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

UNITED STATES OF AMERICA *ex rel.* BROOK JACKSON,	§	
	§	
Plaintiff,	§	
	§	CIVIL ACTION NO. 1:21-CV-00008
v.	§	JUDGE MICHAEL J. TRUNCALE
	§	
VENTAVIA RESEARCH GROUP, LLC; PFIZER, INC; ICON, PLC,	§	
	§	
Defendants.	§	

ORDER AND OPINION GRANTING DEFENDANTS' MOTIONS TO DISMISS

Before the Court are three Motions to Dismiss filed by Defendants Pfizer, Inc. ("Pfizer") [Dkt. 37], ICON, PLC ("ICON") [Dkt. 51], and Ventavia Research Group, LLC ("Ventavia) [Dkt. 53]. In her Amended Complaint, Relator Brook Jackson asserts causes of action against Pfizer, ICON, and Ventavia (collectively, "Defendants") for alleged violations of the False Claims Act ("FCA").[1] [Dkt. 17]. Defendants move to dismiss the Amended Complaint pursuant to Federal Rules of Civil Procedure 12(b)(6) and 9(b).[2] On January 18, 2022, the United States declined to intervene in this action. [Dkt. 13]. On October 4, 2022, the United States filed a Statement of Interest Supporting Dismissal of the Amended Complaint. [Dkt. 70]. The Court heard oral argument on the Defendants' Motions on March 1, 2023. [Dkt. 94]. For the reasons discussed below, the Court grants Defendants' Motions.

[1] "Suits to collect statutory damages and civil penalties under the FCA may be brought by the Attorney General or by a private person, known as a relator, in the name of the United States. An action brought by a relator is commonly referred to as a *qui tam* action." *United States ex rel. Longhi v. United States*, 575 F.3d 458, 463 n.1 (5th Cir. 2009) (citing 31 U.S.C. § 3730(a)–(b)).

[2] Defendants incorporate by reference the arguments made by each co-defendant in their respective Motions to Dismiss and Reply Briefs. [Dkt. 51 at 6; Dkt. 53 at 16 n.1; Dkt. 67 at 14; Dkt. 68 at 5; Dkt. 69 at 5].

I. BACKGROUND[3]

A. Operation Warp Speed

There was no vaccine to protect against COVID-19 in the early months of the pandemic. To address this urgent need, the Government launched Operation Warp Speed on May 15, 2020. [Dkt. 17 at 18]. Operation Warp Speed was an interagency partnership between the United States Department of Defense ("DoD") and the United States Department of Health and Human Services that coordinated federal efforts to accelerate the development, acquisition, and distribution of a COVID-19 vaccine. *Id.* Soon thereafter, Pfizer began working to develop a vaccine. *Id.* at 24.

In June 2020, the Food and Drug Administration ("FDA") published guidance regarding the data and information needed to support issuance of Emergency Use Authorization ("Emergency Authorization") for COVID-19 vaccines.[4] [Dkt. 17-1 at 312; Dkt. 37 at 11 n.5]. The guidance explained that the FDA may issue Emergency Authorization upon its determination—based on "the totality of the available scientific evidence"—that: (1) "studies have demonstrated the safety and effectiveness of the vaccine"; and (2) "the known and potential benefits of a product, when used to diagnose, prevent, or treat serious or life-threatening diseases, outweigh the known and potential risks of the product." *Id.* The guidance specifies that "the primary efficacy endpoint estimate for a placebo-controlled efficacy trial should be at least 50%" in order to "ensure that a

[3] The Amended Complaint alleges the following facts.

[4] The Court takes judicial notice of the FDA guidance because it is incorporated into the Amended Complaint by reference [Dkt. 17-1 at 312], cited in Pfizer's Motion to Dismiss [Dkt. 37 at 11 n.5], a publicly-available document produced by the FDA, and central to Ms. Jackson's claims. *See Brand Coupon Network, L.L.C. v. Catalina Mktg. Corp.*, 748 F.3d 631, 635 (5th Cir. 2014) (ruling that on a "Rule 12(b)(6) motion" district courts may "consider documents attached to either a motion to dismiss or an opposition to that motion when the documents are referred to in the pleadings and are central to a plaintiff's claims"); *Funk v. Stryker Corp.*, 631 F.3d 777, 783 (5th Cir. 2011) ("[T]he district court took appropriate 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."); *Swindol v. Aurora Flight Scis. Corp.*, 805 F.3d 516, 519 (5th Cir. 2015) (taking judicial notice of "public records" on Government websites because their accuracy could not reasonably be questioned); *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.").

widely deployed COVID-19 vaccine is effective." *Id.*

In July 2020, while Pfizer's vaccine was still under development, the DoD entered into a contract (the "Project Agreement") with Pfizer, under which Pfizer would deliver 100 million doses of a FDA authorized or approved vaccine to the Government on a fixed price per dose basis, in accordance with a "Statement of Work."[5] [Dkt. 17-1 at 303–37]. The Statement of Work provides that the Government will pay $1.95 billion for 100 million doses—or $19.50 per dose—of Pfizer's vaccine, if Pfizer first secures FDA approval or Emergency Authorization. *Id.* at 319.

B. Pfizer's Clinical Trial and the FDA's Authorization

After executing the Project Agreement, Pfizer endeavored to launch a clinical trial in order gain FDA approval or Emergency Authorization for its vaccine. [Dkt. 17 at 6–7]. Before starting the trial, Pfizer submitted an Investigational New Drug Application ("IND") to the FDA. *Id.* at 19, 36; [Dkt. 17-1 at 51–53]. Pfizer's IND included a cover sheet, known as Form FDA-1571, wherein Pfizer committed to: (1) conduct the trial in accordance with applicable regulatory requirements; and (2) utilize an Institutional Review Board for continuing review and approval of the trial.[6] [Dkt. 17 at 19, 36] (citing 21 C.F.R. § 312.23(a)(iv)–(v)). Pfizer also included its trial protocol in the IND. [Dkt. 17 at 19, 36].

Pfizer enlisted the help of ICON, an Irish-headquartered clinical research organization, and Ventavia, a testing site operator, to conduct the clinical trial. *Id.* at 7. ICON and Ventavia each

[5] The key terms of the Project Agreement are found in two instruments: (1) a Statement of Work and (2) a "Base Agreement." The Statement of Work is attached to the Amended Complaint. [Dkt. 17-1 at 303–37]. The Court takes judicial notice of the Base Agreement because it is incorporated into the Amended Complaint by reference [Dkt 17-1 at 313], attached to Pfizer's Motion to Dismiss [Dkt. 37-1 at 2–56], and central to Ms. Jackson's claims. *See In re Katrina Canal Breaches Litig.*, 495 F.3d 191, 205 (5th Cir. 2007) ("[B]ecause the 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.").

[6] The Amended Complaint does not contain the IND that Pfizer submitted. Instead, Ms. Jackson provides a blank "example" FDA Form-1571. [Dkt. 17 at 19; Dkt. 17-1 at 51-53].

submitted a document titled Form FDA-1572 to Pfizer and the FDA, in which ICON and Ventavia certified that they would: (1) conduct the trial in accordance with protocol and FDA regulations; (2) obey informed consent and Institutional Review Board reporting requirements; (3) report adverse events; (4) ensure that all employees were informed of their obligations; and (5) make no changes to the trial without Institutional Review Board approval.[7] *Id.* at 20, 36, 73; [Dkt. 17-1 at 55–56].

Pfizer conducted a placebo-controlled, randomized, observer-blind clinical trial to evaluate the safety, tolerability, immunogenicity, and efficacy of its vaccine against COVID-19 in healthy individuals.[8] [Dkt. 17-1 at 143]. A total of 43,661 participants enrolled in the clinical trial across 160 testing sites worldwide. [Dkt. 17 at 7, 24; Dkt. 17-1 at 292]. Pfizer delegated oversight of those testing sites to ICON. [Dkt. 17 at 7]. ICON was responsible for ensuring compliance with reporting requirements and clinical trial protocol. *Id.* Pfizer contracted with Ventavia to operate three testing sites in Houston, Fort Worth, and Keller, Texas. *Id.* Approximately 1,500 participants enrolled at the Ventavia testing sites. *Id.*

Pfizer announced the results from its clinical trial on November 18, 2020. *Id.* at 25. Data analysis from 41,135 trial participants showed that a two-dose regimen of the vaccine was 95% effective against COVID-19. [Dkt. 17-1 at 290–92]. Safety data showed a favorable safety profile and raised no serious safety concerns. *Id.* Pfizer asked the FDA to authorize the vaccine for

[7] Instead of providing the FDA Form-1572s that ICON and Ventavia submitted, Ms. Jackson attaches a blank example. [Dkt. 17 at 20; Dkt. 17-1 at 55–56].

[8] 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. An "observer blind" trial 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.

emergency use on November 20, 2020. [Dkt. 17 at 25]. Relying on Pfizer's clinical trial results, the FDA concluded that the key criteria for issuance of Emergency Authorization were met: the "totality of the available data provide[d] clear evidence" that the Pfizer vaccine "may be effective in preventing COVID-19," and that "the known and potential benefits outweigh[ed] the known and potential risks." *Id.* at 25 n.5.[9] The FDA noted that its review process also included "public and independent review" and that it had "conducted a thorough evaluation of the available safety, effectiveness and manufacturing quality information." *Id.* Accordingly, the FDA granted Emergency Authorization on December 11, 2020.[10] *Id.* at 25. Pfizer sent its first invoice to the Government on December 31, 2020.[11] [Dkt. 37-2 at 2]. Pfizer certified in its invoice that the invoice was "true and correct, prepared from Pfizer's books and records, and in accordance with the Pfizer-DoD contract." [Dkt. 17 at 73] (citing 48 C.F.R. 52.232-32(m)).

On August 23, 2021, the FDA fully approved Pfizer's vaccine for individuals sixteen years of age and older by granting a Biologics License Application. [Dkt. 17 at 9]. To date, the FDA has not revoked its approval of Pfizer's vaccine, and the Government continues to provide the vaccine to Americans at no cost.[12] *Id.* at 18 n.2.

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[9] The Court takes judicial notice of the government webpage linked in the Amended Complaint. *See Funk*, 631 F.3d at 783 ("When reviewing a motion to dismiss, a district court must consider . . . documents incorporated into the complaint by reference . . . .") (quoting *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007)); *Swindol*, 805 F.3d at 519 (taking judicial notice of "public records" on Government websites because their accuracy could not reasonably be questioned); *Norris*, 500 F.3d at 461 n.9. ("[I]t is clearly proper in deciding a 12(b)(6) motion to take judicial notice of matters of public record.").

