2016 YEAR IN REVIEW THE FALSE CLAIMS ACT

February 2017



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 2016. This *Year in Review* highlights several key developments, including:

- The U.S. Department of Justice is continuing its strong enforcement of the FCA, including recovering more than \$4.7 billion in settlements and judgments in FCA cases in 2016, as well as continuing its focus on individual culpability.
- The number of FCA lawsuits filed by whistleblowers in 2016 climbed back above 700.
- The U.S. Supreme Court clarified the so-called "implied certification" theory of liability and resolved a circuit split regarding violations of the FCA seal requirements.
- 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 2016, 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 2017.

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TABLE OF CONTENTS

MEET THE AUTHORS

Α.	2016: A LOOK BACK AT
	THE NUMBERS

1.	2016 was another record-breaking year	1
2.	Notable defense victories in 2016.	1
3.	The government prioritizes "individual accountability" in FCA enforcement	1

B. LEGISLATIVE UPDATE

C. SIGNIFICANT JUDICIAL DECISIONS

1.	The Supreme Court's Escobar Decision	2
2.	Seal Requirements	6
3.	Pleading with Particularity	6
4.	Public Disclosure and Original Source	8
5.	First to File	9
6.	AseraCare and Vista Hospice	10
7.	Reverse False Claims	11
8.	Scienter	11
9.	Retaliation Against Whistleblowing	_
10.	Damages, Penalties, and Costs	13

INDEX OF AUTHORITIES / PAGE 15

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A. 2016: A LOOK BACK AT THE NUMBERS

1. 2016 was another record-breaking year

On December 14, 2016, the U.S. Department of Justice reported that it recovered more than \$4.7 billion in settlements and judgments from FCA cases during fiscal year 2016. This was the third highest annual recovery in FCA history, bringing the total recovery to more than \$31 billion since 2009.

DOJ further reported:

- Of the \$4.7 billion recovered, \$2.5 billion came from the healthcare industry.
- \$1.7 billion came from the financial industry as a result of the housing and mortgage fraud crisis.
- The defense industry only contributed about \$120 million of the \$4.7 billion recovery.
- More than half of the \$4.7 billion was recovered in cases filed by private whistleblowers, with the whistleblowers receiving \$519 million for their share of the reward.

Among the cases resolved in 2016, there were several notable settlements and judgments, including:

- A \$785 million settlement with Wyeth (later acquired by Pfizer) to resolve allegations that the drug manufacturer knowingly reported false and fraudulent prices on drugs used to treat acid reflux.
- A \$390 million settlement with Novartis
 Pharmaceuticals Corp. to resolve allegations it paid kickbacks to specialty pharmacies.
- A \$260 million settlement with Millennium Health to resolve allegations that it billed federal healthcare programs for excessive and unnecessary testing, as well as provided free

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items to physicians in order to induce referrals.

 A \$1.2 billion settlement with Wells Fargo to resolve allegations it fraudulently certified loans for Federal Housing Administration insurance.

2. Notable defense victories in 2016

Although the DOJ had a record-breaking enforcement year, the defense bar also enjoyed a few notable victories. Our firm was privileged to represent Abbott Laboratories in a rare FCA jury trial brought by a former sales representative. United States ex rel. Colquitt v. Abbott Labs., No. 3:06-cv-1769-M (N.D. Tex. 2016). The jury returned a complete defense verdict, and the district court entered a take-nothing judgment in Abbott's favor. In another closely watched case, AseraCare, the district court entered summary judgment on behalf of AseraCare after granting the company a new trial following a 2015 jury verdict. The court explained that an expert's subjective judgment alone on the issue of medical necessity was insufficient to prove falsity. United States v. AseraCare Inc., 176 F. Supp. 3d 1282 (N.D. Ala. 2016). The case is currently pending on appeal.

3. The government prioritizes "individual accountability" in FCA enforcement

As promised in the 2015 "Yates Memo" issued by DOJ's Deputy Attorney General Sally Q. Yates, DOJ in 2016 continued its pursuit of *individuals* involved in alleged fraud, not just the *companies* for whom they work. As a practical matter, this meant that DOJ

¹ Available at https://www.justice.gov/opa/pr/justice-department-recovers-over-47-billion-false-claims-act-cases-fiscal-year-2016.

structured numerous settlements in FCA matters to include large payouts by executives in their individual capacities. For example, the former CEO of Tuomey Healthcare System agreed to pay more than \$1 million and to be excluded from participating in federal healthcare programs as part of a larger FCA settlement involving the company. Similarly, a board chairman and senior vice president of North American Health Care Inc. together agreed to pay approximately \$1.5 million as part of an FCA settlement with their employer, After reaching a \$145 million FCA settlement with Life Care Centers of America Inc. in October, the DOJ stated that it would pursue the company's owner for unjust enrichment. We fully expect that the Department will continue emphasizing this objective in 2017.

B. LEGISLATIVE UPDATE

As we reported last year, Congress authorized the increase of FCA penalties for the first time since 1999. Effective August 1, 2016, the penalties for FCA violations nearly doubled from a minimum of \$10,781 (up from \$5,500) to a maximum of \$21,563 (up from \$11,000).² FCA penalties already constitute a large portion of overall recoveries, and this increase could raise serious constitutional concerns under the Excessive Fines Clause of the Eighth Amendment.

Also of note, the Center for Medicare & Medicaid Services (CMS) published a final rule on the requirement for healthcare providers to report and return overpayments within 60 days, which was based on a provision in the 2010 Affordable Care Act. The final rule states that the 60 day clock begins to run "when the person has, or should have through the exercise of reasonable diligence, determined that the person has received an overpayment and quantified the amount of the overpayment." 42 C.F.R. § 401.305; 81 Fed. Reg. 7654 (Feb. 12, 2016). CMS contemplated a 6-month window as reasonable diligence and stated that overpayments must be reported and returned

only if identified within six years of the date the overpayment was received. *Id.* The final rule interprets the term "identified" slightly differently than the *Kane v. Healthfirst* case we discussed last year. *See Kane v. Healthfirst Inc. et al.*, 11-cv-02325, 2015 WL 4619686 (S.D.N.Y. Aug. 3, 2015). The court in *Kane* held that the clock begins to run "when a provider is put on notice of a potential overpayment," rather than when one is "conclusively ascertained." *Id. Kane*, however, involved the improper retention of Medicaid funds, while the final rule speaks only to Medicare Parts A and B.

It is unclear how the 60 day overpayment rule will fare in 2017 in light of the new Administration and the promise to repeal the Affordable Care Act. The Affordable Care Act also made important changes to the public disclosure bar and the definition of an original source, and thus we will continue to monitor how this proposed repeal will affect these critical FCA provisions.

