IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

UNITED STATES OF AMERICA; and THE STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, NEVADA, NEW HAMPSHIRE, NEW JERSEY NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA RHODE ISLAND, TENNESSEE, TEXAS, WASHINGTON, WISCONSIN, VIRGINIA; and the DISTRICT OF COLUMBIA, ex rel. THOMAS JEFFERSON & LAUREL IGBANUGO	*	CIVIL ACTION NO. GLR-14-3665
Plaintiffs	*	
v.	*	
ROCHE HOLDING AG, et al.,	*	
Defendants	*	

MEMORANDUM IN SUPPORT OF MOTION TO DISMISS

In accordance with 31 U.S.C. § 3730(c)(2)(A), the United States respectfully moves this Court for an order dismissing this action, filed under the *qui tam* provisions of the False Claims Act (FCA), 31 U.S.C. §§ 3729–3733. The FCA authorizes a private party, known as a "relator," to bring suit on behalf of the United States to recover damages suffered solely by the United States as a result of fraud or false claims submitted to it. 31 U.S.C. § 3730(b)(1). Because of the

unique nature of the FCA, Congress included several protections in it to ensure that the United States retains substantial control over *qui tam* lawsuits filed on its behalf. Among these protections is the right of the United States to "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). For the reasons that follow, including that the Centers for Disease Control and Prevention (CDC) has long been aware of and has consistently rejected the allegations in the Relator's complaint challenging the efficacy of Tamiflu® (oseltamivir phosphate) (hereinafter "Tamiflu" or "oseltamivir"), the United States has now determined that it is appropriate to exercise its statutory authority under section 3730(c)(2)(A) to dismiss this action, and it asks the Court to order such dismissal.

As discussed below, the Fourth Circuit has yet to address the showing the United States must make when it invokes its statutory authority under this FCA provision. While other circuits have adopted varying standards, those standards all share the same core characteristic: a high level of deference to the United States as the real party in interest in any FCA case. *Compare Swift v. United States,* 318 F.3d 250, 252 (D.C. Cir. 2003) (holding that the United States has an "unfettered right" to dismiss a *qui tam* action), *with United States ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp.*, 151 F.3d 1139, 1145 (9th Cir. 1998) (holding that the United States must identify a "valid government purpose" that is rationally related to dismissal), *with United States ex rel. CIMZNHCA, LLC v. UCB, Inc.*, 970 F.3d 835, 850-51 (7th Cir. Aug. 17, 2020) (holding that where the defendant has already answered or filed a motion for summary judgment, Rule 41(a)(2) applies and courts apply a discretionary standard in ruling on a motion to dismiss by the United States), *with Borzilleri v. Bayer Healthcare Pharmaceuticals, Inc.*, 24 F.4th 32, 42

(1st Cir. 2022) (holding that in reviewing a motion to dismiss, the court's inquiry is limited to ascertaining whether "the government's decision to seek dismissal . . . transgresses constitutional limitations or that, in moving to dismiss, the government is perpetrating a fraud on the court").

In the United States' view, because the FCA does not impose any constraints on the United States' dismissal authority, the only constraints are those imposed by the Constitution on executive action. The Court, however, need not resolve what standard to apply because dismissal is warranted under any applicable standard, where, as here, the United States has reasonably determined that dismissal is appropriate.[1]

PROCEDURAL HISTORY

The Relators, Thomas Jefferson and Laurel Igbanugo, filed this FCA *qui tam* action on November 21, 2014. ECF No. 1. The complaint alleged, among other things, that the defendants, Roche Holding AG, Genentech, Inc., and Hoffman-LaRoche, Inc. (collectively referred to herein as "the Roche Defendants"), knowingly presented false information to the Department of Health and Human Services (HHS) and its operating division, the CDC, to persuade those entities to select Tamiflu for the Strategic National Stockpile (SNS). On September 3, 2019, Relator Jefferson filed an amended complaint.[2] ECF No. 34. The amended complaint alleges that the Roche Defendants prepared, or caused to be prepared, purported scientific "studies" that concluded that Tamiflu reduced complications and shortened hospitalizations associated with influenza. According to the amended complaint, the Roche Defendants knowingly used these flawed studies in the early 2000s to persuade CDC and HHS to

[1] As all of the courts to interpret the Government's authority under 31 U.S.C. §3730(c)(2)(A) have recognized, the right of the Government to dismiss differs from and is much more deferential than the standard that applies under Federal Rule of Civil Procedure 12(b)(6).

[2] Relator Igbanugo's name was dropped in the amended complaint.

select Tamiflu for the SNS, even though the Food and Drug Administration (FDA) had previously declined to approve Tamiflu for these purposes. The amended complaint claims that contrary to the conclusions in the allegedly flawed studies and the Roche Defendants' representations to CDC and HHS, Tamiflu does not, in fact, reduce complications or shorten hospitalizations associated with influenza. And, while the Relator acknowledges that Tamiflu is effective for reducing the duration of influenza symptoms, he alleges that any clinical benefit of taking the drug is offset by its potential side effects (*e.g.*, nausea, vomiting, headaches, and psychiatric and renal effects). The Relator thus claims that Tamiflu should not have been selected for the SNS, and that the Roche Defendants misled the CDC and HHS into doing so.