[10] The December 11, 2020, EUA approved the vaccine for individuals sixteen years of age and older. [Dkt. 17 at 9]. The FDA granted EUA for individuals twelve years of age and older on May 10, 2021, *id.*, and for individuals ages five through eleven on October 29, 2021. *Id.*

[11] The Court takes judicial notice of Pfizer's actual invoices, which are incorporated into the Amended Complaint by reference [Dkt. 17 at 72], attached to Pfizer's Motion to Dismiss [Dkt. 37-2 at 2], and central to Ms. Jackson's claims. *See Brand Coupon Network, L.L.C.*, 748 F.3d at 635.

[12] The Court takes judicial notice of the government webpage cited in the Amended Complaint. *See Funk*, 631 F.3d at 783; *Swindol*, 805 F.3d at 519; *Norris*, 500 F.3d at 461 n.9.

C. Clinical Trial Protocol Violations

Ms. Jackson worked as a Regional Director at two of Ventavia's testing sites from September 8 to September 25, 2020. *Id.* at 11, 15. During her eighteen days of employment, she allegedly witnessed numerous violations of Pfizer's clinical trial protocol. *Id.* at 36–59. Many of the alleged violations involved a failure to maintain accurate documentation. Ventavia was required to scan or enter data from clinical trial participants' "source documents" into a database so that it could be passed on to ICON and Pfizer *Id.* at 12. Ventavia was also responsible for "quality checking" all source documents before scanning or uploading them. *Id.* Ms. Jackson alleges, however, that on multiple occasions, Ventavia falsified information when conducting quality checks or otherwise hid protocol violations from Pfizer and ICON. *Id.* at 36–59. The Court turns to the alleged protocol violations.

1. Ineligible Participants

Pfizer's protocol did not permit pregnant women to participate in the clinical trial. *Id.* at 36. Ms. Jackson alleges that Ventavia nonetheless administered the vaccine or placebo to pregnant women and did not report to Pfizer and ICON that pregnant women participated in the trial. *Id.* at 37.

Relatedly, Ventavia also allegedly considered women with a tubal ligation as not capable of becoming pregnant, even though the protocol did not list tubal ligation as an accepted contraception method. *Id.* Ms. Jackson contends that Ventavia's violations involving tubal ligation would have been "obvious from the source documents," but that Pfizer and ICON ignored these "red flags" and failed to exclude trial data from ineligible participants. *Id.*

Ventavia also allegedly violated protocol by not testing a participant for COVID-19 until after administering the vaccine. *Id.* at 38–39. Ventavia allegedly falsified this participant's source

document by crossing out a question about why vaccination preceded informed consent and adding a comment that the informed consent time was incorrect. *Id.* Ventavia allegedly further violated protocol by enrolling Ventavia employees and their family members in the clinical trial, *id.* at 39, and by examining married couples or groups of friends at the same time instead of individually. *Id.* at 53. Ms. Jackson contends this that last practice would have been apparent to Pfizer and ICON from overlapping times in the source documents. *Id.*

2. Unblinding

The clinical trial was an observer-blinded study. *Id.* at 39. The only "unblinded" people at Ventavia's testing sites should have been those administering shots. *Id.* Ms. Jackson alleges three incidents that unblinded, or had the potential to unblind, staff and participants. First, she alleges that containers marked with numbers that would enable someone to determine whether a participant received the vaccine or placebo were left out in the open. *Id.* at 39, 41. Second, on one occasion Ms. Jackson alleges that she was inadvertently unblinded after receiving an email containing participant numbers and dosing information. *Id.* at 40–41. And third, she alleges that "randomization documents," which reveal whether a participant received a placebo, were improperly placed in the charts of 1,200 participants. *Id.* at 39–40. Ventavia subsequently removed or crossed out this information, but it had allegedly been visible to employees and participants for over two months. *Id.* at 40. Ms. Jackson alleges that instead of reporting this incident to Pfizer or ICON, Ventavia placed "Notes to File" in each participant's chart stating that randomization documents should not be included in the chart. *Id.* The Notes to File were not viewable to Pfizer or ICON until the end of the clinical trial. *Id.* Ms. Jackson asserts, however, that a Ventavia employee alerted Pfizer of this third incident via an email sent to Pfizer employee, Dr. Arturo Alfaro. *Id.* In the email, the Ventavia employee asked Dr. Alfaro to confirm that randomization

documents should not be given to blinded staff. *Id.* Dr. Alfaro concurred with this statement. *Id.* According to Ms. Jackson, Pfizer should have realized that the Ventavia employee's inquiry "could indicate that unblinding had already occurred." *Id.* Pfizer did not follow up on this issue or remove the potentially affected participants' data from the trial results. *Id.*

3. Temperature Deviations

On at least one occasion, a freezer containing vaccines was allegedly unplugged and moved, resulting in a "temperature excursion." *Id.* at 42. Ventavia allegedly reported the excursion to Pfizer late, in violation of the protocol requirement that excursions be reported as soon as discovered. *Id.* In addition, although the protocol required thawing the vaccine for thirty minutes prior to administration, Ms. Jackson alleges that, at times, Ventavia employees only waited twenty minutes and held the vaccine vials in their hands to expedite thawing. *Id.* at 44. Ms. Jackson asserts that an email exchange between a Ventavia employee and Dr. Alfaro should have put Pfizer on notice about these deviations. Pfizer did not remove affected participants' data from the trial results. *Id.*

4. Informed Consent

Ms. Jackson also alleges that Ventavia violated trial protocol by taking participants' vital signs or administering the vaccine before obtaining their informed consent. *Id.* at 38, 42–44. Ventavia, while conducting quality checks, allegedly hid these violations by falsifying source documents to make it appear as though its employees had obtained informed consent before taking the vital signs or administering the vaccine. *Id.* Ms. Jackson asserts, however, that two email chains put Pfizer and ICON on notice about informed consent timing discrepancies, *id.* at 43 (citing [Dkt. 17-2 at 60–67, 69–74]), and that Pfizer and ICON had access to the source documents, thereby imparting constructive knowledge. *Id.* Pfizer included data from affected participants in the trial

results. *Id.*

5. Improper Training

Ventavia allegedly violated trial protocol by allowing improperly trained or unqualified employees to administer the vaccine. *Id.* at 44. One medical assistant allegedly administered vaccines before receiving required training. *Id.* And another employee, with no medical qualifications, allegedly administered the vaccine as well. *Id.* at 45.

6. Improper Administration and Monitoring

Ventavia allegedly administered the second dose of the vaccine to participants outside of the protocol-mandated nineteen-to-twenty-three-day window. *Id.* Ms. Jackson asserts that Ventavia did not report these violations to Pfizer or ICON but that they "would have been obvious from the source documents." *Id.* at 45–46. Further, vaccinators allegedly sometimes used the wrong sized needle to administer the vaccine. *Id.* at 46. Pfizer included data from these participants in the trial results. *Id.*

On at least four occasions Ventavia employees allegedly used 1.7 milliliters instead of 1.2 milliliters of sodium chloride to dilute the vaccine. *Id.* ICON noticed this issue and brought it to Ventavia's attention. *Id.* But Ms. Jackson alleges that Ventavia falsely told ICON that the discrepancy was due to a transcription error. *Id.*

In addition, Ms. Jackson alleges that the trial protocol required placing participants under "medical supervision" for thirty minutes after receiving the vaccine, *id.* (citing [Dkt. 17-1 at 101, 118, 194]), but that some participants were supervised for less than thirty minutes and/or supervised by a "non-medically-qualified employee." *Id.* at 46–47. Ms. Jackson communicated this issue to Dr. Alfaro during an anonymous phone call, which she believes should have alerted Pfizer to the protocol deviation. *Id.* at 47.

7. Adverse Event Reporting

Ms. Jackson alleges that Ventavia did not report all Adverse Events ("AEs") and Serious Adverse Events ("SAEs") to Pfizer and ICON. *Id.* at 48. She asserts that Pfizer and ICON had constructive notice that Ventavia was not reporting all AEs and SAEs because they had access to the participants' "electronic diary" entries, where the participants recorded their post-vaccination symptoms. *Id.* at 28, 49.

8. Improper Recordkeeping

Ms. Jackson alleges that Ventavia also failed to maintain accurate and complete documentation throughout the trial. *Id.* She broadly asserts that Pfizer and ICON "turned a blind eye" to this inadequate recordkeeping "despite obvious warning signs" and that these "sloppy" documents were included in Pfizer's trial results. *Id.* The Amended Complaint alleges four examples of improper recordkeeping.

First, a blood draw log from Ventavia's Fort Worth testing site allegedly contained inaccurate or missing time entries. *Id.* at 50. ICON was aware of this issue because it "directly questioned missing blood collection and processing times." *Id.* at 51. Second, Ms. Jackson allegedly saw a Ventavia employee change the blood pressure readings in participant source documents. *Id.* Third, Ventavia allegedly delayed implementing a review log system to monitor participants for COVID-19 symptoms. *Id.* at 52. Ms. Jackson contends that Notes to File were documented for this third issue, thereby imparting constructive knowledge to Pfizer and ICON. *Id.*

Finally, Dr. Mark Koch, the principal investigator at Ventavia's Fort Worth testing site, allegedly "signed off" on records for participants that were actually examined by sub-investigator doctors or other medical staff. *Id.* at 53. Relatedly, one record did not contain a principal investigator signature. *Id.* at 54. Ventavia did not report the principal investigator oversight issues

to Pfizer or ICON. *Id.* at 53.

9. Privacy Law Violations

Ventavia employees allegedly violated Health Insurance Portability and Accountability Act ("HIPAA") regulations and trial protocol by leaving participants' files unattended and displaying a calendar near a reception area that contained participants' names, phone numbers, and health information. *Id.* at 55. Ventavia employees also allegedly violated HIPAA by using the smartphone and computer application "Slack" to communicate participants' names and identification numbers. *Id.*

D. Alleged Safety and Ethical Issues

In addition to protocol violations, Ms. Jackson claims that she observed several "safety and ethical issues" during her employment with Ventavia. *Id.* at 58. First, she reports seeing used needles disposed of in biohazard bags. *Id.* The needles could have punctured the bags, thereby exposing Ventavia employees to risk of injury or infection. *Id.* Second, Ventavia internally requires participants' charts to contain dosage ranges for epinephrine, a drug used to counter allergic reactions. *Id.* Ventavia allegedly did not follow this internal policy. *Id.* Third, in order to adhere to industry-standard practices, Ventavia employees were required to undergo training in biologics handling as well as occupational safety and health. *Id.* But Ventavia allegedly did not provide all employees with this training. *Id.* Finally, Ventavia allegedly breached its ethical obligations by providing unauthorized compensation to trial participants in the form of gift cards without IRB approval. *Id.*

E. Retaliation Against Ms. Jackson

Ms. Jackson began her employment with Ventavia on September 8, 2020. *Id.* at 11. Her direct supervisor was Director of Operations Marnie Fisher. *Id.* at 60. Her other supervisors were

Executive Director Olivia Ray, Executive Director Kristie Raney, and Chief Operating Officer Mercedes Livingston. *Id.* Ms. Jackson frequently reported her concerns about trial protocol and FDA regulation violations, as well as participant safety, to Ms. Fisher and Ms. Livingston. *Id.* at 61. Ms. Jackson alleges that each time she voiced her concerns to Ms. Fisher, she was instructed to send an email to Ms. Fisher or make a list of affected participants. *Id.*

Ventavia allegedly fell behind schedule on quality checking source documents. *Id.* at 62. As alleged above, Ventavia failed to catch mistakes or falsified data when conducting quality checks. *Id.* Ms. Jackson communicated her concerns about Ventavia's quality checking process to the Fort Worth Principal Investigator, Dr. Koch, as well as Ventavia management. *Id.* at 61–62. On September 15, 2020, Ms. Jackson reported to Ms. Fisher that Ventavia had failed to quality check certain participants' charts and neglected to send some charts to Pfizer. *Id.* at 62.

