen., NYU Program on Corporate Compliance & Enforcement Keynote Address, New York, NY (Oct. 6, 2017), https://wp.nyu.edu/compliance_enforcement/2017/10/06/nyu-program-on-corporate-compliance-enforcement-keynote-address-october-6-2017/; *see* Sally Quillian Yates, Deputy Att'y Gen., *Memorandum: Individual Accountability for Corporate Wrongdoing* (Sept. 9, 2015), http://www.justice.gov/dag/file/769036/download.

[24] David Glaser, *Developing Story: DOJ Will Dismiss Qui Tam Cases Lacking Merit*, RACmonitor (Nov. 2, 2017), https://www.racmonitor.com/developing-story-doj-will-dismiss-qui-tam-cases-lacking-merit.

[25] Daniel Wilson, *DOJ Denies Claims of Change to FCA Dismissal Policy*, Law360 (Nov. 17, 2017), https://www.law360.com/articles/986650/doj-denies-claims-of-change-to-fca-dismissal-policy.

[26] Henry Cutter & Samuel Rubenfeld, *U.S. Lawyers Propose Changes to Justice Dept. Monitor Program*, The Wall St. J. (Nov. 13, 2017), https://blogs.wsj.com/riskandcompliance/2017/11/13/u-s-lawyers-propose-changes-to-justice-dept-monitor-program/.

[27] Rod Rosenstein, Deputy Att'y Gen., Remarks at the Clearing House's 2017 Annual Conference, New York, NY (Nov. 8, 2017), https://www.justice.gov/opa/speech/deputy-attorney-general-rosenstein-delivers-remarks-clearing-house-s-2017-annual.

[28] Health Care Programs: Fraud and Abuse; Revisions to the Office of Inspector General's Exclusion Authorities, 82 Fed. Reg. 4100, 4115 (Jan. 12, 2017), https://www.gpo.gov/fdsys/pkg/FR-2017-01-12/pdf/2016-31390.pdf.

[29] Solicitation of New Safe Harbors and Special Fraud Alerts, 82 Fed. Reg. 61229 (Dec. 27, 2017).

[30] Improving Accountability and Whistleblower Protection at the Department of Veterans Affairs, Exec. Order No. 13793, 82 Fed. Reg. 20539 (May 2, 2017), https://www.gpo.gov/fdsys/pkg/FR-2017-05-02/pdf/2017-08990.pdf.

[31] Andrew Ramonas, *SEC Official Sees Drop in Anti-Whistleblower Severance Deals*, Bloomberg (Oct. 16, 2017), https://www.bna.com/sec-official-sees-n73014470947/.

[32] Whistleblower Awards Process, 82 Fed. Reg. 24,487 (May 30, 2017), https://www.gpo.gov/fdsys/pkg/FR-2017-05-30/pdf/2017-10801.pdf.

[33] The court found that the CIAs did not constitute a public disclosure to the extent the relators alleged fraud that took place after the execution of the agreements. 874 F.3d at 918-20.

[34] Eric Topor, *AmerisourceBergen Ups Fraud Set-Aside Fund to $625M*, Bloomberg BNA (Dec. 6, 2017), http://healthlawrc.bna.com/hlrc/4231/split_display.adp?fedfid=124570386&vname=hfranotallissues&wsn=500046896&searchid=30907229&doctypeid=10&type=oadate4news&mode=doc&split=0&scm=4231&pg=0; Press Release, US Atty's Off., E.D.N.Y., *Amerisourcebergen Specialty Group Pleads Guilty to Distributing Misbranded Drugs and is Sentenced to Pay $260 Million to Resolve Criminal Liability* (Sept. 27, 2017), https://www.justice.gov/usao-edny/pr/amerisourcebergen-specialty-group-pleads-guilty-distributing-misbranded-drugs-and.

[35] Press Release, US Atty's Off., D. Mass., *Mylan Agrees to Pay $465 Million to Resolve False Claims Act Liability* (Aug. 17, 2017), https://www.justice.gov/usao-ma/pr/mylan-agrees-pay-465-million-resolve-false-claims-act-liability.

[36] Press Release, Off. of Pub. Affairs, US Dep't of Justice, *Shire PLC Subsidiaries to Pay $350 Million to Settle False Claims Act Allegations* (Jan. 11, 2017), https://www.justice.gov/opa/pr/shire-plc-subsidiaries-pay-350-million-settle-false-claims-act-allegations.

[37] Press Release, US Atty's Off., C.D. Cal., *Celgene Agrees to Pay $280 Million to Resolve Fraud Allegations Related to Promotion of Cancer Drugs for Uses Not Approved by FDA* (July 24, 2017), https://www.justice.gov/usao-cdca/pr/celgene-agrees-pay-280-million-resolve-fraud-allegations-related-promotion-cancer-drugs; Order by Judge George H. King, *United States v. Celgene Corp.*, No. 2:10-cv-03165, Dkt. 59 (Oct. 1, 2013).

