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False Claims Act: 2016 Year-in-Review

TABLE OF CONTENTS

Introduction: Highlights and Trends	1
Federal Legislative and Regulatory Developments	3
Congress	3
Department of Justice	5
Department of Health and Human Services	5
Department of Defense	6
Department of Labor	6
Federal Case Law Developments	7
Supreme Court Decided Cases: (1) Implied Certification and Materiality; (2) Seal Requirement	7
Supreme Court Pending Case: Public Disclosure Bar	10
D.C. Circuit: Public Disclosure Bar	11
First Circuit: (1) Arm-of-the-State Test; (2) First to File Rule; (3) Rule 9(b); (4) Implied Certification Liability & Materiality; (5) Public Disclosure Bar	12
Second Circuit: Express and Implied False Certification	17
Third Circuit: (1) Public Disclosure Bar; (2) Reverse False Claims	19
Fourth Circuit: (1) Public Disclosure Bar – Amended Pleadings; (2) Successor Corporation Liability; (3) Public Disclosure Bar – Claims Based on Knowledge from Attorneys Barred	20
Fifth Circuit: (1) Retaliation Claims by Agents and Contractors; (2) Retaliation Claims Against Individual Defendants; (3) Reverse False Claims	23
Sixth Circuit: (1) Damages Calculations; (2) Rule 9(b); (3) Presentment; (4) Scierter	25
Seventh Circuit: (1) Original Source Exception; (2) Public Disclosure Bar; (3) Private-Entity Intermediaries; (4) Rule 9(b) – Claims Based on Lack of Medical Necessity; (5) Retaliation; (6) Implied Certification	27

Eighth Circuit: (1) Rule 9(b) and Reverse False Claims; (2) Materiality; (3) Scienter and Ambiguous Legal Requirements	31
Ninth Circuit: (1) Liability Arising from Retrospective Review Initiated by Defendant; (2) Substantial Similarity Under the Public Disclosure Bar; (3) Certifications to Fannie Mae and Freddie Mac	32
Tenth Circuit: Materiality.....	34
Eleventh Circuit: Knowledge Requirement to Qualify as Original Source	35
Federal Settlements, Interventions, and Complaints	36
Healthcare and Pharmaceuticals.....	36
Procurement and Grants.....	38
Financial Institutions	42
State and Local Developments.....	46
About WilmerHale’s False Claims Act Practice	49

INTRODUCTION: HIGHLIGHTS AND TRENDS

In 2016, the Department of Justice (DOJ) continued to give high priority to False Claims Act (FCA) investigations and prosecutions. The government brought in more than \$4.76 billion in settlements and judgments, nearly a billion dollars more than the previous year. Healthcare cases, including ones involving drug and device companies, again accounted for the lion's share at roughly \$2.6 billion. Department of Defense cases dropped to approximately \$122 million, with non-healthcare and non-Defense cases jumping to \$2.04 billion. That increase reflected both a continued focus on financial institutions and the mortgage lending industry, with approximately \$1.6 billion in recoveries there, and an increase in non-Defense procurement recoveries. In 2016, more than 700 new qui tam cases were filed, up over 2015's 630.¹

The Supreme Court Weighs In: Implied Certification, Materiality and the Seal Provision

In *Universal Health Services v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016), the Supreme Court unanimously upheld the "implied certification" theory of liability in some circumstances, holding that liability can attach if 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." *Id.* at 1995, 2001. The Court limited liability, however, to circumstances in which the defendant knows that its non-compliance "is material to the Government's payment decision." *Id.* at 1996. The Court emphasized that materiality is a "rigorous" and "demanding" standard, one that cannot be met if "noncompliance is minor or insubstantial." *Id.* at 1994, 1996. The *Escobar* decision is already having significant effects on FCA litigation in many courts.

In *State Farm Fire and Casualty Company v. United States ex rel. Rigsby*, 137 S. Ct. 436 (2016), the Supreme Court held that a relator's violation of the FCA's seal requirement, 31 U.S.C. § 3730(b)(2), does not mandate dismissal of the action. Instead, the Court held, it is within the district court's discretion to determine whether a violation of the seal requirement warrants dismissal.

The Courts of Appeals

In 2016, the federal appellate courts continued to deal with the perennial issues of FCA litigation—the public disclosure bar and the original source exception, the level of particularity required for fraud allegations under Federal Rule of Civil Procedure 9(b), the appropriate measure of damages in circumstances where there are disputes over the value of the product or services rendered, and, of course, the FCA's materiality standard in light of *Escobar*.

The circuit courts also addressed some less-frequently litigated issues this past year—including the question of successor liability for FCA violations, and the level of certainty required to trigger liability for "reverse" false claims (i.e., cases in which the defendant is alleged to have failed to pay on an obligation owed to the government).

Thus, in *United States ex rel. Bunk v. Government Logistics N.V.*, 842 F.3d 261 (4th Cir. 2016), the government intervened in a qui tam suit that sought to impose successor liability on a corporation created after its predecessor had been found criminally liable in a bid-rigging scheme; the Fourth Circuit held that courts should apply traditional common law principles of successor liability, given the FCA's silence on the issue.

With respect to "reverse" false claims, the Fifth Circuit held that there is no FCA liability for contingent penalties that the government has not yet imposed. See *United States ex rel. Simoneaux v. E.I. duPont de Nemours & Co.*, 843 F.3d 1033 (5th Cir. 2016). The Fifth Circuit reasoned that the statutory reference to an "established" duty precluded liability for contingent obligations that the government had not yet asserted.

Increased Penalties Arrive

The statutory minimum and maximum penalties for FCA violations nearly doubled in 2016. In November 2015, Congress passed the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, which requires agencies to adjust each civil monetary penalty provided by law for inflation. Agencies were required to make an initial “catch up” adjustment by July 1, 2016, and are required to make annual adjustments for inflation by January 15 of every year thereafter.²

On June 30, 2016, DOJ published an interim final rule setting the minimum penalty for an FCA violation at \$10,781 and the maximum penalty at \$21,563 (up from previous levels of \$5,500 and \$11,000).³ The increased penalty amounts apply to penalties assessed after August 1, 2016 for violations that occurred after November 2, 2015.⁴ DOJ has not yet published its 2017 annual adjustment to FCA penalties, but is expected to do so shortly. If DOJ’s adjustments are made in accordance with guidance from the Office of Management and Budget, FCA penalties will rise to a minimum of \$10,957 and maximum of \$21,916 per violation.⁵ The 2017 increased amounts will likely apply to any penalties assessed after the date of publication of the increase for violations occurring after November 2, 2015.⁶

More Individual Defendants

The “Yates Memo,” issued by Deputy Attorney General Sally Quillian Yates in September 2015, established a number of policies designed to hold more individuals accountable for corporate wrongdoing. In FCA cases, the Yates Memo has meant that federal prosecutors are required to consider whether individual executives should be named as defendants and to justify in writing decisions not to name individuals. The result has been a gradual upswing in individuals named as defendants in FCA cases, mostly, though not exclusively, in healthcare cases. Indeed, in its annual roundup of FCA activities for 2016, DOJ pointed to more than half a dozen individual defendants who had paid settlements ranging from \$250,000 to \$9.35 million.⁷

More Organizational Relators?

Historically, FCA relators have been individuals, most often employees or former employees of the companies they name as defendants. But in the last few years, we have begun to see a growing number of organizational relators. Some are companies going after competitors. Some are advocacy organizations targeting companies for alleged practices they believe are harmful. But more and more we are also seeing organizations formed essentially for the purpose of bringing qui tam suits.

What to Expect from the Trump Administration

Whether the arrival of the Trump Administration will bring marked changes in the government’s approach to FCA investigations and litigations remains to be seen. But early comments by the President himself and Senator Jeff Sessions (R-AL), the nominee for Attorney General, suggest that FCA enforcement is likely to remain vigorous, particularly vis-à-vis contractors. At his confirmation hearing, Senator Sessions emphasized that “this government must improve its ability to protect the United States Treasury from waste, fraud, and abuse.” He described qui tam litigation as “an effective method of rooting out fraud and abuse” and “a very healthy thing.”⁸ The likely nominee for Deputy Attorney General is a longtime US Attorney who has served under both Republican and Democratic Presidents. Senator Sessions has criticized DOJ for extending seal periods to excessive lengths, so a Sessions DOJ may see decisions on intervention made more promptly.⁹

FEDERAL LEGISLATIVE AND REGULATORY DEVELOPMENTS

➤ Congress

- On May 11, 2016, President Obama signed into law S. 1890, the Defend Trade Secrets Act of 2016, which included significant protections for whistleblowers. The Act provides immunity from civil and criminal liability for an individual who discloses a trade secret either to a government official or attorney in confidence to report a violation of law, or in a legal complaint filed under seal. The Act requires employers to notify employees of these protections.¹⁰
- On December 14, 2016, President Obama signed into law S. 795, which permanently extends protections from retaliation for employees of federal contractors, subcontractors, grantees, and sub-grantees who report a host of problems relating to federal contracts and funds. Many of these protections were first established in the Fiscal Year 2013 National Defense Authorization Act. The current Act makes these protections permanent, and it also provides these same protections to personal services contractors, who were not previously covered. The Act also prohibits contractors from being reimbursed for legal fees expended in defending against retaliation claims by whistleblowers if the contractor is deemed liable.¹¹
- On December 16, 2016, President Obama signed into law H.R. 6450, the Inspector General Empowerment Act of 2016. A version of the Act was first introduced in 2015 in response to a Department of Justice Office of Legal Counsel opinion which concluded that Inspector General's Act's provision giving inspectors general access to agency records did not supersede limitations on disclosure in the Federal Wiretap Act, Rule 6(e) of the Federal Rules of Criminal Procedure, and Section 626 of the Fair Credit Reporting Act.¹² The Act overturns that opinion, clarifying that inspectors general are entitled to full and prompt access to all agency records, including potentially sensitive information from whistleblowers. The Act also allows inspectors general to match data across agencies to help uncover wasteful spending and potential misconduct among senior government officials.¹³
- Also on December 16, 2016, President Obama signed into law H.R. 5790, the Federal Bureau of Investigation Whistleblower Protection Enhancement Act of 2016. The bill was a truncated version of a bill by the same name, originally introduced by Senators Chuck Grassley (R-IA) and Patrick Leahy (D-VT) in 2015. The original bill would have comprehensively reformed the FBI's whistleblower protection policies. In response to a number of objections from the intelligence community, the enacted version was limited to one major provision from the original bill. Under current regulations, FBI whistleblowers are protected only if they report wrongdoing to nine "designated officials." The Act extends protections to whistleblowers who report wrongdoing to their supervisors or through their managerial chain of command.¹⁴

House of Representatives

- On February 25, 2016, Representative Elijah Cummings (D-MD) introduced the Whistleblower Augmented Reward and Nonretaliation Act of 2016 (WARN Act), H.R. 4619, which is identical to the WARN Act introduced by Sen. Tammy Baldwin (D-WI) in the Senate. The WARN Act includes a number of provisions intended to encourage and protect whistleblowers who disclose information about financial crimes, including increasing awards available under various whistleblower statutes, creating whistleblower protections for a new category of employees, and prohibiting confidentiality agreements that require an employee to waive the right to report misconduct to a government agency.¹⁵
- On March 16, 2016, Representative Rosa DeLauro (D-CT) introduced the Wage Theft Prevention and Wage Recovery Act, H.R. 4763, which would amend the Fair Labor Standards Act in a number of ways, including by increasing to treble damages the penalty for retaliatory

discrimination against or discharge of whistleblowing employees. Senators Patty Murray (D-WA) and Sherrod Brown (D-OH) introduced an identical bill in the Senate.¹⁶

- On April 26, 2016, a bipartisan group of Representatives formed the House Whistleblower Protection Caucus. The founding members of the Caucus, which comes a little over a year after several Senators formed a similar caucus in 2015, are Representatives Mike Coffman (R-CO), Kathleen Rice (D-NY), Jackie Speier (D-CA), and Rod Blum (R-IA). The Caucus “will work to build bipartisan support for strong whistleblower protections, raise awareness about retaliation against whistleblowers, and provide guidance to other House offices about how to respond to whistleblower disclosures and allegations of retaliation.”¹⁷
- On April 28, 2016, the House Judiciary Committee’s Subcommittee on the Constitution and Civil Justice held a hearing titled *Oversight of the False Claims Act*. Witnesses included two lawyers—one representing the plaintiffs’ bar and another the defense bar—a professor, and a hospital CEO. Senator Chuck Grassley (R-IA), chair of the Senate Judiciary Committee submitted a written statement for the record. The hearing focused primarily on two potential proposals: requiring whistleblowers to report fraud internally before filing FCA actions, and limiting a company’s FCA liability if the company has adopted a “gold standard” corporate compliance program. Neither proposal has prompted legislative action.¹⁸
- On June 21, 2016, the House of Representatives passed the Thoroughly Investigating Retaliation Against Whistleblowers Act, H.R. 4639. The bill would amend the Whistleblower Protection Act of 1989 to reauthorize until 2021 the Office of Special Counsel (OSC), an independent federal agency intended to protect federal employees and applicants from prohibited personnel practices, especially reprisal for whistleblowing. The bill would also enhance the OSC’s investigatory powers by giving it “access to any record or other information of any agency under its jurisdiction.” The Act is similar to the Office of Special Counsel Reauthorization Act introduced in the Senate by Senator Ron Johnson (R-WI).¹⁹

Senate

- On February 25, 2016, Senator Tammy Baldwin (D-WI) introduced the Whistleblower Augmented Reward and Nonretaliation Act of 2016 (WARN Act), S. 2591, which is identical to the WARN Act introduced by Rep. Elijah Cummings (D-MD) in the House. The WARN Act includes a number of provisions intended to encourage and protect whistleblowers who disclose information on financial crimes, including increasing awards available under various whistleblower statutes, creating whistleblower protections for a new category of employees, and prohibiting confidentiality agreements that require an employee to waive the right to report misconduct to a government agency.²⁰
- On March 16, 2016, Senators Patty Murray (D-WA) and Sherrod Brown (D-OH) introduced the Wage Theft Prevention and Wage Recovery Act, S. 2697, which would amend the Fair Labor Standards Act in a number of ways, including by increasing to treble damages the penalty for retaliatory discrimination against or discharge of whistleblowing employees. Representative Rosa DeLauro (D-CT) introduced an identical bill in the House.²¹
- On May 19, 2016, Senators John Barrasso (R-WY) and John Thune (R-SD) introduced the Indian Health Service Accountability Act of 2016, S. 2953, which includes a provision that would add protections for whistleblowers reporting problems with the Indian Health Service.²²
- On May 23, 2016, Senator Ron Johnson (R-WI) introduced the Office of Special Counsel Reauthorization Act of 2016, S. 2968. The bill, which is similar to the Thoroughly Investigating Retaliation Against Whistleblowers Act that passed the House, would reauthorize the OSC through 2021 and would enhance the OSC’s investigatory powers.²³

- On July 12, 2016, Senator Orrin Hatch (R-UT) introduced the Taxpayer Protection Act of 2016, S. 3156. The bill includes several provisions previously introduced by Senator Chuck Grassley (R-IA) in an effort to reform the IRS Whistleblower Program. The provisions would extend to IRS whistleblowers anti-retaliation protections like those afforded to whistleblowers under the FCA; allow the IRS to exchange information with whistleblowers that could be helpful to an investigation; and require the Treasury Secretary to notify whistleblowers of the status of their claim at two points in the review process.²⁴
- The Senate Whistleblower Caucus, formed in February 2015 and chaired by Senator Chuck Grassley (R-IA), introduced a resolution designating July 30, 2016 as National Whistleblower Appreciation Day. The Senate unanimously adopted the resolution.²⁵
- On August 5, 2016, Senators Chuck Grassley (R-IA) and Ron Wyden (D-OR), along with Representative Jackie Speier (D-CA), filed an amicus brief with the Department of Labor in *Palmer v. Canadian National Railway/Illinois Central Railroad Co.* The amicus brief urged the agency not to weaken existing whistleblower protections in cases of retaliation against private-sector employees.²⁶

➤ **Department of Justice**

- On June 30, 2016, DOJ published an Interim Final Rule announcing that FCA penalties would nearly double. Beginning August 1, 2016, the penalties increased from \$5,500-\$11,000 per false claim to \$10,781-\$21,563 per false claim.²⁷ A penalty increase was mandated by the Bipartisan Budget Act of 2015, signed into law on November 2, 2015. For more information on civil penalty increases across the federal government, see WilmerHale's publication, [Civil Fines Jump Across Agencies Under Inflation Adjustment Act](#).
- In 2016, DOJ offered guidance as to how it was implementing the "Yates Memo," the September 2015 policy memo issued by Deputy Attorney General Sally Quillian Yates intended to further the Department's effort to hold individuals accountable for corporate wrongdoing.²⁸ In a speech on June 9, 2016, William Baer, the Principal Deputy Associate Attorney General, said that companies would not receive preferred settlement terms for cooperation unless they provide information on individuals, and he noted that early and voluntary reporting of information that might not otherwise be discovered would be important.²⁹ In a speech on September 27, 2016, Baer emphasized the importance of the Yates Memo with respect not only to criminal activity, but also to civil enforcement actions, stating that DOJ "guidance makes clear that the department encourages productive self-disclosure and cooperation from would-be defendants in civil enforcement matters."³⁰
- On March 30, 2016, DOJ's Elder Justice Initiative launched 10 regional Elder Justice Task Forces. According to Principal Deputy Assistant Attorney General Benjamin Mizer, "These regional teams will bring together federal, state and local prosecutors, law enforcement, and agencies that provide services to the elderly, for the purpose of coordinating and enhancing efforts to identify and bring to justice nursing homes that provide grossly substandard care to their residents." This new effort could lead to more FCA cases against nursing homes and other long-term care providers.³¹

➤ **Department of Health and Human Services**

- On February 12, 2016, the Centers for Medicare and Medicaid Services (CMS) provided guidance to Medicare Part A and Part B providers on how to comply with the Affordable Care Act provision requiring that they report and return overpayments within 60 days of those overpayments being identified.³²

- On December 7, 2016, the Department of Health and Human Services Office of Inspector General (HHS OIG) issued a final rule that adds new safe harbors to protect certain payment practices and business arrangements from sanctions under the anti-kickback statute. Specific services covered by the safe harbors include efforts to improve access to care.³³
- Also on December 7, 2016, HHS OIG issued a final rule amending its civil monetary penalty (CMP) rules to incorporate new CMP authorities and to clarify existing authorities, particularly in light of statutory changes made by the Affordable Care Act.³⁴

➤ **Department of Defense**

- On November 14, 2016, the Department of Defense issued a class deviation to the Federal Acquisition Regulation (FAR) that prohibits contracting officers from awarding contracts to contractors that restrict the ability of their employees to report fraud, waste, or abuse. The class deviation applies to any FY 2017 funds. In January 2016, the FAR Council issued a proposed rule with the same intent; the class deviation is expected to remain in place until the FAR's proposed rule is finalized.³⁵

➤ **Department of Labor**

- On April 18, 2016, the Occupational Safety and Health Administration published a final rule establishing procedures for handling retaliation complaints by whistleblowers who report food safety concerns. The rule protects employees who provide information relating to any action that the employee reasonably believes violates the Federal Food, Drug, and Cosmetic Act.³⁶

FEDERAL CASE LAW DEVELOPMENTS

Supreme Court

- **Decided Cases: (1) Implied Certification and Materiality; (2) Seal Requirement**

***Universal Health Services v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016)**

The Supreme Court unanimously upheld the “implied certification” theory of liability, while emphasizing that only material misrepresentations are actionable. The Court held that liability can attach if 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,” which the defendant “knows is material to the Government’s payment decision.” *Id.* at 1995-96.

