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False Claims Act: 2014 Year-in-Review

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LITIGATION/CONTROVERSY

False Claims Act: 2014 Year-in-Review

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I. Introduction: Highlights and Trends

The U.S. Department of Justice (DOJ) collected a record-breaking $5.7 billion in False Claims Act (FCA) recoveries in fiscal year (FY) 2014, up from $3.8 billion in FY 2013.[1] The increased recoveries, which continue a trend during the Obama Administration, are likely to lead to even greater numbers of qui tam suits, as potential relators seek to capitalize on DOJ's success. In FY 2014, relators filed over 700 new qui tam cases, nearly as many as the 753 new qui tam suits in FY 2013.

In a shift, the financial sector displaced healthcare and pharmaceuticals as the sector with the largest share of the government's FCA recoveries. More than $3.1 billion of the $5.7 billion in FCA recoveries in FY 2014 came from financial institutions, mostly for claims related to federal programs created in response to the financial and mortgage crises. This amount was significantly higher than the $2.3 billion recovered in cases related to federal health care programs such as Medicare and Medicaid. While some of the programs that have provided the bases for the boom in financial sector recoveries have finished, financial institutions are likely to remain FCA targets for some time to come. Procurement and grant cases also accounted for significant FCA recoveries during FY 2014, though at approximately $300 million they were down from last year's total of nearly $900 million.

While the Administration and relators continued to press for expansive interpretations of the FCA, this past year saw increased debate, including in Congress, about possible FCA reform, a process in which WilmerHale played a central part. The Supreme Court may take steps to narrow the FCA's reach via the statute of limitations and the first-to-file bar, while lower courts continue to divide on a number of issues with enormous consequences for FCA defendants.

Debate Over FCA Reform. This past year saw increased debate, including in Congress, about possible reform of the FCA. In July 2014, a subcommittee of the House Judiciary Committee held the first hearing on significant proposals for FCA revisions in six years. David Ogden, chair of WilmerHale's Government and Regulatory Litigation Group, testified in favor of reform, drawing on a white paper he co-authored for the U.S. Chamber of Commerce's Institute for Legal Reform.[2] (For a fuller account of the hearing and the reform proposals, see p. 4 below.)

Supreme Court Consideration of Statute of Limitations and First-to-File Bar. The Supreme Court granted certiorari on two of the most important FCA issues to confront the Court in years: (1) whether the Wartime Suspension of Limitations Act (WSLA), 18 U.S.C. § 3287, tolls the FCA's statute of limitations in civil actions in which the government has not intervened, and (2) whether the FCA's first-to-file bar, 31 U.S.C. § 3730(b)(5), applies only when the first-filed action is pending or also bars suits filed after the first action has been dismissed. The case, *Kellogg Brown & Root Services, Inc. v. United States ex rel. Carter*, No. 12-1497, came to the Court from the Fourth Circuit. At the January 13, 2015 oral argument, the Justices seemed inclined to reverse the court of appeals on the WSLA issue and hold that the WSLA is limited to criminal cases. The Justices' likely view on the first-to-file question was less clear.[3]
Other notable FCA developments include:

Increase in Parallel Criminal Investigations on the Horizon? In September 2014, the Criminal Division of DOJ signaled its intent to increase the number of parallel criminal investigations alongside civil investigations triggered by qui tam filings.[4] (For a fuller account, see p. 6 below.)

Fight Over Privilege in Internal Investigations. In *In re Kellogg Brown & Root*, 756 F.3d 754 (D.C. Cir. 2014), the D.C. Circuit held that an internal investigation mandated by Department of Defense (DoD) regulations (which require contractors to maintain compliance programs and investigate allegations of potential wrongdoing) was protected by the attorney-client privilege because obtaining legal advice was "one of the significant purposes" of the investigation. *Id*. at 758-59. WilmerHale represented amicus curiae the Chamber of Commerce of the United States of America. A petition for writ of certiorari was filed with the Supreme Court on November 25, 2014, but was recently denied. *United States ex rel. Barko v. Kellogg Brown & Root, Inc.*, No. 14-637, --- S.Ct. ----, 2015 WL 231997 (cert. denied Jan. 20, 2015).

Continued Debate Over Rule 9(b) and the Need To Identify Particular False Claims. The Third and Eighth Circuits joined a growing majority of Circuits in holding that an FCA plaintiff need not identify particular false claims to satisfy Federal Rule of Civil Procedure 9(b) so long as the plaintiff alleges facts about the underlying fraud and indicia of reliability to support the "strong inference" that false claims were submitted.[5]

Continued Debate Over the Scope of Implied False Certification Liability. On January 8, 2015, the Fourth Circuit joined a large majority of the Circuits in expressly recognizing implied false certification liability. In *United States ex rel. Badr v. Triple Canopy, Inc.,* --- F.3d ----, 2015 WL 105374 (4th Cir. 2015), the Fourth Circuit rejected the view that implied false certification claims must be limited to certifications that were a condition of payment, concluding that materiality to payment, *i.e.*, having a natural tendency to affect the government's willingness to pay, suffices. The Fifth Circuit, by contrast, in *United States ex rel. Spicer v. Westbrook*, 751 F.3d 354 (5th Cir. 2014), held that such claims were permissible only when the alleged false certification "was a prerequisite to receiving payment under the contract." *Id.* at 366.

Debate Over Statistical Sampling. Relators and the government have increasingly argued for the permissibility of statistical sampling as a means of establishing liability in large-scale FCA cases.[6] In *United States ex rel. Martin v. Life Care Centers of America*, 2014 U.S. Dist. LEXIS 142660 (E.D. Tenn. Sept. 29, 2014), a judge in the Eastern District of Tennessee recently endorsed the practice in a Medicare fraud case. The court permitted the government to extrapolate from a random sample of 400 patients to determine that 154,621 claims submitted by the defendant were false. In *United States ex rel. Guardiola v. Renown Health*, 2014 U.S. Dist. LEXIS (D. Nev. Nov. 5, 2014), a judge in the District of Nevada recently ruled that Renown must produce data sufficient to enable the relator to develop "a valid and reliable statistical sampling plan," although the court declined to rule early in the discovery phase of the case on the admissibility of such statistical sampling. *Id.* at *5.

Healthcare and Pharmaceuticals

- Pharmaceutical and medical device companies may see a rise in FCA cases relating to alleged violations of current Good Manufacturing Practices (cGMP). In *United States ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694 (4th Cir. 2014) (cert. denied, Oct. 6, 2014), the Fourth Circuit recently held that cGMP violations cannot suffice by themselves to ground FCA claims because cGMP compliance is not a condition of payment under Medicare and Medicaid. But it remains to be seen whether other courts will agree. Recent scrutiny of cGMP violations by DOJ may signal an expansion of the government's previous focus on off-label marketing violations and enforcement of the Anti-Kickback Statute (AKS).[7] Companies should take a holistic approach to cGMP compliance, prioritizing responses to FDA observations and whistleblower complaints and prioritizing and incentivizing cGMP compliance. Companies should also consider involving their in-house legal departments in cGMP compliance activities and view cGMP compliance issues with an eye towards potential FCA risk.[8]

- Health care providers should anticipate a rise in "reverse false claims" cases based on the 60-day repayment requirement for Medicare and Medicaid enacted in the Affordable Care Act. The provision requires that a provider that received an overpayment must report and return the overpayment by the later of 60 days from the date when the overpayment was "identified" or the date "any corresponding cost report is due."[9] In April 2014, DOJ intervened for the first time in a case involving only "reverse false claims" allegations, in *U.S. ex rel. Kane v. Continuum Health Partners.*[10]

Procurement

- Relators and the government have made increasing use of the Trade Agreements Act's (TAA) country-of-origin limitations as a basis for FCA allegations. In August 2014, two substantial FCA settlements concerned alleged TAA non-compliance. Smith & Nephew settled claims concerning products manufactured in Malaysia for approximately $8.3 million, and Samsung Electronics America, Inc. settled a case involving products manufactured in China for $2.3 million.

- FCA cases based on "most favored customer" provisions continue to proliferate. In July 2014, DOJ announced it was intervening in a qui tam suit against Symantec alleging that Symantec knowingly provided the government with inaccurate information about prices offered to commercial customers and failed to extend the same discounts to government purchasers. In August, Hewlett-Packard agreed to a $32.5 million settlement with DOJ regarding allegations it failed to provide most favored customer pricing to the U.S. Postal Service. And in December, DHS Technologies LLC agreed to pay $1.9 million to settle claims based on an alleged failure to disclose that it had offered greater discounts to a private company during negotiations with the General Services Administration (GSA).

Financial Institutions

- To date, many financial industry-related FCA cases have arisen from allegations of improperly-originated mortgage loans that benefitted from some sort of government support. In 2015 and beyond, banks may face a fresh round of FCA suits focused not on origination, but on allegations concerning other activities, such as loss-mitigation and foreclosure-avoidance measures.

II. Federal Legislative and Regulatory Developments

The FCA saw increased attention in 2014, including a congressional hearing devoted to possible amendments to the law and the announcement of a new caucus dedicated to whistleblower protection. Officials from DOJ and other executive branch agencies made a number of statements aimed at incentivizing more relators to come forward.

➢ <u>Congress</u>

House of Representatives

- On July 30, 2014, the House Judiciary Committee's Subcommittee on the Constitution and Civil Justice held a hearing on the FCA, the first hearing on the FCA within the House Judiciary Committee in six years. A panel of witnesses, including former Deputy Attorney General and current WilmerHale partner David Ogden, testified in support of various amendments to the FCA.[11]
    - Ogden testified on behalf of the U.S. Chamber of Commerce's Institute for Legal Reform (ILR), arguing that the FCA should be amended to incentivize companies to adopt "gold standard" compliance programs to help prevent fraud in the first place. ILR's proposals aim to strike a balance between incentivizing self-disclosure through effective compliance programs and maintaining the FCA's deterrent goals, particularly for companies without certified compliance programs. The proposals would have the added benefit of reducing the number of frivolous qui tam claims.[12]
    - Patricia J. Harned, president of the Ethics Resource Center (ERC), also testified in support of enhanced compliance programs. An ERC study showed that when strong ethics and compliance programs are in place, misconduct decreases by more than half (52%) compared to companies with a weak compliance culture. The study also found that strong compliance programs significantly increase employee disclosure of wrongdoing.[13]
    - John E. Clark, a qui tam attorney representing Taxpayers Against Fraud, testified in favor of several amendments that would greatly expand the FCA's reach and potential penalties for violators. Among his proposed amendments were: allowing the government to recover attorney's fees in successful cases; calculating penalties based on gross damages rather than net damages; requiring all government contractors to educate their employees about the FCA; and expanding the FCA to cover tax fraud.[14]
    - Dr. Rachakonda Prabhu, a Board-certified pulmonologist, testified on the challenges and enormous expense of defending against an FCA claim. Dr. Prabhu testified that he was twice sued by the government for alleged FCA violations. In both cases, the claims were eventually dropped, but only after he had to spend millions of dollars to defend himself. He suggested several changes to the FCA, including: an internal reporting requirement for potential whistleblowers; an amnesty program for individuals who self-report FCA violations; reduced damages amounts; and no threat of debarment for individuals who voluntarily self-report and cooperate with the government.[15]
    - A number of Representatives and Senator Charles Grassley (R-IA) also made or filed statements at the hearing. Representative Steve Cohen (D-TN) and Representative John Conyers (D-MI) expressed concern about whether the ILR's proposals would increase retaliation against genuine whistleblowers. Senator Grassley also advocated against the ILR's proposed amendments, claiming that the compliance certification program lacked sufficient details. He argued for more aggressive enforcement of the FCA, including automatic review for suspension or debarment of companies or individuals subject to a judgment or settlement under the FCA.[16]
- On May 19, 2014, Rep. Jim McDermott (D-WA) introduced the Medicaid Physician Self-Referral Act of 2014 (H.R. 4676), which would make the so-called Stark law apply to Medicaid as it does

to Medicare.[17] The Stark law prohibits physicians from referring patients to medical facilities in which the physician or his or her immediate family members have a financial interest. The amendment would (1) make it clear that the Stark law applies with equal force to Medicaid designated health services, and (2) explicitly apply the FCA to violations of the self-referral provision for both Medicare and Medicaid designated services.[18]

Senate

- On April 10, 2014, Senator Charles Grassley (R-IA) announced his plan to create a Senate Whistleblower Protection Caucus. Senator Grassley intends to serve as the chair of the caucus and Senator Ron Wyden (D-OR) will serve as the vice chair. The Senators are recruiting colleagues to join them with an eye on officially starting the caucus in the 114th Congress, which opens in January 2015. This may lead to an increased focus on enforcement of the FCA and other whistleblower laws in the coming congressional term.[19]

- On November 20, 2014, Senators John Thune (R-SD), Bill Nelson (D-FL), Dean Heller (R-NV), Claire McCaskill (D-MO), and Amy Klobuchar (D-MN) proposed "A Bill to Improve Motor Vehicle Safety by Encouraging the Sharing of Certain Information." The bill would amend 49 U.S.C. § 301 by adding a whistleblower award program for individuals who report safety violations in the auto industry.[20]

    - The program is limited to employees or contractors of vehicle manufacturers, part suppliers, or dealerships. An action must result in a minimum recovery of $1 million to qualify for a whistleblower award.

    - As under the IRS and SEC whistleblower programs, awards would be discretionary and could be up to 30% of any monetary recovery. In determining the award amount, the Secretary of Transportation must consider, among other factors, whether the whistleblower first reported the conduct internally.

    - The bill does not include an anti-retaliation provision, although it does protect whistleblower confidentiality. It also gives the Transportation Secretary discretion to share information with the Justice Department and other federal agencies.

