UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
BEAUMONT DIVISION

UNITED STATES OF AMERICA
ex rel. BROOK JACKSON,

Plaintiff,

- v -

VENTAVIA RESEARCH GROUP, LLC; PFIZER INC.; ICON PLC,

Defendants.

CASE NO. 1:21-CV-00008-MJT

ORAL ARGUMENT REQUESTED

PFIZER'S MOTION TO DISMISS RELATOR'S AMENDED COMPLAINT AND MEMORANDUM OF LAW IN SUPPORT

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Defendant Pfizer Inc. ("Pfizer") respectfully moves, pursuant to Federal Rule of Civil Procedure 12(b)(6), to dismiss Counts I and II of the operative complaint in the above captioned matter, which Plaintiff-Relator Brook Jackson ("Relator") filed on behalf of the United States under 31 U.S.C. § 3730(b), the qui tam provision of the False Claims Act ("FCA"). The Court should dismiss the complaint as to Pfizer because: (1) the complaint does not plead a false or fraudulent claim; (2) its allegations were not material to the Government; and (3) Relator may not pursue the claims against Pfizer without the Government first pursuing them in an administrative proceeding.

INTRODUCTION & STATEMENT OF ISSUES

The President of the United States declared COVID-19 a national emergency on March 13, 2020, approximately two weeks after the first American died from COVID-19. This terrible disease has since claimed more than 990,000 American lives—almost double the number of American lives lost during World War I and World War II combined. Today the U.S. Centers for Disease Control and Prevention ("CDC") recommends that every American over the age of 5 receive one of three COVID-19 vaccines that the U.S. Food & Drug Administration ("FDA") has authorized or approved since the pandemic's onset. According to CDC, two of these products are "preferred," including Pfizer's COVID-19 vaccine, which the company co-developed with BioNTech. FDA first authorized the vaccine for emergency use on December 11, 2020 and then fully approved it on August 23, 2021. These approvals were based on a "landmark" clinical study involving approximately 40,000 participants at 153 clinical sites around the world. The study showed that Pfizer's vaccine was more than 90 percent effective at preventing COVID-19, with a favorable tolerability and safety profile. Upwards of 330 million doses of Pfizer's vaccine have been administered in the United States in the last sixteen months. The U.S. Department of Defense ("DoD") purchased every one of those shots and provided them to Americans at no cost. And,

while the pandemic continues, the Government continues to purchase additional doses of Pfizer's vaccine. As the Secretary for the U.S. Department of Health & Human Services ("HHS") stated recently: "With COVID-19, vaccines remain the best tool we have to prevent severe disease and save lives."[1]

Against this backdrop, Relator comes to court with her qui tam lawsuit, which argues the United States has it all wrong, and attempts to use this litigation to pursue an anti-vaccination agenda. Relator was employed for eighteen days in September 2020 by Defendant Ventavia Research Group, LLC ("Ventavia"), which owned and operated three of the 153 sites that conducted Pfizer's landmark study. Ventavia's sites enrolled approximately 1000 of the 40,000 individuals who participated in the study worldwide. During Relator's short tenure at Ventavia, she served as a Regional Director at two of the company's sites—one in Fort Worth, Texas and the other in Keller, Texas. There Relator alleges she learned "shocking" information that "compromised" the "integrity of the entire clinical trial." (Am. Compl. ¶¶ 31, 161, 287.) She further asserts FDA never should have authorized Pfizer's vaccine—nor should DoD have paid for it—based on events she allegedly observed during eighteen fateful days in Tarrant County. (Am. Compl. ¶ 287.) Her lawsuit is nonsense.

Relator describes her brief time at Ventavia in a lengthy operative complaint, which spans 75 pages and attaches 29 exhibits comprising more than 500 additional pages. But the fundamental requirement of any FCA cause of action—a "false or fraudulent" claim seeking Government payment—is nowhere to be found in those nearly 600 pages. *See* 31 U.S.C. §§ 3729(a)(1)(A) & (a)(1)(B). That's because there was none.

[1] U.S. Department of Health & Human Servs., Statement from HHS Secretary Xavier Becerra on FDA and CDC Expanding Booster Eligibility for the Most Vulnerable, Mar. 29, 2022, https://tinyurl.com/yjrjz7bw.

Rather than identify any false or misleading statements in Pfizer's invoices to DoD, as required under the FCA, the complaint focuses on Ventavia's alleged deviations from the clinical trial "protocol" for the landmark study—a set of written instructions that Pfizer developed for clinical investigators conducting the trial—as well as Pfizer's alleged shortcomings in terms of monitoring the Ventavia sites. Relator alleges this conduct violated assorted federal regulations governing clinical trials and federal procurement. But, as the Supreme Court has stated repeatedly, the FCA is "not an all-purpose anti-fraud statute," nor is it "a vehicle for punishing garden-variety breaches of contract and regulatory violations." *Universal Health Services, Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 194 (2016) (quoting *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 672 (2008)). Relator's complaint attempts to plead regulatory noncompliance, but it never plausibly explains why that so-called noncompliance rendered Pfizer's actual claims for payment "false or fraudulent."

At best, the complaint represents a deficient attempt to state a cause of action under the "implied false certification" theory of FCA liability. Claims for payment can be impliedly "false" under that theory when, among other things, they fail to disclose noncompliance with statutory, regulatory, or contractual requirements that are "material to the Government's payment decision." *Escobar*, 579 U.S. at 192. This materiality standard is a "demanding" one—not "too fact intensive" to decide on a motion to dismiss—that "looks to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation." *Id*. at 194, 195 n.6.

The Government's "actual behavior" here says it all. Both the complaint itself and the public record show the Government has been fully aware of Relator's allegations for nearly two years without withdrawing authorization or stopping payment for Pfizer's vaccine. To the contrary, FDA took regulatory action that made the vaccine widely available and publicly

responded to Relator's allegations by expressing the agency's "full confidence" in the data used to support the vaccine. DoD continues to purchase the product and make it available, free of charge, to all people living in the United States. And the U.S. Department of Justice ("DOJ"), which was required under 31 U.S.C. § 3730(a) to investigate Relator's allegations "diligently," declined to intervene in this lawsuit. All of this is "very strong evidence" that Relator's allegations are not material to the United States, and accordingly Pfizer's vaccine was—and continues to be—eligible for payment by the Government. *Escobar*, 579 U.S. at 195 ("[I]f the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material.").

Congress enacted the FCA's qui tam provision to empower private individuals to bring anti-fraud lawsuits "in the name of the Government" and, if successful, share up to 30 percent of the Government's recovery. 31 U.S.C. §§ 3730(b) & (d). The Relator has no claim separate from the Government's; rather Congress has provided her a financial incentive to pursue litigation that advances *the Government's* interests. A relator may not leverage that opportunity to advance personal agendas that undermine important Government policies and programs. But that is precisely what is happening here. Under the guise of qui tam litigation, Relator challenges a core plank of the federal response to a deadly, ongoing pandemic—namely, the Government's continued authorization and purchases of Pfizer's COVID-19 vaccine. The complaint itself shows that the Government took these actions with full awareness of Relator's concerns. And Relator hasn't been shy about publicly expressing her disagreement with public health authorities. Relator's website, for example, accuses various federal agencies of participating in an "evil, massive, fraudulent scheme to censor and cover up the truth" about Pfizer's vaccine, and demands

"change and resignations, now!" at FDA, which, according to Relator, "quit doing their [sic] job a long time ago."[2]

