2015 YEAR IN REVIEW – THE FALSE CLAIMS ACT

January 2016

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Clients and Friends,

The False Claims Act, 31 U.S.C. §§ 3729, *et seq.* ("FCA") continued to be a significant focus of government and whistleblower activity in 2015. This *Year in Review* highlights several key developments, including:

- The number of new FCA lawsuits filed by whistleblowers declined slightly since last year, but remains very high – exceeding 600 cases filed in 2015 alone.
- The U.S. Department of Justice is continuing its strong enforcement of the FCA, including recovering more than $3.5 billion in settlements and judgments in FCA cases in 2015 and announcing a renewed focus on individual culpability.
- The U.S. Supreme Court resolved a key question about the first-to-file rule, and has agreed to clarify the so-called "implied certification" theory of liability.
- Lower courts continue interpreting the pleading requirements for FCA claims, analyzing the public disclosure bar, and addressing relators' rights and obligations, among other issues.

In 2015, Haynes and Boone represented healthcare providers, defense contractors, and individuals in FCA investigations and lawsuits. We successfully resolved matters before lawsuits were filed, negotiated favorable settlements, and continued to defend our clients in active litigation. We also advised a number of contractors and healthcare providers regarding FCA compliance and other related issues.

If you have any questions about the issues covered in this year's *Review*, please let us know. We look forward to working with our friends and clients in 2016.

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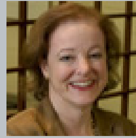

STACY BRAININ has extensive experience in white collar criminal defense and government investigations, including representation of companies and individuals in both criminal and civil False Claims Act matters. Her practice also includes complex business litigation with an emphasis in healthcare and professional liability matters. She has defended cases alleging civil and criminal business fraud in state and federal courts throughout the country. Stacy represents and advises healthcare providers in civil and criminal disputes with state and federal government agencies. She is experienced in handling internal investigations, compliance programs and legal audits.

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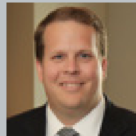
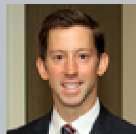
SEAN MCKENNA is a partner and co-chair of the firm's Healthcare Practice Group. He has more than 18 years of healthcare and fraud enforcement experience, spending most of that time in the federal government investigating and resolving civil, criminal, and administrative healthcare and white collar fraud investigations, matters, and cases. As an Assistant U.S. Attorney, Sean resolved hundreds of civil False Claims Act and fraud matters against all manner of healthcare providers and manufacturers. He previously worked in the Office of Counsel to the Inspector General for the Department of Health and Human Services in Washington, D.C., investigating and resolving affirmative civil monetary penalty and exclusion cases against physician groups, clinicians, hospital systems, and other healthcare providers.



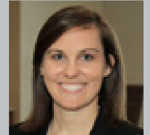
CHRIS ROGERS is a partner whose litigation practice focuses on controversies involving actual or threatened government enforcement. He has represented corporations and individuals who were targets, subjects, or witnesses in criminal investigations by government agencies, including the U.S. Department of Justice, the Securities and Exchange Commission, the U.S. Department of Transportation, and the Texas Attorney General's Office. His clients operate in many different industries, including telecommunications, healthcare, banking, securities, construction, and military contracting.

KENYA WOODRUFF is a partner and co-chair of the Healthcare Practice Group. Her practice is dedicated to healthcare regulatory and related transactional and business matters, including the creation and maintenance of compliant healthcare operations and structures for physicians, hospitals, home health and hospice providers. Kenya also regularly advises clients on compliance with HIPAA/HITECH, Stark, Anti-Kickback and other applicable fraud and abuse laws. Before joining the firm, Kenya served as Deputy General Counsel at the Dallas County Hospital District d/b/a Parkland Health & Hospital System, where she was responsible for government investigations.

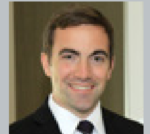


BENJAMIN GOODMAN is an associate in the firm's litigation section. He focuses on securities, healthcare, and False Claims Act litigation, while also navigating clients through internal and government investigations. Benjamin's practice also extends beyond white collar litigation to commercial and products liability disputes.

ANDREW GUTHRIE is an associate whose practice focuses on commercial litigation at both the trial and appellate levels. In 2015, he represented a number of clients in False Claims Act cases across a wide variety of industries, including healthcare, pharmaceuticals, and manufacturing. Andrew graduated first in his class from Baylor Law School and joined the firm after clerking for Texas Supreme Court Justice Don R. Willett.



JENNIFER KREICK is an associate in the firm's Healthcare Practice Group. Her practice focuses on healthcare transactions and regulatory and compliance matters, with a special focus on HIPAA/HITECH and healthcare IT. In 2012, among other matters, she assisted in the formation and advisement of an accountable care organization with over 300 independent physicians. Prior to joining Haynes and Boone, Jennifer managed the implementation of electronic medical record software and patient portal software for hospitals and outpatient clinics, including a large health system with more than twenty specialties.



BILLY MARSH is an associate in the firm's White Collar Criminal Defense, Securities Litigation, and Antitrust Practice Groups. His practice focuses on False Claims Act *qui tam* litigation, securities litigation, and privacy and data breach. He is a graduate of the University of Virginia School of Law.

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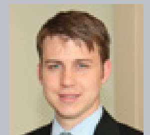
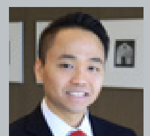


CHRIS QUINLAN is an associate in the firm's Healthcare and White Collar Criminal Defense Practice Groups. His practice focuses on representing individuals and healthcare providers in white collar, regulatory and government investigations. He routinely advises healthcare clients on Anti-kickback, Stark, and HIPAA issues, as well as various state and federal regulatory matters. He also represents healthcare organizations and companies in antitrust and general business litigation.

NICOLE SOMERVILLE is an associate in the firm's litigation section and focuses on False Claims Act *qui tam* litigation, internal investigations, and healthcare litigation. Nicole has experience assisting clients with internal investigations of potential violations of the Anti-Kickback Statute, the Stark Law, and the False Claims Act. In addition, she represents both healthcare and government contracting clients in disputes with state and federal agencies.



PHONG TRAN focuses his practice on complex commercial litigation, cybersecurity and government investigation matters. Phong has assisted clients in litigation and investigations involving class actions, health care, securities regulation, business torts and other complex legal and regulatory matters. Phong has also advised clients on compliance under HIPAA's security rule, the Foreign Corrupt Practices Act and other anti-corruption laws.

A. 2015: A LOOK BACK AT THE NUMBERS

1. 2015 was another record-breaking year.

On December 3, 2015, the U.S. Department of Justice reported that it recovered more than $3.5 billion in settlements and judgments from cases arising under the FCA during fiscal year 2015.[1] Although this amount was significantly less than last year's recovery, it continued DOJ's four-year record of obtaining recoveries in excess of $3.5 billion. DOJ has now recovered more than *$26.4 billion* since January 2009.

DOJ further reported:

- Of the $3.5 billion recovered, $1.9 billion came from companies or individuals in the healthcare industry, including $330 million from hospitals alone.
- More than half of the $3.5 billion – approximately $2.8 billion – was recovered in cases filed by private whistleblowers, with the whistleblowers receiving a record-breaking $597 million for their share of the award.
- Whistleblowers filed 638 *qui tam* suits in fiscal year 2015 – down from more than 700 last year but up from only 30 suits filed in 1987.

Among the cases resolved in 2015, there were several notable settlements and judgments, including:

- Two large recoveries from DaVita Healthcare Partners, Inc., including $450 million to resolve allegations that the company knowingly "generated unnecessary waste in administering the drugs Zemplar and Venofer to dialysis patients and then billed the government for costs that could have been avoided," and $350 million to resolve claims that it paid "kickbacks to physicians to induce patient referrals to its clinics."[2]
- The settlement of nearly 500 hospitals for a total of $250 million arising out of allegations that the hospitals were implanting cardiac devices contrary to criteria established by the Centers for Medicare and Medicaid Services.
- A $212.5 million settlement with First Tennessee Bank N.A. to resolve allegations that the bank, through a subsidiary, originated mortgages for federal insurance that did not meet eligibility requirements and then failed to report such deficiencies despite knowing about them.
- A $39 million settlement with Daiichi Sankyo Inc., a global pharmaceutical company, to resolve allegations that it paid kickbacks to physicians to induce them to prescribe Daiichi drugs.
- A $32.3 million settlement with Extendicare Health Services Inc., a skilled nursing home chain, to resolve allegations that it billed Medicare and Medicaid for deficient services.
- A $146 million settlement with Supreme Group B.V. and several of its subsidiaries to resolve allegations that it submitted false claims for food, water, fuel, and transportation of cargo for soldiers in Afghanistan.