On the night of September 16, 2020, Ms. Jackson took photographs of the biohazard bags that stored used needles. *Id.* She also photographed alleged HIPAA violations: the calendar in the reception area containing participants' names and information, and other participant records that had been left out in public view. *Id.* at 63. Concerned about potential unblinding, she also took pictures of boxes labeled with participant randomization numbers. *Id.* Ms. Jackson shared these photographs with Ms. Fisher and Ms. Livingston via text message and e-mail. *Id.* at 65.

On September 17, 2020, Ms. Jackson spoke with Ventavia's Houston Regional Director, Lovica Downs, and Ventavia's Quality Control Director, William Jones, on the telephone. *Id.* at 13, 65. When she asked for their opinions about what would happen if the FDA audited Ventavia, they allegedly both responded that Ventavia would receive warning letters or be asked to discontinue trial enrollment. *Id.* at 65.

Later that day, during a phone call with Ms. Ray, Ms. Raney, Ms. Fisher, Ms. Downs, and

Ms. Livingston, Ms. Jackson "brought up virtually all of the protocol and regulatory violations she had witnessed to date, as well as Ventavia's HIPAA violations." *Id.* Ms. Jackson explained that "the FDA would likely issue warning letters against Ventavia if it visited or audited the trial sites" and recommended that Ventavia stop enrollment. *Id.* Ms. Jackson also sent text messages to Ms. Ray, Ms. Raney, Ms. Fisher, Ms. Downs, and Ms. Livingston expressing concerns about Ventavia's quality checking of source documents and relaying concerns from the Operations Manager of Ventavia's Fort Worth site about protocol and HIPAA violations. *Id.*

Ventavia paused enrollment on September 17, 2020. *Id.* Ventavia allegedly was not honest with Pfizer about the reason for the enrollment pause. *Id.* at 66. Rather, Ms. Raney allegedly instructed Ventavia employees to respond to questions from Pfizer about the pause by stating that Ventavia was "being responsible" by recognizing that it had reached its "bandwidth." *Id.* Further, during the enrollment pause Ventavia allegedly failed to correct documentation violations and falsified missing or incorrect data. *Id.* at 67.

On September 23, 2020, Ms. Jackson emailed Ms. Ray, Ms. Raney, Ms. Fisher, Ms. Downs, Ms. Livingston, and Mr. Jones to report issues with Ventavia's quality checking process. *Id.* Her email noted outstanding inquiries from ICON about missing or inconsistent data, scheduling errors that resulted in participants receiving their second vaccine dose outside of the nineteen-to-twenty-three-day window, a delay in sending one participant's chart to ICON and Pfizer, and missing participant charts or laboratory specimens. *Id.* The next day she sent a separate email to Ms. Fisher expressing her concerns about Ventavia's failure to include dose ranges for epinephrine in participants' charts. *Id.* at 68.

On September 24, 2020, Ms. Jackson met with Ms. Fisher and Mr. Jones. *Id.* During the meeting, Ms. Jackson discussed her concerns about safety issues, HIPAA violations, unblinding,

and FDA regulatory violations. *Id.* at 68–69. She told Ms. Fisher and Mr. Jones to "get on Google and search for FDA warning letters." *Id.* at 69.

On September 25, 2020, Ms. Jackson "called the FDA's hotline to report the clinical trial protocol violations and patient safety concerns she witnessed." *Id.* at 69. Ventavia terminated Ms. Jackson's employment later that day. *Id.* After her termination, Ms. Jackson spoke with Dr. Alfaro at Pfizer about her concerns regarding unblinding, principal investigator oversight, and participant safety at the trial. *Id.* at 70. She also informed Dr. Alfaro that she had contacted the FDA. *Id.* Shortly after her termination, "the FDA contacted [Ms. Jackson] and spoke to her for several hours regarding the violations she witnessed at Ventavia." *Id.*

A couple days later, Ventavia lifted the enrollment pause. *Id.* Ms. Jackson "estimates that Ventavia had neither completed quality checking nor remedied its ongoing violations by the time it resumed enrollment." *Id.*

II. LEGAL STANDARDS

Federal Rule of Civil Procedure 12(b)(6) authorizes dismissal of a complaint for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). In reviewing a Rule 12(b)(6) motion, the Court "accepts all well-pleaded facts as true, viewing them in the light most favorable to the plaintiff." *Sonnier v. State Farm Mut. Auto. Ins. Co.*, 509 F.3d 673, 675 (5th Cir. 2007). While the Court must accept the well-pleaded facts in the complaint as true, it will "not accept as true conclusory allegations, unwarranted factual inferences, or legal conclusions." *Gentilello v. Rege*, 627 F.3d 540, 544 (5th Cir. 2010).

To survive a Rule 12(b)(6) motion to dismiss, a complaint must contain enough well-pleaded facts "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. 544, 570 (2007)); *see* Fed. R.

Civ. P. 8(a)(2) ("A pleading that states a claim for relief must contain . . . a short and plain statement of the claim showing that the pleader is entitled to relief . . . ."). A claim is "plausible on its face" when the well-pleaded facts allow the Court to "draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. "Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of entitlement to relief.'" *Id.* (quoting *Twombly*, 550 U.S. at 557). Determining whether a complaint states a plausible claim for relief is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id.* at 679.

Complaints filed pursuant to the False Claims Act must also satisfy the "heightened" pleading standard of Federal Rule of Civil Procedure 9(b). *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 185 (5th Cir. 2009). Under Rule 9(b), a relator must plead "with particularity" the circumstances surrounding the alleged fraud. Fed. R. Civ. P. 9(b). Knowledge, however, "may be alleged generally." *United States v. Bollinger Shipyards, Inc.*, 775 F.3d 255, 260 (5th Cir. 2014).

III. PRESENTMENT AND FALSE RECORD CLAIMS

The False Claims Act "generally permits the Government or a party suing on the Government's behalf to recover for false claims made by the defendants to secure payment by the Government." *United States ex rel. Doe v. Dow Chem. Co.*, 343 F.3d 325, 329 (5th Cir. 2003). The FCA imposes liability on any person who (1) "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1)(A); or (2) "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." *Id.* § 3729(a)(1)(B).

Relevant here, "claim" means:

> [A] 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, that—
>
> > [1] is presented to an officer, employee, or agent of the United States; or
> > [2] is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government—
> >
> > > [i] provides or has provided any portion of the money or property requested or demanded; or
> > > [ii] will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded . . . .

Id. § 3729(b)(2)(A).

In order to assess liability under § 3729(a)(1)(A) or § 3729(a)(1)(B), the Fifth Circuit asks "(1) whether 'there was a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter; (3) that was material; and (4) that caused the government to pay out money or to forfeit moneys due (i.e., that involved a claim).'" *United States ex rel. Longhi v. United States*, 575 F.3d 458, 467 (5th Cir. 2009) (quoting *United States ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 376 (4th Cir. 2008)).

Claims brought under § 3729(a)(1)(A) are referred to as presentment claims, while claims brought under § 3729(a)(1)(B) are referred to as false record claims. *United States ex rel. Reddell v. DynCorp Int'l, LLC*, No. 1:14-CV-86, 2019 WL 12875471, at *4 (E.D. Tex. Mar. 20, 2019) (Crone, J.).

A. Defendants' Alleged False Claims

1. Presentment Claims

Ms. Jackson's first cause of action asserts that Defendants, in violation of § 3729(a)(1)(A), "knowingly presented, or caused the presentment of, false and/or fraudulent claims for payment or approval to the United States" because "Pfizer's claims for payment to the DoD were rendered

false and/or fraudulent by express and implied false certifications." [Dkt. 17 at 72]. She alleges the following in support of this claim:

First, when Pfizer submitted its clinical trial protocol to the FDA as part of its IND, Pfizer certified in Form FDA-1571 that it would conduct the clinical trial in accordance with all applicable laws and regulations.[13] *Id.* Ms. Jackson alleges that Defendants violated FDA regulations[14] and Federal Acquisition Regulation ("FAR") requirements[15] when conducting the clinical trial, thus rendering this certification false. [Dkt. 17 at 19, 35–36, 72].

Second, Pfizer acknowledged in Form FDA-1571 that making a willfully false statement is a criminal offense. *Id.* at 72. Ms. Jackson alleges that Defendants rendered Pfizer's acknowledgement in this form false by submitting false data to the FDA. *Id.*

Third, ICON and Ventavia certified to Pfizer and the FDA in Form FDA-1572 that they would: (1) conduct the trial in accordance with protocol and FDA regulations; (2) obey informed

[13] The Amended Complaint states: "when Defendant Pfizer submitted its clinical trial protocol to the United States in connection with its contract, it represented that the clinical trial would comply with all applicable laws and regulations." [Dkt. 17 at 72]. The Court understands this statement to refer to Pfizer's submission of its IND to the FDA, which included Pfizer's trial protocol and Form FDA-1571. *See* [Dkt. 17 at 19, 36; Dkt. 17-1 at 50].

