Hogan Lovells

False Claims Act:
2018 and the road ahead

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Executive summary

We are pleased to bring you the latest edition of the Hogan Lovells False Claims Act (FCA) publication. Rather than prepare a catalogue of cases, we have focused on bringing you an analysis of current trends in FCA enforcement. We hope that this approach will prove useful as we discuss how the most important cases and issues will shape FCA enforcement in the years to come.

Two trends stand out from a review of the year's FCA enforcement. First, *qui tam* relators continue to drive the enforcement agenda, filing cases at a strong and steady pace, and pushing the boundaries of FCA litigation into new areas. Second, the courts continue to express skepticism about some of the more ambitious theories of FCA liability. They have in many cases applied the Supreme Court's statement of the elements required to find implied false certification liability to limit the reach of the Act. Indeed, this year's cases demonstrate that the Supreme Court's opinion in *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016) continues to serve as an obstacle to FCA suits in which the relator lacks allegations or evidence sufficient to meet rigorous scienter and materiality requirements laid out by the Court.

The Department of Justice (DOJ) recovered $2.8 billion through settlements and judgments in civil cases involving fraud and false claims against the government during fiscal year 2018, which ended September 30, 2018. This figure is the lowest since fiscal year 2009 and is down from $3.5 billion in 2017 and $4.9 billion in 2016. It is perilous to read too much into annual variations in total recoveries, given that one or two big cases can often explain large changes from year to year, and DOJ often cannot control with precision when a settlement will get done. But we would note that recoveries from the health care industry climbed slightly from last year and comprised more than three fourths of total recoveries in 2018. Recoveries in non-health care industry sectors therefore accounted for the drop in 2018. Consistent with patterns over the past two decades, the vast majority of cases that resulted in recoveries in 2018 were originally filed by *qui tam* relators.

Top 10 FCA settlements in FY 2018 (in US dollars)

Hospital system*	Pressuring physicians to increase emergency department inpatient admissions, falsely inflating emergency department charges, and paying kickbacks to physicians for referral	$260,000,000
Pharmaceutical manufacturer	Kickbacks to Medicare patients through a purportedly independent charitable foundation that covered patients' co-pays	$210,000,000
Accounting firm	Negligent auditing enabled mortgage company to continue originating mortgage loans insured by the Federal Housing Administration	$149,500,000
Medical testing laboratory executives	Jury verdict for paying remuneration to physicians in exchange for patient referrals	$114,148,662
Hospital system	Offering financial incentives (including below market office space and staff) to physicians in return for patient referral	$84,500,000
Hospice services provider	Submitting claims for hospice services provided to patients who were not terminally ill and paying related incentives to employees	$75,000,000
Fiber manufacturer	Selling defective fiber used in bulletproof vests the U.S. purchased for federal, state, local, and tribal law enforcement	$66,000,000
Hospital system and executive officer	Upcoding and admitting patients who required only outpatient care	$65,000,000
Specialized pharmacy	Billing for prescription medications that were never shipped, shipped but returned, or shipped without documentation of proof of delivery; paying inducements to beneficiaries by accepting manufacturer copayment discount cards in lieu of collecting copayments and writing off beneficiary debts	$63,700,000
Diagnostic testing device manufacturer	Knowingly selling materially unreliable point-of-care diagnostic testing devices to hospitals	$33,200,000

Figures include judgment and settlement amounts to be contributed by related individuals
* DOJ press release indicates total payment will be more than cited figure and settlement documents reference unspecified interest

In other developments, DOJ has, in a series of internal guidance documents, expressed concern about unchecked enforcement of the FCA by *qui tam* relators. DOJ has always exhibited some displeasure about relators forging ahead with *qui tam* suits and creating adverse law, but now that concern has concrete expression and direction. DOJ Trial Attorneys and Assistant U.S. Attorneys have been instructed to consider dismissal of declined *qui tam* suits, and not to use noncompliance with agency guidance documents as a basis of proving violations of applicable law in FCA litigation.

The tension between the aggressive theories of liability being advanced by relators, and the efforts by the courts – and to some extent the DOJ – to cabin FCA liability to more traditional theories, is perhaps inevitable. In any event, the push-and-pull of these sometimes opposing forces produced a number of noteworthy cases and decisions this year.

We begin our review of significant FCA trends with a discussion of continued developments in the post-*Escobar* jurisprudence in the lower courts. The Ninth Circuit has recently joined other Circuits in holding that FCA liability premised upon implied false certification attaches only where both elements of the test set forth in *Escobar* are satisfied: the defendant must have made "specific representations" about the goods or services provided; and the defendant's failure to disclose "noncompliance with material statutory, regulatory or contractual requirements" must have rendered those specific representations false or misleading. Other Circuits have adhered to a broader statement of implied certification liability, but we explain why the emerging majority position that a "specific representation" is required is consistent with the scope and purposes of the FCA. We also summarize the growing body of cases that have applied the demanding *Escobar* materiality requirement to dismiss FCA claims, including a bold decision that overturned a $350 million jury verdict based upon the court's conclusion that the government continued to make payments even though it knew of the alleged violations of the Act.

The *Escobar* decision suggested that continued government payment of claims in the face of knowledge of actual noncompliance would undermine the required finding of a "material" false claim. We note the courts have readily applied that standard to test materiality at both the pleading and proof stages of FCA litigation. In addition, the decision – as predicted by numerous commentators when it was announced – has provided fodder for targeted discovery requests by defendants seeking evidence of the government's knowledge of allegedly fraudulent billing practices. We survey cases in which the courts are sorting out how much discovery defendants are entitled to in defending against FCA claims.

Next, we turn to three recent policy pronouncements by DOJ: the November 16, 2017 memorandum issued by Attorney General Jeff

Sessions directing that DOJ components "may not issue guidance documents that purport to create rights or obligations binding on persons or entities outside the Executive Branch . . . ;" the January 25, 2018 memorandum published by then-Associate Attorney General Rachel Brand ordering DOJ attorneys not to use their enforcement authority effectively to convert agency guidance documents into binding rules in an effort to prove a violation of the FCA; and the January 10, 2018 memorandum from Michael Granston, Director of the Fraud Section in the Commercial Litigation Branch of the Department of Justice, which provides guidance to DOJ attorneys about when to consider seeking dismissal of relators' *qui tam* complaints after the government has declined to intervene. We believe, taken together, these guidance documents reflect the Department is receptive to concerns that unbridled enforcement of the FCA may lead to unfair results, or risk the dilution of case precedent foundational to the government's success in the mainstream of FCA litigation. Although there is not a wealth of information available to assess the real impact of the government's internal documents, there are certainly hints these Memoranda are having an effect on DOJ FCA enforcement policy.

We also examine the opinion in *Digital Realty Trust, Inc. v. Somers*, 138 S. Ct. 767 (2018), in which a unanimous Supreme Court concluded the Dodd-Frank anti-retaliation provision protects only individuals who provide information relating to a violation of the securities laws to the Securities and Exchange Commission (SEC). Under *Digital Realty*, individuals who make internal reports without disclosure to the SEC, are not protected by Dodd-Frank. The decision could influence interpretation of the anti-retaliation provision in the FCA, which courts have historically interpreted as protecting employees who report fraud or false claims internally.

Finally, we take a deeper dive into three hot FCA litigation topics that each reflect some of the broader tensions at play in more controversial applications of the FCA: cases examining whether physician medical opinions about medical necessity or other clinical judgments can be "false" for purposes of criminal fraud and civil FCA purposes; cases involving application of the FCA to customs law violations and evasion of antidumping and countervailing duties notwithstanding the existence of a parallel customs laws under which duties and penalties can be recovered; and FCA issues related to allegations that certain health information technology or electronic health record platforms do not meet federal standards, or that vendors of such programs have paid illegal remuneration to health care providers to employ their technology.

Looking ahead, we survey some of the areas where FCA litigation in 2019 is likely to produce equally interesting and thought-provoking developments. We hope that you find this publication a useful resource.

The continued power of *Escobar*

For two and a half years now, courts have been applying the guidance issued by the U.S. Supreme Court in *Universal Health Services, Inc. v. United States ex rel. Escobar* (*Escobar*).[1] That decision validated an implied false certification liability theory under the False Claims Act (FCA) in some circumstances, but left two key issues open to interpretation. First, the Court declined to explain whether the two-part test laid out by the justices for implied certification liability is mandatory. Second, although the Court underscored the FCA's materiality requirement and noted that it was "demanding," it did not articulate a clear materiality standard. While there is not yet universal agreement on these issues, there is growing support on both fronts for applying the teachings of *Escobar* in ways that significantly cabin FCA liability.

Requiring specific representations to trigger implied certification FCA liability is consistent with the purposes of the FCA

The *Escobar* Court affirmed that an implied false certification theory of liability under the FCA is a valid theory "at least where" the defendant (i) made specific representations about the goods or services provided and (ii) failed to disclose noncompliance with material statutory, regulatory, or contractual requirements that renders those specific representations misleading or false. The facts in *Escobar* included "specific representations," but, since that decision, courts have split over whether establishing both conditions is necessary for a viable implied false certification claim.

The Ninth Circuit's recent opinion in *United States ex rel. Rose v. Stephens Institute*[2] solidifies the emerging view that both prerequisites mentioned in *Escobar* are required for a valid implied false certification FCA claim. In *Stephens Institute*, relators alleged an art school that received Title IV funds failed to disclose it violated various statutory, regulatory, and contractual obligations by linking admissions officers' pay to enrollment goals. The court concluded the government or relator *must* satisfy the two-part test identified in *Escobar* for implied false certification liability to attach. It did so reluctantly, however, after concluding it was bound by two other Ninth Circuit post-*Escobar* decisions that treated *Escobar's* two conditions as mandatory.[3] The *Stephens Institute* court held that a plaintiff "*must* satisfy *Escobar's* two conditions to prove falsity, unless and until a Ninth Circuit court, en banc, interprets *Escobar* differently."[4]

Thus, the Ninth Circuit joined the First[5] and Seventh[6] Circuits in holding that FCA liability for implied false certification attached only where *Escobar's* two-part test is satisfied. By contrast, the Fourth Circuit held in *United States ex rel. Badr v. Triple Canopy, Inc.* that a "misleading half-truth" consistent with that in *Escobar* could alone establish implied false certification liability even in the absence of a clear, specific representation.[7] Two D.C. District Court cases similarly held that "the D.C. Circuit's broader statement of the implied certification theory remains good law after *Escobar*,"[8] but no other court of appeals has joined the Fourth Circuit.