THE U.S. DEPARTMENT OF JUSTICE REPORTED THAT IT RECOVERED MORE THAN $3.5 BILLION IN SETTLEMENTS AND JUDGMENTS FROM CASES ARISING UNDER THE FCA DURING FISCAL YEAR 2015.[1]

[1] *Available at* http://www.justice.gov/opa/pr/justice-department-recovers-over-35-billion-false-claims-act-cases-fiscal-year-2015.

[2] *See id.*

2. The government prioritizes “individual accountability” in FCA enforcement.

DOJ also issued a memorandum on September 9, 2015, addressing “individual accountability for corporate wrongdoing.”[3] Among other things, the memorandum emphasized DOJ’s commitment to use the False Claims Act to combat fraud by individuals, promising that the Department will “fully leverage its resources to identify culpable individuals at all levels in corporate cases.” The memorandum made the following recommendations “to most effectively pursue the individuals responsible for corporate wrongs”:

- Corporations should not qualify for cooperation credit unless they first provide “all relevant facts relating to the individuals responsible for the misconduct”;

- Investigations should “focus on individuals from the inception”;

- Absent “extraordinary circumstances,” DOJ should “not release culpable individuals from civil or criminal liability when resolving a matter with a corporation”;

- DOJ should not settle with a corporation “without a clear plan to resolve related individual cases.”[4]

DOJ demonstrated this commitment in a number of cases in 2015, including by intervening in several healthcare cases against individuals and structuring settlements with companies to include large payouts by individuals associated with them.[5] We fully expect that the Department will continue emphasizing this renewed objective in 2016.

[3] *Available at* http://www.justice.gov/dag/file/769036/download.

[4] *Id.*

[5] *See* http://www.justice.gov/opa/pr/justice-department-recovers-over-35-billion-false-claims-act-cases-fiscal-year-2015, *at 5.*

B. LEGISLATIVE UPDATE

In a move that went largely unnoticed, Congress substantially increased the penalties available in FCA cases. On October 30, 2015, Congress enacted the Bipartisan Budget Act of 2015, including a section entitled the “Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015.” *See* Bipartisan Budget Act Of 2015, Pub. L. No. 114-74, § 701, 129 Stat. 584, 599–600 (2015). That section authorizes federal agencies to increase the amount of civil monetary penalties to account for inflation. The last time the penalty amounts under the FCA were increased was 1999, when they were raised to $5,500 to $11,000 per claim. Under the new law, agencies must implement the increases through interim final rulemaking by August 1, 2016. Our firm will continue to monitor this development. The increase could in some cases raise serious constitutional concerns under the Excessive Fines Clause of the Eighth Amendment, as discussed further below.

DOJ ALSO ISSUED A MEMORANDUM ON SEPTEMBER 9, 2015, ADDRESSING “INDIVIDUAL ACCOUNTABILITY FOR CORPORATE WRONGDOING.”[3]

C. SIGNIFICANT JUDICIAL DECISIONS

The FCA also received considerable attention from the federal courts in 2015. The following is a brief summary of some of those key decisions, organized by issue.

1. Pleading with Particularity

One of the first hurdles for plaintiffs in an FCA suit is the heightened pleading standard of Federal Rule of Civil Procedure 9(b). Under this rule, a complaint must "state with particularity the circumstances constituting the fraud." *United States ex rel. Heath v. AT&T, Inc.*, 791 F.3d 112, 123 (D.C. Cir. 2015). Circuit courts remain divided over how to apply the rule, and particularly whether a plaintiff must specifically allege that false claims were actually submitted to the government, or whether "it is sufficient for a 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.'" *Id.* at 126.

a. The Supreme Court remains silent on the circuit split.

Although the U.S. Supreme Court has had several opportunities to resolve this split, it again declined to do so in 2015. In October 2015, the Supreme Court denied the petition for certiorari filed in a case we discussed last year, *United States ex rel. Grenadyor v. Ukrainian Village Pharmacy*, 772 F.3d 1102 (7th Cir. 2014), *petition for cert. denied*, 136 S. Ct. 49 (2015). The relator in *Grenadyor* was a pharmacist formerly employed by the Ukrainian Village Pharmacy. The relator claimed that the pharmacy gave gifts (such as tins of caviar) and forgave copays in order to induce individuals to have their prescriptions filled there instead of at a competing pharmacy. *Id.* at 1104. However, in applying a narrow pleading standard, the Seventh Circuit upheld the district court's dismissal of the kickback claims in the complaint, stating: "To comply with Rule 9(b) [the pharmacist] 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." *Id.* at 1107.

The relator sought review by the Supreme Court, arguing that the Seventh Circuit applied too "rigid" a pleading standard – one that conflicts with the more "flexible, content specific" approach in other circuits. The relator asked the Court to resolve the issue and articulate a standard that permits courts to draw reasonable inferences from the allegations, including that a healthcare provider submitted false claims based on allegations of a scheme to defraud. The Court denied the request on October 5, 2015, keeping this conflict—at least for the time being—alive in the lower courts.

ALTHOUGH THE U.S. SUPREME COURT HAS HAD SEVERAL OPPORTUNITIES TO RESOLVE THIS SPLIT, IT AGAIN DECLINED TO DO SO IN 2015.

b. The D.C. Circuit applies a more lenient pleading standard.

In contrast with the Seventh Circuit, the D.C. Circuit issued an opinion in 2015 arguably applying a "more flexible" standard – like the one referenced by the *Grenadyor* relator. In *United States ex rel. Heath v. AT&T, Inc.*, the court held that a complaint was sufficiently pled where it laid "out in detail the nature of the fraudulent scheme, the specific governmental program at issue, the specific forms on which misrepresentations were submitted or implicitly conveyed, the particular falsity in the submission's content, its materiality, the means by which the company concealed the fraud, and the timeframe in which the false submissions occurred." 791 F.3d 112, 115 (D.C. Cir. 2015), *petition for cert. filed* (Sept. 23, 2015). It did not matter that the relator had failed to identify the specific false statements, the individuals who allegedly made them, or even "'representative samples' of the claims that specify the time, place, and content of the bills." *Id.* at 125.

Requiring that level of detail, the D.C. Circuit held, "goes too far." "Rule 9(b) does not inflexibly dictate adherence to a preordained checklist of 'must have' allegations." *Id.* "Instead, the point of Rule 9(b) is to ensure that there is sufficient substance to the allegations to both afford the defendant the opportunity to prepare a response and to warrant further judicial process." *Id.* And all that will depend "on the nature of the fraud alleged and its statutory or common-law source." *Id.*

c. District courts apply the pleading standard in a variety of cases.

District courts continued to wrestle with Rule 9(b)'s pleading requirements. Below are a few key cases analyzing FCA complaints for compliance with Rule 9(b):

- Complaint failed to satisfy Rule 9(b) where it did not specify any false claim that was actually submitted to the government, even though the relator (a therapist) had personal knowledge that charts for therapy sessions lacked the required time documentation. Although the court might apply a more "relaxed standard" in certain cases where a relator had "personal knowledge" that claims were submitted, the court would not do so here, where the relator did not allege "any involvement with Defendants' billing or claims submission process." *McFeeters v. Nw. Hospital, LLC*, No. 3-13-0467, 2015 WL 328212 (M.D. Tenn. Jan, 23, 2015). *See also, United States ex rel. Prather v. Brookdale Senior Living Cmtys., Inc.*, No. 3:12-CV-00764 (M.D. Tenn. Nov. 5, 2015) (dismissing complaint where plaintiff failed to identify any false claim that was actually submitted to the government for payment).

- Complaint satisfied Rule 9(b) where relator alleged that a pharmacy did not reverse claims for federal reimbursement for prescriptions that were returned, and in some cases were resold, where the relator specified two instances of such returns, included a photograph of an envelope containing receipts for prescriptions that the pharmacy billed for but never dispensed, and alleged that an audit of a particular store revealed $98,000 in excess drug inventory. *United States v. Walgreen Co.*, No. 2:13-cv-8473 BRO (ASx), (C.D. Cal. Mar. 17, 2015).

