IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

UNITED STATES OF AMERICA, et al., ex rel. THOMAS JEFFERSON, Relator, v. ROCHE HOLDING AG, et al., Defendants.	Civil Action No.: GLR-14-3665

MEMORANDUM OPINION

THIS MATTER is before the Court on Defendant Hoffmann-La Roche Inc.'s ("Roche") Motion to Dismiss Relator's Amended Complaint (ECF No. 72) and Relator Thomas Jefferson's Motion to Strike Exhibits A, C, D, E, F, G, H, I, and K to Defendant Roche's Motion to Dismiss First Amended Complaint and Related Factual Assertions and Legal Arguments (ECF No. 89).[1] The Motions are ripe for disposition, and no hearing is necessary. See Local Rule 105.6 (D.Md. 2018). For the reasons outlined below, the Court will deny both Motions.

[1] Also pending are Genentech, Inc.'s ("Genentech") Motion to Dismiss for Failure to State a Claim and for Failure to Plead Fraud with Particularity (ECF No. 73); Roche Holding AG's ("Roche Holding") Motion to Dismiss Relator's Amended Complaint (ECF No. 78); and Roche's Motion for Leave to File a Surreply in Further Support of its Opposition to Relator Thomas Jefferson's Motion to Strike (ECF No. 110). Because Jefferson voluntarily dismissed Genentech and Roche Holding as Defendants on June 30, 2020, (see ECF Nos. 91, 92), their Motions to Dismiss will be denied as moot. The Court will also deny as moot Roche's Motion for Leave to File a Surreply, because the Court will deny Jefferson's Motion to Strike without considering the "new arguments" Jefferson allegedly made for the first time in his Reply in support of his Motion.

I. BACKGROUND[2]

A. Tamiflu, FDA Approval, and the Strategic National Stockpile

In 1996, Gilead Sciences, Inc. created Tamiflu, an oral antiviral prescription drug, and licensed it to Roche under a Development and License Agreement.[3] (Am. Compl. ¶¶ 4, 24, ECF No. 34). Roche subsequently marketed and sold Tamiflu as a seasonal influenza treatment. (Id. ¶ 26). On April 30, 1999, Roche filed a New Drug Application ("NDA") seeking a Food and Drug Administration ("FDA") indication for influenza ("flu") treatment. (Id. ¶ 38).

Roche's NDA came on the heels of the World Health Organization's ("WHO") flu pandemic guidelines ("WHO Pandemic Guidelines" or "Guidelines"). (Id. ¶¶ 30, 37). The Guidelines, issued on April 1, 1999, "strongly recommended that all countries establish multidisciplinary National Pandemic Planning Committees (NPPCs) responsible for developing strategies appropriate for their countries in advance of the next influenza pandemic." (Id. ¶ 31). The Guidelines included proposed measures aimed at reducing the spread and severity of—in addition to the hospitalizations and deaths resulting from—the flu, including "restricting travel and public gatherings, quarantine, vaccine development" and establishing "strategic stockpiles of an antiviral drug." (Id. ¶¶ 33–34). WHO recognized that preexisting flu treatments, specifically amantadine and rimantadine, were

[2] Unless otherwise noted, the Court takes the following facts from Jefferson's Amended Complaint and accepts them as true. See Erickson v. Pardus, 551 U.S. 89, 94 (2007) (citations omitted).

[3] Tamiflu is a formulation of the generic drug Oseltamivir, and the terms are used interchangeably in the Amended Complaint. (Am. Compl. ¶ 2 n.4, ECF No. 34). For consistency, the Court will only refer to the drug as Tamiflu.

clinically proven to reduce the severity and duration of flu symptoms. (Id. ¶ 36). With this new pandemic market identified, Roche sought to position Tamiflu as a pandemic treatment. (Id. ¶ 37).

On October 25, 1999, Tamiflu received an FDA indication "for the treatment of uncomplicated acute illness due to influenza infection in adults." (Id. ¶ 38). However, the FDA concluded that clinical trial data did not support an indication that Tamiflu reduced the severity of flu symptoms or prevented hospitalizations, secondary bacterial infections, or mortality. (Id. ¶¶ 40–42).

In 2000, Roche submitted a supplemental NDA seeking an indication for flu prophylaxis and treatment indications for reduction of flu-related complications and hospitalizations. (Id. ¶ 43). The FDA concluded that Tamiflu only prevented people from developing symptomatic influenza and approved an indication for the prophylaxis of influenza in adults and adolescents thirteen years and older. (Id. ¶¶ 44–45). In doing so, the FDA also concluded that the clinical trial data did not support claims that Tamiflu prevented either asymptomatic influenza infection or viral transmission. (Id. ¶ 46).

Roche sought broader treatment indications consistent with the pandemic uses outlined in WHO's Pandemic Guidelines—i.e., lower respiratory tract infections and pneumonia—but the FDA rejected these treatment indications. (Id. ¶¶ 47–48). The FDA also challenged Roche's marketing statements regarding Tamiflu. Specifically, on or about April 14, 2000, the FDA sent Roche a cease-and-desist letter regarding claims that Tamiflu had "the power to stop the flu" and reduced the "duration of the flu by 31%," the "severity

of influenza symptoms by 38%," and "incidence[s] of secondary complication (i.e., bacterial infections) by 45%." (Id. ¶ 140) (internal quotation marks omitted).