The emerging majority understanding that a "specific representation" is required to establish falsity for an implied certification claim is consistent with the scope and purposes of the FCA. In *Escobar*, the Supreme Court emphasized that the FCA is not "a vehicle for punishing garden-variety breaches of contract or regulatory violations."[9] Requiring that any alleged falsity be rooted in affirmative misrepresentations by a defendant helps ensure the FCA is not misused to enforce "garden-variety" regulatory or contractual violations, but is instead reserved to combat the submission of fraudulent claims. Indeed, the *Escobar* Court pointed to the FCA's stringent materiality and scienter requirements as a means of addressing concerns about fair notice and open-ended liability. Limiting implied false certification liability to cases involving specific representations further helps to ensure this theory of liability does not impermissibly expand the scope of the FCA.

1. 136 S.Ct. 1989 (2016).
2. 901 F.3d 1124 (9th Cir. 2018).
3. Id. at 1130 (citing *United States ex rel. Kelly v. Serco, Inc.*, 846 F.3d 325, 332 (9th Cir. 2017) and *United States ex rel. Campie v. Gilead Sciences, Inc.*, 862 F.3d 890, 901 (9th Cir. 2010)).
4. Id. at 1130 (emphasis added).
5. *United States ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29, 37 (1st Cir. 2017) (highlighting the importance of the existence of specific representations as a basis for potential FCA liability in an implied false certification context without explicitly holding the *Escobar* two-part test is mandatory).
6. *United States v. Sanford-Brown, Ltd.*, 840 F.3d 445, 447 (7th Cir. 2016).

Growing body of law indicates materiality requirement has teeth

The *Escobar* Court emphasized that for an alleged falsity to form the basis for an FCA claim it must be "material" to the government's decision to pay that claim. The Court further noted this is a "demanding" standard, but did not announce a clear rule or standard for determining materiality. As a result, the materiality requirement has been hotly litigated for the past two and a half years. Although the Court did not announce a clear rule, it did provide a number of illustrative examples of what should and should not be deemed material. It noted, for instance, "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*."[10]

Many lower courts have relied on this example from *Escobar* to conclude that evidence of continued payment by the government when agency officials are aware of the alleged falsity indicates that falsity is immaterial. For example, in *United States ex rel. Ruckh v. Salus Rehabilitation LLC*,[11] a district court overturned a $350 million jury verdict after concluding the evidence at trial indicated the government continued to make payments to a nursing home operator, despite long being aware of alleged record-keeping violations and some "upcoding" on claims for reimbursement. Other courts have made similar findings throughout 2018.[12] Even where there is no evidence the government continued to pay with knowledge of the alleged falsity, courts frequently find that a relator has not adequately alleged or proven the government would *not have paid* if it had known about the falsity.[13]

These decisions are in tension with the Ninth Circuit's decision in *United States ex rel. Campie v. Gilead Sciences, Inc.*,[14] which involved allegations that a pharmaceutical company made false statements in the course of obtaining FDA approval for several HIV drugs. The court declined to hold, as Gilead urged, that evidence the FDA was aware of

7. 857 F.3d 174 (4th Cir. 2017).
8. *United States v. DynCorp Int'l LLC*, No. 16-1473, 2017 WL 2222911, at *100 (D.D.C. May 19, 2017); accord *United States ex rel. Landis v. Tailwind Sports Corp.*, No. 10-cv-00976, 2017 WL 573470 (D.D.C. Feb. 13, 2017).
9. *Escobar*, 136 S. Ct. at 2003 (internal citation omitted).
10. Id. (emphasis added).
11. 304 F. Supp. 3d 1258 (M.D. Fla. 2018).
12. See e.g. *United States ex rel. Berg v. Honeywell Int'l, Inc.*, No. 17-35083, 2018 WL 3237518 (9th Cir. July 3, 2018); *United States ex rel. Mei Ling v. City of Los Angeles*, No. CV 11-974 PSG (JCX), 2018 WL 3814498 (C.D. Cal. July 25, 2018); *United States ex rel. Cressman v. Solid Waste Servs., Inc.*, No. CV 13-5693, 2018 WL 1693349 (E.D. Pa. Apr. 6, 2018).

the alleged regulatory violations for years and did nothing to retract its approval or halt distribution of the drugs combined with continued government reimbursement for the drugs precluded a finding that the alleged false statements were material. The court noted "there are many reasons the FDA may choose not to withdraw a drug approval," and held that relators had adequately alleged materiality.[15]

Gilead subsequently petitioned for Supreme Court review, and in April 2018, the Court asked the U.S. Solicitor General to weigh in on whether the Court should review the *Gilead* decision. The Solicitor General responded by urging the court to deny the petition. In doing so, the government argued that the Ninth Circuit's decision did not create a circuit split because appellate courts are in agreement that evidence of continued government payment after the government learns of a misrepresentation can be very strong evidence the alleged misrepresentations are not material. The Solicitor General argued that the Ninth Circuit's conclusion that, under the circumstances of the *Gilead* case, continued government payment did not *by itself* require dismissal is not at odds with the rulings from other circuit courts of appeal.[16] The Solicitor General said DOJ would seek to terminate the case on remand. The Supreme Court subsequently denied Gilead's petition, leaving the Ninth Circuit ruling intact.

It is possible Congress will take action to address the relevance of continued government payment on materiality. Senator Chuck Grassley (R-Iowa), a longtime advocate for an expansive FCA, has voiced his opinion that evidence the government continued to make payments despite some level of knowledge of falsity should not be viewed as proof of immateriality.[17]

Although Senator Grassley and some courts[18] have expressed concern that the FCA's materiality standard should not create too high of a bar for relators, the Supreme Court offered strong guidance in *Escobar* that FCA materiality and scienter requirements are meant to provide a check on expansive theories of FCA liability promoted by heavily incentivized relators. In addition, the *Salus* court expressed a separate, and perhaps equally important, policy concern that if the punitive judgments available under the FCA are imposed in the absence of strong evidence of materiality,

13. See e.g. *United States v. Catholic Health Initiatives*, 312 F. Supp. 3d 584, 605 (S.D. Tex. 2018); *United States ex rel. Mei Ling v. City of Los Angeles, No*. CV 11-974 PSG (JCX), 2018 WL 3814498, at *16-*18 (C.D. Cal. July 25, 2018). See also *United States ex rel. Coffman v. City of Leavenworth, Kansas*, 303 F. Supp. 3d 1101, 1120 (D. Kan. 2018) (granting summary judgment to defendant because relator failed to show alleged implied false certification with environmental laws in bills for sewage service was material because there was no evidence the agencies would have refused to pay their sewer bills had they been aware of the environmental violations).
14. 862 F.3d 890 (9th Cir. 2017).
15. Id. at 906-07.
16. The Solicitor General went on to advise the Court that if the case is remanded, DOJ will move to dismiss under 31 U.S.C. 3730(c)(2)(A) due in part to concerns that litigating the materiality issue would lead to burdensome discovery from

businesses may be deterred from providing much-needed services to the government. That court asserted the massive judgment awarded by the jury was "sufficient in proportion and irrationality to deter any prudent business from providing services and products to a government armed with the untethered and hair-trigger artillery of a False Claims Act invoked by a heavily invested relator."[19]

Looking ahead

The *Escobar* decision is another in a line of cases that reject the use of the FCA as an "all-purpose antifraud statue" or a mechanism to punish garden-variety breaches of contract or regulatory violations. We expect courts to continue to apply the teachings of *Escobar* in ways that narrow the circumstances which give rise to FCA liability.

The government's position articulated in its *Gilead* amicus brief is likely to lead to increased discovery relating to the extent and timing of government knowledge and to government payment practices. The government has made its position clear: continued government payment made with knowledge of alleged falsities or misrepresentations *can be* very strong evidence that the alleged misrepresentations are not material *but will not necessarily* render such falsities and misrepresentations immaterial in every case. The Solicitor General's additional decision to move to dismiss the *Gilead* case to avoid extensive discovery from a government agency implicitly recognizes such discovery is relevant to the question of materiality. We therefore expect FCA litigation to include increased requests for discovery from government agencies in the future.

The U.S. Supreme Court denied the *Gilead* petition for certiorari, but could provide additional guidance about the FCA materiality standard in a subsequent case, however, it is equally possible that the Court will allow the questions surrounding materiality to continue to percolate in the district and appellate courts. In fact, an appeal of *Salus* is pending before the Eleventh Circuit Court of Appeals and that decision could shape the appellate court landscape.

Finally, we expect the teachings of *Escobar* will increasingly apply beyond the FCA context and shape criminal prosecutions in the coming year. The *Escobar* court noted the FCA employs a definition of "materiality" mirrored in a number of federal criminal statutes and is tied to a common law understanding of the term. The lower courts have not yet broadly applied the teachings of *Escobar* to criminal cases. However, we expect prosecutors, criminal defense attorneys, and courts will increasingly begin to examine the real-world impact of criminal defendants' alleged frauds on the government (or other alleged victims) when deciding whether a misrepresentation or omission is material.

the FDA aimed at determining what the government knew and when, "which would distract from the agency's public-health responsibilities." Brief for the United States as Amicus Curiae, *Gilead Sciences, Inc. v. United States ex rel. Campie*, No. 17-936 (U.S. Nov. 30, 2018) at 23. This is an example of the government's increased use of its authority to dismiss FCA actions pursued by relators, which we discuss in the following Brand and Granston memos section.