- On December 1, 2014, in a speech on the floor of the Senate, Senator Grassley reiterated many of his comments opposing the ILR's FCA reform proposals, including a renewed call for judgments or settlements under the FCA to result in automatic review for suspension or debarment. He also urged Congress to make it clear that the Affordable Care Act is a federal health care program subject to the AKS and the FCA.[21]

- On October 7, 2014, Kimberly Brandt, minority investigative counsel for health care on the Senate Finance Committee announced that the committee plans to take a fresh look at physician-owned distributors (POD) of medical devices in 2015. This announcement, together with the Department of Health and Human Services (HHS) Office of the Inspector General (OIG) 2013 special fraud alert on PODs, signals likely increased FCA enforcement in the medical device arena.[22]

➢ **<u>Department of Justice</u>**

- In a speech at New York University School of Law on September 17, 2014, Attorney General Eric Holder said his office was placing an increased emphasis on bringing criminal charges against individuals accused of financial fraud. He called on Congress to consider amending the Financial Institutions Reform, Recovery, and Enforcement Act (FIRREA) to bring its whistleblower provisions in line with the FCA. Currently under FIRREA, a whistleblower who initiates a claim is entitled to 20-30 percent of the first $1 million recovered, 10-20 percent of the next $4 million recovered, and 5-10 percent of the next $5 million recovered, for a maximum total reward of $1.6 million. The amount of the award within this range is subject to the Attorney General's discretion. Holder stated that the $1.6 million limit meant awards were insufficient to incentivize disclosure of

wrongdoing in the financial sector.[23]

- Also on September 17, 2014, Leslie Caldwell, Assistant Attorney General for the Criminal Division, gave a speech at the Taxpayers Against Fraud Education Fund Conference in Washington, D.C., indicating a likely increase in joint criminal-civil fraud investigations in the healthcare, defense procurement, and financial services industries. She stated that the Justice Department is redoubling its efforts to share information internally between the Civil and Criminal Divisions, including all FCA claims. Caldwell also encouraged qui tam attorneys at the conference to reach out directly to the Criminal Division with evidence of wrongdoing and promised to increase prosecutors' efforts to work with relators.[24]

- At a September 19, 2014 hearing before the House Judiciary Committee's Subcommittee on Regulatory Reform, Stuart Delery, Acting Associate Attorney General, touted the work of the Health Care Fraud Prevention and Enforcement Action Teams (HEAT). Fiscal Year 2013 marked the fourth straight year the Justice Department had obtained more than $2 billion in health care fraud cases, he noted, and DOJ is continuing to focus on manufacturers of pharmaceuticals and medical devices, which make up approximately 70% of that recovery. Delery also noted that DOJ has placed a renewed emphasis on non-monetary, preventive measures. He highlighted recent resolutions with two pharmaceutical companies that included compliance commitments and required certifications from company officers and directors.[25]

- On December 17, 2014, DOJ announced a 131-count criminal indictment against 14 individuals associated with the New England Compounding Center (NECC) for their role in a 2012 fungal meningitis outbreak stemming from contaminated steroid injections. At the press conference, Acting Assistant Attorney General for the Civil Division Joyce R. Branda spoke about the investigation and the Department's broader efforts to combat health care fraud. Branda called heath care fraud a "top priority" for the Administration and vowed to use every criminal and civil tool at the Department's disposal to prosecute those who violate health and consumer safety laws.[26]

➢ **<u>Department of Health and Human Services</u>**

- On October 3, 2014, HHS's Office of Inspector General issued a proposed rule that would amend its AKS safe harbors. Public comments to the rule were due by December 2, 2014. The proposed rule seeks to create five new safe harbors, including codifying three existing statutory exceptions created by the Affordable Care Act and the Medicare Modernization Act of 2003 and creating two additional safe harbors. The rule would also create new exceptions to the definition of remuneration under the Beneficiary Inducement Civil Monetary Penalty (CMP). This proposed rule change has potential implications for the FCA. Compliance with the AKS is a condition of payment under federal health care programs, and a violation of the AKS thus may provide a premise for FCA liability.[27] One way the AKS may be violated is through the improper reduction or waiver of federal health care program cost-sharing amounts (*e.g.*, co-pays and deductibles). The rule would give medical providers more flexibility to enter into cost-sharing agreements without violating federal health care laws or the FCA. Specifically, it provides protection for:

    - Cost-sharing waivers for Medicare Part-D discounts provided by pharmaceutical manufacturers;

    - Cost-sharing waivers or discounts for emergency ambulance services;

    - Free or discounted local transportation provided by an eligible entity to "established patients."[28]

➢ **<u>Internal Revenue Service</u>**

- On August 12, 2014, the IRS adopted new regulations regarding its whistleblower award program.[29] The regulations provide new guidance for the program aimed at streamlining the process of receiving, reviewing, and investigating claims by whistleblowers. Senator Grassley

issued two statements in 2014 calling for the IRS to do more to incentivize whistleblowers to come forward, including expanding the categories of awards available to whistleblowers and improving communication with whistleblowers.[30]

- **<u>Securities and Exchange Commission and Commodity Futures Trading Commission</u>**

- In its annual report to Congress on the Dodd-Frank Whistleblower Program, the SEC stated that it had given more and larger awards to whistleblowers than in any prior year. The SEC issued nine awards in FY 2014, more than in all previous years combined. The SEC also issued its largest ever individual award ($30 million) and brought its first anti-retaliation enforcement action. The SEC also filed amicus briefs in several pending cases arguing that the anti-retaliation provision should be interpreted to protect employees who report wrongdoing internally and not just those who report directly to the Commission.[31]

- In a speech at Georgetown University Law Center's Corporate Counsel Institute, Sean McKessy, head of the SEC's Whistleblower Office, warned against companies using confidentiality or severance agreements to limit their employees' ability to report misconduct to the Commission. McKessy also noted that the SEC's whistleblower program continues to grow—it is now receiving nine or ten tips per day—and he expects to be making "continuous" and "rolling" payouts within the next two to three years.[32]

- Christopher Ehrman, head of the Commodity Futures Trading Commission's Whistleblower Office, also spoke at the event. He said that the CFTC had "some very big matters coming in," and he expected tips to the CFTC to increase by 55 to 60 percent in the coming year.[33]

III. Federal Settlements, Interventions, Judgments, and Complaints

➢ Healthcare and Pharmaceuticals

Healthcare and Pharmaceuticals Settlements

- **DaVita:** In October, DOJ announced that DaVita Healthcare Partners, one of the largest dialysis providers in the United States, had agreed to pay $350 million to resolve FCA allegations that it paid kickbacks to induce referrals to its clinics. Among other allegations, the government asserted that DaVita entered into joint ventures with physicians, either by purchasing interests in physicians' clinics or selling physicians interests in DaVita clinics. DaVita allegedly manipulated the value of the transactions so as to give the physicians above-market rates of return. DaVita then allegedly ensured referrals to those clinics by entering into agreements that prohibited physicians from referring patients to other dialysis providers. The settlement resolved allegations in a qui tam action filed by a former DaVita financial analyst in the District of Colorado. DaVita also agreed to forfeit civilly $39 million and to enter into a corporate integrity agreement (CIA) with HHS OIG, which requires DaVita to unwind and restructure some of its business arrangements and to retain an independent monitor.[34]

- **Endo:** In February, DOJ announced that Endo Health Solutions and its subsidiary Endo Pharmaceuticals had agreed to pay approximately $192.7 million to resolve criminal and civil allegations that Endo marketed its anesthetic, Lidoderm, for off-label uses. The civil portion of the settlement totaled approximately $171.9 million and resolved allegations in three qui tam actions in the Eastern District of Pennsylvania. The criminal portion, which was negotiated by the U.S. Attorney's Office for the Northern District of New York, totaled approximately $20.8 million. As part of the criminal resolution, Endo entered into a Deferred Prosecution Agreement, the terms of which require enhanced compliance measures and an annual certification of compliance by Endo's CEO. Endo also entered into a separate CIA with HHS OIG.[35]

- **Amedisys:** In April, DOJ announced that Amedisys had agreed to pay $150 million to resolve allegations in seven qui tam actions pending in the Eastern District of Pennsylvania and the Northern District of Georgia. The settlement is the largest ever with a home health care services provider and resolved allegations that Amedisys billed Medicare for services that were not medically necessary, misrepresented patients' conditions, and maintained a financial relationship with a Georgia oncology practice that violated both the AKS and the Stark Law.[36] The matter was handled by the U.S. Attorney's Offices for the Eastern District of Pennsylvania, the Northern District of Alabama, the Northern District of Georgia, the Eastern District of Kentucky, the District of South Carolina, and the Western District of New York. Amedisys also entered into a separate CIA with HHS OIG.[37]

- **Omnicare:** In June, DOJ announced that Omnicare, the country's largest nursing home pharmacy, had agreed to pay $124.24 million to resolve allegations that it violated the FCA by offering improper inducements to nursing homes in return for the nursing homes' continued use of Omnicare's services. The settlement resolved allegations in two qui tam actions in the Northern District of Ohio and the District of New Jersey.[38] In addition, in February, DOJ announced that Omnicare agreed to pay $4.9 million to resolve allegations that the company solicited and received kickbacks from Amgen in return for switching patients from a competitor drug to Amgen's drug Aranesp. The settlement resolved allegations in a qui tam action in the District of South Carolina.[39]

- **Community Health Systems:** In August, DOJ announced that Community Health Systems, the largest acute care hospital operator in the United States, had agreed to pay $98.15 million to resolve allegations that the company improperly billed the government for inpatient services that should have been billed as outpatient or observation services, and that one of the company's affiliated hospitals violated the Stark Law. According to DOJ, the company "engaged in a deliberate corporate-driven scheme to increase inpatient admissions of Medicare, Medicaid and the Department of Defense's . . . TRICARE program beneficiaries over the age of 65 who

originally presented to the emergency departments at 119 CHS hospitals." The settlement resolved allegations in seven qui tam suits filed in the Southern District of Texas, the Southern District of Illinois, the Middle District of Tennessee, the Western District of North Carolina, the Northern District of Illinois, and the Northern District of Indiana. Community Health Systems also entered into a separate CIA with HHS OIG.[40]

- **Halifax Hospital Medical Center:** In March, DOJ announced that Halifax Hospital Medical Center had agreed to pay $85 million to resolve allegations in a qui tam action in the Middle District of Florida that the hospital maintained improper financial relationships with physicians in violation of the Stark Law. The parties agreed to settle the matter just one day before trial was scheduled to begin.[41] In July, Halifax settled for $1 million the remaining allegations in the qui tam complaint, related to improper billing (as to which the government had not intervened).[42] Halifax also entered into a separate CIA with HHS OIG.[43] This settlement follows last year's groundbreaking $237.5 million judgment against Tuomey Healthcare System premised on Stark Law violations. The Tuomey matter is on appeal before the Fourth Circuit.[44]

- **OtisMed**: In December, DOJ announced that OtisMed had agreed to pay $80 million to resolve criminal and civil allegations that the company distributed knee replacement surgery cutting guides that were rejected for market clearance by the FDA. The company pleaded guilty to distributing adulterated medical devices with the intent to defraud or mislead, and its CEO pleaded guilty to distributing adulterated medical devices without the intent to defraud or mislead. OtisMed was fined $34.4 million, ordered to pay $5.16 million in criminal forfeiture, and agreed to be excluded from federal health care programs for 20 years. The civil settlement, $40 million, resolved allegations in a qui tam action filed in the District of New Jersey. OtisMed had been acquired by Stryker in November 2009. DOJ entered into a separate non-prosecution agreement with Stryker in which DOJ acknowledged that the criminal activity had occurred prior to Stryker's acquisition of OtisMed and Stryker agreed to a number of compliance measures.[45]

- **Shire:** In September, DOJ announced that Shire Pharmaceuticals had agreed to pay $56.5 million to resolve allegations that the company violated the FCA by making unsupported and misleading claims about Adderall XR, Vyvanse, Daytrana, and Lialda, improperly inducing physicians to prescribe Vyvanse and Daytrana, and promoting Adderall XR, Lialda, Pentasa for off-label uses.[46] The settlement resolved allegations in two qui tam actions in the Eastern District of Pennsylvania and the Northern District of Illinois. Shire also entered into a separate CIA with HHS OIG.[47] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **King's Daughters Medical Center:** In May, DOJ announced that Ashland Hospital Corp., doing business as King's Daughters Medical Center, had agreed to pay $40.9 million to resolve allegations that it submitted false claims for medically unnecessary coronary stents and diagnostic catheterizations and violated the Stark Law by paying certain cardiologists salaries that exceeded fair market value. The matter was handled by the U.S. Attorney's Office for the Eastern District of Kentucky and the Kentucky Attorney General's Office. King's Daughters also entered into a separate CIA with HHS OIG.[48]

- **CareFusion:** In January, DOJ announced that CareFusion, a pharmaceutical products manufacturer, had agreed to pay $40.1 million to resolve allegations that it violated the FCA by paying kickbacks, making unsubstantiated claims about its products, and promoting its products for off-label uses. The settlement resolved allegations in a qui tam lawsuit filed by a former CareFusion employee in the District of Kansas.[49] In October, Becton Dickinson announced that it would acquire CareFusion for $12.2 billion.[50]

- **Extendicare**: In October, DOJ announced that Extendicare Health Services and its subsidiary Progressive Step Corporation had agreed to pay $38 million to resolve allegations that it provided "effectively worthless" nursing care and that it billed Medicare for unnecessary rehabilitation therapy services. Among the allegations were that Extendicare failed to provide care that met federal and state standards of care, including by failing to have a sufficient number of skilled

nurses on staff, failing to provide adequate catheter care to patients, and failing to follow protocols for the prevention of ulcers and falls. DOJ described the resolution as the "largest failure of care settlement with a chain-wide skilled nursing facility in the Department's history." The settlement, which resolved allegations in two qui tam actions in the Eastern District of Pennsylvania and the Southern District of Ohio, was announced less than two months after the Seventh Circuit vacated an approximately $9 million FCA verdict against an Illinois nursing home for providing substandard care. (The Seventh Circuit's decision is summarized in our Federal Case Law Developments section below.)[51] Extendicare, which operates 146 facilities, also entered into a separate CIA with HHS OIG.[52]

- **Dignity Health**: In October, DOJ announced that Dignity Health, one of the largest hospital systems in the United States, had agreed to pay $37 million to resolve allegations that it overbilled federal health care programs by treating certain patients (including patients undergoing elective cardiovascular procedures, patients undergoing elective kyphoplasty procedures, and patients with common medical diagnoses) on an inpatient basis when they should have been treated on an outpatient or observation basis. The settlement resolved allegations in a qui tam action filed by a former Dignity employee in the Northern District of California. Dignity also entered into a separate CIA with HHS OIG.[53]

- **Carondelet Health Network:** In August, DOJ announced that Carondelet Health Network had agreed to pay $35 million to resolve allegations that the non-profit corporation's hospitals, Carondelet St. Mary's Hospital and Carondelet St. Joseph's Hospital, had billed federal health care programs for inpatient rehabilitation facility services for patients that did not qualify for such services. The settlement resolved allegations in a qui tam action filed in the District of Arizona.[54]

- **Visiting Nurse Service of New York**: In November, DOJ announced that the Visiting Nurse Service of New York and its affiliates (VNS) had agreed to pay approximately $35 million to resolve allegations that VNS had enrolled ineligible individuals into its Medicaid managed long-term care program, that social adult day care centers in its provider network did not provide covered personal care services, and that VNS both improperly induced Medicaid beneficiaries to use certain social adult day care centers and received improper referrals from certain social adult day care centers. The settlement resolved certain allegations in a qui tam suit filed in the Southern District of New York, but the United States' investigation is continuing, and the agreement does not resolve all claims against VNS.[55]

- **Organon**: In October, various state Attorneys General announced that Organon, a subsidiary of Merck & Co., had agreed to pay $31 million to resolve allegations that the company underpaid rebates pursuant to the Medicaid Drug Rebate Program, offered kickbacks to nursing home pharmacies, promoted its drugs Remeron and Remeron SolTab for off-label uses, and reported inflated prices to state Medicaid programs.[56] The settlement resolved allegations in two qui tam actions in the District of Massachusetts and the Southern District of Texas.[57] The United States declined to intervene.[58] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **RehabCare:** In January, DOJ announced that RehabCare Group, RehabCare Group East, Rehab Systems of Missouri, and Health Systems Inc. had agreed to pay $30 million to resolve allegations that they engaged in a kickback scheme to induce the referral of nursing home business. In particular, RehabCare allegedly paid a lump sum of $400,000 to $600,000 to Rehab Systems in return for referrals to provide therapy to patients at more than sixty nursing homes controlled by the majority owner of Rehab Systems (who was also the majority owner of Health Systems Inc.), as well as a percentage of revenue generated by the referrals. The settlement resolved allegations in a qui tam action in the Eastern District of Missouri.[59]