- Complaint failed to satisfy Rule 9(b) where the relator, an emergency room physician, had involvement in filling out patient charts but no first-hand knowledge of a hospital's actual billing practices, submission of claims for payment or receipt of payments from government payors. The court held that "Courts of Appeal are in agreement that unless the relator is in a special position of personal knowledge or involvement in the billing practices of the defendant that affords some indicia of reliability to the allegations, the failure to provide specific information of at least a single false claim that was actually submitted for payment is fatal to a relator's action under the FCA." *United States ex rel. Gravett v. Methodist Med. Ctr. of Ill.*, 82 F. Supp. 3d 835 (C.D. Ill. March 4, 2015).

- Complaint failed to satisfy Rule 9(b) where it failed to provide representative examples of the conduct of each individual defendant that resulted in a false claim. *United States ex rel. Radke v. Sinha Clinic Corp.*, No. 1:12-cv-06238 (N.D. Ill. Aug. 5, 2015).

- Complaint satisfied Rule 9(b) where it identified actual CMS Form 1500 claims that defendants had allegedly submitted for reimbursement. *United States ex rel. Green v. Inst. of Cardiovascular Excellence, PLLC*, No. 5:11-cv-00406-RBD-TBS (M.D. Fla. Nov. 5, 2015).[6]

[6] *See also United States ex rel. Cestra v. Cephalon, Inc.*, No. 2:14-cv-01842-TON (E.D. Penn. June 3, 2015) (complaint satisfied Rule 9(b) where relator alleged a pharmaceutical company provided payments and services to induce off-label sales of a chemotherapy drug and ensure reimbursement, and tracked return on investment in terms of increased sales, even though no specific false claims were identified); *United States ex rel. Jacobs v. CDS, P.A.*, No. 4:14-cv-00301-BLW (D. Idaho Sept. 28, 2015) (complaint satisfied Rule 9(b) when a recruited physician alleged that a physician recruitment arrangement between a hospital and clinic violated the federal Anti-Kickback Statute and Stark Law, resulting in false claims, since the medical center submitted its cost report certification each year from 2010 to 2013 and the physician had knowledge of the improper financial relationship through his position as a recruited physician); *United States ex rel. Ortiz v. Mount Sinai Hosp.*, No. 1:13-cv-04735-RMB (S.D.N.Y. Nov. 9, 2015) (complaint satisfied Rule 9(b) when relator alleged specific facts such as the name of the physician performing the treatment, the procedure and date it was performed, the amount paid by Medicare and an explanation of why the claim was fraudulent).

2. Public Disclosure and Original Source

The public disclosure bar provides a strong defense to claims under the FCA. It prohibits *qui tam* claims that are based on publicly-disclosed allegations of fraud, unless the relator has sufficient knowledge of the alleged fraud to qualify as an "original source." 31 U.S.C. § 3730(e)(4). This defense is a constant source of litigation, as courts attempt to strike the congressionally-intended balance between discouraging parasitic lawsuits and properly incentivizing true whistleblowers. Complicating the analysis further is the fact that Congress amended the public disclosure bar in 2010, so courts often find themselves addressing two different versions of the statute in the same case. Federal courts in 2015 thus wrestled with a number of issues common to both versions of the statute and issues unique to one or the other. The key developments are discussed below.

a. When do the 2010 amendments apply?

The threshold question for any FCA case—at least for the time being—is to determine which version of the statute applies: the pre-2010 version or the amended version. The Supreme Court has held that the 2010 amendments may not be applied retroactively to cases that were filed before 2010, but some say it is an open question whether the amendments apply to conduct that occurred before that date. *See Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280, 293 n.1 (2010); *Schindler Elevator Corp. v. United States ex rel. Kirk*, __ U.S. __, 131 S.Ct. 1885, 1889 n.1 (2011). We have reported on this issue before, and in 2015, two more circuit courts joined a growing consensus that the amended version of the public disclosure bar does not apply where the alleged conduct occurred before 2010.

The Third Circuit reasoned in *United States ex rel. Judd v. Quest Diagnostics, Inc.* that "there is a presumption against retroactive litigation . . . that is applied unless Congress had clearly manifested its intent to the contrary, and the legal effect of conduct should be assessed under the law that existed when the conduct took place." No. 14-3156, 2015 WL 5025447, at *2 (3d Cir. Aug. 26, 2015). The Third Circuit found this presumption to be even stronger in the FCA context because the amended version of the public disclosure bar could eliminate an applicable defense to a *qui tam* suit in certain circumstances. *Id.* The Sixth Circuit reached a similar result in *United States ex rel. Antoon v. Cleveland Clinic Foundation* and collected a number of cases in accord. 788 F.3d 605, 615 (6th Cir. 2015).

One reason this inquiry can be important is that some argue the 2010 amendments removed the jurisdictional nature of this defense. The Eleventh Circuit held as much in *United States ex rel. Osheroff v. Humana Inc.*, 776 F.3d 805, 807-08 (11th Circ. 2015). The court noted that the 2010 amendments removed any "jurisdiction" language from the public disclosure bar, and therefore held that the amended provision "creates grounds for dismissal for failure to state a claim" under Rule 12(b)(6), "rather than for lack of jurisdiction" under Rule 12(b)(1). In support, the panel found it "significant that Congress did not remove similar jurisdictional language from surrounding provisions . . . , which suggests that the amended [provision] should operate differently than those other provisions." *Id.*; *see also United States ex rel. Griffith v. Conn*, Civil No. 11-157-ART, 2015 WL 779047, at *12 (E.D. Ky. Feb. 24, 2015) ("Because the bar is no longer jurisdictional, . . . the post-PPACA public-disclosure bar poses no separation-of-powers concerns.").

b. When is the public disclosure bar triggered?

Under either version of the statute, the first step in the analysis asks whether the fraud alleged in the complaint had been publicly disclosed through one of several statutorily-defined methods. The Eleventh Circuit joined a host of other courts in holding that the term "news media" is expansive enough to include disclosures on publicly-available websites. *Osheroff*, 776 F.3d at 813. A related question that often arises under this element is whether the alleged disclosure was truly "public" under the statute. One court held that the disclosure of a government audit report to the whistleblower was sufficiently public to trigger the bar because the whistleblower was an "outsider" to the government investigation. *United States ex rel. Swoben v. SCAN Health Plan*, No. CV-09-5013-JFW, slip op. at 7-8 (C.D. Cal. June 1, 2015).

Another issue that continues to divide the courts is whether a disclosure to the government itself is sufficiently "public" to trigger the bar. Several courts answered that question in the negative in 2015. *See, e.g., United States ex rel. Wilson v. Graham Cnty. Soil & Water*, 777 F.3d 691, 697 (4th Cir. 2015) ("[P]ublic disclosure requires that there be some act of

disclosure outside of the government."); *United States ex rel. Whipple v. Chattanooga-Hamilton Cnty. Hosp. Auth.*, 782 F.3d 260, 268 (6th Cir. 2015) (holding that information disclosed to government during investigation did not constitute a public disclosure). The Seventh Circuit, however, has held that disclosure to a government official during the government's investigation does qualify as a public disclosure, and thus one lower court within the Seventh Circuit followed that holding in 2015. *United States ex rel. Gravett v. Methodist Med. Ctr. of Ill.*, 82 F. Supp. 3d 835, 840 (C.D. Ill. 2015) (citing *United States ex rel. Fowler v. Caremark RX, L.L.C.*, 496 F.3d 730, 736 (7th Cir. 2007)) (finding target's disclosure to federal prosecutor during investigation was a public disclosure). This is certainly an issue we will be monitoring in the future.

THE EN BANC NINTH CIRCUIT COURT OF APPEALS OVERRULED DECADES OF CIRCUIT PRECEDENT TO HOLD THAT AN ORIGINAL SOURCE NEED NOT "HAVE A HAND" IN THE PUBLIC DISCLOSURES.

c. Who is an Original Source?

If the public disclosure bar is triggered, the court must dismiss the *qui tam* suit unless the relator is an "original source" of the information underlying the complaint. 31 U.S.C. § 3730(e)(4). The most common issue in the original source analysis is whether the relator has sufficient firsthand knowledge of the fraud to qualify as a true whistleblower. The 2010 amendments changed the language on this point—from requiring "direct and independent knowledge" of the fraud to requiring knowledge that is "independent of and materially adds to" the public disclosures—but the significance of this change is still something of an open question. In *Osheroff*, for example, the Eleventh Circuit held that under either version of the statute, a relator cannot become an original source simply by investigating the specific details of a generally-disclosed fraudulent scheme. 776 F.3d at 815. In the same way that such knowledge is not "direct and independent" (old version), the Eleventh Circuit found that the relator's investigation did not "materially add to" the public disclosures (new version).

