

1 JOSEPH H. HUNT
Assistant Attorney General, Civil Division

2 DAVID L. ANDERSON (CABN 149604)
3 United States Attorney
4 SARA WINSLOW (DCBN 457643)
Chief, Civil Division
5 450 Golden Gate Avenue, Box 36055
San Francisco, California 94102
6 Telephone: (415) 436-6925
Facsimile: (415) 436-6748
7 E-mail: sara.winslow@usdoj.gov

8 MICHAEL D. GRANSTON
9 JAMIE YAVELBERG
EDWARD CROOKE
Attorneys, Civil Division
10 P.O. Box 261, Ben Franklin Station
Washington, D.C. 20044
Telephone: (202) 353-0426
11 Facsimile: (202) 514-0280
E-mail: edward.crooke@usdoj.gov

12 Attorneys for the United States of America
13

14
15 UNITED STATES DISTRICT COURT
16 NORTHERN DISTRICT OF CALIFORNIA
17 SAN FRANCISCO DIVISION

18 UNITED STATES OF AMERICA, ex rel.) CASE NO. C-11-0941 EMC
19 CAMPIE,)
20 Plaintiff and Relators,) **UNITED STATES’ MOTION TO**
21 v.) **DISMISS RELATORS’ SECOND**
22 GILEAD SCIENCES, INC.,) **AMENDED COMPLAINT; [PROPOSED]**
Defendant.) **ORDER**
) Date: June 20, 2019
) Time: 1:30 p.m.
) The Honorable Edward M. Chen
) Courtroom 5, 17th Floor

TABLE OF CONTENTS

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

TABLE OF AUTHORITIESii

NOTICE OF MOTION AND MOTION TO DISMISS1

MEMORANDUM OF POINTS AND AUTHORITIES1

I. STATEMENT OF ISSUES TO BE DECIDED1

II. STATEMENT OF FACTS1

 A. Relators’ Allegations1

 B. The Government’s Investigation.....2

 C. FDA’s Ongoing Regulatory Oversight4

III. STATEMENT OF LEGAL AUTHORITY5

 A. The False Claims Act.....5

 B. The United States’ Decision to Dismiss a *Qui Tam* Case is a Matter of
 Prosecutorial Discretion Entitled to Deference.....6

IV. DISCUSSION8

V. NO EVIDENTIARY HEARING IS WARRANTED.....10

VI. CONCLUSION.....11

TABLE OF AUTHORITIES

Page(s)

CASES

1
2
3
4
5 *United States ex rel. Campie v. Gilead Scis. Inc.*,
862 F.3d 890 (9th Cir. 2010) 9
6 *Heckler v. Chaney*,
7 470 U.S. 821 (1985)..... 7, 8
8 *Ridenour v. Kaiser-Hill Co., LLC*,
397 F.3d 925 (10th Cir. 2005) 6, 11
9 *Swift v. United States*,
10 318 F.3d 250 (D.C. Cir. 2003) 6, 8
11 *United States ex rel. Thrower v. Acad. Mortg. Corp.*, No. 16-cv-2120,
2018 WL 1947760 (N.D. Cal. April 25, 2018)..... 7
12 *United States ex rel. California v. Washington Twp. Health Care Dist.*,
13 No. 06-cv-00261, 2006 WL 2053494 (N.D. Cal. July 21, 2006) 8
14 *United States ex rel. Hyatt v. Northrop Corp.*,
91 F.3d 1211 (9th Cir. 1996) 6
15 *United States ex rel. Mateski v. Mateski*,
16 634 F. App’x 192 (9th Cir. 2015) 11
17 *United States ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp.*,
151 F.3d 1139 (9th Cir. 1998) passim
18 *United States ex rel. Touhy v. Ragen*,
19 340 U.S. 462 (1951)..... 9

STATUTES

20
21 21 U.S.C. § 355 10
22 21 U.S.C. § 355-1 10
23 21 U.S.C. § 393 10
24 31 U.S.C. § 3729 5
25 31 U.S.C. §§ 3729-3733 2
26 31 U.S.C. § 3730 passim
27
28

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

REGULATIONS

21 C.F.R. § 201.57 10
21 C.F.R. § 314.80 10
21 C.F.R. § 314.200 10

1 **NOTICE OF MOTION AND MOTION TO DISMISS**

2 PLEASE TAKE NOTICE THAT on June 20, 2019 at 1:30 p.m., or as soon thereafter as
3 the matter may be heard by the Court, in the courtroom of the Honorable Edward M. Chen,
4 located at 450 Golden Gate Avenue, San Francisco, California, Courtroom 5, real party in
5 interest the United States of America will and hereby does move the Court, pursuant to 31 U.S.C.
6 § 3730(c)(2)(A), for an order dismissing Relators’ Second Amended Complaint.

