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FCA Materiality May Return To High Court

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(March 13, 2018, 3:14 PM EDT)

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In Escobar,[1] the U.S. Supreme Court held that a defendant could be found liable under the False Claims Act for submitting impliedly false claims for payment. Under the implied certification theory of liability, a claim for payment can be false if it is based on an implied representation that the individual or company who submitted the claim is in compliance with all applicable statutes, regulations, or government contract provisions, when in fact the individual/company is not in compliance. In ratifying this theory, however, the Supreme Court also imposed an important qualification on the plaintiffs: The government or any relator must demonstrate that the requirements at issue were material. Furthermore, the Supreme Court stated that "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."[2]

In other words, if the government continues to pay a contractor after becoming aware that the contractor is not complying with applicable statutes, regulations, or government contract provisions, then that acquiescence is strong evidence that compliance with those requirements is not material to payment and the contractor's noncompliance cannot give rise to FCA liability.

Since Escobar, the U.S. Courts of Appeal have weighed in on the materiality requirement and, in particular, on the issue of continuing payments. Until recently, their decisions generally followed the Supreme Court's guidance in Escobar regarding government acquiescence. In two recent cases, however, the Seventh and Ninth Circuits have suggested that this rule is not without exceptions and that, although government acquiescence is pertinent to the materiality inquiry, the government can walk back such acquiescence at the drop of a hat.

The General Rule: Continued Post-Violation Payments and Inaction by Government Agencies Are Evidence of Immateriality

In the months and years following Escobar, a number of circuit courts of appeals have weighed in on the issue of government acquiescence. In separate cases, the First, Third, Fifth and Seventh Circuits have found that continued payment and

inaction by government agencies that are aware of a contractor's noncompliance with applicable law or contract provisions constituted evidence that such noncompliance is not material to payment and cannot form the basis for FCA liability.

In United States ex rel. D'Agostino v. ev3 Inc.,[3] the relator alleged that his former employer, a medical device manufacturer, made misrepresentations to the U.S. Food and Drug Administration when it applied for and obtained the FDA's approval of two new devices. The relator alleged that these fraudulent representations had caused healthcare providers using the devices to submit false claims to the Centers for Medicare and Medicaid Services for reimbursement. The First Circuit stated that "[t]he fact that CMS has not denied reimbursement for Onyx in the wake of D'Agostino's allegations casts serious doubt on the materiality of the fraudulent representations that D'Agostino alleges."[4] The court added that "[i]n the six years since D'Agostino surfaced the alleged fraud, the FDA has apparently demanded neither recall nor relabeling of Onyx."[5] Accordingly, the court concluded that the relator failed to satisfy the materiality requirement and affirmed the district court's dismissal.

Similarly, in United States ex rel. Petratos v. Genentech Inc.,[6] the Third Circuit concluded that the relator did not satisfy the materiality requirement where the government appeared to acquiesce to the noncompliance. In that case, Gerasimos Petratos, then a health care analyst for Genentech, disclosed evidence to the FDA and the U.S. Department of Justice that Genentech was suppressing data that would have shown that its cancer drug had more severe side effects for certain patients than initially reported. Petratos alleged that this data would compel the company to file adverse-event reports with the FDA, and could affect whether the drug was "reasonable and necessary," a requirement for Medicare reimbursement. Despite knowledge of Petratos' allegations, however, neither the FDA nor the DOJ took action against the pharmaceutical manufacturer, and Medicare continued to pay reimbursement claims. Petratos brought an FCA action against the pharmaceutical company, but conceded that the government would have paid the claims with full knowledge of the alleged noncompliance. In light of this concession, the Third Circuit found that the alleged misrepresentations were not "material to the Government's payment decision."[7]

In United States, ex rel. Joshua Harman, v. Trinity Industries Inc., the Fifth Circuit continued to use the Supreme Court's logic. In that case, the Federal Highway Administration approved Trinity's guardrail end terminals, which allowed states to seek reimbursement from the FHWA for the installation of the terminals. The FHWA later found that Trinity had inadvertently omitted some of the design changes made to the terminal from the report sent to the FHWA. The testing and subsequent certification, however, were conducted on a terminal with the same design modifications as those that were later sold throughout the country. As a result, the FHWA concluded that the terminals were still eligible for reimbursement despite Trinity's failure to include the changes in the report.