- **Teva:** In March, DOJ announced that Teva Pharmaceuticals and its subsidiary IVAX had agreed to pay approximately $27.6 million to resolve allegations that the company violated the FCA by making payments to induce an Illinois physician to prescribe Teva's generic version of Clozapine, an anti-psychotic medication. Teva allegedly provided the physician, who became the largest

prescriber of Clozapine in the country, with consulting payments and all-expenses-paid trips to Miami. The matter was resolved by the U.S. Attorney's Office for the Northern District of Illinois and the Illinois Attorney General's Office. A separate FCA action is pending against the physician in the Northern District of Illinois. [60]

- **CareAll**: In November, DOJ announced that CareAll Management, a home healthcare provider, had agreed to pay $25 million to resolve allegations that the company billed for services that were not medically necessary and provided to patients that were not homebound, and that the company misrepresented the severity of patients' conditions. The settlement resolved allegations in a qui tam action filed in the Middle District of Tennessee. CareAll also agreed to extend and enhance a separate CIA with HHS OIG.[61]

- **Infirmary Health Systems:** In July, DOJ announced that Infirmary Health Systems, two of its affiliated clinics, and Diagnostic Physicians Group, had agreed to pay $24.5 million to resolve allegations in a qui tam action in the Southern District of Alabama premised on violations of the Stark Law and the AKS. The government's intervening complaint alleged that the clinics agreed to pay the physicians' group a percentage of Medicare payments for the tests and procedures which the group referred. Infirmary and Diagnostic Physicians Group also agreed to enter into separate CIAs with HHS OIG. [62]

- **McKesson:** In August, DOJ announced that McKesson had agreed to pay $18 million to resolve allegations that it violated the FCA by failing to comply with the shipping and handling requirements of a vaccine distribution contract with the Centers for Disease Control and Prevention. The settlement resolved allegations in a qui tam action filed in the Middle District of Tennessee.[63]

- **St. Joseph Health System:** In January, DOJ announced that Saint Joseph Health System had agreed to pay $16.5 million to resolve allegations that it submitted claims for medically unnecessary invasive cardiac procedures and violated the Stark Law and the AKS by entering into sham agreements with physicians to induce referrals. The settlement resolved allegations in a qui tam action in the Eastern District of Kentucky. St. Joseph also entered into a CIA with HHS OIG. Separately, one of the physicians who performed many of the medically unnecessary procedures pleaded guilty to health care fraud and was sentenced to thirty months in prison.[64]

- **BioScrip**: In January, DOJ announced that BioScrip had agreed to pay approximately $15 million to resolve allegations that the company, a specialty pharmacy, accepted kickbacks from Novartis in exchange for counselling patients to order refills for the Novartis drug Exjade. The settlement was concluded simultaneously with the U.S. Attorney's Office for the Southern District of New York filing an amended complaint against Novartis in a qui tam action in which the office had intervened in April 2013.[65]

- **Medtronic:** In May, DOJ announced that Medtronic had agreed to pay $9.9 million to resolve allegations that the company made payments to physicians to induce them to use Medtronic pacemakers and defibrillators. Among the allegations were that Medtronic paid physicians to speak at events, developed marketing plans for physicians at no cost, and provided sporting event tickets to physicians. The settlement resolved allegations in a qui tam action filed by a former Medtronic employee in the Eastern District of California.[66] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **Smith & Nephew:** In August, Smith & Nephew agreed to pay approximately $8.3 million to resolve allegations in a qui tam action in the Western District of Tennessee that the company sold medical devices to the federal government that were not compliant with the Trade Agreements Act (TAA) because they originated in Malaysia or other non-designated countries. The government declined to intervene in the matter.[67] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **EndoGastric:** In February, DOJ announced that medical device manufacturer EndoGastric Solutions had agreed to pay up to $5.25 million to resolve allegations that it caused health care providers to bill for procedures using its EsophyX devices at higher rates than were applicable to those procedures and that it paid physicians to induce the use of EsophyX. The actual settlement amount is contingent upon company revenues and whether a code for the EsophyX procedure is included in future editions of the CPT Manual.[68] The settlement resolved allegations in a qui tam action filed by a former employee in the District of Montana. EndoGastric also entered into a separate CIA with HHS OIG.[69]

Healthcare and Pharmaceuticals Interventions

- **Tenet and HMA:** In February, DOJ intervened in a qui tam action in the Middle District of Georgia against Tenet Healthcare, four of its hospitals in Georgia and South Carolina, a hospital owned by Health Management Associates in Georgia, and clinics in Georgia known as Hispanic Medical Management doing business as Clinica de la Mama. The government alleged that the hospitals paid kickbacks to obstetric clinics that served primarily undocumented immigrants in exchange for referrals for labor and delivery services at the hospitals.[70]

- **Continuum Health Partners:** In April, DOJ intervened in a reverse FCA qui tam action in the Southern District of New York against Continuum Health Partners, Beth Israel Medical Center, and St. Luke's-Roosevelt Hospital Center (all now part of Mt. Sinai Health System). The government alleged that because of a computer problem, Continuum, on behalf of the hospitals, impermissibly submitted secondary payment claims for the treatment of Medicaid beneficiaries when secondary payment was not appropriate. Continuum then failed to return the overpayments within 60 days after the date on which the overpayments were identified.[71]

- **Evercare**: In August, DOJ intervened in two qui tam actions in the District of Colorado against Evercare Hospice and Palliative Care (now known as Optum Palliative and Hospice Care, a subsidiary of UnitedHealth Group). In its consolidated intervening complaint, the government alleged that Evercare "consistently and deliberately sought to increase the number of patients for whom it could bill for end of life hospice care despite repeated warnings that a substantial portion of its patients were not, in fact, terminally ill and in need of hospice care."[72]

- **City of New York, Computer Sciences Corp.**: In October, the United States filed an intervening complaint against the City of New York and Computer Sciences Corp. (CSC) in a qui tam action in the Southern District of New York. The government alleged that the City and CSC submitted Medicaid claims for early intervention services where private insurance was not exhausted, in violation of the applicable regulations and in contravention of their certifications, and that they submitted claims with diagnosis information that had not been supplied by service providers and did not reflect the conditions for which the early intervention service had been rendered.[73]

- **Omnicare**: In December, the United States filed an intervening complaint against Omnicare in a consolidated qui tam action in the Western District of Virginia. The government alleges that Omnicare solicited and received kickbacks from Abbott Laboratories in exchange for purchasing and recommending the prescription of the drug Depakote for nursing home patients suffering from dementia. Abbott resolved Depakote kickback allegations in May 2012 as part of a $1.5 billion civil and criminal resolution.[74]

- **Procurement and Grants**

Procurement and Grants Settlements[75]

- **Supreme Group B.V.:** In December, DOJ announced that Supreme Group had agreed to pay $146 million to settle FCA allegations related to three contracts. First, Supreme Group agreed to pay $101 million to settle FCA allegations that it knowingly overcharged for supplying food and water to U.S. troops serving in Afghanistan, as well as failed to disclose and pass through to the government rebates and discounts it obtained from its suppliers as required by the contract. The

relator in the qui tam suit, a former employee, received $16.16 million as his share of the settlement. Second, Supreme Site Services GmbH, a Supreme Group subsidiary, agreed to pay $20 million to settle allegations that Supreme Site Services' drivers were stealing fuel destined for government generators for which the company nonetheless billed the government. Third, subsidiary Supreme Logistics FZE had agreed to pay $25 million to resolve allegations that the company billed the government for higher-priced refrigerated trucks when it actually used lower-priced non-refrigerated trucks to transport food to U.S. troops in Afghanistan.[76]

- **Iron Mountain:** DOJ announced in December that Iron Mountain Incorporated and Iron Mountain Information Management LLC (collectively Iron Mountain) had paid $44.5 million to resolve allegations under the FCA that Iron Mountain overcharged federal agencies for record storage services under GSA contracts. Iron Mountain allegedly failed to meet its contractual obligations to provide GSA with accurate information about its commercial sales practices during contract negotiations, failed to comply with the price reduction clause of the GSA contracts by not extending lower prices to government customers during its performance of the contracts, and charged for storage meeting National Archives and Records Administration requirements when the storage provided did not meet such requirements. Two qui tam relators received $8,010,000 as their share of the settlement.[77]

- **Hewlett-Packard Company (HP):** In August, DOJ announced that HP had agreed to pay $32.5 million to resolve allegations that it overcharged the U.S. Postal Service by failing to provide prices that were no greater than those offered to HP customers with comparable contracts. The government further alleged that HP made misrepresentations during contract negotiation regarding the most favored customer pricing.[78] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **Lockheed Martin Integrated Systems (LMIS):** DOJ announced in December that LMIS had agreed to pay $27.5 million to settle allegations that it knowingly overbilled the government for work performed by LMIS employees who lacked the job qualifications required by the contract.[79]

- **Boeing Company:** In October, DOJ announced that Boeing had agreed to pay $23 million to resolve allegations that it submitted false claims for labor charges on maintenance contracts with the U.S. Air Force for the C-17 Globemaster aircraft. The government alleged that the company knowingly and improperly billed a variety of labor costs in violation of applicable contract requirements, including for time its mechanics spent at meetings not directly related to the contracts. Boeing employees were relators in the qui tam suit and received $3,910,000 as their share of the settlement.[80] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **McKesson Corp.:** In August, DOJ announced that McKesson had agreed to pay $18 million to resolve allegations that it improperly set temperature monitors used in shipping vaccines under its contract with the Centers for Disease Control and Prevention. The government alleged that McKesson failed to comply with the shipping and handling requirements of its vaccine distribution contract by failing to set temperature monitors at the appropriate specified range, and thus did not satisfy its contractual obligations. The allegations arose from a qui tam suit filed by a former McKesson employee, whose share of the settlement has not yet been determined.[81]

- **DRS Technical Services Inc.:** In October, DOJ announced that DRS Technical Services Inc. had agreed to pay $13.7 million to settle allegations that it knowingly overbilled the government for work performed by DRS personnel who lacked the job qualifications required by the contract. The government alleged that using underqualified employees falsely increased the amount of money DRS claimed and the government paid.[82]

- **First RF Corporation:** DOJ announced in October that First RF had agreed to pay $10 million to settle allegations that it violated the FCA by submitting inflated claims for electronic warfare antennas sold to the U.S. Army to combat improvised explosive devices (IEDs). Based on an investigation in connection with a 2005 Army contract, the government alleged that First RF

knowingly submitted false data to the Army that misrepresented First RF's cost to manufacture the antennas and thereby inflated the price for the antennas and the payments First RF received for them.[83]

- **Columbia University**: In October, DOJ announced that Columbia University had agreed to pay approximately $9 million to resolve allegations that ICAP (formerly the International Center for AIDS Care and Treatment Program), a center located within the University's School of Public Health, allocated the salaries and wages of certain of its New York City employees without using a suitable means of verifying whether the charges applied to specific sponsored agreements were based on an employee's actual effort for that agreement. The settlement resolved allegations in a qui tam action in the Southern District of New York. The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **Vector Planning and Services Inc. (VPSI):** In February, DOJ announced that VPSI had agreed to pay $6.5 million to settle allegations that the company inflated claims for payment under several Navy contracts. The government alleged that, from 2005 to 2009, VPSI inflated its indirect cost billings to the government by improperly including direct costs, for which it had already been paid, in indirect cost accounts that were then allocated across its government contracts and billed again, as well as submitted claims for other costs that were never incurred. The relator in the qui tam suit will receive $1.28 million.[84]

- **M.K. Battery, Inc. (MK Battery), East Penn Manufacturing Co., Inc. (East Penn), NPC Robotics, Inc. (NPC), BAE Systems, Inc., and BAE Systems Tactical Vehicle Systems LP (BAE):** In September, five defense contractors had agreed to pay $4.4 million to settle allegations that the companies misled the government about the effectiveness of batteries installed in Humvees. As part of the resolution, the relator will receive a payment of $990,000.[85] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **Washington Metropolitan Area Transit Authority (WMATA):** In August, WMATA agreed to pay $4.2 million to resolve allegations that it filed false claims in connection with using federal funds when awarding a contract for a financial management information technology. The government alleged that WMATA competitively awarded a smaller assessment contract and then non-competitively awarded the far more lucrative integration project to the same contractor in violation of the federal procurement conflict-of-interest rules. The settlement resolved an FCA action by the U.S. Attorney's Office for the District of Columbia. The relator, a former WMATA employee, received nearly $1 million as his share of the settlement. There has been no allegation that the contractor engaged in any wrongdoing.[86]

- **Maricopa County Community College District (MCCCD):** DOJ announced in December that MCCCD had agreed to pay $4.08 million to resolve allegations that it submitted false claims to the Corporation for National and Community Service (CNCS) concerning AmeriCorps state and national grants. MCCCD allegedly improperly certified that students had completed the required number of service hours so that they would earn an education award such that CNCS inappropriately provided education awards to these students. MCCCD also allegedly improperly received grant funds from CNCS to administer the project. An MCCCD employee was the whistleblower in the qui tam suit and received $775,827 as her share of the settlement.[87]

- **Cadillac Asphalt LLC and Michigan Paving and Materials Co.:** In January, DOJ announced that two related entities, Cadillac Asphalt and Michigan Paving, had agreed to pay $3.8 million to settle allegations that they falsely claimed Disadvantaged Business Enterprise (DBE) credits on a number of federally funded transportation projects. The government alleged the companies knowingly and falsely claimed DBE credit for procuring asphalt from a DBE, but in reality the DBE was merely a pass-through for a large business.[88]

- **Sikorsky Aircraft Corp.:** In March, Sikorsky Aircraft agreed to pay $3.5 million to resolve allegations arising from the submission of inflated costs in the pricing of spare parts. The government alleged that Sikorsky Aircraft failed to disclose accurate, complete, and current cost

and pricing data in violation of the Truth in Negotiations Act; the failure to disclose lower prices for certain parts led the government to pay artificially excessive prices.[89]

- **Sea Star Line LLC and Horizon Lines LLC:** In March, DOJ announced that Sea Star Line and Horizon Lines had agreed to pay $1.9 million and $1.5 million, respectively, to resolve allegations that they fixed the price of government cargo transportation contracts between the continental United States and Puerto Rico. The government alleged that former executives of the defendant ocean shippers used personal email accounts to communicate confidential bidding information, thereby enabling each of the shippers to know the transportation rates that its competitor intended to submit to federal agencies for specific routes. A former Sea Star Line executive was the relator in the qui tam suit and received $512,719 as his share of the settlement.[90]