7 The United States brings this motion on the grounds that it has a valid governmental
8 purpose in dismissing the case, and that there is a rational relationship between dismissal and
9 accomplishment of the purpose. This motion to dismiss constitutes a determination by the
10 United States as a matter of its prosecutorial discretion that Relators’ pursuit of this case is
11 contrary to the United States’ interests on whose behalf Relators are supposed to be pursuing the
12 case.

13 The United States’ motion is based on this Notice of Motion and Motion, the attached
14 Memorandum of Points and Authorities, all pleadings and papers filed in this action, oral
15 argument of counsel, and any other matters as may come before the Court.

16 **MEMORANDUM OF POINTS AND AUTHORITIES**

17 **I. STATEMENT OF ISSUES TO BE DECIDED**

18 Whether Relators’ Second Amended Complaint should be dismissed where the United
19 States, real party in interest, has moved for dismissal pursuant to 31 U.S.C. § 3730(c)(2)(A), and
20 has shown a valid government purpose in dismissing the case and a rational relationship between
21 dismissal and accomplishment of that purpose.

22 **II. STATEMENT OF FACTS**

23 **A. Relators’ Allegations**

24 In October 2010, Relators Jeff Campie and Sherilyn Campie (“Relators”) filed this *qui*
25 *tam* action against defendant Gilead Sciences, Inc. (Gilead), a manufacturer of numerous
26 prescription drugs. Although their Second Amended Complaint catalogues a lengthy list of
27 allegations about a number of different products, Relators’ key allegations concern alleged
28 deficiencies in Gilead’s manufacturing of certain pharmaceutical drugs. *See* ECF 126.

1 Relators allege that, in the course of manufacturing various pharmaceutical drugs
2 approved by the Food and Drug Administration (FDA), Gilead covertly arranged to have certain
3 key ingredients made at two manufacturing facilities (one in China and one in Canada) that had
4 quality control problems. Relators allege that problematic ingredients produced at these
5 facilities, as well as assorted problems at several other facilities, led to Gilead producing
6 substantial quantities of drugs that were contaminated and/or did not have the proper potency
7 levels. Relators further allege that, for at least part of the time that Gilead used these facilities,
8 the facilities had not been approved by FDA to make pharmaceutical ingredients destined for the
9 U.S. market but that Gilead nonetheless introduced the resulting drugs into U.S. commerce.

10 Relators also allege that Gilead took a number of steps to conceal these underlying
11 problems. For example, the Second Amended Complaint states that when Gilead eventually
12 sought FDA approval for the new Chinese facility (Synthetics China), it made false statements to
13 FDA about quality testing results. Relators also contend that Gilead falsified shipping labels to
14 conceal from FDA the fact that Gilead had been (and still was) using ingredients made at the
15 unapproved Chinese facility. And Relators allege that in a variety of instances, Gilead either
16 failed to file required reports with FDA noting problems with its drugs or made false
17 representations or material omissions in applications seeking FDA's approval for various drugs.

18 Relators contend that Gilead violated the False Claims Act (FCA), 31 U.S.C.
19 §§ 3729-3733, by causing the submission of false claims to federal health care programs. More
20 specifically, Relators assert that Gilead's conduct gives rise to violations of the FCA because
21 FDA would have denied or revoked the relevant drugs' approval had it known the truth, which in
22 turn would have affected the drugs' eligibility for payment under federal health care programs.

23 **B. The Government's Investigation**

24 The government investigated Relators' allegations for over two years. Accompanying
25 Declaration of Leonard Russo, ¶ 2.¹ The government reviewed Relators' complaint and
26 amended complaint, their disclosure statement, and the accompanying materials. *Id.* The

27
28 ¹ This case was originally filed in the Eastern District of Pennsylvania in August 2010
and transferred to this District in 2011.