Osheroff presented a commonly-litigated fact pattern, as courts often address questions of whether the original source exception applies to relators who are not corporate insiders, but instead claim "direct and independent knowledge" through their own investigations of fraud. *See, e.g., United States ex rel. Morgan v. Express Scripts, Inc.*, 602 F. App'x 880, 833 (3d Cir. 2015) (dismissing case where relator assessed publicly available files using his experience in the industry); *United States ex rel. Sonnier v. Standard Fire Ins. Co.*, 84 F. Supp. 3d 575, 591 (S.D. Tex. 2015) (dismissing case where relator's investigation uncovered specific occurrences of what public already knew). One common theme is that a relator does not qualify as an original source if he learned about the fraud secondhand, by talking to someone else, and courts generally followed that approach in 2015. *E.g., United States ex rel. Swoben v. Scan Health Plan*, No. CV 09-5013-JFW, slip op. at 10, (C.D. Cal. Aug. 28, 2015); *see also United States ex rel. Advocates for Basic Legal Equality v. U.S. Bank, N.A.*, No. 3:13-cv-704, 2015 WL 2238660, at *9–10 (N.D. Ohio May 12, 2015) (legal aid group not an original source where knowledge of mortgage fraud was derived from conversations with others, including the foreclosed mortgagors).

But perhaps the most interesting developments in 2015 dealt with sometimes-peripheral aspects of the original source exception that are not necessarily tied to either version of the statute. For example, the *en banc* Ninth Circuit Court of Appeals overruled decades of circuit precedent to align itself with a majority of federal courts on an issue we wrote about last year. Previously, courts in the Ninth Circuit required an original source to "have a hand" in the public disclosures, in addition to having sufficiently firsthand knowledge. But in *United States ex rel. Hartpence v. Kinetic Concepts, Inc.*, the Ninth Circuit acknowledged that this requirement has no textual basis in the FCA and as a result, the relator "need not have played any role in making the disclosure public" to qualify as an original source. 792 F.3d 1121, 1128 (9th Cir. 2015).

Another issue that continues to divide the courts is whether a relator can qualify as an original source for allegations of fraud following the termination of their employment with the defendant. The Eastern District of Pennsylvania held this year that dates of employment do not place strict limits on original source status—if the relator acquires sufficient firsthand knowledge of the fraudulent scheme while employed by the defendant, he may in certain circumstances qualify as an original source for allegations that the scheme continued after he left (despite not having firsthand knowledge of that particular conduct). *United States ex rel. Galmines v. Novartis Pharms. Corp.*, 88 F. Supp. 3d 447, 451 (E.D. Pa. 2015). Other courts disagree, finding that a relator cannot have firsthand knowledge for allegations of fraud after his or her employment is terminated. *See, e.g., United States ex rel. Gravett v. Methodist Med. Ctr. of Ill.*, 82 F. Supp. 3d 835, 840 (C.D. Ill. 2015).

In addition to the substantive knowledge requirement, the original source exception (both versions) also has a procedural component—the relator must "voluntarily provide" the information underlying his complaint to the government prior to filing suit. 31 U.S.C. § 3730(e)(4)(B). Several cases in 2015 demonstrated that a failure to strictly comply with this requirement can result in dismissal of a *qui tam* case just the same as a lack of firsthand knowledge. For example, one court found that a disclosure to the government one day before filing suit was insufficient because the purpose of this requirement is to give the government time to investigate. *United States ex rel. King v. Solvay*, No. H-06-2662, 2015 WL 925612, at *10 (S.D. Tex. March 3, 2015). Another court interpreted this "voluntary" disclosure requirement to mean that a government employee cannot qualify as an original source while employed by the government. *See United States ex rel. Griffith v. Conn*, No. 11-157-ART, 2015 WL 779047, at *7-8 (E.D. Ky. Feb. 24, 2015). Using principles of statutory construction, the court found that "voluntary" under this provision means an act done "without a present legal obligation or without valuable consideration." Thus, if a government employee is required to disclose fraud as a part of her job duties, she cannot comply with the voluntary disclosure requirement—at least while employed. *Id.* at *8-9 (suggesting that former government employee could be an original source).

THE U.S. SUPREME COURT IN 2015 CLARIFIED THAT THE FIRST-TO-FILE RULE BARS ONLY A RELATED ACTION FOR AS LONG AS THE FIRST-FILED SUIT REMAINS "PENDING."

3. First-to-File Rule

The FCA's first-to-file rule is another strong defense in many FCA cases. It bars anyone other than the government from bringing "a related action based on the facts underlying the pending action." 31 U.S.C. § 3730(b)(5). The purpose is to protect against seriatim lawsuits making similar allegations. In a much-anticipated decision, the U.S. Supreme Court in 2015 clarified that the first-to-file rule bars only a related action for as long as the first-filed suit remains "pending."

a. What constitutes "pending" for purposes of the first-to-file rule?

As noted above, the first-to-file bar applies only where there is a "pending action." 31 U.S.C. § 3730(b)(5). In recent years, a circuit split had developed regarding the meaning of "pending." Some courts held that the bar does not apply if the first-filed case has been dismissed, and is therefore no longer pending; whereas, the D.C. Circuit held that the bar nevertheless applies in those circumstances.

The Supreme Court resolved this conflict in *KBR, Inc. v. United States ex rel. Carter*, 575 U.S. __, 135 S. Ct. 1970 (2015). The Court held that the rule bars only related actions as long as the first-filed suit remains pending. The Court focused on the ordinary meaning of "pending," which means "remaining undecided; awaiting decision." To read it as shorthand for "first-filed," as the D.C. Circuit apparently did, fails to "comport with any known usage of the term" and "push[es] the term 'pending' far beyond the breaking point," "lead[ing] to strange results that Congress is unlikely to have wanted." For example, under the D.C. Circuit's interpretation, a "first-filed suit would bar all

subsequent related suits even if that earlier suit was dismissed for a reason having nothing to do with the merits," a result Congress could not have intended. *Id.* at 1979.

The Court acknowledged that its interpretation could produce some practical problems. For example, the prospect of subsequent related suits might discourage defendants from settling for the full amount they would otherwise have settled for in a first-filed case. The relator and the United States argued that the doctrine of claim preclusion might protect defendants in instances where the first-filed action is decided on the merits rather than dismissed. However, that particular issue was not before the Court. The Court stated that "[t]he False Claims Act's *qui tam* provisions present many interpretive challenges, and it is beyond our ability in this case to make them operate together smoothly like a finely tuned machine." *Id.*

One court of appeals has already applied *KBR* in an unusual procedural posture. In *United States ex rel. Gadbois v. PharMerica Corp.*, No. 14-1264 (1st Cir. Dec. 16, 2015), the First Circuit vacated the dismissal of a second-filed case because the first-filed action was dismissed while the appeal was pending. Applying *KBR*, the First Circuit held that the relator in the second-filed action should be able to amend his pleading to make clear that the first-filed case was no longer "pending" and thus did not preclude his action from going forward. The court held that, in light of *KBR*, the case should be remanded to the district court for consideration of relator's motion to supplement. Slip op. at 11.

b. What is a "related action" for purposes of the first-to-file bar?

A second issue that often arises is the meaning of a "related action." Courts generally hold that a later-filed suit is "related" if it includes the same "material elements" or "essential facts" as the first case, even if the later-filed suit includes additional or somewhat different facts. In 2015, the D.C. Circuit applied that standard narrowly in *United States ex rel. Heath v. AT&T, Inc.*, 791 F.3d 112 (D.C. Cir. 2015).

At issue in *AT&T* were two complaints filed by the same relator—the first against an AT&T subsidiary in Wisconsin, and the second against AT&T. The first complaint alleged a limited scheme by the subsidiary to defraud the E-Rate program within Wisconsin by making affirmative misrepresentations to Wisconsin schools and libraries. The second complaint alleged a far-reaching scheme by AT&T to defraud the federal government through service contracts it entered into nationwide. The alleged fraud was accomplished through "institutionalized disregard of the lowest-corresponding-price requirement altogether," rather than by "affirmative misrepresentations about the lowest corresponding price."

COURTS GENERALLY HOLD THAT A LATER-FILED SUIT IS "RELATED" IF IT INCLUDES THE SAME "MATERIAL ELEMENTS" OR "ESSENTIAL FACTS" AS THE FIRST CASE, EVEN IF THE LATER-FILED SUIT INCLUDES ADDITIONAL OR SOMEWHAT DIFFERENT FACTS.