- **MPRI Inc.:** DOJ announced in February that MPRI had agreed to pay $3.2 million to settle allegations that it submitted false labor charges on a contract to support the Army in Afghanistan. The government alleged that MPRI billed for employees who had not worked because they had been granted leave and were out of the country. A former MPRI employee was the relator and received $576,000 as his share of the settlement.[91]

- **Sevenson Environmental Services Inc.:** DOJ announced in November that Sevenson had agreed to pay more than $2.72 million to settle allegations that it violated the FCA and the AKS by accepting kickbacks, rigging bids, and passing inflated charges to the U.S. Environmental Protection Agency (EPA) in connection with work performed at the Federal Creosote Superfund Site. The government alleged that Sevenson conspired with the subcontractors to pass the majority of those kickbacks to the EPA and conspired with one subcontractor to pass to the EPA additional inflated charges for soil disposal.[92]

- **General Electric Hitachi Nuclear Energy Americas LLC:** DOJ announced in January that GE Hitachi had agreed to pay $2.7 million to resolve FCA allegations that it made false statements and claims to the Department of Energy and the Nuclear Regulatory Commission concerning an advanced nuclear reactor design. The government alleged that GE Hitachi concealed known flaws in its analysis of a part component and falsely represented that it had properly analyzed the part in accordance with applicable standards and had verified the accuracy of its modeling using reliable data. A former GE Hitachi employee was the relator in the qui tam suit.[93] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **Eyak Technology LLC and Eyak Services LLC:** In December, DOT announced that Eyak Technology and Eyak Services had agreed to pay $2.5 million and relinquish any rights to additional payments from the government to resolve allegations that it violated the FCA and the AKS. The government alleged that Eyak Technology's then-director of contracts accepted kickbacks from subcontractors in return for directing subcontract to them. Eyak Technology and Eyak Services then allegedly submitted invoices to the U.S. Army Corps of Engineers that included charges for work that was never performed by the subcontractors. The director of contracts pleaded guilty to bribery and kickback charges in 2012.[94]

- **Samsung Electronics America Inc.:** In August, DOJ announced that Samsung had agreed to pay $2.3 million to settle allegations that it caused the submission of false claims for products sold on GSA Multiple Award Schedule (MAS) contracts in violation of the TAA. Samsung was alleged to have represented to the resellers, who in turn represented to federal agencies, that the specified products were made in TAA-designated countries, when in fact the specified products were manufactured in China, which is not a TAA-designated country. The allegations arose from a qui tam suit filed by a former Samsung employee who received a share of the settlement.[95]

- **Sanborn Map Company Inc.:** In February, DOJ announced that Sanborn had agreed to pay $2.1 million to resolve allegations that it violated the FCA. Sanborn allegedly used unapproved foreign subcontractors on three projects, which violated contractual obligations and caused delays on these projects; used unapproved domestic subcontractors when it was required to

complete all map work in-house; and charged unrelated work to the government contracts. The relator was a former Sanborn employee; his share of the settlement has not been determined.[96]

- **DHS Technologies LLC:** In December, DHS agreed to pay $1.9 to settle claims that it violated the FCA by failing to disclose to the GSA that it offered greater discounts to a private company for the same items during the negotiation for the re-award of a government contract, resulting in higher prices to the government. A DHS employee was the relator in the qui tam case.[97]

- **Frazier Masonry Corp., F-Y Inc., CTI Concrete & Masonry Inc., Masonry Technology Inc., Masonry Works Inc., Russell Frazier and Robert Yowell:** DOJ announced in April that five California-based masonry subcontractors and two individuals had paid the government nearly $1.9 million to resolve allegations that they misrepresented their disadvantaged small business status in connection with military construction contracts. The government alleged that the defendant masonry subcontractors and their principals misrepresented to the prime contractors that they were small businesses, and that these misrepresentations caused the prime contractors to falsely certify that they had complied with the small business provisions of the contracts in claiming payment. A former Frazier employee was the relator in the qui tam suit and received $393,383 as his share of the settlement.[98]

- **Science Applications International Corporation (SAIC):** In October, DOJ announced that SAIC, now known as Leidos Holdings, Inc., had agreed to pay $1.5 million to resolve an FCA lawsuit alleging that it knowingly engaged in prohibited conflicts of interest as a contractor for the U.S. Nuclear Regulatory Commission (NRC) between 1992 and 2000. SAIC held contracts that included assisting the NRC with certain rulemaking activities. The government alleged that SAIC repeatedly and falsely certified that it had no impermissible conflicting business relationships, when SAIC actually engaged in multiple business relationships with entities that had a financial interest in the outcome of the NRC's rulemaking effort. This case went to trial, where the jury returned a verdict in favor of the United States. On appeal, in December 2010, the U.S. Court of Appeals for the D.C. Circuit affirmed the judgment on the breach of contract claim, but partially reversed the judgment on the FCA claims based on two instructions given to the jury and remanded the case for a new trial on those claims. The parties then settled the FCA claim.[99] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **Computer Sciences Corporation, Inc.:** In April, CSC agreed to pay $1.1 million to resolve allegations that the company falsified qualifications of its employees in order to bill for labor charges at rates higher than allowed under a government contract.[100]

- **North Florida Shipyards:** In October, DOJ announced that North Florida Shipyards and its president had agreed to pay $1 million to resolve allegations that they violated the FCA by creating a front company in order to be awarded Coast Guard contracts that were designated for Service Disabled Veteran Owned Small Businesses. The claims were originally made in a qui tam suit, and the relators received $180,000 under the settlement.[101]

- **Okland Construction Co.:** DOJ announced in March that Okland had agreed to pay the government $928,000 to resolve allegations that it made false statements and submitted false claims under the Small Business Administration's (SBA) Section 8(a) Program for Small and Disadvantaged Businesses. Okland allegedly entered into the mentor-protégé program with a small business, but failed to form a qualifying joint venture. Okland was further alleged to have concealed its extensive involvement in performing the 8(a) contracts by misrepresenting to the government that its employees were employees of the small business. The qui tam suit was filed by the small business protégé after it terminated its mentor-protégé agreement with Okland, and Saiz Construction will receive a total of $148,480.[102]

- **Esri, Inc.:** In November, Esri paid $550,000 to settle allegations that it violated the FCA by overbilling the Bureau of Land Management's (BLM) National Operations Center (NOC). Esri allegedly added prohibited profit and fees to invoices for payment in time and materials contracts,

which it did not disclose, as well as billed for employees to attend conferences unrelated to the contract and the purchase of computer services for which BLM did not contract.[103]

- **RE/MAX Allegiance Relocation Services:** In July, DOJ announced that RE/MAX had agreed to pay the government $509,807 to resolve allegations that it violated the FCA by overbilling for transportation services. A former RE/MAX employee was the relator in the qui tam suit and received $86,667 as his share of the settlement.[104]

- **Lane Construction Corporation and McAfee Design and Distributing Co., Inc.:** In May, Lane Construction and McAfee Design agreed to pay $400,000 to settle allegations that they submitted false claims under the Department of Transportation's Disadvantaged Business Enterprise (DBE) program. The companies were alleged to have claimed that a DBE performed work on the contract, when the DBE actually subcontracted the work to non-DBE contractors. The whistleblower in the qui tam case received $80,000.[105]

- **GRH Technologies Construction Co., Ltd.:** The government announced in September that GRH Technologies had paid $285,000 to settle allegations that it submitted a claim for reimbursement of equipment that was never actually purchased.[106]

- **J.M. Waller Associates, Inc.:** In February, J.M. Waller Associates agreed to pay $229,060 to resolve allegations of FCA violations, including the use of inappropriate labor categories and billing rates for certain tasks, billing for inspection services on days when no construction had been performed, and billing of time charged to a particular task order for work that allegedly was outside the scope of that task order.[107]

- **Lynx Machine Tool Corp.:** In June, the former president and sole owner of Lynx agreed to pay $70,405 to settle allegations that Lynx (now defunct) failed to perform required testing on parts for the government and submitted false certificates of compliance and falsified test reports.[108]

Procurement and Grants Complaints

- **Kellogg, Brown & Root Services, Inc. (KBR):** In January, the government filed a complaint against KBR and two Kuwaiti companies, La Nouvelle General Trading & Contracting Co. (La Nouvelle) and First Kuwaiti Trading Co. (First Kuwaiti), for submitting false claims in connection with KBR's contract with the Army to provide logistical support in Iraq. The complaint alleges that KBR employees took kickbacks from La Nouvelle and First Kuwaiti in connection with the award and oversight of subcontracts awarded to these companies; that KBR then claimed reimbursement from the government for costs it incurred under the subcontracts that allegedly were inflated or for goods and services that were grossly deficient or not provided; and that KBR used refrigerated trailers to transport ice for consumption by the troops that had previously been used as temporary morgues without first sanitizing them. Some of the allegations were originally made in a qui tam suit. The government intervened in that case and has filed this complaint with additional allegations. Three KBR subcontract managers have admitted to taking kickbacks or making false statements in connection with the allegations made in the government's complaint.[109]

- **Stevens-Henager College, Inc.:** In May, DOJ announced that it intervened in a complaint against Stevens-Henager College, Inc. and its owner, The Center for Excellence in Higher Education, for illegally compensating recruiters. The college is alleged to have falsely certified compliance with provisions of federal law that prohibit a university from paying incentive-based compensation to its admissions recruiters based on the number of students they recruit. The qui tam suit was brought by two former employees.[110]

- **CA Inc.:** In May, DOJ announced it was filing a complaint against CA for allegedly knowingly overcharging the government for software licenses and maintenance in various ways, including providing incomplete and inaccurate information about commercial practices to GSA contracting officers during negotiation of contract extensions. The government also alleges that CA failed to

apply properly the contract's price reduction clause and pass along higher discounts to the government. Some of the allegations were originally alleged in a qui tam suit filed by a former employee, and the government also intervened in that case.[111]

- **Symantec Corporation:** DOJ announced in July that it was intervening in an FCA suit against Symantec for submitting false claims on a GSA software contract. The case alleges that Symantec knowingly provided the government with inaccurate and incomplete information about the prices it was offering to its commercial customers during the negotiation and performance of the contract. Symantec is also alleged to have failed to update GSA when commercial discounts improved and extend the same improved discounts to government purchasers. [112] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **Sikorsky Aircraft Corporation:** In October, DOJ announced that it was intervening in a qui tam suit against Sikorsky Aircraft and two of its subsidiaries. The suit alleges that Sikorsky Aircraft Corporation approved an illegal cost-plus-a-percentage-of-cost subcontract between its two subsidiaries. The complaint further alleges the defendants used this illegal subcontract to overcharge the Navy on parts and materials that were used to maintain Navy aircraft. The whistleblower is a former employee of one of the subsidiaries.[113]

- **Air Ideal Inc.:** DOJ announced in December that it intervened in an FCA suit against Air Ideal and its owner for allegedly making false statements to the SBA about the location of its business to obtain certification as a Historically Underutilized Business Zone (HUBZone) company. The complaint alleges that Air Ideal then used its fraudulently-procured HUBZone certification to obtain millions of dollars in government contracts.[114]

➢ **Financial Institutions**

Financial Institutions Settlements

- **Bank of America:** On August 21, DOJ announced that it had reached a $16.65 billion settlement with Bank of America and its former and current subsidiaries, including Countrywide Financial Corporation and Merrill Lynch.[115] The settlement resolved several investigations "related to the packaging, marketing, sale, arrangement, structuring and issuance of RMBS, collateralized debt obligations (CDOs), and the bank's practices concerning the underwriting and origination of mortgage loans."[116] As part of the settlement, Bank of America paid $1 billion to resolve liability under the FCA arising from three qui tam suits and an investigation by the U.S. Attorney's Office for the Southern District of New York.[117] The FCA allegations related to the origination of residential mortgage loans and the sale of such loans to Fannie Mae and Freddie Mac. The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **SunTrust Mortgage, Inc.:** On June 17, DOJ announced a $968 million settlement between SunTrust and DOJ, the Department of Housing and Urban Development (HUD), and the Consumer Financial Protection Bureau (CFPB), along with the attorneys general of 49 states and the District of Columbia.[118] As part of the settlement, SunTrust paid $418 million to resolve potential FCA liability relating to the origination and underwriting of FHA-insured loans that did not meet FHA requirements.[119] SunTrust admitted that between January 2006 and March 2012, it originated and underwrote FHA-insured mortgages that did not meet FHA requirements, failed to carry out an effective quality control program to identify non-compliant loans, and failed to report to HUD the defective loans it did identify.

- **JPMorgan Chase:** On February 4, DOJ announced that it had reached a $614 million settlement with JPMorgan Chase to resolve allegations arising from a qui tam suit claiming that JPMorgan Chase submitted non-compliant mortgage loans for insurance coverage and guarantees by the Federal Housing Administration (FHA) and the Department of Veterans Affairs (VA).[120] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **U.S. Bank:** On June 30, DOJ announced a $200 million settlement with U.S. Bank to resolve potential FCA liability relating to the origination and underwriting of FHA-insured loans that did not meet FHA requirements.[121] As part of the settlement, the bank admitted that from January 2006 through 2011, it had originated and underwrote FHA-insured mortgages that did not meet FHA requirements, failed to carry out an effective quality control program to identify non-compliant loans, and failed to self-report to HUD the defective loans it did identify.

Financial Institutions Judgments

- **American International Group, Inc. (AIG):** On March 29, a judge in the Southern District of California dismissed with prejudice a qui tam action filed against AIG.[122] The relators had alleged that AIG and others had fraudulently induced the Federal Reserve Bank of New York to issue three loans to AIG during the 2008 financial crisis. In dismissing the action, the court found that that the allegations in the complaint were based on information that already had been publicly disclosed and that the relators were not the original source of any of the information on which their complaint was based.[123] As an alternative and independent basis for dismissal, the court held that the relators had failed to plead fraud with the specificity required by Rule 9(b). The district court's decision is being appealed to the Ninth Circuit.

- **Wells Fargo:** On June 10, the D.C. Circuit issued a per curiam opinion affirming the district court's decision allowing an FCA suit against Wells Fargo to proceed.[124] Wells Fargo had argued that the suit was precluded by the government's previous $5 billion settlement with the bank for similar claims. The district court and the D.C. Circuit, however, concluded that the scope of the consent judgment entered as part of that settlement was not broad enough to encompass the new claims.[125]

- **Wells Fargo and Countrywide:** On July 15, the district court for the Central District of California dismissed a qui tam suit alleging that the banks fraudulently submitted loans for FHA insurance.[126] The relator alleged that the banks falsely certified that borrowers made down payments of at least 3% as required by statute. The complaint focused on alleged manipulations of charitable Down Payment Assistance programs that provided borrowers with funds to make down payments. The court dismissed the complaint with prejudice, finding that the information underlying the allegations had been publicly disclosed and that the relator was not the original source of the information.

Financial Institutions Complaints

- **Wells Fargo and Onewest Bank:** In April and June, two complaints filed by the same relator against Wells Fargo and OneWest Bank were unsealed in the Southern District of New York. The complaints focus on the banks' allegedly fraudulent certifications to Fannie Mae and others that they would make certain required disclosures to consumers in connection with their participation in the Home Affordable Modification Program (HAMP).[127] DOJ declined to intervene in both actions.