[38] Press Release, Off. of Pub. Affairs, US Dep't of Justice, *Drug Maker United Therapeutics Agrees to Pay $210 Million to Resolve False Claims Act Liability for Paying Kickbacks* (Dec. 20, 2017), https://www.justice.gov/opa/pr/drug-maker-united-therapeutics-agrees-pay-210-million-resolve-false-claims-act-liability; United Therapeutics Corp., Current Report (Form 8-K) (Dec. 20, 2017), http://www.secinfo.com/d11MXs.k28Jm.htm#1stPage.

[39] Press Release, Off. of Pub. Affairs, US Dep't of Justice, *Electronic Health Records Vendor to Pay $155 Million to Settle False Claims Act Allegations* (May 31, 2017), https://www.justice.gov/opa/pr/electronic-health-records-vendor-pay-155-million-settle-false-claims-act-allegations.

[40] Press Release, Off. of Pub. Affairs, US Dep't of Justice, *Chemed Corp. and Vitas Hospice Services Agree to Pay $75 Million to Resolve False Claims Act Allegations Relating to Billing for Ineligible Patients and Inflated Levels of Care* (Oct. 30, 2017), https://www.justice.gov/opa/pr/chemed-corp-and-vitas-hospice-services-agree-pay-75-million-resolve-false-claims-act.

[41] Press Release, US Atty's Off., N.D. Tex., *Davita Rx Agrees to Pay $63.7 Million to Resolve False Claims Act Allegations* (Dec. 14, 2017), https://www.justice.gov/usao-ndtx/pr/davita-rx-agrees-pay-637-million-resolve-false-claims-act-allegations.

[42] Press Release, Off. of Pub. Affairs, US Dep't of Justice, *Healthcare Service Provider to Pay $60 Million to Settle Medicare and Medicaid False Claims Act Allegations* (Feb. 6, 2017), https://www.justice.gov/opa/pr/healthcare-service-provider-pay-60-million-settle-medicare-and-medicaid-false-claims-act.

[43] Press Release, Off. of Pub. Affairs, US Dep't of Justice, *Novo Nordisk Agrees to Pay $58 Million for Failure to Comply with FDA-Mandated Risk Program* (Sept. 5, 2017), https://www.justice.gov/opa/pr/novo-nordisk-agrees-pay-58-million-failure-comply-fda-mandated-risk-program.

[44] Press Release, US Atty's Off., S.D.N.Y., *Acting U.S. Attorney Announces $54 Million Settlement of Civil Fraud Lawsuit Against Benefits Management Company for Improper Authorization of Medical Procedures* (May 11, 2017), https://www.justice.gov/usao-sdny/pr/acting-us-attorney-announces-54-million-settlement-civil-fraud-lawsuit-against-benefits.

[45] Press Release, Off. of Pub. Affairs, US Dep't of Justice, *Genesis Healthcare Inc. Agrees to Pay Federal Government $53.6 Million to Resolve False Claims Act Allegations Relating to the Provision of Medically Unnecessary Rehabilitation Therapy and Hospice Services* (June 16, 2017), https://www.justice.gov/opa/pr/genesis-healthcare-inc-agrees-pay-federal-government-536-million-resolve-false-claims-act.

[46] Press Release, US Atty's Off., S.D.N.Y., *Manhattan U.S. Attorney Announces $50 Million Settlement with Walgreens for Paying Kickbacks to Induce Beneficiaries of Government Healthcare Programs to Fill Their Prescriptions at Walgreens' Pharmacies* (Jan. 19, 2017), https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-50-million-settlement-walgreens-paying-kickbacks-induce.

[47] Press Release, Off. of Pub. Affairs, US Dep't of Justice, *Los Angeles Hospital Agrees to Pay $42 Million to Settle Alleged False Claims Act Violations Arising from Improper Payments to Physicians* (June 28, 2017), https://www.justice.gov/opa/pr/los-angeles-hospital-agrees-pay-42-million-settle-alleged-false-claims-act-violations-arising.

[48] Press Release, Off. of Pub. Affairs, US Dep't of Justice, *Drug Maker Aegerion Agrees to Plead Guilty; Will Pay More Than $35 Million to Resolve Criminal Charges and Civil False Claims Allegations* (Sept. 22, 2017), https://www.justice.gov/opa/pr/drug-maker-aegerion-agrees-plead-guilty-will-pay-more-35-million-resolve-criminal-charges-and; Press Release, US Food & Drug Admin., *Criminal and civil actions filed against Aegerion Pharmaceuticals Inc.* (Sept. 22, 2017), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm577101.htm; Memorandum & Order, *United States v. Aegerion Pharmaceuticals, Inc.*, No. 1:17-cr-10288, Dkt. 23 (D. Mass. Nov. 20, 2017); Status Report Regarding Settlement by United States of America, *United States v. Aegerion Pharmaceuticals, Inc.*, No. 1:13-cv-11785, Dkt. 74 (D. Mass. Dec. 11, 2017).

