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9th Circ. Decision Could Be A Bitter Pill For Pharma Cos.

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Law360, New York (August 8, 2017, 6:06 PM EDT) -- Last month, the Ninth Circuit revived a False Claims Act complaint that a lower court had twice dismissed for failure to state a claim. In United States ex rel. Campie v. Gilead Sciences,[1] the Ninth Circuit relied heavily on the U.S. Supreme Court's landmark decision in Universal Health Servs. Inc. v. United States (Escobar)[2] in holding that relators plausibly alleged an FCA violation under several theories of liability and in finding that the alleged violations could be material to the government's decision to pay for HIV drugs manufactured by biopharmaceutical giant Gilead Sciences.

In a request for an extension of time to file a motion for a rehearing, Gilead emphasized the decision's "enormous potential implications for the pharmaceutical industry," predicting that it "may open the floodgates to a host of False Claims Act cases in the Ninth Circuit based on pharmaceutical regulatory violations, even when the government and the Food and Drug Administration have declined to take any action." It remains to be seen if the FCA floodgates will hold, but the Ninth Circuit's application of Escobar — and the court's willingness to allow the FCA suit to advance and "wade into the regulatory regime" of the Food and Drug Administration — make the Campie decision an opinion worth reading.

Bad Allegations Make for Bad Law

In Campie, two former quality control staffers alleged that Gilead falsified information about its drug suppliers and concealed problems of adulteration in HIV drugs in order to gain U.S. Food and Drug Administration approval. According to the relators' complaint, Gilead represented that it would source the active ingredient emtricitabine (commonly known as FTC) from approved facilities. Instead, Gilead contracted with Synthetics China to manufacture unapproved FTC from unregistered facilities in China at a lower cost. Gilead eventually sought and received approval from the FDA to use Synthetics China as a supplier. However, by that point, Gilead had been using Synthetics China's FTC in its products for at least two years.

Relators also allege that Gilead falsified and concealed data in order to get Synthetics China approved by the FDA as a supplier. Gilead's application stated that it received three batches of FTC from Synthetics China that passed testing and were equivalent to

FTC made by approved manufacturers. According to relators, two of those initial batches failed testing because they were contaminated with arsenic, metal and microbes. Instead of reporting the failures, however, Gilead ordered two new batches and substituted their data in its application.

Relator's Theories of Falsity: Let Me Count the Ways

At the district court, the judge dismissed the case on several grounds including that the fraud was directed at the FDA, not the payor agency and that payment was not conditioned on compliance with FDA regulations.

On appeal, not only was the lower court's decision reversed, but the panel found that relator's allegations were sufficient to state a claim under three theories of FCA liability: (1) factually false certification, (2) implied false certification and (3) promissory fraud.

First, under the factually false certification theory, Gilead made a false statement by representing to the FDA that its active ingredients had been manufactured in approved facilities when in fact the company was using FTC manufactured by Synthetics China before the supplier was approved.

Second, under the implied false certification theory of liability, by submitting claims for payment or reimbursement for "FDA approved" drugs, Gilead impliedly certified that its drugs were manufactured at approved facilities and were not adulterated or misbranded, when in fact Gilead had acquired unapproved FTC from a Chinese supplier and had falsified the test results to conceal contamination. Quoting the Supreme Court's decision in Escobar, the Ninth Circuit found that Gilead's failure to disclose its noncompliance with FDA standards meant that "[t]he claims in this case do more than merely demand payment. They fall squarely within the rule that half-truths — representations that state the truth only so far as it goes, while omitting critical qualifying information — can be actionable misrepresentations."[3]

Third, the court held that the relator's allegations stated a claim under a promissory fraud theory of liability. Under this theory, liability attaches to each claim for payment submitted under a contract if the contract — or in this case, government approval — was obtained through false statements or fraudulent conduct. Here, the court found sufficient the allegations that Gilead fraudulently obtained approval of Synthetics China so that Gilead was eligible to receive government payments.

In performing the falsity analysis, the Ninth Circuit addressed the district court's finding that relators did not state a claim because the alleged fraud was directed at the FDA rather than a payor agency — i.e., Medicare or Medicaid. The lower court's ruling was consistent with recent decisions from other courts that have been reluctant to find liability when the alleged fraud was in the context of noncontract interactions with government regulatory bodies.[4] But the Ninth Circuit found that it is not the distinction between regulatory and payor agencies that matters, "but rather the connection between the regulatory omissions and the claim for payment." Because the government only pays for drugs that are FDA approved, Gilead's alleged misrepresentations to the FDA are what allowed the company to seek reimbursement from the payors.

Relators face "Uphill Battle" on Materiality but Surmount Motion to Dismiss

In Escobar, the Supreme Court narrowed its application of the implied certification theory of liability to situations where compliance with a statute, regulation or contractual provision was material to the government's decision to pay.[5] Rather than setting forth a bright-line rule for determining materiality,

the court's standard laid out several factors that could contribute to a finding of materiality, focused on how violations would affect payment in the real world.[6] For example, if the government regularly refuses to pay contractors that violate a particular requirement, this is evidence that the requirement is material. If the government regularly pays claims despite knowledge that a particular requirement has been violated, this indicates the requirement is not material.