[14] The Amended Complaint alleges several FDA regulatory violations: (1) Defendants violated 21 C.F.R. §§ 312.66 and 312.53(c) by not reporting additional compensation paid to trial participants, not following trial protocols, and not following informed consent requirements. [Dkt. 17 at 56]; (2) Defendants violated 21 C.F.R. § 312.32(d) by not promptly investigating and reporting all adverse event information received during the trial. *Id.*; (3) Defendants violated 21 C.F.R. § 312.50 by not notifying the FDA of potential serious risks or adverse reactions. *Id.*; (4) ICON and Ventavia violated 21 C.F.R. § 312.64(b) by not timely reporting all adverse events, temperature excursions, and protocol deviations to Pfizer. *Id.* at 56–57; (5) Pfizer violated 21 C.F.R. §§ 312.50 and 312.56(b) by not properly overseeing ICON and Ventavia and not ensuring that they complied with the trial protocol. *Id.* at 56; (6) Pfizer and ICON violated 21 C.F.R. § 312.56(b) when they learned of Ventavia's regulatory and protocol violations and elected to not promptly secure Ventavia's compliance, discontinue shipments of the vaccine to Ventavia, or discontinue Ventavia's participation in the trial. *Id.*; (7) Ventavia violated 21 C.F.R. 312.62 by not maintaining adequate records of vaccine administration and trial participants' case histories. *Id.* at 57; (8) Defendants violated 21 C.F.R. §§ 50.27(a), 312.60, and 312.62(b) by not obtaining and documenting informed consent records for all participants prior to their participation in the trial. *Id.*; (9) Ventavia violated 21 C.F.R. § 312.61 by administering the vaccine to participants under the personal supervision of principal investigators or sub-investigators. *Id.*; and (10) Ventavia violated 21 C.F.R. § 312.61 by administering the vaccine to ineligible participants. *Id.*

[15] The Amended Complaint alleges the following FAR requirement violations: (1) Pfizer violated 48 C.F.R. 52.203-13(b) by not detecting or disclosing FCA violations. *Id.* at 35, 57–58; (2) Pfizer violated 40 C.F.R. 42-202(e)(2) by not monitoring ICON and Ventavia. *Id.* at 35, 58.

consent and IRB reporting requirements; (3) report adverse events; (4) ensure that all employees were informed of their obligations; and (5) make no changes to the trial without IRB approval. *Id.* at 73. ICON and Ventavia acknowledged when submitting Form FDA-1572 that willfully making a false statement is a criminal offense. Ms. Jackson alleges that ICON and Ventavia rendered this certification and acknowledgement false by violating the clinical trial protocol, violating FDA regulations, and engaging in fraudulent conduct. *Id.*

Fourth, Ms. Jackson alleges that in accordance with FAR requirements, Pfizer certified in its claims for payment that the claims "were true and correct, prepared from Pfizer's books and records, and in accordance with the Pfizer-DoD contract," *id.* (citing 48 C.F.R. 52.232-32(m)), and that Defendants' alleged submission of false data, violation of FDA regulations, violations of FAR, and fraudulent conduct rendered this certification false. *Id.*

Ms. Jackson alleges that "Defendants' fraudulent schemes transform these certifications into false certifications, rendering [Pfizer's] claims for payment to the DoD false and/or fraudulent." *Id.* She further alleges that Defendants' knowing submissions of false claims were material to the Government's payment decision and that the DoD would not have paid Pfizer's claims if it had known of Defendants' allegedly fraudulent conduct. *Id.* at 73–74.

2. False Record Claims

In her second cause of action, Ms. Jackson asserts that Defendants violated § 3729(a)(1)(B) by "knowingly ma[king], us[ing] or caus[ing] to be made or used, false records or statements that were material to false and/or fraudulent claims paid or approved by the [DoD]." *Id.* at 74. She alleges that these "false records or statements include the clinical trial protocol Pfizer submitted to the United States and the falsified source documents and data behind Defendants' trial results and [Emergency Authorization] application." *Id.* She asserts that Defendants knowingly violated

§ 3729(a)(1)(B), and that Defendants' fraudulent scheme was material because the DoD would not have paid Pfizer's claims had it known about Defendants' alleged use of false records and trial protocol deviations. *Id.* at 74–75.

B. False Statement or Fraudulent Course of Conduct

The first element that a relator must plausibly allege in order to bring a *qui tam* action is the existence of "a false statement or fraudulent course of conduct." *Longhi*, 575 F.3d at 467.

1. Presentment Claims—§ 3729(a)(1)(A)

Ms. Jackson first alleges violations of § 3729(a)(1)(A), which, as stated above, makes liable any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." § 3729(a)(1)(A). [Dkt. 17 at 72–74]. "This provision includes an express presentment requirement." *Grubbs*, 565 F.3d at 188. Indeed, "the statute attaches liability, not to the underlying fraudulent activity or to the government's wrongful payment, but to the *claim* for payment." *Longhi*, 575 F.3d at 467 (quoting *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 785 (4th Cir. 1999)) (emphasis added); *see also United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 902 (5th Cir. 1997) (noting that "[v]iolations of laws, rules, or regulations alone do not create a cause of action under the FCA").

A claim for payment under the FCA may be either factually false or legally false. *Reddell*, 2019 WL 12875471, at *12 (citing *United States ex rel. Barko v. Halliburton Co.*, 241 F. Supp. 3d 37, 49–50 (D.D.C. 2017)). Factually false claims represent that the claimant has provided goods or services that that the Government never received. *Id.* Legally false claims, by contrast, contain an "express" or "implied" certification of compliance with statutory, regulatory, or contractual requirements when, in fact, the claimant has not complied with such requirements. *Thompson*, 125 F.3d at 902; *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 186–90

(2016). Here, Ms. Jackson asserts that Pfizer's claims for payment were rendered legally false by express and implied certifications. [Dkt. 17 at 72–74].

i. Express False Certification

The "express false certification theory of FCA liability is predicated upon outright misrepresentations made to the Government on an invoice or other claim for payment." *United States ex rel. Campbell v. KIC Dev., LLC*, No. EP-18-CV-193-KC, 2019 WL 6884485, at *7 (W.D. Tex. Dec. 10, 2019). Two elements are required to plead express false certifications. First, the relator must allege that "the government 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. Second, the relator must allege that the claimant "falsely certifie[d] compliance with that statute or regulation." *Id.*

a. Condition of Payment

With respect to the first element, Defendants argue that the Government did not condition payment on compliance with FAR requirements or FDA regulations. [Dkt. 37 at 26]. As an initial matter, Defendants assert that the Government could not have conditioned payment on compliance with FAR requirements because FAR does not apply to contracts such as the Project Agreement. *Id.* at 11–12. Defendants claim that "due to pandemic-related exigencies, the Project Agreement was not a standard federal procurement contract, but rather a 'prototype' agreement executed pursuant to 10 U.S.C. § 2371b, which as of January 1, 2022, is now cited as 10 U.S.C. § 4022."[16] *Id.* (citing [Dkt. 17-1 at 304]).

Such prototype agreements are executed under the DoD's "Other Transaction Authority"

[16] The Project Agreement states: "In accordance with 10 U.S.C. [§] 2731b(f), and upon a determination that the prototype project for this transaction has been successfully completed, this competitively awarded prototype [Other Transaction Authority] may result in the award of a follow-on production contract or transaction without the use of competitive procedures." [Dkt. 17-1 at 304].

and, as a statutory matter, are not subject to FAR, which is the primary regulation otherwise used by Government agencies in their acquisition of supplies and services with appropriated funds. 10 U.S.C. § 4022(f)(2); *see NSTI, LLC v. Def. Energy Ctr. Of Excellence*, No. 4:19-CV-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.").

In her Response, Ms. Jackson argues that the Project Agreement was not properly authorized under § 4022. [Dkt. 65 at 39–41]. Section 4022 provides that an official designated by the Secretary of Defense may "carry out prototype projects that are directly relevant to enhancing the mission effectiveness of personnel of the Department of Defense." 10 U.S.C. § 4022(a)(1). Ms. Jackson reasons that because the vaccine "ended up in many more people than just military personnel," the Project Agreement was not "directly relevant" to enhancing the mission effectiveness the military. [Dkt. 65 at 40]. Accordingly, she urges this Court to treat the Project Agreement as a traditional acquisition contract and rule that Defendants were required to comply with FAR. *Id.* at 39–41.

Ms. Jackson's contention is unreasonable. The fact that both military personnel and civilians received the vaccine does not indicate that acquiring the vaccine was irrelevant to enhancing the military's mission effectiveness. More importantly, Ms. Jackson is in effect asking this Court to overrule the DoD's decision to exercise Other Transaction Authority to purchase Pfizer's vaccine. But as the United States Supreme Court has long emphasized, the "complex subtle, and professional decisions as to the composition, training, equipping, and control of a military force are essentially professional military judgments." *Gilligan v. Morgan*, 413 U.S. 1, 10 (1973). Thus, it is "difficult to conceive of an area of governmental activity in which the courts have less competence." *Id.* This Court will not veto the DoD's judgments concerning mission

effectiveness during a national emergency.

Turning to the language of the Project Agreement, Defendants correctly note that the Statement of Work makes no mention of the FDA or FAR provisions cited in Ms. Jackson's complaint. [Dkt. 37 at 26]. The Statement of Work instead conditioned payment, more simply, on Pfizer's delivery of an FDA authorized or approved vaccine. *Id.* Defendants emphasize that Pfizer's vaccine has satisfied that condition since December 2020 and continues to satisfy that condition to this day. *Id.*

In her Response to Defendants' Motions, Ms. Jackson concedes that Pfizer's invoices were "contractually justified" and that "[Emergency Authorization] [was] the express condition in the [Project] Agreement." [Dkt. 65 at 18, 28]. At the hearing on Defendants' Motions, however, Ms. Jackson pulled back on the concessions made in her pleading. *See* [Dkt. 94 at 9:7–13:10]. During oral argument, she asserted that the Statement of Work conditioned payment on compliance with FDA regulations. *Id*. To support her argument, Ms. Jackson highlighted a line in the "Activities" section of the Statement of Work that reads: "Pfizer will meet the necessary FDA requirements for conducting ongoing and planned clinical trials . . . ." *Id.* (quoting [Dkt. 17-1 at 307]). The Court is not persuaded.

"If there is a conflict between a general provision and a specific provision, the specific provision prevails . . . ." Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 183 (2012). "Under this cannon, the specific provision is treated as an exception to the general rule." *Id.* (citing *Radzanower v. Touche Ross & Co.*, 426 U.S. 148, 153 (1976)). Another way to think of this is that "the specific provision comes closer to addressing the very problem posed by the case at hand and is thus more deserving of credence." *Id.* This rule applies to both statutes and contracts. *Id.* at 184.

Here, the "Introduction" section of the Statement of Work states that the "intent" of the project is "to demonstrate that Pfizer has the business and logistics capability to manufacture 100M doses of its currently unapproved mRNA-based COVID-19 vaccine for the Government." [Dkt. 17-1 at 306]. The "Activities" section of the Statement of Work explains that the statement about Pfizer meeting all necessary FDA requirements is provided "[s]olely for background and context" for certain Government-funded projects. *Id.* at 307. But Pfizer's clinical trial was not funded by the Government. Indeed, while clinical activities are described for background and context, the "Scope" section of the Statement of Work specifies that clinical activities "not related to the large-scale manufacturing" of the vaccine are "out-of-scope" for the project as Pfizer "ha[s] and will continue to fund these activities, without the use of Government funding." *Id.* at 312.

