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Relators Continue to Face Pleading Hurdles in FCA Cases Post-*Escobar*

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The Northern District of Illinois is the latest court to grant a defendant's motion to dismiss in a False Claims Act (FCA) case, after the relator failed to meet the substantial pleading burden established in the U.S. Supreme Court's 2016 *Escobar* decision (available at: https://www.pepperlaw.com/publications/lessons-from-a-year-of-escobar-2017-06-20/). In *United States ex rel. Thornton v. Pfizer*, the U.S. District Court for the Northern District of Illinois dismissed an FCA suit against Pfizer and its subsidiary, Hospira, Inc., because the relator, a former employee, failed to plead falsity with particularity under Rule 9(b) and failed to establish materiality. The decision reinforces that regulatory violations alone are not enough to get relators beyond Rule 9(b) and *Escobar's* materiality hurdle.

Background

In *Thornton*, the relator claimed that his former employer, Hospira, knowingly mischarged Medicare for defective and dangerous medical devices and that Hospira retaliated against him when he brought the issues to the attention of Hospira's senior management.

The relator claimed that the defendants were liable under an implied false certification theory of FCA liability because Hospira violated FDA regulations regarding reporting recalls, removals, and corrections, which in turn caused the government to make payments for claims it otherwise would not have.

Specifically, the relator alleged that Hospira — in an effort to avoid FDA scrutiny — engaged in a "silent recall" in 2015 to replace dangerous power cords for its Sapphire medical pumps, update software that caused the pumps to administer the wrong dosage of medication, and replace microbore sets that were prone to leak medication. The relator also alleged that Hospira partnered with another company to co-manufacture the pumps to avoid the FDA's import ban on Hospira, which was enacted in 2012 due to quality problems at Hospira's Costa Rican manufacturing plant.

Pfizer and Hospira moved to dismiss the relator's FCA claim.

Northern District of Illinois Decision

The district court granted the motion to dismiss, finding that the relator's implied false certification theory failed from the outset because the relator did not allege a single false claim submitted to the government. The court held that the relator's allegation that the defendants sell their products to hospitals, pharmacies, private citizens and other medical organizations and "therefore request payment and receive funds . . . from the U.S. and/or Illinois" was insufficient because, under governing Seventh Circuit precedent, a "simple demand for payment does not constitute a specific representation about the goods and services provided."

The relator further argued that Hospira's alleged regulatory violations were "omissions of relevant consequence" and therefore sufficient to plead falsity under his implied false certification theory. The court, however, concluded that these allegations were not enough. It held that a relator must plead an actual misrepresentation or omission under the FCA, stating:

> [T]he Seventh Circuit has made clear that even under an implied certification theory, "it is not enough to allege, or even prove, that [Defendants] engaged in a practice that violated a federal regulation. Violating a regulation is not synonymous with filing a false claim." Absent an allegation of a single claim, this Court cannot begin to determine whether Defendants' alleged regulatory violations misrepresented or omitted information about the Sapphire sets under the FCA.

(Internal citations omitted.)

Finally, the court added to the body of cases interpreting *Escobar's* "rigorous" materiality standard. The court explained that, even if the relator had pleaded falsity with particularity, the relator also failed to establish materiality because, among other things, he failed to allege that the government's decision to pay actually was, or would have been, different due to the alleged regulatory violations. The court stated:

> In implied certification cases, "materiality looks to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation," *therefore requiring specific facts showing that the Government's payment decision would likely or actually have been different if the Government knew about the alleged regulatory violation.*

In assessing materiality, the court also noted that the relator failed to "allege that compliance with the applicable reporting and safety regulations is expressly or implicitly a condition of payment." Citing the Fourth Circuit's decision in *United States ex rel. Rostholder v. Omnicare, Inc.,* the court distinguished regulatory violations from implied false certifications actionable under the FCA by explaining that "the Medicare and Medicaid statutes . . . do not require compliance with . . . FDA safety regulations as a precondition to reimbursement."

The court offered the relator only two weeks to amend his complaint, noting that the relator had previous opportunities to file a second amended complaint, yet failed to do so.

Implications

The *Thornton* decision once again illustrates that, following *Escobar*, a relator's pleading burden is substantial — particularly in cases brought under an implied false certification theory. Consistent with *Escobar's* observation that the "False Claims Act is not a means for imposing treble damages and other penalties for insignificant regulatory or contractual violations," relators must plead more than regulatory violations to survive a motion to dismiss.

Moreover, pharmaceutical and medical device companies, and other companies that do business with the government, are likely to prevail on a motion to dismiss (or other early dispositive motion) in FCA suits if they can show that the relator has not pleaded a misrepresentation or omission associated with an actual claim for payment or has not pleaded more than conclusory allegations regarding the government's actual or likely payment decision.