17. Senator Chuck Grassley, Chairman, Senate Judiciary Committee, Prepared Senate Floor Statement about Interpreting the False Claims Act (February 13, 2018), available at https://www.grassley.senate.gov/news/news-releases/interpreting-false-claims-act (noting that "[t]here could be many important reasons to pay a claim that have nothing to do with whether the fraud is material.")
18. See e.g. *United States v. Brookdale Senior Living Communities, Inc.*, 892 F.3d 822, 834 (6th Cir. 2018) (pet. for cert. pending).
19. *Salus Rehab.* 304 F. Supp. 3d at 1265.

One year in: The Brand and Granston Memos

The past year has been an unusual one in FCA enforcement, if for no reason other than DOJ issuing a flurry of policy pronouncements (through a mix of internal memoranda, Justice Manual updates, official statements during speeches, and CLEs) that could have significant impacts on how the Act is enforced. Below we discuss how two of the most important DOJ policy updates are impacting DOJ FCA enforcement.

On January 10, 2018, Michael Granston, the Director of DOJ's Civil Division Civil Fraud Section, issued a memorandum providing guidance on when to consider dismissals of relators' complaints under section 3730(c)(2)(A) of the FCA (Granston Memo).[1] The memo was widely viewed as signaling that DOJ would be more proactive in seeking to dismiss nonmeritorious *qui tam* actions.

On January 25, 2018, Rachel Brand, then-Associate Attorney General, issued a public memorandum limiting the use of executive branch agency guidance documents in litigation and investigations (Brand Memo).[2] The Brand Memo extended the principles laid out in a November 2017 memorandum from then-Attorney General Jeff Sessions (Sessions Memo), which was designed to limit the number, scope, and authority of DOJ's own guidance documents. The Brand Memo applied those limitations to the use of other, non-DOJ executive branch agency guidance documents in government investigations and litigation.

These memos represented a shift in fraud enforcement policy at DOJ. Questions remained, however, about how they would be implemented.

Tone from the top

Deputy Associate Attorney General Stephen Cox, speaking at the February 28, 2018 Federal Bar Association *Qui Tam* Conference, described the desired effect of these DOJ policy changes as an effort to "avoid any attempts to push the envelope by seeking to regulate through our enforcement efforts."[3] Cox explained that monitoring meritless cases "is not a good use of department resources," litigating them is not a good use of judicial resources, and forcing defendants to defend against them is "not in the interests of justice," with bad cases also potentially leading to bad law. And sometimes, Cox explained, the government simply believes it has suffered no harm even from what is technically a false claim.

The Brand memo unpacked

The Brand Memo dictates that the "Department may not use its enforcement authority to effectively convert agency guidance documents into binding rules"[4] and that DOJ "litigators may not use noncompliance with [agency] guidance documents as a basis for proving violations of applicable law" in FCA and other affirmative civil enforcement cases".[5] This is because a party's failure "to comply with agency guidance expanding upon statutory or regulatory requirements does not mean that the party violated those underlying legal requirements; agency guidance documents cannot create any additional legal obligations."[6]

However, the Brand Memo change that, to the extent agency guidance documents simply explain or paraphrase legal mandates found in existing

1. Memorandum from Michael D. Granston, Dir., Com. Lit., Fraud Section, U.S. Dep't of Justice, To Att'ys in the Com. Lit., Fraud Section and U.S. Att'ys, Handling False Claims Act Cases, Factors for Evaluating Dismissal Pursuant to 31 U.S.C. 3730(c)(2)(A) (Jan 10, 2018), available at https://assets.documentcloud.org/documents/4358602/Memo-for-Evaluating-Dismissal-Pursuant-to-31-U-S.pdf
2. Memorandum from Rachael Brand, Associate Att'y Gen., To Heads of Civ. Lit. Components and U.S. Att'ys, Handling False Claims Act Cases, Limiting Use of Agency Guidance Documents in Affirmative Civil Enforcement Cases (Jan 10, 2018), available at https://www.justice.gov/file/1028756/download.
3. Stephen Cox, Assoc. Att'y Gen., Dep't of Justice, Remarks at the Fed. Bar Ass'n Quit Tam Conf. (Feb. 28, 2018) available at https://www.justice.gov/opa/speech/deputy-associate-attorney-general-stephen-cox-delivers-remarks-federal-bar-association.
4. Brand *supra* n. 2 at 1.
5. Id.
6. Id. at 2.


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statutes or regulations, DOJ may continue to "use evidence that a party read such a guidance document to help prove that the party had the requisite knowledge of the mandate." Thus, even after the Brand Memo, DOJ may point to agency guidance as evidence that the subject of an FCA investigation *knowingly* presented a false or fraudulent claim, or *knowingly* caused a false or fraudulent claim to be presented.

The Brand Memo's impact, thus far, is unclear, mainly because the government can still use such guidance documents to prove knowledge under the FCA. Yet, the government has also previously relied on guidance documents to establish falsity; these are the cases that could be influenced by the Brand Memo.

For example, the government and relators have used Local Coverage Determinations (LCDs), prepared by Medicare Administrative Contractors (MACs), in cases alleging a lack of medical necessity for services billed to Medicare. LCDs have been used both (i) to create a standard for demonstrating claims were not medically necessary and, (ii) as a means for arguing the documentation supporting the disputed claims was insufficient. The Brand Memo could put in jeopardy cases where the FCA liability is based on a "binding" LCD.[7]

DOJ also could face difficulties when trying to rely on Medicare provider billing and reimbursement manuals as a basis for establishing noncompliance in FCA cases. For example, *In re: Cardiac Device Qui Tam Litigation* was completely based on coverage rules for services related to certain cardiac devices as set forth in the CMS Provider Manual.[8]

The Granston memo unpacked

The Granston Memo advised that DOJ attorneys should be "judicious in utilizing Section 3730(c)(2)(A)," while acknowledging that "[h]istorically" DOJ has been "sparing" and "circumspect" in using its power to dismiss *qui tam* cases.[9] A study based on

statistical sampling conducted in 2013 concluded that DOJ invoked §3730(c)(2)(A) in less than 4 percent of *qui tam* cases.[10] Nearly all of these dismissals were based on DOJ's determination that a relator's claim was jurisdictionally barred, typically on "public disclosure," "original source," or "first-to-file" grounds, or because of national security concerns relating to disclosure of classified information.[11] And some cases involved government-employee relators – a particular annoyance to DOJ. But most DOJ dismissals were unrelated to case merits.

DOJ's increased interest in flexing its dismissal authority may be linked to the fact that in recent years, fueled in part by litigation financing firms and significant relator recoveries in declined cases, relators are less likely to voluntarily dismiss *qui tam* complaints after the government declines to intervene. The Granston Memo revisits the idea of dismissals of declined FCA cases before defendants are subjected to extensive litigation and identified the following list of "non-exhaustive" and "not mutually exclusive" factors that have, in the past, supported DOJ's dismissal of such cases:

1. Curbing meritless claims
2. Preventing parasitic or opportunistic *qui tam* actions
3. Preventing interference with agency policies and programs
4. Controlling litigation brought on behalf of the United States
5. Safeguarding classified information and national security interests
6. Preserving government resources
7. Addressing egregious procedural errors

Civil Division leaders appear focused on implementing the Granston Memo. On June 14, 2018, Acting Associate Attorney General Jesse Panuccio gave remarks highlighting recent enforcement activity and policy initiatives by DOJ.

7. See e.g., *United States ex rel. Youn v. Sklar*, 273 F. Supp. 3d 889 (N.D. Ill. 2017) (holding that the LCDs that governed four different types of treatment were binding and could provide a basis for relator's claim that the podiatrist violated the FCA).
8. 221 F.R.D. 318 (D. Conn. 2004).
9. Granston, *supra* n.1.
10. David Freeman Engstrom, *Public Regulation of Private Enforcement: Empirical Analysis of DOJ Oversight of Qui Tam Litigation Under the False Claims Act*, 107 Nw. U. L. Rev. 1689, 1755 (2013).
11. Id.

With regard to *qui tam* dismissal criteria, Mr. Panuccio noted that DOJ attorneys have been instructed to consider whether moving to dismiss the action would be an appropriate use of prosecutorial discretion under the FCA. He suggested DOJ may use that authority more frequently going forward in order to free up resources for matters in the public interest.

In 2018, DOJ filed 16 motions to dismiss based on § 3730(c)(2)(A). Of those, 10 are connected to relators backed by the National Healthcare Analysis Group – all against drug companies (NHCA Cases).[12] Moreover, DOJ asserted the same justifications for dismissal: protecting government resources and preserving the "important policy prerogatives of the federal government's healthcare programs." The government resource at issue in the NHCA Cases is the expenditure of time monitoring and litigating massive discovery requests for the hundreds of thousands of prescriptions at issue with regard to each defendant drug company.[13] As for the policies, the government recognized the value and importance of the nurse education and patient assistance programs that were the subject matters of the FCA suits.[14]

The remaining six motions were filed for their own case-specific reasons.[15] Three of these motions were granted by the courts and three still are pending (and all of the NHCA Cases motions are pending). Interestingly, in *United States ex rel. Sibley v. Delta Regional Medical Center*, the court even weighed in on the dismissal. There, the government filed a motion to dismiss based on § 3730(c)(2)(A) after being invited by the *court* to do so.[16]

To provide some context, in both 2016[17] and 2017,[18] we were able to find three motions to dismiss filed by DOJ based on § 3730(c)(2)(A). Therefore, even counting the NHCA Cases as one motion, the increase since the release of the Granston Memo, while slight in number, was greather than a 100% increase over dismissals in 2017. And four of these motions were filed after the September 2018 revision to the Justice Manual that incorporated the key portions of the Granston Memo.[19]