The United States Attorney's Office for the District of Maryland (USAO) and the Fraud Section of the Department of Justice's (DOJ's) Civil Division in Washington, D.C., and investigators from multiple federal agencies, diligently investigated the Relators' allegations over several years, an investigation that included reviewing tens of thousands of documents, including Government documents as well as those subpoenaed from the Roche Defendants and multiple third parties; consulting extensively with CDC, FDA, and HHS; and conducting many witness interviews. Upon completing that comprehensive investigation, on September 3, 2019, the United States filed a Notice of Election to Decline Intervention.[3] ECF No. 35. On September 10, 2019, the Court entered the order on the United States' Amended Notice of Election to Decline Intervention and unsealed the Relator's complaint. ECF No. 37.

On January 17, 2020, Defendants Genentech, Inc. and Hoffman-La Roche, Inc. each filed motions to dismiss the Relator's complaint based on Fed. Rule Civ. P. 12(b)(6) and 9(b). ECF Nos. 73 and 72. On January 31, 2020, Defendant Roche Holding AG filed a motion to dismiss

[3] On September 4, 2019, the United States filed an Amended Notice of Election to Decline Intervention. ECF No. 36-1.

the Relators' complaint based on Fed. Rule Civ. P. 12(b)(6) and 9(b) as well as on lack of jurisdiction, as Defendant Roche Holding AG is a Swiss company that does not conduct business or any substantial activity in the United States. ECF No. 78.

On June 26, 2020, the Relator filed motions to voluntarily dismiss Defendants Genentech, Inc. and Roche Holding AG. ECF Nos. 90 and 87. On June 30, 2020, the Court granted both of those motions. ECF Nos. 91 and 92. On September 28, 2020, the Court denied Defendant Hoffman-La Roche's (hereafter "Roche's") motion to dismiss. ECF No. 112. On November 13, 2020, the Court issued a Scheduling and Discovery Order that set forth discovery and pre-trial deadlines. ECF No. 122.

After discovery began, on November 19, 2020, Roche served document requests on the CDC and FDA. The original scheduling order set a deadline for document production of October 8, 2021. ECF No. 122. On October 5, 2020, the parties filed a joint motion seeking a 6-month stay of the case. ECF No. 125. The parties requested the stay at the request of the United States so that its agencies could "continue to focus on the current COVID-19 pandemic, without diverting resources to field the substantial discovery requests that . . . [were] served upon it in this case." *Id.* at 2. The Court granted the stay and reset the deadlines in the scheduling order. ECF No. 126. The order stayed the case until April 6, 2022. *Id.* On April 6, 2022, the Relator served document requests on HHS. That same day, the parties requested a 60-day extension of the stay, again at the request of the United States, so that "the limited resources of [its] . . . agencies [need not] be expended on this case rather than on the Government's continued pandemic efforts." ECF No. 130. The Court granted the stay and reset the deadlines in the scheduling order. ECF No. 131. The order stayed the case until June 6, 2022. *Id.* The stay

expired on that date, and the parties are currently engaged in discovery. The revised scheduling order sets a deadline for document production of December 6, 2022. ECF No. 131.

ARGUMENT

The United States respectfully submits that dismissal of this case is warranted for two reasons. First, the Government has reasonably determined that the Relator's claim that the defendants violated the FCA lacks merit. His allegation centers on a scientific study that was published in the Archives of Internal Medicine in 2003, Laurent Kaiser*, et al.*, *Impact of Oseltamivir Treatment on Influenza-Related Lower Respiratory Tract Impact of Oseltamivir Treatment on Influenza-Related Lower Respiratory Tract Complications and Hospitalizations*, 163(14) Arch. Intern. Med. 1667-72 (July 29, 2003) (Kaiser 2003). According to the Relator, this study was flawed, the flaws were concealed by Roche and unknown to the United States, and the flaws were material to the United States' decision to stockpile Tamiflu.

The FCA case is thus grounded on the theory that Roche fraudulently induced the United States to stockpile Tamiflu and that the United States would not have done so had it known the truth. The Relator is mistaken on several counts. Kaiser 2003 was not the sole basis for selecting Tamiflu for the SNS. In fact, the United States would have selected Tamiflu even if Kaiser 2003 had never been published. At the time, Tamiflu was the most efficacious orally administered FDA-approved drug for the treatment and prophylaxis of influenza, which made it the most logical choice for the SNS. Further, while Kaiser 2003 has limitations, they do not invalidate its conclusions that Tamiflu reduces complications and hospitalizations associated with influenza. Subsequent studies have validated those conclusions.

At base, the Relator seeks to use the FCA to press his position on a longstanding, open, and public scientific debate regarding the efficacy of Tamiflu. HHS and CDC have been aware

of that debate and have reached a conclusion, which they have expressed publicly, that differs from the Relator's. In other words, the United States has reasonably concluded that it got what it paid for and that it was not duped into purchasing Tamiflu for the SNS. Moreover, the Relator's disagreement with that view does not mean a fraud was perpetrated on the United States or that it was misled.

