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A Material Change: FCA Defendants Confront Altered Pleading Standard in Ninth Circuit after *Rose* and *Campie*

by Stephen A. Wood

In 2016 the U.S. Supreme Court handed down its decision in *Universal Health Services, Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016), a watershed in False Claims Act jurisprudence. The Petitioner asked the Court to decide whether the statute permitted liability for falsely certifying compliance with federal requirements where that certification was not expressly stated, but implied by a defendant's conduct. On that issue, the High Court held unanimously in the affirmative, resolving a conflict among the courts of appeals.

In response to defense arguments that the theory would dramatically expand the scope of False Claims Act liability, the Court sought to reassure government contractors that certain pleading and proof principles applicable to these cases would constrain post-*Escobar* expansion of False Claims Act liability. Expansive liability "'can be effectively addressed through strict enforcement of the Act's materiality and scienter requirements.' Those requirements are rigorous." *Escobar*, 136 S. Ct. at 2002 (citations omitted). The Court's statements regarding the element of materiality in particular have spawned significant litigation in federal courts throughout the country over what type and quantum of evidence bears on the question of whether a claimed violation is material.

Last year, I wrote in the *WLF Legal Pulse* about one such case, the U.S. Court of Appeals for the Ninth Circuit's decision in *United States ex rel. Rose v. Stephens Institute*, 909 F.3d 1012 (9th Cir. 2018), in which the Court of Appeals considered the effect of *Escobar* on existing Circuit precedent regarding false certification and materiality. That case resulted in a divided opinion affirming the trial court's application of *Escobar* in denying the defendant's motion for summary judgment. At the time of the *Rose* decision another Ninth Circuit False Claims Act case, *United States ex rel. Campie v. Gilead Sciences, Inc.*, 862 F.3d 890 (9th Cir. 2017), weighing the post-*Escobar* pleading of materiality, was before the U.S. Supreme Court on a petition for writ of certiorari. The Supreme Court recently denied that petition. Given that we cannot expect further guidance from the High Court on materiality in the near term, and because the courts in the Ninth Circuit have become popular venues for false claims suits, it is worth examining the state of the law on this issue in that circuit in light of *Escobar* and *Rose*.

The disagreement between the members of the *Rose* court was over the sufficiency of the evidence of materiality to create a fact issue in light of *Escobar's* holding. In short, the *Rose* majority held, consistent with *Escobar*, that whether the affected agency was aware of, and how it responded to, the claimed violation was central to the issue of materiality. Yet, evidence of the agency's past

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enforcement response regarding violations of others, considered in light of the evidence of the defendant's violation, even if the circumstances were different, could lead a reasonable factfinder to the conclusion that the violation was material, precluding summary judgment.

The dissent maintained that *Escobar* required the allegations and ultimate proof of materiality to be defendant specific, that a plaintiff has the burden to allege and prove that the agency would have responded to the defendant's claimed violations with meaningful enforcement. Because there had been no such defendant-specific showing, the dissent would have remanded the case for further discovery and, if warranted, motion practice.

In *United States ex rel. Campie v. Gilead Sciences, Inc.*, the Ninth Circuit also found the allegations of material violation to be sufficient under *Escobar*. In *Campie*, the relator claimed that the defendant drug manufacturer imported the active ingredient for its anti-retroviral drugs from a Chinese source that was not approved by the Food and Drug Administration and concealed this fact from regulators through various means. The defendant's use of non-approved ingredients allegedly resulted in contamination and adulteration of the product necessitating a recall, at the same time rendering them ineligible for reimbursement under federal and state health care programs. *See id.* at 896-97. The government declined to intervene in the case. Ultimately, the district court dismissed the action for failure to state a claim.

The Ninth Circuit examined the relator's pleading on various issues, including the issue of materiality. Defendant argued that the FDA continued to approve its drugs and reimbursement for their cost, despite knowing of the problems raised by the relators in their pleadings, leading to the conclusion that the violations, even if true, were not material:

> Gilead insists that because the government continued to pay for the medications after it knew of the FDA violations, those violations were not material to its payment decision. Relators outline a variety of facts that speak to the government's knowledge, such as a September 2010 warning letter regarding impurities in the form of black specks and spots, a June/July 2012 inspection and noncompliance letter regarding product from Synthetics China, December 2012 and July 2013 inspections of a specific facility, and two recalls that took place in 2014. Gilead's argument is premised on the continued FDA approval of the drugs even after the agency became aware of certain noncompliance.

Id. at 906.