In addition to seeking broader FDA treatment indications, Roche published scientific journal articles touting Tamiflu's efficacy for pandemic uses. (Id. ¶¶ 71–84). For example, a February 14, 2001 article by Robert Welliver and others ("Welliver Article") asserted that Tamiflu prevented flu transmission within households, implying that the drug prevented person-to-person transmission even though the clinical data did not support that implication. (Id. ¶ 72). Another article, published July 29, 2003 by Laurent Kaiser and Frederick Hayden ("Kaiser Article"), reported a pooled analysis of ten clinical studies—nine of which were included in the original and supplemental NDAs that Roche submitted to the FDA—and purported to show that Tamiflu reduced flu-related respiratory complications as measured by antibiotic use and hospitalizations. (Id. ¶¶ 58, 76).

Contemporaneous with or shortly after these publications, Roche's CEO, medical director, and marketing team met with various health care agencies, including the Department of Health and Human Services ("HHS") and the Centers for Disease Control and Prevention ("CDC"), regarding Tamiflu's inclusion in the Strategic National Stockpile ("National Stockpile"). (Id. ¶ 85). Roche's efforts yielded favorable results, and Tamiflu was added to the list of drugs approved for the National Stockpile on August 1, 2003. (Id. ¶ 82).

In August 2004, HHS issued a draft Pandemic Preparedness and Response Plan ("Draft Pandemic Plan"). (Id. ¶ 87). The Draft Pandemic Plan incorporated representations that Roche made about Tamiflu in various scientific articles, including the Welliver and

Kaiser articles, as well as a February 1, 2004 article by Frederick Hayden ("Hayden Article"), which claimed that Tamiflu prevented flu transmission within households, even though the data only showed that Tamiflu reduced the incidence of symptomatic influenza. (Id. ¶¶ 83, 86–91).

During an October 26, 2004 presentation, Roche informed HHS that Tamiflu could be used to treat influenza and to prevent infection, even though clinical data did not support the latter assertion. (Id. ¶ 92). Hayden made similar misrepresentations in an April 20, 2005 presentation to HHS' Pandemic Influenza Working Group ("HHS Working Group"). (Id. ¶ 93). During that presentation, Hayden cited his 2004 article and the Welliver and Kaiser articles while arguing that Tamiflu reduced the spread, severity, complications, hospitalizations, and deaths related to flu infections. (Id.). The presentations also included a PowerPoint slide discussing Tamiflu's ability to prevent transmission within households. (Id. ¶¶ 94–95).

Hayden's representations regarding Tamiflu's ability to prevent viral infections were echoed by Roche's medical director, Dominick Iacuzio. (Id. ¶ 96). During a May 26, 2005 legislative hearing, Iacuzio falsely testified that certain antiviral drugs, including Tamiflu, could be used as a prophylactic to prevent a flu infection. (Id.).

When the HHS Working Group met again on July 19, 2005, it adopted recommendations for implementing a Pandemic Influenza Preparedness Plan, which included maintaining a minimum stockpile of approximately forty million flu treatments, ninety percent of which would consist of Tamiflu. (Id. ¶¶ 97–98). Its recommendations were forwarded to Cristina Beato, M.D., acting Assistant Secretary for HHS' National

Vaccine Program. (Id. ¶ 99). HHS' final Pandemic Influenza Plan ("Final Pandemic Plan"), released November 1, 2005, referenced Tamiflu's ability to decrease duration of illness, viral transmission, pneumonia, and mortality. (Id. ¶¶ 100–06). The Final Pandemic Plan also cited the Kaiser Article in support of HHS' belief that Tamiflu would reduce hospitalizations by at least fifty percent. (Id. ¶ 103).

On November 4, 2005, HHS Secretary Michael Leavitt presented the Final Pandemic Plan to the United States House of Representatives' Committee on Government Reform. (Id. ¶ 108). On December 30, 2005, Congress passed PL 109-148 appropriating $3.3 billion for HHS' flu pandemic planning—$731 million of which was designated for antiviral treatments. (Id. ¶ 109). Congress appropriated another $2.3 billion for HHS' pandemic planning on June 15, 2006, with $350 million designated for antiviral treatments. (Id. ¶ 110).

On January 8, 2009, HHS issued Pandemic Planning Update VI, reporting that HHS had purchased fifty million courses of Tamiflu and another antiviral drug for the National Stockpile, which would be distributed to state governments to treat forty-four million Americans, with six million courses reserved to prevent the spread of an emerging pandemic. (Id. ¶ 111).

B. Jefferson's Tamiflu Investigation

Relator Thomas Jefferson is a physician and medical researcher who specializes in public health and acute respiratory infections. (Am. Compl. ¶ 55). Since 1999, Jefferson has researched neuraminidase inhibitors, which include Tamiflu. (Id.).

