United States v. Gilead Scis., Inc.

Decided Nov 5, 2019

EDWARD M. CHEN United States District Judge

ORDER GRANTING UNITED STATES' MOTION TO DISMISS

Docket No. 183

Relators Jeff and Sherilyn Campie are former employees of Defendant Gilead Sciences, Inc., a pharmaceutical drug manufacturer. They have filed a qui tam action against Gilead, asserting, *inter alia*, a claim for violation of the federal False Claims Act ("FCA"). According to the Campies, Gilead violated the FCA by submitting or causing to be submitted false claims for payment under government payment programs such as Medicare and Medicaid. *See* 31 U.S.C. § 3729(a)(1)(A).

Previously, this Court granted Gilead's motion to dismiss the Campies' second amended complaint ("SAC"). The Court dismissed not only the FCA claim but also related claims based on state law, plus claims for retaliation under both the FCA and state law. On appeal, the Ninth Circuit reversed and remanded to this Court. Currently pending before the Court is the United States' motion to dismiss. Although the government is not a party to this action (having declined to intervene), it is a real party in interest and moves to dismiss pursuant to a provision in the FCA that states as follows: "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." 31 U.S.C. § 3730(c)(2)(A). The United States is moving to dismiss only the FCA claim, and not *2 any related claims based on state law or any retaliation claims, whether based on the FCA or state law.

Having considered the parties' and the United States' briefs and supporting documents, as well as the oral argument of counsel, the Court hereby **GRANTS** the motion.

I. FACTUAL & PROCEDURAL BACKGROUND

A. Operative Second Amended Complaint

As reflected in the Ninth Circuit's decision on appeal, the gist of the Campies' SAC is as follows. Gilead, a drug manufacturer, produces anti-HIV drug therapies, including the drugs Atripla, Truvada, and Emtriva. *See United States ex rel. Campie v. Gilead Scis.*, 862 F.3d 890, 895 (9th Cir. 2017). All three drugs contain the active ingredient embricitabine, commonly known as FTC. *See id.* at 896.

To sell the three drugs, Gilead had to obtain approval from the FDA by filing new drug applications ("NDAs").

> In its NDA applications, Gilead represented to the FDA that it would source the FTC from specific registered facilities in Canada, Germany, the United States, and South Korea. But . . . as early as 2006, Gilead contracted with Synthetics China to manufacture unapproved FTC at unregistered facilities. For a period of sixteen months beginning in December 2007, Gilead brought illicit FTC from a Synthetics China facility into the United States to use in its commercial drugs, claiming that the FTC had come from its approved South Korean manufacturer. . . .
>
> Gilead ultimately sought approval from the FDA to use Synthetics China's FTC in October 2008, but . . . had been including products from Synthetics China in its finished drug products for at least two years before this approval was obtained in 2010.

Id.

According to the Campies, Gilead also engaged in misconduct because it used "falsified or concealed data in support of its application to get Synthetics China approved by the FDA" - *e.g.*, Gilead claimed in its application that "it had received three full-commercial-scale batches of FTC from Synthetics China that passed testing and were consistent with or equivalent to FTC batches made from existing, approved manufacturers" but concealed the fact that two of the three batches actually failed internal testing. *Id*. "One of the batches purportedly contained 'residual solvent *3 levels in excess of established limits' and other impurities. A second batch had 'microbial contamination' and showed the presence of arsenic, chromium and nickel contaminants." *Id*. Instead of reporting the failure to the FDA, Gilead "secured two new batches and amended its [application] to include the substitute data." *Id*.

