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The expanding False Claims Act materiality requirement

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JANUARY 29, 2018

There is a renewed focus on the Government's activities for purposes of the False Claims Act ("FCA") materiality analysis and as demonstrated by a number of recently issued decisions, the roster of relevant government actors is expanding.

The FCA imposes treble damages and penalties on anyone who "knowingly presents, or causes to be presented" false claims to the Government, 31 U.S.C. § 3729(a)(1)(A), or "knowingly makes, uses, or causes to be made or used," false records or statements "material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(B).

Under the implied certification liability theory, a defendant implicitly represents compliance with relevant contractual or regulatory provisions with each request for payment; undisclosed violations may render the request for payment a false or fraudulent claim under § 3729(a)(1)(A).

The Supreme Court's decision in *Universal Health Services, Inc. v. United States ex rel. Escobar*, -- U.S. --, 136 S. Ct. 1989, 2001 (2016) ("*Escobar*"), confirmed the implied certification theory as a basis for liability where two conditions are satisfied:

> First, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths.

The Court cautioned "that not every undisclosed violation of an express condition of payment automatically triggers liability." *Id*. Rather, the "misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be *material* to the Government's payment decision in order to be actionable under the [FCA]." *Id*. at 2002 (emphasis added).

The Court noted that regulation of the implied certification theory can be achieved through "strict enforcement of the Act's materiality and scienter requirements," requirements the Court described as "rigorous." *Id*. The Court went on to provide the following clarification as to application of the "demanding" materiality standard:

> If the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material. Or, if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material.

Id. at 2003-04.

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The court's emphasis on the Government's payment decision is notable. The statute itself defines materiality as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). And the Court noted this definition mirrors that used in other federal fraud statutes. *Escobar*, 136 S. Ct. at 2004.

Yet, Courts interpreting the FCA materiality requirement, both under the implied certification theory and under § 3729(a)(1)(B), are looking with increasing regularity beyond the Government's payment decision. Recent cases interpret materiality in light of the action or inaction of other Government entities to include the Government's debarment actions, intervention decisions, and regulatory approvals.

SUSPENSION, DEBARMENT, EXCLUSION

A recent case out of the Court of Appeals for the Seventh Circuit, *United States v. Luce*, 873 F.3d 999 (7th Cir. 2017), involved the Government's administrative remedies activities after learning of the fraud.

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The Government alleged that the principal of a mortgage company submitted false certifications by failing to disclose an indictment pending against him as part of his annual reverification.

The defendant argued that the omission was not material because the Government continued to approve loans originated even after learning of the false certifications and the pending charges.

The Seventh Circuit disagreed, stating, that although new loans issued, "the Government also began debarment proceedings, culminating in actual debarment."

It further noted that "[t]here was no prolonged period of acquiescence" after learning of the fraud.

The court referred to the regulations prohibiting the Government from doing business with individuals who have a criminal record and found that:

> [The Agency's] action upon learning of Mr. Luce's indictment and false certifications confirms the centrality of this requirement: It instituted debarment proceedings to end Mr. Luce's participation in the program. It did not simply refuse payment in one instance, but terminated its relationship with the loan originator so that no future payments could be made.

Id. at 1007.

INTERVENTION IN *QUI TAM* CASE

Two recent appellate decisions focus on the Department of Justice's decision of whether or not to intervene in the *qui tam* suit and its bearing on materiality.

In *United States ex rel. Badr v. Triple Canopy, Inc.*, 857 F.3d 174, 179 (4th Cir. 2017), the Fourth Circuit Court of Appeals found on remand from the Supreme Court that the Government's decision to "immediately intervene" suggested the alleged failure to provide guards who met the arms requirements was material to the Government's decision to pay the invoices.

Conversely, in *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 490 (3d Cir. 2017), the Third Circuit Court of Appeals found that the Government's decision not to intervene in the *qui tam* suit suggested the alleged false certifications were not material to the Government's decision to continue to pay claims for the affected drug.

REGULATORY APPROVALS OR CERTIFICATION

In *A1 Procurement, LLC, v. Thermacor, Inc.*, No: 2:15cv15, 2017 WL 2881350 (E.D.VA. July 5, 2017), the District Court for the Eastern District of Virginia looked to the action, or inaction rather, of a certifying body after learning of the non-compliance.

The defendant allegedly failed to comply with various continued eligibility requirements for certification by the Small Business Administration as an 8(a) Business Development company.

The court found the issues to be non-material because despite the SBA's awareness of the non-compliances, the SBA did not prematurely end or terminate defendant from the 8(a) program. The court recognized that by allowing the defendant to maintain the 8(a) certification, it could continue to obtain new 8(a) contracts.

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The *Petratos* decision is also notable for this topic. The relator claimed Genentech withheld adverse side effect data from the Food and Drug Administration ("FDA") and failed to file requisite adverse event reports that could have led to a label change for the drug.

Without the label change, doctors allegedly issued prescriptions, and patients sought reimbursement from federal programs, for the drug at dosages or frequencies that were more than medically necessary.

The Third Circuit found FDA's decision to not only maintain approval of the drug, but to increase the number of approved indications, even after learning of the concerns precluded a finding that the concerns were material.

The inclusion of additional Governmental stakeholders may favor companies in the long run. Companies facing Governmental investigation frequently cite to contrarian positions previously advanced by regulators, auditors, program officials, or contracting offices.

The Government usually resists these positions, noting that (a) Government officials cannot sanction violations of federal rules or waive violations after they occur, and (b) the settlement of matters involving fraud lies outside the purview of the contracting agencies and auditors. *See, e.g.*, 41 U.S.C. § 7103(c)(1) ("This section does not authorize an agency head to settle, compromise, pay, or otherwise adjust any claim involving fraud."); 48 C.F.R. § 33.210(b) ("The authority to decide or resolve claims does not extend to ... The settlement, compromise, payment or adjustment of any claim involving fraud."); Medicare Program Integrity Manual § 3.7.3.3 (2017),

available at http://go.cms.gov/2iUyMKx ("If it is believed that the overpayment resulted from potential fraud, a refund may not be requested from the provider until the potential fraud issue is resolved.").

But post-*Escobar*, there is a renewed relevance of the paying agency's action or inaction. Coupled with the newfound appreciation of the actions by other government stakeholders, companies may find themselves benefiting from the more holistic viewpoint.

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This article appeared in the January 29, 2018, edition of Westlaw Journal Government Contract.

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