In rejecting this argument, the Ninth Circuit noted that the relators alleged that the FDA's approval was fraudulently obtained, that is, the agency's approval was premised at least in part on inaccurate data and information that defendant knowingly submitted. What's more, the FDA may have had a number of reasons for continuing to approve the drugs at issue, reasons that took precedence over a potentially material concern regarding defendant's use of active ingredient from an unapproved source. Finally, the defendant eventually ceased using the Chinese source as a supplier, removing the adulterated condition and thus the FDA's need to withdraw its approval. *Id.* at 906-07. Because the parties disputed what the government knew and when, theirs was a dispute over "matters of proof, not legal grounds to dismiss relators' complaint." *Id.* at 907. Importantly, the Court of Appeals did not consider whether the complaint passed muster under Rule 9(b), "as that question was not addressed by the district court." *Id.*

As noted above, the defendant in *Campie* sought review of the Ninth Circuit's decision before the U.S. Supreme Court. Although materiality was only one of several issues the Ninth Circuit considered, the defendant argued that the Court of Appeals' decision was out of step with *Escobar* as well as decisions from other federal circuit courts on the issue of materiality. Before deciding the fate of the petition, the Supreme Court invited the federal government to weigh in on the matter.

Eventually, the Solicitor General filed an *amicus* brief supporting the Ninth Circuit's application of the law, urging denial of the petition. Shortly thereafter the Supreme Court obliged. Notably, in its *amicus* brief the government indicated that it would seek dismissal of the action on remand based on its review of the allegations, investigation of the merits of the relator's claims, and to avoid the possibility of burdensome discovery of the government that would "disserve the interests of the United States." Brief for the United States as Amicus Curiae at 15, *Gilead Sciences Inc. v. United States ex rel. Campie*, No. 17-936, *petition for cert. denied*, 2019 WL 113075 (Jan. 7, 2019).

Both the government and the *Campie* relators argued that this case was a poor vehicle for clarifying the materiality standard or determining whether the Ninth Circuit got it right. For one, materiality was not the only or even primary issue before the Court of Appeals. In fact, the appellate briefing was complete before *Escobar* was decided. In addition, the Court of Appeals expressly declined to consider whether the relators' pleading was Rule 9(b) compliant "as that question was not addressed by the district court." *Campie*, 862 F.3d at 907.

It is likely that the Supreme Court denied cert in this case because the record was not adequately developed and because the government indicated an intention to dismiss the action on remand. The failure of the lower courts to address the Rule 9(b) issue was especially problematic. *Escobar* itself mandates that the elements of a claim under the False Claims Act must be pled with 9(b) particularity. In response to the argument that the materiality standard was too vague and fact intensive to permit disposition at the pleading stage, the Supreme Court held that ". . . False Claims Act plaintiffs must also plead their claims with plausibility and particularity under Federal Rules of Civil Procedure 8 and 9(b) by, for instance, pleading facts to support allegations of materiality." *Escobar*, 136 S. Ct. at 2004, n. 6.

Thus, the Rule 8 requirement to state a claim that is plausible on its face, as well as the Rule 9 requirement to plead a claim of fraud with particularity, govern pleading the element of materiality, as with all elements of a claim under the False Claims Act, and if those standards are not met, the action should be dismissed. In essence, the Ninth Circuit determined only that the pleading satisfied Rule 8 plausibility. Any statement by a reviewing court regarding Rule 9(b) arguably would have been *dicta*.

With cert denied, *Campie* remains good law in the Ninth Circuit. But because the *Campie* court did not address Rule 9(b), its value as pleading precedent is limited. From a Rule 9(b) perspective, the *Campie* relators' pleading should be suspect. In the face of evidence that the FDA continuously approved reimbursement for defendant's drugs, relators should have been required to allege facts showing why the violations were nonetheless material, facts evidencing the agency's reaction to the particular violations at issue. It is true that nonconsensual withdrawal of drug approval is relatively rare.

As long as the drug remains safe and effective for the approved indication, despite regulatory noncompliance or even deception in either the pre- or post-approval regime, approval may or may

not be withdrawn. But the failure to address the agency's rationale in this instance should have rendered the *Campie* complaint deficient. And for *Campie* to rest its holding on the argument that the FDA may have many reasons for not withdrawing approval of a drug seems, in essence, akin to alleging that the affected agency had the option to refuse payment, an allegation that *Escobar* teaches is insufficient.

Ideally, the plaintiff should have to plead facts specific to the defendant, both facts regarding the defendant's conduct and the government's reaction to the defendant's conduct. Under *Rose*, however, facts regarding the government's reaction in similar circumstances (in that case, the department's response to other violations of the incentive compensation ban) may suffice to establish materiality. And in that instance, the similarity of the violations of other parties will obviously be important. The more closely the violations of other parties resemble the defendant's, the more relevant those facts are to the issue of materiality. It would also appear that some enforcement response short of payment termination could satisfy the materiality requirement. And, finally, if no enforcement response can be shown despite government awareness, a scenario strongly suggestive of a lack of materiality, the plaintiff would need to plead and prove facts showing that the government nonetheless viewed the violation as material and did not take action due to a specific and compelling countervailing consideration.