WilmerHale represented the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Advanced Medical Technology Association (AdvaMed) as *amici curiae* supporting the petitioner.

About the Case

The FCA prohibits the submission of a “false or fraudulent” claim for payment to the government, or the making of a “false record or statement material” to such a false or fraudulent claim. 31 U.S.C. § 3729(a)(1)(A), (B). Prior to *Escobar*, a majority of the federal courts of appeals had held that a claim could be false or fraudulent by implication, on the theory that submitting a claim for payment is itself an implied certification that the party seeking payment is entitled to be paid—i.e., that the party has complied with all the requirements for payment set by statute, regulation, or contract.

The relators in *Escobar* were the parents of a teenager who died after being treated by allegedly unlicensed and inadequately supervised staff at a mental health clinic. The premise of their claim was that because the provider allegedly failed to hire and supervise its staff properly, in violation of state regulations, its submission of reimbursement claims to the state Medicaid agency violated both the FCA and its state counterpart.

The district court dismissed the action. Distinguishing between conditions of payment and conditions of participation, the court held that only non-compliance with statutory or regulatory conditions of payment could render a contractor’s claims for payment actionably false. The conditions in this case, the district court held, were conditions of the defendant’s participation in the relevant program, not conditions for receiving payments.

The First Circuit reversed, holding that “any payment/participation distinction is not relevant,” because “the provisions at issue in this case clearly impose conditions of payment.” *United States ex rel. Escobar v. Universal Health Servs., Inc.*, 780 F.3d 504, 513 (1st Cir. 2015). In a footnote, the court observed that “[a]lthough the record is silent as to whether [the mental health center] explicitly represented that it was in compliance with conditions of payment when it sought reimbursement from” the state Medicaid agency, the First Circuit had “not required such ‘express certification’ in order to state a claim under the FCA.” *Id.* at 514 n.14.

Universal Health Services, the owner of the mental health center, petitioned for certiorari, and the Supreme Court granted on two questions: (1) “[w]hether the ‘implied certification’ theory of legal falsity under the FCA—applied by the First Circuit below but recently rejected by the Seventh Circuit—is viable”; and (2) if so, “whether a government contractor’s reimbursement claim can be legally ‘false’ under [the implied certification] theory if the provider failed to comply with a statute, regulation, or contractual provision that does not state that it is a condition of payment, as held by the First, Fourth, and D.C.

Circuit; or whether liability for a legally ‘false’ reimbursement claim requires that the statute, regulation, or contractual provision expressly state that it is a condition of payment, as held by the Second and Sixth Circuits.”

The Supreme Court’s Decision

In a unanimous opinion by Justice Thomas, the Court held first that implied certification is a viable theory of FCA liability: “[L]iability can attach when 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.” 136 S. Ct. at 1995. Second, the Court held that “liability for failing to disclose violations of legal requirements does not turn upon whether those requirements were expressly designated as conditions of payment,” as some circuits had held. *Id.* at 1996. Rather, “[w]hat matters is not the label the Government attaches to a requirement, but whether the defendant knowingly violated a requirement that the defendant knows is material to the Government’s payment decision.” *Id.*

On the first point—the viability of implied certification—the Court reasoned that Congress intended to incorporate the common law meanings of the terms “false” and “fraudulent” into the FCA. *Id.* at 1999. At common law, fraud encompassed not only express misrepresentations, the Court decided, but also certain “half-truths,” or representations “that state the truth only so far as it goes, while omitting critical qualifying information.” *Id.* at 2000. The Court held that the FCA incorporates that common law concept. Thus, when a claim “makes specific representations about the goods or services provided,” it can be considered fraudulent if “the defendant’s failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those misrepresentations misleading half-truths.” *Id.* at 2001. For example, the Court explained, in this case the defendant submitted claims for reimbursement that used billing codes that corresponded to specific counseling services. Using such codes was, in the Court’s view, a specific representation that the defendant had provided the services corresponding to the codes—a representation that could be considered “fraudulent” under the FCA, given the defendant’s alleged violation of various regulations governing those services. *Id.* at 2000-01.

On the second point—whether a requirement must be expressly designated a condition of payment in order for noncompliance with it to give rise to implied certification liability—the Court rejected both parties’ positions in favor of a renewed emphasis on materiality. *Id.* at 1996. Whether the requirement is designated as an express condition of payment is relevant to materiality, but not dispositive. The fact that the government designates a particular requirement as a precondition of payment is not sufficient, in and of itself, to render the requirement material. Nor is it sufficient that the government would have been legally entitled not to pay the claim had it known of the violation. Courts should also consider other evidence on the issue of materiality, such as whether the government has consistently refused to pay claims for noncompliance with the particular requirement at issue in the past, and whether the Government in fact paid a particular claim despite actual knowledge that the payee had not complied with the requirement at issue.

In language defendants will no doubt emphasize in future cases, the Court described two prior examples of material misrepresentations in seemingly strong parenthetical language: “*See United States ex rel. Marcus v. Hess*, 317 U.S. 537, 543 (1943) (contractors’ misrepresentation that they satisfied a noncollusive bidding requirement for federal program contracts violated the False Claims Act because “[t]he government’s money would never have been placed in the joint fund for payment to respondents had its agents known the bids were collusive”); see also *Junius Constr.*, 257 N.Y., at 400, 178 N.E., at 674 (an undisclosed fact was material because “[n]o one can say with reason that the plaintiff would have signed this contract if informed of the likelihood” of the undisclosed fact).” *Id.* at 2003.

Implications for Future FCA Cases

The implied certification theory is now firmly established. In those circuits that had previously declined to permit FCA claims based on implied certification theories, such as the Seventh Circuit, the door is now open for FCA relators and the government to pursue such claims. The decision also abrogates the rule in

some circuits, including the Second Circuit, that implied certification liability could lie only for noncompliance with expressly designated conditions of payment. In both respects, the decision expands the scope of potential FCA liability.

That said, the decision also contains language that may serve to limit the expansive theories of implied certification advanced by some FCA relators and the government. The Court emphasized that materiality is a “rigorous” and “demanding” standard, one that cannot be met if “noncompliance is minor or insubstantial.” *Id.* at 2003. The Court also stressed that the defendant must *know* that a particular requirement is material to the government before FCA liability will attach. Finally, the Court explained in a footnote that an FCA plaintiff must plead a plausible basis for materiality to withstand dismissal, expressly “rejecting ... [the] assertion that materiality is too fact intensive for courts to dismiss False Claims Act cases on a motion to dismiss.” *Id.* at 2004 n.6.

PhRMA, AdvaMed and other *amici* had argued that stricter enforcement of the FCA’s “materiality” standard might not be enough to cabin the expansive theories of FCA liability advanced in some implied certification cases, in part because some courts had accepted the government’s own *post hoc* representation that particular requirements were material. The Court did not directly address those concerns, but its renewed emphasis on a “rigorous” materiality standard may do so. The Court explained, for example, that “evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance” might show materiality; conversely, “if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material.” *Id.* at 2003. Materiality, the Court stressed, is a “demanding standard” that looks to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.

***State Farm Fire and Casualty Company v. United States ex rel. Rigsby*, 137 S. Ct. 436 (2016)**

In this case, the Supreme Court held that a relator’s violation of the FCA’s seal requirement, 31 U.S.C. § 3730(b)(2), does not mandate dismissal of the action.

About the Case

This case involved insurance claims related to Hurricane Katrina. The relators, independent claims adjusters who provided State Farm with adjustment services in the wake of the hurricane, alleged that State Farm defrauded the government by directing claims adjusters to misclassify wind damage (which would be covered by State Farm) as flood damage (which would be covered by the government).

The FCA’s seal requirement, 31 U.S.C. § 3730(b)(2), provides that relators must serve a *qui tam* complaint on the government and that the complaint must remain sealed (to permit the government to investigate the allegations) for sixty days, subject to extensions permitted by the court. While the complaint was sealed under that provision, the relator’s counsel emailed a sealed evidentiary filing disclosing the existence of the complaint to several journalists. The district court nonetheless denied State Farm’s motion to dismiss the suit. Instead, after balancing several factors—harm to the government, severity of the seal violations, and evidence of bad faith—the court decided that dismissal was not warranted. The Fifth Circuit affirmed.

The Supreme Court’s Decision

The Supreme Court affirmed as well. The Court reasoned that while the FCA provides that a complaint “shall” be kept under seal, the seal provision—unlike numerous other provisions of the FCA—does not specify dismissal of the relator’s action as the required sanction for noncompliance. *Id.* 442-43. The Court further reasoned that the seal provision was meant to encourage *qui tam* suits by “allay[ing] the Government’s concern that a relator filing a civil complaint would alert defendants to a pending federal criminal investigation,” and that it would be inappropriate to read a provision meant to assist the government as harming its interests by requiring dismissal of a *qui tam* action. *Id.* at 443.

Implications for Future FCA Cases

Violations of the seal requirement in qui tam actions are rare, so the Supreme Court's holding is unlikely to have significant effects in the mine run of FCA litigation.

➤ **Pending Case: Public Disclosure Bar**

***United States ex rel. Advocates for Basic Legal Equality v. U.S. Bank N.A.*, No. 16-130, 137 S. Ct. 273 (2016) (Call for the Views of the Solicitor General issued October 3, 2016)**

This case concerns the level of generality at which courts should interpret public disclosures and a relator's allegations in determining whether a qui tam action should be dismissed under the public disclosure bar, 31 U.S.C. § 3730(e)(4).

About the Case

The case involves a mortgage insurance program administered by the Federal Housing Administration (FHA), under which lenders may claim reimbursement from the government when a borrower defaults on an insured loan. To participate, lenders must agree to comply with various regulations of the Department of Housing and Urban Development (HUD), including by taking measures to mitigate the risk of default on insured loans. For example, lenders must have face-to-face meetings with borrowers and must certify that they have considered various "loss mitigation techniques" to avoid foreclosure. The goal of these loss-mitigation requirements is to reduce foreclosures and thus limit the government's liability for insurance claims. The relator, an advocacy organization, alleges that U.S. Bank foreclosed on insured loans without complying with loss-mitigation requirements and that it then submitted insurance claims, misrepresenting that it had complied. No. 3:13-704, 2015 WL 2238660, at *1 (N.D. Ohio May 12, 2015).

U.S. Bank moved to dismiss the case under the public disclosure bar, contending that certain public sources—including a government investigative report and consent decree—had disclosed the "allegations or transactions" underlying the relator's claims. The district court agreed, as did the Sixth Circuit. 816 F.3d 428, 431 (6th Cir. 2016). The Sixth Circuit rejected the relator's argument that the suit was not "based upon" the public disclosures because the complaint's allegations were more specific than the disclosures. The Sixth Circuit held that the public disclosures placed the government on notice of the relator's claims even if they dealt with mortgages in general rather than the specific category of federally insured mortgages, and even if they concerned loss-mitigation requirements in general rather than the specific requirements addressed in the complaint. *Id.* at 432-43.

The relator petitioned for certiorari, arguing that the Sixth Circuit's approach to assessing public disclosures conflicted with decisions by the Seventh and Ninth Circuits in which those courts cautioned that public disclosures should not be read at too high a level of generality in applying the public disclosure bar. The defendant responded that there is no genuine division among the courts of appeals and that the Sixth Circuit was correct. On October 3, 2016, the Supreme Court invited the Acting Solicitor General to submit a brief expressing the government's views.

Implications for Future FCA Cases

If certiorari is granted, this case could have a significant effect on one of the most frequently litigated defenses in qui tam actions—the public disclosure bar.

DC Circuit: Public Disclosure Bar

***United States ex rel. Oliver v. Philip Morris USA Inc.*, 826 F.3d 466 (D.C. Cir. 2016) (*Oliver II*)**

In a case involving a military cigarette pricing dispute, the DC Circuit affirmed the district court's dismissal of a qui tam action brought by a relator against the tobacco company Philip Morris USA based on the public disclosure bar.

About the Case

In 2008, the relator (the CEO of a competing cigarette company) brought a qui tam action alleging that Philip Morris violated the FCA by charging higher cigarette prices than was allowed under “Most Favored Customer” pricing provisions of contracts with the Navy Exchange Service Command and the Army and Air Force Exchange Service (collectively the Exchanges). *Oliver II*, 826 F.3d at 469. In particular, the relator alleged that Philip Morris sold its cigarette products to Philip Morris Duty Free, Inc., and Philip Morris International, Inc., at lower prices than what it charged the Exchanges and hence violated the MFC provisions and the FCA. *Id.*

The district court dismissed the complaint in 2013 based on the public disclosure bar, but the DC Circuit vacated and remanded. *Id.* at 470. In “*Oliver I*,” the DC Circuit held that the public disclosure bar was not triggered because Philip Morris had failed to show that its allegedly false certifications of compliance with the MFC provisions were disclosed in the public domain. *Oliver I*, 763 F.3d 36, 41, 44 (D.C. Cir. 2014). On remand, the district court heard additional evidence and again dismissed the action based on the public disclosure bar. *U.S. ex rel. Oliver v. Philip Morris USA, Inc.*, 101 F. Supp. 3d 111, 123-27 (D.D.C. 2015). On this second appeal, the DC Circuit affirmed the dismissal. *Oliver II*, 826 F.3d at 469.

The DC Circuit first clarified that the public disclosure bar applied when “either the allegation of fraud . . . or the critical elements of the fraudulent transaction themselves were in the public domain.” *Id.* at 471. The critical elements—which are defined as elements “that, when considered together, give rise to an inference [of fraud]”—were that Philip Morris (a) was not charging the best price to the Exchanges (the price differential practice) and (b) falsely certified its compliance with the MFC provisions (the false certifications). *Id.* at 471.

The Court approached the analysis in two steps. The first step determined whether the two critical elements were *disclosed*, *id.* at 472-74; the second step determined whether the elements were disclosed through *statutorily prescribed channels*, *id.* at 474-76.

Under the first step, the Court held that an inter-office memo at Philip Morris, dated December 1999, disclosed the relevant price differential practice, even though the price differentials outlined in the memo concerned different time periods and MFC provisions than those alleged in the relator's complaint. *Id.* at 472-73. The Court explained that, because the allegations in the complaint need only be “substantially similar” to those in the public domain, the relator's provision of more details on the price differential practice, or specific examples thereof, could not negate the substantial similarity of his allegations to the price differentials disclosed in the memo. *Id.* The Court also held that the false certifications were disclosed because the government would have been able to infer it from the fact that Philip Morris engaged in the price differential practice, and the fact that the MFC provisions were incorporated by reference into every contract with the Exchanges. *Id.* at 473-74.

The second step in the analysis examined the method of disclosure—specifically, whether these disclosures were made through statutorily enumerated channels. *Id.* at 474. As to the price differential practice, the Court held that the inter-office memo was disclosed in a “civil hearing”—a statutorily specified method of disclosure, see 31 U.S.C. § 3730(e)(4)(A)—because it was published online and subsequently placed in an online database pursuant to court orders relating to settlements of separate civil lawsuits. *Oliver II*, 826 F.3d at 474-75. The Court rejected the relator's argument that the memo was not “actually” publicly available because it is unlikely that the memo would be discovered in an online

database containing over four million documents. *Id.* at 475. As the Court clarified, the test of whether a document is “actually available” is not whether a document is likely to be discovered, but rather whether it is in fact available, as opposed to “only *theoretically* available upon the public’s request.” *Oliver II*, 826 F.3d at 474 (quoting *Springfield Terminal Co. v. Quinn*, 14 F.3d 645, 652 (D.C. Cir. 1994)). Regarding the false certifications, the Court mainly focused on whether the MFC provisions were publicly disclosed through a statutorily authorized method. The Court held that the MFC provisions were publicly disclosed in an “administrative report,” see 31 U.S.C. § 3730(e)(4)(A), because, during the relevant time period, the Exchanges’ websites provided information on the terms and conditions of their contracts, including the MFC provisions. The Court further opined that the statutory term “report” is broadly defined to include such websites. *Oliver II*, 826 F.3d at 476.

After completing the two-step analysis, the DC Circuit also addressed the “original source” exception to the public disclosure bar, see 31 U.S.C. § 3730(4)(e)(B). The court held that the relator was not an “original source” because, while he conducted an investigation to confirm his suspicion of Philip Morris’s fraudulent transaction, he did not have direct knowledge of the information that prompted his investigation in the first place. *Oliver II*, 826 F.3d at 476-77. The lack of first-hand knowledge of the source information, according to the Court, precluded his original source status, even if, as in this case, he had direct knowledge of certain information that helped him confirm his suspicion. *Id.* at 479-80.

Implications for Future FCA Cases

This decision clarified a number of concepts and provides a useful framework for addressing a host of frequently litigated issues under the public disclosure bar.