[49] Press Release, Off. of Pub. Affairs, US Dep't of Justice, *Two Physician Groups Pay Over $33 Million to Resolve Claims Involving HMA Hospitals* (Dec. 19, 2017), https://www.justice.gov/opa/pr/two-physician-groups-pay-over-33-million-resolve-claims-involving-hma-hospitals; Envision Healthcare Corp., Current Report (Form 8-K) (Dec. 19, 2017), http://www.secinfo.com/d1J76c.k65.htm.

[50] Press Release, Off. of Pub. Affairs, US Dep't of Justice, *Kmart Corporation to Pay U.S. $32.3 Million to Resolve False Claims Act Allegations for Overbilling Federal Health Programs for Generic Prescription Drugs* (Dec. 22, 2017), https://www.justice.gov/opa/pr/kmart-corporation-pay-us-323-million-resolve-false-claims-act-allegations-overbilling-federal.

[51] Press Release, Off. of Pub. Affairs, US Dep't of Justice, *Missouri Hospitals Agree to Pay United States $34 Million to Settle Alleged False Claims Act Violations Arising from Improper Payments to Oncologists* (May 18, 2017), https://www.justice.gov/opa/pr/missouri-hospitals-agree-pay-united-states-34-million-settle-alleged-false-claims-act.

[52] Press Release, Off. of Pub. Affairs, US Dep't of Justice, *Medicare Advantage Organization and Former Chief Operating Officer to Pay $32.5 Million to Settle False Claims Act Allegations* (May 30, 2017), https://www.justice.gov/opa/pr/medicare-advantage-organization-and-former-chief-operating-officer-pay-325-million-settle.

[53] Press Release, Off. of Pub. Affairs, US Dep't of Justice, *21st Century Oncology to Pay $26 Million to Settle False Claims Act Allegations* (Dec. 12, 2017), https://www.justice.gov/opa/pr/21st-century-oncology-pay-26-million-settle-false-claims-act-allegations.

[54] Rachel Graf, *Omnicare Pays $23M to End Kickback, Medicaid Fraud Suit*, Law360 (May 26, 2017), https://www.law360.com/articles/928510/omnicare-pays-23m-to-end-kickback-medicaid-fraud-suit; Nate Raymond, *CVS's Omnicare to Pay $23 Million to Resolve U.S. Kickback Case*, Reuters (May 26, 2017), http://www.reuters.com/article/cvs-health-lawsuit/cvss-omnicare-to-pay-23-million-to-resolve-u-s-kickback-

case-idUSL1N1IS1P0; Notice by United States of America of Election to Decline to Intervene in Part, *United States v. Organon USA Inc.*, No. 1:07-cv-12153, Dkt. 36 (D. Mass. April 23, 2010).

[55] Press Release, Off. of Pub. Affairs, US Dep't of Justice, *Baxter Healthcare Corporation to Pay More Than $18 Million to Resolve Criminal and Civil Liability Relating to Sterile Products* (Jan. 12, 2017), https://www.justice.gov/opa/pr/baxter-healthcare-corporation-pay-more-18-million-resolve-criminal-and-civil-liability.

[56] Press Release, N.Y. Off. of Att'y Gen., *A.G. Schneiderman Announces Criminal Guilty Plea and Multi-Million Dollar Civil Settlement with Narco Freedom* (May 31, 2017), https://ag.ny.gov/press-release/ag-schneiderman-announces-criminal-guilty-plea-and-multi-million-dollar-civil; Dani Kass, *Rehab Cops to $27M Medicaid Fraud, Will Pay NY Millions*, Law360 (June 2, 2017), https://www.law360.com/articles/930062/rehab-cops-to-27m-medicaid-fraud-will-pay-ny-millions; Motion to Approve Compromise, *In re Narco Freedom, Inc.*, No. 1:16-bk-10123, Dkt. 193 (Bankr. S.D.N.Y. Apr. 19, 2017); Order (A) Approving Settlement Between the Trustee and Government Claimants and (B) Authorizing the Trustee to Enter a Criminal Plea on Behalf of Debtor as part of the Settlement, *In re Narco Freedom, Inc.*, No. 1:16-bk-10123, Dkt. 197 (Bankr. S.D.N.Y. May 15, 2017).