In 2009, Jefferson began to question Tamiflu's efficacy and sought to independently corroborate Roche's claims. (Id. ¶ 56). Jefferson contacted Hayden and Kaiser to obtain the data used in the ten clinical trials described in the Kaiser Article, which supported Roche's claim that Tamiflu reduced flu-related respiratory complications.[4] (Id. ¶¶ 58, 76). Jefferson eventually obtained the data from Roche in 2013 and confirmed Roche's claim that Tamiflu reduced the duration of flu symptoms. (Id. ¶¶ 59–61). However, Jefferson concluded that this benefit was offset by severe side effects, namely nausea and vomiting. (Id. ¶ 63). Jefferson's analysis of the data also disproved Roche's claim that Tamiflu reduced flu-related complications, hospitalizations, deaths, and person-to-person transmission. (Id. ¶ 61). He also determined that Tamiflu had no significant effect on the rate of flu-related bronchitis, sinus infections, or ear infections. (Id.).

An individualized review of the tenth clinical trial discussed in the Kaiser article revealed that although Tamiflu alleviated flu symptoms and increased tolerability, the clinical data did not support Roche's conclusion that Tamiflu reduced flu-related complications or severity by fifty percent. (Id. ¶ 126). Jefferson also discovered that the results of the tenth clinical trial were never presented to the FDA or peer reviewed.[5] (Id. ¶

[4] Jefferson questioned the veracity of other scientific articles touting Tamiflu's pandemic uses based on a conversation he had with two former medical writers for Adis International ("Adis"), a medical publishing service, in 2009. (Am. Compl. ¶¶ 67–69). Jefferson alleges that the writers informed him that Roche sent Adis processed clinical trial data for publication and instructed the writers to identify Tamiflu as the solution to influenza. (Id.).

[5] Jefferson asserts that Roche's failure to provide the results of the tenth clinical trial to the FDA in its original or supplemental NDAs violates the New Drug Application regulations requiring submission of all relevant studies regardless of the information's source. (Am. Compl. ¶ 131; see 21 C.F.R. §§ 314.50, 314.50(d)(5)(iv)).

125). Moreover, the results of that clinical trial were only published in a one-paragraph abstract, and the alleged author, Dr. John Treanor, denied ever writing the abstract. (Id. ¶¶ 127–28).

Jefferson's attempts to replicate the results of the Kaiser study also proved unsuccessful, as did an independent attempt by another researcher. (Id. ¶¶ 135–38). Jefferson's replication efforts and independent investigation revealed several methodological flaws. (Id. ¶ 133). For example, Jefferson noted that Roche, among other errors, "failed to predefine in study protocols what constituted secondary illnesses, including sinusitis, bronchitis, and pneumonia, leading to inconsistent diagnoses"; "counted self-reported, unverified pneumonia as a complication rather than radiologically confirmed pneumonia"; "failed to consistently ensure the recording of complications on diary cards"; and "failed to follow data handling rules and procedures in the clinical trials." (Id.).

Jefferson also learned that Roche funded all of the clinical trials described in the Kaiser Article. (Id. ¶ 76). Jefferson's confidence in the Kaiser Article was further corroded when he discovered that Roche compiled, processed, and analyzed the data that was used in those trials; that several of the article's co-authors were Roche employees; and that Hayden, one of those co-authors, received significant payments from Roche as a consultant. (Id. ¶¶ 75–77). Moreover, the Kaiser Article relied on an abstract that was never peer-reviewed or published in any medical or scientific journal. (Id. ¶ 129).

Based on the foregoing, Jefferson ultimately concluded that "there was no evidence for clinicians or policy-makers to use Tamiflu to prevent serious outcomes in pandemic

influenza outbreaks and that the drug labeling should be changed to reflect these findings." (Id. ¶ 64).

C. Procedural History

On November 21, 2014, Jefferson, proceeding as a qui tam relator on behalf of the United States, sued Roche, Roche Holding AG, and Genentech, Inc.[6] (ECF No. 1). Jefferson filed an Amended Complaint on September 3, 2019. (ECF No. 34). The Amended Complaint alleges violations of §§ 3729(a)(1)(A) and (a)(1)(B) of the False Claims Act ("FCA"), 31 U.S.C. §§ 3729 et seq. (Count 1); and violation of state law equivalents of the FCA in the District of Columbia and the following states: California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Washington, and Wisconsin (Counts 2–30). (Am. Compl. ¶¶ 162–312). Jefferson seeks an order directing Roche to cease violating the FCA and its state equivalents; damages on behalf of the United States government and the individual states; a relator's share pursuant to 31 U.S.C. § 3730(d) and its state equivalents; attorneys' fees and costs; and civil penalties. (Id. at 66–67).