1 government interviewed Relators. *Id.* The investigation included consultation with experts from
2 the Department of Health and Human Services (HHS), including FDA. *Id.* The government met
3 with counsel for Gilead on multiple occasions to discuss the allegations. *Id.* The government
4 collected over 600,000 pages of documents related to the allegations and interviewed numerous
5 witnesses. *Id.* The government also selected multiple manufacturing lots for which Relators had
6 alleged specific and potentially serious problems and obtained a complete review of the history
7 of the lots from “cradle to grave,” which accounted for the disposition of each lot with
8 supporting documentation. *Id.* at ¶ 3.

9 After thoroughly investigating and meaningfully assessing the Relators’ allegations, in
10 January 2013, the United States declined to intervene in the action, pursuant to 31 U.S.C.
11 § 3730(b)(4)(B). Relators elected to proceed with the action and filed an amended complaint.
12 Defendant Gilead moved to dismiss the amended complaint. ECF 58.² The United States filed a
13 statement of interest in response to the motion to dismiss to set forth its position on the proper
14 interpretation and application of certain legal issues raised by Gilead. The United States took no
15 position on the merits of Relators’ claims or whether the Relators’ allegations were adequately
16 pled. The Court granted Gilead’s motion and dismissed the complaint, but granted Relators
17 leave to amend. ECF 117. The Court instructed Relators to organize and streamline their
18 747-paragraph complaint and permitted them to allege a new theory of liability based on alleged
19 “worthless services” and an actionable misrepresentation made as part of the payment process.
20 *Id.* The Second Amended Complaint did not allege new conduct or alter the overall focus of the
21 allegations, and did not change the government’s view about its decision to decline to intervene
22 in this matter. *See* ECF 126. Gilead moved to dismiss the Second Amended Complaint, and the
23 United States again filed a statement of interest. ECF 128, 129. The Court dismissed the Second
24 Amended Complaint, and Relators appealed. ECF 142, 145. The United States once again
25 participated as an *amicus* in the briefing to inform the Ninth Circuit of its views on the legal
26 issues raised by the appeal. The Ninth Circuit reversed this Court’s dismissal of the action. ECF

27
28 ² Some of the docket entries remain sealed, and therefore the docket numbers for certain
entries are not included here.

1 150-51. After a petition for rehearing *en banc* was denied, defendants petitioned for certiorari to
2 the United States Supreme Court. ECF 154, 162. The Supreme Court denied certiorari, and the
3 case was remanded to this Court. ECF 166, 168.

4 **C. FDA's Ongoing Regulatory Oversight**

5 Before Relators disclosed their allegations to the government, FDA was already
6 conducting ongoing regulatory oversight of Gilead's manufacturing processes. In 2008, Gilead
7 submitted a Prior Approval Supplement (PAS) to allow the use of active pharmaceutical
8 ingredients (API) from a new manufacturer (Synthetics China) in its finished drug products.
9 Accompanying Declaration of George Scavdis, ¶ 2. In the PAS, Gilead committed to providing
10 additional stability data when it became available. *Id.* In March 2009, FDA conducted an on-
11 site inspection of Synthetics China. *Id.* As part of the inspection, Gilead disclosed that two
12 validation batches of API did not meet the specifications in the drugs' label, but that changes
13 were made to the process design and the validation was repeated and acceptable results were
14 obtained. *Id.* At the conclusion of an inspection, FDA may issue a "Form 483" if the
15 investigators observed violations of the FDCA. In this case, however, FDA did not issue a Form
16 483, having recorded no deficiencies with the manufacturing or testing operations at Synthetics
17 China that warranted further regulatory action. *Id.* In April 2009, Gilead submitted a PAS
18 amendment with additional stability data. *Id.* On May 8, 2009, FDA approved the PAS for
19 Synthetics China. *Id.*