C. SIGNIFICANT JUDICIAL DECISIONS

Federal courts continued interpreting and applying the FCA in various contexts in 2016. The following is a brief summary of some of those key decisions, organized by issue.

1. The Supreme Court's Escobar Decision

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 governing statutes, regulations, or contractual provisions in the process of submitting a claim for payment—even if the defendant never expressly certifies compliance. The courts disagreed over the theory's validity. Some rejected or refused to adopt it altogether; others limited its application to violations of expressly designated conditions of payment; and

² Available at https://www.gpo.gov/fdsys/pkg/FR-2016-06-30/pdf/2016-15528.pdf.

still others applied the theory without requiring express preconditions. On June 16, 2016, the U.S. Supreme Court finally resolved the issue in *United States ex rel. Escobar v. Universal Health Services Inc.*, 136 S. Ct. 1989, __ U.S. __ (2016).

First, the unanimous Court held that "the implied certification theory can, at least in some circumstances, provide a basis for liability." Id. at 1999. The Court reasoned that the meaning of "false or fraudulent claims" in the FCA encompasses all "fraudulent misrepresentations, which include certain misleading omissions." Id. Thus, the implied certification theory can be a basis for FCA liability where two conditions are satisfied: "first, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths." Id. at 2001.

Second, the Court held that a defendant can face FCA liability under the theory even if the government has not "expressly designated" compliance as a condition for payment. *Id.* But the Court clarified "that not every undisclosed violation of an express condition of payment automatically triggers liability." *Id.* Instead, "[w]hether a provision is labeled a condition of payment is relevant to but not dispositive of the materiality inquiry." *Id.* What matters is whether the defendant "knowingly violated a requirement that the defendant knows is material to the Government's payment decision." *Id.* at 1996.

This led the Court to "clarify how the materiality requirement should be enforced" under the FCA. *Id.* at 2001. Noting that the requirement "descends from 'common-law antecedents," the Court held that materiality "looks to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation." *Id.* at 2002. The materiality standard in the FCA, moreover, is "rigorous" and "demanding" because the statute is not "an all-purpose antifraud statute" to punish "garden-variety breaches of contract or regulatory violations." *Id.* The Court held that it is insufficient to prove materiality merely by showing that "the Government would have the option

to decline to pay if it knew of the defendant's noncompliance." *Id.* at 2003. The Court stated:

In sum, when evaluating materiality under the False Claims Act, the Government's decision to expressly identify a provision as a condition of payment is relevant, but not automatically dispositive. Likewise, proof of materiality can include, but is not necessarily limited to. evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement. Conversely, if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material. Or, if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material.

Id. The Court rejected the notion that "materiality is too fact intensive for courts to dismiss False Claims Act cases on a motion to dismiss or at summary judgment." Id. at 2004, n.6. Finally, the Court expressly disagreed with the government's argument "that any statutory, regulatory, or contractual violation is material so long as the defendant knows that the

THE COURT EXPRESSLY DISAGREED WITH THE GOVERNMENT'S ARGUMENT "THAT ANY STATUTORY, REGULATORY, OR CONTRACTUAL VIOLATION IS MATERIAL SO LONG AS THE DEFENDANT KNOWS THAT THE GOVERNMENT WOULD BE ENTITLED TO REFUSE PAYMENT WERE IT AWARE OF THE VIOLATION."

Government would be entitled to refuse payment were it aware of the violation." *Id.* "The False Claims Act does not adopt such an extraordinarily expansive view of liability." *Id.*

The Court then vacated the judgment in favor of the defendant Universal Health Services and remanded the case to the First Circuit, which has since issued its decision, discussed below.

a. Interpretations of *Escobar* regarding implied certification claims

In the wake of *Escobar*, the lower federal courts have disagreed over whether the opinion established a mandatory "two-part test" that applies to every implied false certification claim—(i) a request for payment with specific representations and (ii) the failure to disclose material noncompliance.

On the one hand, the Northern District of California held that *Escobar* did *not* establish "a rigid 'two-part test' for falsity that applies to every single implied false certification claim," but rather meant only that a claim *could* arise under those circumstances. *See Rose v. Stephens Institute*, 2016 WL 5076214 (N.D. Cal. Sept. 20, 2016), *appeal filed*, No. 16-80167 (9th Cir. Nov. 7, 2016). The court reasoned that *Escobar* said liability attached "at least where two conditions are satisfied" and further said it would not resolve whether implied certification is viable for "all claims." *Id.*

Other courts have disagreed, holding that a relator must, at a minimum, satisfy both prongs of the test in order to state an implied certification claim. See, e.g., United States ex rel. Handal v. Ctr. Emp't Training, 2016 U.S. Dist. LEXIS 105158 (E.D. Cal. Aug. 8, 2016); United States ex rel. Doe v. Health First, Inc., 2016 U.S. Dist. LEXIS 95987 (M.D. Fla. July 22, 2016); United States ex rel. Creighton v. Beauty Basics Inc., 2016 WL 3519365 (N.D. Ala. June 28, 2016).

This dispute will undoubtedly continue to grow until the courts of appeals weigh in, which may occur in early 2017, as the district court in *Rose* has now certified the question for interlocutory appeal under 28 U.S.C. § 1292(b).

We also want to briefly mention a case discussed in our 2015 year-end update, *United States v. Triple Canopy, Inc.*, 775 F.3d 628 (4th Cir. 2015), in which the Fourth Circuit squarely adopted the implied certification theory. The court held that 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.* at 636 (citation omitted). Following its decision in *Escobar*, the Supreme Court granted the petition for writ of certiorari in *Triple Canopy*, vacated the judgment, and remanded the case to the "Fourth Circuit for further consideration in light of" its ruling in *Escobar*. 136 S. Ct. 2504 (2016). We will be monitoring that case for further developments.

b. Interpretations of Escobar regarding materiality

Escobar applies beyond implied certification cases because of its discussion of materiality. As a reminder, the FCA prohibits only false statements or claims that are material—regardless of the theory of liability. 31 U.S.C. § 3729(a)(1)(B). The statute defines material as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money." Id. § 3729(b)(4). The following discussion highlights four court of appeals decisions addressing Escobar's materiality analysis at the end of 2016.

Eighth Circuit. In United States ex rel. Miller v. Weston Educ., Inc., 840 F.3d 494 (8th Cir. 2016), the Eighth Circuit relied on *Escobar* to reverse summary judgment in favor of the defendant after finding that the defendant's certifications could be material. Citing Escobar, the court held that "a false statement or record is 'material' for FCA purposes if either (1) a reasonable person would likely attach importance to it or (2) the defendant knew or should have known that the government would attach importance to it." Id. at 503. Here, the court stated, "[t]he government expressly conditioned [the defendant's] participation in Title IV on compliance with the recordkeeping requirement," "impos[ing] the condition in three ways." Id. at 504. "In addition to this triple conditioning, the significance of the requirement and the government's own acts show that the recordkeeping promise was material," including that the government "sometimes terminates otherwise eligible institutions for falsifying [compliance with the requirement]." Id. at 505.