12. See *United States ex rel. Health Choice Group, LLC v. Bayer Corp.*, 5:17-CV-126-RWS-CMC, Doc. 116, at *14 (E.D. Tex. Dec. 17, 2018); *United States ex rel. Health Choice Alliance, LLC v. Eli Lilly & Co.*, 5:17-CV-123-RWS-CMC, Doc. 192 (E.D. Tex. Dec. 17, 2018); *United States ex rel. Health Choice Advocates LLC v. Gilead Sciences, Inc.*, 5:17-CV-121-RWS-CMC, Doc. 70 (E.D. Tex. Dec. 17, 2018); *United States ex rel. Miller v. AbbVie, Inc.*, 3:16-CV-2111-N, Doc. 52 (N.D. Tex. Dec. 17, 2018); *United States ex rel. CIMZNHCA, LLC v. UCB, Inc.*, 3:17-CV-00765-SMY-DGW, Doc. 63 (S.D. Ill. Dec 17, 2018); *United States ex rel. Clare v. Otsuka Holdings Co.*, 17-CV-00966, Doc. 30 (N.D. Ill. Dec. 17, 2018); *United States ex rel. SCEF, LLC v. AstraZeneca PLC*, 2:17-CV-01328-RSL, Doc. 15 (W.D. Wash. Dec. 17, 2018); *United States ex rel. SMSF LLC v. Biogen Inc.*, 1:16-cv-11379-IT, Doc. 52 (D. Mass. Dec. 17, 2018); *United States ex rel. SAPF LLC, v. Amgen Inc.*, 2:16-CV-05203-GJP, Doc. 18 (E.D. Pa. Dec. 17, 2018); *United States ex rel. SMSPF LLC v. EMD Serono Inc.*, 2:16-cv-05594-TJS, Doc. 23 (E.D. Pa. Dec. 17, 2018); *United States ex rel. NHCA-TEV LLC v. Teva Pharmaceutical Products Ltd.*, 2:17-cv-02040-JD, Doc. 30 (E.D. Pa. Dec. 17, 2018)
13. See e.g., *United States ex rel. Health Choice Group, LLC v. Bayer Corp.*, 5:17-CV-126-RWS-CMC, Doc. 116, at *15.
14. Id. at *16.
15. *United States ex rel. Borzilleri v. Abbvie, Inc.*, No. 1:15-CV-07881-JMF, Doc. 275 (S.D.N.Y. Dec. 21, 2018); *United States ex rel. Vanderlan v. Jackson HMA, LLC*, No. 3:15-CV-767-DPJ-FKB, Doc. 81 (S.D. Miss. Nov. 5, 2018); *United States ex rel. Sibley v. Delta Regional Medical Center*, 4:17-cv-00053-GHD-RP, Doc. 61 (N.D. Miss. Nov. 5, 2018); *United States ex rel. Stovall v. Webster Univ.*, No. 3:15-CV-03530-DCC, 2018 WL 3756888, at *1 (D.S.C. Aug. 8, 2018); *United States ex rel. Maldonado v. Ball Homes, LLC*, No. CV 5:17-379-DCR, 2018 WL 3213614, at *1 (E.D. Ky. June 29, 2018); *United States ex rel. Chang v. Children's Advocacy Ctr. of Delaware*, No. CV 15-442-GMS at *4 (Doc. No. 56) (D. Del. May 14, 2018).
16. *United States ex rel. Sibley v. Delta Regional Medical Center*, 4:17-cv-00053-GHD-RP at *1–2, Doc. 59, (N.D. Miss. Sept. 25, 2018) ("[T]he Court finds it prudent to ask the position of the United States in this matter . . . . the United States shall inform the Court whether it intends to seek dismissal under 31 U.S.C. § 3730(c)(2)(A).").
17. *United States ex rel. Mesi v. Nat'l Default Servicing Corp.*, No. 315CV00508RCJVPC, 2017 WL 3749677, at *3 (D. Nev. Aug. 30, 2017); *United States ex rel. Johnson v. Ferguson*, No. 3:16-CV-08838, 2017 WL 1196466, at *1 (S.D.W. Va. Mar. 7, 2017), *report and recommendation adopted*, No. CV 3:16-8838, 2017 WL 1196448 (S.D.W. Va. Mar. 29, 2017); *United States ex rel. Dreyfuse v. Farrell*, No. 3:16-CV-05273, 2017 WL 1173976, at *1 (S.D.W. Va. Mar. 7, 2017), *report and recommendation adopted*, No. CV 3:16-5273, 2017 WL 1170867 (S.D.W. Va. Mar. 28, 2017).
18. *See United States ex rel. Toomer v. TerraPower, LLC*, No. 4:16-CV-00226-DCN, 2018 WL 4934070, at *8 (D. Idaho Oct. 10, 2018); *United States v. Acad. Mortg. Corporation*, No. 16-CV-02120-EMC, 2018 WL 1947760, at *4 (N.D. Cal. Apr. 25, 2018) *appeal filed* No. 18-16408 (9th Cir. filed July 27, 2018); *United States ex rel. Eanes v. O'Hanlan*, No. 3:16-CV-10563, 2017 WL 1196468, at *1 (S.D.W. Va. Mar. 7, 2017), *report and recommendation adopted*, No. CV 3:16-10563, 2017 WL 1193732 (S.D.W. Va. Mar. 29, 2017).
19. Justice Manual, 4-4.111 - DOJ Dismissal of a Civil Qui Tam Action, https://www.justice.gov/jm/jm-4-4000-commercial-litigation#4-4.111.

Looking forward

It will be very difficult to measure the impact of the Brand Memo going forward given agency guidance is still in play with regard to knowledge in FCA cases. Government attorneys have told us the Brand Memo really does not change much, that actions they pursue are always based on a statutory or regulatory violation. That said, policy guidance and manuals have played an important role in past FCA cases, particularly in the health care arena. In such cases, several avenues to claim FCA liability have been shut off. To the extent relators proceed on guidance-based FCA theories, defense counsel may be able to point to the policies set forth in the Granston Memo to seek government dismissal of cases that run afoul of the Brand Memo.

It is early, but government-initiated dismissals are increasing at a gradual pace, with a noticeable uptick in the last half of 2018. The multiple motions to dismiss in the NHCA Cases may somewhat skew the government dismissal figures. DOJ did go out of its way in those motions to dismiss to make a policy/merit point about the value of nursing and patient support programs, perhaps signaling a growing emphasis on merit in making dismissal decisions, which would be a refreshing and welcome development.

We expect the policies articulated in the Brand and Granston Memos to increasingly shape FCA litigation as the defense bar continues to advocate for their implementation in specific cases. It may be more cost effective to push arguments rooted in these policies early with government lawyers before embarking on Rule 12 motions. Mapping out potential government arguments for dismissal that anticipate government interest and resources arguments may prove fruitful now that the government is increasingly willing to exercise its dismissal authority.

The effects of *Digital Realty Trust v. Somers*

On February 21, 2018, the Supreme Court unanimously resolved a split between the Second, Ninth, and Fifth Circuits, concluding the anti-retaliation provision of the Dodd-Frank Act protects only those individuals who provide information relating to a violation of the securities laws to the Securities and Exchange Commission (SEC). Individuals who report such violations to their employer or another entity receive no protection under Dodd-Frank unless they *also* report to the SEC.[1] The decision may have implications for interpretation of the analogous provisions in the FCA.

Background

Dodd-Frank enacted a provision, codified at 15 U.S.C. § 78u-6, to encourage whistleblowers to report securities-law violations and protect them against retaliation.[2] Section 78u-6 begins with a definition of a whistleblower: "any individual who provides . . . information relating to a violation of the securities laws to the [SEC]."[3] That definition applies in Section 78u-6.[4] The provision's incentive is a potential reward of between 10 percent and 30 percent of sanctions the SEC collects based on the information provided.[5] Employers may not retaliate against an individual based on three categories of acts: providing information to the SEC "in accordance with this section"; participation in SEC actions related to that information; and "making disclosures that are required or protected" under a broad set of securities laws and regulations.[6] After Dodd-Frank was enacted, the SEC issued an interpretive rule stating that the anti-retaliation protections were not contingent on whether a whistleblower provided information to the SEC; this rule expanded the scope of individuals protected by the anti-retaliation provision beyond those covered by the definition of "whistleblower" in Section 78u-6.

The question in *Digital Realty* was whether Section 78u-6's definition of whistleblower applied to its anti-retaliation protections.[7] This case arose in 2014, when Digital Realty Trust, Inc. - a real estate investment trust - terminated Paul Somers from his position as Vice President. Somers sued under Dodd-Frank's anti-retaliation provision, alleging he was terminated after reporting securities-law violations to senior management. Digital Realty moved to dismiss, arguing Somers was not a whistleblower within the meaning of Section 78u-6, thus unafforded its anti-retaliation protections.[8]

The lower courts sided with Somers, interpreting Section 78u-6's anti-retaliation protections to cover individuals whose actions fall within any one of the provision's three categories of protected acts. The Supreme Court unanimously reversed in an opinion authored by Justice Ginsburg.[9] It held that Section 78u-6 unambiguously "describes who is eligible for protection—namely, a whistleblower who provides pertinent information 'to the Commission.'"[10] The provision, it explained, left "no doubt as to" the reach of the definition of whistleblower, as it "instructs that the 'definition shall apply' '[i]n this section,' that is, throughout §78u–6."[11] The Court was not bothered by the apparent tension that troubled the lower courts. The three categories of protected activities, it explained, simply set out the conduct for which a whistleblower receives protection. Section 78u-6 "protects a whistleblower who reports misconduct both to the SEC and to another entity, but suffers retaliation because of the latter, non-SEC, disclosure."[12] In view of the clear statutory text, the Court did not defer to the SEC's interpretation.[13]

1. The SEC has since made public proposed amendments to their whistle program rules as a result of *Digital Realty*. The proposed rules align with the Court's holding, noting only those who report to the SEC are covered by the anti-retaliation provisions. The comments period closed on September 18, 2018, and no final rule has as of the date of this publication been posted.
2. Pub. L. No. 111-203, § 922, 124 Stat. 1376 (2010) codified at 15 U.S.C. § 78u-6(a).
3. 15 U.S.C. § 78u-6(a)(6).
4. Id. § 78u-6(a).
5. Id. § 78u-6(b)-(c).
6. Id. § 78u-6(h)(1)(A).
7. *Digital Realty Trust, Inc. v. Somers*, ___ U.S. ___ (Feb. 21, 2018), slip op. at 2.
8. Id. at 7-8.
9. 119 F. Supp. 3d 1088, 1092 (ND Cal. 2015).
10. Id. at 10.
11. Id. at 9.
12. Id. at 14.
13. Id. at 18-19.