In the 14 months since Escobar was decided, defendants in several cases have successfully argued that an alleged violation was not material to the government's payment decision because the government continued to process and pay claims despite having notice of the defendant's alleged or actual conduct.[7] Several of the appellate level decisions were resolved at the summary judgment stage, however, where there was evidence in the record showing government knowledge of the alleged violation. In contrast, Campie was before the Ninth Circuit on relators' appeal of a motion to dismiss, so the court's materiality analysis was limited to the pleadings.

In its opinion, the panel began its discussion of materiality by stating that relators faced an "uphill battle" to sufficiently allege materiality under Escobar. The court observed that during the relevant period of time, the government continued to make direct payments and provide reimbursements for the drugs despite its awareness of FDA violations. For example, the government did not withdraw FDA approval after finding impurities in the drugs or after two recalls of contaminated products. Nonetheless, the court refused to find, at the motion to dismiss stage, that the violations were not material:

> "[T]o read too much into the FDA's continued approval — and its effect on the government's payment decision — would be a mistake. First, to do so would allow Gilead to use the allegedly fraudulently-obtained FDA approval as a shield against liability for fraud. Second, as argued by Gilead itself, there are many reasons the FDA may choose not to withdraw a drug approval, unrelated to the concern that the government paid out billions of dollars for nonconforming and adulterated drugs. Third ... Gilead ultimately stopped using FTC from Synthetics China. Once the unapproved and contaminated drugs were no longer being used, the government's decision to keep paying for the compliant drugs does not have the same significance as if the government continued to pay despite continued noncompliance."

The court also emphasized that the parties disputed what the government knew and when, calling into doubt whether the government had actual knowledge of any violation. Ultimately, the court decided that there were too many factual questions to resolve at the motion to dismiss stage. In sum, the court's ruling on materiality is narrow, but it underscores the difficulty of making a "government knowledge" challenge to materiality at the pleading stage before there is a developed record of what the government knew and when it knew it.

Serious Consequences for the Pharmaceutical Industry?

Campie is a case worth watching, whether it is reheard by the Ninth Circuit or remanded to the district court. As Gilead's post-decision filing observed, the panel's decision could have "serious consequences for the pharmaceutical industry." At the very least, Campie is a break from the Fourth Circuit's ruling in United States ex rel. Rostholder v. Omnicare Inc. In Rostholder, the Fourth Circuit held that once a drug is approved by the FDA, the submission of a reimbursement request for that drug could not constitute a "false" claim under the FCA on the sole basis that the drug had been adulterated in violation of FDA safety regulations.[8] Under Rostholder, the fact that a drug was FDA-approved gave pharmaceutical

companies some assurance that a manufacturing problem or issue with adulteration would be dealt with as a regulatory violation, rather than an FCA cause of action.

In its brief before the Ninth Circuit, Gilead relied on Rostholder to argue that the only way for a previously FDA-approved medicine to become ineligible for payment is for the FDA to withdraw approval of the drug. However, the Ninth Circuit — relying on Escobar — allowed the case to go forward because in addition to submitting claims for payment, Gilead misrepresented its compliance with FDA regulations by omitting critical information regarding compliance with FDA standards. In doing so, the Ninth Circuit has opened the door for more plaintiffs to attempt to transform FDA violations into FCA suits.

The Ninth Circuit recognized that other courts have cautioned against allowing claims under the FCA to intrude on the FDA's complex regulatory regime. But it was undeterred, reasoning that FDA approval could not preclude FCA liability, especially where such approval was allegedly procured fraudulently in the first instance, through the very misrepresentations at issue. Here too the Ninth Circuit's decision stands in contrast to the law in other circuits — specifically the First Circuit's 2016 ruling in D'Agostino v. EV3 Inc., in which the court upheld dismissal of a complaint alleging that misrepresentations about safety and training relating to a medical device "could have" influenced the FDA to approve the device, leading to later false claims.[9]

It remains to be seen what impact the Campie decision will have on the pharmaceutical industry as a whole, but there is little doubt the panel's decision could have serious consequences for Gilead. The company appears to have received over $5 billion from the federal government during the period in question. When that dollar figure is combined with the risk of treble damages, the Ninth Circuit's decision is likely a tough pill to swallow.

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[1] United States ex rel. Campie v. Gilead Scis. Inc., No. 15-16380, 2017 WL 2884047 (9th Cir. July 7, 2017).

[2] Universal Health Servs. Inc. v. United States 136 S. Ct. 1989 (2016).

[3] 136 S.Ct. at 2000.

[4] In re Plavix Mktg., Sales Practice & Prod. Liab. Litig. (No. II), 2017 WL 2780744, at *1 (D. N.J. June 27, 2017).

[5] 136 S. Ct. at 2003.

[6] Id. at 2002.

[7] See, e.g., United States ex rel. McBride v. Halliburton, 848 F.3d 1027 (D.C. Cir. 2017) (headcount data

could not have been material because the Defense Contract Audit Agency had investigated the relator's allegations and had not disallowed any charged costs); United States ex rel. Kelly v. Serco Inc., 846 F.3d 325 (9th Cir. 2017) (finding no materiality because government accepted cost reports despite knowing that such cost reports did not follow certain guidelines).

[8] United States ex rel. Rostholder v. Omnicare Inc., 745 F.3d 694, 701–02 (4th Cir. 2014); In re Plavix Mktg., Sales Practices & Prod. Liab. Litig., 123 F. Supp. 3d 584, 606 (D. N.J. 2015).

[9] D'Agostino v. EV3 Inc., 845 F.3d 1 (1st Cir. 2016).