The "Payment" section, moreover, identifies a single condition of payment: Pfizer's delivery of an FDA authorized or approved vaccine for COVID-19. *Id.* at 319. This section further specifies "[f]or clarity" that "the Government will have no right to withhold payment in respect of any delivered doses, unless the FDA has withdrawn approval or authorization of the vaccine." *Id.* at 320. And to date, the FDA has not withdrawn its approval or authorization of Pfizer's vaccine. [Dkt. 17 at 18 n.2].

Put differently, the "Activities" section contains a "general provision," *see* Scalia, *supra* at 183, that Pfizer will meet FDA regulations for its clinical trial. But the "Scope" and "Payment" sections clarify through several "specific provisions," *id.*, that Pfizer's privately funded clinical trial is not governed by the Statement of Work; the sole condition for payment is delivery of an FDA authorized or approved vaccine, and that the Government has no right to refuse payment unless and until the FDA revokes its approval or authorization. [Dkt. 17-1 at 305–20].

Moreover, this Court's "only function" when construing a contract is to "interpret its lawful

meaning, discover the intention of the parties as found within the agreement, and give effect to it." *Koontz v. Thomas*, 333 S.C. 702, 708 (Ct. App. 1999) (quoting *Ebert v. Ebert*, 320 S.C. 331, 338 (Ct. App. 1995)).[17] The United States—the other party to this contract—agrees with Pfizer that the parties did not intend to condition payment on regulatory or protocol compliance. The United States' Statement of Interest puts it this way:

> The complaint does not identify any provision in the SOW for the Project Agreement between Pfizer and the Army that conditioned Government payment for the vaccine on Pfizer's compliance with the clinical trial protocol or regulations. The SOW, which is attached to the complaint, further specifies that the Army did not regulate the conduct of the clinical trial, which is "out-of-scope" for the purchase agreement between the Army and Pfizer. In short, the complaint does not plead factual content to support a conclusion that compliance with the clinical trial protocol or regulations was necessary under the contract between Pfizer and the Army such that clinical trial violations would give rise to a claim for express or implied certification liability.

[Dkt. 70 at 10].

In sum, Ms. Jackson has failed to plead that the Government conditioned payment on Defendants' certification of compliance with regulatory provisions or clinical trial protocol.

b. False Certification of Compliance

The Amended Complaint also fails the second element of the express certification test: Pfizer did not make a claim for payment that falsely certified compliance with a statute or regulation. At the outset, the Court notes that the submission of Pfizer's trial protocol, Pfizer's Form FDA-1571, and ICON and Ventavia's Form FDA-1572s, were not claims for payment. *See* 31 U.S.C. § 3729(b)(2)(A); *Longhi*, 575 F.3d at 467 (noting that the FCA attaches liability to the "claim for payment"). Accordingly, the Court only addresses Ms. Jackson's contention that Pfizer's invoices for payment contained express false certifications. [Dkt. 17 at 73].

[17] The Project Agreement's Base Agreement contains a choice-of-law provision stating that the contract "shall be governed by the laws of the state of South Carolina." [Dkt. 37-1 at 3].

The Amended Complaint asserts that Pfizer, as required under FAR, certified in its claims for payment "that they were true and correct, prepared from Pfizer's books and records, and in accordance with the Pfizer-DoD contract." *Id.* (citing 48 C.F.R. 52.232-32(m)). As discussed above, the Project Agreement was not subject to FAR. Therefore, contrary to Ms. Jackson's allegations, Pfizer's invoices were not required to contain the certification.

Defendants point out that Pfizer's actual invoices do not contain any certifications about compliance with clinical trial protocol, FDA regulations, or FAR. [Dkt. 37 at 17]. Rather, Pfizer's invoices 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." [Dkt. 37-2 at 2].

Again, Ms. Jackson's pleadings contradict the assertions that she made at the hearing on Defendants' Motions to Dismiss. Her Response admits that Pfizer's invoices "do not contain false statements." [Dkt. 65 at 18]. But during oral argument, Ms. Jackson contended that the words "in accordance with the agreement" contained in Pfizer's invoice was a representation that Pfizer would "deliver something that met the FDA's requirements for clinical testing." [Dkt. 94 at 11:22–12:20]. The Court disagrees for two reasons.

First, reading "in accordance with the agreement" in isolation is misleading. When the phrase in which those words appear—"I certify that the amounts invoiced are for costs incurred in accordance with the agreement"—is read in its entirety, the meaning becomes clear. That is, the price reflected in the invoice—$19.50 per dose—matches the price stated in the Project Agreement. [Dkt. 17-1 at 319; Dkt. 37-2 at 2]. Second, even if "in accordance with the agreement" did refer to some other part of the Project Agreement, the Court has already found that Pfizer's clinical trial—the activity that Ms. Jackson bases her claims on—was "out of scope" for the Project

Agreement between Pfizer and the DoD. Put simply, Pfizer's invoices do not contain any express false certifications.

Ms. Jackson has failed to allege facts that support either of the elements that are required to adequately plead liability under the express false certification theory of liability.

ii. Implied False Certification

FCA liability can arise not only from fraudulent misrepresentations that include express falsehoods, but also from fraudulent misrepresentations that include misleading half-truths. *Escobar*, 579 U.S. at 187–90 (2016). The implied false certification theory recognizes that a fraudulent course of conduct is actionable under the FCA where two conditions are satisfied: "first, [a claim submitted to the United States] 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." *Id.* at 190 (emphasis added).

For example, in *Escobar*, Massachusetts Medicaid required mental health counselors to possess certain licenses and qualifications. *Id.* at 183–84, 189–91. The defendant, a mental health facility, specifically represented through the billing codes listed on its claims for payment to Medicaid that it was providing certain kinds of counseling services, and that its counselors were licensed and qualified to provide those services. *Id.* But many of the defendant's staff were either unlicensed or unqualified. *Id.* Because the defendant failed to disclose its "many violations of basic staff and licensing requirements," its claims were rendered fraudulently misleading half-truths. *Id.* at 189–91.

Here, relying on the same facts and arguments that she used to support her theory of express false certification liability, Ms. Jackson alleges that Defendants are also liable under the implied

false certification theory of liability. [Dkt. 17 at 72–74]. For brevity, the Court will not retread the details, contentions, and conclusions discussed above.[18]

In short, just as Ms. Jackson fails to identify any expressly false certifications of compliance in Pfizer's invoices seeking payment from the DoD, she similarly fails to identify any "specific representations" about Pfizer's vaccine, or compliance with protocols or regulations, in those invoices. *Id.* Without a "specific representation" alleged anywhere in her lengthy complaint, Ms. Jackson cannot plead an implied certification claim because that theory requires that a "misleading half-truth" be submitted to the Government in a claim for payment. *See Escobar*, 579 U.S. at 190.

Thus, the Amended Complaint does not adequately plead the express or implied presentment of a false claim under § 3729(a)(1)(A).

2. False Record Claims—§ 3729(a)(1)(B)

Ms. Jackson's second cause of action asserts false record claims against Defendants pursuant to § 3729(a)(1)(B). [Dkt. 17 at 74–75]. She specifically identifies "the clinical trial protocol Pfizer submitted to the United States and the falsified source documents and data behind Defendants' trial results and [Emergency Authorization] application" as false records. *Id.* at 74. Further, it is the Court's understanding that by realleging and incorporating "all paragraphs" of her Amended Complaint, Ms. Jackson contends that Pfizer's Form FDA-1571 and ICON's and Ventavia's Form FDA-1572s also constituted false records. *Id.* at 76.

Defendants move to dismiss the second cause of action on the theory that § 3729(a)(1)(B) contains a "double falsity" requirement: the relator must plead both a false statement and a

[18] The Court does, however, observe again that Ms. Jackson conceded in her Response that Defendants' invoices "were contractually justified" and did "not contain false statements," but that she made contradictory assertions during oral argument. [Dkt. 65 at 18; Dkt. 94 at 9:7–13:10].

corresponding false claim. [Dkt. 37 at 31]. In other words, Defendants argue that false records and statements alone do not create liability; there must be an actual false claim seeking payment from the government at the end of the chain. *Id.* Defendants base their argument on *United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 675 (5th Cir. 2003) (en banc).

In *Southland*, the defendants—owners of an apartment project—falsely certified that their property was safe and sanitary in connection with their requests for housing assistance payments from a government-funded program. *Id.* at 671. Nonetheless, the Fifth Circuit reasoned that the defendants could not be held liable for making false records or statements under § 3729(a)(2), now codified at § 3729(a)(1)(B), because the defendants' claims for payment were contractually justified. *Id.* at 674–76. In reaching this conclusion, the Fifth Circuit held:

> Although § 3729(a)(2) prohibits the submission of a false record or statement, it does so only when the submission of the record or statement was done in an attempt to get a false claim paid. There is no liability under this Act for a false statement unless it is used to get [a] false claim paid.

Id. at 675 (citing *Hutchins v. Wilentz, Godlman & Spitzer*, 253 F.3d 176, 184 (3d Cir. 2002) (noting that the FCA "was not intended to impose liability for every false statement made to the government")); *see also United States ex rel. Willard v. Humana Health Plan of Texas Inc.*, 336 F.3d 375, 380–81 (5th Cir. 2003) (affirming the district court's finding that "[u]nder section 3729(a)(2), the plaintiff must identify both a false claim and a false record or statement made or used to get that false claim paid"); *Thompson*, 125 F.3d at 903 (instructing the district court to consider the false statements prong *if* it determined that the relator properly alleged false claims).

Yet that does not end the analysis. This Court must address whether *Southland*'s mandate—that a false record claim cannot survive where there cannot be an accompanying false claim for payment—remains valid in light of the Fraud Enforcement & Recovery Act of 2009 ("FERA"). FERA amended several sections of the False Claims Act, including 31 U.S.C. §

3729(a)(2). Pub. L. No. 111-21, § 386, 123 Stat. 1617, 1621 (2009). The pre-FERA false record provision imposed liability only on those who "knowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement to get a false or fraudulent claim *paid or approved by the Government*." 31 U.S.C. § 3729(a)(2) (2008) (emphasis added). FERA expanded liability to anyone who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." *Id.* § 3729(a)(1)(B).

In short, FERA replaced § 3729(a)(2)'s requirement that a false record or statement be made to get a false claim paid by the *government itself* with a broader standard that permits imposing liability on the use of false records or statements that are made to get false claims paid by government funds, even if the funds are not directly paid by the government. *See United States ex rel. Steury v. Cardinal Health Inc.*, 625 F.3d 262, 267 n.1 (5th Cir. 2010) (noting legislative intent to overrule the Supreme Court's holding in *Allison Engine Co. v. United States ex re. Sanders*, 554 U.S. 662, 688–69 (2008) "that a false record or statement implicated the FCA only when it was made with the specific 'purpose of getting a false or fraudulent claim' paid by 'the Government itself'"); *United States ex rel. Bennett v. Medtronic, Inc.*, 747 F. Supp. 2d 745, 764 n.17 (S.D. Tex. 2010) (comparing § 3729(a)(2) with § 3729(a)(1)(B)).