First Circuit: (1) Arm-of-the-State Test; (2) First to File Rule; (3) Rule 9(b); (4) Implied Certification Liability & Materiality; (5) Public Disclosure Bar

***United States ex rel. Willette v. University of Massachusetts, Worcester, aka University of Massachusetts Medical School*, 812 F.3d 35 (1st Cir. 2016), cert. denied, No. 15-1437, 2017 WL 69179 (Jan. 9, 2017)**

The First Circuit joined the Fourth, Fifth, Sixth, Ninth, Tenth and Eleventh Circuits in holding that the arm-of-the-state test is “the appropriate test under the FCA for actions brought by private parties [against state agencies],” to determine whether an entity is subject to the FCA. *Id.* at 38-39. Applying that test, the Court held that the University of Massachusetts Medical School is an arm of the Commonwealth of Massachusetts and is not a “person” subject to suit under the FCA. *Id.* at 43.

About the Case

The relator was an employee at the University of Massachusetts Medical School’s (UMMS) Center for Health Care Financing (CHCF), a department tasked with recovering funds from third parties to repay previous Medicaid expenditures made by the federal government and the Commonwealth of Massachusetts. He alleged that another CHCF employee embezzled nearly \$4,000,000 prior to his death, and upon bringing this scheme to light, that UMMS officials retaliated against him. *Id.* at 38.

The district court dismissed the case, applying the arm-of-the-state test used to determine whether an entity is a “state” entitled to immunity under the Eleventh Amendment. *Id.*

The First Circuit affirmed, holding that “[w]e join th[e] unbroken precedential chain [of the Fourth, Fifth, Sixth, Ninth, Tenth, and Eleventh Circuits] and today hold, as did the court below . . . that the appropriate test under the FCA for actions brought by private parties is identical to the one we have employed in determining whether an entity is an arm of the state for Eleventh Amendment purposes.” 812 F.3d at 39. Applying this test to UMMS, and considering factors such as “the degree of state control over the entity, the way in which the entity is described and treated by its enabling legislation and other state statutes, how state courts have viewed the entity, the functions performed by the entity, and whether the entity is

separately incorporated,” the court observed that “[a]s a general matter, public universities ‘usually are considered arms of the state,’” and that “the statutory framework crafted by the Massachusetts legislature lends itself to the conclusion that the University of Massachusetts . . . and thus UMMS, is an arm of the state.” *Id.* at 40. The Court further noted that “[t]his overwhelming statutory evidence is matched by the treatment that the University and its medical school have consistently received from state” and federal courts. *Id.* at 42. In light of this conclusion, the First Circuit determined that it did not need to consider “whether the state’s treasury would be at risk in the event of an adverse judgment.” *Id.* at 40. After concluding that UMMS is an arm of the state, the Court concluded that “UMMS is not a ‘person’ subject to suit under the FCA.” *Id.* at 43.

Implications for Future FCA Cases

This case adheres to the established framework for determining whether state-created entities qualify as “persons” subject to liability under the FCA.

United States ex rel. Kelly v. Novartis Pharmaceuticals Corp., 827 F.3d 5 (1st Cir. 2016)

The First Circuit joined the DC Circuit in holding that the first-to-file rule applies to the relator of the first action just as it does to any future relators. Acknowledging that cases dismissed under the first-to-file rule are generally dismissed without prejudice, the First Circuit upheld the lower court’s dismissal with prejudice under a Rule 9(b) analysis.

About the Case

The two relators, Kelly and Garcia, were drug sales representatives from Novartis and Genentech, respectively. In 2006, they jointly filed a qui tam complaint (2006 Garcia Complaint) alleging that with respect to the allergy drug Xolair, both companies paid kickbacks to doctors, promoted the drug for off-label use, and encouraged doctors to falsify Statement of Medical Necessity forms. *Id.* at 7. Fauci, another Genentech sales representative, filed suit in 2010 making similar allegations. *Id.* at 8. In 2011, after the United States declined to intervene and relators’ counsel withdrew, Kelly asked to be—and was—dismissed without prejudice from the 2006 Garcia Complaint. *Id.* at 7-8. In June 2012, all three relators retained new counsel and Kelly again brought suit (2012 Kelly Complaint). *Id.* at 9. Kelly, Garcia, and Fauci then sought to consolidate and amend their complaints. After the court denied the relators’ motion to consolidate and amend, Fauci voluntarily dismissed his 2010 complaint, and the defendants moved to dismiss both the 2006 and 2012 complaints. *Id.* at 9 & n.7.

Although the district court ultimately dismissed both complaints with prejudice based on their failure to plead fraud with particularity, it held that the first-to-file rule did not bar the 2012 complaint because Kelly co-filed the first complaint. *Id.* at 10. The First Circuit disagreed, and following reasoning of the DC Circuit, held that the first-to-file bar applied to Kelly because “[n]othing about her prior involvement in the 2006 Garcia Action could serve to dissolve the independent statutory bar to her bringing a new, and essentially identical, action in 2012.” 827 F.3d at 12.

Observing that “[c]omplaints dismissed under the first-to-file bar are usually dismissed without prejudice,” the First Circuit stated that if the 2006 Garcia Complaint had been “properly dismissed,” the 2012 Kelly Complaint would not have been subject to the first-to-file bar. *Id.* Nevertheless, the First Circuit determined that remand was unnecessary because it agreed with the lower court’s determination that the relators failed to plead fraud with particularity, and its decision to dismiss the complaints with prejudice for “repeatedly fail[ing] to cure the deficiencies in their complaints” and offering only “more of the same” in the proposed joint complaint. *Id.* at 12-15.

Implications for Future FCA Cases

The First Circuit held that the first-to-file bar applies to the relator filing the prior action just as it does to any other relators.

***Lawton ex rel. United States v. Takeda Pharmaceutical Co. Ltd.*, 842 F.3d 125 (1st Cir. 2016)**

The First Circuit held that, even where the more flexible approach to a Rule 9(b) analysis applies for statistical evidence regarding a third party's claim submissions, plaintiffs must still provide information regarding who submitted false claims to the government, how many such claims were submitted, or the causation between the defendant's actions and the claim submissions, to satisfy Rule 9(b).

About the Case

The relator was a former chemist and patent litigator at GlaxoSmithKline, a competitor of defendant Takeda Pharmaceutical. He alleged that Takeda and Eli Lilly conspired in a fraudulent marketing campaign regarding off-label uses for Actos, a treatment for Type 2 diabetes, that ultimately induced third parties to submit false claims for reimbursement to the government. *Id.* at 127-28.

The district court dismissed the case for failure to allege fraud with the particularity required by Rule 9(b). The First Circuit, acknowledging that courts "apply a 'more flexible' standard" to cases "alleging that the defendant induced third-parties to file false claims with the government," which allows relators to "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 [submitted] false claim," went on to list several pieces of information required to strengthen this inference. 842 F.3d at 130. For example, relators are generally required to plead "specific medical providers who allegedly submitted false claims, the rough time periods, locations, and amounts of the claims, and the specific government programs to which the claims were made." *Id.* at 131. After setting forth this framework, the First Circuit affirmed the dismissal with relatively little analysis. *Id.* at 131-32.

Implications for Future FCA Cases

This case reflects the demanding standards of Rule 9(b), even where relators relying on statistical evidence of third-party claim submissions are subject to a more "flexible" Rule 9(b) standard. The First Circuit provided further guidance to relators attempting to use statistical evidence to support their claims.

***Hagerty ex rel. United States v. Cyberonics, Inc.*, 844 F.3d 26 (1st Cir. 2016)**

The First Circuit upheld the lower court's dismissal of all but two of the relator's claims based on failure to plead fraud with particularity under Rule 9(b). The Court also affirmed the dismissal with prejudice, given the relator's undue delay in prosecuting his case.

About the Case

The relator, a former sales representative for Cyberonics, alleged that the defendant induced third parties to submit false claims for payment by promoting medically unnecessary replacements of nerve simulator devices, which are used to treat patients with refractory epilepsy. After the United States and various state governments declined to intervene, and after several amendments to relator's complaint, the defendant moved to dismiss for failure to state a claim and failure to plead fraud with particularity as required by Rule 9(b).

The lower court dismissed the case on Rule 9(b) grounds and subsequently denied relator's motion to amend the complaint for undue delay. The First Circuit agreed with both rulings. Observing that courts apply a more "flexible standard" when the defendant is alleged to have induced a third party to submit a false claim to the government, the First Circuit compared the allegations put forth by relator with those in *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 29-30 (1st Cir. 2009) and *United States ex rel. Escobar v. Universal Health Servs., Inc.*, 780 F.3d 504 (1st Cir. 2015), *overruled on other grounds* by 136 S. Ct. 1989 (2016). *Id.* at 31-32. The Court held that because "[t]he allegations in [relator's] First Amended Complaint are neither as specific as those in *Duxbury* nor as systematic as those in *Escobar*," relator had failed to plead fraud with sufficient particularity. *Id.* The First Circuit affirmed

the district court's decision that inexcusable undue delay counseled in favor of dismissing the complaint with prejudice. *Id.* at 34-35.

Implications for Future FCA Cases

The First Circuit further fleshed out a framework defendants can use to challenge a relator's complaint based on its failure to plead fraud with particularity in qui tam actions alleging that the defendant induced third parties to file false claims with the government.

***United States ex rel. Escobar v. Universal Health Services, Inc.*, 842 F.3d 103 (1st Cir. 2016)**

As discussed above, the Supreme Court, upon reviewing this case, ruled that the implied false certification theory can be a basis for FCA liability. *See supra* pp. 7-9. The Supreme Court vacated and remanded the case back to the First Circuit "for further consideration of whether Relators' complaint sufficiently alleged that the regulatory violations in question were material to the government's payment decision, a requirement for an actionable FCA claim." 842 F.3d at 105-06. The First Circuit ultimately concluded that defendant's misrepresentations were material, and that the relators' complaint sufficiently stated a claim under the FCA. Accordingly, the First Circuit remanded the case to the district court for further proceedings consistent with its ruling.

About the Case

As discussed above, the Supreme Court ultimately held that "[w]hen, as here, a defendant makes representations in submitting a claim but omits its violations of statutory, regulatory, or contractual requirements, those omissions can be a basis for liability if they render the defendant's representations misleading with respect to the goods or services provided." *Universal Health Servs., Inc. v. United States and Commonwealth of Mass. ex rel. Escobar*, 136 S. Ct. 1989, 1999 (2016). The Supreme Court further explained that FCA liability attaches only where misleading omissions are material to the government's decision to pay a claim, and "[w]hat matters is . . . whether the defendant knowingly violated a requirement that the defendant knows is material to the Government's payment decision." *Id.* at 1996.

After "[a]pplying the holistic approach to determining materiality laid out by the Supreme Court," the First Circuit observed that it had "little difficulty in concluding that Relators have sufficiently alleged that UHS's misrepresentations were material." 842 F.3d at 110. The First Circuit cited three reasons for its decision: (1) "the government conditioned MassHealth's payments on compliance with the licensing and professionalism regulations"; (2) "the centrality of the licensing and supervision requirements in the MassHealth regulatory program, . . . is strong evidence that a failure to comply with the regulations would be 'sufficiently important to influence the behavior' of the government in deciding whether to pay the claim"; and (3) although the Supreme Court stated that 'if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material,' the Court did not state that such knowledge is dispositive. . . . and there is no evidence in the record that MassHealth paid th[e] claims [relating to services provided to relators' daughter] to UHS despite knowing of the violations." *Id.* at 110-11 (internal citations omitted).

Implications for Future FCA Cases

The First Circuit is one of many courts to have applied the Supreme Court's guidance in *Escobar* on whether a misrepresentation is material under the FCA.

***United States ex rel. D'Agostino v. ev3, Inc.*, 845 F.3d 1 (1st Cir. 2016)**

In yet another application of the materiality standard articulated by the Supreme Court in *Escobar*, the First Circuit ruled that, except in limited circumstances, fraudulent misrepresentations made to the FDA likely cannot form the basis for FCA liability.

About the Case

The relator, a former sales representative for ev3, alleged that ev3 submitted false claims or caused false claims to be submitted for two of its devices (Onyx and Axium). In particular, he alleged that with respect to Onyx, ev3 made fraudulent representations to the FDA to obtain approval to market Onyx, and caused third parties to submit false claims by encouraging physicians to use it in medically unnecessary and dangerous ways. *Id.* at 9. He also alleged that various manufacturing or design defects for Axium rendered false every claim involving that product. *Id.* at 10. After multiple attempts to amend his complaint, and after the district court dismissed his third amended complaint, relator requested to file a fourth amended complaint. *Id.* at 3. The district court denied his request, holding that amendment would be “futile because the amended complaint fails to state a claim upon which relief can be granted.” *Id.* at 5.

The First Circuit affirmed. The Court reasoned that relator’s fraudulent misrepresentation claims failed both on materiality and causation grounds. Relator, by “alleging that the fraudulent representations ‘could have’ influenced the FDA to approve Onyx falls short of pleading a causal link between the representations made to the FDA and the payments made by CMS.” *Id.* at 6. With respect to materiality, the Court stated that “the fact that CMS has not denied reimbursement for Onyx in the wake of D’Agostino’s allegations casts serious doubt on the materiality of the fraudulent representations that D’Agostino alleges.” *Id.* The First Circuit, while declining to hold that “the FCA is in this context preempted by the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399f,” held that “causation is an element of the fraudulent inducement claims D’Agostino alleges and that the absence of official action by the FDA establishing such causation leaves a fatal gap in this particular proposed complaint.” *Id.* at 8. The Court left open a possible exception to this rule, stating that “[c]ertainly some official action by the FDA confirming that its approval was actually procured by the alleged fraudulent representations would fill that particular gap in the proposed complaint. Whether it would suffice to sustain the proposed complaint we need not decide.” *Id.* The First Circuit also upheld dismissal of the remaining claims, regarding Axium, for failure to state a claim. *Id.* at 6-7.

Implications for the FCA:

The First Circuit declined to resolve whether a relator could state an FCA claim based on an alleged fraud perpetrated on the FDA. Although its decision effectively bars FCA cases under a fraudulent misrepresentation theory, the decision left open a potential exception for circumstances where the FDA has affirmatively withdrawn pre-market approval of a medical device based on such fraud.

***United States ex rel. Winkelman v. CVS Caremark Corp.*, 827 F.3d 201 (1st Cir. 2016)**

The First Circuit, in considering whether the relators’ complaint survived the public disclosure bar via the original source exception, held that the relators were not original sources because they offered no new information materially adding to what previously appeared in public disclosures. The analysis of what constitutes a material addition was a matter of first impression in the First Circuit, and the Court based its analysis in part on the Supreme Court’s recent discussion in *Escobar* of what constitutes materiality under the implied certification liability theory, as discussed above. *See supra* pp. 7-9.

About the Case

The relators brought suit against CVS and its affiliates, alleging that CVS’s Health Savings Pass (HSP) program ran afoul of the FCA because the discounts given to HSP program participants were not also extended to Medicaid and Medicare programs. The relators filed their suit in 2011, one year after extensive—and public—initiatives and investigations by several labor unions and the Connecticut Attorney General’s Office into these practices. After both federal and state governments declined to intervene, the defendants moved to dismiss based on the public disclosure bar.

The district court dismissed the case, finding the public disclosure bar dispositive. After declining to decide whether the public disclosure bar is jurisdictional, the First Circuit first considered whether the

public disclosure bar was triggered by the public initiatives, reports and investigations. Citing the Sixth, Ninth, and DC Circuits, the court held that “the public disclosure bar contains no requirement that a public disclosure use magic words or specifically label disclosed conduct as fraudulent,” and that “[e]nough was revealed in the Connecticut disclosures to put the government on notice of the potential fraud without the aid of these relators.” 827 F.3d at 209. The First Circuit also held that “the essential elements of the transactions and events underlying the relators’ allegations were publicly disclosed in the course of the earlier Connecticut dispute and that the scheme depicted in those earlier disclosures was substantially the same as the scheme depicted in the relators’ complaint.” *Id.* at 210-11.

The Court next considered whether the original source exception applied—specifically the exception for individuals who “possess knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions,” and held that it did not. *Id.* at 211. Observing that “[t]he meaning of the ‘materially adds’ language in the original source exception is a matter of first impression for this court,” the First Circuit, citing *Escobar*, stated that materiality can be determined by considering “whether a piece of information is sufficiently important to influence the behavior of the recipient.” *Id.* The First Circuit concluded that none of the additional information relators provided “materially add[ed]” to the public disclosures; their suit was barred. *Id.* at 212-13.

Implications for Future FCA Cases

The First Circuit has now provided a framework for defendants to argue that information provided by relators does not “materially” add to public disclosures, such that the original source exception should not apply.

Second Circuit: Express and Implied False Certification

***Bishop v. Wells Fargo & Co.*, 823 F.3d 35 (2d Cir. 2016), petition for cert. filed (U.S. May 5, 2016) (No. 15-2449)**

The Second Circuit affirmed a dismissal of a suit alleging that Wachovia and World Savings Bank, which were subsequently acquired by Wells Fargo, violated the FCA by making false statements in applications for short-term loans borrowed from the Federal Reserve’s “discount window.” The Court held that the alleged violations of banking regulations and certifying compliance with a broad range of statutory and regulatory obligations constituted a basis for liability under the FCA. Rather, relators must show that a defendant falsely represented that it complied with specific statutory, regulatory or contractual obligations.

About the Case

The relators—former Wachovia and World Saving Bank employees—brought a qui tam claim alleging that their employers engaged in fraud by falsely representing that they had fully complied with Federal Reserve (Fed) regulations in applications for loans borrowed through the Fed’s discount window. The relators claimed that bank executives relied on improper accounting practices to hide toxic assets and undercapitalization and that the banks violated the FCA by making false representations to the Fed that they had complied with its borrowing requirements under three provisions in the Fed’s “Lending Agreement”: (1) Section 9.1(b), requiring a borrowing institution to affirm that it is not in violation of any laws or regulations relevant to the Lending Agreement; (2) Section 9.1(g), attesting that no omissions or false material information has been furnished to the Fed; and (3) Section 9.1(i), attesting that the bank has not been involved in a “default event” whereby it has failed to repay obligations in connection with the Lending Agreement. 823 F.3d at 41-42. The relators sought to recover treble damages and civil penalties under the FCA in the amount of approximately \$900 billion for allegedly false claims filed from 2007 through November 2011. *Id.* at 42.

