The False Claims Act Litigation Landscape 2019[1]

Legal and policy developments that have occurred in 2017 and 2018 will shape the False Claims Act (FCA) litigation landscape for 2019 and beyond. The most significant development has been how lower courts have applied the Supreme Court's holding in *Universal Health Servs., Inc. v. United States ex rel. Escobar* (*Escobar*),[2] that stiffened the materiality element of FCA liability. Judicial decisions subsequent to *Escobar* reveal the lower courts have generally adopted *Escobar*'s materiality reasoning and are demanding greater pleading and evidentiary specificity from the government and relators.

The Department of Justice (the Department or DOJ) has also adopted new enforcement policies that have the potential to impact FCA investigations and litigation. This paper examines (1) the impact of *Escobar*'s materiality holding on FCA jurisprudence as articulated and applied by the lower courts, and (2) three DOJ policies – dismissal of meritless qui tam cases, the use of sub-regulatory guidance as a basis for FCA enforcement, and the Department's cooperation policy – that will likely shape the investigation, litigation and resolution of FCA cases.

A. The Impact of the *Escobar* Decision

In *Escobar*, the Supreme Court expanded potential FCA liability by rejecting the judicially created doctrine that FCA liability can arise only from a "condition of payment" and not a "condition of participation."[3] Conversely, however, it also narrowed FCA liability by raising the evidentiary bar for proving an impliedly false statement was material to the government's payment decision, instructing, "The materiality standard is demanding. The False Claims Act is not 'an all-purpose anti-fraud statute, or a vehicle for punishing garden-variety breaches of contract or

---

[1] David L. Douglass is Office Managing Partner for the Washington D.C. office of Sheppard Mullin Richter & Hampton LLP. His practices focuses on white-collar civil and criminal defense of companies and individuals, with a particular focus on representing health care companies and government contractors.

[2] 136 S. Ct. 1989, 2003 (2016)

[3] *Id.* at 1996.

regulatory violations."[4] The Court grounded this holding in established principles of tort law that require the alleged misrepresentation would *in fact* have made a difference, *i.e.*, mattered, to the payer. In plain and unambiguous terms, the Court held it is not "sufficient for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant's noncompliance."[5]

In other words, the Government's actual behavior in either paying or refusing to pay claims when it is aware of the type of impliedly false statement at issue is the critical evidentiary predicate to proving materiality.[6]

The Court offered examples of the kind of evidence that would bear upon materiality:

- **Reasonableness** (An Objective Test) – Whether a "reasonable man [acting on the Government's behalf] would attach importance to [the representation] in determining his choice of action in the transaction."[7]

- **Government Knowledge/Government Treatment of Violations** (A Subjective Test) – Whether the Government knew of a claim's falsity and nevertheless paid the claim, which would tend to negate a finding of materiality.[8] Conversely, "evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance" supports a finding of materiality. [9]

---

4 *Id.* at 2003 (quoting *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 672 (2008)).

5 *Escobar*, 136 S. Ct. at 2003.

6 *See also Coyne v. Amgen*, 717 Fed. Appx. 26, 29–30 (2d Cir. 2017) (finding lack of materiality when "[t]he mechanics of the … reimbursement scheme and its operation in practice [may] show that any [misrepresentation or omission] was immaterial to [the Government's payment decisions." *Escobar*, 136 S. Ct. at 30.

7 *Id.* at 2003.

8 *Id.* at 2003.

9 *Id.* Although *Escobar* addressed government knowledge insofar as it bears upon materiality, government knowledge also constitutes a defense to the FCA's scienter element. The reasoning is that if the contractor informs the government of the facts comprising the allegedly false claim, then the contractor's claim could not have been knowingly false because it made no misrepresentation to the government. See *United States ex rel. Berg v. Honeywell Int'l, Inc.*, No. 3:07-CV-00215-SLG, 2017 WL 1843688, at *6 (D. Alaska May 8, 2017) (discussing the doctrine and citing cases). Despite the cases treating government knowledge as a defense to scienter, analyzing government knowledge as bearing on materiality is a more natural interpretation and more consistent with the Court's general plain meaning approach to interpreting the FCA.

- **Labels Used** – Whether the Government has "expressly identif[ied] a provision as a condition of payment," bears on materiality, although such identification is "relevant but not automatically dispositive."[10]

- **Essence of the Bargain** – Whether the false statement goes to the "essence of the bargain."[11]

FCA practitioners immediately recognized the potential significance of the Court's pronouncement regarding materiality but they also recognized that its practical impact would largely be a function of how lower courts applied the Court's instruction. Now, approximately two years later, there is an established body of post-*Escobar* materiality decisions that provide useful guidance to those litigating FCA claims.