- Seventh Circuit. In United States v. Sanford-Brown, Ltd., 840 F.3d 445 (7th Cir. 2016), the Seventh Circuit relied on Escobar to affirm the dismissal of an FCA suit against a for-profit higher education enterprise. The court held that implied false certification can be a basis of liability "where two conditions are met": first, the claim makes a specific representation about the goods or services provided, and second, the defendant's failure to disclose noncompliance with statutory or regulatory requirements makes those representations misleading half-truths. Id. at 447. "Neither condition is met here," the court explained, because the relator offered no evidence that the defendant "made any representations at all in connection with its claims for payment, much less false or misleading representations." Id. Further, the relator failed to establish "the independent element of materiality." Id. The relator, for example, "offered no evidence that the government's decision to pay [the defendant] would likely or actually have been different had it known of [the defendant's] alleged noncompliance." Id. On the contrary, the government agencies in this case "have already examined [the defendant] multiple times over and concluded that neither administrative penalties nor termination was warranted." Id.
- First Circuit. In United States ex rel. Escobar v. Universal Health Servs., Inc., 842 F.3d 103 (1st Cir. 2016), the First Circuit reconsidered the case after the Supreme Court's remand. In analyzing whether the relators had sufficiently alleged an FCA claim, the court held that materiality is "demanding," and it is not enough for a relator to allege that "the Government would have the option to decline to pay if it knew of the defendant's noncompliance." Id. at 110. "[T]he fundamental inquiry is whether a piece of information is sufficiently important to influence the behavior of the recipient." Id. The First Circuit concluded that the relators had sufficiently alleged that UHS's misrepresentations about compliance with licensing requirements were material—for three reasons: (1) the government had indicated that compliance was a condition of payment, "a relevant though not dispositive factor," (2) "the centrality of the licensing and supervision requirements ... go to the very essence

- of the bargain," and (3) "there is no evidence in the record that [the government] paid [the] claims to UHS despite knowing of the violations." *Id.*
- First Circuit. In United States ex rel. D'Agostino v. ev3, Inc., __ F.3d __, 2016 WL 7422943 (1st Cir. 2016), the First Circuit relied on *Escobar* to affirm the dismissal of an FCA claim against a medical device company for allegedly fraudulently inducing the Food and Drug Administration to approve a device. It is not enough, the court held, to allege that the representations "could have influenced the FDA to grant approval," which in turn caused the Center for Medicare & Medicaid Services to reimburse physicians for using the device. Id. at *5. Under Escobar, "the fraudulent representation [must] be material to the government's payment decision itself." Id. "The fact that CMS has not denied reimbursement for [the product] in the wake of D'Agostino's allegations casts serious doubt on the materiality of the fraudulent representations that D'Agostino alleges." Id. The court explained:

The FDA's failure actually to withdraw its approval of Onyx in the face of D'Agostino's allegations precludes D'Agostino from resting his claims on a contention that the FDA's approval was fraudulently obtained. To rule otherwise would be to turn the FCA into a tool with which a jury of six people could retroactively eliminate the value of FDA approval and effectively require that a product largely be withdrawn from the market even when the FDA itself sees no reason to do so. The FCA exists to protect the government from paying fraudulent claims, not to second-guess agencies' judgments about whether to rescind regulatory rulings.

Id. at *6.

As courts continue to analyze and apply *Escobar* in 2017, we will report any significant developments.

2. Seal Requirements

The Supreme Court issued a second important opinion in 2016 related to 31 U.S.C. § 3730(b)(2), which requires *qui tam* complaints to remain under seal for at least 60 days to give the government time to investigate the allegations. The courts of appeals have disagreed as to whether a violation of the seal should result in mandatory dismissal of the suit. In *State Farm Fire & Casualty Co. v. United States ex rel. Rigsby*, the Supreme Court held that violation of the FCA's seal requirement is not grounds for automatic dismissal, thereby resolving the circuit split. __ U.S. __, 137 S.Ct. 436 (2016).

State Farm involved the classification of damage caused by Hurricane Katrina. Former claims adjusters for State Farm alleged in a complaint that was filed under seal that they were instructed to misclassify certain damage in order to shift insurance liability to the government under federally-backed flood insurance policies. *Id.* at 3. While the complaint was still under seal, the relators' attorney disclosed a sealed evidentiary filing to journalists at various news outlets, all of which ran stories discussing the allegations, but without specifically discussing the complaint's existence. *Id.* at 4. The attorney at issue was later removed from the case.

State Farm moved to dismiss the case as a sanction for the relators' seal violation. In denying the motion, the district court balanced three factors: (1) actual harm to the government, (2) the severity of the violation, and (3) evidence of bad faith. *Id.* at 5. The case later went to trial, resulting in a victory for relators. On appeal, the Fifth Circuit affirmed.

The Supreme Court affirmed in a unanimous opinion holding that dismissal for seal violations is not mandatory for two reasons. *First*, the Court reasoned that if Congress had intended mandatory dismissal it would have said so—as it had done in other provisions of the FCA involving other issues. *Id.* at 7. *Second*, the Court stated that mandating dismissal for all seal violations is inconsistent with the purpose of the seal requirement, which is to encourage private enforcement suits while protecting any pending federal criminal investigation. *Id.* Rather than mandating automatic dismissal, the Court explained

that "the question whether dismissal is appropriate should be left to the sound discretion of the district court," which in this case exercised that discretion appropriately. *Id.* at 10.

3. 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 fraud." Fed. R. Civ. P. 9(b). As we discussed last year, the courts of appeals remain divided over how to apply the rule, and particularly whether a plaintiff must allege "representatives samples of the alleged fraudulent conduct" or whether it is "sufficient 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." *United States ex rel. Eberhard v. Physicians Choice Lab.*, 642 F. App'x 547, 550 (6th Cir. 2016).

a. Circuit courts apply the pleading standard in a variety of cases.

In 2016, courts of appeals continued to hold that bare bones complaints – those that are vague, sparse, or conclusory – will not satisfy Rule 9(b). See Cooper v Pottstown Hosp. Co., LLC, 651 F. App'x 114 (3d Cir. 2016) (sparse complaint that attached conclusory labels to lawful acts was inadequate to satisfy Rule 9(b)); United States ex rel. Ladas v. Exelis, Inc., 824 F.3d 16 (2d Cir. 2016) (conclusory statements that were not supported by particularized facts were insufficient to satisfy Rule 9(b)). The courts remain divided, however, on how to approach complaints that contain at least some level of detail.