Takeaways for companies subject to Dodd-Frank's retaliation provision

First, companies currently involved in litigation containing Dodd-Frank's retaliation provision should immediately assess whether the plaintiff satisfies the newly announced limitation on who is entitled to whistleblower protection.

Second, companies should be aware of the increased likelihood that, going forward, an employee who has reported suspected misconduct internally will likely have also reported the same alleged misconduct to the SEC. Because *Digital Realty* requires a whistleblower to report to the SEC to receive the benefits and protections of Dodd Frank's anti-retaliation provision, the decision may lead employees to report to the SEC earlier than they would have otherwise. The decision does not prevent an employee from reporting internally, and the Court noted that according to the Solicitor General, "approximately 80 percent of the whistleblowers who received awards in 2016" reported internally before reporting to the SEC.[14] But it means Dodd Frank's whistleblower protections only "shield[] employees . . . *as soon as they also provide relevant information to the [SEC].*"[15] Given that, an employee who may previously have waited for the internal process to resolve before reporting to the SEC, may now report to the SEC simultaneously or soon after reporting internally. Companies should: consider the implications of such reports for how they conduct internal investigations; take remedial actions in response to employee reports; and consider voluntary disclosures in response to employee reports.

Third, although whistleblowers who report only internally will not be protected under Dodd Frank's anti-retaliation provision, they may be protected under the anti-retaliation provisions of the Sarbanes-Oxley Act (SOX). SOX's anti-retaliation provision covers employees who report to the SEC, to another federal agency, to Congress, or to a supervisor.[16] It thus covers a broader category of whistleblowers than Dodd-Frank, although it offers more limited protections. It requires employees to file a complaint with the Department of Labor within 180 days and exhaust administrative remedies before filing in court, and it limits an employee's monetary recovery to back pay with interest.[17] Dodd-Frank, in contrast, allows an employee to go directly to court within a six-year statute of limitations and authorizes double back pay with interest.[18]

Fourth, the Court's interpretation of Dodd-Frank might mean the provision protects an employee who reports to the SEC from retaliation *unrelated* to that report. Both Digital Realty and the Solicitor General acknowledged that Section 78u–6 does not impose a "temporal or topical connection between the violation reported to the Commission and the internal disclosure for which the employee suffers retaliation."[19] So, an employee who reports to the SEC may be protected under Dodd-Frank for retaliation that occurs years later and is unrelated to that reporting. However, the Court merely noted this hypothetical and went on to state that it "need not dwell on the situation hypothesized."[20] As a result, it left open the possibility that Dodd Frank's anti-retaliation provision could be interpreted to avoid that anomalous result.

14. Id. at 14-15.
15. Id. at 15.
16. 18 U.S.C. § 1514A(a)(1).
17. Id. § 1514A(b)(1)(A), (2)(D), (c)(2)(B).
18. Id. § 78u–6(h)(1)(B)(i), (iii)(I)(aa), (h)(1)(C)(ii).
19. *Digital Realty*, slip op. at 17 (quoting Br. for United States as Amicus Curiae at 25).
20. Id.
21. 31 U.S.C. 3730(h)(1).
22. *Manfield v. Alutiiq Int'l Solutions, Inc.*, 851 F. Supp. 2d 196, 204 (D. Me. 2012) ("Since a plaintiff now engages in protected conduct whenever he engages in an effort to stop an FCA violation, the act of internal reporting itself suffices as both the effort to stop the FCA violation and the notice to the employer that the employee is engaging in protected activity.")

Implications for other statutes with retaliation protections

Various other federal statutes, including the FCA, provide anti-retaliation provisions. Under the FCA, "[a]ny employee, contractor, or agent shall be entitled to all relief necessary to make that employee, contractor, or agent whole, if that employee, contractor, or agent is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of lawful acts done by the employee, contractor, agent or associated others in furtherance of an action under this section or other efforts to stop 1 or more violations of this subchapter."[21] The FCA's language includes "other efforts" to prevent violations of it, and lower courts have historically interpreted this language to protect employees who engage in internal reporting.[22] Whether this interpretation holds following *Digital Realty* remains to be seen, and companies involved in litigation should consider *Digital Realty's* narrow interpretation of when anti-retaliation provisions may apply.

New scrutiny of "false" medical judgments

One area where FCA developments have favored relators and DOJ is whether professional medical judgments can be "false" for purposes of imposing liability under the Act. Whether a professional judgment can provide a basis for FCA liability has long been a subject of dispute. In the high-profile case *Boisjoly v. Morton Thiokol, Inc.*,[1] the court dismissed a *qui tam* relator's FCA claim concerning the Space Shuttle Challenger disaster in part because NASA's decision to launch the Challenger was an "engineering judgment," "not a statement of fact that can be said to be either true or false." Various courts have similarly held or stated that "[e]xpressions of opinion, scientific judgments, or statements as to conclusions about which reasonable minds may differ cannot be false."[2]

However, two appellate decisions in 2018 significantly shifted this landscape by holding that a doctor's professional medical judgment could be "false" in some circumstances.[3] Both opinions echo the view of fraudulent opinions the Supreme Court recognized in *OmniCare, Inc. v. Laborers District Council Construction Industry Pension Fund*: a statement of opinion can be actionably misleading if, in the circumstances, it implies the speaker "knows facts sufficient to justify him on forming the opinion, or that he at least knows of no facts incompatible with the opinion."[4] The recent Sixth and Tenth Circuit opinions held that physicians treating particularly high volumes of patients could be liable if a jury believed they diagnosed patients in bad faith in order to profit financially by, for example, rendering opinions that essentially misrepresent the underlying facts.

Paulus and *Polukoff*

In *Paulus*, interventional cardiologist Dr. Richard Paulus was convicted of criminal health care fraud for intentionally inflating the amount of artery blockage (stenosis) in patient angiograms. If a patient's stenosis reached a certain level, that patient would be eligible for a stenting procedure that Dr. Paulus performed. Although the jury returned a guilty verdict, the District Court acquitted Dr. Paulus on the basis that the government had not proved falsity or fraudulent intent.

The Sixth Circuit reversed, holding that "[t]he degree of stenosis *is* a fact capable of proof or disproof" (emphasis in original). The court concluded the jury could find Dr. Paulus did not honestly believe his own angiogram readings – i.e. he misrepresented the blockage amount so he could bill Medicare for unnecessary stenting procedures. Because the jury believed the testimony of

1. 706 F. Supp. 795 (D. Utah 1988).
2. *United States ex rel. Roby v. Boeing Co.*, 100 F. Supp. 2d 619, 625 (S.D. Ohio 2000), aff'd, 302 F.3d 637 (6th Cir. 2002).
3. See *United States v. Paulus*, 894 F.3d 267 (6th Cir. 2018); and U.S. ex rel. *Polukoff v. St. Mark's Hospital*, 895 F.3d 730 (10th Cir. 2018).
4. 135 S. Ct. 1318, 1330 (2015).

government experts espousing this view, the court reasoned, Dr. Paulus should not have been acquitted.

In *Polukoff*, Dr. Gerald Polukoff brought a *qui tam* action alleging former colleague Dr. Sherman Sorensen performed "thousands" of unnecessary heart surgeries. Unlike *Paulus*, *Polukoff* was decided on a motion to dismiss, limiting the court's review to the allegations in the complaint. The District Court granted dismissal on the basis that "medical judgment[s]… cannot be false for the purposes of an FCA claim." (internal quotation ommited).

The Tenth Circuit reversed, holding that "[i]t is possible for a medical judgment to be 'false or fraudulent.'" The court based its decision on three primary concerns: first, the FCA must be read "broadly" as it "was intended to reach all types of fraud"; second, opinions are not insulated from FCA scrutiny; and third, reimbursement claims for medically unnecessary treatment are actionable under the FCA.

The Tenth Circuit held that the *Polukoff* complaint sufficiently alleged Dr. Sorensen performed "an unusually large number" of heart procedures known as patent foramen ovale (PFO) closures, and submitted false certifications of the procedures' necessity to the government so he would be paid. Dr. Sorensen allegedly knew Medicare and Medicaid would not pay for PFO closures to treat migraines, and therefore certified the procedures were necessary to combat recurrent stroke. The court also found Dr. Sorensen's high profits from the procedures allowed an inference of fraudulent intent.

The court further held the complaint sufficiently alleged FCA claims against the two hospitals where Dr. Sorenson performed the surgeries. The court concluded that because the hospitals had allegedly ignored complaints from staff and other physicians about medically unnecessary procedures, the complaint's allegation the hospitals acted with reckless disregard as to whether those procedures were medically necessary was sufficient.

Courts' application of *Paulus* and *Polukoff*

Lower courts, at least within the Sixth Circuit, have been quick to apply the *Paulus* and *Polukoff* approach to falsity in criminal health care fraud matters. In *United States v. Akande*,[5] the court denied the defendant's motion to dismiss an indictment for health care fraud based on his alleged knowing submission of Medicare and Medicaid claims for medically unnecessary urine screens. In accordance with *Paulus*, the court noted "[t]he jury will determine whether Dr. Akande knew the applicable standards but knowingly and willfully disregarded those standards …. His intent is what matters."