Relator's views are impossibly at odds with the Government's. She is not entitled to hijack the qui tam process to pursue an anti-vaccination agenda that the Government rejects. "Congress enacted the FCA to vindicate fraud on the federal government, not second guess decisions made by those empowered through the democratic process to shape public policy." *United States ex rel. Harman v. Trinity Indus., Inc.*, 872 F.3d 645, 668-69 (5th Cir. 2017). "To rule otherwise would be to turn the FCA into a tool with which a jury of six people could retroactively eliminate the value of FDA approval and effectively require that a product largely be withdrawn from the market even when the FDA itself sees no reason to do so." *D'Agostino v. ev3, Inc.*, 845 F.3d 1, 8 (1st Cir. 2017). For all of these reasons, and as discussed more fully in the balance of this Memorandum, the Court should dismiss Counts I and II of the complaint with prejudice.[3]

FACTUAL BACKGROUND

I. OPERATION WARP SPEED.

There was no vaccine to protect against COVID-19 in the early months of the pandemic. To address this urgent and unmet need, the Government launched Operation Warp Speed on May 15, 2020. (Am. Compl. ¶ 54.) Operation Warp Speed was an interagency partnership between HHS and DoD that coordinated federal efforts to accelerate the development, acquisition, and distribution of COVID-19 medical countermeasures, with a particular focus on vaccines. (Am. Compl. ¶¶ 54-56.) Because people were getting sick and dying as a result of the pandemic, the Government "refused to accept business-as-usual timelines for vaccines and other essential tools"

[2] I Am Brook Jackson, https://www.iambrookjackson.com/ and https://www.iambrookjackson.com/whoami (last visited Apr. 21, 2022).

[3] Count III of the complaint does not involve Pfizer; it is a retaliation claim against Ventavia only.

and pledged, in collaboration with private industry, to "squeeze every last inefficiency out of the process and pour every resource" into an unprecedented effort to produce, among other things, hundreds of millions of doses of COVID-19 vaccines by January 2021.[4] This was an audacious, but necessary, goal; at the time, potential vaccine candidates, including Pfizer's, were still in the early phases of clinical development, and their prospects were uncertain.

In connection with Operation Warp Speed, FDA issued guidance to industry in June 2020 concerning the agency's expectations before it would consider licensing any COVID-19 vaccine candidate, including for Emergency Use Authorization ("EUA").[5, 6] This guidance provided that "the primary efficacy endpoint estimate for a placebo-controlled efficacy trial should be at least 50%" in order to "ensure that a widely deployed COVID-19 vaccine is effective."

In July 2020, while Pfizer's vaccine was still under development, DoD entered into an agreement with the company, as part of Operation Warp Speed, to purchase the first 100 million doses of the vaccine if FDA later authorized or approved it. (Am. Comp. ¶ 133.) This was before Pfizer and BioNTech commenced their placebo-controlled efficacy trial, now known as the "landmark study." (*Id*. at ¶ 133.) Because of pandemic-related exigencies, the agreement was not a standard federal procurement contract, but rather a "prototype" agreement executed pursuant to

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[4] U.S. Dept. of Defense, Immediate Release: Trump Administration Announces Framework and Leadership for 'Operation Warp Speed,' May 15, 2020, https://tinyurl.com/3yajcvnd.

[5] U.S. Dept. of Health & Human Servs., Food & Drug Admin., Development and Licensure of Vaccines to Prevent COVID-19: Guidance for Industry, June 2020, https://www.fda.gov/media/139638/download.

[6] U.S. Dept. of Health & Human Servs., Food & Drug Admin., Emergency Use Authorization for Vaccines Explained, Nov. 20, 2020, https://tinyurl.com/46esw485 ("Under an EUA, FDA may allow the use of unapproved medical products, or unapproved uses of approved medical products in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when certain statutory criteria have been met, including that there are no adequate, approved, and available alternatives.").

10 U.S.C. § 2371b, which as of January 1, 2022 is now cited as 10 U.S.C. § 4022. (Am. Compl., Ex. 10 at 1079.) Such agreements are executed under DoD's Other Transaction Authority ("OTA") and, as a statutory matter, are not subject to the Federal Acquisition Regulation ("FAR"), which is the primary regulation otherwise used by Government agencies in their acquisition of supplies and services with appropriated funds. *See* 10 U.S.C. § 4022(f)(2); *see also NSTI, LLC v. Defense Energy Ctr. of Excellence*, No. 19-03854, 2020 WL 1321530, at *1 (S.D. Tex. Mar. 17, 2020) ("Other Transactions are legally binding contracts that are generally exempt from federal procurement laws and regulations[.]"). Relator's allegation that FAR applied to Pfizer's OTA agreement, (*see, e.g.*, Am. Compl. ¶¶ 140-143), is simply wrong.[7]

The key terms of the OTA agreement—the "Contract at Issue" forming the basis for Relator's complaint (Am. Compl. ¶ 133)—are found in two instruments: (1) a Base Agreement executed on July 20, 2020; and (2) a Statement of Work ("SOW") executed on July 21, 2020.

[7] U.S. Dept. of the Air Force, Other Transaction Authority (OTA) Overview, https://www.transform.af.mil/Projects/Other-Transaction-Authority/ ("Other Transactions ('OTs') are legally binding instruments that may be used to engage industry and academia for a broad range of research and prototype projects and include the option to extend to production. OTs are typically defined by what they are not: they are not standard procurement contracts, grants, or cooperative agreements. As such, they are generally not subject to the federal laws and regulations that apply to government procurement contracts [such as] FAR[.]").

Relator attached the SOW to her complaint as Exhibit 10, and this Memorandum attaches the Base Agreement as Exhibit A.[8]

The SOW provides that DoD would pay $1.95 billion—or $19.50 per dose—for Pfizer's vaccine, contingent on the company first securing FDA approval or an EUA for the product. (Am. Compl. ¶ 135.) The SOW describes a "large scale vaccine manufacturing demonstration" that imposes no requirements relating to Good Clinical Practices ("GCP") or related FDA regulations. (Am. Compl., Ex. 10 at 1080.) It states explicitly that Pfizer's "clinical trials" are "out-of-scope," "not related" to the agreement, and that the relevant studies were undertaken at Pfizer's expense "without the use of Government funding." (Am. Compl., Ex. 10 at 1087.) Again, Relator's allegation that the SOW somehow tied payment to Pfizer's compliance with every particular of the clinical protocol or related FDA regulations, (*see, e.g.*, Am. Compl. ¶¶ 275, 278), is mistaken and refuted by the SOW itself.

The SOW identifies a single condition of payment: Pfizer's delivery of an FDA authorized or approved vaccine for COVID-19. (Am. Compl., Ex. 10 at 1087.) The agreement provides that after authorization Pfizer would "invoice the Government . . . every month for released doses that have been shipped during each such monthly period," and the Government, in turn, would "pay all such invoices within thirty (30) days of receipt." (Am. Compl., Ex. 10 at 1094.) The agreement

[8] It is appropriate for the Court to consider the Base Agreement and the SOW together when ruling on the present motion. *See In re Katrina Canal Breaches Litig.*, 495 F.3d 191, 205 (5th Cir. 2007) ("[B]ecause defendants attached the contracts to their motions to dismiss, the contracts were referred to in the complaints, and the contracts are central to the plaintiffs' claims, we may consider the terms of the contracts in assessing the motions to dismiss."); *Shaw v. Digital Equip. Corp.*, 82 F.3d 1194,1220 (1st Cir. 1996) ("A court may properly consider the relevant entirety of a document integral to or explicitly relied upon in the complaint, even though not attached to the complaint, without converting the motion [to dismiss] into one for summary judgment."); *see also Airframe Sys. v. Raytheon Co.*, 520 F. Supp. 2d 258, 263 (D. Mass. 2007) ("[W]here the plaintiff has referenced part of a document in the complaint, it is proper for the court to view the rest of that document so as to be able to understand it in context.").

further states the Government has "no right to withhold payment" for delivered doses for any reason "unless the FDA has withdrawn approval or authorization of the vaccine." (Am. Compl., Ex. 10 at 1095.)