Second, continued litigation of this case will require a substantial expenditure of resources by CDC, FDA, and HHS as third-party participants in discovery. The resources of these agencies are already stretched thin as they continue to address not only the historic COVID-19 pandemic but now also the monkeypox outbreak. In addition, the USAO and the DOJ Civil Division, as well as HHS' Office of General Counsel, will similarly be required to expend significant resources to assist CDC, FDA, and HHS in their responses to discovery requests for documents and testimony and to otherwise protect its interest in these proceedings.

For both of these reasons, dismissal of this action is appropriate.

A. The legal standard for dismissal under 31 U.S.C. § 3730(c)(2)(A)

As noted, the Fourth Circuit has not yet endorsed a particular standard for dismissal of a *qui tam* action under section 3730(c)(2)(A), and a four-way split in authority exists among its sister Circuits as to the applicable standard. The Court of Appeals for the District of Columbia Circuit has interpreted section 3730(c)(2)(A) to grant the United States "an unfettered right to dismiss" a *qui tam* action. *Swift*, 318 F.3d at 252. By contrast, the Courts of Appeals for the Ninth and Tenth Circuits apply a "rational relation test" for dismissal, recognizing that the United States has broad prosecutorial discretion to dismiss even meritorious *qui tam* cases so long as the reasons for dismissal are rationally related to a legitimate government interest. *Sequoia Orange*, 151 F.3d at 1145; *see also Ridenour v. Kaiser-Hill Co.*, 397 F.3d 925, 937

(10th Cir. 2005) (observing that "'it is enough that there are plausible, or arguable, reasons supporting the agency decision [to move for dismissal]'") (quoting *Sequoia Orange*, 912 F. Supp. at 1341). The Courts of Appeals for the Third and Seventh Circuits apply "a standard for dismissal informed by Federal Rule of Civil Procedure 41." *CIMZNHCA,* 970 F.3d at 839; *see also Polansky v. Executive Health Res., Inc.*, 17 F.4th 376, 393 (3d Cir. 2021). Under that standard, where the defendant has filed an answer or motion for summary judgment, the United States may dismiss so long as the court concludes that dismissal is "proper," as determined by factors such as "the interests of the parties, their conduct over the course of the litigation, . . . the Government's reasons for terminating the action," and any "prejudice to the non-governmental parties." *Polansky,* 17 F.4th at 393. Finally, the Court of Appeals for the First Circuit recently announced a standard requiring that the United States provide a reason for seeking dismissal, but limiting the court's review to ascertaining whether "the government's decision to seek dismissal of the *qui tam* action transgresses constitutional limitations or that, in moving to dismiss, the government is perpetrating a fraud on the court." *Borzilleri,* 24 F.4th at 42.[4]

Within the Fourth Circuit, the United States District Court for the Eastern District of Virginia has adopted the *Swift* standard. In *United States ex rel. Henneberger v. Ticom Geomatics, Inc.*, 427 F. Supp. 3d 701, 704 (E.D. Va. 2019), that court found "itself predominantly aligned with the views of the D.C. Circuit in *Swift*," dismissed the relator's complaint, and explained that "[t]he potential cost to the Government in monitoring and responding to discovery requests, particularly when the Government believes that a relator's case

[4] The Court of Appeals for the Fifth Circuit chose not to decide between the D.C. Circuit's *Swift* standard and the Ninth Circuit's *Sequoia Orange* standard, as dismissal was appropriate under either one. *United States ex rel. Health Choice Alliance, LLC v. Eli Lilly & Co.*, 4 F.4th 255, 263-64, 267-69 (5th Cir. 2021).

is unlikely to succeed, is clearly a legitimate purpose for seeking dismissal." *See also United States ex rel. Davidheiser v. Capital Rail Constructors*, 433 F. Supp. 3d 899, 902 (E.D. Va. 2019) (invoking *Swift* and *Ticom* and granting dismissal because the "government has an unfettered right to dismiss a *qui tam* action"). The United States District Court for the District of South Carolina, like the Fifth Circuit, chose not to decide between the D.C. Circuit's *Swift* standard and the Ninth Circuit's *Sequoia Orange* standard – the two prevailing standards at the time – as the court determined that dismissal was appropriate under either one. *United States ex rel. Stovall v. Webster Univ.*, No. 3:15-cv-03530-DCC, 2018 WL 3756888, at *3 (D.S.C. Aug. 8, 2018).

B. Dismissal is appropriate here because it does not violate any constitutional limitations.

In the United States' view, the FCA does not impose any substantive constraint on the Government's exercise of its dismissal right. Thus, when a relator objects to the Government's decision to dismiss a *qui tam* suit, the court's review is limited to determining whether the decision is consistent with the Constitution. Here, dismissal would not present any constitutional violation and the Court should therefore grant the Government's motion to dismiss.

1. The plain language of section 3730(c)(2)(A) is unambiguous in allowing the United States virtually unfettered discretion to dismiss *qui tam* actions.