[6] An individual may assert a claim under the False Claims Act ("FCA"), 31 U.S.C. §§ 3729 et seq., in the name of the United States government, but the complaint must be filed under seal and served on the government so that the government has the opportunity to intervene. 31 U.S.C. § 3730(b)(2). If the government declines to intervene, the individual may still pursue the case. Id. § 3730(c)(3). Here, the United States declined to intervene and notified the Court. See id. § 3730(b)(4)(B).

On January 17, 2020, Roche filed its Motion to Dismiss. (ECF No. 72). Jefferson filed his Opposition on June 26, 2020 together with a Motion to Strike Exhibits A, C, D, E, F, G, H, I, and K from Roche's Motion. (ECF Nos. 88, 89). Roche filed an Opposition to the Motion to Strike and a Reply in support of its Motion to Dismiss on July 31, 2020. (ECF Nos. 104, 105). Jefferson filed a Reply in support of his Motion to Strike on August 14, 2020. (ECF No. 108).

II. DISCUSSION

A. Motion to Strike

Pursuant to Federal Rule of Civil Procedure 12(f), Jefferson moves to strike all but two exhibits attached to Roche's Motion to Dismiss and any references to the exhibits within the Motion. The challenged exhibits memorialize publicly available statements that the CDC and FDA made about Tamiflu. Specifically, these exhibits include the FDA's current informational page about Tamiflu's approved indications (Exhibit A); several articles and transcripts posted in the "CDC Online Newsroom" (Exhibits C, D, E); the most recent version of HHS' Pandemic Influenza Plan, earlier versions of which are cited throughout Jefferson's Amended Complaint (Exhibit F); and the CDC's current webpages addressing "Questions and Answers" about "Pandemic Influenza" (Exhibit G), "What You Should Know About Flu Antiviral Drugs" (Exhibit H), "Flu Treatment" (Exhibit I), and "Pandemic Influenza" (Exhibit K). The Court declines to strike these exhibits.

First, Jefferson's Motion to Strike is procedurally improper. Under Rule 12(f), a court may strike "from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." Fed.R.Civ.P. 12(f) (emphasis added). Federal Rule of

Civil Procedure 7 defines pleadings as "(1) a complaint; (2) an answer to a complaint; (3) an answer to a counterclaim designated as a counterclaim; (4) an answer to a crossclaim; (5) a third-party complaint; (6) an answer to a third-party complaint; and (7) if the court orders one, a reply to an answer." Fed.R.Civ.P. 7(a). A motion to dismiss is not a pleading. See Mellon Bank, N.A. v. Ternisky, 999 F.2d 791, 795 (4th Cir. 1993). "Although some cases have held that Rule 12(f) may be used to strike documents other than pleadings, the weight of recent authority is that such an action is not contemplated or permitted by the Rules." Anusie-Howard v. Todd, 920 F.Supp.2d 623, 627 (D.Md. 2013), aff'd, 615 F.App'x 119 (4th Cir. 2015). Accordingly, Rule 12(f) does not permit the Court to strike Roche's Motion to Dismiss or the exhibits attached thereto.[7] See McCormick v. Hous. Auth. of Balt. City, No. SAG-19-2415, 2020 WL 4003169, at *1 (D.Md. July 15, 2020) (concluding that "a motion to strike another pending motion is not an appropriate procedural tool"); see also Bird v. Bank of New York Mellon Tr. Co., N.A., No. GLR-19-464, 2019 WL 4750289, at *3 n.5 (D.Md. Sept. 30, 2019) (denying motion to strike defendant's motion to dismiss). To the extent Jefferson sought to challenge legal or factual assertions in the Motion to Dismiss, he could have done so in his Opposition.

[7] The Court does have inherent authority to strike other documents. See Iota Xi Chapter of Sigma Chi Fraternity v. Patterson, 566 F.3d 138, 150 (4th Cir. 2007). However, "[b]ecause of their very potency, inherent powers must be exercised with restraint and discretion." Chambers v. NASCO, Inc., 501 U.S. 32, 44 (1991). Here, the Court declines to exercise its inherent authority to strike Roche's Motion and exhibits, because Jefferson had the opportunity to challenge the factual and legal assertions raised therein through his Opposition.

Second, even if Jefferson could challenge Roche's Motion and the attached exhibits through Rule 12(f), his Motion is moot, as the Court does not rely upon any of the challenged exhibits when evaluating the sufficiency of Jefferson's claims.

Thus, Jefferson's Motion will be denied because it is procedurally improper and, even if properly plead, is mooted by the Court's resolution of Roche's Motion without consideration of the challenged exhibits or arguments arising therefrom.

B. Motion to Dismiss

1. Standard of Review

The purpose of a Rule 12(b)(6) motion is to "test[ ] the sufficiency of a complaint," not to "resolve contests surrounding the facts, the merits of a claim, or the applicability of defenses." King v. Rubenstein, 825 F.3d 206, 214 (4th Cir. 2016) (quoting Edwards v. City of Goldsboro, 178 F.3d 231, 243 (4th Cir. 1999)). A complaint fails to state a claim if it does not contain "a short and plain statement of the claim showing that the pleader is entitled to relief," Fed.R.Civ.P. 8(a)(2), or does not "state a claim to relief that is plausible on its face," Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). A claim is facially plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. (citing Twombly, 550 U.S. at 556). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." Id. (citing Twombly, 550 U.S. at 555). Though the plaintiff is not required to forecast evidence to prove the elements of the claim, the complaint must allege sufficient facts to establish each element. Goss v. Bank of Am., N.A., 917 F.Supp.2d

445, 449 (D.Md. 2013) (quoting Walters v. McMahen, 684 F.3d 435, 439 (4th Cir. 2012)), aff'd, 546 F.App'x 165 (4th Cir. 2013).