II. THE LANDMARK STUDY.

Pfizer and BioNTech launched the landmark study six days after finalizing the OTA agreement. The landmark study was a placebo-controlled, randomized, observer-blind study to evaluate the safety, tolerability, immunogenicity, and efficacy of the Pfizer-BioNTech vaccine against COVID-19 in healthy individuals. (Am. Compl., Ex. 7 at 918.)[9] Approximately 40,000 participants enrolled in the study at 153 clinical research sites across six countries. Under the clinical protocol that Pfizer developed for the study, about half of the participants received two doses of the vaccine, with 21 days between each dose, and the remaining participants received placebo injections (saline) on the same schedule. (Am. Compl., Ex 7 at 932.)

Pfizer and BioNTech announced initial results from the landmark study on November 18, 2020. (Am. Compl. ¶ 81.) They showed a two-dose regimen of the vaccine conferred 95 percent protection against COVID-19 in persons 16 years of age and older. In these individuals, the vaccine's safety profile was characterized by short-term, mild-to-moderate pain at the injection site, fatigue, and headache. The incidence of serious adverse events was low and similar among individuals whether they received the vaccine or the placebo.

[9] A "placebo-controlled" trial is one in which there are at least two groups—one gets the active treatment, the other gets the placebo, and everything else is held the same between the groups, so that any difference in their outcome can be attributed to the active treatment. A "randomized" trial is one in which the participants are divided by chance into separate groups that compare different treatments or other interventions. An "observer-blind" study is one in which those charged with measuring, recording, and assessing changes in research participants do not know which of the participants have received the active treatment and which have received the placebo.

Based on these results, Pfizer and BioNTech asked FDA to authorize the vaccine for emergency use in individuals ages 16 and older, and the agency issued the EUA on December 11, 2020. (Am. Compl. ¶ 81.) It was widely reported that Pfizer started shipping the first batches of its vaccine to DoD immediately thereafter, with the first doses administered in the U.S. outside of the clinical trial setting on December 14, 2020.[10] Pfizer sent its first invoice to the Government at the end of that month. (*See* Am. Compl., Ex. 10 at 1094.) This qui tam action would soon follow.

III. THE OPERATIVE COMPLAINT.

Relator's complaint recounts events she allegedly observed while employed by Ventavia beginning on September 8, 2020. (Am. Compl. ¶ 23.) At that time, the landmark study was ongoing and Ventavia was under contract to conduct the study at three of the company's ten investigative sites in Texas. (Am. Compl. ¶¶ 49-50.) Relator worked at two of these sites where, in her words, she witnessed "noncompliance with virtually every . . . provision of the clinical trial protocol at issue." (Am. Compl. ¶ 145.) At a high-level, Relator claims Ventavia enrolled ineligible clinical trial participants; failed to maintain clinical trial documentation in a blinded way; violated temperature control requirements for investigational product; injected clinical trial participants prior to obtaining informed consent; rushed preparation of the "frozen concentrate" form of the vaccine; used improperly-trained and unqualified vaccinators; performed inadequate post-injection monitoring of study subjects; neglected to report adverse events in a timely manner; maintained "careless and sloppy" documentation practices; and, in certain instances, "fabricat[ed] new numbers" in clinical trial documents. (Am Compl. ¶¶ 148-205.)

[10] Ben Guarino et al., *'The Weapon That Will End The War': First Coronavirus Vaccine Shots Given Outside Trials In U.S.*, THE WASHINGTON POST, Dec. 14, 2020, https://tinyurl.com/4na9kyby.

Relator asserts the above protocol deviations "call the integrity and validity of both the entire clinical trial and Pfizer's EUA into question." (Am. Compl. ¶ 286.) But her complaint shows FDA did not agree with that assessment. On September 25, 2020—Relator's last day as a Ventavia employee—she "called FDA's hotline to report the clinical trial protocol violations and patient safety concerns she witnessed." (Am. Comp. ¶ 262.) FDA contacted Relator shortly thereafter and, according to the complaint, "spoke to her for several hours regarding the violations she witnessed at Ventavia." (Am. Comp. ¶ 266.) FDA later granted the EUA, which allowed for administration of Pfizer's vaccine outside of the clinical trial setting. (Am. Comp. ¶ 81.) FDA issued this authorization on December 11, 2020 despite the agency's actual knowledge of Relator's allegations.

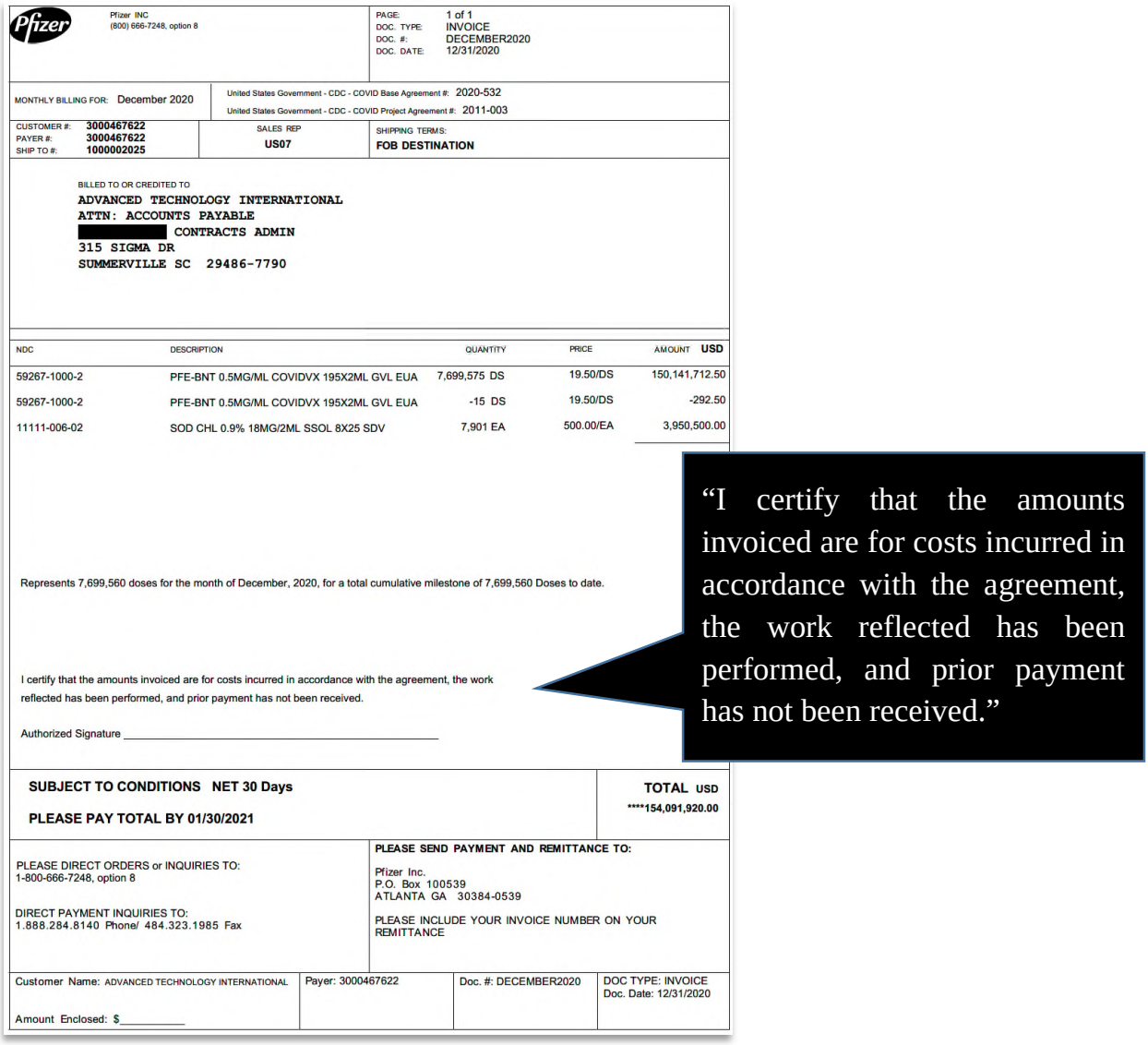
With respect to Pfizer, the complaint alleges the company failed to "properly oversee" Ventavia, and this allegedly violated FDA requirements found at 21 C.F.R. §§ 312.50 and 312.56, as well as FAR requirements found at 48 C.F.R. §§ 42-202(e)(2) and 52.203-13. (Am. Comp. ¶¶ 143, 214, 223-24.) The FDA regulations referenced in the complaint provide that clinical trial sponsors must "ensur[e] proper monitoring of the investigation" and "monitor the progress of all clinical investigations being conducted." 21 C.F.R. §§ 312.50, 312.56. The FAR provisions described in the complaint state that "prime contractors" with the Government are "responsible for managing [their] subcontracts" and must maintain a "business ethics awareness and compliance program and internal control system" that applies to any subcontracts as well. 48 C.F.R. §§ 42-202(e)(2), 52.203-13.