A court begins, as it must, with the text of section 3730(c)(2)(A). *United States v. DiCristina*, 726 F.3d 92, 96 (2d Cir. 2013) ("When interpreting a statute, we must begin with the language employed by Congress and the assumption that the ordinary meaning of that language accurately expresses the legislative purpose.") (internal quotations omitted). Section 3730(c)(2)(A), by its terms, specifies who may dismiss a *qui tam* action: "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 hearing on the motion." 31 U.S.C. § 3730(c)(2)(A) (emphasis added).[5] This language contrasts sharply with language from the very same section, just a few provisions below: "The *court* shall dismiss an action . . . if substantially the same allegations or transactions . . . were publicly disclosed." 31 U.S.C. § 3730(e)(4)(A) (emphasis added). Because Congress "says in a statute what it means and means in a statute what it says there," *Connecticut National Bank v. Germain*, 503 U.S. 249, 253–54 (1992), this Court must presume Congress meant "The Government"—*i.e.*, the Executive—to have exclusive dismissal authority under section 3730(c)(2)(A).

Likewise, Congress knows how to impose express limits on the Attorney General's authority when it so intends. The very next paragraph after section 3730(c)(2)(A) states:

> The Government may settle the action with the defendant notwithstanding the objections of the person initiating the action *if the court determines*, after a hearing, that the proposed settlement is fair, adequate, and reasonable . . . .

31 U.SC. § 3730(c)(2)(B) (emphasis added). Section 3730(c)(2)(B) thus imposes judicial review on the Attorney General's power to settle a *qui tam* action when a relator objects, and specifies the proper standard of that review. By contrast, the absence of any such limitation in section

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[5] As the *Swift* court framed it, "the function of a hearing [under 3730(c)(2)(A)] when the relator requests one is simply to give the relator a formal opportunity to convince the government not to end the case," *Swift*, 318 F.3d at 253. *See also United States ex rel. Piacentile v. Amgen, Inc.*, No. 04 CV 3983 (SJ)(RML), 2013 WL 5460640, at *2 (E.D.N.Y. Sept. 30, 2013) (opportunity to respond to United States' motion and appear at oral argument satisfied hearing requirement); *United States ex rel. Levine v. Avnet, Inc.*, No. 2:14-cv-17 (WOB-CJS), 2015 WL 1499519, at *4 (E.D. Ky. Apr. 1, 2015) (opportunity to respond and oral argument sufficient, noting that a more substantive hearing standard could raise constitutional concerns given the discretion conferred on the United States by the statute). *But see United States ex rel. Health Choice Alliance, LLC v. Eli Lilly and Co.*, 4 F.4th 255, 267 (5th Cir. 2021) (finding no procedural due process error in section 3730(c)(2)(A) dismissal because the relator was afforded the opportunity to present evidence at a hearing).

3730(c)(2)(A), and the absence of any standard of review, make clear that Congress intended to commit the United States' decision to dismiss under this provision to the Government's discretion. *See Mendez v. Holder*, 566 F.3d 316, 321 (2d Cir. 2009) ("[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.") (quoting *Russello v. United States*, 464 U.S. 16, 23 (1983)). In sum, there simply is nothing in the text or framework of the FCA that constrains the United States' authority to dismiss under section (c)(2)(A).

2. The United States Supreme Court has long recognized the general unsuitability for judicial review of agency decisions to refuse enforcement.

The Supreme Court "has recognized . . . over many years that an agency's decision not to prosecute or enforce, whether through civil or criminal process, is a decision generally committed to an agency's absolute discretion" and is therefore "presumed immune from judicial review." *Heckler v. Chaney,* 470 U.S. 821, 831-32 (1985)*; see also id.* at 831 ("[T]he decision of a prosecutor in the Executive Branch not to indict . . . has long been regarded as the special province of the Executive Branch."); *United States v. Nixon*, 418 U.S. 683, 693 (1974) ("[T]he Executive Branch has exclusive authority and absolute discretion whether to prosecute a case."); *Newman v. United States*, 382 F.2d 479, 480 (D.C. Cir. 1967) ("Few subjects are less adapted to judicial review than the exercise by the Executive of his discretion in deciding when and whether to institute criminal proceedings . . . or whether to dismiss a proceeding once brought."); *see also Citizens for Resp. and Ethics in Wash. v. Fed. Election Comm'n*, 892 F.3d 434, 438 (D.C. Cir. 2018) (discussing applicability of doctrine to civil enforcement).