Express False Certification

Affirming the district court's dismissal of the relators' claim, the Second Circuit concluded that the banks' blanket certification that they had complied with "any laws or regulations" (per Section 9.1(b)) or made "any false statements" in submissions to the Fed (under Section 9.1(g)), did not constitute express or implied false certification of compliance with a particular statute or regulation. *Id.* at 45, 47. Regarding the certification that the banks were not in violation of "any laws or regulations" when they borrowed from the Fed's discount window, the court explained that the certification was too broad to support an FCA-based claim of violation with a *specific* statute or regulation. *Id.* at 45. Interpreting the FCA to encompass such a broad certification, the court explained, would "[in]sufficiently cabin[] the sweep of the provision." *Id.*

Implied False Certification

The Second Circuit also rejected the relators' claim that the banks were liable under the FCA by making implied false certifications under Section 9.1(b) of the Fed's Lending Agreement. Implied certification—which renders an actor liable on the basis that the act of submitting a claim for reimbursement itself implies compliance with federal rules—the court explained, "is appropriately applied only when the underlying statute or regulation upon which the plaintiff relies *expressly* states the provider must comply in order to be paid." *Id.* at 48 (quoting *Mikes v. Straus*, 274 F.3d 687, 700 (2d Cir. 2001)).

Following the court's ruling, however, the Supreme Court in *Escobar* specifically rejected limiting implied certification liability to circumstances in which compliance is expressly designated as a condition of payment. 136 S. Ct. at 2001-02. The relators unsuccessfully sought rehearing by the Second Circuit in light of *Escobar*, and have now asked the Supreme Court to grant *certiorari*, vacate and remand *Bishop* in light of *Escobar*.

Implications for Future FCA Cases

If the Supreme Court vacates and remands *Bishop*, this case may give the Second Circuit an early opportunity to clarify the materiality standard for implied certification cases post-*Escobar*. Regardless, the Court's holding that express certification liability cannot be based on a broad certification of compliance with "any laws or regulations" is significant and should affect FCA matters in a wide variety of contexts.

***United States ex rel. Polansky v. Pfizer, Inc.*, 822 F.3d 613 (2d Cir. 2016)**

The Second Circuit affirmed the dismissal of qui tam claims against Pfizer, rejecting the relator's allegations that Pfizer engaged in off-label marketing of Lipitor.

About the Case

The relator, a former Pfizer medical director, alleged that Pfizer improperly marketed Lipitor to patients who were not candidates for the drug under the National Cholesterol Education Program Guidelines (NCEP Guidelines). He alleged that since the Guidelines were part of Lipitor's FDA-approved label, Pfizer's conduct amounted to inducing doctors, pharmacists, and federal and state care programs to pay for "off-label" prescriptions in violation of the FCA.

In a ruling that strongly endorsed the district court's reasoning dismissing the case below, the Second Circuit concluded that Pfizer did not improperly market Lipitor because the Guidelines—which were included in the Lipitor labeling—amounted to recommendations that did not carry the force of law. "We 'cannot accept plaintiff's theory,'" the court explained, "that what scientists at the National Cholesterol Education Program clearly intended to be advisory guidance is transformed into a legal restriction simply because the FDA has determined to pass along that advice through the label." 822 F.3d at 619 (quoting *United States ex rel. Polansky v. Pfizer, Inc.*, No. 04-cv-0704, 2009 WL 1456582, at *5-10 (E.D.N.Y. May 22, 2009)).

In dicta, the court went further and voiced doubt over whether “off-label” marketing of a drug could ever be a basis for finding a pharmaceutical company liable under the FCA. The court explained that a physician is “permitted to issue off-label prescriptions; the patient follows the physician’s advice, and likely does not know whether the use is off-label; and the script does not inform the pharmacy . . . whether or not the use is on label or off.” *Id.* at 619-20. On those assumptions, the court remarked it was “dubious” that any actor in the transaction chain could have “knowingly, impliedly certified that any prescription . . . was for an on-label use.” *Id.* at 620.

Implications for Future FCA Cases

The case emphasizes that an FCA violation premised on certification does not follow from alleged noncompliance with guidance or recommendations lacking the force of law. It also strongly suggests (at least in the Second Circuit) that off-label marketing may never be used as a reason for finding that a drug-maker violated the FCA, since, as the Court explained, doctors may prescribe medicines for any use not expressly prohibited on a drug’s FDA label, and patients and pharmacies will seldom know whether the drug is being prescribed for an on- or off-label use.

Third Circuit: (1) Public Disclosure Bar; (2) Reverse False Claims

***United States ex rel. Moore & Co. v. Majestic Blue Fisheries, LLC, et al.*, 812 F.3d 294 (3rd Cir. 2016)**

The Third Circuit held that a person may bring an FCA suit based on information revealed through discovery in a separate lawsuit not involving the government consistent with the “original source” exception to the public disclosure bar.

About the Case

The relator, Moore & Co. (Moore), a law firm, alleged that defendants (Korean nationals and LLCs formed by them) unlawfully obtained US tuna-fishing licenses by fraudulently certifying to the US Coast Guard that the LLCs were controlled by US citizens and that their fishing vessels were commanded by US captains, when in fact the companies were owned and the fishing vessels commanded by Korean nationals. The details about the alleged fraud were obtained through discovery in a separate wrongful death action in which Moore was counsel, in response to a FOIA request, and through publicly available online news articles and blog posts. The district court dismissed for lack of subject matter jurisdiction under the public disclosure bar. 69 F. Supp. 3d 416 (D. Del. 2014).

The Third Circuit reversed. The Court explained that the 2010 amendments to the disclosure bar “radically changed” the hurdle for relators, in three key ways: (1) the bar no longer deprives the court of jurisdiction; (2) information disclosed in a lawsuit between private parties no longer qualifies as a public disclosure; and (3) a relator no longer needs to have direct knowledge of the fraud to qualify as an original source, so long as the relator has “knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions.” 812 F.3d at 298-300. In light of these amendments, the Court held that the public disclosure bar as amended is not jurisdictional, and that the district court should have decided the motion under Rule 12(b)(6) rather than 12(b)(1). *See id.* at 297. On the merits, the Court went on to hold that while “the transaction setting forth the alleged fraud was publicly disclosed via the two news articles and the FOIA documents,” Moore qualified as an “original source” because the information it obtained in discovery “is independent of, and materially adds to, the publicly disclosed transaction of fraud.” *Id.* at 304.

Implications for Future FCA Cases

The Third Circuit joined the Fourth, Sixth and Eleventh Circuits in holding that the public disclosure bar is non-jurisdictional. The Third Circuit also adopted a definition of “original source” that is arguably broader than that adopted by the Seventh Circuit in *United States ex rel. Bogina v. Medline Industries, Inc.*, 809

F.3d 365, 370 (7th Cir. 2016) (relator not an original source “if he merely ‘adds details’ to what [was] already known” as a result of previous lawsuit).

***United States ex rel. Custom Fraud Investigations, LLC v. Victaulic Co.*, 839 F.3d 242 (3d Cir. 2016)**

The Third Circuit held that failure to pay customs duties on imported goods may give rise to a reverse FCA claim.

About the Case

The relator, Customs Fraud Investigations, LLC (CFI), alleged that defendant Victaulic Co. (Victaulic), a pipe distributor, deprived the government of customs duties it owed for foreign-manufactured unmarked pipe fittings that it imported and sold in the United States. Federal law requires that pipe fittings manufactured outside the United States be marked with the country of origin; improperly marked goods are subject to a non-discretionary 10 percent *ad valorem* tax known as a “marking duty,” which accrues from the time of importation. 19 U.S.C. § 1304(c). Importers are obligated to disclose to US Customs and Border Protection any information necessary to assess whether imported goods may be released into the stream of commerce and whether such goods are subject to customs duties. *See id.* CFI alleged that Victaulic imported millions of pounds of unmarked pipe fittings over several years and purposefully failed to inform the government that the pipe fittings were improperly marked in order to avoid paying the marking duty, thereby giving rise to a reverse FCA claim under 31 U.S.C. § 3729(a)(1)(G). The district court dismissed the complaint, holding that failure to pay marking duties could not give rise to a reverse FCA claim as a matter of law and that CFI’s proposed amended complaint failed to meet Rules 8 and 9(b).

The Third Circuit reversed, holding that the text and history of the reverse false claims provision of the FCA as amended by the Fraud Enforcement and Recovery Act of 2009 (FERA) make clear that the provision unambiguously covers failure to pay customs duties. *See* 839 F.3d at 254-55. In so holding, the Court explained that the availability of reverse false claims liability for such conduct makes sense from a policy perspective, because it incentivizes importers to report improperly marked goods rather than run the risk of treble damages if the unmarked goods are later discovered. *See id.* at 255-56. The Court also held that the district court abused its discretion in refusing to allow CFI to amend the complaint. Although it expressed skepticism about the reliability of the methodology employed by CFI to determine whether Victaulic had imported unmarked goods, the Court determined that these concerns were “misplaced” at the pleadings stage. *Id.* at 257. The Third Circuit further held that the complaint alleged sufficient facts to satisfy the particularity requirements of Rule 9(b). *See id.* at 258.

Implications for Future FCA Cases

The Third Circuit’s holding that the post-FERA reverse false claim provision recognizes claims for failures to pay “marking duties” or custom fees is significant.

Fourth Circuit: (1) Public Disclosure Bar – Amended Pleadings; (2) Successor Corporation Liability; (3) Public Disclosure Bar – Claims Based on Knowledge from Attorneys Barred

***United States ex rel. Beauchamp v. Academi Training Center*, 816 F. 3d 37 (4th Cir. 2016)**

The Fourth Circuit held that the date of the first pleading to allege the relevant fraud with particularity, not the date of any subsequent pleading, governs the determination of when a relator’s claims arise for purposes of the public disclosure bar.

About the Case

Relators alleged that defendant Academi Training Center submitted false claims in connection with a State Department contract to provide security services for officials and embassy workers across the

Middle East. 816 F. 3d at 40. The contract required Academi's personnel to maintain certain weapons qualifications and regularly submit marksmanship scores to the government. *Id.* Relators' original complaint in April 2011 raised allegations about the submission of bills for contractors employed in positions in which they did not work and for unissued equipment. *Id.* at 40-41. Relators filed their first-amended complaint in May 2011, adding allegations that Academi failed to ensure its contractors met weapons qualifications, fabricated scorecards showing firearm proficiency to submit to the government, and fraudulently billed the government for security services performed by unqualified contractors. *Id.*

After the first-amended complaint had been filed, two individuals came forward with additional information about the alleged scheme to falsify weapons qualifications and filed a separate lawsuit (the *Winston* complaint), which spurred a news article about the case that was published online in July 2012. *Id.* at 41. Relators filed a second-amended complaint in November 2012, which added information from the *Winston* complaint providing further details regarding the weapons qualification scheme. *Id.*

Academi moved to dismiss under the public disclosure bar, among other grounds. The district court found that the July 2012 news article was a qualifying public disclosure that preceded the filing of the second-amended complaint and required application of the public-disclosure bar under *Rockwell International Corp. v. United States*, 549 U.S. 457 (2007). *Id.* at 42. The Court of Appeals reversed, finding that the district court misapplied the Supreme Court's decision in *Rockwell* by "mechanically appl[ying] the statement that 'courts look to the amended complaint to determine jurisdiction.'" *Id.* at 45. The Court of Appeals concluded that *Rockwell* does not limit the public disclosure analysis to the latest pleading; instead, courts should determine "when the relevant claims first appeared in the case." *Id.* Applying this standard, the Court of Appeals determined that the relevant fraud was the weapons qualification scheme, which was pled with sufficient specificity in the first-amended complaint and therefore pre-dated the qualifying public disclosure. *Id.* at 46. Although the second-amended complaint contained information from the public disclosure, the court of appeals concluded that it "merely added further detail about a claim already alleged." *Id.* at 45.

Implications for Future FCA Cases

This decision clarifies the application of *Rockwell* in the Fourth Circuit and, consistent with the Fifth Circuit, finds that the public disclosure bar turns on the timing of the public disclosure in relation to the relevant fraud claim, not the most recent pleading.

***United States ex rel. Bunk v. Government Logistics N.V.*, 842 F. 3d 261 (4th Cir. 2016)**

The Fourth Circuit determined that traditional common law principles govern successor corporation liability under the FCA and reversed the district court's award of summary judgment to the defendant.

About the Case

Defendant Gosselin Group N.V. was found criminally liable for conspiracies related to a bid-rigging scheme over a decade ago, and a qui tam suit was later filed regarding the same conduct. 842 F. 3d at 264. This case concerns the government and relators' entitlement to recover on their judgment from a successor corporation, Government Logistics N.V., created after the conclusion of the criminal proceedings and during the early stages of the qui tam litigation. *Id.* at 268. The government intervened in the qui tam action, and named Government Logistics as a defendant, alleging it was a successor in interest of Gosselin Group. *Id.* at 269. The government and relators moved for summary judgment on the question of successor liability under two theories: the substantial continuity theory and the fraudulent transaction theory. *Id.* at 270, 273.

The court of appeals agreed with the district court's determination that under the Supreme Court's decision in *United States v. Bestfoods*, 524 U.S. 51 (1998), traditional common law principles should govern because the FCA is silent on successor liability. *Id.* at 274. Accordingly, the substantial continuity theory of successor liability set forth by the Fourth Circuit in *United States v. Carolina Transformer Co.*,

978 F. 2d 832 (4th Cir. 1992), was not applicable as it altered the common law's mere continuation rule. *Id.*

The Fourth Circuit then analyzed the district court's two rulings on the fraudulent transfer theory of liability, an alternative basis for holding the successor corporation liable. The Court ruled, without deciding whether Rule 9(b)'s pleading requirements apply to a fraud-based successor liability claim, that the allegations in the complaint meet Rule 9(b) and were sufficiently pleaded. *Id.* at 275-76. However, the Court also ruled that the existence of factual disputes regarding the intent behind the transfer could not be resolved on summary judgment and remanded for further proceedings. *Id.* at 279.

Implications for Future FCA Cases

This case provides guidance on successor liability under the FCA in the Fourth Circuit, although it leaves open the question of whether Rule 9(b) applies to a fraud-based successor liability claim.

***United States ex rel. May v. Purdue Pharma L.P.*, 811 F.3d 636 (4th Cir. 2016)**

The Fourth Circuit held that the pre-2010 public disclosure bar applied to allegations derived from knowledge an attorney learned during a prior litigation (a public disclosure).

WilmerHale represented Purdue in all phases of this litigation and the preceding case.

About the Case

In 2005, a former Purdue employee sued Purdue, alleging that it improperly marketed its prescription drug OxyContin. The Fourth Circuit ultimately upheld the dismissal of that lawsuit on the ground that the employee had signed a release when he left Purdue that barred the action. 811 F.3d at 638.

Two months after the Supreme Court denied certiorari in that case, the employee's wife and another former Purdue employee, represented by the same attorney who handled the previous lawsuit, filed a nearly identical action. *Id.* The district court dismissed the case on res judicata grounds in 2012, based on the same release. *Id.* at 639. On appeal, the Fourth Circuit rejected that res judicata holding on the ground that the release was specific to the employee who signed it, but remanded the case for consideration of Purdue's public disclosure bar and Rule 9(b) defenses. *Id.*

The district court dismissed the amended complaint with prejudice, holding that the public disclosure bar foreclosed the action. The Fourth Circuit unanimously upheld that dismissal, deeming it consistent with the Court's prior holdings and the purpose of the public disclosure bar. *Id.* at 643. The Fourth Circuit ruled that, although relators did not derive their allegations from reading publicly filed versions of the complaint in the first lawsuit, their allegations were based on the knowledge their attorney learned from representing the first relator and were therefore based on a public disclosure. *Id.* at 641-42. The court of appeals stated that the FCA is "not designed to encourage lawsuits by individuals like the Relators who (1) know of no useful new information about the scheme they allege, and (2) learned of the relevant facts through knowledge their attorney acquired when previously litigating the same fraud claim." *Id.* at 643.

Implications for Future FCA Cases

This decision closes a potential loophole for relators bringing claims under the pre-2010 version of the public disclosure bar, reinforcing the public disclosure bar's aim of preventing parasitic claims.

Fifth Circuit: (1) Retaliation Claims by Agents and Contractors; (2) Retaliation Claims Against Individual Defendants; (3) Reverse False Claims

***United States ex. rel. Bias v. Tangipahoa Parish School Bd.*, 816 F.3d 315 (5th Cir. 2016)**

The Fifth Circuit held that the 2009 amendments to the False Claims Act allow for retaliation claims outside the traditional employer-employee relationship, including by agents and contractors.

About the Case

Plaintiff Ronald Bias was a retired Lt. Colonel in the Marine Corps working for the defendant school board in the Junior Reserve Officers' Training Corps (JROTC). The Marine Corps then recalled him to active duty and began paying his salary but allowed him to remain affiliated with the school. Bias reported that another JROTC officer had improperly sought funds from the Marine Corps to pay for athletic events not connected to or sponsored by the federal program. Bias alleged that, in retaliation, the other officer and the principal harassed him and made unfounded complaints about his performance, which resulted in his transfer, over his objections, by the Marine Corps to a school district an hour away from his home. Bias sued the school district, as well as the school principal and the other JROTC officer in their official capacities, asserting a qui tam action and retaliation claims under the FCA. The parties settled the qui tam claim, and the district court dismissed the retaliation claim because the Marine Corps—not the school board—was responsible for the terms and conditions of Bias's employment, including his compensation.

The Fifth Circuit looked to the 2009 FCA amendments, and the addition to Section 3730(h) of "agent" and "contractor" to the existing "employee," as potentially injured parties. 816 F.3d at 323. The court of appeals held that under the amendments there must be an "employer-type relationship" to support a cause of action. *Id.* at 324. "Defendants ... must be those by whom plaintiffs are employed, with whom they contract, or for whom they are agents. In addition, the retaliatory action must be related to 'terms and conditions of *employment*,' or the contract or agency relationship." *Id.* (citations omitted). Though Bias had conceded no contract existed between himself and the school, the Court—looking to the common law definitions of agency and employee—found that Bias had plausibly asserted that an employer-type relationship existed sufficient to avoid dismissal.

