CLIENT ALERT

The Solicitor General Provides an Unexpected and Quicker Path to Victory for Gilead

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Over seven months ago, the Supreme Court asked the Solicitor General for the views of the United States in *Gilead Sciences, Inc. v. United States ex rel. Campie*, an important False Claims Act case. Last Friday evening, the Solicitor General responded by asking the Court to deny certiorari. But what appeared to be a major setback for the Petitioner, Gilead Sciences, Inc., actually offered an unexpected route to victory. The Solicitor General agreed with the relators' (and the Ninth Circuit's) position that the Government's continued payment did not necessarily undermine the materiality of the alleged violations. But the Solicitor General told the Court that, were the case remanded to the district court, the United States would dismiss the case to avoid burdensome litigation costs and other litigation-related interference with government operations. That surprising announcement sheds further light on the DOJ's FCA-enforcement priorities, consistent with its recent amendments to the Yates Memo. Those developments provide valuable insight for companies facing *qui tam* FCA actions.

What Happened

In their complaint, the relators alleged that Gilead violated the FCA by concealing its use of contaminated drug ingredients supplied by a Chinese manufacturer that lacked FDA approval. The district court dismissed the complaint for failure to state a claim. The Ninth Circuit reversed, rejecting Gilead's argument that any misconduct was immaterial because the Government continued to pay for Gilead's products even after learning what Gilead had done.[1] The Ninth Circuit noted that the relators faced an "uphill battle" on the issue of materiality. But it ultimately decided that dismissal was premature, in part because of factual disputes about "what the government knew and when."[2] We reported on that decision here.

Gilead filed a petition for certiorari, asking the Supreme Court to clarify the materiality standard it announced in *Universal Health Services v. United States ex rel. Escobar*, a seminal case on which we reported here and here. *Escobar* held that the FCA's materiality requirement takes a variety of circumstances into account and 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."[3] Gilead asked the Supreme Court to resolve an alleged circuit split over how strong such evidence of past conduct is, arguing that Ninth Circuit's decision conflicted with the position of the First, Second, Third, Fifth, Seventh, Tenth, and D.C. Circuits. According to Gilead, those circuits require a relator to rebut evidence of continued Government payment with other evidence of materiality.

As we reported here, the Sixth Circuit recently addressed a similar question in *United States ex rel. Prather v. Brookdale Senior Living Communities, Inc.*, holding that a relator who makes no allegations about the Government's past payment decisions can adequately allege materiality by pointing to evidence that compliance with a given requirement went to the essence of the bargain and was an express condition of payment.[4] The defendants in that case have also petitioned for certiorari.

Friday's brief argued that the Ninth Circuit rightly interpreted *Escobar*, disagreed with Gilead that other circuits have adopted a stricter interpretation of the FCA's materiality requirement, and disagreed with Gilead that this case provides a suitable vehicle for considering the materiality question. Although the Solicitor General sided with the relators on many points, he shared Gilead's policy concern that the litigation could interfere with the FDA's regulatory objectives by allowing a jury to second-guess agency judgments.

But the Solicitor General concluded that those policy concerns do not support Supreme Court review. He explained that, under § 3730(c)(2)(A) of the FCA, the DOJ may dismiss *qui tam* cases even when they are meritorious.[5] And the Solicitor General assured the Court that the DOJ will exercise that authority if the Ninth Circuit's ruling remains in place. The Solicitor General observed that the DOJ could also end the litigation if the relevant agencies simply stated their view that Gilead's misconduct was not material to their payment decisions.

Historically, DOJ dismissal of *qui tam* cases has been rare. So why dismiss this case?

The Solicitor General explained that the decision to dismiss was based on the public interest and it takes into account both the DOJ's "thorough investigation of respondents' allegations" and the extensive costs of litigation. Among those costs, the Solicitor General emphasized the burdens of discovery, *Touhy* requests, and possible trial testimony—which would "distract from the agency's public-health responsibilities."

What It Means for FCA Enforcement

The Solicitor General's brief reinforces the DOJ's increased emphasis on factors other than the merits of the claims in making FCA enforcement decisions. It follows just one day after Deputy Attorney General Rod Rosenstein stated that civil prosecutors would place renewed focus on a defendant's ability to pay because "[t]he primary goal of affirmative civil enforcement cases is to recover money, and we have a responsibility to use the resources entrusted to us efficiently." We covered his speech, which announced changes to several Yates-era policies, here.

The DOJ's recognition of litigation costs factors into its dismissal decisions under a memorandum by Michael Granston, the Director of the DOJ's Civil Fraud Section, on which we reported earlier this year. The Granston Memo instructs prosecutors to consider several factors that could justify dismissal, including the importance of preserving government resources and preventing interference with agency policies and programs. The memo states that the DOJ should consider dismissal when expected gains do not justify expected costs, including the opportunity cost of foregoing other litigation with a higher or more certain recovery. It explains that government costs include the cost of monitoring or participating in litigation, responding to discovery requests, and potential liability for the litigation costs of defendants who prevail. Although DOJ dismissal usually occurs at or near the time that the DOJ declines to intervene, the Granston Memo notes that "there may be cases where dismissal is warranted at a later stage, particularly when there has been a significant intervening change in the law or evidentiary record."