In *United States v. Chalhoub*,[6] the defendant was charged with health care fraud based on 31

5. 2018 WL 3318877 (E.D. Ky. Jul. 3, 2018).
6. 2018 WL 3651584 (E.D. Ky. Aug. 1, 2018).

pacemaker implantations. Witnesses included the defendant's former patients, who testified they felt pressured into agreeing to the procedure, and experts, who disagreed with the amount of artery blockage the defendant recorded. Similar to *Paulus*, the government in *Chalhoub* alleged the defendant knowingly inflated patients' need for pacemakers. However, during the relevant time period, only 2.8% of the defendant's compensation was based on his pacemaker installations – unlike in *Paulus*, where the defendant made an "enormous" salary from his stenting work. Despite this difference, the *Chalhoub* court relied on *Paulus* and denied the defendant's motions for a judgment of acquittal and for a new trial, noting "falsity in the practice of medicine does exist and to hold otherwise would be 'an insult to common sense.'"

Awaiting further appellate rulings

Additional courts of appeals are expected to weigh in soon regarding whether *Polukoff* and *Paulus* will impact FCA claims based on professional judgment in other contexts. The Eleventh Circuit has long been considering *United States v. GGNSC Admin. Servs.* (commonly known as "*AseraCare*"), a closely-watched FCA case involving allegedly false certifications by physicians that hospice patients had a life expectancy of six months or less. The district court overturned the verdict in favor of the government, ruling a medical expert's disagreement with the clinical judgment on a hospice patient's eligibility cannot prove falsity as a matter of law without "additional objective evidence." Following the March 2017 oral argument, the government filed letters citing *Paulus* and *Polukoff* in support of its position that based on patient medical records and expert testimony interpreting those records, a jury could find AseraCare submitted false claims. AseraCare argued in response that life expectancy is inherently subjective, distinguishing it from the facts in *Paulus* and *Polukoff*. The Eleventh Circuit's decision may shed light on whether courts will consider all medical necessity determinations to be alike for purposes of FCA liability.

Meanwhile, the Ninth Circuit is considering the dismissal of a relator's complaint in *Winter ex rel. United States v. Gardens Regional Hospital and Medical Center*. In *Winter*, a nurse alleged FCA violations based on patient admissions to the hospital as inpatients even though admission was not medically necessary. The district court held that, *inter alia*, the claims relied on a difference of opinion, which does not demonstrate falsity, and the determination of whether an admission is medically necessary is inherently subjective and therefore cannot be false.

Looking ahead

These 2018 court decisions suggest dispositive motions in medical judgment cases will now be harder for defendants to win. Claims for a particular treatment will be less likely to escape FCA liability solely because that treatment was based upon a medical judgment, particularly where relators have alleged facts indicating bad faith and/or intent to defraud, and where the judgment at issue can be framed as one of fact rather than subjective opinion. Moreover, courts are more likely to deny summary judgment and allow cases to proceed to a jury if the government can produce expert testimony challenging the defendant's diagnosis or treatment decisions, thereby rendering the relevant medical judgments potentially "false."

Cases involving high-volume, high profit practices may be particularly challenging for defendants. In *Paulus*, the court allowed the jury to infer fraudulent intent based on Dr. Paulus' "astronomical" number of stenting procedures and his "enormous salary." In *Polukoff*, the court inferred intent from the allegation that one of the defendant's employers actively courted his practice, while the defendant also allegedly received preferential treatment because of his "excessively large number of profitable PFO closures." Volume of and profit from medical procedures will be key to the potential for liability based on a medical judgment that those procedures were necessary.

Defending False Claims Act matters in the midst of the trade war

The President has made the imposition of import tariffs a centerpiece of his Administration's trade policy, emphasizing that our trading partners must treat the U.S. fairly, or risk new tariffs on imported products.

The current administration has said it will use all tools available to support this effort, and two Executive Orders punctuate that statement:

> Exec. Order No. 13415 (March 31, 2017) calls for Customs and Border Protection (CBP) to increase its efforts to fight custom law violations, especially those involving evasion of antidumping and countervailing duties; and
>
> Exec. Order No. 13788 (April 18, 2017) exhorts all Executive Branch agencies to "scrupulously monitor, enforce, and comply with Buy American Laws," like the Buy America Act (BAA) and the Trade Agreements Act (TAA).

Companies relying on foreign imports have always been mindful of the enforcement risks of actions brought by CBP or U.S. Immigration and Customs Enforcement (ICE). Similarly, companies with multiple award schedule contracts with the General Services Administration or the Department of Veterans Affairs are aware of the need for compliance with the BAA and the TAA. But, increasingly, violations of these laws have been alleged in seeking treble damages and penalties under the FCA. Many of these suits are instigated by private citizens filing claims under the *qui tam* provisions of the Act. A pair of cases decided in 2018 offer promising routes to defeating these claims.

Application of the FCA to evasion of duties and tariffs

Typically, trade-related FCA suits are brought under the so-called reverse false claims provision and allege that an importer knowingly avoided paying duties by making false statements about tariff classification, valuation, country of origin, eligibility for trade preference program treatment, or the applicability of antidumping or countervailing duties.

As the politically-charged and media-rich trade landscape has heightened FCA risk for companies operating cross-border supply chains, such companies must understand how to defend trade-related FCA suits.

The impact of *Escobar* on materiality in trade-related FCA cases

Not surprisingly, the Supreme Court's decision in *Universal Health Servs., Inc. v. United States ex rel. Escobar*[1] is already focusing the scope of FCA claims in international trade and customs cases.

In July 2018, for example, the Seventh Circuit affirmed the dismissal of a *qui tam* action alleging TAA noncompliance in *United States ex rel. Berkowitz v. Automation Aids, Inc.*[2] In *Berkowitz*, the relator alleged his competitors were selling products to the government that did not comply with the TAA, while impliedly certifying the products were compliant when submitting claims for payment.

The court dismissed the complaint under Rules 12(b)(6) and 9(b), finding the relator failed to allege any specific facts demonstrating what occurred at the individualized transactional level for each defendant. The court observed that the "fact that the defendants may have sold non-compliant products during a certain time period in violation of the TAA does not equate to the defendants making a knowingly false statement in order to receive money from the government."[3] Further, the court expressed skepticism the relator could satisfy the materiality prong of the implied certification theory under *Escobar*, noting the government paid "millions of dollars" for products it knew were allegedly noncompliant.[4]

1. Universal Health Servs., Inc. v. United States ex rel. Escobar 136 S.Ct. 1989 (2016).
2. 896 F.3d 834 (7th Cir. 2018).
3. Id. at 841-42.
4. Id. at 843.

Preclusion under the "Government Action Bar": *Schagrin*

The FCA's "government action bar" prohibits *qui tam* actions from proceeding if they are "based upon allegations or transactions which are the subject of a civil suit or an administrative civil monetary penalty proceeding in which the Government is already a party."[5] In *Schagrin v. LDR Industries, LLC*,[6] a federal court recently held, for the first time, that a penalty issued by CBP in an administrative proceeding bars a *qui tam* action under the government action bar.

In *Schagrin*, the relator's November 2014 complaint alleged the defendant companies underpaid antidumping and countervailing duties on steel pipe imported from China. The relator – an attorney with experience in international trade – previously reported his suspicion that defendants underpaid required duties to CBP. The resulting CBP investigation led to an assessment of penalties of more than $38.8 million pursuant to 19 U.S.C. § 1592. However, CBP ultimately billed defendants for only $6.7 million, later reducing that to $4.85 million. In September 2014, defendants filed for bankruptcy and CBP filed a proof of claim in the bankruptcy proceeding in February 2015. When the bankruptcy court entered an order in October 2016 approving the defendants' Chapter 11 plan, it noted the plan incorporated terms of a settlement between defendants and CBP as "full and complete satisfaction" of disputed CBP claims.

The defendants moved to dismiss relator's *qui tam* action, arguing the court lacked jurisdiction under the FCA's government action bar. The relator argued the bar did not apply because CBP never pursued an "administrative civil money penalty proceeding," only sending the defendants "a bill for duties."[7] Rejecting this argument, the court indicated the key to determining whether 31 U.S.C. § 3730(e)(3) bars a subsequent FCA suit is whether the government has already imposed a "penalty" against the defendants. Because CBP explained to the bankruptcy court that it had a claim against the defendants that far exceeded the $6.7 million for which the defendants were allegedly "billed," and this claim was "the result of the penalty pursuant to 19 U.S.C. § 1592," the court concluded CBP had pursued penalties against the defendants. This pursuit, the court explained, was an "administrative civil money penalty proceeding" that barred the *qui tam* action under 31 U.S.C. § 3730(e)(3) .