The Ninth Circuit continued to take a more lenient view of the pleading requirements. In *United States ex rel. Swoben v. United Healthcare Ins. Co.*, the court found that the complaint satisfied Rule 9(b) as to two of the five defendants because it offered "more than broad allegations lacking supporting detail and provide[d] a strong factual basis for [the relator's] claims." 2016 WL 7378731 (9th Cir. Dec. 16, 2016). Similarly, the Ninth Circuit reversed the district court in *United States ex rel. Driscoll v. Spencer*, finding that

the alleged examples of misconduct observed by the relator were "sufficiently specific" to survive dismissal. 2016 WL 4191896 (9th Cir. Aug. 9, 2016).

The Seventh Circuit also allowed a relator past a motion to dismiss, despite failing to allege with particularity the defendant's actual submission of a false claim. *United States ex rel. Presser v. Acacia Mental Health Clinic, LLC.* 836 F.3d 770 (7th Cir. 2016). Because the relator was a nurse practitioner and did not have access to billing systems, the court accepted that the relator could not plead the actual submission of claims with particularity. Indeed, "the alleged facts necessarily led one to the conclusion that the defendant[s] had presented claims to the Government," permitting the relator to proceed on the billing allegations. *Id.* at 778.

The Sixth Circuit, on the other hand, arguably applied a stricter pleading standard in United States ex rel. Eberherd v. Physicians Choice Laboratory Services, LLC., 642 F. App'x 547 (6th Cir. 2016). The Eberherd court joined the Fourth, Eighth, and Eleventh Circuits in holding that the relator must plead representative samples of fraudulent conduct, rather than merely the details of a scheme to submit false claims. Id. at 550. Although the court stated that Rule 9(b) may be relaxed in circumstances "where a relator demonstrates that he cannot allege the specifics of actual false claims that in all likelihood exist," the court found that the relator in this case alleged only personal knowledge of a fraudulent scheme, not personal knowledge of the submission of specific fraudulent claims. The court found that was insufficient to satisfy Rule 9(b). Id. at 551; but see United States ex rel. Prather v. Brookdale Senior Living Cmtys., Inc., 838 F.3d 750, 773 (6th Cir. 2016) (allowing a relator with personal billing knowledge past motion to dismiss).

The First Circuit likewise took a narrow view of Rule 9(b) in the long-running *United States ex rel. Kelly v. Novartis*, 827 F.3d 5 (1st Cir. 2016). There, the court stated that mere insinuation of false claims, without "factual or statistical evidence that would strengthen the inference of fraud beyond possibility," was inadequate to satisfy the pleading requirements of Rule 9(b). *Id.* at 15; *see also Lawton ex rel. United*

States v. Takeda Pharm. Co., Ltd., 842 F.3d 125 (1st Cir. 2016) (same).

b. District courts continue to grapple with Rule 9(b).

District courts likewise 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 satisfied Rule 9(b) by pleading details that relator personally witnessed, even though she did not plead specific dates or locations where a false diagnosis was allegedly made. United States ex rel. Ramsey-Ledesma v. Censeo Health, LLC, 2016 WL 5661644 (N.D. Tex. Sept. 30, 2016). According to the court, it was sufficient to plead "particular details of an alleged scheme to submit false claims to the Government and allegations stating a likelihood that false claims were actually submitted. Id. at *4.
- Complaint <u>failed to satisfy</u> Rule 9(b) where relator failed to allege the who, what, where, when, and how of any fraudulent submissions to the government. *Jallali v. Sun Healthcare Group*, 2016 WL 3564248 (S.D. Fla. July 1, 2016).
- Complaint <u>failed to satisfy</u> Rule 9(b) where relator failed to connect allegations of fraudulent promotion to any false claims for reimbursement. *United States ex rel. Witkin v. Medtronic, Inc.*, No. 11-10790-DPW (D. Mass. May 23, 2016).
- Complaint failed to satisfy Rule 9(b) where relator described the scheme in detail, but failed to allege the "'facts as to time, place, and substance of the defendant's alleged fraud." United States ex rel. Chase v. Lifepath Hospice, Inc., et al., 2016 WL 5239863, at *7 (M.D. Fla. Sept. 22, 2016) (quoting United States ex rel. Clausen v. Laboratory Corp. of America, Inc., 290 F.3d 1301, 1310 (11th Cir. 2002)). The court held that Chase did "not identify a single claim submitted to the government, let alone a false one." Id.

4. 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 fraud to qualify as an "original source." 31 U.S.C. § 3730(e) (4). This defense is continually a source of litigation, as courts attempt to strike the congressionally-intended balance between discouraging parasitic lawsuits and properly incentivizing true whistleblowers. In 2016, a number of appellate courts addressed the issue. The key developments are discussed below.

a. When is the public disclosure bar triggered?

In 2016, several courts provided additional clarity on the public disclosure bar. In United States ex rel. May v. Purdue Pharma, L.P., for example, the Fourth Circuit held that the public disclosure bar was triggered where the relators' allegations were derived from facts learned by their attorney in a prior lawsuit and available in public filings. 811 F.3d 636, 640 (4th Cir. 2016). The Fourth Circuit rejected the argument that the relators had not read the prior lawsuit. See id. Instead, the court emphasized that the relators did not independently discover the facts, which were publicly disclosed before their suit was filed. Id. at 642. The Fourth Circuit also addressed the timing of the public disclosure in United States ex rel. Beauchamp v. Academi Training Center, 816 F.3d 37 (4th Cir. 2016). There, the district court had dismissed the claims because a news article disclosing the allegations was published after the first complaint was filed, but before a later amended complaint was filed. See id. The Fourth Circuit reversed the dismissal, holding that "the determination of when a plaintiff's claims arise for purposes of the public disclosure bar is governed by the date of the first pleading to particularly allege the relevant fraud and not by the timing of any subsequent pleading." Id. at 46.

The Seventh Circuit also addressed the public disclosure bar, emphasizing the bar's goal to discourage parasitic lawsuits in the context of a claim based on allegations already addressed in a government disclosure. In Cause of Action v. Chicago Transit Authority, the court rejected the relator's argument that the public disclosure bar should not

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apply where the disclosure occurred in the form of: (1) a government disclosure (in a letter sent by the Federal Transit Administration (FTA) to the Chicago Transit Authority (CTA)); and (2) an audit report publicly available on the Auditor General's website. 815 F.3d 267 (7th Cir. 2016). The relator argued that the public disclosure bar was not triggered because the FTA had done nothing to recover money it was owed from the CTA. Id. at 275-276. The court found the relator's distinction "not relevant" to its analysis and affirmed the district court's dismissal. Id. at 276. Notably, the Seventh Circuit acknowledged the fact that other circuits would disagree with its interpretation that the government disclosure alone was enough to trigger the public disclosure bar. See id. at 277. But the court found there was no question that the Auditor General's report was a public disclosure because one could infer from the report that CTA knew it was presenting a false set of facts to the government. Id. at 279.