The district court dismissed the later-filed complaint, holding that the relator's first-filed complaint barred the second complaint under the first-to-file rule. But the D.C. Circuit disagreed, stating that the two complaints allege "factually distinct types of frauds." *Id.* at 121. The first merely disclosed "rogue actions of individuals within a single AT&T subsidiary and their specific, overt misrepresentations." It did not disclose the "nationwide fraud grounded in institutionalized training and enforcement failures, and compounded by efforts at concealment," disclosed by the later-filed complaint. *Id.* at 122.

The D.C. Circuit clarified that the second complaint did not simply add some new facts or "widen[] the circle of victims of the same fraudulent conduct." Rather, the second complaint put the government on notice of two materially distinct types of fraud. While the "greater fraud often includes the lesser," the "lesser fraud does not, without more, include the greater." The court explained that the purpose of the first-to-file rule is to prevent copycat litigation, not to "allow isolated misconduct to inoculate large companies against comprehensive fraud liability." *Id.* at 123.

c. How does the first-to-file rule affect the relator's share of the recovery?

The FCA provides that a whistleblower is entitled to a percentage of the recovery, which varies depending on a number of factors. 31 U.S.C. § 3730(d). But "only the first-filed relator is entitled to a relator's share award from a settlement." *United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs, Inc.*, 149 F.3d 227, 232-33 (3d Cir. 1998).

The Third Circuit affirmed this principle in *United States ex rel. Dhillon v. Endo Pharmaceuticals*, No. 14-3377 (3d Cir. June 11, 2015). In that case, Dhillon filed the last of three *qui tam* complaints alleging off-label marketing of a particular drug. The defendant then entered into a settlement resolving the off-label allegations of all three relators but reserving for the district court the issue of the relators' awards.

In the district court, the first-filed relator requested that she be awarded the entire share because she was the first to file. Dhillon argued that he should be entitled to a share because he was the "first to state a plausible claim to relief," arguing that his complaint was the one that caused the defendant to settle, and also that the first-filed complaint did not comport with Rule 9(b)'s pleading requirements. The district court agreed with the first-filed relator, finding that her complaint was filed first and that her later amendment satisfied Rule 9(b)'s pleading requirements. On appeal, the Third Circuit affirmed, stating that "[o]nly the first-filed Relator is entitled to a Relator's share award from a settlement . . . and Dhillon is not a first-filed Relator." The court was not persuaded that Dhillon deserved a portion of the award because his complaint, though filed last, was the one that forced the settlement.

4. Identification of an Overpayment

One issue that has been percolating since the enactment of the Patient Protection and Affordable Care Act in 2010 ("PPACA") is the identification of "overpayments" received from Medicare or Medicaid. The issue has been one of serious concern for healthcare providers because retaining an "overpayment" can give rise to FCA liability. Indeed, the FCA assigns liability to one who "knowingly conceals or … avoids or decreases an *obligation* to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(1)(G) (emphasis added). PPACA requires a person who receives an overpayment from Medicare or Medicaid to report and return such overpayments to HHS, the State, or another appropriate party. 42 U.S.C. § 1320a-7k(d)(1). Such an overpayment must be reported and returned within sixty days of the "date on which the overpayment was *identified*." *Id.* § 1320a-7k(d)(2) (emphasis added). Any overpayment returned by a person *after* the deadline becomes an "obligation" subject to liability under the FCA. *Id.* § 1320a-7k(d)(3).

In August 2015, the Southern District of New York issued the first court interpretation of this sixty-day overpayment provision. *See Kane v. Healthfirst Inc. et al*, No. 11-cv-02325, 2015 WL 4619686 (S.D.N.Y. Aug. 3, 2015). In a huge win for the Department of Justice, the court adopted the government's definition of "identified," concluding that "the sixty day clock begins ticking when a provider is put on notice of a potential overpayment," rather than when one is "conclusively ascertained."

ONE ISSUE THAT HAS BEEN PERCOLATING SINCE THE ENACTMENT OF THE PATIENT PROTECTION AND AFFORDABLE CARE ACT IN 2010 ("PPACA") IS THE IDENTIFICATION OF "OVERPAYMENTS" RECEIVED FROM MEDICARE OR MEDICAID.

The fact pattern in this particular case involved a software glitch at Healthfirst, Inc., which caused three NYC hospitals operated by Continuum Health Partners, Inc. to submit improper claims to Medicaid beginning in 2009. In 2010, auditors from the New York State Comptroller's Office raised questions about the incorrect billing, and subsequent discussions revealed the glitch. After the glitch was discovered, Continuum asked the relator (then an employee) to ascertain which of the claims had been improperly billed. In February 2011, the relator sent an email to management attaching 900 claims he had identified as containing the erroneous billing code, stating that further analysis would be needed to confirm his findings. Four days later, the relator was fired. The government alleged in

its complaint that Continuum "did nothing further" with his analysis or the claims he identified. Continuum initially reimbursed the government for five improperly submitted claims, and later reimbursed the government for another 300 claims only after the government issued a CID in June 2012. Continuum did not finish reimbursing the government until March 2013.

Continuum argued that the sixty-day clock does not begin until an overpayment is pinpointed conclusively, and therefore did not begin when the relator sent his February 2011 email requiring additional analysis. The court disagreed, reasoning that such an interpretation would provide "a perverse incentive to delay learning the amount due." Instead, the court adopted the government's definition of "identified" such that the sixty-day clock starts "when a provider is put on notice of a potential overpayment," not when one is "conclusively ascertained." *Id.* at *11.

The court acknowledged that under this definition, an overpayment technically becomes an "obligation" under the FCA even where a provider receives a similar email (and thus is put "on notice"), struggles to conduct an internal audit and report its findings within sixty days, but fails to isolate and return all overpayments within the same time period. But the court emphasized that the very existence of an "obligation" does not establish a violation of the FCA. Rather, "it is only when an obligation is *knowingly concealed* or *knowingly and improperly avoided or decreased* that a provider has violated the FCA." The court noted that prosecutorial discretion would prevent enforcement actions against "well-intentioned healthcare providers working with reasonable haste to address erroneous overpayments." *Id.* at *13.

We will continue to monitor the law in this area as it develops. In the meantime, under *Kane*, a provider should act diligently and in good faith to understand any affected claims and report its actions to the government within the sixty-day period, even if the actual repayment process takes longer.

5. Statistical Sampling

In recent years, relators and the government have been arguing that they can prove liability and damages by using statistical sampling evidence – proving that a larger data set is false based on a smaller sample. "The general purpose of statistical sampling is to 'provide a means of determining the likelihood that a large sample shares characteristics of a smaller sample." *E.g., United States ex rel. Martin v. Life Care Ctrs. of Am., Inc.*, No. 1:08-cv-251, slip op. at 15 (E.D. Tenn. Sept. 29, 2014).

IN RECENT YEARS, RELATORS AND THE GOVERNMENT HAVE BEEN ARGUING THAT THEY CAN PROVE LIABILITY AND DAMAGES BY USING STATISTICAL SAMPLING EVIDENCE – PROVING THAT A LARGER DATA SET IS FALSE BASED ON A SMALLER SAMPLE.

The issue received prominent coverage in 2015. *First,* a district court in Florida held that a relator could prove liability based on a small statistical sample of billing data, rejecting the argument that extrapolation in *qui tam* cases is outright impermissible. *See United States ex rel. Ruckh v. CMC II LLC*, No. 8:110-cv-001303 (M.D. Fla. Apr. 28, 2015). The court reasoned that the FCA does not require individualized proof and that requiring such proof in that case – which targeted 53 nursing home facilities and a large universe of potentially false claims – would be impractical. The court held that the defendants could always argue "defects in method, among other evidentiary defects," which could potentially result in exclusion of the sampling at a later date.

Second, the Fourth Circuit agreed in September 2015 to hear an interlocutory appeal on the use of statistical sampling to prove liability in FCA cases, marking the first time an appellate court will address the issue. *See United States ex rel. Michaels v. Agape Senior Cmty., Inc. et al.*, No. 0:12-cv-03466 (4th Cir. Sept. 29, 2015). *Agape* involves claims submitted by a network of 24 nursing homes to Medicare, Medicaid, and Tricare for care that was allegedly not medically necessary. More than 60,000 claims were supposedly submitted during the relevant period, prompting the relators to request the use of statistical sampling to prove liability. The relators argued that their expert could review a fraction of the total claims at issue, determine what percentage of those claims was fraudulent, and then extrapolate over the universe of submitted claims to arrive at

evidence of liability and damages. The district court rejected the request, in large part because determining whether care is medically necessary is a "highly fact-intensive inquiry involving medical testimony after a thorough review of the detailed medical chart of each individual patient," and thus does not lend itself to statistical sampling. However, the court certified the question for interlocutory appeal.