Implications for Future FCA Cases

The decision is a reminder that organizations that rely on independent contractors or agents should carefully consider how they handle whistleblower allegations, and should be mindful as to potential liability by plaintiffs whom they do not directly employ.

***Howell v. Town of Ball*, 827 F.3d 515 (5th Cir. 2016), cert. denied, 2017 U.S. LEXIS 732 (Jan. 17, 2017)**

The Fifth Circuit declined to expand the class of defendants in FCA whistleblower retaliation lawsuits beyond the whistleblower's employer to include individuals responsible for the alleged retaliation.

About the Case

Plaintiff Thomas Howell, a police officer, sued the Town of Ball and several individuals, alleging that he was fired because of his assistance to a covert FBI investigation relating to the fraudulent procurement of disaster recovery funds from the Federal Emergency Management Agency (FEMA). Howell had served as a confidential informant, and his participation led to the indictment of several municipal officials, including Ball's mayor and police chief. The new chief of police recommended firing Howell, though a Board of Aldermen formally terminated him.

Howell brought a retaliation suit under 31 U.S.C. § 3730(h), in addition to a section 1983 First Amendment claim, which was dismissed based on qualified immunity. The district court dismissed the

FCA claims against the individual defendants because all parties acknowledged that the Town was Howell's only employer. The Fifth Circuit affirmed, reasoning "that the reference to an 'employer' [in § 3730(h)] was deleted to account for the broadening of the class of FCA plaintiffs to include 'contractors' and 'agents,' not to provide liability for individual, non-employer defendants." 827 F.3d at 530.

Implications for Future FCA Cases

While the Fifth Circuit declined to expand the FCA's retaliation provisions to impose liability against non-employer individuals, it bears noting that in *Bias* (discussed above), the court also recognized that the 2009 amendments allow suits against those with whom the plaintiff has an "employer-*type*" relationship (i.e., as a contractor or agent).

***United States ex rel. Simoneaux v. E.I. duPont de Nemours & Co.*, 843 F.3d 1033 (5th Cir. 2016)**

The Fifth Circuit held that the 2009 amendments to the FCA do not impose reverse false claims liability for contingent penalties or invoices that the government has not yet imposed or asserted.

About the Case

The relator, Jeffrey Simoneaux, sued his former employer, E.I. duPont de Nemours & Company under the reverse-false-claims provision, 31 U.S.C. § 3729(a)(1)(G). Simoneaux alleged that duPont concealed the company's obligation to pay the government by not reporting sulfur dioxide and sulfur trioxide leaks to the EPA as required by Section 8(e) of the Toxic Substances Control Act (TSCA). The TSCA requires chemical manufacturers to notify the EPA when they have "information which reasonably supports the conclusion that [a] substance or mixture presents a substantial risk of injury to health or the environment." 15 U.S.C. § 2607(e). The relator asserted that, because the EPA has authority to assess civil penalties for failing to report such health or environmental risks, duPont's failure to report also constituted a concealment of its obligation to pay fines to the EPA.

DuPont had filed for summary judgment, relying on Fifth Circuit precedent that there is no reverse-false-claims liability with respect to potential or contingent obligations to pay the government fines or penalties which have not yet been levied or assessed. See *United States ex rel. Bain v. Georgia Gulf Corp.*, 386 F.3d 648, 657 (5th Cir. 2004); *United States ex rel. Marcy v. Rowan Cos.*, 520 F.3d 384, 391 (5th Cir. 2008). The district court denied summary judgment, holding that the 2009 FCA amendments abrogated *Marcy* and *Bain*. Under the district court's view of the FCA, as amended, violating a statute that imposes monetary penalties is a basis for reverse-false-claims liability.

31 U.S.C. § 3729(b)(3) defines the term "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." While the district court had relied on the phrase, "whether or not fixed," the Fifth Circuit reversed, holding that "fixed" refers only to the amount of the monetary obligation. 843 F.3d at 1037. The statute's reference to an "established duty," limits its applicability to non-contingent obligations. *Id.* at 1039-40.

Implications for Future FCA Cases

The Fifth Circuit was the first to address reverse-false-claims contingent liabilities under the 2009 amendments to the FCA. The holding allows whistleblowers to file reverse-false-claims *qui tam* actions earlier than they did before 2009 in instances where the dollar value of the fraud is still subject to change, but also sets firm limitation on the scope of substantive liability by ruling out liability for contingent obligations to pay the government.

Sixth Circuit: (1) Damages Calculations; (2) Rule 9(b); (3) Presentment; (4) Scienter

United States ex rel. Wall v. Circle C Construction, LLC, 813 F.3d 616 (6th Cir. 2016)

The Sixth Circuit reversed a district court's award of "taint" damages for wage underpayment to the government, reasoning that the services in question were still usable (and used), and thus, the only actual damages under the FCA stemmed from the underpayment.

About the Case

The defendant, a contractor that built several dozen warehouses at an army base, paid electricians \$9,916 less than the Davis-Bacon wages specified in the contract. 813 F.3d at 617. The government obtained a damages award under the FCA, arguing that all of the electrical work in all of the warehouses was tainted by this underpayment; the district court awarded the government \$763,000. *Id.*

The Sixth Circuit reversed. *Id.* The court explained that the FCA provides for an award of actual damages, which is the difference between what the government bargained for and what the government received. *Id.* at 618. The court further reasoned that the services provided here were not "tainted" or worthless—the government actively uses the warehouses. *Id.* Accordingly, the only actual damages originate from the wage underpayment. *Id.* The court then entered an order awarding only those actual damages (trebled, minus any settlement amount). *Id.*

Implications for Future Cases

This case underscores that FCA damages are based on actual damages to the government and should not reflect the full value of the contract where the government obtained and used the goods that were provided.

United States ex rel. Sheldon v. Kettering Health Network, 816 F.3d 399 (6th Cir. 2016)

The Sixth Circuit dismissed the relator's suit for failure to state a claim, finding that individual data breaches did not themselves reflect noncompliance with the Health Information Technology for Economic and Clinical Health Act (HITECH Act).

About the Case

The relator alleged that the defendant, a network of hospitals, medical facilities and physicians, had submitted certifications to the government confirming compliance with the HITECH Act, even though there had been individual breaches of the defendant's data security. 816 F.3d at 405. The relator also alleged that the defendant had not used a certain brand of software to run security reports, which also violated the HITECH Act, and thus resulted in false claims for payment. *Id.* The district court dismissed her claims, and the Sixth Circuit affirmed. *Id.* at 407, 409.

First, with respect to the individual breaches, the Sixth Circuit concluded that the individual breaches identified by the relator did not reflect noncompliance with the HITECH Act. *Id.* at 410. Instead, the court pointed out that her own allegations showed that the defendant *did* have those policies and procedures, as the defendant had informed the relator when there were breaches of her data and told her that it would be investigating pursuant to its policies and procedures. *Id.* With respect to the software, the Court held that neither the HITECH Act nor HIPAA requires providers to use a brand of data security software. *Id.* at 411.

Notably, the Sixth Circuit also found that the relator had failed to allege that the defendant had submitted a false claim for payment. *Id.* at 413. The Court considered whether to relax this presentment requirement for the relator based on her personal knowledge of the defendant's billing procedures, but ultimately decided not to do so, noting that she did not claim that she worked in the security or billing departments,

nor that she had ever spoken with those directly responsible for the HITECH Act certification. *Id.* at 413-14.

Implications for Future Cases

This case illustrates the intersection between cases involving data breaches, cybersecurity policies and the FCA. This case, along with the *Prather* case discussed below, also illustrates the circumstances under which the Sixth Circuit will relax pleading standards for presentment (and when it will not).

United States ex rel. Prather v. Brookdale Senior Living Communities, 838 F.3d 750 (6th Cir. 2016)

The Sixth Circuit affirmed in part and reversed in part the dismissal of a relator's claim that a home-health agency had submitted false claims to Medicare. In doing so, the court, for the first time, applied a relaxed pleading standard to the presentment requirement of the FCA, finding that the relator's personal knowledge and pleaded facts supported an inference of presentment even without specific evidence.

About the Case

The relator brought an FCA suit against a home-healthcare agency, alleging that the operator had submitted false Medicare claims knowing that those claims did not comply with Medicare regulations because they included physician certifications of the patient's need for home-health services that had been completed well after the care had been provided. 838 F.3d 754. The United States declined to intervene, and the district court dismissed the relator's claims for failure to adequately plead presentment. *Id.* at 755. The Sixth Circuit reversed in part. *Id.*

After finding that Medicare does require the certifications to be completed before treatment unless there are justifiable reasons for doing so afterwards, the Sixth Circuit held that the relator had sufficiently pleaded presentment. *Id.* at 771. The Sixth Circuit explained that the requirement that a relator identify an actual false claim may be relaxed in circumstances where the relator pleads facts supporting a strong inference that the claim was submitted—the first time it had applied this relaxed standard. *Id.* at 769. The Sixth Circuit held that the relator's detailed knowledge of the billing and treatment documentation related to the submission of requests for final payment supported the inference necessary to satisfy the relaxed standard. *Id.* at 770.

The Court did, however, affirm the district court's dismissal of the relator's false records claim, as the relator had not pleaded with particularity that any diagnosis or treatment submitted to the government was actually false. *Id.* at 774.

Implications for Future Cases

Prather is the first case in which the Sixth Circuit has applied the relaxed pleading standard for relators who do not allege specific facts of presentment, but whose personal knowledge may support such an inference.

United States ex rel. Harper v. Muskingum Watershed Conservancy, 842 F.3d 430 (6th Cir. 2016)

The Sixth Circuit affirmed dismissal of the relators' claims under the reverse-false-claim and conversion provisions of the FCA, ruling that the relators had failed to allege scienter required under the FCA as amended by FERA.

About the Case

The relators alleged that the defendant watershed conservancy district's sale of rights to conduct hydraulic fracturing operations on a parcel of land represented an "attempt to alienate" the land that triggered a reverter clause in the deed or, in the alternative, that the land was no longer being used for

“recreation, conservation, and reservoir development” as the deed required. 842 F.3d 434. Accordingly, the relators alleged that district was improperly in possession of US property and filed a suit under the FCA’s reverse-false-claim and conversion provisions. *Id.* The district court dismissed the claims. *Id.*

With respect to the reverse-false-claim provision, the Sixth Circuit affirmed on the ground that the relators failed to adequately allege scienter. *Id.* at 437-38. The Sixth Circuit identified the changes to the “knowledge” requirement of the FCA in FERA, and interpreted the new language to mean that, unless the circumstances of a case show that a defendant knows of, or “acts in deliberate ignorance” or “reckless disregard” of, the fact that she is involved in conduct that violates a legal obligation to the United States, the defendant cannot be held liable under the reverse-false-claim provision of FCA. *Id.* at 437. Because the relators’ complaints did not allege whether or how district knew or should have known that it was in violation of the deed restrictions, the Court affirmed the dismissal of their complaint. *Id.* at 438.

With respect to the conversion provision, the Sixth Circuit affirmed, also on scienter grounds. *Id.* at 439. The district court had previously held that breach of contract, without evidence of fraud, falls short of an FCA claim, but the Sixth Circuit noted that FERA also amended the conversion provision, replacing the “intent to defraud” language with a knowledge requirement. *Id.* Nonetheless, the Court again found that the relators did not show whether or how the district knew or should have known that it was in violation of the deed restrictions, and dismissed the claim. *Id.*

Implications for Future Cases

This case provides a possible roadmap for how courts will interpret the new scienter requirements for the reverse-false-claim and conversion provisions of the FCA, as amended by FERA, which had not previously been interpreted by any circuit court.

Seventh Circuit: (1) Original Source Exception; (2) Public Disclosure Bar; (3) Private-Entity Intermediaries; (4) Rule 9(b) – Claims Based on Lack of Medical Necessity; (5) Retaliation; (6) Implied Certification

***United States ex rel. Bogina III v. Medline Industries, Inc.*, 809 F.3d 365 (7th Cir. 2016)**

The Seventh Circuit affirmed the dismissal of the relator’s claims based on the public disclosure bar. In doing so, the panel applied the 2010 amendment to the public disclosure bar “original source” exception retroactively, diverging from other circuits that have applied the pre-2010 exception to pre-2010 conduct.

About the Case

The relator alleged that, from 2003-2009, a seller of medical equipment had given bribes and kickbacks to a nursing home in exchange for purchasing the medical equipment. 809 F.3d at 367. The defendant had been sued before for engaging in such conduct to hospitals, though not to nursing homes. The United States declined to intervene in this suit, and the district court dismissed the federal claims as being too similar to those in the prior suit. *Id.*

The Seventh Circuit determined that the information underlying the allegations had already been publicly disclosed in the prior suit, as the “differences between the two suits [were] unimpressive.” *Id.* at 370. The Seventh Circuit reasoned that the government was already on notice (and had reached a settlement) concerning the bribes and kickbacks to hospitals, as well as the sales to nursing homes, so the government knew about the possibility that the bribes and kickbacks had been provided to nursing homes as well. *Id.*

The Seventh Circuit rejected the relator’s claim that he was the “original source” of the information. The Court explained that the 2010 amendments require an original source to be “an individual who . . . has knowledge that is independent of and materially adds to the publicly disclosed allegations . . . and who has voluntarily provided the information to the Government” *Id.* at 368. The Seventh Circuit reasoned

that the Supreme Court’s footnote in *Graham County Soil & Water Conservation District v. United States ex rel. Wilson*, 559 U.S. 280, 283 n.1 (2010), which cautioned that the 2010 amendment to the public disclosure bar was not retroactive, only applied to a substantive change in 31 U.S.C. § 3730(e)(4)(A), not the clarifying provision in 31 U.S.C. § 3730(e)(4)(B). *Id.* at 369. In applying this original source provision retroactively, the court determined that the relator had not “materially add[ed]” to publicly disclosed allegations against the medical equipment supplier. *Id.* at 370.

Implications for Future Cases

Other circuits have interpreted the 2010 changes to the public disclosure bar to not be retroactive, and have not distinguished between the substantive change to the public disclosure bar and the “original source” exception. This decision creates a new circuit split on the approach to assessing pre-2010 conduct under this exception.

***Cause of Action v. Chicago Transit Authority*, 815 F.3d 267 (7th Cir.), cert. denied, 137 S. Ct. 205 (2016)**

The Seventh Circuit affirmed the dismissal of the relator’s claims under the public disclosure bar, but acknowledged a willingness to reconsider its minority definition of “public domain” from its prior *Bank of Farmington* decision.

About the Case

The relator, a nonprofit government watchdog, alleged that the defendant had been misreporting transit data to the Federal Transit Administration to obtain inflated federal grants. 815 F.3d at 269. The United States declined to intervene, and the district court dismissed the claims under the public disclosure bar. *Id.*

The Seventh Circuit affirmed. First, the Seventh Circuit acknowledged that it has previously held in *United States v. Bank of Farmington*, 166 F.3d 853 (7th Cir. 1999) that, in determining whether a disclosure was “in the public domain” for purposes of the public disclosure bar, facts held in the government’s possession are considered to be in the public domain, even if they were not disclosed outside of the government. *Id.* at 274-75. Several other circuits have criticized this view and declined to adopt it, and the court acknowledged that, were the facts in this case held only by the government, there would be grounds for “in-depth reconsideration of our precedent.” *Id.* at 277. Here, however, the Illinois Attorney General had released an audit report of the defendant’s operations, so the facts were in the public domain regardless of which standard was applied—and the disclosures were sufficient to warrant application of the bar. *Id.* at 277, 280-82.

Implications for Future Cases

The case indicates that the Seventh Circuit’s minority view on whether disclosures within the government are sufficient to trigger the public disclosure bar is poised for reconsideration.

***United States ex rel. Garbe v. Kmart Corp.*, 824 F.3d 632 (7th Cir. 2016), cert. denied, 2017 WL 69207 (Jan. 9, 2017)**

The Seventh Circuit construed the amendments to the presentment requirements under FERA to allow suits to go forward against intermediaries or private entities that administer government programs or use government funds (even if they have not directly sought payment from the government).

About the Case

The relator, a pharmacist who had worked for Kmart, brought a qui tam action claiming that Kmart routinely charged customers with insurance higher prices than customers who paid out of pocket. 824

F.3d at 634. The government declined to intervene, and the district court granted partial summary judgment to the relator on some issues, while denying Kmart's summary judgment motion on others. *Id.* at 635.

The Seventh Circuit first held that the FERA amendments to the FCA were retroactive. *Id.* at 637. The court explained that FERA eliminated the presentment requirement of the FCA; instead, the relator is only required to demonstrate that the entity (public or private) was implementing a government program or using government funds. *Id.* at 638. The Seventh Circuit reasoned that Congress's intent was to apply FERA to all cases under the FCA (rather than all claims for payment) pending after June 7, 2008. *Id.* at 637. As a result, the court affirmed the district court's ruling that the relator's claims did not need to meet the presentment requirement pre-FERA.

The Seventh Circuit also rejected Kmart's contention that individuals who join its discount program are not members of the "general public" and therefore not subject to its "usual and customary" pricing. *Id.* at 643. The court reasoned that Kmart's reading would insulate high "usual and customary" prices from the FCA and undermine the regulatory structure. *Id.* at 645.

Implications for Future Cases

This decision brings intermediaries and private entities that use government funds or implement government programs within the reach of the FCA, possibly resulting in a significant expansion of FCA liability.

United States ex rel. Presser v. Acacia Mental Health Clinic, LLC, 836 F.3d 770 (7th Cir. 2016)

The Seventh Circuit affirmed the district court's dismissal of the relator's claims for failure to plead fraud with particularity under FRCP 9(b). The Court held that the relators must plead "context," such as external or objective standards, when asserting that federal programs were billed for unnecessary procedures.

About the Case

The relator, a nurse and nurse practitioner, alleged that a health clinic had engaged in procedures and policies that she believed were medically unnecessary, including recommending certain patients for psychotherapy who were allegedly inappropriate candidates and requiring urine drug screenings for each visit. 836 F.3d at 773-74. The United States declined to intervene, and the district court dismissed the suit for failure to plead fraud with particularity because the relator had failed to identify to whom the bills were presented. *Id.* at 775.