United States, et al., ex rel. Ruckh. v. Salus Rehabilitation, LLC, et al.[12] offers a thoughtful, cogent reflection on both the letter and spirit of *Escobar*. The relator alleged the defendant owners and operators of specialized nursing facilities violated the FCA by submitting impliedly false statements in support of false claims by (1) failing to maintain comprehensive care plans as required by Medicaid and (2) upcoding RUG levels.[13] The court reversed a jury's $350 million verdict in favor of the United States and Florida (as well as the relator). The decision provides valuable guidance concerning how the *Escobar* holding should be applied to analyzing the actual evidence established under a FCA case, as distinguished from mere allegations.

The court's decision carefully traced the Supreme Court's analysis of the FCA statutory text . The court pointed out that *Escobar*'s "rigorous" and "demanding" materiality and scienter requirements preclude FCA liability "based on a 'minor or unsubstantial' or a 'garden variety' breach of contract or regulatory violation."[14] FCA liability "rests comfortably on proven and

---

10 *Id.* at 2002.
11 *Id.* at 2003 n.5.
12 Case No. 8:11-cv-1303-T-23TBM (M.D. Fl. Jan. 11, 2018).
13 *Id.* at 1-2.
14 *Id.* at 7 (quoting *Escobar*, 136 S. Ct. at 2003).

successful principles of exchange – fair value given for fair value received."[15] The court noted the unfairness of a system that imposes "essentially punitive" consequences of FCA's liability. Liability "requires proof that a vendor committed some non-compliance that resulted in a material deviation in the value received and requires proof that the deviation would materially and adversely affect the buyer's willingness to pay."[16]

The court, applying *Escobar*'s holding and reasoning, set aside the jury verdict, finding the relator "offered no meaningful and competent proof" that the responsible government agencies would have regarded the disputed practices as material to their payment decision, nor evidence that defendants knew or should have known the governments would have refused to pay the claims if they had known of the practices.[17] Importantly, the court added, "In fact, both governments were — and are — aware of the defendants' disputed practices, aware of this action, aware of the allegations, aware of the evidence, and aware of the judgments for the relator — but neither government has ceased to pay or even threatened to stop paying the defendants for the services provided to patients throughout Florida continuously since long before this action began in 2011."[18]

The court's opinion captured the essence of the *Escobar* holding, observing, "*Escobar* rejects a system of government traps, zaps, and zingers that permits the government to retain the benefit of a substantially conforming good or service but to recover the price entirely — multiplied by three — because of some immaterial contractual or regulatory non-compliance."[19] Adding force to this view, the court noted the FCA is not the only remedy available to the government for

---

15 *Id.* at 8.
16 *Id.* at 8-9.
17 *Id.* at 2.
18 *Id.* at 2.
19 *Id.* at 8.

a contractor's non-compliance. The government has alternative and more measured remedies, including providing notice of the deficiency and demanding a cure, administrative remedies, or a price adjustment, and proving materiality may require showing that the government would not have chosen one of those more measured remedies.[20] The opinion also recognized there may be numerous and legitimate reasons the government might choose to pay deficient claims, such as the impact on program beneficiaries or the government's needs. For example, the government might understandably elect not to withhold payment for mission-critical goods or services. In *Ruckh*, the defendants provided care to vulnerable, elderly nursing home patients. The decision reinforces the principle established in *Escobar* that FCA liability cannot be premised on mere allegations or post-payment rationalizations. Rather, liability depends on proof of the parties' agreement, their conduct, and knowledge.

Decisions subsequent to *Escobar* reflect that the courts have generally, although not universally, followed the Court's instruction to scrutinize more carefully pleadings and evidence in support of materiality. For example, one district court held the mere fact that the government chooses to establish a regulation does not demonstrate that a misrepresentation concerning compliance was material to the government's decision to pay. "[T]hat the Government or a federal agency found a particular issue important enough to regulate speaks little to the intended consequence of noncompliance … Ultimately, the relevant inquiry is whether the Government's payment decision was influenced by claimant's purported compliance with a particular requirement, not whether a given issue has been deemed worthy of regulation."[21]

In applying the reasonable person test, Courts have looked to what the agency would have done had it known of the allegedly false statement. For example, in *Grabcheski v. American*

---

20 *See Id.* at 12-13.

21 *U.S. ex rel. Schimelpfenig v. Dr. Reddy's Labs. Ltd.*, 2017 WL 1133956 (E.D. Pa. Mar. 27, 2017).