[57] Press Release, Off. of Pub. Affairs, US Dep't of Justice, *United States Intervenes in False Claims Act Lawsuit Against UnitedHealth Group Inc. for Mischarging the Medicare Advantage and Prescription Drug Programs* (May 2, 2017), https://www.justice.gov/opa/pr/united-states-intervenes-false-claims-act-lawsuit-against-unitedhealth-group-inc-mischarging; Press Release, Off. of Pub. Affairs, US Dep't of Justice, *United States Intervenes in Second False Claims Act Lawsuit Alleging that UnitedHealth Group Inc. Mischarged the Medicare Advantage and Prescription Drug Programs* (May 16, 2017), https://www.justice.gov/opa/pr/united-states-intervenes-second-false-claims-act-lawsuit-alleging-unitedhealth-group-inc; Jeff Overley, *DOJ Drops Medicare Advantage Suit Against UnitedHealth*, Law360 (Oct. 13, 2017), https://www.law360.com/articles/974340/doj-drops-medicare-advantage-suit-against-unitedhealth.

[58] Carolina Bolado, *Judge Triples Nursing Home Cos.' Fraud Penalty to $347M*, Law360 (Mar. 1, 2017), https://www.law360.com/articles/897292/judge-triples-nursing-home-cos-fraud-penalty-to-347m; Eric Topor, *Consulate Health Care Clobbered with $347M Fraud Judgment*, Bloomberg BNA (Mar. 3, 2017), http://dailyreport.bna.com/drpt/7010/split_display.adp?fedfid=106526107&vname=dernotallissues&wsn=546554000&searchid=30979586&doctypeid=1&type=date&mode=doc&split=0&scm=7010&pg=0; Jeff Overley, *$350M FCA Judgments threaten 'Extinction,' Nursing Cos. Say*, Law360 (Mar. 13, 2017), https://www.law360.com/articles/901312/-350m-fca-judgments-threaten-extinction-nursing-cos-say; Carolina Bolado, *Judge Stays $350M FCA Judgments Against Nursing Cos.*, Law360 (Mar. 15, 2017), https://www.law360.com/articles/902483/judge-stays-350m-fca-judgments-against-nursing-cos-; John Kennedy, *Nursing Cos. Want New Trial After $350M FCA Jury Verdict*, Law360 (Mar. 30, 2017), https://www.law360.com/articles/908002/nursing-cos-want-new-trial-after-350m-fca-jury-verdict; Order granting application for stay of execution, *Ruckh v. CMC II, LLC*, No. 8:11-cv-01303, Dkt. 451 (M.D. Fla. Mar. 15, 2017); Notice of nonintervention by USA, *Ruckh v. CMC II, LLC*, No. 8:11-cv-01303, Dkt. 10 (M.D. Fla. Apr. 10, 2012); Motion for judgment as a matter of law, *Ruckh v. CMC II, LLC*, No. 8:11-cv-01303, Dkt. 452 (M.D. Fla. Mar. 29, 2017); Notice re motion for judgment as a matter of law, *Ruckh v. CMC II, LLC*, No. 8:11-cv-01303, Dkt. 462 (M.D. Fla. Nov. 16, 2017).

[59] Press Release, Off. of Pub. Affairs, US Dep't of Justice, *Defense Contractor Resolves Criminal, Civil and Administrative Liability Related to Food Contracts* (May 26, 2017), https://www.justice.gov/opa/pr/defense-contractor-resolves-criminal-civil-and-administrative-liability-related-food.

[60] Press Release, Off. of Pub. Affairs, US Dep't of Justice, *CA Inc. to Pay $45 Million for Alleged False Claims on Government-Wide Information Technology Contract* (Mar. 10, 2017), https://www.justice.gov/opa/pr/ca-inc-pay-45-million-alleged-false-claims-government-wide-information-technology-contract.

[61] Press Release, Off. of Pub. Affairs, US Dep't of Justice, *SolarCity Agrees to Resolve Alleged False Claims Act Violations Arising from Renewable Energy Grant Claims to Treasury* (Sept. 22, 2017), https://www.justice.gov/opa/pr/solarcity-agrees-resolve-alleged-false-claims-act-violations-arising-renewable-energy-grant.

[62] Press Release, Off. of Pub. Affairs, US Dep't of Justice, *Defense Contractor ADS Inc. Agrees to Pay $16 Million to Settle False Claims Act Allegations Concerning Fraudulently Obtained Small Business Contracts* (Aug. 10, 2017), https://www.justice.gov/opa/pr/defense-contractor-ads-inc-agrees-pay-16-million-settle-false-claims-act-allegations.

[63] Press Release, US Atty's Off., E.D. Cal., *Sierra Nevada Corporation Pays $14.9M to Settle Allegations of Improper Contract Billings* (Feb. 15, 2017), https://www.justice.gov/usao-edca/pr/sierra-nevada-corporation-pays-149m-settle-allegations-improper-contract-billings.