The Seventh Circuit affirmed with respect to all but one claim, but on different grounds. First, the court held that a plaintiff is not required to present allegations about a document or bill that was submitted to the government. *Id.* at 777. The Court explained that allegations the defendant had patients on Medicare was enough to draw a reasonable inference that Medicare was billed for these services. *Id.* at 778.

The Seventh Circuit then provided additional guideposts for interpreting FRCP 9(b) in the context of claims based on a lack of medical necessity. The Court stated that the relator had failed to provide "medical, technical, or scientific context which would enable a reader of the complaint to understand why [the defendant's] alleged actions amount to unnecessary care forbidden by the statute." *Id.* at 779. The Seventh Circuit further explained that the relator's complaint failed to compare the defendant's policies to other clinics or provide an explanation as to why the practices involved were "unusual." *Id.* at 780. Accordingly, the Court refused to give deference to the relator's subjective assessment of the medical necessity of the procedures, and dismissed under FRCP 9(b) all claims except the one that involved an expressly false statement. *Id.* at 781.

Implications for Future Cases

This is one of the Seventh Circuit's first cases since the Supreme Court's *Escobar* decision, and sets a high bar for claims based on an alleged lack of medical necessity.

***United States ex rel. Uhlig v. Fluor Corp.*, 839 F.3d 628 (7th Cir. 2016)**

The Seventh Circuit affirmed the district court's dismissal of the relator's qui tam and retaliation claims under the FCA. The panel held that whether the relator was engaging in protected conduct, as assessed for purposes of retaliation claims, contains a subjective and objective component, and the relator was unable to demonstrate that he had an objectively reasonable belief that the defendant was defrauding the government.

About the Case

The relator, an electrician working for military contractors in Afghanistan, alleged the defendants were using unlicensed electricians in violation of compliance requirements. 839 F.3d at 632. The relator was scheduled to be terminated because he could not obtain an electrician's license, but because he was fired after he sent an email to a human resources supervisor voicing these concerns, he also alleged retaliation under the FCA. *Id.* at 633. The United States declined to intervene, and the district court granted the defendants' motion for summary judgment. *Id.*

The Seventh Circuit affirmed. First, the Court rejected the claim that the defendant had submitted a false claim because the relevant contract did not require that electricians be licensed. *Id.* at 634. The Seventh Circuit then rejected the relator's retaliation claim. The Court explained that, a relator must prove that he was engaged in protected conduct and was fired because of that conduct. *Id.* at 635. "Protected conduct" is assessed both subjectively and objectively — the relator must show that he had a good faith *and* reasonable belief that the employer was committing fraud against the government. *Id.* Because the relator had not read the contracts, he could not have a reasonable belief regarding whether the defendant had to use licensed electricians, and therefore his retaliation claims failed on the objective component. *Id.*

Implications for Future Cases

This case not only illustrates the application of the objective element for purposes of retaliation claims, but shows that this requirement ensures that courts will continue to be reluctant to find a retaliation claim without an underlying FCA violation.

***United States v. Sanford-Brown, Ltd.*, 840 F.3d 445 (7th Cir. 2016)**

The Seventh Circuit, which had previously rejected the theory of "implied certification" in this case, reconsidered its decision in light of *Escobar*. The court still dismissed the relator's claim, finding that the relator had failed to meet the standards for implied certification from *Escobar* and also failed on materiality grounds.

About the Case

The relator alleged that a for-profit educational institution violated the FCA through its noncompliance with numerous federal regulations that it was obligated to follow under its agreement with the US Secretary of Education. 840 F.3d at 447. The United States declined to intervene, the district court then granted summary judgment to the defendants, and the Seventh Circuit affirmed, rejecting the theory of implied certification. *Id.*

In light of the *Escobar* decision recognizing implied certification, the Seventh Circuit reconsidered its decision on remand, but still rejected the relator's claim. *Id.* The Seventh Circuit found that the relator had not demonstrated that the defendant had made specific representations about the goods or services

provided, nor were those representations false or misleading, as required under *Escobar* for an implied certification theory to proceed. *Id.* Moreover, the court found that the relator's claims failed on materiality grounds, as he had offered no evidence that the government would not have paid had it known about the defendant's noncompliance. *Id.* at 447-48. Accordingly, the Seventh Circuit once again affirmed the district court's dismissal. *Id.*

Implications for Future Cases

This case is a helpful reminder that the materiality requirement under the FCA remains rigorous and provides a means of disposing of cases even under an implied certification theory recognized by the Supreme Court in *Escobar*.

Eighth Circuit: (1) Rule 9(b) and Reverse False Claims; (2) Materiality; (3) Scienter and Ambiguous Legal Requirements

***Olson v. Fairview Health Services of Minnesota*, 831 F.3d 1063 (8th Cir. 2016)**

The Eighth Circuit held that Rule 9(b)'s heightened pleading standards apply to "reverse false claims" under 31 U.S.C. § 3729(a)(1)(G).

About the Case

A hospital submitted a reimbursement claim to the Minnesota Department of Human Services (MDHS) for one of its departments, which it characterized as a "children's hospital" so as to qualify for an exemption from certain otherwise applicable reductions. *Id.* at 1066-67. MDHS concluded the department was not a "children's hospital" and issued a notice of recovery. *Id.* at 1074. The relator filed suit against the hospital's operator alleging that it was liable for "reverse" false claims under 31 U.S.C. § 3729(a)(1)(G), which provides recovery from someone who "knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government."

Relying on the Supreme Court's *Escobar* decision, the Eighth Circuit held that to "knowingly conceal[] an obligation to pay money to the government" is "equivalent to a misrepresentation," and is therefore "fraudulent conduct to which Rule 9(b)'s pleading requirements apply." 831 F.3d at 1074.

Implications for Future FCA Cases

While some other circuits have not yet addressed this issue, in the Eighth Circuit, reverse false claims must be pled with particularity.

***United States ex rel. Miller v. Weston Educational, Inc.*, 840 F.3d 494 (8th Cir. 2016)**

The Eighth Circuit held that the "materiality" element of an FCA violation requires a factual determination as to whether the government's payment decision was, in fact, affected by the allegedly false statement in question.

About the Case

A for-profit college altered grade and attendance records required to be maintained as part of a Department of Education Title IV program. *Id.* at 498. The Supreme Court vacated a prior Eighth Circuit judgment for further consideration in light of the *Escobar* decision. On remand, the Eighth Circuit held that "a false promise to comply with express conditions is material if it would affect a reasonable government funding decision or if the defendant had reason to know it would affect a government funding decision." *Id.* at 503, citing *Universal Health Services v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2002-03 (2016). Here, the government expressly conditioned the college's Title IV participation on compliance with the recordkeeping requirement, and the Eighth Circuit reasoned that "[a] reasonable person would attach

importance to a promise to do what is necessary to ensure funds go where they are supposed to go.” *Id.* at 504. The court noted that the government’s decision to expressly identify a provision as a condition of payment is relevant to, but not automatically dispositive of, materiality. *Id.* at 503-04. The court reversed summary judgment for the defendant college and ordered further factual findings on materiality in light of the articulated standard.

Implications for Future FCA Cases

In the Eighth Circuit, “materiality” is generally a fact-intensive inquiry into whether an allegedly false statement affected the government’s decision to make payment.

United States ex rel. Donegan v. Anesthesia Associates of Kansas City, PC, 833 F.3d 874 (8th Cir. 2016)

The Eighth Circuit held that a defendant’s reasonable interpretation of an ambiguous statute precludes a finding that it knowingly submitted a false claim.

About the Case

Relator claimed that his former employer submitted Medicare reimbursement claims for “medical direction,” even though the anesthesiologist was not present during patients’ “emergence” from anesthesia, as required by Medicare regulations governing reimbursement. *Id.* at 876-77.

Affirming summary judgment for the defendant, the Eighth Circuit noted that “emergence” is an ambiguous term not defined by the regulation and that the relator had submitted no evidence that “the government had warned [defendant] that the agency interpreted [“emergence”] differently.” *Id.* at 879-80. The Eighth Circuit thus held that a defendant’s “reasonable interpretation of [an] ambiguous regulation precludes a finding that it *knowingly* submitted false or fraudulent claims, even if [the government] or a reviewing court would interpret the regulation differently.” *Id.* at 879.

Implications for Future FCA Cases

The case adds to the existing authority supporting the proposition that a defendant who reasonably interprets an ambiguous legal requirement—absent contrary, contemporaneous guidance from the government—lacks the requisite scienter to support FCA liability.

Ninth Circuit: (1) Liability Arising from Retrospective Review Initiated by Defendant; (2) Substantial Similarity Under the Public Disclosure Bar; (3) Certifications to Fannie Mae and Freddie Mac

United States v. United Healthcare Ins. Co., No. 13-56746, 2016 WL 7378731 (9th Cir. Dec. 16, 2016)

The Ninth Circuit recognized a new theory of liability for false certification claims: Where an organization undertakes a retrospective review of data submitted in support of claims for reimbursement, it must correct for all errors, not only ones in the organization’s favor, or it cannot certify the accuracy, completeness or truthfulness of the data.

About the Case

Under the Medicare Advantage program, participants are reimbursed on the basis of “diagnosis codes” they submit for each of their patients to the CMS. This submission must be certified to be “accurate, complete, and truthful.”

The defendants conducted a retrospective review of patients’ medical records to ensure the accuracy of diagnosis codes reported to CMS. The relator alleged the reviews were designed to identify only

“underreporting errors”—that is, to find diagnosis codes supported by a patient’s medical records but not previously submitted to CMS—but they did not identify “overreporting” errors of which the defendants were independently aware. *Id.* at *10.

The Ninth Circuit held that the defendants could not design their reviews in a one-sided manner to avoid identifying “overreporting” errors, explaining that the FCA does not permit a defendant to “bur[y] his head in the sand” and that once a review is undertaken it must adjust for all errors before the defendant could certify to the accuracy, completeness, and truthfulness of data submitted to CMS. *Id.* at *9.

Implications for Future FCA Cases

Although the Ninth Circuit did not suggest that one-sided retrospective reviews necessarily result in false certifications, the decision potentially creates a new rule for Medicare Advantage organizations that elect to conduct retrospective data reviews. This is noteworthy given that CMS proposed in 2014—but declined to finalize—its own rule that would have prohibited one-sided retrospective reviews. Organizations should evaluate carefully whether the benefits of conducting a retrospective review are worth the costs, given that they must now attempt to identify both overreporting and underreporting errors to avoid FCA liability.

United States ex rel. Mateski v. Raytheon, 816 F.3d 565 (9th Cir. 2016)

The Ninth Circuit held that specific allegations of fraudulent activity are not “substantially similar” to more general allegations already in the public domain for purposes of the FCA’s public disclosure bar.

About the Case

The relator was an engineer working on one component of a satellite construction project. The project was the subject of public criticism and reports by the Government Accountability Office and Office of Inspector General. The relator alleged that Raytheon built components using prohibited materials and forged approvals for these actions. These details were not included in the GAO or OIG reports. *Id.* at 568, 578.

Adopting Seventh Circuit precedent, the Ninth Circuit held that a relator can overcome the public disclosure bar by alleging specific details of a fraud even if there is public information generally describing “problems” or otherwise alluding to general instances of fraud on the same project at issue in the relator’s suit. The Ninth Circuit explained that construing the public disclosure bar more broadly would deprive the government of information that could lead to recovery of defrauded funds. *Id.* at 577-78.

Implications for Future FCA Cases

The Ninth Circuit’s decision provides a path for relators to overcome the public disclosure bar. Even where there are publicly known allegations about general fraudulent activity or specific activity on a portion of a project, relators will be able to pursue false claims allegations related to other portions of the project where they can allege specific details that go beyond general disclosures in the public domain.

United States ex rel. Adams v. Aurora Loan Servs., 813 F.3d 1259 (9th Cir. 2016)

The court held that personnel at Fannie Mae and Freddie Mac are not “officer[s], employee[s] or agent[s] of the United States” and thus cannot be presented with a false claim under 31 U.S.C. 3729(b)(2)(A)(i). *Id.* at 1260.

About the Case

The relators alleged that various lenders and loan servicers falsely certified that they sold loans to Fannie Mae and Freddie Mac that were free of homeowner association liens and charges. *Id.* The Ninth Circuit ruled that Fannie Mae and Freddie Mac are private companies, even though they are chartered by the

federal government. *Id.* The court also determined that the federal government’s conservatorship of Fannie Mae and Freddie Mac did not transform the companies into federal instrumentalities, reasoning that, while the government could step into the shoes of Fannie Mae and Freddie Mac, the reverse was not true. *Id.* at 1261.

The Court specified that it was not determining whether the action could proceed under a neighboring subsection in the statute—31 U.S.C. § 3729(b)(2)(A)(ii)—which defines a claim as a “request or demand made upon non-governmental third parties.” The relator had not brought this claim in his complaint. *Id.*

Implications for Future FCA Cases

Whether statements made to government-sponsored enterprises are subject to FCA liability is a developing area of the law. The Ninth Circuit’s decision is a narrow one, but stands for the proposition that claims presented to such enterprises do not give rise to liability under § 3729(b)(2)(A)(i). It does not speak to whether actions may be brought under § 3729(b)(2)(A)(ii), which thus remains as a potential source of liability.

Tenth Circuit: Materiality

***United States ex rel. Thomas v. Black & Veatch Special Projects Corp.*, 820 F.3d 1162 (10th Cir. 2016).**

The Tenth Circuit held that “materiality” for the purpose of an implied false certification claim can be established if the defendant violated contractual provisions in a manner that “undercut the purpose of the contract[],” or violated the contract in such a way that “may have persuaded the government not to pay the defendant.” 820 F.3d at 1171.

About the Case

The relators alleged that their employer altered documents to obtain visas and work permits from the Afghan government, and then falsely certified to US Agency for International Development (USAID) that it had complied with the relevant contract to supply electrical power to Afghanistan. USAID knew the defendant company had altered documents, but paid the company anyway. The Tenth Circuit affirmed summary judgment for the defendant—explaining that, even if the company altered the documents in violation of the contract, “the undisputed facts show that the violation was not material to USAID’s payment decisions.” *Id.* 1172-73.

The Tenth Circuit held that a relator “may establish materiality by demonstrating that the defendant violated a contractual or regulatory provision that ‘undercut the purpose of the contract[].’” *Id.* at 1171. Importantly, the Court held that the government’s actions after learning of the violation are relevant to this analysis. Here, USAID knew that the company “had submitted altered documents,” but “did not withhold or suspend payment pending the outcome of the investigations of the altered documents,” nor did it “reserve any rights while attempting to confirm the truth of Relators’ allegations.” *Id.* at 1174. Accordingly, the government’s payment decisions demonstrated that this contractual violation was not material.

Implications for Future FCA Cases

Government knowledge is relevant to various potential defenses against an FCA action. This case demonstrates that government action is relevant to a materiality analysis where a defendant is accused of falsely certifying compliance with contractual provisions, especially where the government pays the contractor despite knowledge that the contractual provision was breached.

Eleventh Circuit: Knowledge Requirement to Qualify as Original Source

***United States ex rel. Saldivar v. Fresenius Med. Care Holdings, Inc.*, 841 F.3d 927 (11th Cir. 2016)**

The Eleventh Circuit narrowly construed for the requirement that an original source have “direct and independent” knowledge of fraud to mean that the relator must be involved in submitting fraudulent claims for reimbursement.

About the Case

The relator alleged the defendant’s practice of administering surplus drugs obtained at no charge—known as “overfill”—and seeking reimbursement for their use in treating Medicare patients violated the FCA. These billing practices were publicly known, as defendant had previously disclosed its practice of billing for overfill to the Office of Inspector General and the Securities and Exchange Commission. *Id.* at 931.

In conducting its original source analysis, the Eleventh Circuit looked to the Seventh Circuit for guidance, and found that relators who had direct and independent knowledge of a defendant’s billing practices were original sources, as distinguished from relators who merely had knowledge of the treatments the defendant administered. *Id.* at 936. The Court thus found that the relator did not qualify as an original source because he only handled the inventory of overfill drugs for the defendant and did not participate in any activities related to billing for those drugs. *Id.* at 936-37.

Implications for Future FCA Cases

This case limits the universe of relators who might qualify as an original source for claims of billing fraud to individuals with personal knowledge of billing activities.

FEDERAL SETTLEMENTS, INTERVENTIONS AND COMPLAINTS

➤ Healthcare and Pharmaceuticals

Healthcare and Pharmaceuticals Settlements

- **Pfizer, Inc.:** In April, DOJ announced that Pfizer and Wyeth agreed to pay \$784.6 million to resolve allegations that the company overcharged Medicaid for the heartburn drug Protonix by not offering the government discounts that were made available to other parties in violation of Medicaid's "best price" rules.³⁷ The settlement resolves two qui tam actions filed in the District of Massachusetts.³⁸
- **Olympus Corporation of the Americas:** In March, DOJ announced that Olympus Corporation of the Americas agreed to pay \$646 million to resolve FCA and criminal allegations that Olympus provided kickbacks to hospitals and doctors to induce purchases of its products.³⁹ The FCA portion of the settlement totaled \$310.8 million and resolved allegations in a qui tam action in the District of New Jersey. The criminal portion, which was negotiated by the US Attorney's Office for the District of New Jersey, totaled \$312.4 million for Anti-Kickback Statute violations and \$22.8 million for Foreign Corrupt Practices Act violations.⁴⁰ As part of the criminal resolution, the company will enter into a three-year Deferred Prosecution Agreement with DOJ. Olympus also entered a separate five-year Corporate Integrity Agreement (CIA) with HHS OIG.⁴¹
- **Tenet Healthcare Corporation:** In October, DOJ announced that Tenet Healthcare Corp. and its subsidiaries agreed to pay \$513 million to resolve civil and criminal allegations related to prenatal clinics and Medicare's Disproportionate Share Hospital program.⁴²
- **Shire Pharmaceuticals PLC:** In August, biotech company Shire announced in its 8-K filing that it agreed in principle to pay \$350 million to resolve FCA allegations regarding marketing of the skin substitute Dermagraft.⁴³ A formal settlement has not yet been announced.
- **Life Care Centers of America:** In October, Life Care Centers of America and its owner agreed to pay \$145 million to resolve FCA allegations that the company recorded patients in the highest reimbursement category irrespective of condition and provided unnecessary treatment.⁴⁴ The settlement resolves two qui tam actions filed in the Eastern District of Tennessee as well as a separate unjust enrichment claim action by DOJ against the company's sole shareholder.⁴⁵ The claims resolved by the settlement were allegations only, and there was no determination of liability.
- **Kindred Healthcare Inc., RehabCare Group Inc. and RehabCare Group East Inc.:** In January, DOJ announced that Kindred/RehabCare agreed to pay \$125 million to resolve FCA allegations that the company submitted false claims to Medicare for unnecessary, unreasonable, and nonexistent rehabilitation therapy services.⁴⁶ The settlement resolves a qui tam action filed in the District of Massachusetts. The claims resolved by the settlement were allegations only, and there was no determination of liability.
- In June, DOJ announced that a pharmaceutical company agreed to pay \$67 million to resolve FCA allegations that the company made misleading statements about a cancer drug.⁴⁷ The settlement resolves a qui tam action filed in the Northern District of California. The claims resolved by the settlement were allegations only, and there was no determination of liability.
- **Salix Pharmaceuticals, Inc.:** In June, DOJ announced that Salix Pharmaceuticals agreed to pay \$54 million to resolve FCA allegations that the company used speaker programs to provide kickbacks in return for prescriptions of Salix products.⁴⁸ The settlement resolves two qui tam actions filed in the Southern District of New York.