International Group, Inc., 2017 WL 1381264 (2nd Cir. Apr. 18, 2017), the Court held the relator failed to state a claim because he failed to allege how a 0.4% difference in value would have affected whether the parties would have entered into an agreement. Similarly, compliance issues that would not cause the agency to deny payment will not likely trigger FCA liability under an implied certification theory. *See e.g., United States ex rel. Petratos v. Genentech Inc.,* 855 F.3d 481, 490 (3d Cir. 2017) ("Petratos does not claim that Genentech's safety-related reporting violated any statute or regulation. He acknowledges that the FDA would not "have acted differently had Genentech told the truth." And as we have explained, he does not dispute that CMS would reimburse these claims even with full knowledge of the alleged reporting deficiencies."); *United States v. Sanford-Brown, Ltd.,* 840 F.3d 445 (7th Cir. 2016) ("At bottom, even assuming Nelson's allegations are true, the most he has shown is that SBC's supposed noncompliance and misrepresentations would have entitled the government to decline payment. Under *Universal Health*, that is not enough."); *United States ex rel. Kelly v. Serco, Inc.,* 846 F.3d 325 (9th Cir. 2017) ("Evidence that the government 'would be entitled to refuse payment were it aware of the violation' is insufficient by itself to support a finding that the violation is material to the government's payment decision."); *United States ex rel. McBride v. Halliburton Co.,* 848 F.3d 1027 (D.C. Cir. 2017) ("Nevertheless, McBride persists, claiming as "dispositive" an Administrative Contracting Officer's (ACO) statement in a declaration that he "might" have investigated further had he known false headcounts were being maintained, and that such an investigation "might" have resulted in some charged costs being disallowed. The ACO's speculative statement could be true of the maintenance of any kind of false data; it tells us nothing special about headcounts."); *United States v. DynCorp Int'l, LLC,* 2017 WL 2222911 (D.D.C. May 19, 2017) ("The fact that 'the Government would have the option to decline to pay' is relevant but

not sufficient to find materiality. Therefore, the FAR's provision for contracting officers to refuse to pay unreasonable costs is one indication that unreasonableness may be material to some claims, but it does not automatically render unreasonableness material in every instance.").

Where the government has a demonstrated record of enforcing compliance or prosecuting non-compliance, courts are more likely to find such violations "material" for purposes of the FCA. For example, in *Scott Rose v. Stephens Institute*, 2016 WL 5076214 (N.D. Cal. Sept. 20, 2016), the court relied on government actions against other parties that violated the regulatory provision at issue. The court noted that the Department of Education had recovered tens of millions of dollars by pursuing cases against parties that made misrepresentations equivalent to the one at issue. Such enforcement activity, the court held, showed the government was concerned about violations and that such violations were material to the government's decision to pay. The court also found that enforcement had become more aggressive over time. The government also eliminated various regulatory safe harbors as time went on. These changes in policy demonstrated that the violations were indeed material to the government.

In *U.S. ex rel. Emanuele v. Medicor Assocs*., 2017 WL 1001581 (W.D. Pa. Mar. 15, 2017), the court found the failure to adhere to a Stark Law exception's 'writing' requirement was not "minor or insubstantial." The Stark Law generally prohibits a physician from referring Medicare patients for designated health services to an entity with which the physician maintains a financial relationship. Many exceptions to that general prohibition require the financial relationship at issue to be "set out in writing."[22] In finding that the 'writing' requirement was not "minor or insubstantial," the court explained, "[c]ompliance with the writing requirement permits a reviewer to analyze the timeframe, rate of compensation, and the identifiable services contemplated in the

[22] *See, e.g.*, 42 C.F.R. § 411.357(d).

arrangement to determine whether any portion is based on the volume or value of physician referrals."[23] The requirement, therefore "plays a role in preventing fraud and abuse."[24] Because of the writing requirement's role in preventing fraud in abuse, the *Emanuele* court held that the writing requirement "go[es] to the very 'essence of the bargain' between the government and health care providers with respect to Stark [Law] compliance."[25] Because the court found that the writing requirement was not minor or insubstantial, it denied the defendants' motion for summary judgment holding that whether the agency would have declined to pay a claim in the absence of a writing was a question for the jury.

Government Knowledge

If materiality is determined by whether the alleged misrepresentation would have influenced the agency's payment decision, it follows that when the government pays a claim despite knowing of a misrepresentation that supports the claim, then the misrepresentation could not possibly have been material to the government's payment decision. The *Escobar* decision did not go so far to say that government knowledge alone precludes establishing materiality but it came close, saying:

> [I]f 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.[26]

With the exception of a few cases in the Ninth Circuit, the lower courts have issued decision after decision finding no materiality when the government makes payments to a contractor despite its knowledge of alleged violations. For example, in *United States ex rel. Petratos v. Genentech,*

---

23 *Emanuele, 2017 WL 1001581, at *18.*

24 *Id.* (quoting 80 Fed. Reg. 70886, 71333-71334).

25 *Emanuele, 2017 WL 1001581, at *18 (quoting Escobar, 136 S. Ct. at 2003 n.5).*

26 *Escobar*, 136 S. Ct. at 2003-04 (emphasis added).