[64] Press Release, US Atty's Off., W.D. Pa., *Brothers Sentenced to Prison for Defrauding U.S. Department of Defense* (Oct. 10, 2017), https://www.justice.gov/usao-wdpa/pr/brothers-sentenced-prison-defrauding-us-department-defense.

[65] Press Release, Off. of Pub. Affairs, US Dep't of Justice, *Defense Contractor Agrees to Pay $9.2 Million to Settle False Billing Allegations* (Aug. 15, 2017), https://www.justice.gov/opa/pr/defense-contractor-agrees-pay-92-million-settle-false-billing-allegations.

[66] Press Release, Off. of Pub. Affairs, US Dep't of Justice, *Virginia Department of Social Services Agrees to Pay $7.1 Million to Resolve Alleged False Claims for SNAP Funds* (Apr. 10, 2017), https://www.justice.gov/opa/pr/virginia-department-social-services-agrees-pay-71-million-resolve-alleged-false-claims-snap.

[67] Press Release, Off. of Pub. Affairs, US Dep't of Justice, *Wisconsin Department of Health Services Agrees to Pay Nearly $7 Million to Resolve Alleged False Claims for SNAP Funds* (Apr. 12, 2017), https://www.justice.gov/opa/pr/wisconsin-department-health-services-agrees-pay-nearly-7-million-resolve-alleged-false-claims.

[68] Press Release, US Atty's Off., N.D.N.Y., *SRCTec, LLC to Pay Over $6.3 Million to Resolve False Claims Act Allegations* (Jan. 12, 2017), https://www.justice.gov/usao-ndny/pr/srctec-llc-pay-over-63-million-resolve-false-claims-act-allegations.

[69] Press Release, Off. of Pub. Affairs, US Dep't of Justice, *Washington River Protection Solutions Agrees to Pay $5.275 Million to Settle False Overtime and Premium Pay Allegations* (Jan. 23, 2017), https://www.justice.gov/opa/pr/washington-river-protection-solutions-agrees-pay-5275-million-settle-false-overtime-and.

[70] Press Release, US Atty's Off., D.D.C., *Pacific Architects and Engineers, LLC to Pay $5 Million in False Claims Act Settlement* (Sept. 13, 2017), https://www.justice.gov/usao-dc/pr/pacific-architects-and-engineers-llc-pay-5-million-false-claims-act-settlement.

[71] Press Release, Off. of Pub. Affairs, US Dep't of Justice, *Energy & Process Corp. Agrees to Pay $4.6 Million for Alleged False Claims Regarding Defective Steel Rebar and Quality Control Failures in Nuclear Waste Treatment Facility* (Apr. 24, 2017), https://www.justice.gov/opa/pr/energy-process-corp-agrees-pay-46-million-alleged-false-claims-regarding-defective-steel.

[72] Press Release, US Atty's Off., M.D. Ga., *Mercer Transportation Company Agrees to Pay $4.4 Million to Resolve Alleged Violations of the False Claims Act* (Nov. 8, 2017), https://www.justice.gov/usao-mdga/pr/mercer-transportation-company-agrees-pay-44-million-resolve-alleged-violations-false.

[73] Press Release, Off. of Pub. Affairs, US Dep't of Justice, *Western New York Contractors and Two Owners to Pay More Than $3 Million to Settle False Claims Act Allegations* (Oct. 3, 2017), https://www.justice.gov/opa/pr/western-new-york-contractors-and-two-owners-pay-more-3-million-settle-false-claims-act.

[74] Press Release, US Atty's Off., E.D. Va., *Government Contractor Pays $2.6M to Settle False Claims Act Suit* (Oct. 16, 2017), https://www.justice.gov/usao-edva/pr/government-contractor-pays-26m-settle-false-claims-act-suit.

[75] Press Release, Off. of Pub. Affairs, US Dep't of Justice, *Alaska Department of Health and Social Services to Pay Nearly $2.5 Million to Resolve Alleged False Claims for SNAP Funds* (Sept. 18, 2017), https://www.justice.gov/opa/pr/alaska-department-health-and-social-services-pay-nearly-25-million-resolve-alleged-false.

[76] Press Release, Off. of Pub. Affairs, US Dep't of Justice, *North Texas Contractor and Executive Agree to Pay United States $2.475 Million to Resolve False Claims Act and Anti-Kickback Act Allegations* (June 5, 2017), https://www.justice.gov/opa/pr/north-texas-contractor-and-executive-agree-pay-united-states-2475-million-resolve-false-1.

[77] Press Release, US Atty's Off., E.D. Wash., *Hanford DoE Subcontractor Agrees to Pay $2.0 Million to Settle Allegations of Small Business Fraud* (Sept. 22, 2017), https://www.justice.gov/usao-edwa/pr/hanford-doe-subcontractor-agrees-pay-20-million-settle-allegations-small-business-fraud.

