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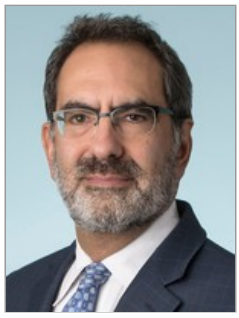
2017 Health Care Enforcement Review: Materiality Under FCA

By **Laurence Freedman and Jordan Cohen**



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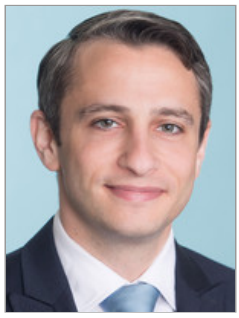

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Throughout 2017, the lower courts built upon the standard for determining materiality under the False Claims Act established by the U.S. Supreme Court in Universal Health Servs. Inc. v. United States ex rel. Escobar, 136 S. Ct. 1989 (2016). In Escobar, decided in June 2016, the court endorsed the "implied false certification" theory of liability under the FCA, premised on a "rigorous" and "demanding" element of "materiality." As expected, this decision triggered a spate of litigation over what "materiality" means, and how to apply this requirement.

This article, the third of four in our "2017 Health Care Enforcement Review" series, discusses developments related to the materiality requirement in FCA cases. Part 1 addressed several trends in FCA cases from 2017 and part 2 discussed some of the most important FCA-related court decisions from last year.

By way of background, the court held that the "implied false certification" theory has two elements:

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

The court described the materiality standard as centered on "the likely or actual behavior" of the agency that made the payment decision, not whether the agency had the legal authority to deny payment, as argued by the U.S. Department of Justice prior to the court's decision. To be material, the court reasoned, the misrepresentation must go to the essence of the bargain, and noncompliance cannot be "minor or insubstantial." The court noted that materiality can be determined based on a number of factors — none of which are dispositive — and held that a court's decision, though fact-specific, still could lead to dismissal on a motion to dismiss or at summary judgment. Those looking for additional background on the Escobar decision should see our "Health Care Enforcement Defense Advisory."

DOJ's Position

The DOJ has routinely filed briefs and statements of interest in declined cases to establish its view of the materiality requirement. The DOJ asserts that Escobar reaffirms the "natural tendency" definition of "materiality" as defined in the FCA and incorporated in the "false statements" prong of the statute. Under this view, Escobar does not require that the government or a relator "demonstrate that the government would in fact refuse payment" if it knew of the misrepresentation at issue. Instead, the DOJ has focused on the factors in the Escobar analysis. Further, the DOJ has argued that the Escobar analysis is an example of, rather than a limit on, the implied false certification theory.

U.S. Courts of Appeals

Materiality has become a central feature of litigation under the FCA. U.S. courts of appeal in seven circuits have analyzed the Escobar materiality requirement in a variety of contexts, and we highlight below a

number of decisions that set the stage for litigation in 2018. A number of cases were, in fact, dismissed at early stages based on the relator's failure to satisfy the materiality standard set forth in Escobar.

First Circuit

On Remand, Court Adopts a Holistic Approach

On remand in Escobar, the First Circuit found that the relator had met its burden on materiality based on "the holistic approach to determining materiality." The core of its reasoning was that, even though payment in full despite actual knowledge of legal violations can support a finding of materiality, the record lacked evidence of the relevant agency's actual knowledge of state law violations at the time it paid the claims.

A month later, in D'Agostino v. ev3, Inc., 845 F.3d 1 (1st Cir. 2016), the First Circuit affirmed dismissal under Rule 12(b)(6) in a case involving alleged fraud on the U.S. Food and Drug Administration. The court reasoned that "[t]he fact that [the Centers for Medicare & Medicaid Services] has not denied reimbursement for [the device] in the wake of [the relator's] allegations casts serious doubt on the materiality of the fraudulent representations that [the relator] alleges." Further, on causation, the court aptly noted that the FDA did not withdraw its approval of the device in the six years following the relator's allegations. Permitting the claim to proceed thus could "turn the FCA into a tool with which a jury of six people could retroactively eliminate the value of FDA approval and effectively require that a product be withdrawn from the market even when the FDA itself sees no reason to do so.

Third Circuit

Lack of Evidence the Government Would Not Have Paid Claims if it Had Known of a Drug Manufacturer's Alleged Shortcomings Is Significant

This past summer, in United States ex rel. Petratos v. Genentech Inc., 855 F.3d 481 (2017), the Third Circuit affirmed the dismissal of a qui tam case brought by a former employee who alleged that Genentech ignored and suppressed data about Avastin, one of its cancer drugs. According to the relator, this data would have shown that side effects for certain patients were more common and severe than initially reported. As a consequence, the relator claimed that Genentech caused physicians to submit Medicare claims that were not "reasonable and necessary," as Medicare requires. On that basis, the relator argued that the data suppression led to the submission of false claims to CMS.

On remand, the Third Circuit pointed to the district court's finding — which the relator did not dispute — that there were no factual allegations showing that CMS would not have reimbursed these claims had the alleged reporting deficiencies been cured. The court also focused on the government's actions, highlighting the fact that the FDA continued to approve Avastin — even for additional indications — after the relator had disclosed his evidence to the FDA and DOJ. For its part, the DOJ had not taken any action against the defendant in the intervening six years since the relator's disclosures. In dismissing the claim, the court described the relator's allegations as "much like the sort of 'minor or insubstantial' noncompliance that the Supreme Court explained [in Escobar] should not be litigated under the [FCA]."