The Campies allege that Gilead violated the FCA because it sought payment for its drugs containing FTC either directly or indirectly from government programs, but payment for drugs under these programs is contingent on FDA approval and, "because the drugs paid for by the government contained FTC sourced at unregistered facilities, they were not FDA approved and therefore not eligible for payment under the government programs." *Id*. at 897. B. Procedural History

In March 2015, Gilead moved to dismiss the Campies' SAC. Although the government had declined to intervene in this lawsuit, it filed a statement of interest (as the real party interest) in response to Gilead's motion, just as it did when Gilead moved to dismiss an earlier complaint filed by the Campies. *See* Docket No. 129 (government's statement). Although the government did not take a position on the ultimate merits of the Campies' lawsuit, it made some arguments that were favorable to the Campies - *e.g.*, that the FCA can be violated even if the defendant did not make a "direct misrepresentation . . . to the payor agency" and that "a deviation from the drug manufacturing process approved by the [FDA] could be . . . tantamount to producing a drug that is not the same drug approved by the FDA, thereby potentially forming the basis of a FCA violation." Docket No. 19 (St. at 2-2).

In June 2015, this Court granted Gilead's motion to dismiss - dismissing not only the FCA claim but also all remaining claims, including those based on retaliation. *See* Docket No. 142 (order). The Campies appealed. On appeal, the United States filed an amicus brief. Again, the government made arguments that were favorable to the Campies (without taking a position on the ultimate merits of their case) - *e.g.*, that "a claim can be 'false or fraudulent' when someone represents that it has sold something different from what was actually provided - regardless of whether or not the resulting product was 'worthless'" and that "it is possible to state an FCA claim when a defendant

makes false statements to one government agency, and those false statements *4 are material to the submission of false or fraudulent claims to another government agency." *United States ex rel. Campie v. Gilead Scis., Inc.*, No. 15-16380 (9th Cir.) (Docket No. 20) (Br. at 15, 22). Ultimately, the Ninth Circuit found in favor of the Campies.

Gilead thereafter petitioned the Supreme Court for review. Apparently, the Supreme Court asked the United States for its views on petition, *see* Docket No. 200 (Friedman Decl. ¶ 7), and, in response, the government filed an amicus brief in November 2018. *See* Docket No. 200 (Friedman Decl., Ex. B) (amicus brief). In the brief, the government argued, *inter alia*, that the Ninth Circuit correctly held that "the government's continued payment for a product, after learning that the manufacturer has made misrepresentations to the government regarding that product, can be strong evidence that the misrepresentations were not material to the government's payment decisions" but that, "under the circumstances of this case, . . . the fact of continued government payments did not by itself require dismissal of respondents' claims at the pleading stage." Docket No. 200 (Friedman Decl., Ex. B) (Amicus Br. at 7).

However, in the same brief, the government also asserted for the first time that, if the case were remanded back to the district court, it would

> move to dismiss [the Campies'] suit under Section 3730(c)(2)(A). That determination is based in part on the government's thorough investigation of respondents' allegations and the merits thereof. In addition, if this suit proceeded past the pleading stage, both parties might file burdensome discovery and *Touhy* requests for FDA documents and FDA employee discovery (and potentially trial testimony), in order to establish "exactly what the government knew and when," which would distract from the agency's public-health responsibilities." Based on all those considerations, the government has concluded that allowing this suit to proceed to discovery (and potentially a trial) would impinge on agency decisionmaking and discretion and would disserve the interests of the United States.

Docket No. 200 (Friedman Decl., Ex. B) (Amicus Br. at 15).

II. DISCUSSION

A. Legal Standard

> The purpose of the FCA is "to discourage fraud against the government." The FCA imposes civil liability on any person who knowingly uses a "false record or statement to get a false or fraudulent claim paid or approved by the Government," and any

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> person who "conspires to defraud the Government by getting a false or fraudulent claim allowed or paid." To encourage the disclosure of potential fraud, under the qui tam provisions of the FCA, relators may "bring a civil action for a violation of [§] 3729 for the person and for the United States Government."

Cell Therapeutics, Inc. v. Lash Grp., Inc., 586 F.3d 1204, 1205 (9th Cir. 2010)

6 Although the FCA allows a private individual to bring a qui tam action, as noted above, the act also contains a provision that allows the government to dismiss the action. Section 3730(c)(2)(A) states as follows: "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." 31 U.S.C. § 3730(c)(2)(A).