In the qui tam action, Harman alleged that Trinity knowingly and falsely certified that its guardrail end terminals had been approved for reimbursement by the FHWA to induce state governments to purchase its end terminals. The Fifth Circuit rejected the claim, finding Trinity's inadvertent omissions concerning the design changes were not material to the agency's decision to reimburse states for installing the terminals. The Fifth Circuit emphasized that the FHWA had full knowledge of Harman's claims, yet determined Trinity's terminals still were eligible for federal reimbursement. The court thus concluded that Trinity's alleged misstatements were not material to the agency's payment decision and thus could not serve as a foundation for FCA liability.

The Fifth Circuit came to the same conclusion in Abbott v. BP Exploration & Production Inc.[8] Abbott concerned BP's Atlantis Platform, a semi-submersible floating oil production facility located in the Gulf

of Mexico. Keith Abbott, who previously worked for BP, alleged that BP lacked required documentation for the Atlantis and failed to obtain approvals as required by applicable regulations. Abbot filed a qui tam complaint alleging that BP falsely certified compliance with applicable regulatory requirements. The lawsuit prompted the U.S. Department of the Interior to conduct an investigation of BP's regulatory compliance. Thr DOI concluded that Abbott's allegation was unfounded and "found no grounds for suspending the operations of the Atlantis … or revoking BP's designation as an operator."[9] When the matter reached the Fifth Circuit, the court concluded that "when DOI decided to allow the Atlantis to continue drilling after a substantial investigation into Plaintiff's allegations, that decision represents 'strong evidence' that the requirements in those regulations are not material."[10] The court therefore held that the relator had failed to establish a violation of the FCA.

Finally, in United States v. Sanford-Brown Ltd.,[11] the Seventh Circuit rejected the relator's allegations for failure to meet the materiality requirement. In the case, the relator alleged that Sanford-Brown College (SBC) had submitted claims for federal subsidies under the Higher Education Act but had failed to disclose its noncompliance with HEA regulations. The court noted that the "subsidizing agency [the U.S. Department of Education] and other federal agencies in this case 'have already examined SBC multiple times over and concluded that neither administrative penalties nor termination was warranted.'"[12] The court therefore ruled that even if the relator's allegations were 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."[13] The government's theoretical ability to deny payment is insufficient under Universal Health to satisfy the "rigorous" materiality requirement, while actual denial of payment provides a stronger showing of materiality.

Recent Exceptions to the Rule: Government Action May Overcome Continued Payments and Government Inaction Does Not Require Dismissal

Although the government's continued payments after knowledge of a contractor's noncompliance with applicable laws and contract provisions generally are evidence that the contractor's compliance was not material to payment, the Seventh Circuit's decision in Luce introduced a wrinkle into that principle. In addition, although many of the post-Escobar circuit cases demonstrate that the government acquiescence will undercut FCA liability, the Ninth Circuit's decision in Gilead shows this evidence is not a silver bullet that requires dismissal of a complaint.[14]

In United States v. Luce,[15] Robert Luce falsely certified on annual verification reports that he was not currently subject to criminal proceedings so that his company could participate in the Fair Housing Act's insurance program. Three years after Luce's indictment, his company informed the U.S. Department of Housing and Urban Development's Office of the Inspector General about the pending criminal charges. Following an investigation, the investigator issued a referral for suspension/debarment. Luce later was debarred and his company went out of business.

In the FCA action that ensued, the district court held that Luce's false verification forms were material to HUD's decision to continue insuring mortgages originated by his company. On appeal, Luce contended that HUD's continued issuance of insurance for new loans originated by the company after the government learned about Luce's indictment showed that the forms were not, in fact, material. The Seventh Circuit disagreed. It found that Luce's false certification was material because "the Government's actions following its discovery of his fraud support, rather than undercut, a finding of materiality. Although new loans were issued, the Government also began debarment proceedings, culminating in actual debarment. There was no prolonged period of acquiescence."[16] Luce thus demonstrates that evidence of government acquiescence can be overcome where the government

cures that acquiescence through timely adverse action, such as suspension or debarment in response to a contractor's misconduct.