Inc., 855 F.3d 481 (3d Cir. 2017), the court held there was no materiality when the government continued to pay claims for the defendant's drugs despite being informed by relator of "material, non-public evidence of [the defendant's] campaign of misinformation."[27] The Court went on to explain, "[s]ince [the time that Relator disclosed non-public evidence to the FDA and DOJ], the FDA has not merely continued its approval of Avastin for the at-risk populations that Petratos claims are adversely affected by the undisclosed data, but has added three more approved indications for the drug. Nor did the FDA initiate proceedings to enforce its adverse-event reporting rules or require Genentech to change Avastin's FDA label, as Petratos claims may occur. And in those six years, the Department of Justice has taken no action against Genentech and declined to intervene in this suit."[28]

Likewise, *United States ex rel. Harman v. Trinity Indus., Inc.*, 872 F.3d 645 (5th Cir. 2017), the court reversed a $663 million jury verdict after finding no materiality in the alleged false certifications at issue. On the issue of government knowledge, the court held that what was important was not what was disclosed to the government, but instead what the government actually knew.[29] The court noted that the government was made aware of the relator's allegations and continued to pay claims because the government was not persuaded by the allegations.[30]

Similarly, in *United States ex rel. McBride v. Halliburton Co.*, 848 F.3d 1027 (D.C. Cir. 2017), the court found no materiality after a DCAA investigation found no wrongdoing by the contractor. "In fact," the court noted, "KBR continued to receive an award fee for exceptional performance under Task Order 59 even after the Government learned of the allegations. This is

---

[27] *Id.* at 490.

[28] *Id.*

[29] This is distinguishable from the "government knowledge defense," which in fact does focus on what was disclosed to the government.

[30] *Id.* at 667.

'very strong evidence' that the requirements allegedly violated by the maintenance of inflated headcounts are not material."[31]

There are numerous other cases that have reached similar results.[32] These cases suggest that if the relevant agency or agency officials are aware of the alleged violations and nevertheless continue to pay claims or fail to take enforcement action, then there is no materiality. But what about the converse? Does a government agency's refusal to pay or does a government enforcement action in the face of alleged violations render such violations material? Not surprisingly, the case law suggests yes. For example, in *United States ex rel. Badr v. Triple Canopy, Inc.*, 857 F.3d 174 (4th Cir. May 16, 2017), the government immediately cut off payments and intervened in the relator's *qui tam* suit after learning that contracted security guards could not meet the marksmanship requirement in their contract. "Here, the Government did not renew its contract for

---

[31] *Id.* at 1034 (quoting *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2003 (2016)).

[32] *See, e.g.*, *Abbott v. BP Expl. & Petroleum, Inc.*, 851 F.3d 384 (5th Cir. 2017) (noting that the Department of the Interior allowed BP to continue drilling after a substantial investigation into the plaintiff's allegations of requirements violations and thus the Department's decision represents strong evidence that the requirements were not material); *United States v. Sanford-Brown, Ltd.*, 840 F.3d 445 (7th Cir. 2016) ("the subsidizing agency and other federal agencies in this case 'have already examined SBC multiple times over and concluded that neither administrative penalties nor termination was warranted.'"); *United States ex rel. Kelly v. Serco, Inc.*, 846 F.3d 325 (9th Cir. 2017) ("[T]he government's acceptance of Serco's reports despite their non-compliance with ANSI-748, and the government's payment of Serco's public vouchers for its work under Delivery Orders 49 and 54, we conclude that no reasonable jury could return a verdict for Kelly on his implied false certification claim."); *United States ex rel. Schimelpfenig v. Dr. Reddy's Labs., Ltd.*, 2017 WL 1133956 (E.D. Pa. Mar. 27, 2017) (no allegation that the Government ever refused payment or sued a defendant for failure to comply with federal packaging requirements); *United States ex rel. Quartararo v. Catholic Health Sys. of Long Island, Inc.*, 2017 WL 1239589 (E.D.N.Y. Mar. 31, 2017) ("Even assuming that Defendants' conduct violated the DOH regulations, Relator's implied-false certification argument fails, as the reimbursement rate provisions of the DOH regulations could not have been "material" to the DOH's payment decision where the DOH continued to reimburse the Nursing Home despite understanding that the Nursing Home was using an outdated rate."); *United States ex rel. Hall v. LearnKey, Inc.*, 2017 WL 1592472 (D. Utah Apr. 28, 2017) ("The VA's complacency is very strong evidence that the minor regulatory violations alleged by Hall were not material to the VA's decision to reimburse LearnKey under Chapter 31."); *United States ex rel. Kolchinsky v. Moody's Corp.*, 2017 WL 825478 (S.D.N.Y. Mar. 2, 2017) (finding no materiality in light of evidence that the government had knowledge of Moody's credit ratings' alleged inaccuracies, was aware of the alleged fraud during the proscribed time period, and continued to pay Moody's for its credit-ratings products).

base security with Triple Canopy and immediately intervened in the litigation. Both of these actions are evidence that Triple Canopy's falsehood affected the Government's decision to pay."[33]

Similarly, in *United States ex rel. Miller v. Weston Educational, Inc.*, 840 F.3d 494 (8th Cir. 2016), the court found materiality based on the consequences of non-conformance with a requirement that educational institutions "maintain such … records as may be necessary to ensure proper and efficient administration of funds" in connection with its participation in programs under Title IV of the Higher Education Act of 1965, which gave the defendant's students access to certain federally sponsored grants, loans, and scholarships.[34] Noting that "the DOE sometimes terminates otherwise eligible institutions for falsifying student attendance and grade records," and that "[t]he DOE relies on school-maintained records to monitor regulatory compliance," the court held that "[t]he government's reliance on colleges' accurate recordkeeping shows the importance of Heritage's initial promise to maintain accurate records."[35]