- **U. S. Bank:** In September, a judge in the Northern District of Ohio unsealed a qui tam suit against U.S. Bank alleging that the Bank violated the FCA by foreclosing on mortgage loans and submitting claims for FHA insurance without first pursuing loss mitigation measures required by HUD regulations.[128] The complaint alleges that when borrowers default, the applicable regulations require banks to evaluate the borrower for foreclosure alternatives, including deeds-in-lieu of foreclosure, special forbearances, and loan modifications. As part of the evaluation process, the complaint alleges, the regulations require that banks make reasonable efforts to hold a face-to-face-meeting with the delinquent borrowers. The relator alleges that U.S. Bank failed to pursue these loss mitigation measures, despite the fact that it had certified to HUD that it would comply with the regulations. In August 2014, DOJ declined to intervene in the action. *The New York Times* has speculated that this case could signal "fresh legal problems for other big mortgage banks, as well."[129]

IV. Federal Case Law Developments

<u>Pending Supreme Court Cases</u>: (1) Tolling of Statute of Limitations; (2) First-to-File Bar

***Kellogg Brown & Root Services, Inc. v. United States ex rel. Carter*, No. 12-1497**

The Supreme Court granted certiorari on two critical questions under the FCA: (1) whether the WSLA, 18 U.S.C. § 3287, suspends the FCA's six-year statute of limitations in civil FCA cases, even in qui tam suits in which the government has declined to intervene; and (2) whether the FCA's first-to-file bar, 31 U.S.C. §3730(b)(5), applies to bar qui tam actions even after the first-filed action is no longer pending. The Court heard oral argument on January 13, 2015.[130]

About the Case

The relator alleged that Kellogg Brown & Root Services (KBR) falsely billed the government for services performed in Iraq in early 2005. He filed his original qui tam complaint in early 2006, and the government declined to intervene. In 2010, as the case was set for trial, the government informed the parties that another relator had filed suit in late 2005 regarding the same alleged fraud. The district court then dismissed Carter's suit under the FCA's first-to-file bar. The earlier suit was later dismissed for failure to prosecute, and (after some procedural skirmishing) Carter refiled his complaint in June 2011. By the time he refiled, however, two other relators had filed suits alleging essentially the same fraud, and the district court again dismissed Carter's suit with prejudice on first-to-file grounds.

The Fourth Circuit reversed, holding that the FCA's first-to-file bar does not bar qui tam suits filed after the first-filed action is no longer pending. *See* 31 U.S.C. § 3730(b)(5) ("When a person brings an action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the *pending* action.") (emphasis added). Thus, the court of appeals held that the case should not have been dismissed with prejudice, and that Carter should be permitted to refile because the previously pending actions that supported dismissal had themselves been dismissed. The court also held—over a vigorous dissent—that the WSLA tolled the FCA's six-year statute of limitations such that Carter was free to bring claims from early 2005 that otherwise would have been barred as untimely.

The Supreme Court granted KBR's petition against the recommendations of the Solicitor General, who supports the Fourth Circuit's position on both questions. With respect to the first-to-file bar, KBR argues that the bar is not merely a "one-case-at-a-time" rule, but rather a bar on all subsequent suits based on the same underlying facts. On this point, KBR's position is supported by the D.C. Circuit's subsequent decision in *United States ex rel. Shea v. Cellco Partnership*, 748 F.3d 338 (D.C. Cir. 2014), discussed below. With respect to the WSLA, KBR argues that the statute, which is codified in Title 18 and refers only to "offenses," should be limited to criminal statutes of limitation and not extended to reach civil actions brought by relators under the FCA. *See* 18 U.S.C. § 3287 ("When the United States is at war or Congress has enacted a specific authorization for the use of the Armed Forces…, the running of any statute of limitations applicable to any *offense* … involving fraud or attempted fraud against the United States ... shall be suspended until 5 years after the termination of hostilities[.]") (emphasis added).

Implications for Future FCA Cases

If the Court holds that the WSLA has tolled the FCA's statute of limitations since Congress authorized the use of military force in Iraq and Afghanistan, defendants could face potentially indefinite tolling under the statute (though they may still argue that the FCA's statute of repose, 31 U.S.C. § 3731(b)(2), imposes an absolute 10-year limit on FCA suits). Lower courts have applied the WSLA in civil actions having nothing to do with war procurement, in health care and financial services cases, such that the potential for indefinite liability is by no means limited to defense contractors. If the Court holds that the first-to-file bar applies only to pending actions, defendants could continue to face the burden of follow-on suits even after an earlier relator has pursued (and the government has investigated) the same underlying facts.

D.C. Circuit: (1) Privilege Protection for Internal FCA Investigations; (2) First-To-File Bar; (3) "Reckless Disregard" and Duty To Investigate; (4) Public Disclosure Bar

***In re Kellogg Brown & Root*, 756 F.3d 754 (D.C. Cir. 2014)**

In a rare mandamus proceeding, the D.C. Circuit held that an internal investigation mandated by DoD regulations (which require contractors to maintain compliance programs and investigate allegations of potential wrongdoing) was protected by the attorney-client privilege because obtaining legal advice was "one of the significant purposes" of the investigation. WilmerHale represented amicus curiae the Chamber of Commerce of the United States of America.

About the Case

Relator Harry Barko worked for Kellogg Brown & Root (KBR) and filed a qui tam complaint under the FCA alleging KBR inflated costs and accepted kickbacks on military contracts. In discovery, Barko sought documents relating to KBR's internal investigation into the alleged fraud, which KBR had conducted pursuant to its internal Code of Business Conduct and which was overseen by KBR's law department. KBR argued that the internal investigation was protected from disclosure by the attorney-client privilege because it was conducted for the purpose of obtaining legal advice, but the district court disagreed, reasoning that because the investigation was compelled by DoD regulations, it was not undertaken for the purpose of obtaining legal advice. The district court ordered KBR to produce the requested documents and declined to certify the issue for interlocutory appeal; accordingly, KBR petitioned the D.C. Circuit for a writ of mandamus.

The D.C. Circuit granted the writ, explaining: "So long as obtaining or providing legal advice was *one of the significant purposes of the internal investigation*, the attorney-client privilege applies, even if there were also other purposes for the investigation and even if the investigation was mandated by regulation rather than simply an exercise of company discretion." 756 F.3d at 758-59 (emphasis added). The court explained that the "extraordinary" writ of mandamus was warranted because the district court was clearly wrong and KBR had no other adequate means of obtaining the relief requested.

Implications for Future FCA Cases

While this widely publicized decision does not affect FCA doctrine, it is relevant to all corporate defendants who may be called upon to conduct internal investigations into potential wrongdoing. To be sure, it is controlling only within the D.C. Circuit, but it is an important decision that will fortify the privilege protections available to internal corporate investigations. Moreover, it confirms the availability of mandamus to preserve the attorney-client privilege—an important safeguard given the general lack of interlocutory review of district court privilege rulings.

***United States ex rel. Shea v. Cellco Partnership*, 748 F.3d 338 (D.C. Cir. 2014)**

A divided panel of the D.C. Circuit held that the FCA's first-to-file rule bars subsequent related suits even if the first-filed action is no longer pending, creating a split with the three other circuits to have considered the issue. WilmerHale represented the defendant before the D.C. Circuit.

About the Case

In 2007, relator Stephen Shea filed a qui tam action claiming that Verizon had knowingly overcharged the GSA by adding surcharges to government bills. The United States intervened, and the parties settled the case in February 2011. Meanwhile, in June 2009, Shea filed another complaint that closely mirrored the complaint in Shea's first-filed action against Verizon, alleging that Verizon overcharged the government by billing for non-allowable surcharges, with the only difference being the inclusion of more contracts, more charges, and more government agencies than were identified in the first-filed action. Shea filed an amended complaint in 2012.

In the district court, Verizon argued that the second-filed action should be dismissed with prejudice under the first-to-file bar, but the relator argued dismissal should be without prejudice because the first-filed

action was no longer pending when the court disposed of the second-filed action (such that, in his view, a re-filed action would not be subject to the bar).

The panel unanimously agreed that the second-filed action should be dismissed because it was filed before the first-filed action was settled. 748 F.3d 343. The panel divided over whether the dismissal should be with prejudice, with the majority holding that dismissal with prejudice was warranted because the first-to-file bar does not expire with the first-filed case, but continues to operate even when the first-filed case is no longer pending. 748 F.3d 343-44.

Implications for Future FCA Cases

As noted, the D.C. Circuit's decision created a circuit split. On July 1, the Supreme Court granted certiorari in *Kellogg Brown & Root Services, Inc. v. United States ex rel. Carter*, a case presenting the same first-to-file issue as *Shea* (along with an important issue related to the application of the WSLA to qui tam suits under the FCA). The Supreme Court heard oral argument on January 13, 2015; a decision is expected by the end of the term.

***United States ex rel. Folliard v. Government Acquisitions*, 764 F.3d 19 (D.C. Cir. 2014)**

The D.C. Circuit addressed the standard for scienter under the FCA in a case alleging customs fraud, holding that it is not necessary for a company independently to investigate the accuracy of statements made by suppliers in order to avoid running afoul of the FCA's "reckless disregard" standard.

About the Case

The relator in *Folliard* alleged the defendant (Govplace) sold products to the government that originated in countries that were not specially designated under the TAA, as required for government sales. In moving for summary judgment, Govplace argued that it reasonably relied on express certifications provided by its supplier that the products in question originated in TAA-designated countries, and it did not independently investigate the origin of the products. The D.C. Circuit held that it was reasonable for Govplace to rely upon the supplier's certifications under the circumstances, noting that it had disclosed its reliance on these third-party certifications during regular GSA audits of the company. 764 F.3d 29-30.

Implications for Future FCA Cases

Potential FCA defendants often rely on certifications of third parties such as suppliers to ensure compliance with government program requirements and regulations. *Folliard* lessens the risk that, in the absence of "red flags" indicating that third-party certifications are inaccurate, a company that has relied on such certifications will be found to have recklessly disregarded the truth or falsity of assertions made to the government based on the certifications.

***United States ex rel. John Doe v. Staples*, --- F.3d --- (D.C. Cir. Dec. 2, 2014)**

The D.C. Circuit held that a relator's claims were based on public information because the relator contributed nothing significant to the existing public record. WilmerHale represented defendant Staples.

About the Case

An anonymous relator alleged that Staples, Office Max, Target, and Industries for the Blind imported pencils they knew were made in China, but falsely declared to U.S. Customs that the pencils were manufactured elsewhere in Asia to avoid substantial antidumping and other duties imposed on Chinese-made pencils. In particular, the relator alleged the defendants' Asian suppliers "transshipped" Chinese pencils through their own countries before shipping them to the United States.

During the relevant time, the FCA stripped courts of jurisdiction over actions "based upon the public disclosure of allegations or transactions." The defendants argued that the relator's allegations were publicly disclosed in reports of the International Trade Commission (ITC) and in the defendants' printed and online marketing materials, and in any event, the pencils themselves could be easily viewed in the

defendants' stores. The D.C. Circuit agreed, holding that the relator's allegations were based at least in part on the pencil characteristics in the ITC reports. In responding to the relator's argument that the ITC reports were non-specific to the defendants' pencils, the court of appeals said that allowing relator's claim to proceed would frustrate the purpose of the public disclosure bar—to prevent opportunistic plaintiffs who have no significant information to contribute of their own.

Implications for Future FCA Cases

The decision provides a strong precedent for defendants seeking to have claims dismissed under a functional approach to the public disclosure bar and to defeat claims by relators who have pieced together an alleged fraud from public information, but who "have no significant information to contribute on their own." No. 13-7071, 2014 WL 6765033 at *5 (D.C. Cir. Dec. 2, 2014).

***United States ex rel. Oliver v. Philip Morris USA*, 763 F.3d 36 (D.C. Cir. 2014)**

The D.C. Circuit held that the FCA's public disclosure bar does not operate where a company's failure to comply with its legally required certifications to government customers could be inferred from the company's conduct and the existence of legal requirements the government is presumed to know, but the certifications themselves were not publicly disclosed.

About the Case

The relator, the president of a tobacco company that competes with Philip Morris, alleged that Philip Morris was required to provide the government with most-favored-customer pricing but failed to do so because Philip Morris sold cigarettes to its affiliates for lower prices, while certifying to the government that it had, in fact, provided most-favored customer pricing. Philip Morris argued that the allegedly fraudulent transactions were publicly disclosed in a Philip Morris memorandum, which recounted a circumstance in which a U.S. Military buyer sought to purchase Phillip Morris products from a duty-free wholesaler at lower prices than Philip Morris sold the same products to the U.S. Military buyer.

The court of appeals held that, while the Philip Morris memorandum disclosed that it was not providing the U.S. Military buyer the best price for its products, the certification to the contrary was not public so the relator's claim could proceed. The court rejected arguments that the most-favored-customer requirements were in the public domain because they were legal requirements of which the government was presumed to be aware. Rather, the court explained: "a public disclosure requires that there be some act of disclosure to the public outside of the government. The mere fact that the disclosures are contained in government files someplace, or even that the government is conducting an investigation behind the scenes, does not itself constitute a public disclosure." 763 F.3d at 42.

Implications for Future FCA Cases

While in some ways limited to its facts, *Philip Morris* could be used by relators to defeat defendants' public disclosure arguments where the relevant facts are publicly disclosed, but require knowledge of the applicable legal requirements to understand. *Philip Morris* increases the burden on defendants advancing public disclosure arguments where some aspect of the disclosure is in the general background—such as a congressional enactment or promulgated regulation—and not in the public disclosure itself.

First Circuit: (1) First-To-File Bar; (2) Tax Treatment of FCA Settlements

***United States ex rel. Wilson v. Bristol-Myers Squibb, Co.*, 750 F.3d 111 (1st Cir. 2014)**

The First Circuit held that the FCA's first-to-file rule barred a relator's claims alleging illegal promotion of drugs for certain off-label uses where an earlier-filed action had alleged the same marketing techniques by the same defendants with respect to different off-label uses of the drugs.

About the Case

Relator Michael Wilson alleged that Bristol-Myers Squibb, Co. (BMS) and SanofiAventis U.S., LLC (Sanofi) unlawfully promoted off-label uses of Plavix and Pravachol. In particular, he alleged that the companies engaged in a nationwide scheme in which they sponsored and promoted off-label research for the drugs; trained their sales forces to promote off-label prescriptions, including the use of altered “fax back” requests, which made it appear that physicians had requested third-party publications describing off-label uses; and promoted off-label uses in continuing medical education programs. Before Wilson filed his original complaint, an earlier relator filed a similar complaint that also alleged that BMS and Sanofi promoted off-label uses of Pravachol and Plavix using the same marketing techniques. However, the off-label uses alleged in the first-filed suit were for different diseases and symptoms.

The district court dismissed the later-filed suit under the FCA’s first-to-file rule, which bars relators from bringing “a related action based on the facts underlying [a] pending action,” 31 U.S.C. § 3730(b)(5).

