Updates
December 14, 2018

Belated Government Dismissal of False Claims Act Cases: DOJ Maneuvering in Post-Escobar and Granston Memo Era

The solicitor general filed an amicus brief in the U.S. Supreme Court last month supporting the relators' opposition to certiorari in *Gilead Sciences, Inc. v. United States ex rel. Campie, et al.*, No. 17-936. Yet the government's brief disclosed for the first time that it would dismiss the relators' *qui tam* complaint on remand, allegedly because discovery would interfere with federal agency responsibilities.

This follows the U.S. Department of Justice's hands-off approach notwithstanding extensive litigation between the *qui tam* relators and the defendants, and after district and appellate court decisions weighing in on the disposition of the case, which begs the question: why now?

The answer likely lies in the Justice Department's attempt to preserve a lenient pleading standard for materiality in the U.S. Court of Appeals for the Ninth Circuit. It may also represent tangible action wrought by DOJ's so-called "Granston memorandum" in January 2018, which foreshadowed a more rigorous DOJ posture toward dismissing abusive or burdensome relator-driven FCA litigation.

Government's Amicus Brief in *Campie*

When the U.S. Supreme Court asked the United States for its view on certiorari in a high-profile and extensively litigated *qui tam* False Claims Act case, the Department of Justice shocked nobody by agreeing that the relators had adequately pleaded materiality. *See* Brief of United States as Amicus Curiae at 8-14, *Gilead Sciences, Inc. v. United States ex rel. Campie, et al.*, No. 17-936 (U.S. Nov. 30, 2018). But the government's brief surprised most by indicating that it would nevertheless seek to dismiss the *qui tam* complaint once the case is remanded. *Id.* at 15-16. The government's justification for dismissal included the potential for "burdensome discovery" or disruptive "trial testimony" by agency employees, all of which, the government said, would interfere with the routine operation of the U.S. Food and Drug Administration (FDA). *Id.* at 15.

That justification would seemingly be in play for any *qui tam* action that would require significant testimony and document production by government officials, whether as here pertaining to materiality or relating to government regulatory guidance and/or interaction with the litigants. But discovery into materiality may be especially onerous given the materiality standard for submission of false claims articulated in *Universal Health Services, Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016), which generally expands the burden on the government for discovery into government payment decisions.

If the government does not want to respond to disruptive discovery—or discovery that could reveal actual knowledge of regulatory violations or of its payment practices—it can seek to use its authority to dismiss *qui tam* actions as an off-ramp. In FCA cases relating to drugs and devices, the government may also be keen to avoid imputed knowledge among multiple sub-agencies within a larger executive department, such as between the FDA and the Centers for Medicare & Medicaid Services (CMS) within the U.S. Department of Health and Human Services, as was the case in *Campie*. These developments suggest that FCA defendants should carefully evaluate whether discovery into materiality might encourage DOJ to jettison dubious *qui tam* litigation or claims.

Background on *Campie* and Post-*Escobar* Pleading Standards

In the *qui tam* complaint, relators allege that defendant Gilead received FDA approval for certain antiretroviral drugs used to treat HIV in the mid-2000s. *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 895-96 (9th Cir. 2017). In its applications for FDA approval, Gilead told the FDA that it would obtain the drugs' main ingredient from registered facilities in Canada, Germany, South Korea, and the United States. *Id.* at 896. Yet Gilead allegedly obtained that ingredient from a Chinese company called Synthetics China without informing the FDA. *Id.* A number of the produced batches were allegedly contaminated, and relators alleged that Gilead concealed other information about the drugs' alleged adulteration from the FDA. *Id.*

Gilead sought to dismiss the complaint for, among other things, a failure to plead with plausibility and particularity that Gilead's noncompliance with FDA requirements was material to CMS's payment decisions under *Escobar*. Gilead argued that relators did not plead sufficient facts to disprove that the regulatory violations were immaterial because the federal government continued to pay for the drugs even after the FDA sent noncompliance letters regarding Synthetics China, and because the FDA never revoked its approval of the drugs. *Id.*