There are at least three cases, however, all in the Ninth Circuit, in which courts held that certain kinds of government knowledge will not defeat materiality. For example, in *United States ex rel. Brown v. Celgene Corp.,*[36] the court held that the government's reimbursement of prescription drugs for off-label uses "does not establish that the requirement [prohibiting off-label use] is immaterial as a matter of law."[37] Similarly, "[t]he fact that the FDA knew generally about off-label use does not mean CMS knew about and agreed to reimburse particular off-label claims."[38] And "the fact that CMS included off-label uses of Thalomid [the drug at issue] in a program designed to expand the scope of Medicare's prescription drug coverage on a temporary

---

33 *Id.* at 179.
34 *Id.* at 504.
35 *Id.* at 505.
36 226 F.Supp.3d 1032 (C.D. Cal. 2016).
37 *Id.* at 1050.
38 *Id.*

basis and for a limited number of patients does not show that CMS was willing to pay for these uses more generally."[39] This ruling is significant because off-label marketing is a frequent basis for FCA suits brought by relators. It suggests such cases will continue to proliferate in the future following *Escobar*.

In another case involving a pharmaceutical company, *United States ex rel. Campie v. Gilead Sciences, Inc.*,[40] the Court of Appeals for the Ninth Circuit, citing *Escobar*, reversed a district court's dismissal of a FCA suit.[41] The relator alleged that the defendant sourced ingredients for its anti-HIV drug therapies from a Chinese manufacturer that were not listed in its "new drug application" to the FDA.[42] The relator further alleged that the defendant concealed its use of ingredients from the Chinese manufacturer before the FDA formally approved the use of the Chinese source.[43] Additionally, it was alleged that the Chinese ingredients contained impurities, were contaminated, and were unable to pass internal testing.[44] The relator, noting that payment for drugs by federal payers is contingent on FDA approval, contended that the FDA would never have approved the use of the Chinese manufacturing facility had it known of the ingredients' impurities, contamination, and failure to pass internal testing.[45] The relator further alleged that

---

39 *Id.*

40 862 F.3d 890 (9th Cir. 2017).

41 *Id.* at 895.

42 *See id.* ("In its NDA applications, Gilead represented to the FDA that it would source the FTC from specific registered facilities in Canada, Germany, the United States, and South Korea. But, relators allege that as early as 2006, Gilead contracted with Synthetics China to manufacture unapproved FTC at unregistered facilities.")

43 See id. at 896 ("For example, Gilead claims in its application that it had received three full-commercial scale batches of FTC from Synthetics China that passed testing and were consistent with or equivalent to FTC batches made from existing, approved manufacturers. Relators contend that this representation was false as two of three batches had failed internal testing.").

44 See id. ("One of the batches purportedly contained "residual solvent levels in excess of established limits" and other impurities. A second batch had "microbial contamination" and showed the presence of arsenic, chromium and nickel contaminants. Gilead did not report this to the FDA, but rather secured two new batches from the unapproved Chinese site and amended its PAS on April 24, 2009, to include the substitute data.").

45 See id. ("Relators allege that the drug products made with FTC affecting the quality and purity of the drug and produced at a different, uninspected manufacturing site are not FDA-approved. And, according to relators, had the FDA been aware of these issues, it would not have approved the use of the Synthetics China manufacturing facility.").

federal payers, such as Medicare, would not have paid claims for the anti-HIV drug therapies under Medicare Part D if they knew the drugs were contaminated, impure, or unable to pass internal testing.[46]

The materiality issue in *Campie* was this: just how much knowledge about the alleged violations did the government have? According to the defendant, the government continued to pay for the drugs after it knew of alleged FDA violations, and thus, those violations could not possibly have been material to the decision to pay claims.[47] The defendant noted the government issued a warning letter regarding impurities in the drug, it inspected the drug and issued a noncompliance letter regarding the Chinese ingredients, and that as a result, two recalls took place in 2014.[48] In other words, the defendant argued that continued FDA approval of the drugs after it became aware of certain noncompliance rendered the alleged violations immaterial for purposes of assessing implied false certification liability under the FCA.[49]

The *Campie* court distinguished the case from similar FCA cases, *Petratos* (discussed above), noting that in *Petratos*, there was no dispute that CMS would reimburse claims even with full knowledge of the alleged violations.[50] In contrast, in *Campie*, there was a dispute as to whether federal payors would reimburse claims if the government had knowledge of all the facts alleged in

---

[46] *See id.* at 897 ("Relators allege that because the drugs paid for by the government contained FTC sourced at unregistered facilities, they were not FDA approved and therefore not eligible for payment under the government programs.").

[47] *See id.* at 906 ("Here, Gilead insists that because the government continued to pay for the medications after it knew of the FDA violations, those violations were not material to its payment decision.").

