Whistleblower Defense Alert: Third Circuit Decision Erodes FCA Pleading Requirements

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By Victor A. Walton and Joseph A. Harper

The Third Circuit's recent decision in *U.S. ex rel. Foglia v. Renal Ventures Mgmt., LLC*, 2014 U.S. App. Lexis 10549 (3d. Cir. June 6, 2014), evens the circuit split regarding whether a FCA plaintiff must identify at least one representative false claim before being granted a ticket to discovery—a troubling development for anyone who does business with the federal government and therefore runs the risk of dealing with an FCA lawsuit. The Third Circuit joined the First, Fifth and Ninth Circuits in holding that a FCA complaint satisfies Rule 9(b) and should withstand a 9(b)/12 (b)(6) challenge so long as it provides "reliable indicia that lead to a strong inference that claims were actually submitted." The Fourth, Sixth, Eighth and Eleventh Circuits do not let off a FCA plaintiff so easily, requiring the identification of a false claim before embarking upon what is often expensive, protracted discovery.

In *Foglia*, a registered nurse formerly employed by defendant Renal Ventures brought a *qui tam* FCA suit in the United States District Court for the District of New Jersey, alleging that Renal Ventures, a dialysis services company, violated the FCA by falsely certifying that it was in compliance with state regulations regarding quality of care, falsely submitting claims for reimbursement for the drug Zemplar, and by improperly reusing single-use Zemplar vials. The district court found these allegations lacking under Rule 9(b), which requires that a party "state with particularity the circumstances constituting fraud or mistake," and dismissed the relator's claims. The district court's opinion focused on the relator's failure to identify even a representative sample of the false claims that were allegedly submitted, as well as his failure to allege with particularity how any alleged express or implied false certification related to a condition of payment.

In reversing the district court's decision, the Third Circuit did not delve deeply into the bases for the circuit split or its decision to side with what was, until *Foglia*, the minority rule. It stated that the requirement of identifying a representative false claim is "hard to reconcile [with] the text of the FCA," but did not further explain the textual analysis that

culminated in this view. The Third Circuit seemed to be heavily swayed by the Solicitor General's *amicus curiae* brief filed recently in *Nathan v. Takeda*, in which the U.S. Supreme Court declined to hear a case involving similar questions regarding FCA pleading requirements. The Court quoted from the Solicitor General's brief for the proposition that the "rigid" pleading standard required by the Fourth, Sixth, Eighth and Eleventh Circuits is "unsupported by Rule 9(b) and undermines the FCA's effectiveness as a tool to combat fraud against the United States." The Court contrasted this approach with the more lax standard applied previously by the First, Fifth and Ninth Circuits, which—again borrowing from the Solicitor General—it described as the more "nuanced" approach. Recognizing that one purpose of Rule 9(b) is to "provide defendants with fair notice of the plaintiffs' claims," the *Foglia* Court concluded that identifying a specific false claim was not a prerequisite to providing this notice. The Court did not comment on other well-established purposes of Rule 9(b), such as ferreting out frivolous FCA claims prior to engaging in costly and time-intensive discovery.

As we have pointed out in the past, to prevail on a false certification theory, a FCA plaintiff must show that the alleged false certification certified compliance with a rule, regulation, or other requirement that was a precondition to payment of a claim. *See* Whistleblower Defense Client Alert: How To Defeat An Implied Certification Claim. In *Foglia*, the Third Circuit effectively sidestepped this requirement by interpreting the relator's allegations that Renal Venture falsely certified compliance with Medicare regulations as a theory of factual falsity in disguise, which, critically, does not implicate the prerequisite to payment analysis. This re-styling of relator's allegations had a profound impact on the result of the case. Relator alleged that Renal Ventures overcharged the government for Zemplar, a drug that was used, at least by Renal Ventures, exclusively in five microgram vials. These vials were originally designed to be single-use—if less than the full five micrograms were used in treating a particular patient, the government could be billed for the full vial, but the remaining, unused Zemplar was to be discarded. However, in 2002, the Department of Health and Human Services began to allow "leftover" medicine in Zemplar vials to be re-used, provided that six specific conditions for safe re-use were followed. (The Court indicated that it was "highly doubtful" that these conditions for safe use were conditions of payment, but stated that this was not relevant to a factual falsity claim.) Relator alleged that Renal Ventures billed Medicare as if it were using the five microgram Zemplar vials in the single-use fashion, when it in fact harvested unused Zemplar and administered it, without complying with the conditions for multiple use outlined by HHS. Accepting the factual allegations in relator's complaint as true, the Third Circuit assumed that 1) patient logs would show that less Zemplar was used than would be required if it were used in a single-use fashion, and 2) Renal Venture did not follow the procedures that it was required to have followed in order to use the "leftover" Zemplar from partially used Zemplar vials. The Court concluded that relator had satisfied Rule 9(b) because Renal Venture had sufficient notice of the charges being leveled against it, and because documents that could "easily" prove or disprove relator's claims were in its exclusive possession.

Hopefully, the next Circuit Court to address Rule 9(b) pleading requirements in the FCA context will make clear that the *Foglia* approach remains the minority view. In the interim, peculiarities of the specific facts of this case and the Court's reasoning could potentially diminish its significance and the scope of its precedential impact. First, the Third Circuit expressly acknowledged that "[t]his is a close case as to meeting the requirements of 9(b)." Given this pronouncement, defendants will have good grounds to argue that any complaint alleging even marginally less detail than the complaint in *Foglia* does not comply with Rule 9(b). Second, the Court reasoned that specific billing records that "could easily prove the claim one way or another" were accessible to defendant "Renal, and only Renal." It is rare that FCA claims

are so easily resolved through limited discovery, and the key documents are not always in the exclusive possession of the defendant. Finally, at least according to the relator, there is an apparent inconsistency within the Court's opinion. The Third Circuit stated that, to satisfy Rule 9(b), a relator must provide details of a scheme to submit false claims "paired with reliable indicia that lead to a strong inference that claims were actually submitted." Later—in the same paragraph—it concluded that relator's allegations were "not enough to establish a 'strong inference' that false claims were submitted." Nonetheless, the Court held that relator had met the Rule 9(b) pleading standard. On June 20, 2014, Defendant Renal Ventures filed a petition for rehearing on this basis, arguing that the Third Circuit's holding was inconsistent with its own articulation of Rule 9(b).

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