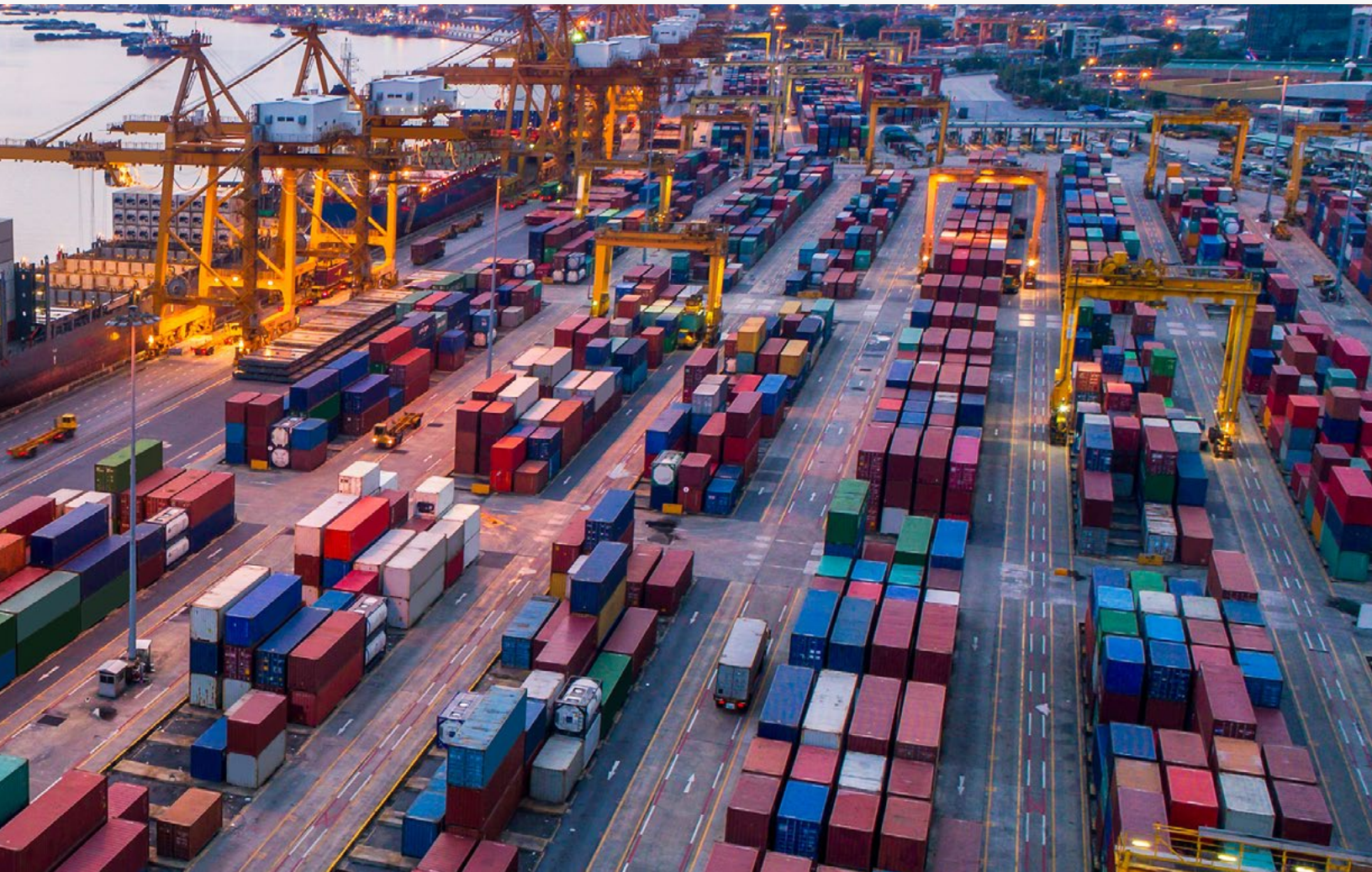
Looking ahead

The Trump Administration's trade policy and enforcement priorities certainly inject additional risk for importers and companies that rely upon overseas manufacturing operations. Some FCA claims brought by private citizens have both attracted intervention by DOJ and resulted in significant settlements premised on schemes to avoid customs duties. But the courts continue to enforce the strict materiality requirements articulated by the Supreme Court in *Escobar* to curtail FCA risk in trade cases. The decision in *Schagrin* is also significant because it reduces the importer's risk of facing penalties under two separate statutory regimes governing trade.

Schagrin may also expand the benefit of the Tariff Act's "safe harbor" provisions, which incentivize importers to report errors in classification or valuation of imported goods to CBP, thereby avoiding significant penalties.[8] CBP penalty reductions can be dramatic, even in cases that involve the use of materially false documents to import goods into the U.S., so long as the importer discloses the circumstances of a violation before, or without knowledge of, the commencement of a formal investigation by CBP.

CBP is obliged to conduct a formal investigation upon receiving a report of underpaid tariffs or customs duties. Thus, after *Schagrin*, invocation of the prior disclosure procedure under 19 U.S.C. § 1592(c)(4) arguably commences an "administrative civil money penalty proceeding" for the purposes of the FCA's government action bar. Certainly, if CBP imposes penalties as a result of an investigation following a prior disclosure, there would be a strong argument that a whistleblower should not be permitted to maintain a *qui tam* suit under the FCA for the same conduct. Even if penalties have not yet been imposed, a prior disclosure may form the basis for an argument that any *qui tam* complaint based on the conduct disclosed to CBP should be barred.

5. 31 U.S.C. § 3730(e)(3).
6. No. 1:14-cv-09125 (N.D. Ill. May 23, 2018),
7. *Schagrin*, Slip. Op. at 5.
8. See 19 U.S.C. § 1592(c)(4); 19 C.F.R. § 162.74.



Health IT and the FCA

After an industry-shifting 2017 for the health IT industry, health IT vendors should not be lulled into a false sense of security around potential FCA exposure. The $155 million eClinicalWorks civil FCA settlement – which settled allegations the company misrepresented the capabilities of its electronic health records (EHR) software – and its continued ripple effects on the industry demonstrate that health IT software companies are expected to ensure their products continually comply with the Office of the National Coordinator for Health Information Technology's (ONC) increasingly challenging regulatory standards. Given the explosion in the use of EHRs, this area will almost certainly continue to be an active area of FCA litigation.

The ONC's statutory authority & regulations

The ONC became a legislatively mandated agency under the 2009 HITECH Act – enacted to improve health care quality, safety, and efficiency through the promotion of health information technology and the electronic exchange of health information. To achieve this, the HITECH Act requires the ONC to determine which "standard[s], implementation specification[s], and certification criteri[a] for the electronic exchange and use of health information" will be adopted nationwide.[1] The ONC is also tasked with oversight of EHRs certified to its standards.

The ONC has published three sets of standards and certification criteria upon which certification is conditioned, and each set builds off the prior version. The 2014 Edition, the result of the ONC's second rulemaking cycle, created a standardized set of clinical data information – including medications, problems, and laboratory tests – and further required the use of particular medical code sets to represent the specified data.[2]

The certification process

In order to ensure compliance with designated EHR standards, the ONC requires certification "testing" to be performed by third-party companies, or Authorized Certification Bodies (ACBs), to whom the ONC delegates its oversight authority.[3] Test Methods, which can serve as a roadmap for EHR developers on how to appropriately implement the ONC's standards, are provided to EHR companies in advance of such testing.[4] These Test Methods provide the structure for evaluating an EHR's conformance with the certification criteria, as contemplated by the HITECH Act.

Even after becoming certified, EHR companies remain subject to oversight by ACBs. Under the ONC's regulatory regime, ACBs "must" continue to assess certified capability and ensure "continued conformity" to the certification requirements when complaints are raised about certified technology.[5] This continued oversight is known as "surveillance" and is documented on a public website called the Certified Health IT Product List (CHPL).

The ONC's certification process serves as a complement to the concept of "meaningful use" of EHRs by health care providers, which is similarly born out of the HITECH Act. Under the federal "Meaningful Use" program, the Centers for Medicare & Medicaid Services (CMS) provides Medicare incentive payments to eligible professionals (providers) or hospitals that demonstrate they used certified EHR technology in a meaningful manner. To receive the payments, health care providers must provide the required reporting and "attest" to CMS they satisfied meaningful use measures using data from their EHR software. So, although EHR companies do not themselves receive payments from the government, the health care providers relying on certified EHR systems to attest to CMS *do*.

1. HITECH Act of 2009, Sec. 3001
2. ONC Final Rule, published Sept. 4, 2012 (https://www.federalregister.gov/documents/2012/09/04/2012-20982/health-information-technology-standards-implementation-specifications-and-certification-criteria-for)
3. 45 C.F.R. § 170.510; 45 C.F.R. §170.511.
4. Certification Test scripts are another condition of certification. Not expressly stated in the HITECH Act or in the ONC's final rule. They are roadmaps for both EHR developers and ACBs in how the ONC contemplates that certification testing will be completed.
5. 45 C.F.R. §170.556.

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The *eClinical Works* settlement and subsequent litigation

On May 31, 2017, DOJ announced a $155 million civil FCA settlement in a suit initiated by a whistleblower against EHR vendor eClinicalWorks (eCW).[6] The government's complaint-in-intervention alleged a host of problematic conduct by eCW in connection with its 2014 Edition certification, including the coding and interface of its EHRs.[7] The government alleged, by this conduct, eCW "knowingly caused the submission of false claims and false statements material to false claims to be submitted to the Government" by virtue of health care providers' meaningful use attestations.

According to DOJ's press release, the settlement marked the largest FCA recovery in the District of Vermont.[8] Significantly, the settlement required payment not only from the company, but also from individual officers and employees. eCW was further required under settlement terms to enter into a five-year Corporate Integrity Agreement (CIA) with the HHS Office of the Inspector General (HHS-OIG). The CIA requires, among other things, eCW retain an Independent Software Quality Oversight Organization to assess software quality control systems and provide semi-annual reports to HHS-OIG and eCW documenting reviews and recommendations. Under the CIA, eCW must also provide prompt notice to its customers of any safety-related issues and maintain on its customer portal a comprehensive list of such issues, as well as any steps users should take to mitigate potential patient safety risks.

Shortly after DOJ's public announcement, a civil class action was filed against eCW by customers.[9] Although this suit was voluntarily dismissed in 2018, a separate class action remains pending and subject to arbitration in the District of Massachusetts.[10]

The eCW settlement resulted in increased introspection in connection with the providers who benefit from the Meaningful Use (MU) incentive program. For example, 21st Century Oncology, which provides integrated cancer care, entered into a $26 million settlement with DOJ to repay Medicare incentive payments and avoid MU penalties after self-disclosing it "knowingly submitted, or caused the submission of, false attestations to CMS concerning employed physicians' use of EHR software."[11]

Looking ahead

The ONC's latest regulatory standards under the 2015 Edition are even more onerous than the 2014 Edition at issue in the eCW case. With 2015 Edition certification criteria comes a higher standard for interoperability, application program interfaces, and enhanced functionality such as patient generated health data capture.[12] Several EHR companies have either recently been certified to the 2015 Edition, or are now in the process of certifying, which will provide new fodder for FCA whistleblower actions in the health IT industry. CMS incentive programs have also evolved, providing new snares for unwitting EHR companies.

Further, although CMS did not require health care providers to reimburse their MU incentive payments if they "in good faith successfully attested using eClinicalWorks software" in the eCW settlement,[13] it remains to be seen whether CMS will continue to take this stance now that health care providers and EHR companies are on notice of potential FCA liability. If CMS does attempt to recover payments made to physicians due to defects in their EHR systems, this could provide grounds for civil litigation with CMS, providers, and their EHR companies.