Section 3730(c)(2)(A), in and of itself, does not provide any standard by which to evaluate a motion to dismiss by the government. However, the Ninth Circuit addressed the standard in *United States ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp.*, 151 F.3d 1139 (9th Cir. 1998), as both parties acknowledge.

In *Sequoia*, the Ninth Circuit recognized that the FCA "is silent regarding the circumstances under which the government may dismiss a qui tam action," but "the decision to dismiss has been likened to a matter within the government's prosecutorial discretion in enforcing federal laws." *Id.* at 1143; *see also id.* at 1144 (noting that amendments to the FCA "actually increased, rather than decreased, executive control over qui tam lawsuits"). Accordingly, the court rejected the proposition that "lack of merit" is the only ground upon which the government may seek dismissal. *Id.* Even "a meritorious suit may be dismissed upon a proper showing." *Id.*

As to what constitutes a proper showing, the Ninth Circuit endorsed the district court's two-step analysis to test the justification for dismissal

> "(1) identification of a valid government purpose; and (2) a rational relation between dismissal and accomplishment of the purpose." If the government satisfies the two-step test, the burden switches to the relator "to demonstrate that dismissal is fraudulent, arbitrary and capricious, or illegal."

*6 *Id.* at 1145[1]; *see also United States ex. rel. Sequoia Orange Co. v. Sunland Packing House Co.*, 912 F. Supp. 1325, 1341 (E.D. Ca. 1995) (district court stating that the first step is "whether the challenged action has a legitimate purpose" and that the second step is whether there is "a reasonable fit between the governmental purpose and the agency action"). The Ninth Circuit also indicated that a hearing on a motion to dismiss would be appropriate where "'the relator presents a *colorable claim* that the settlement or dismissal is unreasonable in light of existing evidence, that the Government has not fully investigated the allegations, or that the Government's decision was based on arbitrary or improper considerations.'" *Sequoia*, 151 F.3d at 1145 (quoting the Senate Report). Finally, the Ninth Circuit commented that the two-step analysis above was essentially "[t]he same analysis [that] is applied to determine whether executive action violates substantive due process." *Id.*

> [1] Given the reference to substantive due process, the Court rejects the Campies' suggestion that the Administrative Procedures Act provides guidance in determining whether government action is "arbitrary and capricious."

In *Sequoia*, the district court had similarly commented that "there need not be a tight fitting relationship between [the governmental purpose and the agency action]; it is enough that there are plausible, or arguable, reasons supporting the agency decision." *Id.* Citing *Heckler v. Chaney*, 470 U.S. 821 (1985), the district court had also underscored that "[a]n agency's decision not to prosecute or enforce, by criminal or civil means, is a decision generally committed to an agency's absolute discretion." *Sequoia*, 912 F. Supp. at 1351. In *Heckler*, the Supreme Court explained that

> an agency decision not to enforce often involves a complicated balancing of a number of factors which are peculiarly within its expertise. Thus, the agency must not only assess whether a violation has occurred, but whether agency resources are best spent on this violation or another, whether the agency is likely to succeed if it acts, whether the particular enforcement action requested best fits the agency's overall policies, and, indeed, whether the agency has enough resources to undertake the action at all. An agency generally cannot act against each technical violation of the statute it is charged with enforcing. The agency is far better equipped than the courts to deal with the many variables involved in the proper ordering of its priorities.

7 *7 *Heckler*, 470 U.S. at 831.

Consistent with the above, the Ninth Circuit noted in *Sequoia* that "a rational relation test avoids any separation of powers concerns," *id*.; that is, there was no indication that the judicial review would pose a significant barrier to the executive branch's exercise of its prosecutorial authority. *See Sequoia*, 151 F.3d at 1145-46. The executive branch's prosecutorial authority was respected because no more was required to justify "the dismissal motion than [what] is mandated by the Constitution itself - *i.e*., due process prohibits arbitrary or irrational prosecutorial decisions. *Id*. at 1146.

