THE
NATIONAL LAW REVIEW

Materiality Part II: Government Knowledge

SheppardMullin

Article By
Matt Turetzky
Sheppard, Mullin, Richter & Hampton LLP
False Claims Act Defense

- Government Contracts, Maritime & Military Law
- Labor & Employment

- All Federal

Wednesday, January 3, 2018

Editor's Note: This is the second in a five-part series on how U.S. district courts and courts of appeal have applied the materiality standard set forth in Universal Health Services, Inc. v. United States ex rel. Escobar, 136 S. Ct. 1989 (2016).

In the context of implied certification cases brought under the False Claims Act (FCA), materiality is simply whether an alleged statutory, regulatory, or contractual violation has some bearing on the government's decision to pay claims. It follows that when the government knows of the alleged statutory, regulatory, or contractual violations and pays claims anyway, then those violations could not possibly have been material to the government's payment decision. For this reason, the government's knowledge and its subsequent behavior in the face of that knowledge have tremendous implications for false certification defendants.

The *Escobar* decision did not go so far to say that government knowledge is a *per se* defense in a false certification case. But it came close. In full, here is what *Escobar* said about government knowledge:

[P]roof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement. Conversely, ***if the Government pays a particular claim in full despite its actual knowledge*** that certain requirements were violated, that is ***very strong evidence*** that those requirements are not material. Or, ***if the Government regularly pays a particular type of claim in full despite actual***

knowledge that certain requirements were violated, and has signaled no change in position, that is ***strong evidence*** that the requirements are not material.

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

With the exception of a few cases in the Ninth Circuit, the district courts and courts of appeal have issued decision after decision finding no materiality when the government makes payments to a contractor despite its knowledge of alleged violations.

In this article, we examine those decisions. First, we will discuss the many decisions from virtually every Circuit that has found no materiality when the government knows of alleged violations and continues to pay claims. Second, we will examine the cases that reach the opposite conclusion when armed with the same factual scenario—*i.e.*, cases that find materiality when the government has knowledge of alleged violations and takes concrete steps to stop payments. Third, we will look at the California decisions that have found no materiality despite possible government knowledge of alleged violations and see if there is any silver lining in these decisions. Fourth, we will take a look at an interesting case from the District of Columbia where the facts relating to government knowledge went both ways. And finally, we will look at who in the government needs to know to trigger government knowledge.

It is probably worth mentioning that we will not be discussing the so-called "government knowledge defense." Prior to *Escobar*, FCA cases that addressed government knowledge did so in the context of scienter. The thinking went (and still goes) that if the contractor informs the government of the facts comprising the alleged 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). But this series does not address scienter: it addresses materiality. So we are not going to cover government knowledge as a defense to the scienter element, (the "government knowledge defense") here. Rather, we are going to discuss what kinds of government knowledge trigger a finding of materiality in implied certification cases.

1. No Materiality When The Relevant Government Officials Are Aware of Alleged Violations

The vast majority of cases that have examined the issue have held that there is no materiality when the relevant government officials are aware of the alleged violations and nevertheless continue to pay claims.

For example, in *United States ex rel. Petratos v. Genentech, 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." *Id.* at 490. 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." *Id.*

Likewise, in a case we covered previously, *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.[1] 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. *Id.* at 667.

Similarly, in *United States ex rel. McBride v. Halliburton Co.*, 848 F.3d 1027 (D.C. Cir. 2017), another case we covered, 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 'very strong evidence' that the requirements allegedly violated by the maintenance of inflated headcounts are not material." *Id.* at 1034 (quoting *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2003 (2016)).

There are numerous other cases as well that have reached similar results. *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 rating inaccuracies, and was aware of the alleged fraud during the proscribed time period. Nevertheless, the Government continued to pay Moody's for its credit-ratings products).

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.

2. There Is Materiality When The Relevant Government Officials Are Aware of Alleged Violations And Take Action To Stop Payments

We have discussed how continued government payments in the face government knowledge of alleged violations render a violation immaterial. 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? The case law seems to say 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 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." *Id.* at 179.

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 the government puts for 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. *Id.* at 504. 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." *Id.* at 505.

Thus, government knowledge cuts both ways. When the government, armed with ***all*** of the facts alleged in a FCA complaint, refuses to pay claims or takes enforcement action, then greater potential exists for a court to find materiality.

3. California Cases Finding Potential Government Knowledge Does Not Affect Materiality

There are at least three cases, all in the Ninth Circuit, in which courts held that certain kinds of government knowledge are not sufficient to establish materiality. These cases either focus on differences between regulatory decisions and decisions to pay claims or the myriad reasons why an agency might not take enforcement action against a potential defendant.

For example, in *United States ex rel. Brown v. Celgene Corp.*, 2016 WL 7626222 (C.D. Cal. Dec. 28, 2016), 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." 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." 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 basis and for a limited number of patients does not show that CMS was willing to pay for these uses more generally." 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.*, 862 F.3d 890 (9th Cir. 2017), the Court of Appeals for the Ninth Circuit, citing *Escobar*, reversed a district court's dismissal of a FCA suit. The relator alleged that the defendant sourced ingredients for its anti-HIV drug therapies from a Chinese manufacturer that was not listed in its "new drug application" to the FDA. 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. Additionally, it was alleged that the Chinese ingredients contained impurities, were contaminated, and were unable to pass internal testing. The relator, noting that payment for drugs by federal payors 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. The relators further alleged that federal payors, 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.

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. 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. 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.