6. *United States ex rel. Delaney v. eClinialWorks LLC*, 2:15-CV-00095-WKS (D. Vt.).
7. The government also alleged that eCW's referral and reference programs violated the Anti-Kickback Statute, but did not include a separate Anti-KickBack Statute substantive count in the claims for relief.
8. Electronic Health Records Vendor to Pay the Largest Settlement in the District of Vermont, https://www.justice.gov/usao-vt/pr/electronic-health-records-vendor-pay-largest-settlement-district-vermont
9. *Tot v. eClinicalWorks, LLC*, No. 1:17-cv-08938-ALC (S.D.N.Y. Nov. 16, 2017)
10. Carrollton Family Clinic, LLC v. eClinicalWorks, LLC, No. 1:17-cv-12530-RGS (D. Mass. Dec. 21, 2017)
11. 21st Century Oncology to Pay $26 Million to Settle False Claims Act Allegations, https://www.justice.gov/opa/pr/21st-century-oncology-pay-26-million-settle-false-claims-act-allegations
12. https://ehrintelligence.com/news/onc-working-with-health-it-innovators-to-improve-interoperability; see also 45 C.F.R. § 170.315.
13. https://www.healthcareitnews.com/news/cms-wont-punish-eclinicalworks-customers-meaningful-use-ehr-attestations
14. 2012 letter to several hospital associations from then-HHS Secretary Kathleen Sebelius and Attorney General Eric Holder.
15. Order on Mot. to Dismiss, *United States v. Epic Systems Corporation*, No. 8:15-CV-1408 (M.D. Fla. Feb. 6, 2018).
16. https://www.himssconference.org/
17. https://www.himssconference.org/session/lessons-ecw-case-insider-s-perspective

Finally, the eCW case by no means cabins the kind of FCA exposure health IT companies may face in the coming years. In 2012, for example, then-HHS Secretary previewed EHR billing and "upcoding" issues as a basis for future FCA actions, explaining: "There are troubling indications that some providers are using this technology to game the system, possibly to obtain payments to which they are not entitled…There are also reports that some hospitals may be using electronic health records to facilitate 'upcoding' of the intensity of care or severity of patients' condition as a means to profit with no commensurate improvement in the quality of care."[14] Another whistleblower attempted to use this argument to impose FCA liability on a large EHR company for alleged double-billing of Medicare and Medicaid.[15] Although dismissed, the suit provides insight into the types of creative actions whistleblowers could explore in the future.

A final note

The Health Information and Management Systems Society (HIMSS) sponsors what is widely considered the "leading health information and technology conference."[16] It is no surprise the 2018 HIMSS conference featured a panel titled "Whistleblowing Under the False Claims Act." Who were the speakers?[17] None other than the whistleblower and plaintiff's attorney in the eCW case. 2019 is sure to bring new developments around the FCA as applied to health IT companies.

Looking ahead

False Claims Act enforcement is in a transitional period. New suits under the *qui tam* provisions continue to surge, and *qui tam* relators continue to drive an aggressive enforcement agenda for the United States. At the same time, DOJ recently adopted policies that may reflect a shift away from expansive interpretations of the Act and a more cautious approach to reliance upon agency guidance as a basis for FCA enforcement. The lower courts, taking a cue from the Supreme Court's ruling in *Escobar*, continue to develop case law in which a rigorous materiality standard is applied to dismiss complaints – especially declined *qui tam* cases – where there is scant evidence any alleged misrepresentation had, or is likely to have had, an impact on the actual behavior of the government in paying or approving a claim. As we look forward, we see six issues likely to warrant continued close scrutiny in the coming year:

1. The Granston Memo

Historically, the power granted to the government by the Act to seek dismissal of declined *qui tam* cases has been invoked sparingly. But there is mounting evidence – and recent examples – that DOJ will increasingly use this power to: reduce the number of non-meritorious cases; contain the proliferation of adverse precedent; conserve DOJ resources; and avoid discovery on questions of government knowledge and materiality under the *Escobar* standard.

2. The materiality standard under *Escobar*

The Supreme Court's materiality ruling in *Escobar* will continue to have repercussions in FCA jurisprudence (and other cases) in the lower courts in the coming year. Materiality has become the most significant question raised at the threshold of FCA litigation. Lack of evidence of materiality has become a dispositive issue for many declined cases, and it appears the courts have embraced a rigorous materiality requirement as a safeguard against declined cases that are perceived to be lacking in merit.

3. A Supreme Court ruling on the statute of limitations

On November 16, 2018, the Supreme Court granted a petition for a writ of certiorari in *U.S. ex rel. Hunt v. Cochise Consultancy, Inc.*, 887 F.3d 1081, 1083 (11th Cir. 2018), indicating that it would resolve a circuit split about how the FCA statute of limitations is to be applied in declined *qui tam* cases. Under the FCA statute of limitations, a civil action cannot be commenced more than six years after the date on which the violation is committed (subsection 3731(b)(1)), or more than three years after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances, but in no event more than 10 years after the date on which the violation is committed, whichever occurs last (subsection 3731(b)(2)). The question the courts have struggled with is whether a relator is permitted to take advantage of the statutory tolling provision and proceed with a case brought more than six years after the violation, but less than three years from the date when the government learned of the material facts. The courts have split into three camps: In the Fourth, Tenth, and Fifth Circuits, relators must file their claims within six years of the violation, strictly in accordance with plain language of subsection 3731(b)(1). In the Eleventh Circuit, under *Cochise*, relators can file within three years after the date when the material facts are known to the government, consistent with the statutory tolling provision in subsection 3731(b)(2). In the Ninth and Third Circuits, relators can commence an action within three years after the date when the material facts are known to the relator. The approach taken by the Ninth and Third Circuits assumes that *qui tam* relators stand in the shoes of government officials for purposes of section 3731(b)(2), which is a gloss on the express language of the Act. A ruling from the Supreme Court will affect only a small number of cases, but it is significant to note that the Court continues to take a keen interest in FCA jurisprudence.

4. Proof issues in health care kickback cases

In 2010, Congress amended the federal Anti-Kickback Statute (AKS) in order to establish once and for all that the FCA could be used as a remedy for illegal kickbacks. With that threshold issue resolved, litigation in recent years has turned to the language of the amendment and the burden it imposes on relators and the government to show an actual causal connection between the kickback and a claim. Under the amended statute, only "a claim that includes items and services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g). Focusing on the phrase "resulting from a violation," courts are requiring plaintiffs to present evidence showing a causal link between the alleged kickback and any claims subsequently presented for payment by Medicare or

Medicaid. See, e.g., *U.S. ex rel. King v. Solvay Pharms., Inc.*, 871 F.3d 318, 332 (5th Cir. 2017) (holding that it would be speculation to infer that compensation for professional services legally rendered actually caused physicians to recommend a pharmaceutical company's drugs to patients covered by government programs); see also *U.S. ex rel. Greenfield v. Medco Health Solutions, Inc.*, 880 F.3d 89, 100 (3d Cir. 2018) ("A kickback does not morph into a false claim unless a particular patient is exposed to an illegal recommendation or referral and a provider submits a claim for reimbursement pertaining to that patient."). Some district courts have insisted that allegations that a claim is "tied to a kickback" are necessary to survive a motion to dismiss. See *U.S. ex rel. Fla. Sec'y of Anesthesiologists v. Choudry*, 2017 WL 2604930 at *8 (M.D. Fla. June 14, 2017); see also *Guilfoile v. Shields Pharm., LLC*, 2017 WL 969329 at *7 (D. Mass. Mar. 10, 2017) (holding that the complaint must allege how the AKS violation could have led to the submission of false claims). While DOJ and relators prefer to make that proof by showing of proximate cause – i.e., referrals are the "natural and probable consequence" of a kickback, these courts seem to view the "resulting from" standard as requiring something more. Litigation is likely to give rise to a majority rule in the coming months.

5. An Eleventh Circuit ruling in *AseraCare*

When the Eleventh Circuit does finally rule in *U.S. v. GGNSC Admin. Servs.* (the *AseraCare* case), it could have profound ramifications in cases where the relator or the government alleges statements of clinical judgment and other medical and scientific opinion are actionable under the Act. As noted in this publication, the trend in recent decisions has been unfavorable for defendants attempting to raise the defense that medical judgments cannot be "false" for purposes of the FCA. If the Eleventh Circuit rules that life expectancy is not inherently subjective, and that a case can proceed upon a physician's prognostication that a patient has less than six months to live – and therefore is "terminally ill" and eligible for the Medicare hospice benefit – the court may be sounding the death knell for the argument that such statements of medical judgment cannot be actionably false.

6. The proper measure of damages

Finally, there is a distinct trend in recent cases for courts to award traditional "benefit of the bargain" damages in FCA cases, rejecting the more expansive "tainted claims" measure of damages advocated by DOJ. Relatedly, some courts have been inclined to hold that the FCA's treble damages provision applies to the government's net losses, not gross losses, in calculating damages. *See, e.g., United State ex rel. Harman v. Trinity Industries Inc.*, 872 F.3d 645 (5th Cir. 2017), *United States ex rel. Wall v. Circle C Construction, LLC*, 813 F.3d 616 (2016), *United States v. United Technologies*, No. 13-4057 (6th Cir. April 6, 2015), *United States v. Anchor Mortgage Corp.*, 711 F.3d 745 (7th Cir. 2013), *United States v. Science Applications Int'l Corp.*, 626 F.3d 1257 (D.C. Cir. 2010), *United States ex rel. Landis v. Tailwind Sports Corp.*, 234 F. Supp. 3d 180 (D.D.C. 2017). The development of this case law in the coming year could be an important factor in limiting the overall exposure for defendants in FCA cases even where liability may be established.

In conclusion

Staying informed on these topics is incredibly important given the potential for impactful case law. Please visit our False Claims Act page at hoganlovells.com for updates on these items and other FCA-related issues in 2019.

Contributors

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