Not all courts have agreed with the Ninth Circuit's approach. In fact, even though the Ninth Circuit's review is limited in nature, several circuit courts have endorsed an even less rigorous review. For example, the D.C. Circuit has indicated that the government has an "unfettered right to dismiss an action" under § 3730(c)(2)(A) and that "[t]he relator's right to a hearing" is "simply to give the relator a formal opportunity to convince the government not to end the case." *Swift v. United States*, 318 F.3d 250, 252-53 (D.C. Cir. 2003); *see also United States v. UCB, Inc*., No. 17-CV-765-SMY-MAB, 2019 U.S. Dist. LEXIS 64267, at *5-6 (S.D. Ill. Apr. 15, 2019) (noting split of authority, with the Tenth Circuit following the Ninth Circuit, but with the Fifth and Eighth Circuits following the D.C. Circuit). B. Valid Government Purpose

In its papers, the United States has identified two government purposes that would be served by dismissal of the FCA claim: (1) "to prevent [the Campies] from undermining the considered decisions of FDA and CMS about how to address the conduct at issue here," and (2) "to avoid the additional expenditure of government resources on a case that it fully investigated and decided not to pursue," especially as the FDA has "taken into account [the Campies'] claims in its regulatory oversight of Gilead[] and taken actions it deemed appropriate." Mot. at 8-9. In response, the Campies do not claim that the identified purposes are invalid or illegitimate. Indeed, they acknowledge that such purposes have been identified as relevant considerations by the U.S. Department of Justice ("DOJ"). *See* Docket No. 200 (Friedman Decl., Ex. C) (in DOJ memo, dated January 10, 2018, identifying factors for
8 evaluating dismissal under § 3730(c)(2)(A), *8 including preventing interference with agency policies and programs and preserving government resources); Docket No. 230 (Friedman Decl., Ex. C) (DOJ Manual § 4-4.111) (identifying same factors); *see also* Docket No. 241 (3d Crooke Decl. ¶ 4) (noting that the DOJ manual incorporated the substance of the DOJ memo from January 2018).

The Campies, however, do argue that there is an insufficient factual basis to support the asserted government purposes. *Cf. United States v. Acad. Mortg. Corp*., No. 16-cv-02120-EMC, 2018 U.S. Dist. LEXIS 70096, at *10 (N.D. Cal. Apr. 25, 2018) (noting that "a more searching form of rational basis analysis applies *where the factual record, not any conceivable justification*,

matters"). For example, the Campies contend that, to the extent that the government seeks dismissal based on cost, the government has not provided any evidence to show that it "meaningful considered what the cost of the suit might be" and "failed to make even a cursory showing that it had considered the potential proceeds from the litigation, a central factor in the cost analysis." *United States v. Academy Mortgage Corp.*, No. 16-cv-02120-EMC, 2018 U.S. Dist. LEXIS 171251, at *7, 9 (N.D. Cal. Oct. 3, 2018).

The Court does not agree. Although the Campies have tried to analogize the instant case to *Academy Mortgage* - another case over which the Court presided - *Academy Mortgage* was a markedly different case from the case at bar. In *Academy Mortgage*, there was no indication that the government had conducted any real investigation of the FCA claim, *see United States v. Acad. Mortg. Corp.*, No. 16-cv-02120-EMC, 2018 U.S. Dist. LEXIS 109489, at *2, 4 (N.D. Cal. June 29, 2018) (stating that "[t]he Relator's evidence showed that the Government performed only a limited investigation of the original complaint" - *i.e.*, interviewing the Relator and examining documents produced by her and also turning down an "offer[] to provide additional information" - and "appears not to have investigated the amended complaint at all").