Justice Rehnquist, writing for the *Heckler* Court, cited many practical reasons—all relevant to the decision of the Attorney General not to prosecute—in acknowledging "the general

unsuitability for judicial review of agency decisions to refuse enforcement." 470 U.S. at 831-32. To begin with, "an agency decision not to enforce often involves a complicated balancing of a number of factors which are peculiarly within its expertise." *Id.* at 831. The agency must not only assess whether a violation has occurred, but also whether agency resources are best spent investigating or prosecuting other violations. *Id.* An agency must also consider whether it "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." *Id.*

DOJ undertakes a similar analysis in deciding whether an FCA action should be pursued. Even in instances where a relator conducts the action after the United States declines to intervene, it may be that the pursuit of the action is contrary to the Government's policy objectives. Moreover, the Government may be required to expend limited resources responding to discovery and otherwise monitoring the action. Because balancing these considerations is within the exclusive province of the Executive, the United States respectfully submits that in those very limited circumstances where it elects to dismiss a *qui tam* action pursuant to section 3730(c)(2)(A), it has virtually unfettered discretion to do so. [6]

3. The only constraints on the Government's dismissal authority are those imposed by the Constitution.

Although the FCA does not limit the Government's discretion to dismiss a *qui tam* action, the Government's dismissal decision is still subject to constitutional constraints.

[6] The fact that a relator has brought suit on behalf of the United States does not limit the Attorney General's authority to dismiss a *qui tam* action. *See, e.g.*, *Riley v. St. Luke's Episcopal Hosp.*, 252 F.3d 749, 753 ("That a private citizen may pursue a *qui tam* litigation under the FCA . . . does not interfere with the President's constitutionally assigned functions under Article II's Take Care Clause.") (*en banc*).

Accordingly, the Government may not dismiss for a constitutionally impermissible reason, such as the relator's religion, race, or sex. *Cf. United States* v. *Armstrong*, 517 U.S. 456, 464, 465 (1996) (recognizing that equal-protection principles constrain the government's prosecutorial decisions, but requiring "'clear evidence'" to "dispel the presumption that a prosecutor has not violated equal protection") (citation omitted). Nor may the Government engage in conduct so "egregious" that it "shocks the conscience"—the standard that the Supreme Court has held applicable to executive action under the Due Process Clause. *Cnty. of Sacramento* v. *Lewis*, 523 U.S. 833, 846 (1998). Unless a relator establishes a constitutional violation, however, a court has no substantive basis for setting aside the Government's decision to dismiss an FCA action.

In sum, where, as here, the United States has made a considered determination that this is one of the unique circumstances where the FCA is not a proper vehicle for the Relator to pursue his concerns and that it would be contrary to the public interest for the Relator to do so, and that decision does not offend any constitutional constraints on executive action, this court should defer to the Government's determination and dismiss the action.

C. Dismissal is warranted under any standard.

While we submit that dismissal is appropriate because the United States enjoys virtually unfettered authority to dismiss within the limited boundaries imposed by the Constitution, this Court need not resolve whether that is the appropriate standard for evaluating the Government's request that this matter be dismissed. That is because the United States has valid reasons for seeking dismissal that justify dismissal under any applicable standard.

1. The Government has reasonably determined that the Relator's claim is flawed.

As noted above, based on a lengthy and thorough investigation, the United States reasonably determined that the Relator's claim lacks merit. The Relator alleges that Roche

knowingly used "flawed" scientific analyses regarding the efficacy of Tamiflu, published in the early 2000s, to trick the United States into purchasing Tamiflu for the SNS. His allegation focuses on Kaiser 2003, a meta-analysis comprised of 10 individual studies that was funded and conducted in part by Roche and that concluded that Tamiflu decreases the incidence of complications and shortens hospitalizations associated with influenza, two properties that render Tamiflu ideal for use in an influenza pandemic. According to the Relator, the United States based its selection of Tamiflu heavily, if not exclusively, on Kaiser 2003. He claims that the Kaiser 2003 conclusions "were false … because the underlying studies were inherently flawed, could not be replicated, and the person listed as the author of the study involving the largest number of subjects (M76001) disclaimed involvement in the study." *See* Amended Complaint, ¶ 80. Moreover, he claims that Roche knew that the conclusions were false, as the FDA had previously rejected those claims (*i.e.*, reduction of complications and shortening of hospitalizations) when it reviewed the NDA for Tamiflu. Notwithstanding that knowledge, Roche allegedly presented that flawed analysis and its allegedly unsupported conclusions to CDC and HHS to persuade those agencies to select Tamiflu for the SNS. The Relator alleges that had CDC and HHS known that Tamiflu lacked those two properties, the United States would not have purchased Tamiflu for the SNS. In sum, he alleges that Roche duped the United States into purchasing Tamiflu, which, he claims, "does not reduce the incidence of influenza spread, severity, complications, hospitalizations, or mortality." *See* Amended Complaint, ¶ 112. As explained below, the Relator's claim has multiple shortcomings.

First, the United States would have selected Tamiflu for the SNS even if Kaiser 2003 had never been published. Beginning in 2004, there were increasing numbers of human infections with the avian influenza A(H5N1) virus, a highly pathogenic virus associated with a high

mortality (commonly known as "bird flu") in infected humans. These infections were believed to have resulted, in part, from human-to-human transmission of the virus, and an increasing number of countries with human cases set off global alarms of an influenza pandemic of high severity. That year the World Health Organization recommended that "countries should consider developing plans for ensuring the availability of antivirals" and that countries should "stockpile [those drugs] in advance."[7] Thus, there was urgency for HHS to stockpile antiviral FDA-approved drugs that could be rapidly distributed in an influenza pandemic. And of the available options, Tamiflu was the most logical choice, as it was FDA-approved for use in both adults and children for the treatment and prophylaxis of influenza, is administered orally, and has a relatively low incidence of adverse effects and drug-drug interactions.