In contrast, the Ninth Circuit in *United States ex rel*. Mateski v. Raytheon Co. found that disclosures in publicly available reports did not trigger the public disclosure bar where they did not contain "an explicit accusation of wrongdoing." 816 F.3d 565, 571 (9th Cir. 2016). The court stated that "[a]llowing a public document describing 'problems'-or even some generalized fraud in a massive project or across a swath of an industry—to bar all FCA suits identifying specific instances of fraud in that project or industry would deprive the Government of information that could lead to recovery of misspent Government funds and prevention of further fraud." Id. at 577.

The Supreme Court may address the public disclosure bar in 2017 as a result of *United States ex rel*. Advocates for Basic Legal Equality, Inc. v. U.S. Bank, N.A., 816 F.3d 428 (6th Cir. 2016). In that case, the Sixth Circuit held that disclosures in the form of a consent order between U.S. Bank and the federal government, as well as a foreclosure practices review from federal agencies, triggered the public disclosure bar because they put the government on notice regarding the possibility of fraud. Id. at 431. The relator filed a certiorari petition arguing that the same disclosures would not have triggered the bar in the Seventh and Ninth Circuits. The relator argued that,

"'[i]n those circuits, public disclosure of some wrongdoing does not bar an FCA action unless it 'alerted the government to the specific areas of fraud alleged' in the action." See Pet. at 1. Emphasizing the purpose behind the public disclosure bar, the petition argues that the Sixth Circuit's "restrictive" reading "disrupts the FCA's 'effort to strike a balance between encouraging private persons to root out fraud and stifling parasitic lawsuits." See Pet. at 3. In October, the Supreme Court asked the U.S. Solicitor General for his views on the pending petition. We will continue to monitor developments in this case into 2017.

b. 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). To qualify as an "original source," the 2010 amendments to the public disclosure bar require knowledge that is "independent of and materially adds to" the public disclosures. A number of courts in 2016 addressed what constitutes a "material" addition.

In United States ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC, the Third Circuit for the first time interpreted the phrase "materially adds." 812 F.3d 294 (3d Cir. 2016). At issue was whether the relator, Moore, had "materially added" to the publicly disclosed fraud by adding factual details regarding the alleged fraud that it uncovered through discovery in a separate civil case. The Third Circuit held that it did, clarifying that to "'materially add[]' to the publicly disclosed allegation or transaction of fraud, a relator must contribute significant additional information to that which has been publicly disclosed so as to improve its quality." Id. at 306. The court held that Moore did so when it contributed "significant details to the essential factual background of the fraud—the who, what, when, where, and how of the alleged fraud—that were not publicly disclosed." Id. at 308. Moore thus qualified as an original source.

Other circuits also addressed the "materially adds" requirement, shedding some light on the amount of additional detail required. The Seventh Circuit held that adding a few additional details was not enough to

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"materially add" to publicly disclosed allegations where the allegations in the first suit put the government on notice of the broader scheme. See United States ex rel. Bogina v. Medline Industries, Inc., 809 F.3d 365 (7th Cir. 2016). Bogina's second suit added a defendant, identified some additional government programs, and noted the fact that the fraud was apparently ongoing rather than concluded. *Id.* at 370. Even then, the court found the differences between the two suits "unimpressive," focusing on the fact that the allegations in the first suit put the government "on notice of the possibility of a broader bribe-kickback scheme before Bogina sued." Id. Similarly, the First Circuit held that relators did not "materially add" to publicly disclosed allegations where the complaint merely identified additional government programs, added some details, and broadened the temporal scope of the alleged fraud. United States ex rel. Winkelman v. CVS Caremark Corp., 827 F.3d 201, 212 (1st Cir. 2016). Like the Seventh Circuit, the First Circuit held that "a relator who merely adds detail or color to previously disclosed elements of an alleged scheme is not materially adding to the public disclosures." Id. Finally, the Ninth Circuit also weighed in, holding that a relator did not "materially add" to what the Department of Housing and Urban Development (HUD) already knew about seller-funded downpayment assistance programs because he "provided only background information and examples of loans that had been made using seller-funded downpayment assistance programs," which "did not materially add to what HUD already knew." United States ex rel. Hastings v. Wells Fargo Bank, NA, Inc., 656 F. App'x 328, 332 (9th Cir. 2016).

These cases thus clarify that offering specific examples of the conduct, broadening the temporal scope, and identifying additional federal programs does not "materially add" to the allegations where the conduct has already been publicly disclosed.

5. First to File

The FCA's first-to-file rule 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). Courts have interpreted this phrase to bar actions based on the same "material" or "essential"

facts. See, e.g., United States ex rel. Johnson v. Planned Parenthood, 570 F. App'x 386 (5th Cir. June 4, 2014). Last year, the U.S. Supreme Court resolved a circuit split regarding the meaning of "pending," holding that the rule no longer applies if the first-filed case has been dismissed. See KBR, Inc. v. United States ex rel. Carter, 135 S. Ct. 1970 (2015).

We discussed last year *United States ex rel. Gadbois v. PharMerica Corp.*, No. 14-1264 (1st Cir. Dec 16, 2015), in which the First Circuit applied *KBR* to vacate the dismissal of a second-filed case because the first-filed action was dismissed while the appeal to the First Circuit was pending. 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.

In January of this year, the First Circuit denied PharMerica's motion for rehearing en banc. PharMerica then filed a petition for writ of certiorari in April 2016, arguing that the First Circuit's decision conflicts with decisions in the Fourth, Seventh, and Tenth Circuits, and also misapplies *KBR*. See Pet. at 2. PharMerica emphasized that the inevitable resolution of the first-filed case years after the relator brought his claim "should not give life to Gadbois's prohibited case simply because he managed to keep it on a court's docket until [the first-filed case] was dismissed." *Id.* at 3. The Supreme Court denied the petition in June 2016, letting the First Circuit's decision stand.

6. AseraCare and Vista Hospice

The legal industry has closely followed two FCA cases against for-profit hospice providers AseraCare Hospice and Vista Hospice Care. *United States v. AseraCare, Inc.*, 176 F. Supp. 3d 1282 (N.D. Ala. 2016); *United States ex rel. Wall v. Vista Hospice Care, Inc.*, 2016 WL 3449833 (N.D. Tex. June 20, 2016). In both cases, relators accused the providers of falsifying certifications of hospice eligibility for patients who were not terminally ill. The providers then allegedly improperly billed Medicare for hospice benefits in violation of the FCA.