The First Circuit affirmed, applying the well-established “essential facts” test that courts have developed for the first-to-file rule. Under that test, a later action is barred if a previous action stated all the essential elements of the claim, even if some of the details differ. The court held the test was satisfied here, noting that the earlier allegations about BMS and Sanofi were sufficient to put the government on notice that they were allegedly engaged in systematic, nationwide schemes to promote certain drugs for off-label uses.

Implications for Future FCA Cases

The case is a reminder that the essential facts test is not an “identical facts” test, and that if earlier allegations have put the government on notice of a larger body of alleged fraud, a claim may be subject to dismissal under the first-to-file rule.

***Fresenius Medical Care Holdings, Inc. v. United States*, 763 F.3d 64 (1st Cir. 2014)**

The First Circuit held that the portion of an FCA civil settlement that a jury had determined to be compensatory, rather than punitive, in nature, was deductible for federal income tax purposes. The court rejected the government’s argument that settlement payments attributable to multiple damages under the FCA cannot be deducted except when the defendant and the government have explicitly agreed to characterize them as compensatory.

About the Case

In 2000, Fresenius Medical Care Holdings, Inc. (Fresenius) settled a range of civil and criminal FCA claims against its subsidiaries. Fresenius and the government entered into a set of criminal and civil settlement agreements under which the company paid $101 million in criminal fines and $385 million in exchange for the release of civil claims by the government and the dismissal of associated qui tam suits.

Fresenius claimed tax deductions for the entire $385 million civil settlement. The Internal Revenue Service initially disallowed the deduction for the portion of the payment in excess of single damages ($192.6 million) under a tax code provision that makes a “fine or similar penalty” non-deductible. I.R.C. § 162(f). After an administrative appeal, the Service conceded that the portion of the settlement paid to the relators ($65.8 million) was deductible. Fresenius then filed a tax-refund action in district court, claiming a deduction for the remaining $126.8 million. Fresenius presented evidence that the government had negotiated the multiple damages in part as compensation for the time value of money and the costs of resolving the action, and a jury found that an additional $95 million was deductible. The court entered judgment for Fresenius in the amount of $50.4 million of tax and interest, which the government appealed.

The government argued on appeal that any settlement amount in excess of single damages for FCA claims is a non-deductible fine or penalty for tax purpose unless the parties have explicitly agreed otherwise. The First Circuit rejected that argument, holding that in the absence of an agreement as to tax treatment the proper test was to look to the “economic reality” of the settlement. The court noted, however,

that if the parties do specifically agree how to treat an FCA settlement for tax purposes, “it is hard to envision any reason why a reviewing court should not honor that agreement.” 763 F.3d at 70.

Implications for Future FCA Cases

The First Circuit’s decision is significant for any company considering an FCA settlement with the government. Given the size of many FCA settlements, the availability of a tax deduction may be a significant consideration. FCA defendants should consult with counsel and other tax advisors concerning the portion of a settlement that may be attributed to compensation of the government (and therefore deductible) and the contemporaneous documentation that may be needed to support such an attribution.

<u>Second Circuit</u>: [None]

<u>Third Circuit</u>: (1) Rule 9(b) Pleading Standards; (2) Public Disclosure Bar

***United States ex rel. Foglia v. Renal Ventures Management,* 754 F.3d 153 (3d Cir. 2014)**

The Third Circuit deepened an existing circuit split by holding that, to satisfy the requirement that FCA claims be pled with particularity, a relator must allege particular details of a scheme to submit false claims, together with reliable indicia that lead to a strong inference that false claims were actually submitted.

About the Case

The relator, a former Renal Ventures employee, alleged that the company falsely certified to the government that it was in compliance with state regulations regarding quality of care, falsely submitted claims for reimbursement for the drug Zemplar, and improperly reused single-use Zemplar vials. The district court dismissed the claim for failure to plead fraud with sufficient particularity under Rule 9(b), focusing on Foglia’s failure to provide a representative sample false claim or to identify specific false claims submitted to the government.

The court of appeals noted that the Fourth, Sixth, Eighth, and Eleventh Circuits each require a relator to allege representative samples of the alleged fraudulent conduct, but that the First, Fifth, and Ninth Circuits have held that a relator may merely allege “particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims are actually submitted.” 754 F.3d at 156 (quoting *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009)). After considering the views of its sister circuits, and the views of the United States (as expressed in a brief filed by the Solicitor General to the Supreme Court in support of review of a case arising from the Fourth Circuit) that the Fourth, Sixth, Eighth, and Eleventh Circuits had misinterpreted Rule 9(b), the Third Circuit sided with those circuits requiring only detailed allegations of a scheme and reliable indicia supporting a strong inference the claims were actually submitted. 754 F.3d 156.

Implications for Future FCA Cases

Arguments based on the requirement in Rule 9(b) that fraud must be pled with particularity are among the strongest tools for defendants to successfully defeat FCA claims at an early stage. As reflected by the growing circuit split on the requirements of Rule 9(b), the grounds and strength for motions to dismiss on Rule 9(b) grounds will continue to vary significantly by circuit.

***United States ex rel. Schumann v. AstraZeneca Pharmaceuticals*, No. 13-1489, 2014 WL 5315251 (3d Cir. Oct. 20, 2014)**

The Third Circuit affirmed the district court’s dismissal of a relator’s claims because he did not have the requisite direct and independent knowledge to meet the original source exception to the public disclosure bar.

About the Case

The relator was a vice president of a pharmacy benefit manager, Medco. He alleged that Bristol-Myers Squibb Company, E.I. du Pont de Nemours and Company, and DuPont Pharmaceuticals Company, AstraZeneca Pharmaceuticals LP, and AstraZeneca LP caused Medco to submit false best price reports for drugs to the government. The defendants moved to dismiss the claims under the public disclosure bar, arguing that the relator lacked the requisite knowledge to be an original source of the claims.

The Third Circuit expressed the test for direct and independent knowledge using the familiar algebraic formulation that courts have applied to determine whether allegations or transactions have been publicly disclosed: if X + Y = Z, and Z represents the allegation of fraud and X and Y represent its essential elements, then the plaintiff must have independent knowledge of either Z or both X and Y to qualify under the original source exception. The relator had asserted that his knowledge of the claims was based on: (1) his review of confidential agreements between Medco and the defendants and discussions with individuals who participated in the negotiations of the agreements; and (2) his understanding, based on his industry experience, that the defendants intended to pay kickbacks to Medco and submit false claims to the government. The court of appeals rejected this as insufficient, reasoning that a relator's knowledge is not direct where it depends on reviewing documents memorializing the alleged illicit schemes and speaking with the individuals who were actually involved in the agreements, and that a relator's general experience in the industry (or expertise derived therefrom) does not evince direct and independent knowledge of the alleged fraud.

Implications for Future FCA Cases

Schumann reflects a stringent application of the original-source exception to the public disclosure bar that should favor defendants litigating against relators who lack direct personal knowledge of publicly disclosed allegations of fraud.

Fourth Circuit: (1) Regulatory Noncompliance as Insufficient Basis for FCA Liability; (2) Original Source Exception; (3) FCA Liability of State-Created Entities; (4) Anticompetitive Conduct as Insufficient Basis for FCA Liability

***United States ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694 (4th Cir. 2014)**

The Fourth Circuit held that because compliance with the Food and Drug Administration's (FDA) Current Good Manufacturing Practices (cGMP) regulations is not a precondition for reimbursement under Medicare and Medicaid, violations of the cGMP regulations by themselves cannot form the basis of FCA claims under those programs.

About the Case

A pharmacist filed a qui tam lawsuit against his former employer, Omnicare, alleging that it operated a facility that packaged both penicillin and non-penicillin products in the same building, with inadequate separation and controls, in contravention of the FDA's cGMP regulations. The relator alleged that Omnicare violated the FCA by submitting Medicare and Medicaid reimbursement claims for drugs that were not manufactured in compliance with applicable regulations. The Fourth Circuit held that despite Omnicare's failure to comply with the particular regulations, the drugs were subject to reimbursement and, accordingly, there was no "false statement or fraudulent course of conduct as required for an FCA claim." 745 F.3d at 700. The Court emphasized that the FCA is not "a sweeping mechanism to promote regulatory compliance." *Id.* at 702.

Implications for Future FCA Cases

In addition to its application in the cGMP context, this decision provides general support for arguments that regulatory noncompliance does not give rise to FCA liability unless the regulations at issue are a condition of payment.

***United States ex rel. Ahumada v. NISH et al.*, 756 F.3d 268 (4th Cir. 2014)**

The Fourth Circuit held that relators claiming the original source exception to the public disclosure bar must establish their original source status as to *each* claim, and found that a majority of the relator's claims were precluded by the public disclosure bar.

About the Case

The relator alleged that his former employer and several other companies engaged in various schemes to overcharge the government in connection with a program to promote employment for blind and disabled persons. Participation in the program required certain annual certifications.

The Fourth Circuit concluded that the relator's allegations were at least partly based on public disclosures, and that many of the "allegations appear to have been lifted almost verbatim from various articles." 756 F.3d at 275. In analyzing whether the relator qualified as an original source, the Court evaluated the relator's knowledge with respect to each defendant separately, noting that the original source exception "does not permit claim smuggling . . .[;] the fact that a relator is an original source with respect to *some* claim does not confer jurisdiction in gross over *all* of his claims." *Id.* at 276 (emphasis in original). Finally, while the Fourth Circuit held that the relator was an original source of the allegations against one defendant, the Court held that the relator failed to adequately plead a claim under Rule 8 or Rule 9(b) as to that defendant. With respect to the relator's claim that the companies violated applicable regulations, the Fourth Circuit again emphasized that "the FCA cannot be used as a regulatory-compliance mechanism in the absence of fraudulent conduct directed at the federal government." *Id.* at 281.

Implications for Future FCA Cases

This decision illustrates that relators claiming the original source exception to the public disclosure bar must establish their original source status as to *each* claim. Further, like the *Rostholder* decision discussed above, this case reflects the Fourth Circuit's often-stated view that the FCA requires fraud, such that regulatory violations standing alone cannot form the basis of FCA liability.

***United States ex rel. Oberg v. Pennsylvania Higher Educ. Assistance Agency, et al.*, 745 F.3d 131 (4th Cir. 2014)**

A divided panel of the Fourth Circuit held that whether a state-created corporation is a "person" subject to liability under the FCA is an appropriate question to resolve on a motion to dismiss; the court applied the four-factor "arm-of-the-state" analysis used in the Eleventh Amendment context to determine whether certain state-created corporations qualified as such.

About the Case

The relator sued multiple state-established student loan corporations alleging FCA violations related to subsidies provided by the U.S. Department of Education. The district court initially dismissed the case on the ground that the state-created corporations were not "persons" subject to liability under the FCA, but the Fourth Circuit reversed and remanded for the district court to apply the "arm-of-the-state" framework developed in the Eleventh Amendment context. *See U.S. ex rel. Oberg v. Ky. Higher Educ. Student Loan Corp.*, 681 F.3d 575 (4th Cir. 2012). The district court did so and again dismissed the case.

As an initial matter on appeal, a divided panel held that whether a state-created corporation was an "arm of the state" was appropriate for resolution on a motion to dismiss, holding that "personhood is an element of the statutory FCA claim, not an immunity providing a defense from suit as in the Eleventh Amendment context." *Id.* at 136; the dissent argued that lack of personhood was an affirmative defense that cannot be decided at the pleading stage. The majority then applied four factors to determine whether each corporate defendant was an arm-of-the-state: (1) "whether any judgment against the entity as defendant will be paid by the State;" (2) "the degree of autonomy exercised by the entity, including such circumstances as who appoints the entity's directors or officers, who funds the entity, and whether the State retains a veto over the entity's actions;" (3) "whether the entity is involved with state concerns as distinct from non-state concerns, including local concerns;" and (4) "how the entity is treated under state

law, such as whether the entity's relationship with the State is sufficiently close to make the entity an arm of the State." *Id.* at 136-38. Ultimately, the court held that further discovery was required as to two of the defendants, but dismissed the third corporation based on the pleadings.

Implications for Future FCA Cases

Together with the Fourth Circuit's earlier decision in 2012, the case provides a framework for determining whether state-created entities qualify as "persons" subject to liability under the FCA.

***United States ex rel. Bunk v. Birkart Globalistics GmbH & Co., et al.*, Nos. 1:02–cv–1168 (AJT/TRJ), 1:07–cv–1198 (AJT/TRJ), 2014 WL 7359585 (E.D. Va. Dec. 24, 2014)**

A district court in the Eastern District of Virginia overturned a jury verdict in favor of the government, holding as a matter of law that anticompetitive conduct standing alone, without any misrepresentations or fraudulent conduct, is insufficient to establish FCA liability.

About the Case

The defendant provided services to American carriers who contracted with the United States to assist military personnel in moving household goods to and from Germany through the International Transportation Government Bill of Lading program (ITGBL program). The defendant and other local agents entered into an agreement among themselves to charge a "landed rate" that resulted in higher prices.

The government alleged that this was an anticompetitive scheme to inflate the prices paid by the United States, which "directly undermined the integrity of the price that [the government was] charged" and was thus sufficient to impose FCA liability. 2014 WL 7359585, at *7. The government did not allege that the defendant made any affirmative misrepresentation or failed to comply with a contract provision or regulation.

The district court overturned a jury verdict in favor of the government, holding that "[a]s a matter of law, actionable False Claims Act conduct must contain an element of falsehood to be fraudulent. Anti-competitive conduct, in and of itself, does not necessarily; and absent some affirmative misrepresentation, expressed or implied, the government's 'expectations' or Gosselin's anti-competitive conduct, standing alone, cannot supply the false statement or fraudulent conduct necessary to impose False Claims Act liability." *Id.* at *10. The court distinguished the case from instances of bid-rigging, which "involve[] an element of deception that is absent in this case[;]" here, the defendant disclosed the agreement to charge a "landed rate." *Id.* at 8, 10.

Implications for Future FCA Cases

This decision illustrates that anticompetitive conduct, in and of itself, is insufficient to impose FCA liability; the FCA requires fraudulent conduct.

<u>Fifth Circuit</u>: (1) Requirement that Financial Loss Be Traced to U.S. Treasury Funds; (2) No Liability Regarding Funds from FCC's E-Rate Program; (3) Certifications of Compliance Must be Prerequisite to Payment to Create FCA Liability; (4) Relators' Rights to Criminal Restitution Amounts as Alternate Remedy

***United States ex rel. Shupe v. Cisco Systems, Inc., et al.*, 759 F.3d 379 (5th Cir. 2014)**

The Fifth Circuit held that the government "provides any portion" of requested money (as required to qualify as a "claim" under the FCA) when United States Treasury dollars flow to the defrauded entity or the false claim is submitted to a government entity; the court held that funds received from the FCC's E-Rate program did not qualify under this standard.