In the instant case, the Court has been presented with substantial evidence that, after the Campies filed their lawsuit in 2010,[2] the United States investigated their allegations "for over two years." Docket No. 184 (Russo Decl. ¶ 2). The
9 investigation included review of the Campies' *9 pleadings and disclosure statement (including accompanying materials), interviews of the Campies, consultations with experts from the Department of Health and Human Services ("DHHS") (including the Food and Drug Administration ("FDA"), meetings with Gilead, collection of documents (over 600,000 pages), interviews of witnesses, and review of the history of multiple manufacturing lots identified by the Campies as having serious problems (including supporting documentation). *See* Docket No. 184 (Russo Decl. ¶¶ 2-3).

[2] As stated in the United States' motion, "[t]his case was originally filed in the Eastern District of Pennsylvania in August 2010 and transferred to this District in 2011." Mot. at 2 n.1.

Moreover, the instant case is somewhat unique in that the above was not the only government investigation of the alleged misconduct identified by the Campies. Even before the Campies filed suit - as well as thereafter - the FDA was involved with oversight of Gilead, including specifically with respect to its use of Synthetics China. This is detailed in the Scavdis Declaration submitted by the United States. *See* Docket No. 185 (Scavdis Decl. ¶ 1) (testifying that he is an Assistant Special Agent in Charge at the FDA, Office of Criminal Investigations). For example:

> • In 2008, Gilead applied (through a Prior Approval Supplement or "PAS") for permission to use FTC from a new manufacturer, *i.e.*, Synthetics China. *See* Docket No. 185 (Scavdis Decl. ¶ 2); *see also* Docket No. 198-6 (Wiener Decl. ¶ 23 & Ex. 6) (initial PAS). "In March 2009, FDA conducted an on-site inspection of Synthetics China" and, "[a]s part of the inspection, Gilead disclosed that two validation batches of API [active pharmaceutical ingredient] did not meet the specifications for the drug[], but that changes were made to the process design and the validation was repeated and acceptable results were obtained. FDA did not issue a Form 483,[3] having recorded no deficiencies with the manufacturing or testing operations at Synthetics China that warranted further action." Docket No. 185 (Scavdis Decl. ¶ 2). In May 2009, FDA approved the PAS. *See* Docket No. 185 (Scavis Decl. ¶ 2).

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• In early 2010, "FDA inspected Gilead's San Dimas facility and identified certain violations of the Current Good Manufacturing Practice (cGMP) regulations. . . . FDA issued a Warning Letter on September 21, 2010."[4] Docket No. 185 (Scavdis Decl. ¶ 3). Thereafter, "FDA evaluated the corrective actions that Gilead took in response to the Warning Letter," and, in August 2011, "FDA issued a letter to Gilead stating that those corrective actions appeared to address the violations identified in the Warning Letter." Docket No. 185 (Scavdis Decl. ¶ 3).

• In April 2011, FDA did a second on-site inspection of the Synthetics China facility but did not issue a Form 483 based on that inspection. *See* Docket No. 185 (Scavdis Decl. ¶ 4).

• "Between November 2011 and January 2012, Gilead submitted Field Alert Reports to FDA related to particulates in finished product at Gilead's Foster City facility." Docket No. 185 (Scavdis Decl. ¶ 5); *see also* Docket No. 201 (Wiener Decl. ¶ 41) (referring to Gilead's FAR in January 2012). FDA inspected the Foster City facility in June 2012 and issued a Form 483 relating to cGMP deficiencies. *See* Docket No. 185 (Scavdis Decl. ¶ 5). Gilead responded to the Form 483 in July 2012. In its response, Gilead addressed, *inter alia*, contamination of FTC sourced from Synthetics China. *See* Docket No. 198-6 (Wiener Decl. ¶¶ 34, 42 & Ex. 13) (Gilead's response to Form 483). After receiving the response, FDA took no further action, neither a recall nor a physician or consumer alert.