In considering a Rule 12(b)(6) motion, a court must examine the complaint as a whole, consider the factual allegations in the complaint as true, and construe the factual allegations in the light most favorable to the plaintiff. Albright v. Oliver, 510 U.S. 266, 268 (1994); Lambeth v. Bd. of Comm'rs of Davidson Cty., 407 F.3d 266, 268 (4th Cir. 2005) (citing Scheuer v. Rhodes, 416 U.S. 232, 236 (1974)). But the court need not accept unsupported or conclusory factual allegations devoid of any reference to actual events, United Black Firefighters v. Hirst, 604 F.2d 844, 847 (4th Cir. 1979), or legal conclusions couched as factual allegations, Iqbal, 556 U.S. at 678.

Because this action involves allegations of fraud, the complaint is also subject to Federal Rule of Civil Procedure 9(b), which requires that "the circumstances constituting fraud" be stated "with particularity." Fed.R.Civ.P. 9(b). The "circumstances constituting fraud" include the "time, place and contents of the false representation, as well as the identity of the person making the misrepresentation and what was obtained thereby." Superior Bank, F.S.B. v. Tandem Nat. Mortg., Inc., 197 F.Supp.2d 298, 313–14 (D.Md. 2000) (quoting Windsor Assocs. v. Greenfeld, 564 F.Supp. 273, 280 (D.Md. 1983)).

By its terms, however, Rule 9(b) permits a general averment of aspects of fraud that relate to a defendant's state of mind. The Rule states, in part: "Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Moreover, Rule 9(b) is "less strictly applied with respect to claims of fraud by concealment" or omission of material facts, as opposed to affirmative misrepresentations, because "an omission 'cannot

be described in terms of the time, place, and contents of the misrepresentation or the identity of the person making the misrepresentation.'" Shaw v. Brown & Williamson Tobacco Corp., 973 F.Supp. 539, 552 (D.Md. 1997) (quoting Flynn v. Everything Yogurt, No. HAR-92-3421, 1993 WL 454355, at *9 (D.Md. Sept. 14, 1993)); accord Gadson v. Supershuttle Int'l, No. AW–10–1057, 2011 WL 1231311, at * 9 (D.Md. Mar. 30, 2011). Thus, "[i]n cases involving concealment or omissions of material facts, . . . meeting Rule 9(b)'s particularity requirement will likely take a different form." Piotrowski v. Wells Fargo Bank, N.A., No. DKC-11-3758, 2013 WL 247549 (D.Md. Jan. 22, 2013) (citing Shaw, 973 F.Supp. at 552). Further, a "court should hesitate to dismiss a complaint under Rule 9(b) if the court is satisfied (1) that the defendant has been made aware of the particular circumstances for which she will have to prepare a defense at trial, and (2) that plaintiff has substantial prediscovery evidence of those facts." Harrison v. Westinghouse Savannah River Co., 176 F.3d 776, 784 (4th Cir. 1999).

2. Analysis

The FCA protects the government against false claims that are presented to it in federal contracts. The FCA prohibits any person from "knowingly present[ing], or caus[ing] to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). The FCA also prohibits any person from "knowingly mak[ing], us[ing], or caus[ing] to be made or used, a false record or statement material to a false or fraudulent claim." Id. § 3729(a)(1)(B).

In order for a false statement to be actionable under either subsection, it must be made as part of a false or fraudulent claim. Harrison, 176 F.3d at 786. A "claim" is "any request or demand, whether under a contract or otherwise, for money or property that . . . is presented to an officer, employee, or agent of the United States." 31 U.S.C. § 3729(b)(2)(A), (A)(i). Thus, to plead a claim under Section 3729(a)(1)(A) or (a)(1)(B), "a relator must plausibly allege four distinct elements: (1) there was a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter [knowledge]; (3) that was material; and (4) that caused the government to pay out money . . . (i.e., that involved a 'claim')." U.S. ex rel. Rostholder v. Omnicare, Inc., 745 F.3d 694, 700 (4th Cir. 2014) (alteration in original) (citation omitted); see also U.S. ex rel. Kelly-Creekbaum v. L'Academie De Cuisine, Inc., No. DKC-17-3525, 2019 WL 3817264, at *5 (D.Md. Aug. 14, 2019).