20 FDA's ongoing regulatory oversight continued after Relators filed their complaint and
21 the government was aware of their allegations. Between January and February 2010, FDA had
22 inspected a Gilead facility in San Dimas, California and identified certain violations of the
23 Current Good Manufacturing Practice (cGMP) regulations. *Id.* at ¶ 3. FDA discussed its
24 findings with Gilead. FDA issued a Warning Letter on September 21, 2010. *Id.* FDA evaluated
25 the corrective actions that Gilead took in response to the Warning Letter, and on August 4, 2011,
26 FDA issued a letter to Gilead stating that those corrective actions appeared to address the
27 violations contained in the Warning Letter. *Id.* Meanwhile, in April 2011, FDA conducted a
28 second on-site inspection of the Synthetics China facility. *Id.* at ¶ 4. FDA did not issue a Form

1 483 based on the April 2011 inspection. *Id.* Between November 2011 and January 2012, Gilead
2 submitted Field Alert Reports to FDA related to particulates in finished product at the Foster
3 City facility. *Id.* at ¶ 5. In June 2012, FDA inspected the Foster City facility and issued a Form
4 483 relating to cGMP deficiencies. *Id.* In March 2012, FDA requested additional information
5 about validation and reprocessing of batches at Synthetics China, and received additional
6 information from Gilead in April 2012. *Id.* at ¶ 6. In March 2013, FDA conducted a third on-
7 site inspection of the Synthetics China facility. *Id.* FDA did not issue a Form 483 based on the
8 March 2013 inspection. *Id.*

9 FDA did not initiate any action in response to these inspections that caused or required
10 Gilead to stop production at any Gilead facility, recall any lots of the drugs at issue, or remove
11 the drugs from commerce. *Id.* at ¶ 7.

12 **III. STATEMENT OF LEGAL AUTHORITY**

13 **A. The False Claims Act**

14 The FCA enables the United States to recover monies lost due to the submission of false
15 claims. 31 U.S.C. § 3729. Among other unique features, the FCA allows private parties, known
16 as relators, to bring an action on behalf of the United States through filing a *qui tam* action. A
17 *qui tam* action is brought in the name of the United States, but a relator has a right to a share of
18 up to thirty percent of the recovery, plus attorneys' fees and costs. 31 U.S.C. § 3730(b), (d).

19 The FCA directs that the relator must file his or her complaint under seal and serve it,
20 together with a "written disclosure of substantially all material evidence and information the
21 person possesses," upon the United States. 31 U.S.C. § 3730(b)(1), (2). The United States has at
22 least 60 days to investigate the allegations and elect whether or not to intervene in the action,
23 with extensions of time for good cause. 31 U.S.C. § 3730(b)(2), (3).

24 If the United States intervenes, "the action shall be conducted by the Government." 31
25 U.S.C. § 3730(b)(4)(A). The government assumes "the primary responsibility for prosecuting
26 the action" and is not bound by any act of the relator. 31 U.S.C. § 3730(c)(1). The relator
27 remains a party to the suit, but the government may settle the case over the relator's objection, or
28 may otherwise seek to limit the relator's participation in the litigation. 31 U.S.C.

1 § 3730(c)(2)(B), (C).

2 Even if the United States declines to intervene in the action, the government retains
3 substantial control over the action. For example, the Court may stay discovery in the *qui tam*
4 action if it interferes with the government’s investigation or prosecution of another matter. 31
5 U.S.C. § 3730(c)(4). The relator cannot dismiss the action without written consent of the
6 Attorney General. 31 U.S.C. § 3730(b)(1). And if the Attorney General initially declines to
7 intervene in the suit, the court “may nevertheless permit the Government to intervene at a later
8 date upon a showing of good cause.” 31 U.S.C. § 3730(c)(3).

9 Most important for purposes of the present motion, the FCA expressly authorizes the
10 United States to dismiss the action over the relator’s objection:

11 The Government may dismiss the action notwithstanding the objections of the
12 person initiating the action if the person has been notified by the Government of
13 the filing of the motion and the court has provided the person with an opportunity
14 for a hearing on the motion.