[78] Press Release, Off. of Pub. Affairs, US Dep't of Justice, *Charles River Laboratories International Inc. Agrees to Pay United States $1.8 Million to Settle False Claims Act Allegations* (Mar. 13, 2017), https://www.justice.gov/opa/pr/charles-river-laboratories-international-inc-agrees-pay-united-states-18-million-settle-false.

[79] Press Release, US Atty's Off., W.D. Pa., *New Jersey Translations Company to Pay U.S. $1.5 Million to Settle False Claims Act Allegations* (Feb. 6, 2017), https://www.justice.gov/usao-wdpa/pr/new-jersey-translations-company-pay-us-15-million-settle-false-claims-act-allegations.

[80] Press Release, US Atty's Off., E.D. Pa., *E.D. Pa. U.S. Attorney Reaches Settlement for False Claims Act Violations on Project Management Oversight Contract* (Feb. 28, 2017), https://www.justice.gov/usao-edpa/pr/ed-pa-us-attorney-reaches-settlement-false-claims-act-violations-project-management.

[81] Press Release, US Atty's Off., S.D. Miss., *Jackson State University Agrees to Pay $1.17 Million to Settle False Claims Act Allegations* (Feb. 1, 2017), https://www.justice.gov/usao-sdms/pr/jackson-state-university-agrees-pay-117-million-settle-false-claims-act-allegations.

[82] Press Release, Off. of Pub. Affairs, US Dep't of Justice, *Misr Sons Development S.A.E. Agrees to Pay $1.1 Million to Resolve False Claims Act Allegations* (June 13, 2017), https://www.justice.gov/opa/pr/misr-sons-development-sae-agrees-pay-11-million-resolve-false-claims-act-allegations.

[83] Press Release, US Atty's Off., N.D. Tex., *Information Technology Firm Pays $1 Million to Settle Allegations of Visa Fraud* (Mar. 23 2017), https://www.justice.gov/usao-ndtx/pr/information-technology-firm-pays-1-million-settle-allegations-visa-fraud.

[84] Press Release, US Atty's Off., S.D.N.Y., *Acting Manhattan U.S. Attorney Announces Settlement of Civil Fraud Claims Against Garment Wholesaler in Scheme to Avoid Paying Customs Duties* (Oct. 3, 2017), https://www.justice.gov/usao-sdny/pr/acting-manhattan-us-attorney-announces-settlement-civil-fraud-claims-against-garment.

[85] Press Release, Off. of Pub. Affairs, US Dep't of Justice, *U.S. Files New Complaint Against City of L.A. and a Former Redevelopment Agency to Recover Millions of Federal Grant Dollars Allegedly Obtained by Making False Promises to Provide Housing to Persons with Disabilities* (Aug. 1, 2017), https://www.justice.gov/opa/pr/us-files-new-complaint-against-city-la-and-former-redevelopment-agency-recover-millions.

[86] Press Release, US Atty's Off., E.D. Pa., *Lawsuit Filed Against Defense Contractors Over Alleged False Claim* (Sept. 28, 2017), https://www.justice.gov/usao-edpa/pr/lawsuit-filed-against-defense-contractors-over-alleged-false-claim.

[87] Wells Fargo & Co., Form 10-Q for the period ended June 30, 2017 at 126 (Aug. 4, 2017), https://www08.wellsfargomedia.com/assets/pdf/about/investor-relations/sec-filings/2017/second-quarter-10q.pdf.

[88] *United States ex rel. Bibby v. Wells Fargo Bank, N.A.*, No. 1:06-cv-00547-AT (N.D. Ga.).

[89] Press Release, Off. of Pub. Affairs, US Dep't of Justice, *Financial Freedom Settles Alleged Liability for Servicing of Federally Insured Reverse Mortgage Loans for $89 Million* (May 16, 2017), https://www.justice.gov/opa/pr/financial-freedom-settles-alleged-liability-servicing-federally-insured-reverse-mortgage.

[90] Press Release, Off. of Pub. Affairs, US Dep't of Justice, *PHH Agrees to Pay Over $74 Million to Resolve Alleged False Claims Act Liability Arising from Mortgage Lending* (Aug. 8, 2017), https://www.justice.gov/opa/pr/phh-agrees-pay-over-74-million-resolve-alleged-false-claims-act-liability-arising-mortgage.

[91] Press Release, Off. of Pub. Affairs, US Dep't of Justice, *IBERIABANK Agrees to Pay Over $11.6 Million to Resolve Alleged False Claims Act Liability for Submitting False Claims for Loan Guarantees* (Dec. 8, 2017), https://www.justice.gov/opa/pr/iberiabank-agrees-pay-over-116-million-resolve-alleged-false-claims-act-liability-submitting.