We will be monitoring the case – and this issue – in 2016.

6. Relator's Obligations and Rights

Under the FCA, a private person may bring an FCA action on behalf of the government. 31 U.S.C. § 3730. For bringing the case to the attention of the government, the relator is permitted to share in any award. *Id.* § 3730(d)(1). But a relator may also be liable for a defendant's attorneys' fees if the defendant prevails and the court finds that the claim was "clearly frivolous, clearly vexatious, or brought primarily for purposes of harassment." 31 U.S.C. § 3730(d)(4). Courts addressed both of these provisions in 2015, as well as the question of when a relator should be disqualified for bad conduct.

a. Is a relator entitled to a large share of the recovery when the case settles with little or no litigation?

The provision entitling a relator to a share of any recovery often causes tension between the relator and the government, as the two dispute how much of the share is owed and whether the relator has earned it. A court in the Eastern District of Pennsylvania addressed this issue in a case in which the government recovered $171.9 million in a *qui tam* suit that settled before litigation began. *See United States ex rel. Ryan v. Endo Pharms., Inc.*, Nos. 05–3450, 10–2039, 11–7767, 2015 WL 4273290, at *4 (E.D. Pa. July 15, 2015). The relator in *Ryan* filed a *qui tam* under seal, which prompted "a lengthy investigation" by the government. *Id.* at *1. Upon concluding its investigation, the government intervened solely for settlement purposes. That same day, the relator entered into a settlement agreement, whereby the defendant agreed to pay approximately $171.9 million to resolve the allegations. The relator later argued that she was entitled to a 24% share because she provided substantial support during the investigation. The government argued for a lower share, in part because the case never went to trial and thus the relator never experienced litigation's "attendant demands." *Id.* at *4.

The court rejected the government's argument, holding that the relator "provided not only the spark for the investigation, but [] she nurtured the flame at the darkest times when the possibility of a favorable outcome seemed most remote." *Id.* at *34. "Applying the Government's argument to cases like this would punish a relator … for providing a level of incriminating information that would make the defendant's prospects of winning at trial less likely." *Id.* at *4.

b. When is a relator liable for attorneys' fees for bringing a "clearly frivolous" action?

Under the FCA, if the government declines to intervene in an FCA action, "the court may award to the defendant its reasonable attorneys' fees and expenses if the defendant prevails in the action and the court finds that the claim of the person bringing the action was clearly frivolous, clearly vexatious, or brought primarily for purposes of harassment." 31 U.S.C. § 3730(d)(4).

Although this provision is rarely invoked, the Sixth Circuit applied it in full force in 2015. In *United States ex rel. Jacobs v. Lambda Research, Inc.*, the court affirmed sanctions against a relator and his counsel for bringing a frivolous FCA action, and threatened to sanction them for bringing the appeal. 622 F. App'x 477, 477 (6th Cir. 2015). The relator in *Jacobs* had brought an FCA case against his former employer two months after being ordered to pay the employer $9.4 million for allegedly stealing trade secrets. *Id.* In part because of the timing, the district court was concerned that the relator had filed the suit in retaliation and repeatedly warned of sanctions if discovery did not reveal any evidence to support the relator's claims. *Id.* at 479. Following discovery, the district court granted summary judgment to the defendant and ordered the relator to pay $511,633.58 in attorneys' fees, and further ordered the relator's counsel to pay $194,522.89 in fees. *Id.* at 480. On appeal, the Sixth Circuit affirmed, concluding that the relator presented no evidence to support his claims, and then ordered relator's counsel to show cause as to why he should not be sanctioned for filing a frivolous appeal. *Id.*

c. When should a relator be disqualified?

Some individuals are not qualified to bring a *qui tam* suit by virtue of their position (*e.g.*, members of the military) or by virtue of their involvement in the alleged violation. Specifically, "[i]f the person bringing the action is convicted of criminal conduct arising from his

or her role in the violation of section 3729, that person shall be dismissed from the civil action and shall not receive any share of the proceeds of the action." 31 U.S.C. § 3730(d)(3).

In *Schroeder ex rel. United States v. CH2M Hill*, the Ninth Circuit affirmed the dismissal of a relator from a case in which the relator was convicted of a felony related to the conduct underlying the FCA allegations—even though the relator had only a minor role in them. 793 F.3d 1080, 1086 (9th Cir. 2015). There, the relator was charged and pled guilty to conspiracy to commit fraud for submitting false time cards. *Id.* at 1081–82. Thereafter, the relator brought an FCA action against his employer, alleging similar misconduct. *Id.* at 1082. The government eventually intervened and successfully dismissed the relator from the case. *Id.* In affirming the dismissal, the Ninth Circuit explained that there is no exception for participants that play only a minor role in the alleged fraud. *Id.* at 1086. Although there was some support in the legislative history to support relator's argument, the court concluded that it "was not convincing enough to warrant departing from the plain meaning" of the statute. *Id.*

7. Retaliation Against Whistleblowing Employees

The FCA prohibits employers from retaliating against employees that initiate and pursue FCA actions or otherwise attempt to stop violations of the FCA. 31 U.S.C. § 3730(h). To maintain a retaliation action, the employee must prove that (1) she engaged in a protected activity; (2) her employer knew about these acts; and (3) the employer took adverse action against them as a result of the protected activity.

Judicial decisions in 2015 primarily focused on the first prong of the FCA retaliation analysis: the circumstances under which an employee engages in a "protected activity" sufficient to trigger anti-retaliation protections. Several courts followed the general rule that an employee's "protected activity" must be opposition to fraud "in a context where litigation is a distinct possibility." *e.g., United States ex rel. King v. Solvay*, No. H-06-2662, 2015 U.S. Dist. LEXIS 90965, at *3 (S.D. Tex. July 14, 2015). Under that standard, the court held that one of the relators was not engaged in protected activity because her internal complaints about off-label promotion had been "merely criticisms about the way [the employer] was doing business." *Id.* at *5. The other relator, however, was engaged in protected activity because he had complained internally that the practices were "illegal." *Id.*

At least one court, however, applied a different standard, joining a growing number of courts questioning the viability of the "distinct possibility" standard. The district court in *Arthurs v. Global TPA LLC*, No. 6:14-cv-1209, 2015 U.S. Dist. LEXIS 37741 (M.D. Fla. Mar. 25, 2015), held that that prior cases requiring a "distinct possibility" of litigation are inapposite in light of the 2009 amendments extending protection to employees engaged in "other efforts" to stop violations of the FCA. Thus, under this more flexible standard, the court held, an employee's internal complaints that the employer was violating Medicare's marketing regulations were sufficient to survive a motion to dismiss. *Id.* at *6.

Finally, the Sixth Circuit provided additional guidance regarding protected activity in *United States ex rel. Jones-McNamara v. Holzer Health Sys.*, No. 15-3070, 2015 U.S. App. LEXIS 19365 (6th Cir. Nov. 2, 2015). There, the court held that an employee's retaliation claim failed as a matter of law where the conduct she was complaining about was not in fact unlawful. The employee in *Jones-McNamara* asserted that she was terminated after informing executives about a "potential kickback issue" arising from gifts of nominal value—*e.g.*, hotdogs, hamburgers, and one $23.50 jacket. The court, however, rejected the retaliation claim, holding that, even though the employee believed in good faith that her opposition to a company practice was required by law, her activity was not protected because her belief was manifestly inconsistent with applicable law. *Id.* at *7-8.

JUDICIAL DECISIONS IN 2015 PRIMARILY FOCUSED ON THE FIRST PRONG OF THE FCA RETALIATION ANALYSIS: THE CIRCUMSTANCES UNDER WHICH AN EMPLOYEE ENGAGES IN A "PROTECTED ACTIVITY" SUFFICIENT TO TRIGGER ANTI-RETALIATION PROTECTIONS.

8. Conditions of Participation v. Conditions of Payment

In many FCA actions, the claims are alleged to be false because the defendant falsely certified compliance with some legal requirement—statutory, regulatory or contractual—in the process of submitting a claim for payment. Under this theory, a critical question arises: whether compliance is actually a condition of payment or whether it is merely a condition of participating in the government program. Courts in 2015 continued the trend toward distinguishing between conditions of payment, which can lead to an FCA violation, and conditions of participation, which generally cannot.

