



## *Escobar* Materiality Standard for Implied False Certification Claims Poses Acute FCA Compliance Challenge

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In the aftermath of the Supreme Court's 2016 decision to uphold the validity, "at least in some circumstances," of the "implied false certification" theory of liability under the False Claims Act (FCA), there has been extensive analysis of that decision's impact on pending and future FCA litigation. That analysis, which has played out in expert commentary as well as in lower court decisions, is notable for the breadth of continued disagreement over the meaning and impact of *Universal Health Services, Inc. v. United States ex rel. Escobar*.<sup>1</sup> The Court's endorsement of a "demanding" materiality standard for implied false certification claims and its refusal to implement a bright-line standard for determining the validity of such claims has resulted in significant variance in lower court rulings as to what is required to plead a plausible implied false certification claim. One year out from the *Escobar* decision, FCA litigants face continued uncertainty as to what conduct may lead to exposure under the implied false certification liability theory.

### False Claims Act

The FCA prohibits any person from knowingly presenting or causing to be presented a false or fraudulent claim for payment or approval.<sup>2</sup> A claim includes any request or demand for money or property made to the U.S. government, or to another recipient, if the money or property is provided or reimbursed by the government.<sup>3</sup> Violators of the FCA may be liable for per claim penalties and treble damages as well as exclusion from federal health care or other government procurement programs.<sup>4</sup>

In *Escobar*, the Supreme Court was confronted with a circuit split regarding the viability of the implied false certification theory of FCA liability. The implied false certification theory expands the FCA's reach to situations in which a party fails to disclose a violation of a statutory, regulatory, or contractual requirement relating to the submission of a claim. The First Circuit reinstated an FCA action against the defendants in *Escobar* previously dismissed by a federal district court and, in doing so, endorsed a broad implied false certification doctrine. The First Circuit held that whenever a defendant falsely misrepresents compliance with a "material precondition of payment," which precondition could be express or implied, the FCA is violated.

### *Escobar* Materiality Standard

The Supreme Court—in a unanimous opinion by Justice Thomas—reversed the First Circuit but endorsed the viability of implied false certification liability under a more narrowly tailored standard focused on the materiality of a defendant's misrepresentation. The Court held that the implied false certification theory may apply under the FCA where at least two conditions are satisfied: a defendant must (1) make a specific representation on a claim for payment to the government, and (2) knowingly fail to disclose noncompliance with a material requirement for payment, which failure renders that representation a "misleading half-truth" (even if the representation is true on its face).<sup>5</sup> Justice Thomas's opinion cautioned that "what matters is not the label the government attaches to a require-

ment, but whether the defendant knowingly violated a requirement that the defendant knows is material to the government's payment decision.<sup>6</sup> The Court explained further that not all undisclosed violations of express conditions of payment trigger FCA liability. Designation as a condition of payment is "relevant to but not dispositive of" a materiality inquiry.<sup>7</sup>

The Court explained that a requirement may be material where either a reasonable person would attach importance to the particular requirement or the defendant knew or had reason to know that the government attached importance to that requirement for purposes of paying a claim.<sup>8</sup> Evidence in support of (or against) the materiality of a requirement can include knowledge that the government consistently refuses to pay (or pays) claims where the government has actual knowledge of noncompliance with that particular statutory, regulatory, or contractual requirement.<sup>9</sup> That said, materiality "cannot be found where noncompliance is minor or insubstantial."<sup>10</sup>

The Supreme Court's *Escobar* holding is notable for its near-categorical refusal to endorse any universal, bright-line rules governing an implied false certification claim. The decision provokes a series of questions on materiality that individuals and entities who submit claims to the government will need to confront when considering potential exposure to FCA liability. On the one hand, the Court upheld the implied false certification theory. On the other hand, the Court emphasized that the materiality standard is "demanding" and "rigorous" and rejected FCA liability based solely on the label attached to a particular statutory, regulatory, or contractual requirement. This leaves open a wide area of interpretation as to what types of "specific representations" are sufficiently "misleading" as to substantiate an implied false certification claim. That uncertainty has made providing pre-litigation counseling on potential FCA liability even more complex. And, as arguments and briefs in *Escobar* repeatedly observed, the myriad overlapping requirements applicable to the provision of health care services create innumerable bases for a possible implied false certification claim.

### Government View of *Escobar*

In briefs and other filings following the *Escobar* decision, the government has emphasized that the post-*Escobar* materiality standard requires a holistic inquiry into a variety of factors to determine whether an alleged misrepresentation is actionable under the FCA. On remand in the *Escobar* case, the government specifically identified the following factors as relevant to a materiality determination, while also emphasizing that none of the factors standing alone is dispositive:<sup>11</sup>

1. Is the label the government gives to the requirement allegedly violated (for example, is it an express condition of payment)?
2. Does the requirement at issue go to the essence of the government's bargain with the contractor or individual/entity submitting the claim?
3. How pervasive or extensive is the alleged violation?
4. What has the government done in previous similar circumstances?

The government rejects the position that *Escobar* has implemented an outcome-determinative standard for materiality (that is, a misrepresentation is material if the government

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would not have paid the claim had it known). In *Escobar*, the Court also expressly rejected a more relaxed standard for materiality under the FCA, stating that 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."<sup>12</sup> The government has instead pointed to the FCA's statutory definition of "material"—"having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property"<sup>13</sup>—to advocate for a more expansive standard under which the government views as material those facts and representations that are important or substantial to the government's decision to pay a claim. This flexible standard provides the government with increased discretion to pursue implied false certification cases and, thus, increases the risk that minor noncompliance with a particular requirement could result in an FCA investigation or qui tam case.