Moreover, while clinical data at the time was limited on the efficacy of Tamiflu for reducing complications and shortening hospitalizations, there were other studies in addition to Kaiser 2003 supporting the conclusion that Tamiflu was effective for these purposes. By way of example, a study published in 2000 concluded that early treatment with Tamiflu in children significantly reduced the risk of influenza-associated otitis media (ear infections) by 44% and significantly reduced the incidence of physician-prescribed antibiotics by 24%. *See Whitley et al., Oral oseltamivir treatment of influenza in children*, 20(2) Pediatr. Infect. Dis J. 127-33 (2001).

Furthermore, contrary to the Relator's assumption, the selection of Tamiflu was not based solely on its capacity to reduce complications and shorten hospitalizations. The United States also reasonably relied on the fact that the FDA had approved Tamiflu for the treatment of

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[7] Available at https://apps.who.int/iris/bitstream/handle/10665/70631/WHO_CDS_CSR_RMD_2004.8_eng.pdf?sequence=1&isAllowed=y. Accessed October 28, 2022.

influenza and had specifically concluded that the drug reduced the duration of illness and was effective for prophylaxis of influenza. In short, even setting aside the conclusions of Kaiser 2003, Tamiflu would have been chosen for the SNS.

Second, while Kaiser 2003 has several methodological limitations, contrary to the Relator's allegations those limitations do not invalidate the study's conclusions that Tamiflu reduces complications and shortens hospitalizations associated with influenza. As a threshold matter, nearly all of those limitations were known to the United States when Tamiflu was selected for the SNS.[8] The CDC concluded that those limitations raised questions regarding the extent to which Tamiflu reduces complications and shortens hospitalizations, but not whether Tamiflu has those properties. Moreover, that Tamiflu has those properties has been borne out by subsequent scientific studies that have similarly found that it reduces complications and shortens hospitalizations, though the extent of the drug's efficacy varies among those studies and some studies failed to corroborate the Kaiser 2003 findings altogether. *See, e.g.*, Miguel A. Hernán and Marc Lipsitch, *Oseltamivir and risk of lower respiratory tract complications in patients with flu symptoms: a meta-analysis of eleven randomized clinical trials*, 53(3) Clin. Infect. Dis. 277-9 (2011) (re-analyzing the Kaiser 2003 data plus one additional unpublished study using a scientifically superior methodology and concluding that Tamiflu reduces the risk of lower respiratory tract complications requiring antibiotic treatment by 37 percent among patients with confirmed influenza); Joanna Dobson, *et al., Oseltamivir treatment for influenza in adults: a*

[8] The patent methodological limitations include, among other things, (1) failing to account for a heterogenous patient population across the 10 individual studies, (2) including patients who were taking antibiotics at the time of enrollment, (3) failing to account for a statistically significant imbalance between the proportion of participants in the placebo and treatment groups, using clinically subjective outcomes (*e.g.*, clinical diagnosis of bronchitis), and (4) failing to standardize clinical decision-making for determining whether to prescribe antibiotics to study participants across the 10 individual studies.

meta-analysis of randomized controlled trials, 385(9979) Lancet 1729-1737 (2015) (concluding that "oseltamivir in adults with influenza accelerates time to clinical symptom alleviation, reduces risk of lower respiratory tract complications, and admittance to hospital …."); Chang-Bi Wang*, Prompt Oseltamivir Therapy Reduces Medical Care and Mortality for Patients with Influenza, Infection*, 94(27) Medicine e1070 (2015) (concluding that "[o]seltamivir … exhibits superior effectiveness in reducing outpatient visit[s], hospitalization, and mortality when much larger sizes of patients were treated promptly…."); and Malosh RE *et al., Efficacy and safety of oseltamivir in children: Systematic review and individual patient data meta-analysis of randomized controlled trials*, 66(10) Clin. Infect. Dis. 1492-1500 (2018) (concluding that oseltamivir significantly reduces the duration of illness and reduced the risk of otitis media by 34 percent in children). *But cf.* Mark H. Ebell*, et al., Effectiveness of oseltamivir in adults: a meta-analysis of published and unpublished clinical trials*, Apr. 30(2) Family Practice 125-33 (2013) (concluding that "[t]here is no evidence that [oseltamivir] reduces the likelihood of hospitalization or complications [of influenza]….").[9]

The Relator alleges that, unbeknownst to the United States, Kaiser 2003 also suffered from the methodological limitation that one of the ten individual studies, M76001, improperly employed an "area under the curve" (AUC) analysis based on subjective symptom scores. The Relator's claim that this analysis invalidates the conclusions of Kaiser 2003, however, is overstated. While better scientific methods may exist for determining anti-viral efficacy, AUC analyses have been used in other peer reviewed studies. *See, e.g.*, Nicholson KG *et al.*, *Efficacy*

