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The Important Reasons DOJ Wants To Toss Gilead FCA Case

By **Derek Adams** (April 3, 2019, 6:08 PM EDT)

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Last November, the U.S. Department of Justice responded to the U.S. Supreme Court's invitation to file an amicus brief in Gilead Sciences Inc. v. United States ex rel. Jeffrey Campie et al., No. 17-936[1], a qui tam case alleging that Gilead covertly arranged to have key ingredients in certain pharmaceutical drugs produced at two non-U.S. manufacturing facilities with purported problems.

While expected to weigh in on the question presented for certiorari — does the government's continued payment for a product, after learning of allegations that the manufacturer made misrepresentations to the government regarding that product, require dismissal at the pleading stage of a suit under the False Claims Act[2] on the ground that any misrepresentations were not material as a matter of law — the DOJ took the opportunity to do the unexpected.

The DOJ's amicus first addressed the issue of materiality, agreeing with the relators that the complaint should not be dismissed at the pleading stage. The DOJ contended that "the government may have a variety of reasons for continuing to pay … for goods or services."[3] It explained that "the government may pay claims in order to keep federal programs operating, and to ensure compliance with the government's own legal and contractual obligations" or it "may have investigated the allegations but concluded (perhaps incorrectly) that no violation has occurred."[4]

Furthermore, the government "may have investigated and found past violations but believe (perhaps incorrectly) that the defendant will comply going forward."[5] The DOJ stressed that all of these potential explanations do not imply "that the requirements alleged to have been violated were not material to the government's payment decision."[6]

Notwithstanding its agreement with the relators' legal position, the DOJ unexpectedly announced, much to the relators' chagrin, that it intended to move to dismiss the case pursuant to its authority under 31 U.S.C. § 3730(c)(2)(A). Under this provision, the DOJ may dismiss an action notwithstanding a relator's objection.

Two different standards — both deferential to the government's decision — have been applied by courts analyzing motions under 31 U.S.C. § 3730(c)(2)(A).[7]

In the U.S. Court of Appeals for the Ninth Circuit, where Campie was brought, the government need only show a valid governmental purpose that is rationally related to the dismissal.[8] In its amicus brief, the DOJ explained that its decision to dismiss was based on its thorough investigation of relators' allegations and the merits thereof, as well as potentially burdensome discovery and Touhy requests that might result if the litigation proceeded.[9] Following the DOJ's amicus filing, the Supreme Court denied cert and the case returned to the district court.

Last Thursday, the DOJ filed its motion to dismiss under 31 U.S.C. § 3730(c)(2)(A).[10] In contrast to its amicus filing, the DOJ detailed significant regulatory oversight of Gilead's manufacturing process by the U.S. Food and Drug Administration, both before and after relators filed their complaint.[11] The DOJ outlined three separate FDA inspections performed from March 2009 to March 2013 at one of two manufacturing sites in question, known as Synthetics China.[12]

The DOJ explained that the FDA may issue a "Form 483" if its investigators observe violations of the Federal Food, Drug, and Cosmetic Act,[13] but the FDA did not issue any Form 483s at the Synthetics China facility.[14] In addition, while the FDA identified corrective actions required at other facilities, it did not initiate any action that caused or required Gilead to stop production at any Gilead facility, recall any lots of the drugs at issue or remove the drugs from commerce.[15]

The DOJ pointed to the FDA's actions — and lack thereof — in support of its motion to dismiss. In addition to avoiding the burdens of discovery, the DOJ also sought to "prevent Relators from undermining the considered decisions of FDA and CMS about how to address the conduct at issue here."[16]

The DOJ wrote that "FDA took the actions that it deemed appropriate," and that relators' case "now asks a jury to find that different action was nevertheless required."[17] The FCA, the DOJ pontificated, "was never intended to allow a relator to substitute his or her own judgment for that of the government as to whether the government received the benefit of its bargain."[18]

Everywhere, FCA defendants' ears should all be perked up, as this sentiment echoes what they have been saying since Escobar on the issue of materiality. Indeed, Gilead's brief to the Supreme Court in Campie mirrors the DOJ's motion to dismiss. There, Gilead wrote:

> "If the alleged manufacturing infractions really were material, the [FDA] would not have stood by for years, and the Government would not have continued paying for Gilead's products without objection." [19]

While typically reserved in its motions to dismiss under 31 U.S.C. § 3730(c)(2)(A), the DOJ may have thought it necessary to elaborate on its reasons for dismissal, given the high-profile nature of the Campie case. The DOJ often walks a tightrope in these motions, providing enough information to support dismissal, yet avoiding language that may serve as fodder for defendants in other actions. This task becomes even more challenging when the DOJ delves into issues such as materiality to support dismissal.

To add one final twist to the Campie story, Judge Edward Chen, a judge in the U.S. District Court for the Northern District of California, will rule on the DOJ's motion to dismiss. Judge Chen is the only judge ever to deny a motion by the DOJ under 31 U.S.C. § 3730(c)(2)(A).[20]

In Academy Mortgage, Judge Chen denied the government's motion to dismiss, finding that the DOJ had not conducted a sufficient investigation of the relator's amended complaint.[21] FCA practitioners will be watching closely to see if Judge Chen grants the DOJ's motion in Campie.

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[1] Gilead Sciences Inc. v. United States ex rel. Jeffrey Campie et al., No. 17-936.

[2] 31 U.S.C. § 3729 et seq.

[3] Brief for the United States as Amicus Curiae, Case No. 17-936, at 12 (Nov. 30, 2018).

[4] Id.

[5] Id. at 12-13.

[6] Id. at 13.

[7] Compare Swift v. U.S., 318 F.3d 250 (D.C. Cir. 2003) with U.S. ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp., 151 F.3d 1139 (9th Cir. 1998).

[8] United States ex rel. Sequoia Orange Co. et al., v. Baird-Neece Packing Corp. et al., 151 F.4d 1139 (9th Cir. 1998).

[9] Amicus Brief at 15.

[10] United States' Motion to Dismiss Relators' Second Amended Complaint, Case No. 3:11-cv-00941, Filed March 28, 2019 (N.D.Cal.).

[11] Id. at 4-5

[12] Id.

[13] 21 U.S.C. § 301 et seq,

[14] Id.

[15] Id.

[16] Id. at 10.

[17] Id.

[18] Id.

[19] Reply Brief for Petitioner, Filed March 20, 2018, at 1.

[20] United States v. Academy Mortgage Corp., 2018 WL 3208157 (June 29, 2018, N.D.Cal.). DOJ is appealing to the Ninth Circuit Court of Appeals.

[21] Id. at *3.