The *Campie* court distinguished the case from similar FCA cases, such as *Petratos*, discussed above, noting that in *Petratos*, there was no dispute that CMS would reimburse claims even with full knowledge of the alleged violations. In contrast, in *Campie*, there was a dispute as to whether federal payors would reimburse claims if it the government had knowledge of all the facts alleged in the complaint. Moreover, there was a dispute over "what the government knew and when, calling into question its 'actual knowledge.'" 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." *Campie*, 862 F.3d at 906-907.

Although the *Campie* decisions is unfortunate, it leaves some room for defendants armed with *actual* government knowledge. In *Campie*, there was a factual dispute over what the government knew and when. But when actual government knowledge is not in dispute, such as in *Petratos*, the prospects for dismissal remain strong.

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."

Again, not all hope is lost. As with *Campie* and *Brown*, there may be some silver lining in *Scott Rose*because it appears the DOE did not conduct an investigation before deciding not to take enforcement action. 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.

4. When The Facts Cut Both Ways, Expect No Help From The Bench

What about when government knowledge is not entirely clear? The obvious answer is there is a strong likelihood that the case will not be resolved by a dispositive motion on the issue of materiality. If you hope to avoid a jury, government knowledge cannot be wishy washy—it must be clear from the facts. Emblematic of this point is a case called *United States ex rel. Scutellaro v. Capitol Supply, Inc.*, 2017 WL 1422364 (D.D.C. Apr. 19, 2017).

The case is important because it shows how a court will handle government knowledge when an agency sends a contractor mixed signals. On one hand, GSA continued to award the defendant new contracts and did not complain about lack of TAA and BAA compliance during a Contractor Assistance Visit (CAV) despite the defendant's lack of country of origin information. On the other hand, GSA's New York office was sending the defendant multiple letters complaining about TAA and BAA compliance. Given these mixed signals, the court denied the defendant's motion for summary judgment, setting the stage for trial earlier this fall. Unfortunately, before the trial began, Capitol Supply declared bankruptcy, so we will never see how a jury would have resolved the factual dispute.

The best rule, in our view, seems to be TAA/BAA non-compliance cannot make an implied certification case. *See United States ex rel. Wood v. Allergan*, 2017 WL 1233991 (S.D.N.Y. Mar. 31, 2017) ("First, violation of the [Anti-Kickback Statute] is a far cry from an 'insubstantial' regulatory violation like, say, requiring 'that [government] contractors buy American-made staplers' rather than foreign staplers."). Indeed, Escobar seems to suggest as much. *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2004 (2006) ("To the Government, liability would attach if the defendant's use of foreign staplers would entitle the Government not to pay the claim in whole or part—irrespective of whether the Government routinely pays claims despite knowing that foreign staplers were used. . . . The False Claims Act does not adopt such an extraordinarily expansive view of liability."). Thus, *Scutellaro* highlights the fact that the materiality of GSA Schedule terms, such as TAA/BAA compliance, can be contentious despite language from *Escobar* suggesting compliance with domestic preference rules should not trigger a materiality finding.

5. Who in the Government Needs to Know?

It cannot be that the knowledge of just one employee within the federal government is sufficient to trigger knowledge on the entire government's behalf, can it? Well, actually, it can. It just depends on ***who*** in the federal government has knowledge of the alleged violations. *See United States v. Public Warehousing Company K.S.C.*, 2017 WL 1021745 (N.D. Ga. Mar. 16, 2017) ("[J]ust because one agency within the vast bureaucracy of the federal government has knowledge of a contractor's wrongdoing does not mean that the Defendants have a "government knowledge" defense. The issue is whether the actors actually involved in the contractual relationship are aware of the alleged fraud.").[2]

The person who is actually authorized to transact on the government's behalf is certainly a person whose knowledge should be imputed to the government for "government knowledge" purposes. In the government contracts context, the individual authorized to act on the government's behalf in the contractual relationship is the warranted contracting officer. These are individuals who are authorized in writing to "enter into, administer, or terminate contracts and make related determinations and findings." 48 C.F.R. (FAR) § 1.602-1. In the Medicare or Medicaid context, it could be the Medicare or Medicaid Administrative Contractor or even certain officials within CMS or the state department of health, depending on the allegations in the Complaint. In most cases, it is generally the government employee responsible for making the payment decision.

Where this gets tricky is when you are dealing with lower level personnel. For example, in the context of government contracts, the vast majority of government personnel are not warranted contracting officers. These individuals might be called "program managers" or some similar title. Although a tougher case, these individuals may bind the government based on a variety of legal theories (implied authority, ratification, or imputation of knowledge).

Conclusion

Government knowledge is a powerful defensive weapon when defending implied certification claims brought under the FCA. It is important, however, to make sure

you have the right type of government knowledge. In other words, did the paying agency know of the alleged violations and decide to pay anyway, or was the government knowledge in the hands of someone without authorization to pay claims? And did the government know of all the pertinent allegations or did it just have some general awareness that there may be certain billing issues that need to be investigated? With the *right* type of government knowledge in the possession of the *right* government employees, a motion to dismiss will have a high likelihood of success.

In Part III of our series on materiality after Escobar, we will discuss a topic closely related to government knowledge—why government inaction alone is insufficient to defeat a finding of materiality.

Part 1 here.

Part 3 here.

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

[2] Although the court referred to the "'government knowledge' defense," it is not clear whether the Court was referring to the government knowledge defense to scienter, or if it was referring to government knowledge in the context of a materiality analysis under *Escobar*, which the court cites in that same section. Regardless, the case highlights the difficulty of identifying who the relevant actors are in the contractual relationship. This is not the first time we have seen courts use the same labels to apply to multiple parts of the statute. *See United States ex rel. Stepe v. RS Compounding LLC*, No. 8:13-CV-3150-T-33AEP, 2017 WL 5178183, at *8 (M.D. Fla. Nov. 8, 2017) (distinguishing statutory materiality from *Escobar* materiality).