According to Relator, Pfizer's purported regulatory violations "went to the very essence of the bargain" between DoD and Pfizer because the Government "contracted to purchase vaccines found effective by a valid clinical trial conducted according to the protocol submitted by Pfizer."

(Am. Comp. ¶ 287.) Relator further states that the alleged regulatory violations resulted in "express and implied false certifications" of compliance in Pfizer's claims for payment to DoD. (Am. Comp. ¶ 274.) Specifically, the complaint alleges that Pfizer's invoices certified, as required under FAR, that they were "true and correct, prepared from Pfizer's books and records, and in accordance with the Pfizer-DoD contract." (Am. Comp. ¶ 278.)

The complaint never mentions, however, that the "Pfizer-DoD contract" was an OTA agreement, not a FAR-based procurement contract. Under federal law, FAR does not apply to OTA agreements, *see* 10 U.S.C. § 4022(f)(2), and thus Pfizer's invoices would not contain the certification that Relator alleges. Pfizer's actual invoices—which are incorporated into the complaint by reference, (Am. Comp. ¶ 278)—do not mention FAR at all. This Memorandum attaches as Exhibit B the company's first invoice under the OTA, which is substantially identical to those that followed (other than the number of doses covered by each invoice).[11] The invoice includes no false or misleading statements. Nor does it represent or certify anything about the study protocol, FDA regulations, or FAR. It simply states, "the amounts invoiced are for costs incurred in accordance with the agreement, the work reflected has been performed, and prior payment has not been received." This invoice is reproduced, in its entirety, below:

[11] It is appropriate for the Court to consider Pfizer's actual invoices, which are incorporated into Relator's complaint by reference, when ruling on the present motion. *See supra* note 8.



Pfizer INC
(800) 666-7248, option 8

PAGE: 1 of 1
DOC. TYPE: INVOICE
DOC. #: DECEMBER2020
DOC. DATE: 12/31/2020

MONTHLY BILLING FOR: December 2020

United States Government - CDC - COVID Base Agreement #: 2020-532
United States Government - CDC - COVID Project Agreement #: 2011-003

CUSTOMER #: 3000467622
PAYER #: 3000467622
SHIP TO #: 1000002025

SALES REP: US07

SHIPPING TERMS: FOB DESTINATION

BILLED TO OR CREDITED TO
ADVANCED TECHNOLOGY INTERNATIONAL
ATTN: ACCOUNTS PAYABLE
[redacted] CONTRACTS ADMIN
315 SIGMA DR
SUMMERVILLE SC 29486-7790

NDC	DESCRIPTION	QUANTITY	PRICE	AMOUNT USD
59267-1000-2	PFE-BNT 0.5MG/ML COVIDVX 195X2ML GVL EUA	7,699,575 DS	19.50/DS	150,141,712.50
59267-1000-2	PFE-BNT 0.5MG/ML COVIDVX 195X2ML GVL EUA	-15 DS	19.50/DS	-292.50
11111-006-02	SOD CHL 0.9% 18MG/2ML SSOL 8X25 SDV	7,901 EA	500.00/EA	3,950,500.00

Represents 7,699,560 doses for the month of December, 2020, for a total cumulative milestone of 7,699,560 Doses to date.

I certify that the amounts invoiced are for costs incurred in accordance with the agreement, the work reflected has been performed, and prior payment has not been received.

Authorized Signature _____

"I certify that the amounts invoiced are for costs incurred in accordance with the agreement, the work reflected has been performed, and prior payment has not been received."

SUBJECT TO CONDITIONS NET 30 Days

PLEASE PAY TOTAL BY 01/30/2021

TOTAL USD
****154,091,920.00

PLEASE DIRECT ORDERS or INQUIRIES TO:
1-800-666-7248, option 8

DIRECT PAYMENT INQUIRIES TO:
1.888.284.8140 Phone/ 484.323.1985 Fax

PLEASE SEND PAYMENT AND REMITTANCE TO:
Pfizer Inc.
P.O. Box 100539
ATLANTA GA 30384-0539

PLEASE INCLUDE YOUR INVOICE NUMBER ON YOUR REMITTANCE

Customer Name: ADVANCED TECHNOLOGY INTERNATIONAL | Payer: 3000467622 | Doc. #: DECEMBER2020 | DOC TYPE: INVOICE Doc. Date: 12/31/2020

Amount Enclosed: $_____

Relator also fails to acknowledge that the SOW, which is attached as an exhibit to her complaint, states explicitly that Pfizer's clinical development activities for the vaccine were "out-of-scope" and not funded by the Government under the OTA. (Am. Compl., Ex. 10 at 1087.) The parties included this language because Pfizer, not the Government, was the entity footing the bill for the very significant costs of the landmark study. For this reason, neither the "Pfizer-DoD contract" referenced in the complaint, nor the invoices submitted under that agreement, make any mention of the FDA clinical trial regulations that Relator identifies as supposedly "material to the [G]overment's decision to pay the claims." (Am. Comp. ¶ 281.) Instead, the agreement is crystal

clear that the Government could only withhold payment for delivered doses if FDA actually withdrew authorization or approval of Pfizer's vaccine. (Am. Compl., Ex. 10 at 1095.)