About the Case

The relator alleged that certain telecommunications companies violated the FCA in connection with contracts to install and operate communications networks. Partial funding for these contracts came through the E-Rate fund administered by the Universal Service Administrative Company (USAC), an entity designated to collect mandatory contributions from telecommunications carriers in accordance with FCC regulations. The Fifth Circuit held that FCA liability does not extend to requests for money from the USAC-administered fund, which was supported by (mandatory) private contributions. It held that "the Government 'provides any portion' of the money requested under § 3729(c) when United States Treasury dollars flow to the defrauded entity or if the false claim is submitted to a Government entity." 759 F.3d at 383. The Fifth Circuit noted that "courts have limited the FCA's application to instances of fraud that might result in financial loss to the Government." *Id.* at 385. Because the money in the fund was not traceable to the United States Treasury, the court reasoned, the United States did not have the requisite financial stake in the allegedly fraudulent losses, regardless of the government's regulatory interest in the program. Moreover, although the FCC retains oversight and regulates the USAC, the Court found "it is explicitly a private corporation owned by an industry trade group." *Id.* at 387.

Implications for Future FCA Cases

The decision provides important precedent that FCA liability requires financial loss that is traceable to the United States Treasury.

***United States ex rel. Spicer v. Westbrook, et al.*, 751 F.3d 354 (5th Cir. 2014)**

The Fifth Circuit held that dismissal was required where a relator failed to allege that certification of compliance with certain regulations was a prerequisite to payment.

About the Case

A bankruptcy debtor brought an FCA claim against a defense contractor alleging that it failed to comply with the performance standards under a manufacturing contract as well as applicable regulations. As an initial matter, the Fifth Circuit first determined that the bankruptcy trustee, not the debtor, had standing as the relator in this case because the debtor had failed to disclose the potential FCA claim during the Chapter 7 proceedings for his company. Turning to the district court's dismissal, the Court affirmed for failure to allege that certification of compliance was a prerequisite to payment, explaining: "false certifications of compliance create liability only when certification is a prerequisite to obtaining a government benefit." 751 F.3d at 365. The Fifth Circuit stated that although the court had previously discussed the prerequisite to payment requirement in terms of materiality, the prerequisite requirement "ultimately has to do with whether it is fair to find a false certification or false claim for payment in the first place." *Id.* at 365-66.

Implications for Future FCA Cases

The case provides further support for the principle that false certifications of regulatory compliance can support FCA liability only where such certification is a condition of payment (or other government benefit).

***United States ex rel. Babalola v. Sharma, et al.*, 746 F.3d 157 (5th Cir. 2014)**

The Fifth Circuit held that because there was no qui tam action pending at the commencement of a related criminal proceeding, relators were not entitled to recover from monies awarded as restitution in those proceedings as an alternate remedy under 31 U.S.C. § 3730(c)(5).

About the Case

Relators, medical assistants for the defendants, allegedly witnessed the defendants submitting fraudulent claims to Medicare, Medicaid, and private insurance companies. The relators sent an anonymous letter setting forth the details of the fraudulent claims to various government agencies, which spurred a criminal investigation by the government. The defendants were criminally charged with numerous counts of

conspiracy, healthcare fraud, and other federal crimes. The defendants pled guilty and were ordered to pay $43 million in restitution to Medicare, Medicaid, and private insurers. While the defendants' appeal of the restitution order was pending, the relators filed an FCA suit based on the same fraudulent claims they had earlier set forth in the anonymous letter.

The only dispute before the district court was whether the relators were entitled to a share of the restitution amount, and the district court granted partial summary judgment for the government, finding that the filing of a valid qui tam action is a prerequisite to the operation of the alternate remedy provision of the FCA. The Fifth Circuit affirmed. Because there was no valid FCA complaint in existence at the time the government initiated the criminal proceeding, it did not constitute an alternate remedy. Under the court's interpretation, a relator who brings fraud to the government's attention but does not file suit before the government pursues an alternate remedy will get no recovery.

Implications for Future FCA Cases

Relators seeking to pursue recovery under the FCA must be vigilant in filing qui tam suits, as they could be precluded from recovery if the government initiates an alternate proceeding before an FCA action is filed.

<u>Sixth Circuit</u>: (1) Arbitrability of FCA Retaliation Claim; (2) Status of Job Applicants as "Employees" Protected by FCA Retaliation Provisions

***United States ex rel. Paige v. BAE Sys. Tech. Solutions & Servs., Inc.*, 566 F. App'x 500 (6th Cir. 2014)**

The Sixth Circuit held that an arbitration clause contained in a corporate defendant's employment agreement was not broad enough to encompass a claim for retaliation under the FCA.

About the Case

The plaintiffs brought qui tam and retaliation claims alleging that they were subject to adverse employment actions in response to protected FCA activity. The district court dismissed the qui tam claims for failure to state a claim and dismissed the retaliation claims in favor of arbitration, relying on a provision of the plaintiffs' employment agreements requiring arbitration of "'any dispute, which arises under the terms of this Agreement.'" *Id.* at 503. The plaintiffs appealed only the dismissal of their retaliation claims. The Sixth Circuit reversed, holding that the claims were "purely statutory" and did not allege a violation of the agreements, but rather asserted "an independent claim that would exist even without the contract;" therefore, in the court's view, the claims did not "arise under" the terms of the agreements. *Id.* It further observed that the agreements made no mention of FCA, retaliation, or statutory claims. The court suggested, however, that the arbitration agreements might have covered retaliation claims if they had used broader language, such as referring to claims "'related'" to the agreements, or "'any dispute arising from your employment.'" *Id.* at 504.

Implications for Future FCA Cases

The decision was limited to the specific arbitration clause at issue but provides a cautionary example for companies seeking to compel arbitration of FCA retaliation claims by their employees. Those who seek to do so should evaluate whether the language of their arbitration agreements is sufficiently broad to capture such claims under the Sixth Circuit's reasoning.

***Boegh v. EnergySolutions, Inc.*, 772 F.3d 1056 (6th Cir. 2014)**

As a matter of first impression among federal appellate courts, the Sixth Circuit held that a job applicant was not an "employee" of the prospective employer permitting suit under the FCA retaliation provisions.

About the Case

The plaintiff worked as a landfill manager at a uranium enrichment facility, during which time he allegedly engaged in FCA-protected activity. Subsequently, the defendant assumed control of waste management services at the facility from the plaintiff's former employer, and the plaintiff applied for, but was denied, employment with the defendant. The plaintiff alleged that the defendant thereby violated the FCA's retaliation provisions. The Sixth Circuit agreed with the district court that, as an applicant for employment with no relationship with defendant, the plaintiff was not an "employee" under the FCA retaliation provisions. In so holding, the Sixth Circuit applied the plain meaning of the term "employee" and the FCA's legislative history.

Implications for Future FCA Cases

The Sixth Circuit was the first appellate court to decide the issue, but its decision was based on a straightforward analysis of the statutory text and its legislative history that can be easily applied outside of the circuit.

<u>Seventh Circuit</u>: (1) "Worthless Services" Theory of Liability; (2) Relators' Burden To Introduce Evidence of Number of False Certifications; (3) Corporate "Reckless Disregard" Standard; (4) Departure from Grant Application Insufficient to Create FCA Liability; (5) Relators' Obligation To Plead Source or Knowledge To Satisfy Rule 9(b) Pleading Standards

***United States ex rel. Absher v. Momence Meadows Nursing Ctr., Inc.,* 764 F.3d 699 (7th Cir. 2014)**

The Seventh Circuit overturned a significant jury verdict on multiple grounds—including that the relators could not prevail on a "worthless services" theory where the services rendered had some value, and that they could not prevail on a "false certification" theory where they failed to introduce evidence establishing the number of false certification forms the defendant allegedly submitted.

About the Case

Relators brought qui tam and retaliation claims against a nursing home in connection with its alleged provision of inadequate care to Medicare and Medicaid patients. The relators sought to recover under both "worthless services" and "false certification" theories of liability. A jury found in favor of the relators and awarded over $3 million in compensatory damages and $19 million in fines to the United States, and over $400,000 to relators on the retaliation claims. The district court trebled the damages award to the United States, set aside the fines as constitutionally excessive, and granted the retaliation damages as awarded.

On appeal, the Seventh Circuit vacated the entire award and remanded for entry of judgment for defendants. The court declined to address the validity of the "worthless services" theory of liability because relators' evidence (which established only that defendants had provided services of a diminished value) would not satisfy that theory. "Services that are 'worth less' are not 'worthless.'" 764 F.3d at 710. With respect to the relators' "false certification" theory, the Seventh Circuit declined to address whether it would permit an "implied certification" theory of liability in the circuit because the relators had not argued to the jury that implied certification was a condition of payment. *Id.* at 711. The court rejected the "express certification" theory of liability for lack of evidence: while relators had offered evidence of the many certification forms the defendants submitted in total, they failed to offer evidence as to how many of those forms were false. *Id.* at 714. "[T]here has to be some evidence—statistical or otherwise—from which the jury could determine (at least approximately) how many of [the defendant's] documents contained false certifications." *Id.* The difficulty of doing so, the court explained, does not relieve relators of their burden to "'prove all essential elements of the cause of action, including damages, by a preponderance of the evidence.'" *Id.* (quoting 31 U.S.C. § 3731).

Implications for Future FCA Cases

The case is significant in that the Seventh Circuit declined to rule on the validity of either the "worthless services" or "implied certification" theories of liability, which remain open issues in the circuit, and did not relieve relators of their burden of proving each essential element of their cause of action.

***Thulin v. Shopko Stores Operating Co., LLC*, 771 F.3d 994 (7th Cir. 2014)**

The Seventh Circuit held that a pharmacy chain's practice of billing Medicaid for the difference between the amount paid by private insurers for prescriptions filled by dual-eligible patients and the price negotiated by Medicaid for the same drugs did not support liability under the FCA.

About the Case

The relator alleged that the defendant pharmacy overbilled Medicaid in violation of the FCA for prescriptions filled by dual-eligible patients (*i.e.*, those with both private prescription drug coverage and Medicaid drug coverage) by charging Medicaid for both the unpaid copays *and* the difference between the lower reimbursement rate negotiated by the private insurer and the higher rate negotiated by Medicaid. The Seventh Circuit affirmed the district court's dismissal because it found the relator's theory of liability invalid as a matter of law, finding nothing to support the relator's theory that the lower reimbursement rates negotiated by private insurers were assignable to Medicaid under 42 U.S.C. § 1396k(a)(1)(A). The court of appeals also rejected the relator's contention that the pharmacy chain acted knowingly; the court went out of its way to say that, even if the relator's theory of liability were viable, allegations that a corporate defendant acted knowingly or with reckless disregard "simply by virtue of its size, sophistication, and reach" are insufficient to satisfy Rule 9(b). 771 F.3d at 1000.

Implications for Future FCA Cases

The Seventh Circuit's admonition that corporate defendants do not face a lower "reckless disregard" standard "simply by virtue of [their] size, sophistication, and reach" should prove useful to companies seeking to dismiss FCA claims on the pleadings. Note that *Thulin* did not address a reverse false claims theory, in which a company may be held liable if it "knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(1)(G). Companies should consider potential liability under this provision as well in cases involving reimbursement arrangements with the federal government.

***United States ex rel. Hill v. City of Chicago*, 772 F.3d 455 (7th Cir. 2014)**

The Seventh Circuit held that a city's departure from the plan in its grant applications was not a basis for FCA liability.

About the Case

The relator alleged that defendant City of Chicago violated the FCA when its equal opportunity program differed in various respects from the written plan it used to secure federal funds.

In an opinion by Judge Easterbrook, the Seventh Circuit affirmed the dismissal of the complaint because the program and plan were in "substantial agreement." 772 F.3d at 456. The panel noted that "[a]ny written plan sensibly can be understood to allow adaptations" and emphasized the importance of "[p]ractical accommodations" over "handling everything by the book." *Id.* The panel further observed that there was no allegation that those who wrote the grant applications were aware of the discrepancies, so there was no knowledge of falsity necessary to impose liability.

Implications for Future FCA Cases

The Seventh Circuit's allowance of practical accommodations free of FCA liability may be useful in any context in which a recipient of federal funds is charged with departing from its grant application.

***United States ex rel. Grenadyor v. Ukrainian Village Pharmacy, Inc.*, 772 F.3d 1102 (7th Cir. 2014)**

The Seventh Circuit strictly applied Rule 9(b) to affirm the dismissal of various FCA claims.

About the Case

The relator brought qui tam and retaliation claims against defendant pharmacies in connection with their alleged payment of kickbacks to customers and billing for drugs never delivered. The district court dismissed the complaint, and the Seventh Circuit affirmed as to the qui tam claims but reversed as to the retaliation claim.

In an opinion by Judge Posner, the Seventh Circuit held that the qui tams claims were insufficiently pled under Rule 9(b). In particular, the court explained: "To comply with Rule 9(b) [the relator] would have had to allege either that the pharmacy submitted a claim to Medicare (or Medicaid) on behalf of a *specific patient* who had received a kickback, or at least name a Medicare patient who had received a kickback[.]" 772 F.3d at 1107 (emphasis added). Further, although defendants expressly had certified that they would comply with anti-kickback rules and acknowledged that such compliance was a condition of payment by Medicare and Medicaid, the court concluded that the relator did not provide sufficient facts to support his allegation that this certification was knowingly false at the time it was made. As in the *Absher* case above, the Seventh Circuit again declined to address the viability of the "implied certification" theory of liability, because it concluded the relator's allegations would be insufficient even under that theory.

Perhaps most significantly, the panel rejected, under Rule 9(b), the relator's claim about a separate multistate scheme to bill for undelivered drugs because he failed to allege how he learned about the scheme. The panel noted that the relator worked only in Illinois and quoted a confidential witness who worked only in Minnesota, yet made allegations regarding the practices in six states. Moreover, the panel faulted the relator for failing to provide detail regarding how he learned about specific instances of the fraud he alleged in Illinois: "things that [the relator], if he isn't fabricating the incident, would know without having to conduct discovery." 772 F.3d at 1108. The Seventh Circuit further stated that pleading essential elements of the claim on information and belief "won't do in a fraud case." *Id.*

Finally, the panel reversed the dismissal of relator's retaliation claims. It concluded that under the pre-2009 version of the FCA, an internal complaint to an employer regarding fraudulent business practices was sufficient to constitute protected activity, even in the absence of a filed lawsuit.

Implications for Future FCA Cases

The panel's strict application of Rule 9(b) – particularly its requirement that relators explain in their complaints precisely how they learned about the fraud – is a useful precedent for defendants.

<u>Eighth Circuit</u>: Rule 9(b) Pleading Standards

***United States ex rel. Thayer v. Planned Parenthood of the Heartland*, 765 F.3d 914 (8th Cir. 2014)**

The Eighth Circuit joined the First, Third, Fifth, and Ninth Circuits in holding that it is sufficient at the pleading stage for an FCA plaintiff to allege "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted" in order to survive a motion to dismiss pursuant to Rule 9(b).

About the Case

The relator alleged that Planned Parenthood violated the FCA by seeking and obtaining Medicaid reimbursements for abortion-related prescriptions and services that were not reimbursable. The relator alleged four fraudulent schemes through which Planned Parenthood sought these reimbursements but did not allege any "representative examples" of the actual false claims that were submitted for reimbursement. 765 F.3d at 916.