Jefferson identifies two categories of false statements and an overarching fraudulent scheme supporting his claim that Roche defrauded the government. First, Jefferson argues that Roche made statements that were factually false by misrepresenting Tamiflu's ability to prevent the spread and severity of the flu during a pandemic, as well as the drug's ability to limit complications, hospitalizations, and deaths resulting from the flu. Second, Jefferson argues that Roche made legally false statements by certifying, either contractually or under a theory of "implied certification," that Tamiflu provided the pandemic efficacies the government sought to obtain. Overall, Jefferson contends that Roche published scientifically inaccurate studies purporting to show Tamiflu's efficacy as a pandemic treatment and prophylactic, and that the government relied upon those studies and was

thereby fraudulently induced into purchasing Tamiflu for pandemic use when Roche knew that Tamiflu could not prevent the spread of the flu or substantially mitigate flu-related complications or deaths. The Court considers each theory of liability in turn.

a. Fraud-in-the-Inducement and Factually False Statements

"Under a fraud-in-the-inducement theory, a defendant violates the FCA if it submits claims to the government 'under a contract which was procured by fraud, even in the absence of evidence that the claims were fraudulent in themselves.'" Cimino v. Int'l Bus. Machines Corp., No. APM-13-0907, 2019 WL 4750259, at *4 (D.D.C. Sept. 30, 2019) (quoting U.S. ex rel. Bettis v. Odebrecht Contractors of Cal., Inc., 393 F.3d 1321, 1326 (D.C. Cir. 2005)).

The crux of Jefferson's fraud-in-the-inducement claim is as follows: Roche obtained FDA indications regarding Tamiflu's ability to treat modest flu symptoms but was denied broader FDA indications that aligned with the government's articulated need to identify and stockpile drugs that would thwart a flu pandemic. Thus, Roche published, or caused to be published, scientific journal articles—the Welliver, Kaiser, and Hayden articles—that falsely reported Tamiflu's ability to offer the treatment and prophylactic efficacies the government sought: specifically, reduction in the incidence of flu spread, severity, and complications, which would, in turn, reduce hospitalization and mortality.

A statement is false if it presents or constitutes "an objective falsehood.'" U.S. ex rel. Rostholder v. Omnicare, Inc., No. CCB-07-1283, 2012 WL 3399789, at *12 (D.Md. Aug. 14, 2012), aff'd, 745 F.3d 694 (4th Cir. 2014) (quoting U.S. ex rel. Wilson v. Kellogg Brown & Root, Inc., 525 F.3d 370, 376–77 (4th Cir. 2008)). In the traditional sense, an

objective falsehood is any statement that incorrectly describes the goods or services provided or requests reimbursements for goods or services that defendant failed to provide. Id. at *13 (citing United States v. Sci. Applications Int'l Corp., 626 F.3d 1257, 1266 (D.C. Cir. 2010)). A claim may also be false if the defendant "misrepresents the quality of a product in an effort to achieve an unwarranted payment for inferior goods." Id. (quoting Mann v. Heckler & Koch Def., Inc., 630 F.3d 338, 346 (4th Cir. 2010)).

The Court identifies three instances in which Jefferson alleges that "factually false" statements were made to the government regarding Tamiflu's pandemic uses. Jefferson first alleges that on October 26, 2004, "Roche presented comments before HHS . . . stating that Tamiflu could be used both to treat the flu and as a prophylactic, preventing those at risk from becoming infected," (Am. Compl. ¶ 92), even though the FDA concluded, as early as 2000, that Roche's clinical trial data did not support claims that Tamiflu prevented either asymptomatic flu infection or viral transmission, (see id. ¶ 46). Second, Jefferson alleges that on April 20, 2005, Hayden informed HHS' Working Group that "Tamiflu reduced influenza spread, severity, complications, hospitalizations, and mortality" and that it was "an effective option for preventing the transmission of influenza within households." (Id. ¶¶ 93–94). Third, Jefferson alleges that Dominick Iacuzio, Roche's medical director, falsely testified during a May 26, 2005 legislative hearing that Tamiflu could be used as a prophylactic to prevent a flu infection. Jefferson contends that these false statements and Roche's overall fraudulent scheme induced the government to purchase fifty million courses of Tamiflu under the mistaken belief that it would assist the government in treating and minimizing the widespread impact of a flu pandemic.

The Court first considers the alleged falsity of the studies described in the Welliver, Kaiser, and Hayden articles. As to the study described in the Welliver Article, Jefferson acknowledges that it proved that Tamiflu offered prophylactic benefits to those who had been in close contact with infected individuals, and that the study's results were consistent with the FDA's findings. Nevertheless, Jefferson alleges that "the final paragraph of the article went further and asserted that the drug effectively prevented transmission of influenza within households following prompt initiation of short-term prophylaxis in families, implying that Tamiflu prevents person-to-person transmission of the influenza virus—which it does not." (Am. Compl. ¶ 72). Jefferson further challenges the veracity of the study, claiming that a ghost writer authored the Welliver Article on Roche's behalf, and by noting that one of the authors, Arnold Monto, was a paid Roche consultant and a member of Roche's advisory board. (See id. ¶ 73).