IV. PROCEDURAL HISTORY & OTHER DEVELOPMENTS.

Relator filed her original complaint, under seal, on January 8, 2021. (ECF 1.) Congress enacted the FCA's sealing requirement to give the Government an opportunity to investigate qui tam allegations without tipping off the defendants. *See* 31 U.S.C. § 3730(b)(2). While the Government's investigation here was underway and the action remained under the Court's sealing order, FDA fully approved Pfizer's vaccine by granting a Biologics License Application ("BLA") on August 23, 2021.[12] The vaccine is now marketed under the brand name "Comirnaty" and the initial approval was for the prevention of COVID-19 in individuals 16 years of age and older.[13] According to a contemporaneous FDA press release, the full approval of the vaccine "builds on the extensive data and information previously submitted that supported the EUA" and "the public can be very confident that this vaccine meets the high standards for safety, effectiveness, and manufacturing quality the FDA requires of an approved product."[14]

About two months later, the British Medical Journal ("BMJ") published two articles summarizing Relator's allegations, based on interviews and documents she provided to a freelance

[12] FDA News Release, FDA Approves First COVID-19 Vaccine, Aug. 23, 2021, https://tinyurl.com/2p933nz6 ("For all vaccines, the FDA evaluates data and information included in the manufacturer's submission of a biologics license application (BLA). A BLA is a comprehensive document that is submitted to the agency providing very specific requirements. . . . The agency conducts its own analyses of the information in the BLA to make sure the vaccine is safe and effective and meets the FDA's standards for approval.").

[13] U.S. Food & Drug Admin., Comirnaty Package Insert, https://www.fda.gov/media/151707/download.

[14] *See supra* note 12.

journalist while her complaint was still under seal.[15] FDA's response to the second BMJ article on November 15, 2021 shows the Government clearly rejected the notion that Relator's allegations "call into question" the landmark study results or FDA's decisions to authorize—and later fully approve—Pfizer's vaccine. In response to Relator's allegations, an FDA spokesperson said, "FDA has full confidence in the data that were used to support the Pfizer-BioNTech Vaccine authorization and the Comirnaty approval." Several other media outlets also reported this public statement from FDA.[16]

DOJ declined to intervene in this action on January 18, 2022, and the Court unsealed the action on February 10, 2022. (ECF 13, 16.) At that time, Relator launched a website to promote her qui tam case, further her anti-vaccination position, and fundraise in support of these efforts.[17] This website includes statements from Relator that are highly critical of DOJ's decision to decline intervention and FDA's continued approval of Pfizer's vaccine.

Her website also includes a repository of relevant documents.[18] Among them are Relator's original email detailing her concerns to FDA on September 25, 2020; FDA's response email acknowledging receipt of Relator's concerns that same day; and a lengthy letter from Relator's counsel notifying DoD about her allegations on December 14, 2020. This Memorandum attaches

[15] Paul Thacker, *COVID-19: Researcher Blows the Whistle on Data Integrity Issues in Pfizer's Vaccine Trial*, B.M.J., Nov. 2, 2021, https://tinyurl.com/pb8uc6yj; Rebecca Coombes, *Rapid Response Re: COVID-19: Researcher Blows the Whistle on Data Integrity Issues in Pfizer's Vaccine Trial*, B.M.J., Nov. 15, 2021, https://tinyurl.com/2s3c9cps.

[16] *See, e.g.*, Cheryl Clark, *Experts Blow the Whistle on Alleged COVID Whistleblower Claims*, MEDPAGE TODAY , Nov. 11, 2021, https://tinyurl.com/2p8uab69.

[17] I Am Brook Jackson, https://www.iambrookjackson.com/support (last visited Apr. 21, 2022).

[18] I Am Brook Jackson, https://www.iambrookjackson.com/documentstore (last visited Apr. 21, 2022).

those documents as Exhibits C, D, and E respectively.[19] Relator's communications to FDA and DoD closely track the substance of her subsequent complaint. She also published on her website an email from one of her former attorneys dated March 2, 2021. This Memorandum attaches that email as Exhibit F.[20] The email references DOJ's then-active investigation into Relator's allegations and states, "The [G]overnment has told us that the FDA was aware of misconduct by Ventavia" and nonetheless the agency "would have approved the vaccine . . . due to the relatively small . . . [number] of patients at Ventavia sites" compared to "the entire trial size."

At all relevant times, Pfizer's vaccine has been authorized, approved, and thus eligible for payment by the Government. The United States has continued to purchase the product with full knowledge of the information and allegations arising from Relator's eighteen days at Ventavia.[21] And the Government continues to make the vaccine "free to everyone age 5 and older living in the United States, regardless of immigration or insurance status."[22] The Government has not wavered

[19] Courts routinely take judicial notice of uncontested facts published on a party's own website, and it is appropriate for this Court to do so here. *See, e.g.*, *O'Toole v. Northrup Grumman Corp.*, 499 F.3d 1218, 1224-25 (10th Cir. 2007) (holding district court abused discretion by failing to take judicial notice of information posted on defendant's website); *Granlund v. Burbank Hill Cmty. Ass'n.*, No. 19-01439, 2020 WL 5498075, at *4 (C.D. Cal. Aug. 5, 2020) ("Courts have found it proper to take judicial notice of a party's own website pursuant to Fed. R. Evid. 201."); *Raymond v. Blair*, No. 09-5507, 2010 WL 11537936, at *4 n.2 (E.D. La. Oct. 8, 2010) ("The court may take judicial notice of the information provided on a party's website.").

[20] It is appropriate for the Court to take judicial notice of this document, which Relator published on her own website, as well. *See supra* note 19.

[21] U.S. Dept. of Health & Human Servs., Biden Administration Purchases Additional Doses of COVID-19 Vaccines from Pfizer and Moderna, Feb. 11, 2021, https://tinyurl.com/36m5fyz3; Pfizer Press Release, Pfizer and BioNTech to Provide U.S. Government an Additional 50 Million Pediatric Doses of COVID-19 Vaccine to Support Further Preparedness for Future Needs, Oct. 28, 2021, https://tinyurl.com/3zntrv5w.

[22] U.S. Dept. of Health & Human Servs., COVID-19 Vaccines, https://tinyurl.com/yyjuu8xt.

from the FDA's statement that it continues to have "full confidence in the data" underlying its authoritative approval of Pfizer's vaccine.[23]

Relator disagrees with the Government's continued approval and payment for the vaccine. She airs that dissent publicly and repeatedly on her Twitter profile (@iambrookjackson), which has accumulated more than 37,000 followers. Her anti-vaccination and anti-Government views are unmistakable. For example, she has tweeted that "there's no way in hell [she] would let a Covid jab" near her children, even though CDC recommends the vaccine for everyone 5 years of age and older. She has tweeted that "booster" doses of the vaccine are "the immunological equivalent of heroin addiction," even though CDC recommends boosters for many Americans. She has called the FDA officials who continue to authorize Pfizer's vaccine "criminals" who should "go to jail & have [their] bank accounts drained and put into a fund for the vaccine injured." She has said the entire Government is "complicit in a scheme to hide the truth" and "complicit in fraud, period." And she has called Dr. Anthony Fauci, the Director of the National Institute of Allergy and Infectious Diseases ("NIAID"), both "scary" and "the face of corruption and evil."

[23] Courts routinely take judicial notice of Government websites and other public pronouncements from federal agencies, and it is appropriate for this Court to do so here. *See*, *e.g.*, *Swindol v. Aurora Flight Sciences Corp.*, 805 F.3d 516, 519 (5th Cir. 2015) (taking judicial notice of "public records" on Government websites because their "accuracy . . . cannot reasonably be questioned"); *Funk v. Stryker Corp.*, 631 F.3d 777, 783 (5th Cir. 2011) (affirming judicial notice of "publicly-available documents and transcripts produced by the FDA, which were matters of public record directly relevant to the issue at hand."); *Norris v. Hearst Tr.*, 500 F.3d 454, 461 n.9 (5th Cir. 2007) ("[I]t is clearly proper in deciding a 12(b)(6) motion to take judicial notice of matters of public record.").