The district court granted Planned Parenthood's motion to dismiss the complaint on the ground that the relator failed "to provide a single specific example of a particular fraudulent claim Planned Parenthood submitted to the government, let alone any representative examples." *Id.* The Eighth Circuit reversed. In doing so, the court clarified its holding in *United States ex rel. Joshi v. St. Luke's Hospital, Inc.*, 441 F.3d 552 (8th Cir. 2006), that when a relator alleges a fraudulent scheme, the complaint "must provide some representative examples of [the defendant's] alleged fraudulent conduct, specifying the time, place, and content of [the defendant's] acts and the identity of the actors." *Thayer,* 765 F.3d at 917. The court held that neither Rule 9(b) nor its previous holding in *Joshi* requires that representative examples be pleaded in *every* FCA complaint that alleges a systematic scheme of submitting false claims. *Id.* Rather, the court concluded that FCA complaints that plead personal knowledge of a defendant's submission of false claims are exempted from *Joshi*'s "representative example" requirement. *Id.* at 918. Because the relator was able to plead firsthand knowledge of Planned Parenthood's Medicaid billing schemes, the court found that her complaint contained sufficient "indicia of reliability" and thus she was not required to plead representative examples of actual false claims. *Id.* at 919.

Implications for Future FCA Cases

The Eighth Circuit joins a deepening split among the circuits regarding the pleading requirements under Rule 9(b) in cases alleging FCA violations. The court adopted a looser, relator-friendly standard that permits a complaint to survive a Rule 9(b) challenge, even in the absence of identification of any actual false claims. The court stated that a relator's personal knowledge of a defendant's billing or claims practices will supply the "reliable indicia" that false claims were actually submitted, thereby excusing a failure to plead representative examples of false claims.

<u>Ninth Circuit</u>: Rule 8 Pleading Standards

***Gonzalez v. Planned Parenthood of L.A.*, 759 F.3d 1112 (9th Cir. 2014)**

The Ninth Circuit upheld the district court's dismissal of an FCA complaint, concluding that it failed to state plausible claims for relief under Rule 8(a) when the complaint attached documents whose contents contradicted the complaint's allegations.

About the Case

The relator alleged that Planned Parenthood knowingly and falsely overbilled state and federal governments for contraceptives supplied to low-income individuals. 759 F.3d at 1113. Planned Parenthood bought contraceptives at a discounted rate and sought reimbursement for its "usual and customary rates," which is what Planned Parenthood would charge an average patient—a price lower than market cost to the individual but higher than Planned Parenthood's purchase price. *Id.* at 1114. Between 1997 and 2004, the California Department of Healthcare Services (CDHS) corresponded with Planned Parenthood and indicated that Planned Parenthood's reimbursements should be made "at cost," a value lower than its "usual and customary rates." *Id.* A 2004 audit of Planned Parenthood by CDHS revealed that Planned Parenthood had obtained more than $5 million in noncompliant reimbursements during the audit period. *Id.* CDHS did not, however, seek reimbursement of this money from Planned Parenthood because it found "conflicting, unclear, or ambiguous misrepresentations" about the definition of "at cost" in statements made to providers. *Id.*

The district court dismissed the complaint on Rule 9(b) grounds. *Id.* The Ninth Circuit affirmed on the alternate ground that the complaint did not state plausible claims for relief under Rule 8(a) and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009). *Id.* The court held that the relator did not state a plausible claim that Planned Parenthood submitted false claims with the requisite scienter because the materials he attached to his complaint—correspondence between Planned Parenthood and CDHS— contradicted the complaint's allegations that Planned Parenthood acted knowingly. *Id.* at 1115. The court concluded that statements made by CDHS regarding "conflicting, unclear, or ambiguous misrepresentations" of "at cost" billing fatally undercut the relator's allegation that Planned Parenthood knowingly submitted false claims for reimbursement. *Id.* at 1116.

Implications for Future FCA Cases

The Ninth Circuit made clear that it will not reach a Rule 9(b) particularity analysis if an FCA complaint fails under Rule 8(a) to plead plausible claims for relief, which includes a requirement that the complaint plausibly make an allegation of knowing scienter. The decision also underscores the danger of attaching documents to a complaint, which are then incorporated by reference, when those documents could be construed to undercut the complaint's allegations. The court demonstrated that it is not bound to treat a complaint's allegations as true when they are at odds with exhibit material.

<u>Tenth Circuit</u>: Release of Retaliation Claim

***VanLandingham v. Grand Junction Regional Airport Authority,* --- F. Supp. 2d ---, Civ. No. 1:13-cv-03414, 2014 WL 2462788 (D. Colo. June 2, 2014)**

The district court held that an individual may waive the right to bring a private retaliation claim under the FCA for valuable consideration, rejecting the plaintiff's argument that she could not waive her statutory rights under the FCA because the statue serves to protect the interests of the public as a whole.

About the Case

After raising concerns with her supervisor that costs associated with the construction of a security fence could not legitimately be reimbursed by the Federal Aviation Administration and the Transportation Security Administration, the plaintiff was discharged from her position as an airport security coordinator. In connection with her discharge, she signed a separation agreement that released all causes of action arising during the employment relationship in exchange for severance pay. She later brought a retaliation claim under the FCA, arguing that the release provision of her separation agreement was unenforceable as contrary to public policy. The district court rejected the argument and dismissed the claims, holding that releases of private claims under the FCA are permitted.

Implications for Future FCA Cases

This case provides strong support for corporate defendants seeking to enforce waivers included in separation agreements to preclude subsequent FCA retaliation claims.

<u>Eleventh Circuit</u>: Amenability of State Entities to FCA Liability

***United States ex rel. Lesinski v. South Florida Water Management District*, 739 F.3d 598 (11th Cir. 2014)**

The Eleventh Circuit affirmed the dismissal of a qui tam suit against the South Florida Water Management District (the District), concluding that the District was an "arm of the state" of Florida and therefore not a "person" subject to suit under the FCA.

About the Case

The relator brought a qui tam action alleging that the District violated the FCA by fraudulently claiming FEMA reimbursements for ineligible canal repairs. The district court dismissed on the ground that the District was not a "person" subject to suit under the FCA.

The Eleventh Circuit joined the Fourth, Fifth, Ninth, and Tenth Circuits in holding that the Eleventh Amendment "arm of the state" analysis should be used to determine whether a state entity is a "person" subject to FCA liability. As developed by the Eleventh Circuit in the Eleventh Amendment context (which is presented in slightly different terms than the test applied by the Fourth Circuit in the *Oberg* case above), this analysis requires a court to analyze four factors: (1) how state law defies the entity; (2) what degree of control the state maintains over the entity; (3) where the entity derives its funds; and (4) who is responsible for judgments against the entity. Pursuant to this analysis, the court concluded that the District acted as an arm of the state when it repaired the canals and sought reimbursement from FEMA, and thus was not subject to FCA liability.

Implications for Future FCA Cases

The Eleventh Circuit joined four other circuits in adopting an "arm of the state" analysis to determine whether a state entity is subject to FCA liability. This test narrows the state entities that can be held liable under the FCA and thus may provide an important defense for many state entities in a growing number of circuits.

V. State and Local Developments

State Legislative Activity

State and local legislatures were active in false claims legislation in 2014. 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.[131] 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 2014, five states were certified as DRA-compliant by the OIG: **Connecticut, Georgia, Indiana, New York,** and **Virginia**. The OIG has certified a total of 18 states as DRA-compliant to date (still well below the 28 that had reached DRA-compliance before the 2009 and 2010 FCA amendments).[132]

- Following prior guidance from the OIG, **Nevada** amended its false claims law to track the federal amendments.[133] But in March 2014, the OIG determined that Nevada's amended law does not comply with the DRA because its retaliation section "provides relief in fewer situations than under the Federal False Claims Act"—namely, the Nevada law "does not provide relief for acts done by 'associated others' in furtherance of an action, or for 'other efforts to stop 1 or more violations of this subchapter.'"[134]

Other significant state legislative developments include:

- Three states—**Maryland**, **Mississippi,** and **West Virginia**—introduced proposed false claims legislation in 2014 that did not pass.[135] The West Virginia bill came to a vote and was defeated,[136] while the Maryland and Mississippi bills died without a formal vote.[137]

- Legislation introduced in **Kentucky** in 2014 remains pending.[138] Also still pending are bills originally introduced in 2013 in **Michigan, Pennsylvania, Alabama, South Carolina,** and **Missouri**,[139] as well as a 2012 bill in **Arizona**.[140]

Noteworthy State Settlements or Judgments

As in previous years, the most significant state FCA settlements in 2014 concerned alleged Medicaid fraud. Pharmaceutical companies in particular were involved in many of these settlements, most of which were based on alleged inflated pricing or alleged illegal marketing or kickback schemes. States have also continued to join forces with the federal government, either individually or in multi-state efforts. Some of the more significant state FCA settlements in 2014 include:

- **Texas settled with Hi-Tech Pharmacal for $25 million.** In January, Hi-Tech Pharmacal agreed to pay $25 million to Texas and the federal government to settle allegations that the company fraudulently reported inflated prices for various generic drugs to the state's Medicaid program.[141]

- **Massachusetts settled with Shell for $4 million.** In February, Shell Oil Company agreed to pay $4 million to Massachusetts to settle allegations that it double-billed the state by seeking reimbursement for environmental cleanup projects for which it had already received payments through insurance companies.[142]

- **New York settled with Lantheus Medical Imaging and Bristol-Myers Squibb for $6.2 million.** In March, Lantheus Medical Imaging and its parent company, Bristol-Myers Squibb, agreed to pay $6.2 million to settle claims that the companies knowingly evaded New York State and City taxes (the New York statute is the only false claims law in the country that expressly covers tax fraud). The case arose out of a qui tam lawsuit brought under New York's False Claims Act.[143]

- **Texas settled with HEB Grocery Company for $12 million.** In March, HEB Grocery Company agreed to pay $12 million to settle allegations that it inflated prices on Medicaid claims for thousands of drug prescriptions filled through its pharmacies. The company allegedly offered a discount drug program to its customers, but did not charge this same discounted rate to the Texas Medicaid program. The case arose out of a qui tam lawsuit initiated by three pharmacists from neighboring states who filled prescriptions for HEB customers, but did not work for the company.[144]

- **Florida settled with All Children's Health System for $7 million.** In April, hospital operator All Children's Health System agreed to pay $7 million to Florida and the federal government to settle allegations that it ran a scheme to illegally overpay its physicians to ensure that referrals and extra procedures stayed within All Children's Hospital.[145]

- **California settled with Office Depot for $80 million.** In August, Office Depot agreed to pay $80 million to settle allegations that it overcharged several California agencies for office supplies. The California suit mirrored a Florida case involving allegations of overcharging, which Office Depot settled in 2010 for $4.5 million.[146]

- **Several states settled with Organon USA for $31 million**. As noted above in our discussion of federal healthcare-related settlements, in October Organon USA agreed to pay $31 million to the federal government and several states to settle allegations that it underpaid rebates to state Medicaid programs. The alleged false claims concerned the company's antidepressant drugs Remeron and SolTab.[147] The claims resolved by the settlement were allegations only, and there was no determination of liability.

- **Texas settled with Ranbaxy for $39.75 million.** In October, Ranbaxy Pharmaceuticals agreed to pay $39.75 million to Texas and the federal government to settle allegations that it reported inflated prices for various drugs to the state's Medicaid program.[148]

<u>Noteworthy State Complaints</u>

There were several noteworthy lawsuits filed by states in 2014, including the following:

- **Texas files $2 billion lawsuit against Xerox.** In May, Texas filed a lawsuit against Xerox Corporation and its wholly owned subsidiary, ACS State Healthcare LLC, alleging that they improperly approved Medicaid payments for orthodontic services. Xerox and ACS Healthcare were the vendor responsible for reviewing dental and orthodontic claims submitted to Medicaid to determine whether claims were covered. Texas's Medicaid statute covers only serious cases where orthodontic disfigurement poses a risk to patient health. The state's lawsuit alleges that Xerox and ACS State Healthcare approved orthodontic services that were not medically necessary and thus not authorized by law. The attorneys for the state estimate that the suit could result in up to $2 billion in damages and penalties.[149]

- **New York files lawsuit against health care providers.** As noted above in our discussion of federal healthcare-related complaints, in June New York and the federal government intervened in a suit against Continuum Health Partners and two of its hospitals, Beth Israel Medical Center and St. Luke's-Roosevelt Hospital Center. The suit alleges that the hospitals submitted improper claims to Medicaid based on a computer error. It further claims that Continuum knew of these improper claims, but failed to repay the state fully in a timely manner. The defendants have filed a motion to dismiss the case, which, to date, remains pending.[150]

- **Washington files lawsuit against educational consulting company.** In December, Washington filed suit against JT Educational Consultants, alleging that the company provided fraudulent training to dozens of school districts around the state and consequently caused tens of millions of dollars in false Medicaid claims.[151]

New York's FCA and Tax Fraud

New York remains at the forefront of developing and expanding false claims law at the state level. The New York False Claims Act (NYFCA) is unique among state laws in that it is the only one to expressly include tax fraud claims. The tax provision—which was added to the NYFCA in 2010—is about to undergo its first major test in New York v. Sprint Nextel Corp., which is the first tax enforcement action filed under the NYFCA.

- New York Attorney General Eric Schneiderman filed a $300 million tax false claims suit against Sprint in 2012 for failing to pay roughly $100 million in state taxes on sales of wireless phone services. The highest state court in New York recently approved an interlocutory appeal in the case to determine whether the state's claims are preempted by federal law (the Mobile Telecommunications Sourcing Act) and whether the retroactive application of the NYFCA to conduct before the tax provision was added is so punitive in nature that it violates the Ex Post Facto Clause of the U.S. Constitution. The New York Court of Appeals' decision bears watching as it could have significant implications on companies' tax exposure.[152]

VI. About WilmerHale's False Claims Act Practice

With a team of veteran litigators and former Justice and Defense Department lawyers, WilmerHale brings unparalleled knowledge and 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 were directly responsible for the litigation, management, and settlement of major FCA investigations and cases during periods of government service and who now defend against them. We 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 plaintiffs and the government by focusing on precedent-setting legal defenses, including innovative uses of the public disclosure bar. 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, 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 the Department of Defense, responsible for overseeing all litigation, including FCA litigation.
- 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 U.S. 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 the Department of Defense, where he supervised all litigation at DoD, including FCA and government-contracts litigation.
- A former First Assistant U.S. Attorney and Deputy Chief of the Civil Division of the Boston U.S. Attorney's Office, one of the most active offices in the country, where she litigated and supervised major FCA actions.
- 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 Deputy U.S. 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 Assistant Attorney General for Legal Policy, who worked extensively on behalf of DOJ negotiating amendments proposed by Congress to the FCA.
- A former Chief of Staff and Assistant Secretary for the United States Department of the Interior, who, in response to the Deepwater Horizon incident, acted as lead negotiator of the Natural Resource Damage Assessment team. He also served as the U.S. Attorney for Colorado.
- Numerous lawyers with FCA 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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