- **CenterLight Healthcare, Inc. and CenterLight Health System, Inc. (collectively CenterLight):** In January, DOJ announced that CenterLight agreed to pay \$46.7 million to resolve FCA allegations that the company marketed to and enrolled ineligible individuals in its long-term healthcare plans.⁴⁹ The settlement resolves a qui tam action filed in the Southern District of New York.
- **Forest Laboratories LLC and Forest Pharmaceuticals Inc.:** In December, DOJ announced that Forest Laboratories, a subsidiary of Allergan, and its subsidiary Forest Pharmaceuticals Inc., agreed to pay \$38 million to resolve FCA allegations that the company provided kickbacks in the form of meals and money to doctors in connection with the drugs Bystolic, Savella and Namenda.⁵⁰ The settlement resolves a qui tam action filed in the Eastern District of Wisconsin. The claims resolved by the settlement were allegations only, and there was no determination of liability.
- **Biocompatibles Inc.:** In November, DOJ announced that medical device manufacturer Biocompatibles, a subsidiary of BTG plc, pleaded guilty to misbranding a liver cancer treatment device and agreed to pay over \$36 million to resolve civil and criminal allegations arising out of that conduct. In the civil portion, Biocompatibles agreed to pay \$25 million to resolve FCA allegations that the company charged government healthcare programs for drug delivery procedures that lacked FDA approval. The settlement resolves a qui tam action filed in the Western District of Texas. In the criminal matter, Biocompatibles pleaded guilty to a misdemeanor in violation of the Food, Drug, and Cosmetic Act. The company will pay an \$8.75 million criminal fine and a \$2.25 million criminal forfeiture.⁵¹ The claims resolved by the civil settlement are allegations only, and there has been no determination of liability.
- **21st Century Oncology Inc.:** In March, DOJ announced that the cancer clinics chain 21st Century Oncology agreed to pay approximately \$35 million to resolve FCA allegations that the company billed Medicare for unreliable radiation measurements made by technology that had not been proven effective and on which staff had not been properly trained.⁵² The settlement resolves a qui tam action filed in the Middle District of Florida. The settlement follows a 2015 FCA settlement in which 21st Century Oncology paid \$19.75 million to resolve allegations of billing federal health care programs for unnecessary urine tests.⁵³ The claims resolved by the settlement were allegations only, and there was no determination of liability.
- **Respironics Inc.:** In March, DOJ announced that Respironics agreed to pay approximately \$35 million to resolve FCA allegations that the company provided free call center services to medical equipment suppliers in return for purchases of the company's sleep apnea masks.⁵⁴ The settlement resolves a qui tam action filed in the District of South Carolina. The claims resolved by the settlement were allegations only, and there was no determination of liability.
- **Novartis AG:** In October, Novartis agreed to pay \$35 million to resolve FCA allegations that the company marketed the eczema cream Elidel for unapproved uses and that the company purchased meals for physicians to induce prescriptions.⁵⁵ The settlement resolves a qui tam action filed in the Eastern District of Pennsylvania. The claims resolved by the settlement were allegations only, and there was no determination of liability.
- **Vibra Healthcare LLC:** In September, DOJ announced that national hospital chain Vibra agreed to pay \$32.7 million to resolve allegations that the rehabilitation and long-term care services provider billed federal healthcare programs for unnecessary services.⁵⁶ Vibra entered into a five-year CIA with HHS OIG as part of the settlement.⁵⁷ The settlement resolves a qui tam action filed in the Southern District of Texas.⁵⁸ The claims resolved by the settlement were allegations only, and there was no determination of liability.
- **Stericycle Inc.:** In February, a federal judge approved a settlement between medical waste disposal company Stericycle, the federal government, 14 states, and the District of Columbia.⁵⁹

Stericycle agreed to pay \$28.5 million to resolve FCA allegations that the company imposed unwarranted increases in long-term, fixed price government contracts. A majority of the settlement resolves state FCA allegations. None of the governments intervened. The settlement resolves a qui tam action filed in the Northern District of Illinois. The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **North American Health Care Inc.:** In September, DOJ announced that nursing facilities provider North American Health Care Inc. agreed to pay \$28.5 million to resolve FCA allegations that the company billed federal healthcare programs for unnecessary rehabilitation therapy services.⁶⁰ The company entered into a five-year CIA with HHS OIG.⁶¹ The company chairman will additionally pay \$1 million, and a senior Vice President will pay \$500,000 to resolve allegations regarding their roles in the activity. The action was brought in the Northern District of California. The claims resolved by the settlement were allegations only, and there was no determination of liability.
- **Omnicare Inc.:** In October, DOJ announced that Omnicare agreed to pay \$28.125 million to resolve FCA allegations that the company solicited and received kickbacks from pharmaceutical manufacturer Abbott Laboratories in return for promoting the epilepsy drug Depakote.⁶² The settlement resolves two qui tam actions filed in the Western District of Virginia. The claims resolved by the settlement were allegations only, and there was no determination of liability.
- **Acclarent Inc.:** In July, DOJ announced that Johnson & Johnson subsidiary Acclarent agreed to pay \$18 million to resolve FCA allegations that the company marketed the sinus-clearing device Stratus for off-label uses.⁶³ The settlement resolves a qui tam action filed in the District of Massachusetts. The claims resolved by the settlement were allegations only, and there was no determination of Acclarent's liability. Two former executives were convicted of misdemeanors related to the off-label promotion.⁶⁴

Healthcare and Pharmaceuticals Interventions and Actions

- **Prime Healthcare Services Inc.:** In May, DOJ intervened in a qui tam action filed in the Central District of California against Prime Healthcare Services Inc. and its CEO.⁶⁵ The government alleged that the company improperly admitted patients, included excess conditions on patient reports, and unnecessarily kept patients in care to increase billing.⁶⁶ The lawsuit contains allegations only, and there has been no determination of liability.
- **Caris Healthcare LP:** In June, DOJ intervened in a qui tam action filed in the Eastern District of Tennessee against Caris Healthcare. The government alleged that the company billed Medicare for hospice care of patients not eligible for such care.⁶⁷ The lawsuit contains allegations only, and there has been no determination of liability.
- **Vanguard Healthcare LLC:** In September, DOJ announced an FCA action in the Middle District of Tennessee against six facilities of now bankrupt Vanguard Healthcare LLC as well as Vanguard's director of operations. The government alleged that Vanguard billed federal healthcare programs for non-existent or substandard care and forged signatures on preadmission forms.⁶⁸ The lawsuit contains allegations only, and there has been no determination of liability.

➤ **Procurement and Grants**

Procurement and Grants Settlements

- DOJ announced in November that two large construction companies agreed to pay \$125 million to resolve allegations that they made false statements and claims to the Department of Energy (DOE) by charging DOE for deficient nuclear quality materials, services and testing that was provided at the Waste Treatment Plant (WTP) at DOE's Hanford Site near Richland, Washington.

The settlement also resolves allegations that one of the companies improperly used federal contract funds to pay for lobbying. The allegations arose from a qui tam suit filed by three individuals that worked on the WTP project, whose shares of the settlement have not yet been determined.⁶⁹ The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **Z Gallerie LLC:** DOJ announced in April that Z Gallerie agreed to pay \$15 million to resolve allegations that the company evaded antidumping duties on wooden bedroom furniture imported from the People's Republic of China (PRC) from 2007 to 2014, by misclassifying, or conspiring with others to misclassify, the imported furniture as pieces intended for non-bedroom use. The settlement resolved a qui tam suit brought by an e-commerce furniture retailer. The relator received \$2.4 million from the settlement.⁷⁰ The claims resolved by the settlement were allegations only, and there was no determination of liability.
- **Deloitte Consulting LLP:** In May, DOJ announced a \$11.38 million settlement with Deloitte Consulting to resolve allegations that between 2006 and 2012 Deloitte failed to comply with a price reductions clause of a GSA contract. In 2000, GSA awarded Deloitte a contract to provide information technology services, under which Deloitte was required to reduce the prices it charged the government if it offered lower prices to specific commercial customers. Deloitte's alleged failure to comply with the price reductions clause caused government customers to pay more for Deloitte services than comparable commercial customers.⁷¹ The claims resolved by the settlement were allegations only, and there was no determination of liability.
- In January, DOJ announced that a large construction company agreed to pay \$9 million to resolve allegations that the company concealed that Contrack International Inc. and Misr Sons Development S.A.E. were partners in the venture, thereby preventing USAID from evaluating their qualifications and eligibility, which was a precondition to contract award. The allegations concerned USAID-funded contracts for the construction of water and wastewater infrastructure projects in Egypt in the 1990s.⁷² The claims resolved by the settlement were allegations only, and there was no determination of liability.
- **Kilgore Flares Company and ESM Group Inc.:** In March, DOJ announced that Kilgore Flares and one of its subcontractors, ESM, agreed to pay a total of \$8 million to resolve allegations that from July 2003 through May 2005, ESM knowingly misrepresented the content of ultrafine magnesium powder imported from the PRC in order to avoid paying antidumping duties. The government also alleged that from March 2005 through August 2006, Kilgore used the illegally imported Chinese magnesium powder purchased from ESM in the countermeasure flares it sold to the US Army. The Chinese magnesium powder allegedly violated both the requirement for domestically produced powder and engineering specifications required by the contracts. The relator, Reade Manufacturing Company, received \$400,000 as part of the settlement.⁷³ The claims resolved by the settlement were allegations only, and there was no determination of liability.
- **Centerra Services International Inc.:** In February, DOJ announced that Centerra, formerly known as Wackenhut Services LLC, agreed to pay \$7.4 million to settle allegations that from 2008 to 2010 Wackenhut double billed and inflated labor costs in connection with a contract for firefighting and fire protection services in Iraq. The government alleged that Wackenhut inflated its labor costs by billing the salaries of certain managers as direct costs under the subcontract, when those salaries had already been charged as indirect costs. The government further alleged that Wackenhut artificially inflated its labor rate by counting its costs for holidays, vacation, sick leave, rest and recuperation, and other variable labor costs twice in calculating the rate. The allegations arose from a qui tam suit filed by a whistleblower in the Eastern District of Texas. The relator received a \$1.33 million payment.⁷⁴ The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **En Pointe Gov. Inc., En Pointe Technologies Inc., En Pointe Technologies Sales Inc., Dominguez East Holdings LLC, and Din Global Corp.:** DOJ announced in July that five information technology companies agreed to pay \$5.8 million to resolve allegations that, between 2011 and 2014, the defendants falsely represented that En Pointe Gov. Inc. met Small Business Administration (SBA) requirements to obtain work that was only available to small businesses. In particular, the government alleged that En Pointe Gov. Inc.'s affiliation with the other defendants rendered it a non-small business and, thus, ineligible for the small business set-aside contracts it obtained. The government also alleged that the companies caused En Pointe Gov. Inc. to file false quarterly reports with the GSA between 2008 and 2015 underreporting sales made pursuant to a GSA schedule contract that allowed other federal agencies to purchase from En Pointe. Under the terms of the contract, En Pointe was supposed to return to GSA a percentage of its sales receipts. By allegedly misrepresenting the amount of its sales, En Pointe underpaid the fees that it owed to GSA. The settlement resolved a suit brought by qui tam relators Minburn Technology Group, LLC and its managing member. The relators received \$1.4 million as part of the settlement.⁷⁵ The claims resolved by the settlement were allegations only, and there was no determination of liability.
- **Lockheed Martin Corporation, Lockheed Martin Energy Systems, and Lockheed Martin Utility Services (collectively Lockheed Martin):** In February, DOJ announced a \$5 million settlement with Lockheed Martin to resolve allegations that it had misrepresented its compliance with the Resource Conservation and Recovery Act, which establishes how hazardous wastes must be managed. The government alleged that Lockheed Martin failed to identify and report hazardous waste produced and stored at the Paducah Gaseous Diffusion Plant in Paducah, Kentucky, and failed to properly handle and dispose of the waste. The settlement resolved two suits filed by the Natural Resources Defense Council, Inc. and several former employees of Lockheed Martin. The relators collectively received \$920,000 as part of the settlement.⁷⁶ The claims resolved by the settlement were allegations only, and there was no determination of liability.
- **Hayner Hoyt Corporation:** DOJ announced in March that Hayner Hoyt agreed to pay \$5 million to resolve allegations that its chairman and chief executive officer, president, several employees, and Hayner Hoyt affiliates LeMoyne Interiors and Doyner Inc., participated in a scheme designed to take advantage of the service-disabled veteran-owned small business program to secure government contracts for a now-defunct company, 229 Constructors LLC, that Hayner Hoyt officials created and controlled. Those officials allegedly caused false certifications and statements to be made to the government representing that 229 Constructors met all requirements to be a service-disabled veteran-owned small business when they knew, or should have known, that 229 Constructors did not meet those requirements. The relator received \$875,000 as part of the settlement.⁷⁷ The claims resolved by the settlement were allegations only, and there was no determination of liability.
- **Ameri-Source International Inc., Ameri-Source Specialty Products Inc., Ameri-Source Holdings Inc., Ajay Goel, Thomas Diener, and SMC Machining LLC:** DOJ announced in February that four affiliated Pennsylvania-based companies and two of their owners agreed to pay \$3 million to resolve allegations that they had engaged in a scheme to evade customs duties on imports of small-diameter graphite electrodes from the PRC. The government alleged that the companies evaded antidumping duties on 15 shipments from December 2009 to March 2012. The relator, Graphite Electrode Sales Inc., received \$480,000 as part of the settlement.⁷⁸ The claims resolved by the settlement were allegations only, and there was no determination of liability.
- **ArmorSource, LLC:** DOJ announced in March that ArmorSource agreed to pay \$3 million to resolve allegations that from 2006 to 2009, ArmorSource delivered Advanced Combat Helmets to the Army that were manufactured and tested using methods that did not conform to contract requirements and that failed to meet contract performance standards. The settlement resolved a

suit brought by employees of ArmorSource subcontractor Federal Prison Industries, Inc. The relators received \$450,000 from the settlement.⁷⁹ The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **Novum Structures LLC:** DOJ announced in January that Wisconsin-based Novum agreed to pay \$2.5 million to resolve allegations that it improperly used foreign materials on construction projects involving federal funds from 2004 to 2013, in violation of contractual provisions implementing various domestic preference statutes, often referred to colloquially as the “Buy America” requirements. Novum also agreed not to contest debarment from federally funded projects. The relator received approximately \$400,000 from the settlement.⁸⁰ The claims resolved by the civil settlement were allegations only, and there was no determination of liability.
- **Mountain States Contractors, LLC:** The US Attorney for the Middle District of Tennessee announced in May that Mountain States agreed to pay more than \$2.25 million to settle allegations that Mountain States and its affiliated company, HMA, as the prime contractors on federally funded construction projects, falsely represented that they used Disadvantaged Business Enterprises (DBEs) to perform subcontracted work on the projects. Although Mountain States subcontracted with G&M Associates, a certified DBE, the government alleged that Mountain States improperly “loaned” its employees to G&M to perform the DBE work on the projects and improperly leased equipment to G&M, which the entities then counted against the projects’ DBE goals. The relator received \$500,000 as part of the settlement.⁸¹ The claims resolved by the settlement were allegations only, and there was no determination of liability.
- **Big Brothers Big Sisters of America Corporation (Big Brothers):** DOJ announced in January that Big Brothers agreed to pay \$1.6 million to resolve allegations that it failed to maintain sound accounting and financial management systems in accordance with federal regulations and guidelines designed to ensure that grant funds would be properly accounted for and used only for appropriate purposes. The government alleged that Big Brothers violated those regulations with respect to three grants awarded from 2009 to 2011 by commingling the grant funds with general operating funds, failing to segregate expenditures to ensure that the funds were used as intended, and failing to maintain internal financial controls to safeguard the proper use of those funds. As part of the settlement, Big Brothers agreed to institute a strict compliance program that requires the organization to engage in regular audits, both internally and by independent auditors; establish a compliance team, an employee code of conduct, whistleblower policies, and a disciplinary policy for employees who engage in or fail to disclose abuses of federal grant funds; provide regular employee training on these policies; and employ risk assessment tools to detect abuses that might otherwise go undetected.⁸² The claims resolved by the settlement were allegations only, and there was no determination of liability.
- **Jacintoport International LLC and Seaboard Marine Ltd.:** In August, DOJ announced that Jacintoport and Seaboard Marine agreed to pay \$1.075 million to settle a lawsuit alleging that beginning around January 2008 and continuing through at least October 2009, Jacintoport, under the supervision and control of Seaboard, charged ocean carriers more for loading humanitarian food aid onto ships than permitted for over 50,000 tons of humanitarian food aid. The government alleged that these inflated charges were subsequently lumped into other costs for delivering humanitarian food aid and passed on to the United States. The relator, a shipping contractor who allegedly received an invoice from Jacintoport that contained the excessive charge, received \$215,000 as part of the settlement.⁸³ The claims resolved by the settlement were allegations only, and there was no determination of liability.