In Gilead, the Ninth Circuit considered whether the relators' complaint sufficiently alleged materiality. The case involved allegations that Gilead Sciences made false statements about its compliance with FDA regulations regarding HIV drugs. In its new drug application to the FDA, Gilead stated it would source the active ingredient from specific registered facilities in Canada, Germany, the United States and South Korea. The relators alleged, however, that the company actually contracted with Synthetics China to manufacture the ingredient at unregistered facilities. Gilead then brought the ingredient into the U.S. to use in its drugs, claiming that it was produced by the approved South Korean manufacturer. Relators argued that Gilead's claims seeking payment for noncompliant drugs were actionable under the FCA, while Gilead argued that because the government continued to pay for the drug after receiving multiple notifications of FDA violations, those violations were not material to its payment decision.

The Ninth Circuit concluded that, despite the FDA's knowledge of the violations and continued approval of the drug, the relators had pled sufficient factual allegations to support materiality under the FCA at this stage of the case because the "relators alleged more than the mere possibility that the government would be entitled to refuse payment if it were aware of the violations."[17] In doing so, the Ninth Circuit appears to disagree with the First Circuit's reasoning in D'Agostino. Indeed, in D'Agostino, the First Circuit concluded that "'the FDA's failure actually to withdraw its approval of [a medical device] ... precludes [the relator] from resting his claims on a contention that the FDA's approval was fraudulently obtained' and that 'the absence of some official agency action confirming its position and judgment in accordance with the law renders [a relator]'s fraud-on-the-FDA theory futile.'" The Ninth Circuit, however, rejected this conclusion as contrary to Escobar and argued that, while the FDA's approval of drugs is a prerequisite for the drug's coverage under reimbursement programs such as Medicare and Medicaid, the FDA's purpose is not to prevent fraud. Accordingly, the Ninth Circuit concluded the FDA's knowledge of regulatory violations and inaction cannot preclude FCA liability.

The Ninth Circuit's reversal in Gilead of the lower court's dismissal for failure to state a claim demonstrates that courts may allow cases to go forward despite continued payment and inaction by government agencies that are aware of a contractor's noncompliance with applicable law or contract provisions. Petition for certiorari in this case was filed on Dec. 26, 2017, and it is a key case to watch in 2018. The Supreme Court's decision in this case could go a long way to clarify whether, under Escobar, a complaint can satisfy the materiality requirement when there is evidence that the government had knowledge of the alleged violations, yet continued to make payments.

Takeaways

These recent cases demonstrate that, despite the Supreme Court's ruling in Escobar, FCA materiality questions remain and continue to be litigated. Although materiality is essential for FCA liability, the cases show that materiality can be a fickle thing. While government acquiescence in the face of a company's noncompliance with applicable laws, regulations and contract provisions suggests compliance with those requirements is not material to payment, the government can cure such acquiescence through aggressive adverse action. Companies thus should not assume government acquiescence means the contractor is out of the woods in terms of FCA liability. Companies therefore would be wise to continue to assess FCA liability and mandatory disclosure obligations thoroughly and in full recognition that government acquiescence may not always be a complete defense.

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[1] Universal Health Services, Inc., v. United States and Massachusetts, ex rel. Julio Escobar and Carmen Correa, 136 S. Ct. 1989 (2016).

[2] Escobar, 136 S. Ct. at 2003.

[3] United States ex rel. D'Agostino v. ev3, Inc., 845 F.3d 1 (1st Cir. 2016).

[4] Id. at 7.

[5] Id. at 8.

[6] United States ex rel. Petratos v. Genentech Inc., 855 F.3d 481 (3d Cir. 2017).

[7] Id. at 490 (quoting Escobar, 136 S. Ct. at 1996).

[8] Abbott v. BP Exploration & Production, Inc., 851 F.3d 384 (5th Cir. 2017).

[9] Abbott, 851 F.3d at 386.

[10] Id. at 388.

[11] United States v. Sanford-Brown, Ltd., 840 F.3d 445 (7th Cir. 2016).

[12] Id. at 447 (quoting United States v. Sanford-Brown, Ltd., 788 F.3d 696, 712 (7th Cir. 2015)).

[13] Id. at 448.

[14] United States ex rel. Campie v. Gilead Sciences, Inc., 862 F.3d 890 (2017).

[15] United States v. Luce, 873 F.3d 999 (7th Cir. 2017).

[16] Luce, 873 F.3d at 1008.

[17] Gilead Sciences, 862 F.3d at 907.