15 31 U.S.C. § 3730(c)(2)(A). The United States can move to dismiss a FCA action even though it
16 did not intervene in the litigation, as it remains the real party in interest. *See United States ex rel.*
17 *Sequoia Orange Co. v. Baird-Neece Packing Corp.*, 151 F.3d 1139, 1145 (9th Cir. 1998) (noting
18 that § 3730(c)(2)(A) “may permit the government to dismiss a *qui tam* action without actually
19 intervening in the case at all”); *Ridenour v. Kaiser-Hill Co., LLC*, 397 F.3d 925, 932 (10th Cir.
20 2005) (affirming dismissal after declination); *Swift v. United States*, 318 F.3d 250, 251-52 (D.C.
21 Cir. 2003) (affirming dismissal prior to intervention); *cf. United States ex rel. Hyatt v. Northrop*
22 *Corp.*, 91 F.3d 1211, 1215 (9th Cir. 1996) (“[*Q*ui tam plaintiffs are merely agents suing on
23 behalf of the government, which is always the real party in interest.”) (citing cases).

24 **B. The United States’ Decision to Dismiss a *Qui Tam* Case is a Matter of
25 Prosecutorial Discretion Entitled to Deference.**

26 The Ninth Circuit, in *Sequoia Orange*, adopted a highly deferential standard of review for
27 a government motion to dismiss a *qui tam* case pursuant to 31 U.S.C. § 3730(c)(2)(A). 151 F.3d
28 at 1145. In order to dismiss a matter such as this, the United States need only (1) identify a
“valid government purpose” for dismissing the case, and (2) show a “rational relationship
between dismissal and accomplishment of the purpose.” *Id.* (quotations omitted). If the United

1 States satisfies this two-step test, “the burden switches to the relator to demonstrate that
2 dismissal is fraudulent, arbitrary and capricious, or illegal.” *Id.* (quotations omitted).

3 In developing this test, the Ninth Circuit observed that “the decision to dismiss has been
4 likened to a matter within the government’s prosecutorial discretion in enforcing federal laws,”
5 and the dismissal provision in the FCA should not be construed to grant the Judiciary an
6 impermissible power to approve or disapprove the Executive’s exercise of prosecutorial
7 discretion. *Id.* at 1143. Consequently, the Ninth Circuit reasoned that when a court considers a
8 motion by the government to dismiss a *qui tam* case, it should “respect[] the Executive Branch’s
9 prosecutorial authority by requiring no greater justification of the dismissal motion than is
10 mandated by the Constitution itself.” *Id.* at 1146. There are good reasons for this type of
11 deference:

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

22 *Heckler v. Chaney*, 470 U.S. 821, 831-32 (1985).

23 This Court has further elucidated its view of how to evaluate whether the government has
24 met its burden and a relator has met his. *See United States ex rel. Thrower v. Acad. Mortg.*
25 *Corp.*, No. 16-cv-2120, 2018 WL 1947760 (N.D. Cal. April 25, 2018). In *Thrower*, the Court
26 explained that “to establish a colorable claim to obtain an evidentiary hearing on the
27 Government’s motion to dismiss, a relator must present ‘some evidence’ that the Government’s
28 decision to dismiss was unreasonable, not a result of a full investigation, or based on arbitrary
and improper considerations.” *Id.* at *4. Although the government does not entirely agree with
this Court’s interpretation and application in *Thrower* of the pertinent standard adopted by the
Ninth Circuit in *Sequoia Orange* (and is currently appealing the *Thrower* decision), the United

1 States submits that its request for dismissal satisfies the test that this Court required in *Thrower*.

2 **IV. DISCUSSION**

3 In this matter, the government has a legitimate purpose for dismissal: to avoid the
4 additional expenditure of government resources on a case that it fully investigated and decided
5 not to pursue. As noted above, in a *qui tam* action, the relator sues on behalf of the United States
6 for fraud against the United States, and to recover damages suffered by the United States.
7 Accordingly, even where the United States declines to intervene in a *qui tam* action, if the relator
8 opts to pursue the case, the government's resources often are still burdened, as relators may
9 litigate FCA cases long after the government has determined that the alleged violations do not
10 warrant further action. Such has already been the case here.