• "In March 2012, FDA requested additional information about validation

and reprocessing of batches at Synthetics China, and received additional information from Gilead in April 2012." Docket No. 185 (Scavis Decl. ¶ 6). Thereafter, "[i]n March 2013, FDA conducted a third on-site inspection of the Synthetics China facility" but "did not issue a Form 483 based" on that inspection. Docket No. 185 (Scavis Decl. ¶ 6).

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[3] A FDA Form 483 is also known as a Notice of Inspectional Observations. *See* Docket No. 201 (Wiener Decl. ¶ 34). "An FDA form 483 is issued at the end of an on-site inspection if the FDA field investigator observes deficiencies in the facility's quality system or conditions that violate the FDCA." Docket No. 201 (Wiener Decl. ¶ 34).

[4] As noted above, the Campies initiated this lawsuit in August 2010. *See* Mot. at 2 n.1.

Given the above investigations spanning from 2009 to 2013, the Court finds that there is a concrete factual basis for the United States to argue that allowing the Campies to proceed with the FCA claim would "undermin[e] the considered decisions of FDA and CMS about how to address the conduct at issue here." Mot. at 10. Unlike *Academy Mortgage*, here, there was no cursory decision to move for dismissal without an adequate record of an investigation by the government.

The Campies protest still that the factual basis for the other identified government purpose supporting dismissal - *i.e.*, cost of continued litigation on the FCA claim - lacks a sufficient factual basis. The Campies note, in particular, that they offered to narrow the scope of their FCA claim which would therefore lessen any burden to the United States if litigation were to continue. The record reflects that the United States considered the Campies' proposal to limit the scope of their FCA claim but still concluded that dismissal was appropriate. *See* Docket No. 241 (3d Crooke Decl. ¶¶ 2-3). Although the specificity of the government's cost analysis in the Third Crooke Declaration could have been more robust (the declaration did not provide specific details), which would have been made this an easier case, the Campies' argument ultimately is not persuasive. As an initial matter, the Court does not accept the Campies' suggestion that a cost-benefit analysis must be quantitative in nature - *i.e.*, that the United States is required to do some kind of mathematical calculation. *See United States ex rel. Balko v. Sr. Home Care, Inc.*, No. 8:13-cv-3072-T-17TBM, 2017 U.S. Dist. LEXIS 121575, at *18-19 (M.D. Fla. May 2, 2017) (rejecting relator's argument that "the settlement amount is by definition 'arbitrary' because it is not based on any mathematical valuation of the false claims and was simply an agreed-upon number to which the Relator originally agreed to with no tether to the number or scope of the false claims presented in the case"; stating that there is no requirement that the amount of a settlement be "based on a mathematical formula of the alleged false claims"). The critical question is whether the United States engaged in a meaningful consideration of cost and benefit such that its decision to seek dismissal is supported by a rational basis.

The Campies assert that, even under a qualitative approach, there was not a meaningful consideration of either benefit or cost. The Campies focus in particular on the benefit side of the equation, maintaining that the United States did not consider in any way the proceeds that could be 12 *12 obtained if the Campies were to prevail (even if the Campies were to narrow their FCA claim). *See*, *e.g.*, Docket No. 228-3 (Friedman Decl., Ex. B) (claiming that the narrowed FCA claim could still be worth more than $100 million). But the United States has certified that it considered the merits of the FCA claim and potential for monetary recovery, including after the Campies proposed to narrow

their FCA claim. *See* Docket No. 225 (2d Crooke Decl. ¶ 3); Docket No. 241 (3d Crooke Decl. ¶¶ 2-3). Although the Campies fairly argue that the certification is conclusory, the Court cannot ignore the particular backdrop for the certification in this case - in particular, the investigations done by the FDA between 2009 and 2013 which led to the issuance of only one warning letter and one Form 483, each of which ultimately resulted in no further action by the FDA after Gilead responded, including but not limited to a recall or even a consumer or physician alert. As the government noted in its brief to the U.S. Supreme Court, the fact that it continued payment notwithstanding its knowledge of Gilead's misrepresentations casts some doubt on the element of materiality.