### *Escobar* One Year Out

Unsurprisingly, in the aftermath of *Escobar*, interpretations of the Supreme Court's holding, and the "demanding" materiality threshold in particular, have produced inconsistent results. The absence of bright-line guidance, but the inclusion of examples of what may or may not constitute materiality, have led courts to varying conclusions based on the particular facts at issue. For example, the Third Circuit expressly cited *Escobar*'s "heightened materiality standard" in May 2017 as a basis for dismissing an FCA claim premised on alleged noncompliance that government agencies had known about and did not act on for years.<sup>14</sup> Similarly, in February 2017 the District of Columbia Circuit dismissed an FCA claim on materiality grounds, citing as "very strong evidence" against materiality the fact that the government audit agency had investigated the allegations and none of the costs at issue were disallowed.<sup>15</sup>

Alternately, on remand in the *Escobar* case, the First Circuit affirmed its prior revival of the relator's FCA suit, characterizing the Supreme Court's materiality test as requiring a "holistic approach" related to a payment decision "with no one factor being necessarily dispositive." In doing so, the First Circuit adopted the position on materiality advocated for by the government in that case.<sup>16</sup> And most recently, the Ninth Circuit relied on *Escobar* to revive an FCA complaint against Gilead Sciences, Inc. that alleges statutory and regulatory violations arising from Gilead's drug manufacturing.<sup>17</sup> Diverging from the Third Circuit's holding in *Petratos*, the Ninth Circuit held that the relators adequately pled material violations in accordance with *Escobar* even though the Food and Drug Administration did not withdraw its approval of the drugs in question after allegedly learning of the claimed noncompliance.<sup>18</sup> The Ninth Circuit distinguished *Petratos* by noting that the relator there conceded that the government would reimburse the claims with full knowledge of the alleged noncom-

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pliance, whereas the relator in *Campie* made no such concession. The court's opinion concluded that, by alleging "more than the mere possibility that the government would be entitled to refuse payment if it were aware of the violations," the relators met the *Escobar* threshold for an FCA claim.<sup>19</sup>

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## Practice Points

The absence of a bright-line standard governing the legitimacy of an implied false certification claim creates a significant compliance challenge, as prospectively determining whether potential violations of statutory, regulatory, or contractual requirements could give rise to an FCA claim necessarily requires some prediction concerning the materiality that the government may attach to a misrepresentation. The risks associated with improperly assessing the validity of an FCA claim also have increased due to the government's near-doubling of the FCA's per claim penalties. FCA defendants should pay close attention to the government's interpretations of *Escobar* for guidance regarding materiality and may consider consulting with legal counsel early on after discovering potential statutory, regulatory, or contractual violations.

The full measure of the "demanding" materiality framework for implied false certification claims currently is being litigated in multiple courts, so government contractors and others who submit claims for payment to the government should continue to review new decisions to inform their risk-management strategy. Counsel reviewing potential exposure to FCA claims should be aware that the government considers a variety of factors underlying an implied false certification claim, and that no one factor is dispositive. Entities concerned about potential FCA liability should undertake a holistic, multifactor review to aggregate information regarding the underlying claim, including (a) how a requirement was labeled, (b) whether that requirement is central to the government's agreement with the entity (for example, under the terms of a Medicare participation agreement), (c) the pervasiveness of an alleged violation, and (d) the government's previous actions in the instant or similar circumstances, if any (for example, government knowledge of the alleged noncompliance, and its reaction). Upfront analysis of specific facts relating to the government's previously cited factors for an implied false certification case may help clients negate or minimize the impact of a threatened FCA claim.

As judicial guidance continues to develop, the challenge posed by *Escobar* will be particularly acute in cases where the alleged

violation is a regulatory requirement not considered a condition of payment. The full reach of *Escobar* is still developing, but it is clear that *Escobar* has raised the stakes for FCA compliance in an already rigorous regulatory environment for government contractors and other recipients of government funds. **C**



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## Endnotes

- 1 136 S. Ct. 1989 (2016).
- 2 31 U.S.C. § 3729(a)(1).
- 3 31 U.S.C. § 3729(b)(2).
- 4 31 U.S.C. § 3729(a)(1); 42 U.S.C. § 1320a-7a(a)(1)(B).
- 5 *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S., 136 S. Ct. 1989, 2001 (2016).
- 6 *Id.* at 1996.
- 7 *Id.* at 2001.
- 8 *Id.* at 2002-03.
- 9 *Id.* at 2003-04.
- 10 *Id.* at 2003.
- 11 See Brief for the United States as Amicus Curiae Supporting Appellant, *United States ex rel. Escobar v. Universal Health Servs., Inc.*, No. 14-1423, at 9 (1st Cir. Aug. 22, 2016).
- 12 *Escobar* at 2003.
- 13 31 U.S.C. § 3729(b)(4).
- 14 *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 492 (3d Cir. 2017).
- 15 *United States ex rel. McBride v. Halliburton Co.*, 848 F.3d 1027, 1034 (D.C. Cir. 2017).
- 16 *United States ex rel. Escobar v. Universal Health Servs.*, 842 F.3d 103, 109 (1st Cir. 2016).
- 17 *United States ex rel. Campie v. Gilead Sciences*, Docket No. 15-16380 (9th Cir. July 7, 2017).
- 18 *Id.* at 33-34.
- 19 *Id.* at 34.