Procurement and Grants Interventions

- **Energy & Process Corporation (E&P):** DOJ announced in September that it had intervened in a lawsuit alleging that E&P knowingly failed to perform required quality assurance procedures and supplied defective steel reinforcing bars in connection with a contract to construct a DOE nuclear

waste treatment facility. The suit was filed by a former employee of the prime contractor building the DOE facility.⁸⁴ The complaint contains allegations only, and there has been no determination of liability.

Procurement and Grants Complaints

- **Savannah River Nuclear Solutions LLC and Fluor Federal Services Inc.:** In March, DOJ announced that it filed a complaint against Savannah River and Fluor Federal for allegedly overcharging the DOE under a management and operations contract at the Savannah River Nuclear Site in Aiken, South Carolina.⁸⁵ The complaint contains allegations only, and there has been no determination of liability.
- **DynCorp International Inc.:** DOJ announced in July that it filed a complaint against DynCorp alleging that it knowingly submitted inflated claims in connection with a State Department contract to train Iraqi police forces. The government alleges that DynCorp knowingly allowed one of its main subcontractors to charge excessive and unsubstantiated rates for hotel lodging, translator, security guard, and driving services and overhead expenses, and included these charges in the claims it submitted to the State Department. The complaint also alleges that DynCorp added its own markup to its subcontractor's excessive charges, further inflating the claims it submitted to the government.⁸⁶ The complaint contains allegations only, and there has been no determination of liability.
- **Derish M. Wolff and Salvatore J. Pepe, former CEO and CFO of Louis Berger Group Inc. (LBG):** In July, DOJ announced that it filed suit against Wolff and Pepe for conspiring to overbill the USAID and other government agencies for costs incurred performing reconstruction contracts in Afghanistan, Iraq and other countries. The government alleges that Wolff and Pepe designed and directed various accounting schemes that resulted in LBG billing the government for indirect overhead costs at inflated rates.⁸⁷ The complaint contains allegations only, and there has been no determination of liability.

➤ **Financial Institutions**

DOJ's financial institutions FCA activity in 2016 retained its heavy focus on housing and mortgage fraud. As was the case last year, the vast majority of settlements and interventions in 2016 involved allegations of improperly originated mortgage loans submitted for government insurance under the Department of Housing and Urban Development's (HUD) Direct Endorsement Lender (DEL) program. According to DOJ, it has recovered \$7 billion in housing and mortgage claims from 2009 to the end of fiscal year 2016 (September 30), including this past fiscal year's recoveries of \$1.6 billion.⁸⁸

Financial Institutions Settlements

- **Wells Fargo Bank, N.A.:** On April 8, DOJ announced a \$1.2 billion settlement with Wells Fargo Bank, N.A, and Wells Fargo executive Kurt Lofrano, to resolve allegations that the bank and its affiliates (collectively Wells Fargo) and Lofrano violated the FCA through Wells Fargo's activity as a direct endorsement lender.⁸⁹ The settlement resolved an action filed by the United States in the Southern District of New York in 2012,⁹⁰ a subsequent investigation by the US Attorney's Office for the Southern District of New York, and an investigation by the US Attorney's Office for the Northern District of California. As part of the settlement, Wells Fargo admitted that between 2001 and 2008, it certified loans that did not meet HUD requirements, and that it had identified high numbers of loans with "material" findings (meaning the loan file did not conform to internal or FHA parameters, contained risk factors affecting underwriting, or evidenced misrepresentation).⁹¹ Wells Fargo also admitted that between 2002 and 2010, it self-reported approximately 300 loans to HUD despite identifying thousands of loans with "material" findings.

- On February 5, DOJ announced a joint federal-state settlement with a large financial institution.⁹² The settlement resolved a complaint filed that same day by the United States, 49 states and the District of Columbia, alleging that financial institution had engaged in various kinds of misconduct relating to originations, servicing and foreclosures, and bankruptcy.⁹³ Under the consent judgment, the company agreed to comply with certain servicing standards, pay \$100 million in direct settlement payments, provide \$370 million in consumer relief, and accept appointment of a monitor.⁹⁴ The company did not admit to the allegations in the complaint.
- **Freedom Mortgage Corp.:** On April 15, DOJ announced a \$113 million settlement with Freedom Mortgage Corp. (FMC) to resolve allegations that FMC violated the FCA as a direct endorsement lender.⁹⁵ As part of the settlement, FMC admitted that between 2006 and 2011, FMC endorsed loans that did not meet HUD requirements, failed to perform required quality control reviews, failed to adhere to HUD's self-reporting requirements notwithstanding reviews that revealed significant defect rates, and thereby caused HUD to insure loans it otherwise would not have.⁹⁶
- **Branch Banking & Trust Company:** On September 29, DOJ announced that Branch Banking & Trust Company (BB&T) agreed to pay \$83 million to resolve allegations that BB&T violated the FCA as a direct endorsement lender.⁹⁷ As part of the settlement, BB&T admitted that between 2006 and 2014, it certified mortgage loans for FHA insurance that did not meet HUD underwriting requirements, failed to maintain a quality control program that complied with HUD requirements, and failed to adhere to HUD's self-reporting requirements. The claims resolved by the settlement were allegations only, and there was no determination of liability.
- **M&T Bank Corp.:** On May 13, DOJ announced a \$64 million settlement with M&T Bank Corp. (M&T) to resolve allegations that M&T violated the FCA as a direct endorsement lender.⁹⁸ The settlement arose from a complaint filed by a relator, a former M&T employee, in 2013 in the Western District of New York; the government intervened in part contemporaneously with the settlement.⁹⁹ As part of the settlement, M&T admitted that between 2006 and 2011, it certified certain loans that did not meet HUD requirements, failed to consistently review an adequate sample of FHA loans through its quality control processes, failed to adhere to HUD's self-reporting requirements, and thereby caused HUD to insure loans it otherwise would not have.¹⁰⁰
- **Regions Bank:** On September 13, DOJ announced that Regions Bank (Regions) agreed to pay \$52.4 million to resolve allegations that it violated the FCA as a direct endorsement lender.¹⁰¹ As part of the settlement, Regions admitted that between 2006 and 2011, it certified mortgage loans for FHA insurance that did not meet HUD creditworthiness requirements. Regions also admitted that it failed to maintain a quality control program that complied with HUD requirements, failed to review Early Payment Default loans in accordance with HUD guidelines, and did not adhere to HUD's self-reporting requirements. The claims resolved by the settlement were allegations only, and there was no determination of liability.
- **United Shore Financial Services LLC:** On December 28, DOJ announced that United Shore Financial Services (USFS) agreed to pay \$48 million to resolve allegations that it violated the FCA as a direct endorsement lender.¹⁰² As part of the settlement, USFS admitted that between 2006 and 2011, it improperly pressured underwriters to approve FHA mortgages, used a compensation formula that tied underwriter compensation to the percentage of loans approved and closed, falsely certified that underwriters had personally reviewed appraisal reports prior to the approval and endorsement of FHA-insured mortgage loans, failed to inform senior management of negative quality control findings, and failed to adhere to HUD's self-reporting requirements. DOJ's announcement also noted that, after the United States had commenced its investigation into USFS, the company made discretionary distributions to one of its shareholders.
- **PNC Bank N.A.:** On August 16, DOJ announced that PNC Bank agreed to pay \$9.5 million to resolve allegations that it violated the FCA as a participant in the SBA's Preferred Lenders Program (PLP).¹⁰³ The allegations stemmed from PNC's approval of SBA-guaranteed loans that

were brokered by Jade Capital & Investments LLC, another bank that admitted in separate plea agreements that its employees created false documents to secure PNC's approval. The government represented that it had civil claims against PNC for failing to adhere to requirements as a PLP lender, including demanding adequate bank and IRS tax records from borrowers, ensuring that borrowers had the ability to repay the loans, and failing to apply prudent lending standards. The government also represented that it had civil claims against PNC for seeking payment on SBA guarantees even though PNC should have known that SBA requirements had not been met. The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **Primary Residential Mortgage Inc.:** On October 3, DOJ announced that Primary Residential Mortgage, Inc. (PRMI), a lender based in Salt Lake City, Utah, agreed to pay \$5 million to resolve allegations that it violated the FCA as a direct endorsement lender.¹⁰⁴ As part of the settlement, PRMI admitted that it failed to document assets used to qualify borrowers for FHA mortgage insurance and omitted liabilities owed by borrowers, failed to document income used by borrowers to qualify for FHA mortgage insurance, failed to verify earnest money deposits, and certified loans for borrowers who were delinquent on pre-existing FHA mortgages. The claims resolved by the settlement were allegations only, and there was no determination of liability.
- **SecurityNational Mortgage Company:** On October 3, DOJ announced that SecurityNational Mortgage Company (SecurityNational), another lender based in Salt Lake City, Utah, agreed to pay \$4.25 million to resolve allegations that it violated the FCA as a direct endorsement lender.¹⁰⁵ As part of the settlement, SecurityNational admitted that it endorsed loans for borrowers who were delinquent on federal debt, had unpaid court-ordered judgments, and were delinquent on an underlying mortgage that SecurityNational had refinanced into an FHA loan. SecurityNational also admitted that it endorsed mortgage loan amounts that exceeded HUD's loan-to-value requirements, failed to document income, and failed to analyze borrowers' delinquent credit history. The claims resolved by the settlement were allegations only, and there was no determination of liability.
- **First American Mortgage Trust:** On October 19, DOJ announced that First American Mortgage Trust, d/b/a NXTLoan.com, a small mortgage lender based in Brighton, Massachusetts, and its CEO agreed to pay \$1.025 million to resolve allegations that the company submitted false insurance claims on FHA-insured mortgages.¹⁰⁶ As part of the settlement, NXTLoan.com and its CEO admitted that between 2005 and 2011, NXTLoan.com ignored the FHA's due diligence requirements, falsely certified that the company's loans qualified for FHA insurance, failed to report loan defects, and falsely certified compliance with quality control requirements. NXTLoan.com also admitted that the CEO falsely certified that the company had conducted post-closing loan audits. When NXTLoan.com started auditing closed loans, the company and its CEO also failed to report serious issues to the FHA.

Financial Institutions Interventions

- **Guild Mortgage Company:** On May 18, the United States filed a complaint in intervention bringing FCA and common law claims against Guild Mortgage Company (Guild) in the US District Court for the District of Columbia.¹⁰⁷ The government alleges that Guild knowingly originated and underwrote defective FHA-insured mortgage loans as a direct endorsement lender from 2006 to 2011. It alleges that, in pursuit of growth, Guild waived mandatory conditions during the underwriting of FHA loans, allowed unqualified junior underwriters to underwrite FHA loans, performed untimely and incomplete quality control reviews, and ignored quality control findings without reporting deficiencies to HUD as required. Guild moved to dismiss and to transfer the case to the Southern District of California; the transfer motion was granted on November 29 after the United States withdrew its opposition.¹⁰⁸

Financial Institutions Complaints

- On June 6, a qui tam complaint against a national bank was unsealed in the Southern District of New York after the government declined to intervene.¹⁰⁹ The four relators, including current and former employees, allege that the bank violated the FCA by fraudulently inducing Fannie Mae to execute a servicer participation agreement with it in connection with the US Department of Treasury's Home Affordable Modification Program (HAMP) in 2009, and by making subsequent false representations and certifications relating to federal requirements and the bank's compliance with state and federal law. The case was subsequently transferred to the Eastern District of Texas.¹¹⁰ The complaint contains allegations only, and there has been no determination of liability.

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.¹¹¹ 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 2016, **Nevada** was certified as DRA-compliant by the OIG, and **Washington**’s certification was confirmed. The OIG has certified a total of 20 states as DRA-compliant to date (still well below the 28 that had reached DRA-compliance before the 2009 and 2010 FCA amendments).¹¹²
- On June 21, 2016, **Alaska** Governor Bill Walker signed into law a bill that included the Alaska Medical Assistance False Claim and Reporting Act. The law creates civil liability for providers or recipients who make false claims under the Medicaid program, and includes a qui tam provision.¹¹³
- On March 31, 2016, **Washington** Governor Jay Inslee signed a bill reauthorizing the state false claims law, which contained a sunset provision and was set to expire on June 30. The bill extended the qui tam provisions until 2023 and removed the sunset provision for much of the rest of the law.¹¹⁴
- A bill introduced in December 2014 that would create a **South Carolina** False Claims Act remained pending in the state Senate Committee on Judiciary at the end of the 2015-2016 legislative session.¹¹⁵
- A bill introduced in February 2016 that would create an **Alabama** Medicaid False Claims Act remains pending in the state Senate Committee on Judiciary.¹¹⁶
- A bill introduced in March 2016 that would create a **Louisiana** False Claims Act failed to pass in May and has been returned to the legislative calendar.¹¹⁷
- A bill introduced in 2015 that would create a **Pennsylvania** False Claims Act remained pending in the Judiciary Committee at the end of the 2015-2016 legislative session.¹¹⁸

Noteworthy State Settlements or Judgments

As in prior years, the most significant state false claims settlements in 2016 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 2016, in chronological order, included:

- **Several states settled with Novartis Pharmaceuticals for \$390 million.** In February, Novartis Pharmaceuticals agreed to pay \$390 million to the federal government and over 40 states to settle allegations that it had given kickbacks to certain specialty pharmacies in exchange for those pharmacies’ recommendation of two of its drugs, Exjade and Myfortic.¹¹⁹
- **Massachusetts settled with Level 3 Communications for \$8 million.** In March, Level 3 Communications, a Colorado-based telecommunications and Internet service provider, agreed to pay more than \$8 million to settle allegations that it had improperly withheld rental payments to

the Massachusetts Department of Transportation under an agreement that allows it to run fiber optic cables alongside state highways. \$2.7 million of the settlement resolved alleged violations of Massachusetts's false claims act and \$5.5 million constituted contract damages.¹²⁰

- **Several states settled with Olympus Corporation for \$306 million.** In May, Olympus Corporation agreed to pay \$306 million to the federal government, five states and the District of Columbia, to settle allegations that it had paid kickbacks to induce doctors and hospital executives to buy its endoscopes and other surgical equipment.¹²¹
- **Several states settled with Wyeth for \$784.6 million.** In May, Wyeth Inc. agreed to pay \$784.6 million to the federal government, 35 states and the District of Columbia to settle allegations that it had engaged in an unlawful scheme to reduce the amount of the rebates it was required to pay state Medicaid programs between 2001 and 2006 for sales of its product Protonix. Massachusetts's share of the settlement, \$68 million, was the largest Medicaid fraud recovery in that state's history.¹²²
- **New York settled with Medford Multicare Center for \$28 million.** In June, Medford Multicare Center, a Long Island nursing home, agreed to pay New York \$28 million to settle allegations relating to a pattern of criminal conduct by employees of the nursing home, including improper diversion of Medicaid funds to the employees and their controlled entities.¹²³
- **California settled with K12 Inc. for \$168.5 million.** In July, K12 Inc., a for-profit online charter school operator, agreed to pay California \$168.5 million to settle allegations that it had induced parents to enroll their children in K-12 schools through misleading advertising; submitted inflated student attendance numbers and consequently collected excessive state funding; and influenced nonprofit online charter schools to enter into unfavorable contracts.¹²⁴
- **Orange County, California settled with Tata Consultancy Services for \$26 million.** In August, software vendor Tata Consultancy Services agreed to pay Orange County, California \$26 million to settle allegations that it had fraudulently induced the County into selecting Tata to develop an automated property tax system and then presented false claims in the form of invoices and reports, provided false and unachievable milestone completion dates, and intentionally understaffed the project to maximize profit.¹²⁵
- **Vermont settled with Burlington Laboratories for \$6.75 million.** In October, Burlington Laboratories, Inc. agreed to pay \$6.75 million to settle allegations that it had overcharged Vermont Medicaid for drug screening services.¹²⁶
- **Pennsylvania settled with Reliant Senior Care for \$2 million.** In October, Reliant Senior Care Holdings, a nursing home chain, agreed to pay \$2 million to settle allegations that it had misled consumers by failing to provide basic services to elderly and vulnerable residents.¹²⁷
- **Several states settled with Bristol-Myers Squibb for \$19.5 million.** In December, Bristol-Myers Squibb Company agreed to pay \$19.5 million to several states and the District of Columbia to settle allegations that it had improperly marketed an antipsychotic drug to children and elderly patients.¹²⁸

Noteworthy State Complaint

- **New York files suit against clinic operator.** In November, New York Attorney General Eric T. Schneiderman announced criminal charges and a parallel civil false claims suit against a clinic operator and two clinics, alleging that they had submitted claims for reimbursement for substance abuse treatment services to Medicaid and to MetroPlus (a state-funded managed care organization) when they were not certified to provide such services, and for medical services allegedly rendered to Medicaid Fraud Control Unit undercover investigators that never occurred.

The civil suit seeks over \$7.7 million dollars in damages, plus penalties.¹²⁹ The complaint contains allegations only, and there has been no determination of liability.

ABOUT WILMERHALE'S FALSE CLAIMS ACT PRACTICE

With a team of veteran litigators and former Justice and Defense Department lawyers, 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 health care, 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 Fraud 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 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.
- Three former US Attorneys, for the District of Colorado 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 US 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.

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¹ All of the figures in this paragraph come from two Justice Department documents: Civil Division, U.S. Dep't of Justice, False Claims Act Statistics (Dec. 13, 2016), <https://www.justice.gov/opa/press-release/file/918361/download>; and Press Release, Off. of Public Affairs, U.S. Dep't of Justice, *Justice Department Recovers Over \$4.7 Billion from False Claims Act Cases in Fiscal Year 2016* (Dec. 14, 2016), <https://www.justice.gov/opa/pr/justice-department-recovers-over-47-billion-false-claims-act-cases-fiscal-year-2016>.

² 28 U.S.C. § 2461 note.

³ Civil Monetary Penalties Inflation Adjustment, 81 Fed. Reg. 42,491, 42,501 (June 30, 2016); <https://www.gpo.gov/fdsys/pkg/FR-2016-06-30/pdf/2016-15528.pdf>.

⁴ 28 C.F.R. § 85.5

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