V. CHRONOLOGY OF IMPORTANT EVENTS.

The following chart summarizes the key dates and events relevant to the present motion.

DATE	EVENT
3/13/2020	President declares national emergency in response to COVID-19
5/15/2020	Government launches Operation Warp Speed
7/21/2020	DoD finalizes agreement to purchase first 100M doses of Pfizer's vaccine
7/27/2020	Pfizer launches "landmark" clinical study of the company's vaccine
9/8/2020	Relator begins her 18-day tenure as a Regional Director at Ventavia
9/25/2020	Relator reports concerns to FDA via email; agency acknowledges receipt in writing
11/18/2020	Pfizer announces initial, favorable results of landmark study in individuals 16+
11/20/2020	Pfizer asks FDA to grant EUA for Pfizer's vaccine in individuals 16+
12/11/2020	FDA grants EUA for Pfizer's vaccine in individuals ages 16+
12/14/2020	Relator sends letter to DoD summarizing her forthcoming qui tam complaint
12/31/2020	Pfizer sends first invoice to DoD seeking payment for the company's vaccine
1/8/2021	Relator files original complaint, under seal, in the Eastern District of Texas
3/2/2021	Relator's counsel sends email reflecting DOJ's active investigation of her claims
5/7/2021	Pfizer initiates submission seeking FDA's full approval of the company's vaccine
8/23/2021	FDA grants full approval of Pfizer's vaccine for use in individuals ages 16+
11/2/2021	BMJ publishes first article summarizing Relator's allegations
11/15/2021	BMJ publishes FDA's statement of "full confidence in the data" for Pfizer's vaccine
1/18/2022	DOJ declines to intervene in Relator's lawsuit
2/10/2022	The Court unseals this action

LEGAL STANDARD

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 555, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. The factual allegations must be sufficient to raise the right to relief above a speculative level. *Lexington Inc. Co. v. S.H.R.M. Catering Servs., Inc.*, 567 F.3d 182, 184 (5th Cir. 2009) (quoting *Twombly*, 550 U.S. at 545). "Where the facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has stopped short of showing that the pleader is plausibly entitled to relief." *Twombly*, 550 U.S. at 57. If "there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief. *Iqbal*, 556 U.S. at 679. In doing so, the court should construe claims in the light most favorable to plaintiff, but also "draw on its judicial experience and common sense." *Id*. at 1940.

When reviewing a complaint, courts "are not bound to accept as true a legal conclusion couched as a factual allegation." *Iqbal*, 556 U.S. at 678. "[A] plaintiff must plead specific facts, not mere conclusional allegations, to avoid dismissal for failure to state a claim." *Kane Enters. v. MacGregor (USA), Inc.*, 322 F.3d 371, 374 (5th Cir. 2003). A pleading that offers "labels and conclusions" or "a formulaic recitations of the elements of a cause of action" will not do. *Iqbal*, 556 U.S. at 678. "Nor does a complaint suffice if it tenders 'naked assertion[s]' devoid of 'further factual enhancement.'" *Id*. (quoting *Twombly*, 550 U.S. at 544).

ARGUMENT

I. RELATOR HAS NOT PLED A "FALSE OR FRAUDULENT" CLAIM.

It is often said in FCA litigation that a false or fraudulent claim is the "*sine qua non*" of a qui tam action. *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 188 (5th Cir. 2009). To satisfy this "indispensable element" of an FCA violation, *United States ex rel. Hebert v. Dizney*, 295 Fed. App'x 717, 722 (5th Cir. 2008), a relator must identify a claim requesting money or property from the United States that is either factually or legally false. *United States ex rel. Ruscher v. Omnicare, Inc.*, 663 Fed. App'x 368, 373 (5th Cir. 2016). Factually false claims represent that the claimant has provided goods or services that the Government never received. *Id.* Legally false claims, by contrast, contain certifications that the claimant has complied with statutory, regulatory, or contractual requirements when, in fact, the opposite is true. *Id.*

Relator does not try to plead factually false claims. Her complaint instead alleges that Pfizer's invoices to DoD were legally false because they contained "express and implied false certifications" of compliance with various provisions of the Code of Federal Regulations. (Am. Compl. ¶¶ 274, 278.) Relator's complaint employs "labels and conclusions," but these are not enough; the Fifth Circuit has made clear that alleged "[v]iolations of laws, rules, or regulations alone do not create a cause of action under the FCA." *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 902 (5th Cir. 1997). Relator's complaint lacks the "further factual enhancement" required to plausibly state a violation of the statute. *See Iqbal*, 556 U.S. at 678.

A. The Complaint Does Not Plead Express False Certifications.

Actionable false certifications come in two flavors: express and implied. Relator attempts to plead a cause of action under each theory. Neither is successful.

Two elements are required to plead express false certifications. First, the relator must allege "the [G]overnment has conditioned payment of a claim upon a claimant's certification of compliance with, for example, a statute or regulation." *Thompson*, 125 F.3d at 902. And second, the relator must allege the claimant "falsely certifie[d] compliance with that statute or regulation." *Id*; *see also Mikes v. Straus*, 274 F.3d 687, 698 (2d Cir. 2001) ("An expressly false claim is, as the term suggests, a claim that falsely certifies compliance with a particular statute, regulation or contractual term, where compliance is a prerequisite to payment.").

The complaint here fails to plead either of these elements. As a threshold matter, Relator has not pled any "prerequisite to payment" that the United States identified and Pfizer failed to satisfy. *See Mikes*, 274 F.3d at 698. The complaint includes some conclusory allegations about payment being tied to compliance with certain FDA regulations and FAR provisions. (*See, e.g.*, Am Comp. ¶¶ 214, 223-24.) But these "naked assertions" are not supported by specific language in the agreement at the heart of Relator's fraud theory, which is incorporated into her complaint by reference. *See Iqbal*, 556 U.S. at 678. In fact, the agreement makes no mention of the FDA regulations and FAR provisions cited in Relator's complaint. The agreement instead conditions payment, more simply, on Pfizer's delivery of an FDA authorized or approved product. (Am. Compl., Ex. 10 at 1095.) Pfizer's vaccine has satisfied that condition since December 2020, as the complaint acknowledges, (Am. Compl. ¶ 81), and the vaccine continues to satisfy that condition today. The Court should reject Relator's express certification claim for this reason alone.

The complaint also fails the second part of the express certification test because it does not plausibly allege that Pfizer's claims for payment included expressly false certifications of compliance. The complaint does allege, in conclusory fashion, that Pfizer's invoices included a certain certification mandated by FAR. (Am. Compl. ¶ 278.) But for reasons discussed earlier in

this Memorandum, FAR clearly does not apply to OTAs like the one at issue here. *See* 10 U.S.C. § 4022(f)(2). Moreover, as the Court can see for itself at page 13 of this Memorandum, Pfizer's invoices do not contain certifications of compliance with FAR or any other federal regulations. Pfizer instead certified, in a more limited way, that "the amounts invoiced [were] for costs incurred in accordance with the agreement, the work reflected ha[d] been performed, and prior payment ha[d] not been received." This certification is a truthful one, and it has nothing to do with the regulatory provisions cited in Relator's complaint. (*See* Am. Comp. ¶¶ 143, 214, 223-24.)[24] Her express certification theory misses the mark.

