

THIRD CIRCUIT ISSUES DECISION EXPLAINING PLEADING STANDARDS AND MATERIALITY AFTER ESCOBAR

On May 1, 2017, the United States Court of Appeals released an important decision interpreting the False Claim Act's ("FCA's") materiality requirement in light of the Supreme Court's 2016 decision in *Universal Health Services Inc. v. United States ex rel. Escobar*. The case, *United States ex rel. Petratos v. Genentech*, revolved around allegations regarding the cancer drug Avastin. According to the relator, Genentech allegedly conducted a "formal campaign" to suppress and conceal clinical data that would have revealed that side effects in certain patient populations were more common and severe. As a result of the campaign, the relator alleged, Genentech avoided the requirement to file adverse event reports with the FDA and avoided more-restrictive FDA labeling. As a result, according to the relator, the use of Avastin was not reasonable and necessary in these patient populations and "the standard of care would have been to prescribe a lower dose of Avastin, a lower frequency of doses, or no dose at all." Essentially, the relator argued, doctors would have altered their of use and prescribing practices for Avastin. The district court dismissed the case for failure to state a claim, reasoning that whether a drug is reasonable and necessary is a determination for the FDA and not individual physicians.

ANALYSIS

Although the circuit court rejected the district court's reasoning, noting that a physician's actions can be relevant in determining whether a service or item billed to the government is reasonable and necessary, the Third Circuit affirmed the district court decision on the grounds that relator could not establish materiality.

As noted by the court, an FCA violation involves four elements: falsity, causation, knowledge and materiality. Materiality is defined by the FCA as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money." 31 U.S.C. § 3729(b)(4). Last year, in the groundbreaking *Escobar* case, [as explained more fully in a previous post](#), the Supreme Court expounded upon the FCA's materiality requirement, describing the requirement as "demanding" and "rigorous." As cited by the circuit court, *Escobar* stands for the proposition that "a material misrepresentation is one that goes to the 'very essence of the bargain.'" The circuit court continued, "[m]ateriality may be found where 'the government consistently refuses to pay claims in the mine run of cases based on noncompliance with statutory, regulatory, or contractual requirement'...On the hand it is 'very strong evidence' that a requirement is not material 'if the government pays a particular claim in full despite its actual knowledge that certain requirements were violated.'" Where noncompliance is "minor or insubstantial," materiality will not be found.

Applying *Escobar* to the matter before it, the Petratos Court held that the relator could not prove materiality for several reasons. First, there were no factual allegations showing that the government would not have reimbursed claims for Avastin if the alleged reporting deficiencies been cured. Indeed, the relator conceded that the government would have paid the claims with full knowledge of the noncompliance. As noted by the court, "where a relator does not plead that that knowledge of the violation could influence the government's decision to pay, the misrepresentation likely does not have a natural tendency to influence payment." Second, the relator failed to plead that CMS consistently refuses to pay claims like those alleged. Rather, the relator's allegations established that CMS would continue to reimburse the claims at issue with full knowledge of the alleged noncompliance. In fact, the relator had reported Genentech's actions to the FDA and neither the FDA nor the Department of Justice had taken any actions against Genentech as a result. In sum, the court held, the allegations were the type of minor or insubstantial noncompliance that the Supreme Court had noted would not be material and that the circuit court held are "not appropriate for a private citizen to enforce through the False Claims Act."

The court soundly rejected the relator's arguments that the campaign was material because "if physicians would have prescribed no or less Avastin, the government would have paid less claims" and that "the relevant question is whether Genentech's fraudulent misrepresentations were material to the *physicians'* determination," finding that the relator had conflated the FCA's materiality and causation requirements. According to the court, the relator's arguments were essentially a "but for" causation argument. In response, the court wrote:

The alleged fraud's effect on physicians is relevant to the extent that it caused claims eventually to reach CMS. That is, evidence of how the claim makes its way to the government should be considered under the causation analysis, while the materiality analysis

begins after a claim has been submitted. The materiality inquiry, in asking whether the government's payment decision is affected, assumes that the claim has in fact reached the government.

Here, the Third Circuit firmly held, citing several sister circuits, that "it is the government's materiality decision that ultimately matters...the alleged fraud must affect the United States' payment decision to be actionable."

PRACTICAL TAKEAWAYS

- It is the government's materiality decision that is dispositive. This does not change when an alleged misrepresentation flows through an intermediary in an indirect causation case.
- A relator's proof of causation, or proof that a claim reached the government, is irrelevant to establishing materiality.
- FCA defendants should examine a relator's pleadings carefully. If a relator fails to plead that knowledge of the alleged violation could influence the government's decision to pay or that the government consistently refuses to pay claims like those alleged, the allegations will likely be susceptible to dismissal on the grounds that the relator cannot meet the FCA's materiality requirement.
- Federal Circuit Courts continue to consistently apply a "heightened" materiality standard in light of *Escobar*, rejecting the **government's arguments that *Escobar* represented little change**.

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