[48] *See id.* ("[A] variety of facts that speak to the government's knowledge [include]…a September 2010 warning letter regarding impurities in the form of black specks and spots, a June/July 2012 inspection and noncompliance letter regarding product from Synthetics China, December 2012 and July 2013 inspections of a specific facility, and two recalls that took place in 2014.").

[49] *See id.* ("Gilead's argument is premised on the continued FDA approval of the drugs even after the agency became aware of certain noncompliance.").

[50] *See id.* ("In making its argument, Gilead specifically cites to *Petratos*, where the Third Circuit concluded the materiality standard was not met where the relator did 'not dispute that CMS would reimburse these claims even with full knowledge of the alleged reporting deficiencies.'" (citing *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 490 (3d Cir. 2017))).

the complaint. Moreover, there was a dispute over "what the government knew and when, calling into question its 'actual knowledge.'"[51] The court also noted that although the government might "regularly pay this particular type of claim in full despite actual knowledge that certain requirements were violated, such evidence is not before us."[52]

The post-*Escobar* decisions considering the FCA's materiality element also demonstrate that while the heightened evidentiary requirement for proving materiality will weed out some cases at the pleading stage, its greatest impact may be at the summary judgment state. Although *Escobar* raises the bar for pleading materiality, it is a bar that the government and relators will likely be able to clear in most cases. From there, however, their evidentiary climb becomes much steeper. First, claims at issue will have been paid long before litigation is commenced, often years before. Thus, the material facts are set and the government will have little meaningful ability to shape (or reshape) them. Second, the nature of agency regulation, practice, and decision-making is characteristically (although not invariably) more flexible than civil or criminal enforcement, and agency decision-makers often have greater discretion over how to address vendor non-compliance. In fact, agency officials are generally expected and required to consider programmatic needs when deciding the appropriate response to non-conforming goods, services, or regulatory paperwork. Proving that the administering agency has elected not to deny payment in favor of a more measured

---

51 *Id.*

52 *See id.* at 906-907. The court reached a similar conclusion in *Scott Rose v. Stephens Institute*, 2016 WL 5076214 (N.D. Cal. Sept. 20, 2016), finding the government's knowledge of an alleged violation was insufficient to render the violation immaterial. In *Scott Rose*, the relators alleged that the Academy of Art University (AAU) violated Title IV of the Higher Education Act's prohibition on paying any commission, bonus, or other incentive payment based on success in securing enrollments or financial aid to any person engaged in student recruiting. The court found "that the DOE's decision to not take action against AAU despite its awareness of the allegations in this case is not terribly relevant to materiality." The court explained "[t]he DOE did not cite any reason for this decision [not to take enforcement action], which could well have been based on difficulties of proof or resource constraints, or the fact that the truth of the allegations has yet to be proven. In such circumstances, the DOE's inaction does not provide any basis for the court to infer that the DOE had 'actual knowledge' of AAU's violations or chose not to act because it considered the ICB unimportant." It should be noted that the *Scott Rose* case is currently on appeal at the Ninth Circuit. Oral argument is in December 2017 and we expect a decision will come a few months thereafter.

remedy may be a decisive defense. Third, among agency contractors, some agencies are notorious for giving little, none, or vague guidance concerning what they expect from contractors in terms of regulatory compliance or how the agency will respond to non-compliance. (Indeed, it is the dearth of agency guidance that has spawned an entire industry of compliance consultants.) This reality of agency practice will likely make it difficult for the government to show a contractor knew or should have known a particular non-compliance would be material to the agency's decision to pay. Fourth, defendants' employees will often be well-versed in the range of responses the regulatory agency makes to instances of non-compliance. If an agency routinely pays a particular type of deficient claim, a contractor would reasonably expect that deficiency was immaterial.

The takeaway from this aspect of *Escobar* is that discovery concerning the payment agency's decision may be key to establishing or defeating materiality in implied certification cases. For example, deposition testimony of government officials or other record evidence will be needed to show that the government would (or would not) have acted differently regardless of whether the defendant actually violated a statutory, regulatory, or contractual requirement. Following *Escobar*, such evidence has taken on a new level of importance and will continue to do so in future litigation.

B. DOJ Enforcement Policy

The DOJ has also affirmed its commitment to policy initiatives that will bear upon the investigation and litigation of FCA cases; (1) dismissal of non-meritorious cases, (2) sub-regulatory guidance and (3) cooperation.[53] In discussing these policies, Acting Associate Attorney General Jesse Pannucio, balanced the Administration's commitment to pursuing "vigorous" False

[53] Press Release, Dept. of Justice, Acting Associate Attorney General Jesse Panuccio Delivers Remarks at the American Bar Association's 12th National Institute on the Civil False Claims Act and Qui Tam Enforcement (June 14, 2018), https://www.justice.gov/opa/speech/acting-associate-attorney-general-jesse-panuccio-delivers-remarks-american-bar (last viewed Nov. 29, 2018).

Claims Act Enforcement against "enforcement that is fair and consistent with the rule of law."[54] The policies appear to reflect the Administration's commitment to a more business-friendly enforcement policy.