B. The Complaint Does Not Plead Implied False Certifications.

Relator's attempt to plead implied false certifications fares no better. Like the express certification theory, the implied certification theory has two elements: "[F]irst, the claim does not merely request payment, but also makes *specific representations* about the goods or services provided; and second, the defendant's failure to disclose noncompliance with *material* statutory, regulatory, or contractual requirements makes those representations misleading half-truths." *Escobar*, 579 U.S. at 190 (emphasis added). The complaint here satisfies neither of these elements.

Just as Relator fails to identify any expressly false certifications of compliance in Pfizer's invoices seeking payment from DoD, she fails similarly to identify any "specific representations" about Pfizer's vaccine in those invoices. Without a "specific representation" alleged anywhere in her 75-page complaint, it is impossible for Relator to plead an implied certification claim because that theory requires, in the language of *Escobar*, a "misleading half-truth" that was submitted to

[24] Again, the "agreement" at issue, Pfizer's OTA agreement with DoD, specifies the number of doses the Government would buy and the price the Government would pay, but does not impose any requirements relating to Pfizer's clinical development activities, FDA regulations, or FAR. And, regardless, the Government paid the resulting invoices with actual knowledge of Relator's allegations concerning regulatory noncompliance.

the Government in a claim for payment. 579 U.S. at 190. This complaint does not identify one, nor do Pfizer's invoices include any. (*See* Exhibit B.) The Court's consideration of Relator's implied certification claim can end there.

For good measure, the complaint fails *Escobar's* second prong as well. That prong requires Relator to identify noncompliance with a statutory, regulatory, or contractual requirement that was "material to the Government's payment decision." *Escobar*, 579 U.S. at 195. The Supreme Court has described this materiality standard as "rigorous." *Id*. at 181. It requires a relator to plead specific facts showing the United States would "likely or actual[ly]" decline to pay had the Government been aware of the noncompliance alleged. *See id*. at 193 ("A misrepresentation cannot be deemed material merely because the Government . . . would have the option to decline to pay if it knew of the defendant's noncompliance.") Moreover, statutory, regulatory, or contractual requirements are "not automatically material, even if they are labeled conditions of payment." *Id*. at 191.

What really matters under *Escobar* is whether "the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement." 579 U.S. at 195. And, "if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is *very strong evidence* that those requirements are not material." *Id*. (emphasis added). "Such very strong evidence becomes compelling when an agency armed with robust investigatory powers to protect public health and safety is told what Relators have to say, yet sees no reason to change its position." *United States ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29, 35 (1st Cir. 2017).

The Fifth Circuit puts it this way: when courts "have the benefit of hindsight," they "should not ignore what actually occurred." *Harman*, 872 F.3d at 667-68 (quoting *United States ex rel.*

McBride v. Halliburton Co., 848 F.3d 1027, 1034 (D.C. Cir. 2017)). This rule applies even at the pleading stage of FCA litigation where "continued payment by the federal government after it learns of the alleged fraud substantially increases the burden on the relator in establishing materiality." *United States ex rel. Porter v. Magnolia Health Plan, Inc.*, 810 Fed. App'x 237, 242 n.7 (5th Cir. 2020) (affirming dismissal of qui tam complaint for lack of materiality where relator "made no allegations that . . . continued payment persisted for reasons other than non-materiality").

Relator's complaint on its face shows the Government has been aware of her allegations since September 2020, months before Pfizer submitted a single invoice for its vaccine or the Government started paying for it. (Am. Compl. ¶¶ 262, 266.) Documents that she published on her own website reveal the extensive information she shared with multiple federal agencies before filing her qui tam action. (Exhibits C & E.) Those documents also show the Government actually investigated her allegations, as required under federal law. (Exhibit F.) With detailed knowledge of Relator's concerns, the Government authorized Pfizer's COVID-19 vaccine, that authorization remains in effect, and the vaccine remains eligible for payment by the United States. *See supra* notes 12, 21, and 22. The Government has also clearly rejected Relator's allegations by issuing a recent public statement expressing "full confidence" in the data supporting authorization and approval of Pfizer's product. *See supra notes* 16, 17. There is nothing to support Relator's allegation that the underlying FDA approval was fraudulent. And the Government declined to intervene in this action to boot. *See United States ex rel. Petratos v. Genentech, Inc.*, 855 F.3d 481, 490 (3d Cir. 2017) (affirming dismissal of qui tam action for lack of materiality in part because "the Department of Justice has taken no action against [defendant] and declined to intervene in the suit"). The case for immateriality is overwhelming.

There is nothing on the other side of the scale. The "noncompliance" that Relator alleges—failure to abide by the clinical trial protocol, FDA regulations, and FAR provisions—are not "labeled conditions of payment" under the OTA agreement between Pfizer and the United States. *See Escobar*, 579 U.S. at 191. Nor does the alleged noncompliance go to the "very essence of the bargain" between the parties, which entered into a "large-scale manufacturing demonstration" and agreed explicitly that Pfizer's clinical development activities would be "out-of-scope." *See id*. at 194 n.5. After all it was Pfizer, not the Government, that funded the landmark study. In addition, Relator "has made no allegations that . . . the continued approval [of Pfizer's vaccine] persisted for reasons other than non-materiality." *See Porter*, 810 Fed. App'x at 242 n.7.

Conclusory allegations are never good enough under federal pleading standards. *Iqbal*, 556 U.S. at 678-79. And Relator's say-so on materiality in the aftermath of *Escobar*, *Harman*, and *Porter* is especially inadequate. Her complaint falls far short of the "demanding" showing required by the Supreme Court and the Fifth Circuit. *See Escobar*, 579 U.S. at 194. For this reason, and others, the complaint fails to plead implied certifications, just as it fails to plead express ones. Lacking either, Relator's causes of action against Pfizer must be dismissed under Rule 12(b)(6) for failure to plead a "false or fraudulent" claim.

II. RELATOR FAILS TO STATE A CLAIM UNDER 31 U.S.C. § 3729(a)(1)(B).

The complaint purports to allege two causes of action against Pfizer. Count I asserts that Pfizer "presented false and/or fraudulent claims to the United States for payment or approval" in violation of 31 U.S.C. § 3729(a)(1)(A). (Am. Compl. ¶¶ 293-94.) That provision imposes liability on "any person who knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" to the United States. For reasons already discussed, the complaint does not plausibly allege a false claim, so the Court should dismiss Count I. Relator's second cause of action against Pfizer, Count II, fails for the same reason.

Count II asserts that Pfizer violated 31 U.S.C. § 3729(a)(1)(B). (Am. Compl. ¶ 300.) That provision imposes liability on "any person who knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." Subsection (a)(1)(B) contains a "double falsity" requirement—the relator must plead "both a false statement and a corresponding false claim." *United States ex rel. Kester v. Novartis Pharms. Corp.*, 23 F. Supp. 3d 242, 252 (S.D.N.Y. 2014). This provision extends FCA liability to those defendants, such as subcontractors, who may not submit claims for payment to the Government directly, but rather make false records or statements knowing they are material to downstream false claims. *United States ex rel. Folliard v. CDW Tech. Servs., Inc.*, 722 F. Supp. 2d 20, 34 (D.D.C. 2010). False records and statements alone do not create liability though; there must be an actual false claim seeking payment from the Government at the end of the chain. *See United States v. Southland Management Corp.*, 326 F.3d 669, 675 (5th Cir. 2003) ("There is no liability under this Act for a false statement unless it is used to get [a] false claim paid."); *United States ex rel. Aflatooni v. Kitsap Physicians Serv.*, 314 F.3d 995, 997 (9th Cir. 2002) ("It seems to be a fairly obvious notion that a False Claims Act suit ought to require a false claim."); *Kester*, 23 F. Supp. 3d at 253; *Folliard*, 722 F. Supp. 2d at 35.