For example, the Middle District of Florida granted the defendant's motion for judgment as a matter of law where the relator had alleged a violation of Florida licensing laws, but was unable to identify any statute or regulation that expressly conditioned payment on those licensing laws. *See United States ex rel. Ortolano v. Amin Radiology*, 5:10-cv-583, 2015 U.S. Dist. LEXIS 9724 (M.D. Fla. Jan. 28, 2015). The court distinguished between conditions of payment, "those which, if the government knew they were not being followed, might cause it to actually refuse payment," and conditions of participation, "the ultimate sanction for violation of such conditions is removal from the government program." *Id.* at 25 (citations omitted). Because the relator could not prove that the licensing violations were a condition of payment, the defendant was entitled to judgment.

ON DECEMBER 4, 2015, THE U.S. SUPREME COURT AGREED TO ADDRESS THE VIABILITY OF THE SO-CALLED "IMPLIED CERTIFICATION" THEORY.

Even the First Circuit, which has historically interpreted the FCA's falsity requirement expansively, suggested that it may be amenable to future arguments distinguishing between conditions of payment and conditions of participation. In *United States ex rel. Escobar v. Universal Health Services*, 780 F.3d 504 (1st Cir. 2015), *cert. granted*, 84 U.S.L.W. 3320 (US. Dec. 4, 2015) (No. 15-7), the court ultimately concluded that the payment/participation distinction was irrelevant because there was a statute, overlooked by the district court, which explicitly made the regulation in question a condition of payment.

9. Implied Certification

For years, courts have debated the so-called "implied certification" theory of FCA liability. Under this theory, a defendant may be liable if it fails to comply with a governing regulation or contractual provision in the process of submitting a claim for payment—even if the defendant never expressly certified compliance. Most courts have rejected the theory, or refused to adopt it, reasoning that it expands FCA liability further than the statute allows. After three significant decisions analyzing the theory in 2015, the U.S. Supreme Court agreed on December 4, 2015, to address its viability.

The first case decided was *United States v. Triple Canopy, Inc.*, 775 F.3d 628 (4th Cir. 2015), in which the Fourth Circuit squarely adopted the implied certification theory. In that case, a defense contractor providing security services in Iraq was required to use guards with certain marksmanship skills, but instead used guards who had failed (or never took) the requisite training. Although the contract did not require the contractor to certify compliance with that requirement, the court held that the government could nevertheless state a viable FCA claim because it alleged that the contractor, "with the requisite scienter, made a request for payment under a contract and withheld information about its noncompliance with *material* contractual requirements." *Id.* at 636 (emphasis added). "The pertinent inquiry is whether, through the act of submitting a claim, a payee knowingly and falsely implied that it was entitled to payment." *Id.* (citation omitted). The court acknowledged that this theory "is prone to abuse" but held that it could be controlled with "strict enforcement of the Act's materiality and scienter requirements." *Id.*

The Seventh Circuit also briefly addressed the theory in *United States v. Sanford-Brown, Ltd.*, 788 F.3d 696 (7th Cir. 2015), but rejected it. In that case, the relator alleged that a for-profit educational institution had failed to comply with various legal requirements

governing its participation in a U.S. Department of Education program from which it received federal subsidies. Although the institution initially agreed to comply with governing regulations, it did not later submit express certifications of compliance with the specific requirements at issue. In affirming the dismissal of the complaint, the Seventh Circuit held, that "[a]lthough a number of other circuits have adopted this so-called doctrine of implied false certification, . . . we decline to join them." *Id.* at 711-12.

The First Circuit attempted to find a middle ground between the Seventh and Fourth Circuits. *See United States ex rel. Escobar v. Universal Health Servs.*, 780 F.3d 504 (1st Cir. 2015). In that case, the First Circuit rejected distinctions between implied and express certification theories, and instead held that the principal inquiry is "whether the defendant, in submitting a claim for reimbursement, knowingly misrepresented compliance with a material precondition of payment." *Id.* The court held that preconditions of payment need not be "expressly designated;" rather, it is a "fact-intensive and context-specific inquiry." *Id.* at 512-13. Because the mental health center in that case failed to comply with regulations that "explicitly condition" government payment on compliance, the relators "have provided sufficient allegations of falsity to survive a motion to dismiss." *Id.* at 514.

On December 4, 2015, the Supreme Court granted the defendant's petition for certiorari in *Escobar*. 84 U.S.L.W. 3320 (U.S. Dec. 4, 2015) (No. 15-7). The Court agreed to address whether the "implied certification theory is viable" and, if so, whether noncompliance with an express condition of payment is required. We will provide an update on the case when the opinion is issued—likely in Spring 2016.

THE COURT HELD THAT PRECONDITIONS OF PAYMENT NEED NOT BE "EXPRESSLY DESIGNATED;" RATHER, IT IS A "FACT-INTENSIVE AND CONTEXT-SPECIFIC INQUIRY."

10. Scienter

Under the FCA, the plaintiff must show that a defendant "knowingly" submitted a claim that was false or fraudulent. 31 U.S.C. § 3729(a)(1). "Knowingly" is defined as having "actual knowledge of the information" or acting in "deliberate ignorance" or "reckless disregard" of the "truth or falsity of the information." 31 U.S.C. § 3729(b)(1). A common question in FCA cases is whether a defendant acts "knowingly" when the contractual or regulatory provision at issue is unclear. Three courts analyzed this question in 2015. While each court ruled in favor of the defendant, the analysis in each case was arguably different.

In *United States ex rel. Donegan v. Anesthesia Associates of Kansas City, PC*, the court reaffirmed and further clarified an Eighth Circuit holding that, "where a regulation is unclear, a defendant's 'reasonable interpretation of any ambiguity inherent in the regulations belies the scienter necessary to establish a claim of fraud under the FCA.'" No. 4:12-CV-0876, 2015 WL 3616640, at *9 (W.D. Mo. June 9, 2015) (quoting *United States ex rel. Ketroser v. Mayo Found.*, 729 F.3d 825, 832 (8th Cir. 2013)). In *Donegan*, the relator alleged that the defendant's claims for reimbursement of anesthesiology services were false because anesthesiologists did not personally participate in "emergence" from anesthesia in the operating room as required by CMS regulation. *Id.* at *8. The defendant argued that one reasonable interpretation of that regulation is that anesthesiologists participate in "emergence" by visiting the patient in the recovery room post-operation. *Id.* In ruling for the defendant, the court held that the relator had failed to show there was "no reasonable interpretation of the regulation that would make the allegedly false claim valid." Although the relator may have presented a *more* reasonable interpretation, that alone was insufficient to prove scienter and thus summary judgment was granted for defendant. *Id.* at *9.

Similarly, the D.C. Circuit in *United States ex rel. Purcell v. MWI Corp.* overturned a jury verdict finding the defendant liable for FCA violations because the underlying contractual provision, which allowed the defendant to pay only "regular commissions," was ambiguous and the defendant's interpretation of "regular commissions" was reasonable. No. 14-5210, 2015 WL 7597536, at *1 (D.C. Cir. Nov. 24, 2015). The

court then also noted that the defendant was never "warned away" from its reasonable interpretation. *Id.* at *6. The record, for example, did not reflect any written guidance from appellate courts or regulatory agencies on the meaning of the provision. Under these circumstances, the D.C. Circuit held, there was insufficient evidence to support the jury's finding of scienter. *Id.*

Finally, the court's analysis in *United States ex rel. Saldivar v. Fresenius Medical Care Holdings, Inc.*, an FCA case involving Medicare reimbursement requests for overfill drugs that the defendant received for free, was the most searching of the three cases. No. 1:10-CV-1614-AT, 2015 WL 7293156 (N.D. Ga. Oct. 30, 2015). Stating that "a defendant's lack of diligence in the face of ambiguity" might suffice to find the defendant acted "recklessly," the court looked at the totality of the circumstances to determine whether the relator there could possibly prove scienter. *Id.* at **33-34. The court held that he could not—in light of evidence that the defendant reasonably believed that the government knew and acquiesced to reimbursement for overfill billing. *Id.* at **34-35. The court also analyzed how the defendant attempted to comply with all relevant regulations and took into account legal advice provided by counsel as to the meaning of certain regulations and CMS policies. *Id.* at **38-39. While the evidence in the record could support a finding that the defendant acted negligently with respect to its interpretation of the relevant regulations, the court held that the evidence could not support a finding of recklessness. *Id.* at *40.