The conclusion that FERA did not eliminate the need to allege the existence of a false claim for payment is confirmed by the plain text of the amended statute, which prohibits the use of a false record or statement that is "material to a false or fraudulent claim." § 3729(a)(1)(B). This presupposes the existence of a claim. *United States ex rel. Folliard v. CDW Tech. Servs., Inc.*, 722 F. Supp. 2d 20, 35 (D.D.C. 2010) (reaching the same conclusion). And a "claim," for present purposes, is defined as a request "for money." § 3729(b)(2)(A). A thorough review of Fifth Circuit

cases analyzing claims brought under § 3729(a)(1)(B) does not reveal a different conclusion.[19]

The upshot is that there is no liability under the FCA for making or using a false record or statement where the claimant is entitled to the payment. *Southland*, 326 F.3d at 675. As discussed above, Pfizer was entitled to its claims for payment. *See supra* Part III.B.1. Therefore, Ms. Jackson has not stated a claim for false record liability under § 3729(a)(1)(B).

3. Fraudulent Inducement Theory

Ms. Jackson asserts, for the first time, in her Response that Defendants are liable under a "fraudulent inducement" theory. [Dkt. 65 at 18]. She argues that "Pfizer's invoices, though contractually justified, were fraudulently induced via prior false certifications" that Defendants "made to the FDA before receiving [Emergency Authorization]." *Id.* According to Ms. Jackson, Pfizer obtained Emergency Authorization for its vaccine through "lies, omissions, and fabrications" submitted to the FDA. *Id.*

"FCA liability may be imposed 'when the contract under which payment is made was procured by fraud.'" *Longhi*, 575 F.3d at 467–68 (quoting *Willard*, 336 F.3d at 384). "This type of FCA claim is characterized as fraudulent inducement." *Id.* "Under a fraudulent inducement theory, although the Defendants' 'subsequent claims for payment made under the contract were not literally false, [because] they derived from the original fraudulent misrepresentation, they, too,

[19] *United States ex rel. Rigsby v. State Farm Fire & Cas. Co.*, 794 F.3d 457, 476–77, 480 (5th Cir. 2015) ("To prove a violation of both § 3729(a)(1) and § 3729(a)(1)(B), the [relator] had to show that the claim presented for payment on the . . . flood policy was false."), *aff'd sub nom. State Farm Fire & Cas. Co. v. United States ex rel. Rigsby*, 580 U.S. 26 (2016); *United States ex rel. Patton v. Shaw Servs., L.L.C.*, 418 F. App'x 366, 369 n.2 (5th Cir. 2011) (noting that any substantive difference between the prior and amended statutes was irrelevant because the relator produced no evidence of a false record or statement); *United States ex rel. Spicer v. Westbrook*, 751 F.3d 354, 364–66 (5th Cir. 2014) (addressing a different issue); *United States ex rel. Steury v. Cardinal Health, Inc.*, 735 F.3d 202, 206–07 (5th Cir. 2013) (same); *United States ex rel. Patel v. Cath. Health Initiatives*, 792 F. App'x 296, 301 (5th Cir. 2019) (same); *United States ex rel. Porter v. Magnolia Health Plan, Inc.*, 810 F. App'x 237, 240–42 (5th Cir. 2020) (same); *United States ex rel. Parikh v. Brown*, 587 F. App'x 123, 130 (5th Cir. 2014) (same); *United States ex rel. Guth v. Roedel Parsons Koch Blache Balhoff & McCollister*, 626 F. App'x 528, 531–34 (5th Cir. 2015) (same); *United States ex rel. Harman v. Trinity Indus. Inc.*, 872 F.3d 645, 654, 669–70 (5th Cir. 2017) (same); *United States v. Hodge*, 933 F.3d 468, 472–76 (5th Cir. 2019), *as revised* (Aug. 9, 2019) (same); *XL Spec. Ins. Co. v. Bollinger Shipyards, Inc.*, 800 F.3d 178, 186 (5th Cir. 2015) (same).

became actionable false claims.'" *Id.* at 468 (quoting *United States ex rel. Laird v. Lockheed Martin Eng'g & Sci. Servs. Co.*, 491 F.3d 254, 259 (5th Cir. 2007)). To succeed on a fraudulent inducement theory, a relator must prove that the defendant: (1) had no intention to perform according to the terms of the contract, and (2) obtained payments under the contract that it was not legitimately entitled to. *Laird*, 491 F.3d at 259.

Defendants contend that it is doubtful whether the "historical" Fifth Circuit decisions recognizing the fraudulent inducement theory remain good law. [Dkt. 67 at 9]. According to Defendants, those opinions pre-date the Supreme Court's *Escobar* decision, which instructs lower courts to adhere strictly to the language of the FCA. *Id.* To support their contention, Defendants cite *United States ex rel. Yu v. Grifols USA, LLC*, No. 1:17-CV-2226-GHW, 2021 WL 5827047, at *11 (S.D.N.Y. Dec. 8, 2021) (noting that "there is a significant dearth of support for Relator's fraud in the inducement theory regarding FDA approval" which is "difficult to square with the plain language of the FCA").

The Court does not agree. As recently as 2019—three years after the *Escobar* decision—the Eastern District of Texas has continued to recognize the fraudulent inducement theory. *See Reddell*, 2019 WL 12875471, at *10 ("Under a theory of fraudulent inducement, claims for payment that are not literally false may become actionable false claims because they were derived from a contract that was procured by fraud.").

Next, Defendants correctly point out that Ms. Jackson does not allege that Pfizer procured its vaccine contract through false or fraudulent statements. [Dkt. 67 at 7]. Rather, she alleges that *after* the DoD contracted to purchase Pfizer's vaccine, the company obtained Emergency Authorization for its product through "lies, omission, and fabrications" submitted to the FDA. [Dkt. 65 at 18]. To the Court's knowledge, the Fifth Circuit has not expanded its recognition of

the fraudulent inducement theory to situations beyond those where "the *contract* under which payment is made was procured by fraud." *Gonzalez v. Fresenius Med. Care N. Am.*, 689 F.3d 470, 476 (5th Cir. 2012) (emphasis added); *Willard*, 336 F.3d at 384; *Longhi*, 575 F.3d at 467–68; *Laird*, 491 F.3d at 259.

The Court, however, need not decide whether liability can attach under the fraudulent inducement theory when a contract was procured through truthful statements, but a condition of payment—here, FDA authorization—was subsequently obtained through misrepresentations. As noted above, Ms. Jackson raised this theory for the first time in her response. "[I]t is axiomatic that the complaint may not be amended by the briefs in opposition to a motion to dismiss." *Roebuck v. Dothan Sec., Inc.*, 515 F. App'x. 275, 280 (5th Cir. 2013) (quoting *Car Carriers, Inc. v. Ford Motor Co.*, 745 F.2d 1101, 1107 (7th Cir. 1984)). This rule extends to new theories of liability under the same cause of action. *Park v. Direct Energy GP, L.L.C.*, 832 F. App'x. 288, 295 (5th Cir. 2020) (holding that a new legal theory for Family and Medical Leave Act liability which was not mentioned in the complaint was not properly before the trial court).

The Court concludes that Ms. Jackson has failed to plead the existence of a false statement or fraudulent course of conduct under § 3729(a)(1)(A) or § 3729(a)(1)(B). Thus, the first element is not satisfied.

C. Materiality

To be actionable under the FCA, a "misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision." *Escobar*, 579 U.S. at 181. "The materiality standard is demanding," and "cannot be found where noncompliance is minor or insubstantial." *Id.* at 194. Nor is a violation material just because the government "would have the option to decline to pay" if it knew of the noncompliance. *Id.*

Moreover, "statutory, regulatory, and contractual requirements are not automatically material, even if they are labeled conditions of payment." *Id.* at 191.

The materiality test looks instead to the "likely or actual behavior" of the Government. *Id.* at 193. Most importantly for this case, "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). This rule applies even at the pleading stage of FCA litigation. *Escobar*, 579 U.S. at 195 n.6 ("We reject [the] assertion that materiality is too fact intensive for courts to dismiss False Claims Act cases on a motion to dismiss or at summary judgment."); *United States ex rel. Porter v. Magnolia Health Plan, Inc.*, 810 F. App'x 237, 239–40 (5th Cir. 2020) (affirming dismissal of a *qui tam* complaint for lack of materiality).

1. Payment Despite Knowledge

i. Whose Knowledge Matters?

A threshold issue that this Court must address is whether the FDA's knowledge or the DoD's knowledge matters when deciding how much weight to give to the Government's decision to continue purchasing Pfizer's vaccine. The FDA has known of Ms. Jackson's allegations since September 2020, months prior to Pfizer submitting its first invoice to the DoD in December 2020. [Dkt. 17 at 69; Dkt. 37-2 at 2]. But the DoD, not the FDA, is the entity that originally purchased Pfizer's vaccine. [Dkt. 17-1 at 303]. The well-pleaded facts require drawing the inference that the DoD did not have knowledge of the alleged fraud prior to February 22, 2022, approximately two years after it paid Pfizer's first invoice.[20] [Dkt. 17 at 15–16]. Thus, the argument could be made

[20] The Amended Complaint, which Ms. Jackson filed on February 22, 2022, pleads that Ms. Jackson had previously provided the DoD with the information that serves as the basis for her allegations. [Dkt. 17 at 15–16]. Defendants ask the Court to take judicial notice of several documents, including a letter from Ms. Jackson's former counsel dated December 14, 2020, notifying the DoD about her allegations, as well as the FDA's formal rejection of comments that Ms. Jackson made during an interview with a news outlet. [Dkt. 37 at 20–21]. Defendants note that courts routinely take judicial notice of facts published on a party's own website and contend that it is appropriate for this Court to do so here. *Id.* at 21 n.19. These documents do not currently appear on Ms. Jackson's website. While these documents

that even though the FDA continues to authorize Pfizer's vaccine despite its knowledge of the alleged fraud, the DoD would not have purchased the vaccine if it possessed the same knowledge.

Ms. Jackson's pleadings do not clarify this issue. In some instances, she asserts, seemingly interchangeably, that the "DoD," *id.* at 74, "United States," *id.* at 77, or "Government," [Dkt. 65 at 28], would not have paid Pfizer's invoices had it known of the alleged misrepresentations. Elsewhere, she makes arguments concerning the "FDA's ongoing payments to [Defendants]." *Id.* at 29.