11 The goal of minimizing expenses and government resources is "a legitimate objective,
12 and dismissal of [a] suit is furthered by that objective." *Swift*, 318 F.3d at 254; *see Sequoia*
13 *Orange*, 151 F.3d at 1146 ("[T]he government can legitimately consider the burden imposed on
14 taxpayers by its litigation, and that, even if the relators were to litigate the FCA claims, the
15 government would continue to incur enormous internal staff costs. . . ."); *cf. United States ex rel.*
16 *California v. Washington Twp. Health Care Dist.*, No. 06-cv-00261, 2006 WL 2053494 (N.D.
17 Cal. July 21, 2006) (noting, in context of relator's voluntary motion to dismiss *qui tam* suit, that
18 "consideration of cost" is a "sufficient justification to approve dismissal" of action). The
19 Supreme Court has observed that an agency's decision not to enforce "often involves a
20 complicated balancing of a number of factors which are peculiarly within [the agency's]
21 expertise," including "whether agency resources are best spent on this violation or another."
22 *Heckler*, 470 U.S. at 831. As a result, such determinations are "general[ly] unsuitab[le] for
23 judicial review" because "[t]he agency is far better equipped than the courts to deal with the
24 many variables involved in the proper ordering of its priorities." *Id.* at 831–32.

25 In this case, the government fully investigated Relators' allegations, including all
26 information provided by Relators and other additional information obtained and reviewed by the
27 government, including information on specific lots identified by Relators as being contaminated.
28 The United States assessed the allegations and determined not to use its resources to pursue this

1 case. FDA has also taken into account Relators' claims in its regulatory oversight of Gilead, and
2 taken actions it deemed appropriate. Relators' continued pursuit of the matter will necessarily
3 entail the further expenditure of the government's resources. As is evident from the
4 government's participation to date, the United States has actively monitored Relators' litigation.
5 In particular, the government has found it necessary on multiple occasions to file briefs to set
6 forth the United States' views on the interpretation and application of the FCA to the legal
7 theories alleged by Relators and the challenges to it presented by defendants. Absent dismissal,
8 the litigation will likely proceed to discovery, requiring the United States to commit even more
9 significant resources to the case. Both parties may well file burdensome discovery and requests
10 pursuant to *United States ex rel. Touhy v. Ragen*, 340 U.S. 462 (1951), for FDA and CMS
11 documents and employee testimony. In particular, the parties likely will seek discovery about
12 "exactly what the government knew and when." *United States ex rel. Campie v. Gilead Scis.,*
13 *Inc.*, 862 F.3d 890, 906 (9th Cir. 2010). Following discovery, the same FDA and CMS
14 employees relevant to discovery would be potential witnesses at any trial. This would divert
15 those employees from their other duties and agency priorities.

16 Having already spent resources extensively investigating Relators' claims, reviewing the
17 merits of the case as presented by Relators, and monitoring the case after declination, the United
18 States has rationally concluded it is not in the public interest to spend further time and resources
19 on Relators' litigation of this matter. Accordingly, the additional burdens that litigation of this
20 case would impose on the United States present a rational basis for the government to seek
21 dismissal under § 3730(c)(2)(A). The valid governmental purpose of conserving resources is
22 undeniably furthered by and bears a rational relation to seeking dismissal. It is also appropriate
23 for such a dismissal to occur now, to prevent any further dissipation of government resources.

24 Significantly, the Ninth Circuit found cost considerations such as those articulated here to
25 be sufficient grounds for dismissal even if a case were meritorious. *Sequoia Orange*, 151 F.3d at
26 1146. It is thus not necessary under the *Sequoia* test to evaluate the potential "benefits" of a
27 relator proceeding with his case. But even if it were, the government has made the rational
28 determination that the costs of continued litigation will outweigh any benefit. Accordingly,

1 because the government has demonstrated a rational basis for dismissal of this action, and
2 Relators cannot meet their burden, the Court should grant the United States' motion.

3 In addition to preserving scarce resources, dismissal is also appropriate to prevent
4 Relators from undermining the considered decisions of FDA and CMS about how to address the
5 conduct at issue here. FDA is authorized to withdraw an existing drug approval under specified
6 circumstances, which generally require findings that the benefits of the drug no longer exceed
7 the risks. *See* 21 U.S.C. § 355(e). If FDA proposes to withdraw approval, the drug's sponsor
8 has substantial procedural rights, including a right to judicial review. *See id.*; 21 U.S.C.
9 § 355(h); 21 C.F.R. § 314.200(g). Given the rigors of this process, and FDA's public-health
10 obligation to avoid unnecessarily limiting patient access to safe and effective drugs, *see*
11 *generally* 21 U.S.C. §§ 355(d), 355-1, 393(b), the agency typically seeks to address any issues
12 through less disruptive mechanisms. *See* 21 U.S.C. §§ 355(e), 355(o)(3)-(4), 355-1; 21 C.F.R.
13 § 201.57, 314.80(j).