[9] The conclusions of *Ebell* 2013 are infirm as that study focused on the "intention to treat study population," which includes patients who do not have influenza. A better approach would have been to focus exclusively on patients with confirmed influenza (*i.e.*, the intention to treat influenza infected study population).

and safety of oseltamivir in treatment of acute influenza: A randomized controlled trial, Lancet 2000;355:1845-50.[10]

Third, the Relator makes much of the fact that in 1999, in response to Roche's New Drug Application (NDA) for Tamiflu, the FDA did not approve language on the label indicating that the drug reduced complications or shortened hospitalizations associated with influenza. The Relator's reliance on the FDA's determination is misplaced. As noted above, the selection of Tamiflu was based on more than just its capacity to reduce complications and shorten hospitalizations (which, to be sure, the Relator disputes). It was also chosen because it was FDA-approved for use in both adults and children for both the treatment and prophylaxis of influenza, is administered orally, and has a relatively low incidence of adverse effects. In addition, the purpose of the FDA's review of Roche's NDA was to determine whether Tamiflu was safe and effective (which the FDA did) and how it could properly be marketed. That review was different than the CDC's review of the scientific evidence years later for purposes of identifying the best available anti-viral that could be stockpiled and deployed on a mass scale in the event of a pandemic.

Fourth, since at least 2009, when a public debate began regarding the efficacy of Tamiflu, the CDC has been aware of, and consistently rejected, the essence of the Relator's claim. After publication of Kaiser 2003, and the decisions by several countries to stockpile Tamiflu, a public debate ensued among the scientific community as to whether the conclusions of Kaiser 2003

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[10] There is one flaw alleged by the Relator that is not methodological. The Relator alleges that the person listed as the author of M76001 has disclaimed involvement in that study. *See* Amended Complaint, ¶ 80. Accepting that allegation as true, it does not invalidate the primary conclusion of Kaiser 2003 that Tamiflu can reduce the severity of complications and length of hospitalizations, which has been substantiated by subsequent studies, as discussed further below, though as noted these studies have found a range as to the extent to which Tamiflu possess those properties.

were valid. That debate was largely ignited by articles authored by the Relator and published by his employer, the Cochrane Collaboration ("Cochrane"), and the British Medical Journal (BMJ) in December of 2009. Those articles, like his FCA allegation, criticized Roche for withholding from Cochrane the Kaiser 2003 raw data and questioned the efficacy of Tamiflu and its suitability for pandemic use as well as the decisions by governments to use it in their stockpiles. Since the Cochrane and BMJ articles were published, there has been a slew of scientific studies about the efficacy of Tamiflu. And as noted above, the conclusions of those studies have been mixed, as certain of the studies concluded that Tamiflu reduces complications and shortens hospitalizations, while others did not corroborate the Kaiser 2003 findings.

Significantly, the CDC has been aware of the Cochrane and BMJ articles since their publication, and has reaffirmed its view – publicly and repeatedly – that the drug is efficacious and suitable for use in a pandemic. For example, during a press briefing in December of 2009, shortly after publication of the Cochrane and BMJ articles, the CDC Director at the time was asked "about the BMJ article this week that suggested that Tamiflu is not effective, or reemphasizes that it is mildly effective." In response, he stated: "All of the evidence that we've seen about Tamiflu is consistent with our recommendations."[11] During a tele-briefing in December of 2014, the Director was asked: "[W]hat [do] you think about the Cochrane review study … that … suggested antivirals [*e.g.*, oseltamivir] are not very effective when it comes to preventing hospitalizations from flu." He responded:

> We looked in detail at the data on oseltamivir. We looked at published and unpublished data. We looked at the full data set, and it is the opinion of the CDC scientists that the evidence is strong that oseltamivir given early in the course of illness will reduce the length of illness by about a day. It is not a miracle drug, but we believe it is an effective drug, and we think there's some methodological issues with that review related to what are some of the outcomes looked at, what are

[11] Available at https://www.cdc.gov/media/transcripts/2009/t091210.htm. Accessed October 28, 2022.

> some of the sample sizes, what was the data included? There was some concern that not all data had been shared by the company. We have looked at a broad swath of data available, and we see a consistency of the data that does indicate to us that there is some efficacy of the drugs.[12]

Finally, the current CDC webpage titled, "For Clinicians: Antiviral Medication: Summary of Influenza Antiviral Treatment Recommendations," provides the following:

> Observational studies in hospitalized adult patients with influenza have reported that starting oseltamivir treatment within 48 hours of hospital admission can reduce 30-day readmissions and mortality compared with no treatment or later initiation of treatment. One observational study reported that hospitalized adult influenza patients who were started on oseltamivir treatment within 48 hours of admission had significantly lower 30-day readmission or 30-day readmission and mortality compared with those not treated or started on oseltamivir treatment >48 hours after admission (Sharma 2021). Another observational study in hospitalized adults with influenza reported that starting oseltamivir treatment <48 hours of hospital admission (median time from symptom onset to oseltamivir initiation: 3 days) significantly reduced 30-day mortality and 30-day mortality or ICU admission >48 hours after admission, compared to untreated patients (Groeneveld 2020).[13]

That the CDC has consistently stated publicly that Tamiflu, while not a perfect drug, is nonetheless efficacious, and continues to stand behind its decision to recommend Tamiflu for the SNS – even after the basis for the Relator's FCA claim became well known to the public and the agency in 2009 – belies the notion that the United States was duped into purchasing the equivalent of "bullets filled with sawdust." *See* Amended Complaint, ¶ 154.