Costs to defendants have featured alongside costs to the Government in more recent DOJ announcements. As we noted here, Deputy Associate Attorney General Stephen Cox followed up on the Granston Memo with a speech that noted the importance of

exercising the DOJ's dismissal authority to avoid "obvious" and "substantial" costs to both defendants and the Government. More recently, then-Acting Associate Attorney General Jesse Panuccio reaffirmed the importance of the DOJ's dismissal power and noted that meritless *qui tam* actions "impose substantial costs on defendants and the judiciary," as well as on the DOJ and other agencies. We covered his speech here and here.

Not every Circuit has embraced the DOJ's dismissal power with equal warmth. The D.C. Circuit recognizes an "unfettered right" for the DOJ to dismiss FCA cases.[6] But the Ninth and Tenth Circuits require the DOJ to (1) identify a valid purpose for dismissal and (2) show a "rational relation" between that purpose and the dismissal.[7]

Although the DOJ enjoys significant discretion even under the Ninth and Tenth Circuits' more restrictive rule, the Northern District of California recently denied a DOJ motion to dismiss in *United States v. Academy Mortgage Corporation*.[8] Like the motion that the DOJ plans to file in *Gilead*, the DOJ's motion in *Academy Mortgage* sought dismissal because of the costs of litigation. Unlike the motion that the DOJ plans to file in *Gilead*, the DOJ's motion in *Academy Mortgage* did not emphasize that the burdens of litigation could interfere with an agency's functions. Thus, *Academy Mortgage* focused solely on the issue of costs to the Government.

In *Academy Mortgage*, the district court denied the DOJ's motion to dismiss because "the Government failed to conduct a full investigation of the amended complaint."[9] Although the DOJ had investigated the relator's initial complaint, the amended complaint had a significantly broader scope. The court determined that the DOJ could not invoke litigation costs as a valid purpose for dismissal without meaningfully assessing the potential proceeds from the suit, as amended, and that the standard of rationality required a full investigation of the allegations in the relator's amended complaint.[10] The DOJ appealed that decision to the Ninth Circuit, which required express authorization from the Solicitor General. But the adverse decision from the district court does not appear to have discouraged the DOJ from seeking dismissal again, at least when armed with the argument that one of the costs of litigation could be disruption to agency operations. Interestingly, the same district judge presides over *Academy Mortgage* and *Gilead*.

The Solicitor General's brief also may make it more difficult for the petitioners in *Prather* to obtain certiorari on *Escobar* grounds. In his brief, the Solicitor General argued that the Sixth Circuit's decision is consistent with *Escobar* and the other courts of appeals.

What Companies Facing FCA Investigations Should Do

For FCA cases, persuading the DOJ is often the most important factor for a favorable resolution, particularly given the Granston Memo. So the DOJ's exercise of prosecutorial discretion and its renewed focus on non-merits considerations play an important role in FCA defense—even in circuits that may give less deference to DOJ motions to dismiss under 31 U.S.C. § 3730(c)(2)(A). The Solicitor General's brief reflects the view of the United States of America. Therefore, it effectively binds the entire DOJ, which

includes all U.S. Attorney's Offices. Companies facing FCA litigation can derive several defense strategies from the Solicitor General's brief in *Gilead*, especially when considered in light of other DOJ announcements.

- **Request DOJ dismissal based on anticipated litigation costs.** The DOJ will likely be receptive to arguments about opportunity cost and the costs of monitoring litigation, discovery (especially if there are complex questions about materiality that preclude a 12(b)(6) motion), answering *Touhy* requests, and making agency employees available to testify at trial. Where a case lacks merit, the DOJ may also consider the burden on the courts and potential liability for a prevailing defendant's costs.
- **Request DOJ dismissal based on potential interference with agency programs.** Defendants should argue this point when the burdens of discovery or trial could substantially disrupt an agency's functions.
- **Request DOJ dismissal even after DOJ has made an initial decision not to intervene.** The DOJ's increasing emphasis on cost-benefit analysis opens a door for defendants to present arguments and information not taken into account by an earlier decision on intervention. The DOJ will reevaluate litigation costs in light of adverse developments such as a lost motion to dismiss that opens the door to discovery on materiality.
- **Request agency statements on materiality.** Even if the DOJ decides not to dismiss an FCA case, contracting agencies can defeat a relator's claims by stating that they do not consider a violation material.

The Solicitor General's views on certiorari carry significant weight with the Court. In at least one recent term, the Court denied every petition for certiorari where the Solicitor General recommended denying certiorari. We will continue to monitor as this case develops.

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[1] *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 904-07(9th Cir. 2017).

[2] *Id.* at 906.

[3] *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1995 (2016).

[4] *United States ex rel. Prather v. Brookdale Senior Living Cmtys., Inc.*, 892 F.3d 822, 831-37 (6th Cir. 2018).

[5] *See* 31 U.S.C. § 3730(c)(2)(A) ("The Government may dismiss the action notwithstanding the objections of the person initiating the action if the person has been notified by the Government of the filing of the motion and the court has provided the person with an opportunity for a hearing on the motion.").

[6] *Swift v. United States*, 318 F.3d 250, 252-53 (D.C. Cir. 2003).

[7] *United States ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp.*, 151 F.3d 1139 (9th Cir. 1998); *United States ex rel. Ridenour v. Kaiser-Hill Co.*, 397 F.3d 925 (10th Cir. 2005).

[8] *United States v. Acad. Mortg. Corp.*, No. 16-CV-02120, 2018 WL 3208157 (N.D. Cal. June 29, 2018).

[9] *Id.* at *2.

[10] *Id.* at *3.

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