# The First Circuit Rules On Materiality And Rule 9(b) In Two FCA Opinions

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On November 22, 2016, the United States Court of Appeals for the First Circuit issued two False Claims Act (FCA) opinions in the continuing debate over the parameters of the FCA. In *United States ex. rel. Escobar et al. v. Universal Health Services*,[1] in a victory for the relator construing the Supreme Court's June decision in the same case,[2] the Court found that Universal Health's (UHS) use of unlicensed mental health professionals would have been material to the state's decision to pay Medicaid claims and remanded the case back to the district court. In *Lawton ex. rel. United States et al. v. Takeda Pharmaceuticals International, Inc.*,[3] in a victory for the defendant, the Court found that the relator's claims failed to meet the particularity requirements of Federal Rule 9(b), and affirmed the district court's dismissal of the complaint.

The proceedings in Escobar offer a virtual primer in FCA interpretation issues over the last five years. Escobar's daughter, Yarushka Rivera, received mental health counseling at Arbour Counseling Services, a UHS subsidiary, for several years. In 2009, following an adverse reaction to medication prescribed by a supposed doctor at Arbour, Rivera died. After her death, her family learned that few Arbour employees were actually licensed to provide mental health counseling or authorized to prescribe medications. In 2011, they filed a *qui tam* lawsuit under the "implied false certification" theory of liability, alleging that Arbour/UHS had defrauded Medicaid by submitting claims for services that failed to disclose the violations of Massachusetts Medicaid regulations pertaining to staff qualifications and licensing requirements for these services.

The district court granted UHS's motion to dismiss on the ground that the relators had failed to state a claim under the "implied false certification theory" because the regulations cited by the relators were not conditions of payment. The First Circuit reversed in relevant part, broadly holding that every submission of a claim implicitly represents compliance with relevant regulations, and that any undisclosed violation of a precondition of payment (whether or not expressly identified as such) made a claim "false or fraudulent" for purposes of the FCA. While the case was closely watched as a test of whether the "implied false certification theory" was valid, the Supreme Court's decision was more nuanced. The implied false certification theory can be a basis for FCA liability when a defendant "fails to disclose noncompliance with *material* statutory, regulatory, or contractual requirements that make those representations misleading with respect to those goods or services" provided.[4]

Since the decision was issued in June, courts have grappled with the question of how to determine whether the requirements cited would have been material to the decision to pay the claims. In *Escobar*, the First Circuit was persuaded that Escobar's claims were clearly material because Massachusetts' Medicaid program, MassHealth, expects and requires that providers be in compliance with professional and licensing requirements. The case returns to the district court for discovery and further proceedings.

In *Takeda*, the First Circuit affirmed the lower court's decision that Lawton's complaint did not sufficiently plead that false claims had been submitted to federal and state programs. Lawton filed

1 *United States ex. rel. Escobar et al. v. Universal Health Services*, 14-1423 (1st Cir. Nov. 22, 2016).
2 *United States ex. rel. Escobar et al. v. Universal Health Services*, 136 S.Ct. 1989 (2016).
3 *Lawton ex. rel. United States et al. v. Takeda Pharmaceuticals International, Inc*, 16-1382 (1st Cir. Nov. 22, 2016).
4 *Escobar*, 136 S.Ct. at 1994 (*emphasis added*).

a qui tam in 2012, alleging that Takeda had engaged in an illegal off-label marketing campaign for its diabetes drug, Actos, and had paid illegal kickbacks as part of the campaign. The complaint alleged that Takeda developed a marketing scheme to develop and promote "quasi-scientific" research studies of Actos' efficacy for off-label use in treating pre-diabetes, and to encourage publications supporting the results of the studies. Lawton further alleged that the researchers and "thought leaders" promoting the studies were paid compensation, illegal kickbacks, and other indirect financial inducements from Takeda for their studies and supporting presentations. Takeda also allegedly established and tasked a specialized sales force to encourage physicians to prescribe Actos off-label for pre-diabetes, marketed Actos off-label directly, and made large contributions to several educational and research organizations to influence their views on the off-label use.

The First Circuit found that, while the complaint described Takeda's marketing machinations "at considerable length," it fell "well short of alleging, with the requisite amount of specificity, *who submitted false claims to the government, how many false claims were submitted to the government, or how the Defendants' actions resulted in the submission of false claims*."[5] (emphasis added). Because Lawton's "evidence and arguments proceed more by insinuation than any factual or statistical evidence that would strengthen the inference of fraud beyond possibility," the court agreed with the district court that the complaint failed under Rule 9(b).[6]

While the court's application of materiality in *Escobar* was likely, its refusal to overturn the district court's decision in *Takeda* on the basis of the pleading requirements in Rule 9(b) serves as a reminder that the submission of a false claim is the *sine qua non* of an FCA case, and that a properly-pleaded complaint is crucial to prosecuting FCA claims.

5 *Lawton*, 16-1382 (emphasis added).
6 *Id.*

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