Ninth Circuit

Continued Payment Is Not Dispositive if Regulatory History is Complex

With respect to the government's regulatory and payment decisions, the Ninth Circuit encountered a complex record in US ex rel. Jeffrey Campie, et al v. Gilead Sciences, Inc, 862 F.3d 890. In Campie, the relators argued that the pharmaceutical manufacturer Gilead contracted with a Chinese firm to manufacture unapproved ingredients at unregistered facilities. According to the relators, Gilead supposedly did not acknowledge or notify the FDA after it received bad test results and discovered contamination and adulteration problems in the Chinese-sourced ingredients. The relators argued that Gilead's drugs were not eligible for payment under government health care programs as a result of its use of ingredients that were sourced at unregistered facilities. According to the relators, if the FDA had known, it would not have approved the use of the Chinese manufacturing facility.

Like the defendants in Petratos, Gilead pointed to the government's continued payment for the medications — even after it knew of the FDA violations — as evidence that the violations were not material to the government's payment decision. The Ninth Circuit found this argument unconvincing, at least at the early stages of the case. The court agreed with the relators and the government that "to read too much into the FDA's continued approval — and its effect on the government's payment decision — would be a mistake." The court pointed to three reasons for that conclusion.

First, reading too much into the FDA's approval would allow Gilead to use an allegedly fraudulently obtained FDA approval as a shield against liability for fraud. Second, the FDA may have reasons to not withdraw a drug's approval that are unrelated to the government's concern about paying for nonconforming and adulterated drugs. Third, Gilead ultimately stopped using ingredients from the Chinese firm. According to the court, once that happened, the government's decision to keep paying for compliant drugs did not have the same significance as it would if the government had continued to pay despite continued noncompliance.

In deciding against dismissal as a matter of law, the panel in Campie specifically distinguished its facts from Petratos, particularly with respect to the factual dispute over the extent and timing of the government's "actual knowledge" of Gilead's violations.

Fifth Circuit

The Importance of Federal Agency's View of the Alleged Fraud Is Emphasized

This past fall, in another declined case, the Fifth Circuit granted dismissal in U.S. ex rel. Joshua Harman v. Trinity Industries Inc., 872 F.3d 645.[1] The Trinity case ended a dramatic and prolonged legal battle over whether Trinity Industries' highway guardrails used in state and federal projects were eligible for federal reimbursement or whether the design had changed in a way that violated applicable regulatory requirements and thus the FCA. Prior to trial, and with full knowledge of the relator's allegations, the Federal Highway Administration (FHWA) issued an official memorandum for the parties' use that concluded that "[a]n unbroken chain of eligibility for Federal-aid reimbursement [for the ET-Plus system] has existed since September 2, 2005 ..." The Fifth Circuit, considering a pre-trial mandamus petition, warned that the agency memorandum supported a "strong argument ... that defendant's actions were neither material nor were any false claims based on false certification presented to the government," but declined, barely, to issue a writ of mandamus. The district court declined to dismiss the case, held a jury trial and issued an astounding judgment against Trinity of $663,360,750 ($575 million in trebled damages, $138,360,750 in civil penalties, plus $19,012,865 in attorney's fees and costs).

On direct appeal, the Fifth Circuit decided that Trinity was entitled to judgment as a matter of law on the issue of materiality. As in Petratos, the Fifth Circuit's materiality analysis focused on actions taken by the government, including the continued payments for Trinity's guardrails as well the FHWA memo. The relator argued that the memo was incomplete because Trinity failed to disclose certain crash tests prior to the memo, but the court was unconvinced by this argument. Those looking for additional analysis of the Trinity decision should see our "Health Care Enforcement Advisory."

Commentary

As the courts grapple with the materiality analysis, a few takeaways are clear:

- The government's knowledge of the alleged violations underpinning the FCA claim is central to the reasoning of the courts of appeals, in terms of the qualitative nature of the government's knowledge (what it knew) and the timing of its knowledge (when it knew it). As stated well by the D.C. Circuit, "courts need not opine in the abstract when the record offers insight into the Government's actual payment decisions." U.S. ex rel. McBride v. Halliburton Co., (D.C. Cir. Feb. 2017). As a practical matter, counsel must develop a strong understanding of government knowledge of the alleged conduct (or similar conduct) and pursue supporting evidence in discovery.

- Courts of appeal are willing to decide, as a legal matter, that materiality is lacking. This avenue for dismissal might be particularly ripe with respect to allegations involving drugs and devices, typically with more attenuated theories of causation and fraud.

- As demonstrated by Trinity, the courts of appeal appreciate that the FCA is a tool for recovering federal funds that agencies would not have paid or authorized if they knew of the alleged fraud, which can be definitively refuted if the relevant agency's view does not support the allegation.

There is no doubt that the past year has been an important year in the evolution of the central issue of materiality in FCA cases. But given the lack of a prospective bright-line rule of materiality, the fact-sensitive nature of FCA cases and the continued drumbeat of cases brought by relators, we expect courts

to continue to grapple with issues of materiality through 2018.

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