1. Qui Tam Dismissal

Noting that, "[t]he number of qui tam suits has grown considerably since 1986 and now routinely clocks in at over 600 per year,"[55] the Department has recommitted to considering whether the relator's pursuit of a *qui tam* in which the Department has declined to intervene serves the public interest or "whether the Department should exercise its dismissal authority to advance the interests of the United States."[56] Non-meritorious cases consume limited resources and also lead to bad law, according to AAG Panuccio. "Thus, when declining intervention, and even throughout the life of the case, we have now instructed our attorneys to consider whether moving to dismiss an action would be an appropriate exercise of the Department's prosecutorial discretion under the False Claims Act."[57]

Prior to AAG Panucicio's statement, Michael Granston, Director of the Department's Civil Fraud Section, had issued what has come to be known as the Granston memo, which announced the Department's renewed commitment exercising its dismissal authority and outlined the seven factors the DOJ will consider in deciding whether to exercise that authority in a given case.[58] Those factors are:

---

54 *Id.*
55 *Id.*
56 *Id.*
57 *Id.*
58 Memorandum from Michael D. Granston, Director, of the Commercial Litigation Branch, Fraud Section to Attorneys in the Commercial Litigation Branch, Fraud Section and to Assistant U.S. Attorneys Handling False Claims Act Cases, Offices of the U.S. Attorneys (Jan. 10, 2018) https://www.fcadefenselawblog.com/wp-content/uploads/sites/561/2018/01/Memo-for-Evaluating-Dismissal-Pursuant-to-31-U-S.pdf (last viewed Nov. 29, 2018).

- "Curbing Meritless *Qui Tams*." The Department should consider dismissal where the *qui tam* complaint is facially lacking in merit or where investigation that the allegations lack substantive merit.[59]

- "Preventing Parasitic or Opportunistic *Qui Tam* Actions." Where a *qui tam* action duplicates a preexisting government investigation and adds no useful information to the investigation, dismissal may be warranted.[60]

- "Preventing Interference with Agency Policies and Programs. Where an agency recommends dismissal to avoid interference with its policies or the administration of its programs.[61]

- "Controlling Litigation Brought on Behalf of the United States." Similarly, where a *qui tam* action threatens the government's litigation prerogatives, dismissal may be appropriate.[62]

- "Safeguarding Classified Information and National Security Interests." Where a *qui tam* action threatens to compromise classified information or national security interests, dismissal, obviously, is appropriate.[63]

- "Preserving Government Resources." Where the costs to the government, such as discovery costs, attorney time or lost opportunity costs, "are likely to exceed any expected gain" dismissal is appropriate.[64]

- "Addressing Egregious Procedural Errors." Where a relator frustrates or interferes with the government's investigation, dismissal may be appropriate.[65]

The memorandum noted that the factors are not mutually exclusive and the Department may rely on one or more of the listed factors as well as factors not listed, where appropriate.[66] The Granston Memorandum provides additional guidance to Department attorneys considering whether dismissal of a non-intervened *qui tam* action is appropriate. Accordingly, practitioners confronted with the prospect of potential dismissal, whether relator or defense counsel, should familiarize themselves with the Granston Memorandum in planning their course of action.

---

59 *Id.* at 3.
60 *Id.* at 4.
61 *Id.*
62 *Id.* at 5.
63 *Id.* at 6.
64 *Id.*
65 *Id.* at 7.
66 *Id.*

2. Sub-regulatory Guidance

Consistent with the Administration's commitment to reducing regulatory burdens, AAG Pannucio reaffirmed the Attorney General's directive that "the Department will no longer issue any kind of binding sub-regulatory guidance" and its "hope" is that "other agencies will follow this example.[67] Importantly, for FCA enforcement, however, Attorney General Sessions has "instructed DOJ attorneys not to use our enforcement authority to convert sub-regulatory guidance into rules that have the force or effect of law."[68] Sub-regulatory guidance can, however, be used to explain existing law.[69] Thus, in the Department's view,

> [I]n the False Claims Act arena, where the allegations are that a party falsely certified to the government that it complied with certain laws, it is full consistent with Department policy to use a party's receipt of a guidance document as probative evidence of knowledge of the law that the document explains. But guidance documents that expand upon statutory or regulatory requirements should not be used by Department attorneys as the basis for contending that legal violations have occurred. That policy keeps government restrained and promotes the rule of law, notice, and due process.[70]

It is too early to gauge the impact this policy will have on FCA litigation. First, in the FCA context, existing case law casts doubt on the government's ability to predicate FCA liability on ambiguous terms unless the government issued formal guidance making the regulatory requirement clear. In *Safeco Insurance Co. of Am. v. Burr*,[71] the Supreme Court held that in the face of an ambiguous regulatory requirement, for liability to attach the government must show that it had issued interpretive guidance that warned the defendant away from the view it took.[72] In

---

67 Press Release, Dept. of Justice, Acting Associate Attorney General Jesse Panuccio Delivers Remarks at the American Bar Association's 12th National Institute on the Civil False Claims Act and Qui Tam Enforcement (June 14, 2018), https://www.justice.gov/opa/speech/acting-associate-attorney-general-jesse-panuccio-delivers-remarks-american-bar (last viewed Nov. 29, 2018).