Because Relator's complaint fails to plead a false or fraudulent claim under any theory, Counts I and II against Pfizer are equally defective. Her allegation that Pfizer submitted to FDA a "false . . . clinical trial protocol" and "falsified source documents and data," (Am. Comp. ¶ 299), does nothing to improve Relator's position. Clinical protocols, source documents, and data are not "claims" within the meaning of the FCA. *See* 31 U.S.C. § 3729(b)(2) ("[T]he term 'claim' means any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property[.]"). "Claims," for present

purposes, are claims *for payment*, and Relator was required to plead a false one to survive the present motion. She did not.

False records and statements must also be "material" to the Government before they can give rise to an FCA violation. 31 U.S.C. § 3729(a)(1)(B). Here, again, the complaint falters because the United States has been aware of Relator's allegations for well over a year, and yet FDA continues to authorize and approve Pfizer's vaccine, DoD continues to pay for it, and DOJ declined to intervene in Relator's lawsuit. The "lack of any further action" by the Government "shows that the FDA viewed the information, including that furnished by Relator[], differently than Relator[] do[es]." *See Nargol*, 865 F.3d at 35 (affirming dismissal of qui tam claims for lack of materiality). And, as discussed previously, her complaint proffers no explanation for the "continued approval" of Pfizer's vaccine "other than non-materiality." *See Porter*, 810 Fed. App'x at 242 n.7. As a result, the Court should dismiss both of Relator's causes of action against Pfizer.

III. RELATOR'S LAWSUIT IS SUBJECT TO AN UNSATISFIED CONDITION PRECEDENT.

While the falsity and materiality questions are dispositive, the Court can also dismiss Counts I and II against Pfizer for the independent reason that they are subject to an unsatisfied condition precedent—alternative dispute resolution ("ADR") requirements—that the Government negotiated back in July 2020 as part of its initial agreement to purchase Pfizer's vaccine. For the reasons discussed below, those ADR requirements apply to FCA causes of action whether brought by the Government directly or by a relator on the Government's behalf.

"In this case, as with every False Claims Act qui tam lawsuit, the 'real party in interest' is the United States." *United States ex rel. Health Choice Alliance, LLC v. Eli Lilly and Co., Inc.*, 4 F.4th 255, 262 (5th Cir. 2021). And the Relator in this action, like all qui tam plaintiffs, has no claim separate from the Government's; she is a "partial assignee" of the Government's rights under the FCA. *Vermont Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 773-74 n.4

(2000); *see also Little v. Shell Expl. & Prod. Co.*, 690 F.3d 282, 285 (5th Cir. 2012) ("a qui tam relator is, in effect, suing as a partial assignee of the United States['s] claim for damages") (brackets in original) (quotation omitted). An assignee stands in the shoes of the assignor and cannot sue if the assignor could not have maintained the action. *Quality Infusion Care, Inc. v. Health Care Serv. Corp.*, 628 F.3d 725, 729 (5th Cir. 2010) ("We have recognized that an assignee takes all of the rights of the assignor, no greater and no less . . . [and] [a]n assignee is also subject to any defenses . . . that could be asserted against the assignor's rights."). Similarly, "[t]he relator stands in the [G]overnment's shoes—in neither a better nor a worse position than the [G]overnment stands when it brings suit." *United States ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1360 (11th Cir. 2006). For this reason, courts cannot "furnish a qui tam relator with an easier burden than the [G]overnment would bear if it intervened and assumed the prosecution of the case." *Id.*

Here the Government could not have sued Pfizer without first following detailed "Dispute Resolution Procedures" contained in the 2020 OTA agreement. (Exhibit A, § 7.02.) They apply broadly to "[a]ny disagreement, claim or dispute among the [p]arties concerning questions of fact or law arising from or in connection with [the OTA] and *whether or not involving an alleged breach of [the OTA]*." (Exhibit A, § 7.02, ¶ 1 (emphasis added).) In other words, the agreement's dispute resolution procedures apply, under their plain terms, both to contractual and non-contractual causes of action, including statutory claims like the present FCA lawsuit.

Under the OTA's dispute resolution provision, the Government cannot file a lawsuit relating to the subject-matter of the agreement unless the Government first provides Pfizer with "a writing documenting the relevant facts, identifying unresolved issues, specifying the clarification or remedy sought, and documenting the rationale as to why the clarification/remedy is

appropriate." (Exhibit A, § 7.02, ¶ 3.) If the parties are unable to resolve the dispute themselves, the Government may "request a decision by the [U.S. Army Contracting Command-New Jersey], Center Director for Emerging Technologies," which must render a decision within 30 days of receiving the parties' written submissions. *Id.* Only upon exhausting administrative remedies may the Government pursue "any right or remedy provided by law." (Exhibit A, § 7.02, ¶ 4.)

Courts have enforced similar ADR provisions in other Government contracts to block the United States from pursuing an FCA claim without first pursuing ADR. *United States v. Bankers Ins., Inc.*, 245 F.3d 315, 324 (4th Cir. 2001) ("We do not share the trepidation of the Government regarding arbitration of its FCA claim. . . . The Government should comply with its contract obligations, and it cannot avoid them merely by invoking a statutory civil claim, such as one contemplated under the FCA.").

The same reasoning applies here. The OTA's dispute resolution procedures are a condition precedent to the Government's FCA claim; Relator cannot sue Pfizer on the Government's behalf unless and until the Government first satisfies that condition. *See, e.g., Arcadis U.S., Inc. v. Stryker Demolition & Env't Servs., LLC*, No. 20-0471, 2021 WL 785138, at *3 (W.D. La. Mar. 1, 2021) ("The consensus among district courts is that failure to mediate a dispute pursuant to a contract that makes mediation a condition precedent to filing a lawsuit warrants dismissal under Rule 12(b)(6).") (quoting *Franke v. Yates*, No. 19-00007, 2019 WL 4856002, at *5 (D. Haw. Oct. 1, 2019)).

The United States has taken no action against Pfizer, administrative or otherwise. Rather, the Government has publicly stated its "full confidence in the data" supporting Pfizer's vaccine, while at the same time continuing to purchase the vaccine, encouraging Americans to take it, and providing it to them at no cost. The Government declined to intervene in this action as well.

"When the [G]overnment, at appropriate levels, repeatedly concludes that it has not been defrauded, it is not forgiving a found fraud—rather it is concluding there was no fraud at all." *Harman*, 872 F.3d at 670. The Government's "actual behavior" in response to Relator's allegations speaks volumes. *See Escobar*, 579 U.S. at 193. Dismissal is required.

CONCLUSION

For all of these reasons, Pfizer respectfully asks the Court to dismiss Counts I and II of Relator's complaint under Rule 12(b)(6), with prejudice. Pfizer also requests oral argument on this motion.

Respectfully submitted,

Dated: April 22, 2022

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CERTIFICATE OF SERVICE

I hereby certify that on April 22, 2022, a true and correct copy of the foregoing document was filed electronically in compliance with Local Rule CV-5. As of this date, all counsel of record has consented to electronic service and are being served with a copy of this document through the Court's CM/ECF system under Local Rule CV-5(a)(3)(A). Service was further made on Ventavia's counsel by e-mail as indicated below.

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