Similarly, Jefferson challenges the validity of the Hayden Article because although the study described therein "showed prophylaxis efficacy only in reducing the incidence of [symptomatic] influenza (i.e., persons did not show symptoms associated with influenza), the conclusion boldly misstated that 'prophylaxis with [Tamiflu] was an effective option for preventing the transmission of influenza within households.'" (Id. ¶ 83). Jefferson concludes that "the article was drafted to claim that a person with influenza who took Tamiflu could not transmit the virus to others, knowing that was not [the] case." (Id.).

Jefferson's list of grievances with the study described in the Kaiser Article is much longer. As previously discussed, Jefferson not only analyzed the data cited in the article but also attempted to replicate the study's findings. His analysis confirmed Roche's claim

that Tamiflu reduced the duration of flu symptoms but disproved claims that Tamiflu reduced hospitalizations, deaths, and viral transmission. Jefferson also determined that Tamiflu had no significant impact on the rate of flu-related complications, such as bronchitis and sinus infections. Additionally, Jefferson was unable to replicate the results, prompting him to note various methodological flaws—i.e., failure to predefine certain study protocols or adherence to data handling rules and procedures.

In all, these allegations are sufficient to state a claim that Roche made factually false statements and engaged in fraud in the inducement. See U.S. ex rel. Hedley v. Abhe & Svoboda, Inc., 199 F.Supp.3d 945, 955 (D.Md. 2016) (declining to dismiss FCA claim on the basis of plaintiff's allegations that defendant's false submissions "were integral to the success of its ultimate goal—payment of government money to [defendant]"). As a preliminary matter, scientific opinions may be deemed false for the purposes of an FCA claim. See Harrison, 176 F.3d at 792 ("[A]n opinion or estimate carries with it an implied assertion, not only that the speaker knows no facts which would preclude such an opinion, but that he does know facts which justify it." (citation and internal quotation marks omitted)); see also U.S. ex rel. Druding v. Care Alternatives, 952 F.3d 89, 100 (3d Cir. 2020) ("[A] difference of medical opinion is enough evidence to create a triable dispute of fact regarding FCA falsity."). Jefferson has adequately laid out his allegations that Roche presented false statements through scientific studies.

Moreover, the instant action is distinguishable from U.S. ex rel. Milam v. Regents of Univ. of Cal., 912 F.Supp. 868 (D.Md. 1995), which Roche relies on to argue that "[d]isagreements over scientific methodology do not give rise to False Claims Act

liability." Id. at 886. As an initial matter, that decision was issued on a motion for summary judgment, after the plaintiff had an opportunity to uncover more specific evidence of fraud. In addition, Jefferson alleges more than mere "[d]isagreements over scientific methodology"; he alleges a fraudulent scheme in which Roche purposefully orchestrated studies with unsound methodology in order to generate support for an FDA indication that it had previously been denied, and which would open the door to significant profits. In other words, Jefferson does not merely allege his disagreement with the conclusions reached in the studies, their perceived methodological flaws, or his inability to successfully replicate the studies, but plausibly alleges Roche's efforts to rely on those studies to facilitate its fraudulent scheme.

Jefferson has also established that the misstatements he alleges were material. A term is material if it has "a natural tendency to influence, or [is] capable of influencing, the payment or receipt of money or property." Universal Health Servs., Inc. v. U.S. ex rel. Escobar, 136 S.Ct. 1989, 2002 (2016). "Materiality does not look to whether the false statements actually influenced agency action, but rather whether the statements are 'capable' of having such an influence." U.S. ex rel. Hedley v. Abhe & Svoboda, Inc., 199 F. Supp. 3d 945, 955 (D. Md. 2016) (citing U.S. ex rel. Harrison v. Westinghouse Savannah River Co., 352 F.3d 908, 916–17 (4th Cir. 2003)).

Roche argues that Jefferson's materiality argument is fatally undermined by an authority he cites in support of his FCA claim: HHS' 2005 Final Pandemic Plan. As Roche notes, the Final Pandemic Plan recognized limitations on the available evidence regarding Tamiflu's effectiveness in a pandemic setting, stating: "The effectiveness of antivirals

against a new pandemic influenza virus cannot be predicted," and "[t]here are no data on the effectiveness of neuraminidase inhibitors in preventing either serious morbidity . . . or mortality." (Def.'s Mot. Dismiss Relator's Am. Compl. ["Mot. Dismiss"] Ex. J ["Final Pandemic Plan"] at S7-12, ECF No. 72-12).[8] The Final Pandemic Plan also recognized Tamiflu's pediatric treatment limitations, stating: "None of the available influenza antivirals are currently FDA approved for use among children aged <1 year," and "the safety and efficacy of [Tamiflu] have not been studied in children aged <1 year for either treatment or prophylaxis of influenza." (Id. at S7-15). Nonetheless, the government purchased Tamiflu with this knowledge and further recommended that healthcare providers refrain from "prescrib[ing] [Tamiflu] to individuals for prophylaxis against pandemic influenza." (Id. at S7-16).

