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CLIENT ALERT

One Step Closer to Building on *Escobar*

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The Supreme Court recently asked for the views of the Solicitor General in *Gilead Sciences, Inc. v. U.S. ex rel. Campie*, No. 17-936 (pet. filed Dec. 26, 2017). The case presents an opportunity for the Court to affirm the prevailing reading of *Escobar*: that the government's continued approval and acceptance of goods or services, after learning of the alleged falsity, renders that falsity immaterial and precludes an FCA claim absent countervailing evidence.

In 2008 and 2009, the federal government spent more than $5 billion on three HIV treatments marketed by Gilead Sciences: Atripla, Truvada, and Emtriva. The government predicated its purchases (through Medicare, Medicaid, TRICARE, and the FEHB) on approval by the Food & Drug Administration. The FDA may continue to approve of a drug even if it has been adulterated, misbranded, or if it departs from manufacturing guidelines. By contrast, the FDA *must* withdraw approval upon learning that "the [drug manufacturer's] application contains any untrue statement of material fact." 21 U.S.C. § 355(e).

The relators in *Gilead* alleged that some batches of emtricitabine—the active ingredient in Gilead's three drugs—were produced by an unregistered source, and that Gilead concealed that source through record manipulation, faulty certificates, and misleading labeling. The undisputed facts on appeal are that the government knew, through a variety of means, about Gilead's relationship with the unregistered source. Notwithstanding FDA's monitoring of Gilead's production and even "warning letters" outlining potential regulatory violations, FDA never rescinded its approval of Gilead's medicines. The case was filed in 2010 and amended in 2015—including an allegation that Gilead "continues to incorporate" the illicitly obtained ingredient. The Department of Justice never intervened (though it did file briefs in the district and appellate courts).

The Supreme Court stated in *Escobar* that "if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material." *Universal Health Servs., Inc. v. United States ex rel.*

Escobar, 136 S. Ct. 1989, 2002 (2016). Under this logic, the district court dismissed the relators' amended complaint. On appeal, the Ninth Circuit reversed. *U.S. ex rel. Campie v. Gilead Scis.*, 862 F.3d 890 (9th Cir. 2017).

The Ninth Circuit's reading of *Escobar* differs—materially—from its sister circuits'. In reversing the district court's dismissal of the case, the Ninth Circuit relied principally on its finding that the relators alleged "more than the mere possibility that the government would be entitled to refuse payment if it were aware of the violations." *Id.* at 907. While acknowledging that it was possible that the government regularly paid claims despite such awareness, the Ninth Circuit found that "such evidence is not before us." *Id.* The Ninth Circuit effectively shifted the burden to the *defendant* to demonstrate *immateriality*. That task is practically impossible at the motion-to-dismiss stage, when the well-pleaded facts in a complaint must be taken as true.

The Supreme Court in *Escobar* went out of its way to reject the argument that materiality is "too fact intensive for courts to dismiss [FCA] cases on a motion to dismiss." 136 S. Ct. at 2004 n.6. Thus, the Ninth Circuit's approach defies *Escobar*, which puts the burden on FCA plaintiffs to "plead their claims with plausibility," including the element of materiality. *Id.* As six other circuits have made clear, the better approach is to require plaintiffs to plead materiality, which requires more than the Government's mere "option to decline to pay," *Escobar*, 136 S. Ct. at 2003, and looks instead to "the likely or actual behavior of the recipient," *id.* at 2002.

The Solicitor General must now advise the Court on whether certiorari is appropriate to answer a question not presented in *Escobar*: whether an FCA complaint must be dismissed, absent some countervailing evidence, if the Government knows about the alleged misrepresentations and yet continues to pay claims fully. Although the logic of *Escobar* certainly suggests that result, *Gilead* would give the Court the opportunity to say so clearly.

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