As for the cost side of the equation, the Campies argue that there will be at most only a limited discovery burden on the government if the FCA claim were to be litigated,[5] but that position is not convincing. A critical issue in this case will be whether Gilead's alleged misrepresentations were material, as Gilead is taking the position that materiality is lacking since the FDA continued to approve the drugs at issue "even after the agency became aware of [Gilead's] noncompliance." *Gilead*, 862 F.3d at 906. Thus, discovery into "exactly what the government knew and when" cannot be avoided. *Id*. Under the facts of this case, this will likely entail extensive discovery into government witnesses and documents by either or both the Campies and Gilead.

> 5 *See* Docket No. 200 (Friedman Decl., Ex. C) (DOJ memo) (noting that "[e]xamples of potential costs may include, among other things, the need to monitor or participate in ongoing litigation, including responding to discovery requests").

Accordingly, the Court concludes that there is a factual basis in this case to support both government purposes asserted by the United States and a rational relationship between
13 dismissal *13 and accomplishment of those purposes.[6] Because the United States has satisfied *Sequoia*'s two-step test, the burden now switches to the Campies "'to demonstrate that dismissal is fraudulent, arbitrary and capricious, or illegal.'" *Sequoia*, 151 F.3d at 1145. C. Arbitrary and Capricious

> 6 This is not to say that, in different circumstances, a more specific showing needs to be made by the government.

The Court holds that the Campies have failed to establish that dismissal would fall under any of the above categories. The Campies primarily argue that the government's request to dismiss is arbitrary and capricious but, as indicated by the discussion above, that position is not well supported under the particular facts and circumstances of this case. There was a multi-year investigation into the Campies' allegations and Gilead's practices related to Synthetics China, and the government made deliberate enforcement decisions in regard thereto. The government considered the burdens of this litigation evident in the nature of, *e.g.*, the materiality issues likely to be central to this case.

Other facts additionally point to a non-arbitrary approach by the United States with respect to the instant case. For example:

• The United States has never been dismissive of the Campies' FCA claim, even participating in the Ninth Circuit appeal and making arguments favorable to the Campies.

• The United States has been involved in this case from 2010 to the present, spanning two different administrations.

• There is nothing to suggest that the United States has a pattern of not taking *qui tam* complaints seriously or a pattern of moving to dismiss. Between October 2017 and September 2019, more than 1,200 *qui tam* complaints have been filed and the United States has intervened or partially intervened in approximately 218.[7]

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Furthermore, since the DOJ memo of January 2018 (discussing factors to consider in whether to move to dismiss), the United States has moved to dismiss in only 36 cases. *See* Docket No. 241 (3d Crooke Decl. ¶ 4).

[7] The United States' involvement in the 218 cases may also have impacted the United States' decision as to how to proceed with the instant case - *i.e.*, given its limited resources, at a certain point, the United States may have had to prioritize which litigations to pursue. *See* Docket No. 200 (Friedman Decl., Ex. C) (DOJ memo) (in Factor No. 4, *i.e.*, noting that "the Department should consider dismissing cases when necessary to protect the Department's litigation prerogatives"). However, the Court expresses no opinion on such. --------

The Court thus concludes that the Campies have failed to satisfy their burden of showing that dismissal is arbitrary, capricious, fraudulent, or illegal.

III. CONCLUSION

The United States' motion to dismiss is thereby granted. Although the main FCA claim has now been dismissed, the Campies may still proceed with their remaining claims (including but not limited to the retaliation claims) absent further order of the Court.

This order disposes of Docket No. 183.

IT IS SO ORDERED. Dated: November 5, 2019

/s/

EDWARD M. CHEN

United States District Judge