14 In this case, FDA exercised continuing regulatory oversight of Gilead's manufacturing
15 processes, including multiple on-site inspections of Gilead's facilities both before and after
16 Relators filed their complaint. FDA took the actions that it deemed appropriate. Relators' case
17 now asks a jury to find that different action was nevertheless required. The FCA was never
18 intended to allow a relator to substitute his or her own judgment for that of the government as to
19 whether the government received the benefit of its bargain.

20 **V. NO EVIDENTIARY HEARING IS WARRANTED**

21 At the recent case management conference, counsel for Relators suggested that they
22 would insist on discovery from the government regarding the basis for its decision to dismiss this
23 action. In *Sequoia Orange*, the Ninth Circuit acknowledged that a court need not reflexively
24 schedule an evidentiary hearing when a motion to dismiss is filed, and it certainly did not suggest
25 that a relator was entitled to discovery in such circumstances. To the contrary, the Ninth Circuit
26 concluded that “[a] hearing is appropriate ‘if the relator presents a colorable claim that the
27 settlement or dismissal is unreasonable in light of existing evidence, that the Government has not
28 fully investigated the allegations, or that the Government’s decision was based on arbitrary or

1 improper considerations.” 151 F.3d at 1145 (quoting S. Rep. No. 99–345, at 26 (1986), as
2 reprinted in 1986 U.S.C.C.A.N. 5266); *see also Ridenour*, 397 F.3d at 931 (noting that hearings
3 “are only to be granted if relators can show a ‘substantial and particularized need for a hearing’”)
4 (quoting S. Rep. No. 99–345, at 26). Thus, neither an evidentiary hearing nor discovery is
5 appropriate unless and until a relator comes forward with credible evidence to suggest that
6 dismissal would be unreasonable, the government had not fully investigated, or the government’s
7 decision was based on arbitrary or improper considerations. *See United States ex rel. Mateski v.*
8 *Mateski*, 634 F. App’x 192, 194 (9th Cir. 2015) (“The district court did not err in denying
9 Mateski a hearing . . .”). Here, Relators cannot proffer any evidence to make such a showing.

10 **VI. CONCLUSION**

11 The government moves to dismiss this action brought in its name for the legitimate
12 purpose of conserving scarce resources that would need to be expended by the government to
13 monitor this case and respond to pleadings, *Touhy* requests, and trial subpoenas. As the Relators
14 cannot establish that this reason is arbitrary, capricious, fraudulent or illegal, the government’s
15 motion to dismiss should be granted.

16 Respectfully submitted,

17 JOSEPH H. HUNT
18 Assistant Attorney General

19 DAVID L. ANDERSON
20 United States Attorney

21 Dated: March 28, 2019

By: /s/ _____
SARA WINSLOW
Assistant United States Attorney

23 Dated: March 28, 2019

By: /s/ *signature on file* _____
EDWARD CROOKE
Civil Division, Fraud Section
Attorneys for the United States of America

[PROPOSED] ORDER

Having considered the United States’ Motion to Dismiss pursuant to 31 U.S.C. § 3730(c)(2)(A), and any opposition, reply, and oral argument presented, the Court finds that the United States has identified a valid government purpose for dismissing the case, and shows a rational relationship between dismissal and accomplishment of the purpose. In addition, Relators have not demonstrated that dismissal is fraudulent, arbitrary and capricious, or illegal. *See United States ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp.*, 151 F.3d 1139 (9th Cir. 1998). It is therefore HEREBY ORDERED that Relators’ Second Amended Complaint is dismissed with prejudice. The Clerk shall close the file.

IT IS SO ORDERED

Dated: _____

EDWARD M. CHEN
UNITED STATES DISTRICT JUDGE