Rejecting Gilead's argument, the Ninth Circuit concluded that to "read too much into the FDA's continued approval—and its effect on the government's payment decision—would be a mistake." 862 F.3d at 906. The court held that a *qui tam* complaint should survive a motion to dismiss the complaint on materiality grounds when "the parties dispute exactly what the government knew and when, calling into question its 'actual knowledge.'" 862 F.3d at 906-07. This opened the door to significant discovery on the issue of government knowledge and payment decisions.

DOJ's Granston Memorandum

Meanwhile, in January 2018, the Justice Department issued a memorandum authored by Michael Granston, Director of the Fraud Section of the Commercial Litigation Branch, regarding the government's exercise of its statutory authority to dismiss FCA actions under 31 U.S.C. § 3730(c)(2)(A). While DOJ has a fairly sparse history of exercising its right to dismiss *qui tam* cases out from under relators, the Granston memorandum appeared to signal greater willingness for DOJ to exercise that authority. The memorandum lists several factors DOJ attorneys should consider, including when "an agency has determined that a *qui tam* action threatens to interfere with an agency's policies or the administration of its programs and has recommended dismissal to avoid these effects." Granston Memorandum at 4. The Granston memorandum also identifies the preservation of government resources as another ground for dismissal, and it cautions government attorneys to consider whether "the government's expected costs [including responding to discovery] are likely to exceed any expected gain." *Id.* at 6.

The standard for dismissal is not demanding. There is a split in the circuits on this point, but the divide may be greater in appearance than in practice. The more lenient standard gives the government an "unfettered right" to dismiss a *qui tam* action. *Swift v. United States*, 318 F.3d 250, 252 (D.C. Cir. 2003). The more stringent standard requires that the government identify to the court how dismissal is rationally related to a "valid government purpose." *United States ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp.*, 151 F.3d 1139, 1145 (9th Cir. 1998). Further percolation testing the government's ability to dismiss is necessary to determine if this rational-relationship standard meaningfully limits the government's discretion.

Government's Belated Dismissal in *Campie*

Despite the government's considerable discretion in seeking dismissal, rarely has it exercised that discretion at the certiorari stage, particularly after sitting on its hands while the case was litigated through the district and appellate courts. *See* Brief of United States as Amicus Curiae at 15-16, *Gilead Sciences, Inc. v. United States ex rel. Campie, et al.*, No. 17-936 (U.S. Nov. 30, 2018). Consistent at least facially with the Granston memorandum, the government represented that it would seek dismissal on remand out of concern that discovery would interfere with the FDA's "public-health responsibilities." *Id.* The government also justified dismissal because it would help "minimize[e] expenses and burdens on government resources" that would otherwise be expended in discovery or at trial. *Id.* at 15-16.

There is something new about the government's approach here. The Justice Department may simply be flexing its statutory muscle in a manner consistent with the Granston memorandum to avoid the burdens of discovery over materiality ushered in by *Escobar*. On the other hand, the government may have been concerned that the U.S. Supreme Court would reject the Ninth Circuit's relaxed interpretation of the materiality pleading standard and in so doing choke off a wellspring of *qui tam* actions at the pleading stage.

The post-*Escobar* emphasis on materiality heightens the possibility of government dismissal, especially if litigation surrounding materiality implicates interference with the affected agency and government costs. As such, defense counsel is likely to litigate materiality with more frequency and depth, all the while pitching government attorneys on dismissal.

Practice Pointers

- Seek dismissal based on failure to allege facts supporting materiality with particularity, including past government payment practices regarding claims for similar violations
- Conduct discovery on the government agency regarding knowledge of alleged violations
- Conduct discovery on the government agency regarding past payment practices
- Pursue government dismissal based on agency interference or increased government costs if materiality at issue

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