In short, the Relator is incorrect that the United States' decision to stockpile Tamiflu was based exclusively on Kaiser 2003 or that the Government would not have done so if it had been aware of the claimed defects in that study. To the contrary, the United States' decision was based on a variety of considerations and would have been the same even in the absence of Kaiser

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[12] Available at https://www.cdc.gov/media/releases/2014/t1204-flu-season.html. Accessed October 28, 2022.

[13] Available at https://www.cdc.gov/flu/professionals/antivirals/summary-clinicians.htm. Accessed on October 28, 2022.

2003. Tellingly, the CDC has repeatedly reaffirmed its view that Tamiflu is the most appropriate choice for meeting its objective of being prepared to address an influenza pandemic. The Relator's opposing view fails to establish a violation of the FCA, which is not an appropriate vehicle to second-guess the United States' conclusions regarding the scientific merits of Tamiflu. At bottom, the issue here is not whether Tamiflu is a wonder drug, but rather whether the United States was defrauded when it purchased the drug for the SNS. The United States contends that it made an informed decision, and that therefore dismissal is appropriate because the gravamen of an FCA claim is fraud.

2. Ongoing litigation will impose a significant resource burden on government agencies addressing public health emergencies.

If the Relator's claims proceed, they will require the CDC, FDA, and HHS to respond to burdensome discovery requests. And critically, these agencies will be required to respond to these discovery requests at a time when their resources are already stretched thin, as they continue to address the historic COVID-19 pandemic and now the ongoing monkeypox outbreak, which the Secretary of HHS recently declared to be a "public health emergency."[14] As they have throughout the COVID-19 pandemic, the CDC, FDA, and HHS continue to employ an "all hands-on deck" approach to these public health challenges, and each hour spent on fielding discovery requests in this case is an hour less that can be devoted to those critically important endeavors. That some of the facts pertain to events that happened more than 20 years ago will only exacerbate the United States' burden. And the burden will not be limited to just these

[14] On August 4, 2022, HHS Secretary Xavier Becerra determined that the monkeypox outbreak in the United States is a "public health emergency," under section 319 of the Public Health Service Act (PHSA), 42 U.S.C. § 247d. Additionally, CDC's Emergency Operations Center (EOC) has been activated for responding to that crisis. COVID-19 remains a public health emergency under section 319 of the PHSA, and the EOC remains activated for responding to that public health emergency as well.

public health agencies. The USAO and the DOJ Civil Division will also be required to continue to expend time and resources in connection with these proceedings, including assisting the agencies with discovery requests and reviewing pleadings and weighing in as necessary to ensure that the United States' interests are protected throughout this litigation.

These concerns about the expenditure of limited resources are heightened where it is the United States' interest alone that the Relator claims to be vindicating and where the United States believes the case lacks merit. Simply put, if the United States does not believe that it is in the public interest to pursue this lawsuit, it should not be required to expend limited resources to support continuation of the lawsuit that are critically needed elsewhere. In such circumstances, "the government's concern with litigation costs" is a valid reason supporting dismissal because "the government can legitimately consider the burden imposed on the taxpayers by its litigation." *Sequoia Orange*, 151 F.3d at 1146; *see Ridenour*, 397 F.3d at 937 (affirming dismissal based, in part, on finding that litigation would "plac[e] an added financial burden" on the agency through a requirement to shift funds from mission efforts to litigation). *Id.* at 937; *Swift*, 318 F.3d at 254 ("the government's goal of minimizing its expenses is … a legitimate objective" in dismissing a *qui tam* action).

CONCLUSION

While the United States does not take lightly the exercise of its inherent dismissal authority under 31 U.S.C. § 3730(c)(2)(A), for the reasons discussed above, it has determined that dismissal is appropriate here, and accordingly respectfully request that the Court order the case dismissed.[15]

[15] The relator brought this suit on behalf of the United States as well as 28 States and the District of Columbia. The States and the District of Columbia are considering whether to consent or join in this motion. Once they make a decision and complete their respective

Dated: Baltimore, Maryland
October 31, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, on October 31, 2022, I caused the foregoing document to be filed by means of this Court's Electronic Case Filing (ECF) system, thereby serving it upon all registered

approval processes, the United States will supplement this motion to inform the Court of their positions.

users in accordance with Federal Rules of Civil Procedure 5(b)(2)(E) and 5(b)(3) and Local Rules Gen 304 and 305.

Dated: October 31, 2022

By: */s/ Tarra DeShields*
Tarra DeShields
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