These actions and statements by the government, which go to whether Roche's actions actually influenced HHS, are not dispositive as to materiality, particularly at the pleading stage. Indeed, that HHS subsequently issued disclaimers regarding the

[8] While the Court generally does not consider extrinsic evidence when resolving a Rule 12(b)(6) motion, see Chesapeake Bay Found., Inc. v. Severstal Sparrows Point, LLC, 794 F.Supp.2d 602, 611 (D.Md. 2011), a court may consider documents referred to and relied upon in the complaint, "even if the documents are not attached as exhibits." Fare Deals Ltd. v. World Choice Travel.com, Inc., 180 F.Supp.2d 678, 683 (D.Md. 2001); accord New Beckley Mining Corp. v. Int'l Union, United Mine Workers of Am., 18 F.3d 1161, 1164 (4th Cir. 1994). Here, Jefferson cites the Final Pandemic Plan throughout his Amended Complaint but did not attach it as an exhibit. Roche includes the Final Pandemic Plan as an exhibit to its Motion to Dismiss. (See ECF No. 72-12). Because Jefferson relied upon and cited the Final Pandemic Plan in his Amended Complaint and failed to challenge Roche's inclusion of the Plan as an exhibit in his Motion to Strike or in his Opposition, the Court may consider the Plan, as attached to Roche's Motion, without converting the Motion to one for summary judgment.

effectiveness of Tamiflu does not preclude a finding that the agency relied on Roche's statements regarding the efficacy of the drug when it decided to spend over ninety percent of its antiviral budget on it. (Am. Compl. ¶¶ 155–59). As Jefferson notes, had Roche not believed the studies were material in the government's pandemic planning determinations, it would not have relied on those studies and related articles in statements it made to HHS, CDC, government working groups, and Congress. (Id. ¶¶ 82, 85, 92–99). Thus, Roche itself apparently believed the statements had "a natural tendency to influence" agency action. Escobar, 136 S.Ct. at 2002. These allegations are sufficient to preclude dismissal at this stage. Accordingly, Roche's motion to dismiss Jefferson's §§ 3729(a)(1)(A) and (a)(1)(B) claims premised on fraud-in-the-inducement and factual falsity will be denied.

b. Legally False Statements

A defendant who falsely certifies compliance with a statutory or regulatory requirement is subject to liability under the FCA if: "a government contract or program required compliance with certain conditions as a prerequisite to a government benefit, payment, or program; the defendant failed to comply with those conditions; and the defendant falsely certified that it had complied with the conditions in order to induce the government benefit." Harrison, 176 F.3d at 786. The Supreme Court has also recognized certification-based liability where the defendant "impliedly certifie[d] compliance with all conditions of payment" but failed to disclose a "violation of a material statutory, regulatory, or contractual requirement." Escobar, 136 S.Ct. at 1995. Under this theory, liability attaches where "the claim does not merely request payment, but also makes specific representations about the goods or services provided" but "the defendant's failure to

disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths." Id. at 2001.

Jefferson alleges that "the U.S. government incorporates FAR 52.212-4[(a)], which would require Roche to 'only tender for acceptance those items that conform to the requirements of th[e] contract,'" and that "[t]he government further would require Roche to contractually warrant and imply that the goods it delivered were 'merchantable and fit for use for the particular purpose described in th[e] contract,'" as required by FAR 52.212-4(o).[9] (Am. Compl. ¶ 152). Jefferson concludes that "payment was conditioned on delivering goods that conformed with the contract." (Id.). Jefferson further asserts that "Roche itself understood that pandemic efficacy was a material term of the contracts, and even affixed labeling on the packaging indicative that the Tamiflu was sold pursuant to government stockpiling contract." (Id. ¶ 153).

At this stage of the action, the Court is required to consider the factual allegations in the complaint as true and construe the factual allegations in the light most favorable to the plaintiff. Albright, 510 U.S. at 268. Based upon these allegations, the Court finds that Jefferson has plausibly alleged the existence of a contract that would require Roche to certify compliance with the applicable FARs, which it could not truthfully do. Accordingly, Roche's motion to dismiss Jefferson's §§ 3729(a)(1)(A) and (a)(1)(B) claims premised on false certification will be denied.

c. State Law Claims

[9] FAR 52.212-4 governs contract terms and conditions related to commercial items under the Federal Acquisition Regulations.

Having denied Roche's motion to dismiss Jefferson's FCA claims, the Court will also deny the motion as to Counts 2–30, which allege violations of the FCA's state law equivalent in the District of Columbia and twenty-eight states, for the reasons set forth above.

III. CONCLUSION

For the foregoing reasons, the Court will deny Defendant Hoffmann-La Roche Inc.'s Motion to Dismiss Relator's Amended Complaint (ECF No. 72) and will deny Relator Thomas Jefferson's Motion to Strike Exhibits A, C, D, E, F, G, H, I, and K to Defendant Roche's Motion to Dismiss First Amended Complaint and Related Factual Assertions and Legal Arguments (ECF No. 89). A separate Order follows.

Entered this 28th day of September, 2020.

/s/
George L. Russell, III
United States District Judge