[92] Press Release, US Atty's Off., N.D. Cal., *Prospect Mortgage, LLC Agrees to Pay $4.157 Million to Resolve False Claims Act Allegations Arising from the FHA Mortgage Lending Practices of Two of its Branches* (July 3, 2017), https://www.justice.gov/usao-ndca/pr/prospect-mortgage-llc-agrees-pay-4157-million-resolve-false-claims-act-allegations.

[93] Press Release, US Atty's Off., S.D.N.Y., *Acting Manhattan U.S. Attorney Settles Civil Lawsuit Against HSBC Bank USA, N.A., Regarding Failure to Disclose Fraud or Potential Fraud in Guaranteed Loans* (Apr. 14, 2017), https://www.justice.gov/usao-sdny/pr/acting-manhattan-us-attorney-settles-civil-lawsuit-against-hsbc-bank-usa-na-regarding.

[94] Press Release, US Atty's Off., S.D.N.Y., *Acting Manhattan U.S. Attorney Settles Civil Mortgage Fraud Lawsuit Against Residential Home Funding Corp.* (Sept. 28, 2017), https://www.justice.gov/usao-sdny/pr/acting-manhattan-us-attorney-settles-civil-mortgage-fraud-lawsuit-against-residential; *United States v. Residential Home Funding Corp.*, No. 1:17-cv-07192-JSR (S.D.N.Y.).

[95] Press Release, US Atty's Off., M.D. Fla., *Middle District of Florida's Civil Division Advances Reverse Mortgage Fraud Enforcement Initiative by Resolving Civil Fraud Claims Against Tarpon Springs Condominium Complex Owner* (July 20, 2017), https://www.justice.gov/usao-mdfl/pr/middle-district-florida-s-civil-division-advances-reverse-mortgage-fraud-enforcement.

[96] *United States ex rel. Liley v. Flagstar Bank*, No. 5:17-cv-10675-JEL-MKM (E.D. Mich.).

[97] *United States ex rel. Houpt v. Wells Fargo Bank N.A*, No. 4:17-cv-00377-DCN (D. Idaho).

[98] Press Release, US Atty's Off., S.D.N.Y., *Acting Manhattan U.S. Attorney Announces Award of $296 Million Judgment Against Allied Home Mortgage Entities for Civil Mortgage Fraud* (Sept. 19, 2017), https://www.justice.gov/usao-sdny/pr/acting-manhattan-us-attorney-announces-award-296-million-judgment-against-allied-home.

[99] *See* 42 US C. § 1396h (if state false claims law meets certain requirements, federal share of Medicaid-fraud amounts recovered by state action shall be decreased by 10 percent).

[100] *See* Off. of the Inspector Gen., US Dep't of Health & Human Servs., *State False Claims Act Reviews*, http://www.oig.hhs.gov/fraud/state-false-claims-act-reviews/index.asp.

[101] 42 US C. § 1396h.

[102] *See* Off. of the Inspector Gen., US Dep't of Health & Human Servs., *State False Claims Act Reviews*, http://www.oig.hhs.gov/fraud/state-false-claims-act-reviews/index.asp.

[103] *See* Ark. Act 978 *(*S.B. 564) (2017),http://www.arkleg.state.ar.us/assembly/2017/2017R/Acts/Act978.pdf.

[104] *See* S.B. 645, 56th Leg., Reg. Sess. (Okla. 2017), https://www.legiscan.com/OK/bill/SB645/2017.

[105] *See* 2017 Md. Laws Ch. 632 (S.B. 26), http://mgaleg.maryland.gov/webmga/frmMain.aspx?id=SB0026&stab=01&pid=billpage&tab=subject3&ys=2017RS.

[106] *See* Ch. 121 *(*S.B. 387) (Cal. 2017), http://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201720180SB387.

[107] *See* Pub. Act 100-0452 (S.B. 1577) (Ill. 2017), http://www.ilga.gov/legislation/BillStatus.asp?DocNum=1577&GAID=14&DocTypeID=SB&LegId=104225&SessionID=91&GA=100.

[108] *See* S.B. 378, Gen. Assemb., 2017 Sess. (N.C. 2017), https://www.ncga.state.nc.us/sessions/2017/bills/senate/pdf/s378v0.pdf; S.B. 669, 99th Leg., Reg. Sess. (Mich. 2017), http://www.legislature.mi.gov/(S(lshd1sob5u5fiyjwjo1rbpjg))/mileg.aspx?page=BillStatus&objectname=20

17-SB-0669; H.B. 2337, 87th Leg., 2017 Reg. Sess. (Kan. 2017), http://www.kslegislature.org/li/b2017_18/measures/hb2337/.