The answer to this question lies in the Project Agreement. As discussed earlier, the "Payment" section of the Statement of Work conditioned payment solely on Pfizer's delivery of an FDA authorized or approved vaccine. [Dkt. 17-1 at 319–20]. Critically, that section provides that "the Government will have no right to withhold payment in any respect of any delivered doses, unless the FDA has withdrawn approval or authorization of the vaccine." *Id.* at 320. Put differently, even if the DoD was concerned about potential regulatory or protocol violations, the Project Agreement did not authorize the DoD to decide whether the vaccines were fit for purchase. Instead, the Project Agreement vested this decision-making authority in the FDA. Thus, what matters when evaluating the Government's continued purchase of the vaccine is that the FDA granted authorization despite its knowledge of Ms. Jackson's allegations.

The First Circuit's opinion in *D'Agostino v. ev3, Inc.*, 845 F.3d 1, 7–9 (1st Cir. 2016) bolsters this reasoning. Post-*Escobar*, the Fifth Circuit has only directly addressed situations where the government entity that had knowledge of the alleged fraud was the same entity that, despite such knowledge, made the decision to continue payment (or to continue approving federal reimbursement). *See, e.g.*, *United States ex rel. Harman v. Trinity Indus. Inc.*, 872 F.3d 654, 668–

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could potentially be introduced through a motion for summary judgment or at trial, they are not properly before the Court at this time. Accordingly, the Court declines to take judicial notice of these documents.

69 (5th Cir. 2017); *Porter*, 810 F. App'x at 243. The Fifth Circuit, however, looked to the First Circuit's reasoning in *D'Agostino* for "guidance on the impact of the government's continued payment." *Harman*, 872 F.3d at 661–62.

In *D'Agostino*, the relator alleged that a medical device manufacturer "made three fraudulent representations to the FDA in seeking approval" to market a device to treat malformed blood vessels in the brain. 845 F.3d at 3, 7. The relator further alleged that the defendants' misrepresentations "could have influenced the FDA to grant that approval," which was a "precondition" to reimbursement by the Centers for Medicare and Medicaid for use of the device. *Id.* at 7. Applying *Escobar*, the First Circuit affirmed dismissal of the complaint, writing that "[t]he fact that [the Centers for Medicare and Medicaid] ha[ve] not denied reimbursement for [the device] in the wake of [the relator's] allegations casts serious doubt on the materiality of the fraudulent misrepresentations that [the relator alleges]." *Id.* at 7.

The First Circuit then turned from materiality to causation, explaining that because the FDA approved the device notwithstanding the relator's allegations of fraudulent representations—and did not withdraw its approval in the years that followed—the connection between the representations to the FDA and a payment by the Centers for Medicare and Medicaid relying on FDA approval disappeared. *Id.* at 8. The Fifth Circuit in *Harman* explained that although "the [First Circuit] was addressing the causation element, given the conceptual juncture points of materiality and causation, its cautions remain forceful in the materiality context . . . ." *Harman*, 872 F.3d at 661–62 (citing *D'Agostino*, 845 F.3d at 8).

Here, the FDA's continued approval of Pfizer's vaccine, despite Ms. Jackson's allegations, breaks any connection between the alleged misrepresentations to the FDA and DoD's payment conditioned on FDA approval. Thus, it is the FDA's knowledge that matters for deciding

materiality. The Court now addresses the reasons why the Amended Complaint does not support a conclusion that Defendants' alleged misrepresentations were material.

ii. Continued Authorization and Payment

"[T]hough not dispositive, continued payment by the federal government after it learns of the alleged fraud substantially increases the burden on the relator in establishing materiality." *Harman*, 872 F.3d at 663.

In *Porter*, the Fifth Circuit affirmed dismissal of an FCA complaint on materiality grounds. 810 F. App'x at 241–42. In doing so, the court highlighted the fact that the Mississippi Division of Medicaid "took no action" after learning of the relator's allegations of fraud and instead "continued payment and renewed its contract with [the defendant] several times." *Id.* at 242; *see also United States ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29, 35 (1st Cir. 2017) (holding that "it is not plausible that the conduct of the manufacturer in securing FDA approval constituted a material falsehood capable of proximately causing the payment of a claim" when "an agency armed with robust investigatory powers to protect public health and safety [was] told what Relators [had] to say, yet [saw] no reason to change its position").

Here, Ms. Jackson argues that the FDA was the victim of "fraud." [Dkt. 65 at 9–10]. But the well-pleaded facts in her Amended Complaint do not support this conclusion. The FDA has known about Ms. Jackson's allegations since September 25, 2020. [Dkt. 17 at 69]. Despite this knowledge, between December 11, 2020, and October 29, 2021, the FDA issued three Emergency Authorizations of Pfizer's vaccine for individuals of various age groups. *Id.* at 9. And on August 23, 2021, the FDA fully approved Pfizer's vaccine by granting a Biologistic License Application. *Id.* To this day, the FDA has not revoked its approval of Pfizer's vaccine, and the Government continues to provide the vaccine to all citizens free of charge. *Id.* at 18 n.2. The Government's

unbroken chain of authorization and payments in the face of Ms. Jackson's allegations does not support an inference that the alleged misrepresentations were material.

This Court's conclusion is reinforced by the Fifth Circuit's recent decision in *Harman*. In *Harman*, the relator alleged that a modified guardrail system designed by the defendants was causing highway accidents. 872 F.3d at 649. The relator presented his findings to the Federal Highway Administration, which after considering all of the facts, issued an official memorandum explaining that the guardrail was safe and that states that purchased the guardrail could continue to seek federal reimbursement. *Id.* at 649–51. Despite this memorandum, the district court permitted the relator's *qui tam* action to proceed to trial and the jury returned a verdict in favor of the relator. *Id.* at 651.

The Fifth Circuit reversed, holding that the defendants were entitled to judgment as a matter of law. *Id.* at 670. The court did not even need to infer the Government's approval from continued payment because the Government's memorandum explicitly stated approval. *Id.* at 663–64. Relevant to the instant case, the Fifth Circuit placed great emphasis on the "gravity" of the Government's decision:

> This system was installed throughout the United States, and the government's rejection of [the relator's] assertions, if in error, risked the lives on our nation's highways, not just undue expense. Where violations of the "certain requirements" described by *Escobar* involve potential for horrific loss of life and limb, the government has strong incentives to reject nonconforming products, and Escobar's cautions have particular bite when deployed to decisions as here.

Id. at 663. The court further observed that in rejecting the relator's "views and proofs, [the government] balances the federal fisc, motorist safety, and other factors." *Id.* at 669. "Such decision making is policy making, not the task of a seven-person jury—such a result confounds the premise of *qui tam* actions: that the government was the victim." *Id.*

The same reasoning applies here. As the Amended Complaint notes, developing a safe and

effective vaccine was a matter of national urgency: the approval of an unsafe vaccine could have put millions of Americans at risk. [Dkt. 17 at 6]. Accordingly, the FDA's review process before granting Emergency Authorization included a "public and independent review" as well as "a thorough evaluation of the available safety, effectiveness, and manufacturing quality information." *Id.* at 25 n.5. Moreover, the United States itself has taken the unusual step of filing a Statement of Interest Supporting Dismissal of the Amended Complaint. [Dkt. 70].

Ms. Jackson disagrees with the FDA's decision to authorize Pfizer's vaccine. Congress, however, "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." *Harman*, 872 F.3d at 668–69. "When the government, at appropriate levels, repeatedly concludes that it has not been defrauded, it is not forgiving a found fraud—rather it is concluding that there was no fraud at all." *Id.* at 670.

iii. Alternative Explanations for Continued Approval and Payment

Ms. Jackson argues that the Government's ongoing payments to Pfizer is "an irrelevant factor because" the Government "had virtually no power to withhold payment under the DoD's contract with Pfizer." [Dkt. 65 at 29]. She is referring to the provision of the Statement of Work that requires the Government to pay for "delivered doses" unless and until the FDA withdraws "approval or authorization of the vaccine." [Dkt. 17-1 at 320]. This argument ignores reality.

The Government itself, through the DoD, negotiated the contract provisions in question. And the Government itself, through the FDA, controls the vaccine's regulatory status. *Id.* at 303–05, 320. When it comes to the vaccine, the Government holds all the cards; its continued authorization, approval, and purchases of the vaccine are unquestionably relevant to materiality.

Ms. Jackson also asks the Court to disregard the Government's continued payments

because there are "numerous reasons unrelated to materiality why the [G]overnment might continue doing business with a contractor despite allegations of fraud."[21] [Dkt. 65 at 31]. She argues that "[g]iven the difference between alleged fraud and actual fraud, the Government may not want to prematurely end a relationship with a contractor over unproven allegations." *Id.* at 30. But Pfizer and the Government's relationship is no longer "premature." The Government has been aware of Ms. Jackson's allegations for several years, has granted Emergency Authorization multiple times, and to this day continues to authorize and provide Pfizer's vaccine at no cost. [Dkt. 17 at 9, 18 n.2, 69–70].

Next, she posits that the Government may have been "forced to rely on [Pfizer] for essential goods and services." [Dkt. 65 at 30]. She hypothesizes that, in this case, "the significant resources already expended" on the clinical trial, along with "the likely lack of other sponsors who could undertake the operation," may explain why the Government "could not divert course" once she came forward with her concerns. *Id.* at 31–32. The well-pleaded facts provide no support for this speculation. Pfizer funded the clinical trial, not the Government. [Dkt. 17-1 at 312]. It is implausible that the *Government* would purchase an ineffective or unsafe vaccine simply because *Pfizer* spent a lot of money developing it. It is similarly unreasonable to suggest that a "lack of other sponsors" forced the Government's hand, especially when many manufacturers besides Pfizer were attempting to develop their own vaccine at the time, which two of them—Moderna and J&J—did successfully. *Id.* at 18 n.2.

"[C]ontinued payment by the federal government after it learns of the alleged fraud

[21] Ms. Jackson also makes the following hypothetical arguments that are purely speculative, not supported by facts in her Amended Complaint, and not connected to her direct allegations against Defendants: "[T]he government initially may continue paying claims to keep federal programs operating or to ensure compliance with the government's own legal and contractual obligations while it investigates the allegations," [Dkt. 65 at 30]; "The government might also have investigated and found past violations but have privately conferred with the [defendant] and believed the [defendant] would comply going forward," *id.*; "[P]erhaps the government investigated the allegations but incorrectly concluded that no violation occurred." *Id.*

substantially increases the burden on the relator in establishing materiality." *Harman*, 872 F.3d at 663. The well-pleaded facts in Ms. Jackson's Amended Complaint cannot plausibly shoulder that burden.