68 *Id.*

69 *Id.*

70 *Id.*

71 551 U.S. 47 (2007)

72 *Id.* at 50 ("[N]o authoritative guidance has yet come from the Federal Trade Commission. Given this dearth of guidance and the less-than-pellucid statutory text, Safeco's reading was not objectively unreasonable, and so falls well short of raising the 'unjustifiably high risk' of violating the statute necessary for reckless liability.").

2015, the influential D.C. Circuit, relying on the *Safeco* decision, held that in the face of an ambiguous regulatory term a defendant cannot be found to have knowingly violated the FCA if the defendant's interpretation was objectively reasonable and the government issued no official guidance to warn the defendant away from its interpretation.[73] Thus, because the courts have already rejected efforts to premise FCA liability on ambiguous regulatory terms in the absence of official, clarifying guidance, it is unclear whether the Department's newly announced policy will significantly impact FCA law. The guidance should, however, be relevant to persuading the Department to decline cases premised on sub-regulatory guidance, as distinguished from liability premised on regulatory guidance that has been clarified by sub-agency guidance.

3. Cooperation

In perhaps the most interesting of AAG Pannucio's comments, he stated that FCA cases are subject to the Departments policy regarding cooperation, which in general has been linked more to criminal than civil investigations. He stated:

> We will continue, for example, to expect and recognize genuine cooperation of corporate entities accused of wrongdoing in both civil and criminal matters. We want to create incentives for companies to help us identify the individuals responsible for wrongdoing, because we remain steadfast in our resolve to hold such individuals accountable.
>
> I want to make perfectly clear that False Claims Act investigations are no exception to this policy on cooperation. Corporate defendants can receive a more favorable resolution for providing meaningful assistance to our False Claims Act investigations – from voluntary disclosure, which is the most valuable form of cooperation, to other efforts such as sharing information gleaned from an internal investigation and making witnesses available. Because the False Claims Act

[73] See *United States ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 283-284 (D.C. Cir. 2015) ("Because the government failed to establish that MWI knowingly made a false claim, we reverse. At the time MWI made the certifications, the government had yet to inform exporters that, contrary to MWI's understanding of 'regular commissions,' the term refers to what is normally paid in the industry, and not what an exporter had historically paid to an individual sales agent. Absent evidence that the Bank, or other government entity, had officially warned MWI away from its otherwise facially reasonable interpretation of that undefined and ambiguous term, the FCA's objective knowledge standard, as the Supreme Court clarified while this litigation was pending in *Safeco Insurance Co. of America v. Burr*, did not permit a jury to find that MWI 'knowingly' made a false claim." (citing *SafeCo*, 551 U.S. at 69-70 & n. 20)).

> allows recovery of treble damages and civil penalties, the Department has tremendous enforcement discretion with respect to structuring settlements that make the government whole while also providing a material discount based on a defendant's cooperation. Of course, the extent of the discount will depend on the nature of the cooperation and how helpful it is to the Department's investigation, including our pursuit of individual wrongdoers.[74]

In contrast to criminal cases, in which the United States Organizational Sentencing Guidelines,[75] and other Department policies and statements, provide guidance concerning how much benefit a defendant will receive by cooperating, the Department has offered virtually no guidance concerning how cooperation will benefit a FCA defendant. In the absence of specific guidance, practitioners would be well-served to consult analogous sources, such as the Sentencing Guidelines.

C. Conclusion

The evolution of FCA jurisprudence has been influenced by a tug of war between the Executive Branch and Congress seeking to expand the FCA's reach versus the Supreme Court, which with some exceptions strives to limit the statute's reach through a plain language approach to interpreting the statute. The past two years appear to signal a change in that relationship, however. The current administration's more business-friendly regulatory philosophy appears to be aligning with the Supreme Court's judicial philosophy, in that both favor limiting the government's power to regulate enforcement policy. Whether this new alignment is favorable depends on one's perspective. Defendants and defense counsel are no doubt pleased with these developments. Relators' counsel, by contrast, are no doubt frustrated. Regardless, for defense

---

[74] Press Release, Dept. of Justice, Acting Associate Attorney General Jesse Panuccio Delivers Remarks at the American Bar Association's 12th National Institute on the Civil False Claims Act and Qui Tam Enforcement (June 14, 2018), https://www.justice.gov/opa/speech/acting-associate-attorney-general-jesse-panuccio-delivers-remarks-american-bar (last viewed Nov. 29, 2018).

[75] United States Sentencing Commission, Guidelines Manual, §3E1.1 (Nov. 2016).

counsel, *Escobar* and DOJ enforcement policy initiatives provide new tools to obtain dismissal of meritless *qui tam* cases and to defeat litigated cases where the harm is more speculative than real.