The cases differ, however, in their treatment of the

plaintiff's evidence. The court in *AseraCare* allowed the government to review a random sample of 233 patient records and extrapolate from the government expert's determination that 123 records did not support a finding of terminal illness. The court in *Vista Hospice Care*, however, held that sampling and extrapolation were improper because each claim at issue involved a physician's subjective judgment regarding an individual patient. Following the reasoning of *United States ex rel. Michaels v. Agape Senior Community*, which we covered last year, the *Vista Hospice Care* court held that the claims must be handled on a case-by-case basis. 2016 WL 3449833 (citing 2015 WL 3903675, at *8 (D.S.C. June 25, 2015)).

In addition to the use of statistical tools, AseraCare is notable for its progression to trial—a rarity in FCA cases—following an unprecedented bifurcation to determine falsity and scienter separately. The court found that it would be inflammatory for jurors to hear the government's evidence of AseraCare's knowledge while attempting to objectively determine whether claims were false. As we reported last year, the court granted the defendants' new trial motion after concluding that the jury instructions should have indicated that mere differences of clinical judgment regarding whether a patient was actually terminally ill, without more, was not enough to show falsity for FCA purposes. United States v. AseraCare, Inc., 153 F. Supp. 3d 1372, 1381 (N.D. Ala. 2015). Since the government could not provide any evidence beyond its expert's subjective disagreement with AseraCare's certifications of terminal illness, the court granted summary judgment in favor of AseraCare. 176 F. Supp. 3d 1282 (N.D. Ala. 2016).

The court in *Vista Hospice Care* followed *AseraCare* in finding that a mere difference of opinion among physicians cannot be the sole basis to prove falsity, as this would "totally eradicate the clinical judgment required of the certifying physicians." 2016 WL 3449833, at *18. While *Vista Hospice Care* was ultimately resolved by mediation, the government has appealed the *AseraCare* decision to the Eleventh Circuit, and oral argument is scheduled for March 2017. Other courts have already relied on *AseraCare* in finding that subjective differences in medical judgment, absent evidence that a physician's

independent medical judgment was compromised, do not constitute false claims. See *United States ex rel. George v. Fresenius Med. Care Holdings, Inc.*, 2016 WL 5361666, at *16 (N.D. Ala. Sept. 26, 2016).

7. Reverse False Claims

A defendant may be liable under the FCA for a "reverse false claim" if the defendant makes or uses a false record or statement for the purpose of avoiding or decreasing an "obligation" owed to the United States. See 31 U.S.C. §3729(a)(1)(G). A plaintiff must show that the defendant failed to give money or property that it was obligated to disburse to the government. Two courts of appeals interpreted this provision in 2016.

First, the Third Circuit clarified the meaning of the term "obligation." United States ex rel. Customs Fraud Investigations, LLC. v. Victaulic Co., 839 F.3d 242, 254 (3d Cir. 2016). In that case, the plaintiff had accused a pipe fittings manufacturer of violating the FCA by mismarking foreign-made fittings and by falsifying customs entry documents to avoid paying statutory duties. The plaintiff argued that the manufacturer concealed, withheld, and avoided its obligation to pay marking duties, making it liable under a reverse false claim theory. The district court rejected the plaintiff's argument, holding that there could not be a reverse false claim because the act of importing cannot both create the obligation and be the conduct that avoids or decreases the obligation. On appeal, the Third Circuit vacated the district court's opinion, concluding that the lower court had made "too fine a distinction between the time at which an importer must pay marking duties and the time at which such duties accrue." Id. Instead, the court explained, the statutory text, legislative history, and policy rationale underlying the FCA's regulatory scheme all support attaching reverse false claims liability to the intentional evasion of marking duties. Id. at 256.

Second, the Fifth Circuit also shed light on the meaning of "obligation." United States ex rel.

Simoneaux v. E.I. du Pont de Nemours & Co., 2016 WL 7228813 (5th Cir. Dec. 13, 2016). In that case, a former safety operator of chemical company DuPont accused the company of failing to comply with its duty to

report sulfuric chemical leaks to the Environmental Protection Agency ("EPA"). The district court denied DuPont's motion for summary judgment, finding the term "obligation" includes fines or penalties associated with a statutory duty—such as the duty to report chemical leaks under TSCA—and the knowing evasion of this duty could form the basis for liability under a reverse false claim theory. The Fifth Circuit reversed. The court explained that, although the amount of an obligation does not need to be fixed, penalties that are contingent, potential, or unassessed are *not* obligations. *Id.* at *5-6.

8. 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). While the law does not require that the plaintiff show a specific intent to defraud, gross negligence is not enough. Not surprisingly, plaintiffs often argue that scienter should be left to the jury and that summary dismissals are inappropriate. But in 2016, several courts of appeals rejected that argument, affirming summary judgment in favor of defendants because there was no evidence of scienter.

■ Seventh Circuit. In United States ex rel. Sheet Metal Workers Int'l Assoc., Local Union 20 v. Horning Investments, LLC, the Seventh Circuit affirmed a grant of summary judgment in favor of defendants, holding that relators had not presented enough evidence to allow a reasonable inference that the defendant made any "knowing" misrepresentations. 828 F.3d 587, 593 (7th Cir. 2016). In that case, the relators had alleged that the defendant submitted false Certified Payroll Reports containing certifications of compliance with the Davis-Bacon Act. Id. at 591. The Davis-Bacon Act establishes a minimum wage for workers on federal construction projects, which is based on the prevailing wage for similar work in the region and includes fringe benefits. The defendant had submitted Certified Payroll

Reports to the Department of Veteran Affairs with the statement that "no deductions have been made either directly or indirectly from the full wages earned by any person, other than permissible deductions." In reality, multiple employees had \$5 per hour deducted from their pay and placed into a fringe-benefits trust, even though they were ineligible to receive benefits from the trust. Id. at 595. The Seventh Circuit affirmed the lower court's grant of summary judgment because there was no evidence that the defendant knew its statements were false and there was "enough ambiguity" in the statute and regulations that "we cannot infer that [the defendant] either knew or must have known that it was violating the Davis-Bacon Act." Id. at 595.

- **Eighth Circuit.** The court in *United States ex rel.* Donegan v. Anesthesia Associates of Kansas City, PC, also affirmed a grant of summary judgment for lack of evidence of scienter, 833 F.3d 874 (8th Cir. 2016). The court explained that "an FCA defendant's reasonable interpretation of an ambiguous regulation belies the scienter necessary to establish a claim of fraud under the FCA." Id. at 879. Further, the court clarified that there is no general duty to seek a legal opinion or prior approval when construing a regulation with a longstanding and obvious ambiguity. Id. at 880. The inquiry in FCA cases is not to determine the proper interpretation of a regulatory ambiguity, but rather to decide whether a defendant's interpretation of the ambiguity "precludes a finding that it knowingly submitted false or fraudulent claims ... even if a reviewing court would interpret the regulation differently." Id. at 879. According to the Eighth Circuit, where a relator fails to submit any evidence refuting a defendant's showing that its interpretation was objectively reasonable, summary judgment is proper. Id.
- Ninth Circuit. In United States ex rel. Ruhe v. Masimo Corp., the Ninth Circuit affirmed a grant of summary judgment to a medical device manufacturer where the relator attempted to establish an FCA violation based on the alleged inaccuracy of the manufacturer's devices. 640 F.