[109] *See* H.B. 1814, 100th Gen. Assemb., 2017 Sess. (Ill. 2017), http://www.ilga.gov/legislation/100/HB/PDF/10000HB1814lv.pdf; S.B. 1250, 100th Gen. Assemb., 2017 Sess. (Ill. 2017), http://www.ilga.gov/legislation/BillStatus.asp?DocNum=1250&GAID=14&DocTypeID=SB&LegID=103502&SessionID=91&GA=100&SpecSess=0.

[110] H.B. 7013, 2018 Reg. Sess. (Fla. 2017), https://www.flsenate.gov/Session/Bill/2018/07013/ByVersion; S.B. 7006, 2018 Reg. Sess. (Fla. 2017), https://www.flsenate.gov/Session/Bill/2018/07006.

[111] *See* H.B. 1027, 201st Gen. Assemb., Reg. Sess. (Pa. 2017), http://www.legis.state.pa.us/cfdocs/legis/PN/Public/btCheck.cfm?txtType=PDF&sessYr=2017&sessInd=0&billBody=H&billTyp=B&billNbr=1027&pn=1186; S.B. 65, 99th Leg., Reg. Sess. (Mich. 2017), http://www.legislature.mi.gov/(S(iqd45tjtobodxzf0fops4nkq))/mileg.aspx?page=getObject&objectName=2017-SB-0065.

[112] *See* S.B. 367, 2017 Reg. Sess. (Ala. 2017), http://alisondb.legislature.state.al.us/alison/searchableinstruments/2017RS/bills/SB367.htm; S.B. 548, 91st Gen. Assemb., 2017 Reg. Sess. (Ark. 2017), http://www.arkleg.state.ar.us/assembly/2017/2017R/Bills/SB548.pdf.

[113] Press Release, N.Y. Off. of Att'y Gen., *A.G. Schneiderman Announces $350 Million Federal and Multi-State Agreement with Shire Plc Subsidiaries to Resolve Investigation into Unlawful Kickbacks* (Jan. 11, 2017), https://ag.ny.gov/press-release/ag-schneiderman-announces-350-million-federal-and-multi-state-agreement-shire-plc.

[114] Press Release, N.Y. Off. of Att'y Gen., *A.G. Schneiderman Announces $40 Million Settlement with Investment Management Company for Tax Abuses, Marking Largest Tax Whistleblower Recovery in Office's History* (Apr. 18, 2017), https://ag.ny.gov/press-release/ag-schneiderman-announces-40-million-settlement-investment-management-company-tax.

[115] Press Release, Ind. Off. of Att'y Gen., *AG Hill Announces $18 Million Settlement in Medicaid Fraud Case Against Indiana University Health and HealthNet* (Apr. 27, 2017), http://www.in.gov/activecalendar/EventList.aspx?fromdate=6/8/2017&todate=6/8/2017&display=Day&type=public&eventidn=264423&view=EventDetails&information_id=268144&print=print.

[116] Press Release, N.Y. Off. of Att'y Gen., *A.G. Schneiderman Announces Joint $54 Million Settlement with CareCore Resolving Allegations Company Submitted Millions in False Claims to Medicaid* (May 11, 2017), https://ag.ny.gov/press-release/ag-schneiderman-announces-joint-54-million-settlement-carecore-resolving-allegations.

[117] Press Release, N.Y. Off. of Att'y Gen., *A.G. Schneiderman Announces Joint State and Federal $4.4 Million Settlement with Visiting Nurse Service Managed Long-Term Care Plan* (July 17, 2017), https://ag.ny.gov/press-release/ag-schneiderman-announces-joint-state-and-federal-44-million-settlement-visiting-nurse.

[118] Press Release, Ark. Off. of Att'y Gen., *Attorneys General Reach $13.4 Million Settlement with U.S. Bioservices Pharmacy* (Sept. 7, 2017), https://arkansasag.gov/media-center/news-releases/attorneys-general-reach-13.4-million-settlement-with-u.s-bioservices-pharmacy/.

[119] Press Release, Haw. Off. of Att'y Gen., *Hawaii Receives More Than $700,000 in Mylan Settlement* (Oct. 4, 2017), https://governor.hawaii.gov/newsroom/latest-news/atg-news-release-hawaii-receives-more-than-700000-in-mylan-settlement/.

[120] Press Release, N.Y. Off. of Att'y Gen., *A.G. Schneiderman Announces Felony Conviction and $13 Million Settlement in Tax Fraud Investigation of JFK Airport Food Companies* (Oct. 19, 2017), https://ag.ny.gov/press-release/ag-schneiderman-announces-felony-conviction-and-13-million-settlement-tax-fraud.

[121] Press Release, Mass. Off. of Att'y Gen., *AG Secures More Than $14 Million from Home Health Agency* (Dec. 5, 2017), https://www.mass.gov/news/ag-secures-more-than-14-million-from-home-health-agency.