11. Attorneys' Fees

A prevailing relator is entitled to an award of "reasonable attorneys' fees and costs." 31 U.S.C. § 3730(d). To calculate fee awards in FCA cases, a growing number of courts apply the "lodestar" method. *See Simring v. Rutgers*, 2015 U.S. App. LEXIS 11669, at *6 (3d Cir. N.J. July 7, 2015) ("Fees are presumed reasonable when calculated using the 'lodestar' method . . . ."); *United States ex rel. Cook-Reska v. Cmty. Health Sys.*, 2015 U.S. Dist. LEXIS 57933, at *21 (S.D. Tex. May 4, 2015) (applying lodestar method and noting that many circuit courts of appeal have approved its use in FCA cases).

Using the "lodestar" method, the court assigns a reasonable hourly rate to each attorney working on the case, based on factors such as the market rate for attorneys of similar experience and skill, and multiplies that rate by the reasonable number of hours worked throughout the litigation. *Cook-Reska*, 2015 U.S. Dist. LEXIS 57933, at *24. The party seeking a fee award must establish entitlement to an award and must provide documentation detailing time spent on the case and hourly rates. *Id.* at *26. Courts may also modify or adjust the total fee award based on the difficulty of the issues in the case, the amount involved and the results obtained, and awards in similar cases, among other factors. *Id.* at *27.

When multiple relators file similar claims, fee awards can become complicated. For instance, in *United States ex rel. Doghramji v. Community Health Sys., Inc.*, seven different cases had been filed against the defendants by seven different relators. 2015 U.S. Dist. LEXIS 103219 (M.D. Tenn. Aug. 6, 2015). The government entered into a settlement agreement with the defendants in which the defendants agreed to pay $97,257,500. *Id.* at *13. Pursuant to the terms of the settlement agreement, the government intervened in and moved to dismiss all seven cases. *Id.* at *14. Even though only two of the relators received any award on the FCA claims, the other relators petitioned the court for fees. *Id.* at **14-15. The defendants argued that the relators' claims for fees were barred by the "first-to-file" or "public disclosure" provisions of the FCA. *Id.* However, the court held that the defendants failed to explicitly reserve their right in the settlement agreement to challenge fee awards to the other relators on those bases, instead reserving only their right to contest requests for attorneys' fees "pursuant to 31 U.S.C. § 3730(d)." *Id.* at **25-32. Because

COURTS MAY ALSO MODIFY OR ADJUST THE TOTAL FEE AWARD BASED ON THE DIFFICULTY OF THE ISSUES IN THE CASE, THE AMOUNT INVOLVED AND THE RESULTS OBTAINED, AND AWARDS IN SIMILAR CASES, AMONG OTHER FACTORS.

section 3730(d) does not discuss "first-to-file" or "public disclosure," the court held that the defendants effectively waived their right to argue those issues before the court. *Id.* at *32.

12. Anti-Kickback Statute

One case addressing the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b, bears mentioning. Because compliance with AKS is a prerequisite for government reimbursement, a violation of that statute can create liability under the FCA. The AKS prohibits "knowingly and willfully soliciting or receiving any remuneration (including any kickback, bribe, or rebate) . . . in return for referring an individual to a person for the furnishing" of health care services paid for, in whole or in part, by a federal health care program. *Id.* § 1320a-7b(b)(1)(A).

In a case of first impression, the Seventh Circuit interpreted the term "referral" to include an authorization of care by a provider—even if the patient independently chose the provider herself. *See United States v. Patel*, 778 F.3d 607 (7th Cir. 2015). In that case, the government alleged that Grand Home Health Care, a home health provider, was paying kickbacks to a physician in exchange for patient referrals. The physician argued, however, that he never recommended a particular provider, but rather gave his patients "an array" of several choices of home health providers. Each patient then independently made the decision about whom to use. Under these facts, the physician argued, he was not making a "referral" prohibited by AKS.

IN A CASE OF FIRST IMPRESSION, THE SEVENTH CIRCUIT INTERPRETED THE TERM "REFERRAL" TO INCLUDE AN AUTHORIZATION OF CARE BY A PROVIDER—EVEN IF THE PATIENT INDEPENDENTLY CHOSE THE PROVIDER HERSELF.

The Seventh Circuit disagreed. For each patient that chose Grand, the court found, the physician would later sign an authorization form permitting Grand to seek reimbursement from Medicare for the patient's treatment. Grand would then pay the physician anywhere from $300-$400 per form. Under these circumstances, the court reasoned, "the doctor acted as a gatekeeper—without his approval, the patient could not receive treatment from the provider the patient had selected." *Id.* at 615. "Exercising this gatekeeping role is one way that doctors refer their patients to a specific provider," and falls within the meaning of "referral" in AKS.

13. Penalties

Under the FCA, violators are not only liable for treble the amount of compensatory damages, but also face civil penalties of $5,500 to $11,000 per false claim. 31 U.S.C. § 3729(a). A 2015 decision from the Fourth Circuit in *Tuomey Healthcare System*—which we have been monitoring for several years—addressed two important issues regarding penalties. *United States ex rel. Drakeford v. Tuomey Healthcare Sys., Inc.*, 792 F.3d 364, 386 (4th Cir. 2015) (an FCA case alleging that the provider had improper financial relationships with referring physicians in violation of the Stark Law).

First, the court upheld the district court's calculation of the number of "false claims" on which to assess penalties. In that case, the jury had determined that Tuomey submitted 21,730 UB-92/04 forms to Medicare for reimbursement, and thus found that the number of claims on which to assess penalties was 21,730. Tuomey argued on appeal that the number of false claims should be limited to four since it submitted only four Medicare cost reports during the relevant period. The Fourth Circuit, however, concluded that "a UB-92-04 form can constitute a discrete fraudulent claim under the FCA when the government proves that the forms were, in fact, false or fraudulent." *Id.* Consequently, because each form asked the government for reimbursement from a prohibited referral, the court held that each UB-92/04 form constituted a separate false claim, resulting in $119,515,000 in penalties. *Id.*

Second, the court rejected Tuomey's argument that the penalty amount was excessive and violated the Excessive Fines Clause of the Eighth Amendment.

"While the award is substantial, we cannot say that it is unconstitutional." *Id.* at 387. Applying Supreme Court precedent, the Fourth Circuit explained that the "degree of reprehensibility" of the defendant's conduct is the "most important indicium of the reasonableness of a punitive award." Here, the penalty reflects "the sheer breadth of the fraud Tuomey perpetrated upon the federal government" and the fact that Toumey acted "knowingly." *Id.* at 389. Moreover, the ratio between the penalties and the trebled compensatory damages was "approximately 3.6-to-1, which falls just under the ratio the [Supreme Court] deems constitutionally suspect." *Id.*

APPLYING SUPREME COURT PRECEDENT, THE FOURTH CIRCUIT EXPLAINED THAT THE "DEGREE OF REPREHENSIBILITY" OF THE DEFENDANT'S CONDUCT IS THE "MOST IMPORTANT INDICIUM OF THE REASONABLENESS OF A PUNITIVE AWARD."

14. Aseracare Trial

The case against AseraCare Inc., 2015 U.S. Dist. LEXIS 167312 (N.D. Ala. Nov. 3, 2015), a for-profit hospice provider, is noteworthy for a number of reasons. First, the case – seeking more than $200 million in damages – actually went to trial in 2015, which is itself unusual. The government had alleged that AseraCare improperly billed Medicare for patients who were falsely certified to be terminally ill. After denying AseraCare's summary judgment motion, U.S. District Judge Karon Bowdre (D. Ala.) ordered the parties to trial, which led to the second notable development in the case. The district court granted AseraCare's request to bifurcate the trial in two parts – one to determine falsity and the other to determine scienter. AseraCare argued that the government's evidence of scienter could inflame and prejudice the jury in a way that would prevent it from properly determining falsity. The court agreed, and the first trial began on August 3, 2015. After a two-month trial, the jury returned a verdict in the government's favor, finding that 104 of the 121 patient samples were false.

The district court then sua sponte concluded that the jury was improperly instructed. 2015 WL 8486874 (N.D. Ala. Nov. 3, 2015). The court said that it should have included an instruction that a mere difference of opinion between experts about whether a patient was terminally ill was insufficient to find falsity. After AseraCare moved for a new trial, the court granted the motion on November 3, 2015, and later announced that it would reconsider the summary judgment motions before setting a new trial date.

The case has a number of implications for FCA matters, and reflects DOJ's increasing willingness to bring FCA cases based on so-called medical necessity. It will be one we continue to monitor and provide updates on throughout 2016.

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