- App'x 666 (9th Cir. 2016) (mem. op.) (not designated for publication). The relator contended that the devices were "so inaccurate that every claim submitted to Medicare by doctors who used the devices" violated the FCA. *Id.* at 668. But there was only "isolated complaints and anecdotal feedback" about any inaccuracies, and the court held that this could not "support an inference that [the manufacturer] committed knowing fraud." *Id.* "Relators have not submitted evidence establishing the requisite scienter." *Id.* at 669. "The FCA is not violated simply if a product fails to perform well; a knowingly false statement is required for liability." *Id.*
- **Fifth Circuit.** Finally, the court in *United States ex* rel. Johnson v. Kaner Medical Group, affirmed a district court's sua sponte grant of summary judgment in favor of the Kaner Medical Group ("KMG"). 641 F. App'x 391 (5th Cir. Mar. 7, 2016) (per curiam). In that case, the relator had alleged that KMG incorrectly filled out the form necessary for seeking Medicare reimbursement. But there was "no summary judgment evidence on which a reasonable jury could find that KMG acted with actual knowledge, deliberate ignorance, or reckless disregard." Id. at 394. "Rather, the record indicates that, at most, KMG's misunderstanding of CMS's requirements [for filling out the form] was negligence, which is not sufficient to attach liability under the FCA." Id. at 394-395.

9. Retaliation Against Whistleblowing Employees

The FCA's whistleblower provision prohibits employers from retaliating against employees who 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 her as a result of the protected activity.

Courts in 2016 continued to grapple with how to interpret "protected activity" under the first prong of the FCA retaliation provision. Before the 2009 amendments to the FCA, courts generally held that

activity was protected if it arose "in a context where litigation is a distinct possibility." *E.g., United States ex rel. King v. Solvay,* 2015 WL 4256402 (S.D. Tex. July 14, 2015). In 2016, the Fourth Circuit in *Carlson v. Dyncorp International LLC*, joined a growing number of courts—*i.e.*, the Sixth, Seventh, Eighth, and Ninth Circuits—in rejecting this definition as the sole measure for identifying protected activity. 657 F. App'x 168, 172 (4th Cir. 2016). Instead, the court applied an "objectively reasonable belief" standard under which activity is protected if it is "motivated by an objectively reasonable belief that the employer is violating or soon will violate, the FCA." *Id.*

Although plaintiffs often argue that this "objectively reasonable belief" standard broadens the scope of protected activity, plaintiffs have not necessarily fared well under the "broader" standard. In Carlson, for example, the Fourth Circuit held that it was not objectively reasonable for the plaintiff in that case to believe that his employer's practice of under-billing the government constituted an FCA violation because it did not result in financial loss to the government. Id. at 173. Similarly, in *Miller v. Abbott Laboratories*, the Sixth Circuit held that it was not objectively reasonable to believe that an offer to split a \$100 prize would induce a person to violate the FCA. 648 F. App'x 555, 562 (6th Cir. 2016); see also United States ex rel. Uhlig v. Fluor Corp., 839 F.3d 628, 635 (7th Cir. 2016) (what the plaintiff knew second-hand "was not sufficient to cause a reasonable person to suspect fraud" by the defendant).

Judicial decisions in 2016 have also helped to clarify the scope of the anti-retaliation provisions. In *United States ex rel. Bias v. Tangipahoa Parish School Board*, the Fifth Circuit—analyzing the effects of the 2009 FERA amendments—concluded that the amendments expanded the class of protected whistleblowers to include contractors and agents of the defendant. 816 F.3d 315, 324 (5th Cir. 2016). Under this reasoning, the court held that a school board could be liable for retaliating against a whistleblower under an agency theory, even though the whistleblower—a school teacher—was employed by a different entity. *Id.* In a later case, the Fifth Circuit held that the amendments did not, however, expand the class of viable defendants, holding that an individual, non-employer

defendant could not be held liable under the antiretaliation provisions in *Howell v. Town of Ball*, 827 F.3d 515, 529-30 (5th Cir. 2016).

Finally, the First Circuit in *United States ex rel. Hamrick* v. GlaxoSmithKline LLC, broadly limited the ability of whistleblowers to defeat summary judgment by limiting what inferences can be drawn based on certain "speculative" theories of retaliatory pretext. 814 F.3d 10 (1st Cir. 2016). In that case, the court held that where an employer has satisfied the burden of advancing a non-retaliatory motive for terminating a whistleblower, the whistleblower must do more than provide speculation to avoid summary judgment. Id. at 19-23. The court thus rejected the whistleblower's argument that a retaliatory inference should be drawn based merely on the temporal proximity of the protected activity and the whistleblower's termination. Id. at 23. This decision should prove particularly helpful to defendants in defeating this common theory raised by whistleblowers.

10. Damages, Penalties, and Costs

The FCA provides for trebling of actual damages. See 31 U.S.C. § 3729(a)(1)(G). Courts generally hold that actual damages are the difference in value between what the government bargained for and what the government received. Judicial decisions in 2016 provided guidance for determining actual damages in FCA cases.

In United States ex rel. Wall v. Circle C Construction, LLC, for example, the Sixth Circuit dramatically reduced an FCA damages award from \$762,894.54 to \$14,748, finding that the damages the government sought to recover were "fairyland rather than actual." 813 F.3d 616, 618 (6th Cir. 2016). In that case, the government had proffered a damages theory under which the actual damages calculation was equal to the total amount paid for performance. Id. According to the government, under this "tainted performance" theory, fraudulent claims allegedly tainted the entire value of the work performed, thus rendering whatever the contractor performed worthless. Id. In rejecting this theory, the Sixth Circuit held that the government "received almost all of the value . . . that it bargained for with respect" to the contracted services. Id. Wall

thus provides useful guidance for defendants seeking to counter overreaching damages theories, particularly in cases where actual damages can be accurately determined.

The Southern District of Ohio also addressed actual damages in the context of disgorgement in FCA cases. In *United States v. United Technologies Corp.*, the court likewise rejected the government's proffered damages theory because it failed to account for retroactive price reductions the government received that offset earlier damages. 2016 WL 3141569 (S.D. Ohio June 3, 2016). According to the court, disgorgement is "measured by the entire amount of profits which were illicitly received as a result of the defendant's wrongdoing." *Id.* at *15 (citation and internal quotations omitted). This decision reiterates a guiding principle in FCA cases that damages are limited to what the government "actually" suffers, even in the context of disgorgement.

Finally, a decision from the Second Circuit could potentially vitiate certain cost-shifting protections afforded to FCA plaintiffs who bring cases in good faith. Under 31 U.S.C. § 3730(d)(4), whistleblowers are afforded protections against expenses, but the provision does not specifically protect plaintiffs from the recovery of "costs" by a prevailing defendant. In Associates Against Outlier Fraud v. Huron Consulting Group, Inc., the Second Circuit affirmed the award of costs under Rule 54 for deposition transcripts to a prevailing defendant in an FCA action, 817 F.3d 433. 437 (2d Cir. 2016). There, the court found clear distinctions between "costs" and "expenses" in both the language of the FCA and the Federal Rules of Civil Procedure and thus no authority to bar the recovery of costs under § 3730(d)(4). Id. at 436-37. In so ruling, the Second Circuit joined the Eighth, Ninth, and Tenth Circuits in holding that § 3730(d)(4) does not displace the court's authority to award costs under Rule 54. Id. at 437.

Associates Against Outlier Fraud v. Huron Consulting Group, Inc., 817 F.3d 433 (2d Cir. 2016)	14
Cause of Action v. Chicago Transit Authority, 815 F.3d 267 (7th Cir. 2016)	8
Cooper v Pottstown Hosp. Co., LLC, 651 F. App'x 114 (3d Cir. 2016)	6
George v. Fresenius Med. Care Holdings, Inc., 2016 WL 5361666 (N.D. Ala. Sept. 26, 2016)	11
Howell v. Town of Ball, 827 F.3d 515 (5th Cir. 2016)	13
Jallali v. Sun Healthcare Group, 2016 WL 3564248 (S.D. Fla. July 1, 2016)	7
Kane v. Healthfirst Inc. et al., 2015 WL 4619686 (S.D.N.Y. Aug. 3, 2015)	2
KBR, Inc. v. United States ex rel. Carter, 135 S. Ct. 1970 (2015)	10
Lawton ex rel. United States v. Takeda Pharm. Co., Ltd., 842 F.3d 125 (1st Cir. 2016)	7
Miller v. Abbott Laboratories, 648 F.App'x 555 (6th Cir. 2016)	13
Rose v. Stephens Institute, 2016 WL 5076214 (N.D. Cal. Sept. 20, 2016)	4
State Farm Fire & Casualty Co. v. United States ex rel. Rigsby, U.S, 137 S. Ct. 436 (2016)	6
United States v. AseraCare, Inc., 153 F. Supp. 3d 1372, 1381 (N.D. Ala. 2015)	10
United States v. AseraCare Inc., 176 F. Supp. 3d 1282 (N.D. Ala. 2016)	1, 10
United States v. Sanford-Brown, Ltd., 840 F.3d 445 (7th Cir. 2016)	5
United States v. Triple Canopy, Inc., 775 F.3d 628 (4th Cir. 2015)	4
United States v. United Technologies Corp., 2016 WL 3141569 (S.D. Ohio June 3, 2016)	14
United States ex rel. Advocates for Basic Legal Equality, Inc. v. U.S. Bank, N.A., 816 F.3d 428 (6th Cir. 2016)	
United States ex rel. Beauchamp v. Academi Training Center, 816 F.3d 37 (4th Cir. 2016)	8
United States ex rel. Bias v. Tangipahoa Parish School Board, 816 F.3d 315 (5th Cir. 2016)	
United States ex rel. Bogina v. Medline Industries, Inc., 809 F.3d 365 (7th Cir. 2016)	9
United States ex rel. Colquitt v. Abbott Labs., No. 3:06-cv-1769-M (N.D. Tex. 2016)	
United States ex rel. Chase v. Lifepath Hospice, Inc., et al., 2016 WL 5239863 (M.D. Fla. Sept. 22, 2016)	
United States ex rel. Clausen v. Laboratory Corp. of America, Inc., 290 F.3d 1301 (11th Cir. 2002)	
United States ex rel. Creighton v. Beauty Basics Inc., 2016 WL 3519365 (N.D. Ala. June 28, 2016)	

United	States ex rel. Customs Fraud Investigations, LLC. v. Victaulic Co., 839 F.3d 242 (3d Cir. 2016)	.11
United	States ex rel. D'Agostino v. ev3, Inc., F.3d, 2016 WL 7422943 (1st Cir. 2016)	.5
United	States ex rel. Doe v. Health First, Inc., 2016 U.S. Dist. LEXIS 95987 (M.D. Fla. July 22, 2016)	.4
United	States ex rel. Donegan v. Anesthesia Associates of Kansas City, PC, 833 F.3d 874 (8th Cir. 2016)	.12
United	States ex rel. Driscoll v. Spencer 2016 WL 4191896 (9th Cir. Aug. 9, 2016)	3, 7
United	States ex rel. Eberhard v. Physicians Choice Lab., 642 F. App'x 547 (6th Cir. 2016)	.6
United	States ex rel. Escobar v. Universal Health Services Inc., 136 S. Ct. 1989, U.S (2016)	3,∠
United	States ex rel. Escobar v. Universal Health Servs., Inc., 842 F.3d 103 (1st Cir. 2016)	
United	States ex rel. Gadbois v. PharMerica Corp., 809 F.3d 1 (1st Cir. 2015)	.10
United	States ex rel. Hamrick v. GlaxoSmithKline LLC, 814 F.3d 10 (1st Cir. 2016)	
United	States ex rel. Handal v. Ctr. Emp't Training, 2016 U.S. Dist. LEXIS 105158 (E.D. Cal. Aug. 8, 2016)	.4
United	States ex rel. Hastings v. Wells Fargo Bank, NA, Inc., 656 F. App'x 328 (9th Cir. 2016)	
United	States ex rel. Johnson v. Kaner Medical Group, 641 F. App's 391 (5th Cir. Mar. 7, 2016)	
United	States ex rel. Johnson v. Planned Parenthood, 570 F. App'x 386 (5th Cir. June 4, 2014)	
United	States ex rel. Kelly v. Novartis, 827 F.3d 5 (1st Cir. 2016)	
United	States ex rel. King v. Solvay, 2015 WL 4256402 (S.D. Tex. July 14, 2015)	
United	States ex rel. Ladas v. Exelis, Inc., 824 F.3d 16 (2d Cir. 2016)	
United	States ex rel. Mateski v. Raytheon Co. 816 F.3d 565 (9th Cir. 2016)	8
United	States ex rel. May v. Purdue Pharma, L.P. 811 F.3d 636 (4th Cir. 2016)	8
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