2. The Government's Actual Behavior

According to Ms. Jackson, "[a]ll that is required under the test for materiality . . . is that the false or fraudulent statements have the potential to influence the [G]overnment's decisions." [Dkt. 65 at 27] (quoting *Longhi*, 575 F.3d at 470). She also argues that if an "objective FDA, without conflicts of interest," saw the alleged fraud, it would not have authorized Pfizer's vaccine. *Id.* at 17, 28. Her contention is unavailing.

The Supreme Court and Fifth Circuit have expounded *Longhi*'s "potential to influence" test that Ms. Jackson relies on. "Under any understanding of the concept, materiality 'look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation,'" *Escobar*, 579 U.S. at 193, and courts "should not ignore what actually occurred" when they "have the benefit of hindsight," *Harman*, 872 F.3d at 667–68. Hindsight here is 20/20. The FDA has been aware of Ms. Jackson's concerns since September 2020. [Dkt. 17 at 69]. The FDA, which is an agency with "robust investigatory powers to protect the public health and safety," *Nargol*, 865 F.3d at 35, authorized Pfizer's vaccine for emergency use, and later granted full approval. [Dkt. 17 at 9, 25]. Those regulatory decisions remain in place and, accordingly, the Government continues to purchase the vaccine. *Id.* at 18 n.2.

3. Safety and Efficacy of the Vaccine

In explaining the FCA materiality standard, the Supreme Court observed that under contract law, a term may be material if it "went to the very essence of the bargain." *Escobar*, 579 U.S. at 193 n.5 (quoting *Junius Constr. Co. v. Cohen*, 257 N.Y. 393, 400 (1931)). Ms. Jackson

argues that Emergency Authorization—being the sole condition of payment—went to the "essence of the bargain" between Pfizer and the Government, which at its core was the delivery of a "safe and effective" vaccine. [Dkt. 65 at 28–29]. She posits that by bypassing trial protocol to secure Emergency Authorization, the Defendants "destroy[ed] the very essence of the bargain." *Id.* at 29.

Absent from the Amended Complaint, however, are factual allegations indicating that the alleged violations at the Ventavia sites resulted in the FDA receiving fabricated, inaccurate, or misleading data about the safety or efficacy of the vaccine. The Amended Complaint does not, for example, identify any safety risk that was hidden from the FDA in the data from the Ventavia sites, any symptomatic participants who Ventavia did not properly test for COVID-19 infection, or any COVID-19 infections in vaccinated participants that Ventavia falsely reported to have occurred in the placebo group. *See, e.g.*, [Dkt. 17 at 38] (alleging that Ventavia did not test a participant for COVID-19 until after the vaccine was administered without alleging that the participant was COVID-19 positive and should have been excluded from the trial); *id.* at 42–43 (alleging that Ventavia likely misrepresented the time that participants' vital signs were taken to conceal the fact that vitals were taken before or during the informed consent process without alleging that informed consent was never obtained or providing any factual basis to conclude that the timing of informed consent could impact the evaluation of the vaccine's safety or efficacy); *id.* at 48–49 (alleging that Ventavia failed to report AEs to Pfizer and ICON without describing or identifying any particular AE that was not properly reported); *id.* at 49, 52 (alleging that Ventavia delayed in implementing a symptom review log but neglecting to mention that symptoms were recorded in participants' electronic diaries as pleaded elsewhere in the Amended Complaint); *id.* at 50 (alleging deviations in blood sample clotting, centrifuge, and freezing times without pleading facts indicating whether or how those alleged deviations could affect the evaluation of the blood samples or the measure of

safety or efficacy of the vaccine); *id.* at 51 (alleging that a Ventavia employee changed a participant's blood reading without explaining how the reading was changed or what impact, if any, the change could have on the safety or efficacy of the results). Indeed, the *only* SAE specifically identified in the Amended Complaint—a participant's positive pregnancy test after receiving her first vaccine dose—was reported and faxed to Pfizer. [Dkt. 17-2 at 31–32]

Furthermore, materiality "cannot be found where noncompliance is minor or insubstantial." *Harman*, 872 F.3d at 660 (quoting *Escobar*, 579 U.S. at 194). Even if Ms. Jackson's allegations could support an inference that Ventavia's safety and efficacy data was unreliable, a conclusion that the Emergency Authorization criteria would not have been met without the Ventavia data is implausible considering that authorization was based on "the totality of available scientific evidence," [Dkt. 17-1 at 312; Dkt. 37 at 11 n.5], and Ventavia only enrolled about 3%—approximately 1,500 of nearly 44,000—of the total clinical trial participants. [Dkt. 17 at 7, 24]. Furthermore, Ms. Jackson's allegations only implicate a fraction of that 3%.

For the foregoing reasons, the well-pleaded facts in Ms. Jackson's Amended Complaint cannot support a conclusion that Defendants' alleged fraud was material.

In conclusion, Ms. Jackson has not met her burden of pleading that Defendants made false statements or engaged in a fraudulent course of conduct, or that their alleged misrepresentations were material. *Longhi*, 575 F.3d at 467. Both deficiencies are independently fatal to her presentment claim and her false record claim. Thus, the Court dismisses Ms. Jackson's first cause of action under 31 U.S.C. § 3729(a)(1)(A) and second cause of action under 31 U.S.C. § 3729(a)(1)(B).[22]

[22] Pfizer also argues that dismissal is warranted because Ms. Jackson failed to comply with a dispute resolution provision in the Project Agreement. [Dkt 37 at 32–35]. Ventavia makes additional arguments concerning causation, Rule 9(b), and Ms. Jackson's violation of the FCA's seal requirement. [Dkt. 53 at 14–18, 24–27, 30–33]. ICON also makes arguments pertaining to scienter, causation, and materiality. [Dkt. 51 at 16–22]. Because the Court finds that

D. Leave to Amend

Ms. Jackson requests leave to file a Second Amended Complaint in the event that the Court finds her Amended Complaint insufficient to state a claim for relief. [Dkt. 65 at 44]. She seeks to include the following: (1) allegations of "Pfizer's interference with medical charting"; (2) further explanation "on widespread unblinding"; (3) "additional outcome data on mRNA injection benefits, or lack thereof, and additional allegations as to misbranding"; (4) citations to "individual patient or source documents which show trial data pertaining to inclusion or exclusion data was falsified"; and (5) allegations of record retention protocol violations. *Id.*

Federal Rule of Civil Procedure 15(a)(2) states that a court "should freely give leave [to amend] when justice so requires. Fed. R. Civ. P. 15(a)(2). While the language of Rule 15(a) "evinces a bias in favor of granting leave to amend," *Smith v. EMC Corp.*, 393 F.3d 590, 598 (5th Cir. 2004) (quoting *Rosenzweig v. Azurix Corp.*, 332 F.3d 854, 863 (5th Cir. 2003)), district courts may deny leave to amend if amendment would be futile. *Stripling v. Jordan Prod. Co., LLC*, 234 F.3d 863, 872–73 (5th Cir. 2000). An amendment is considered futile if "the amended complaint would fail to state a claim upon which relief could be granted." *Id.* at 873.

In *Porter*, the Fifth Circuit affirmed the district court's dismissal with prejudice where the district court found that amendment would be futile. *See* 810 F. App'x at 241–43 (affirming that amendment would be futile because the lack of contractual language requiring compliance with the regulations that the defendant allegedly violated, and the Government's continued payment after learning of the relator's allegations, showed that the defendant's alleged misconduct was not material).

Here, Ms. Jackson seeks to allege additional regulatory violations. The Court already

dismissal is warranted on other grounds, it does not address Defendants' additional arguments.

determined that Ms. Jackson failed to satisfy the first element of an FCA claim—that Defendants made false statements or engaged in a false or fraudulent course of conduct. Pleading additional regulatory violations will not remedy her inability to plead that Defendants made false statements or engaged in a fraudulent course of conduct. Moreover, the proposed amendments would not alter the conclusion that Defendants' alleged fraud was not material in light of the Government's continued authorization and purchase of the vaccine.

Based on these considerations, amendment would be futile. The Court denies Ms. Jackson's request for leave to amend. Her presentment claim under 31 U.S.C. § 3729(a)(1)(A) and false record claim under 31 U.S.C. § 3729(a)(1)(B) are dismissed with prejudice.

IV. RETALIATION CLAIM

Ms. Jackson alleges that "in violation of 31 U.S.C. § 3730(h)," Ventavia "retaliated against [her] as a result of her efforts to stop Defendants from committing violations of the False Claims Act." [Dkt. 17 at 78]. Specifically, she alleges that Ventavia punished her with harassment and termination for engaging in statutorily protected activity and that she has suffered economic loss and emotional harm as a result. *Id.*

"The 'whistleblower' provision of the False Claims Act prevents the harassment, retaliation, or threatening of employees who assist in or bring *qui tam* actions." *Robertson v. Bell Helicopter Textron, Inc.*, 32 F.3d 948, 951 (5th Cir. 1994). The statute provides:

> Any employee, contractor, or agent shall be entitled to all relief necessary to make that employee, contractor, or agent whole, if that employee, contractor, or agent is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of lawful acts done by the employee, contractor, agent or associated others in furtherance of an action under this section or other efforts to stop 1 or more violations of this subchapter.

31 U.S.C. § 3730(h)(1). "To establish a claim under § 3730(h), a party must show (1) that she was

engaged in protected activity with respect to the False Claims Act; (2) that her employer knew she was engaged in protected activity; and (3) that she was discharged because she was engaged in protected activity." *Thomas v. ITT Educ. Servs., Inc.*, 517 F. App'x 259, 262 (5th Cir. 2013) (citing *Robertson*, 32 F.3d at 951).

"A protected activity is one motivated by a concern regarding fraud against the government." *Id.*; *United States ex rel. Johnson v. Kaner Med. Grp., P.A.*, 641 F. App'x 391, 395 (5th Cir. 2016) ("To qualify as protected activity under the whistleblower provision, the activity must be 'in furtherance of' uncovering fraud or potential fraud against the Government.") (quoting 31 U.S.C. § 3730(h)(1)). Mere criticism by an employee of the employer's methods of conducting business, "without any suggestion that the [employee] was attempting to expose illegality or fraud *within the meaning of the FCA*, does not rise to the level of protected activity." *United States ex rel. Patton v. Shaw Servs., L.L.C.*, 418 F. App'x 366, 372 (5th Cir. 2011) (emphasis added).

Here, beginning on September 8, 2020—the day Ms. Jackson began her employment at Ventavia—she reported "on a near-daily basis" to Ventavia management that "patient safety and the integrity of the [Pfizer] vaccine trial was at risk." [Dkt. 17 at 61]. She goes on to allege that throughout her eighteen days of employment, she regularly reported violations of trial protocol, FDA regulations, and HIPAA to Ventavia management. *Id.* at 61–69.

When she asked Houston Regional Director, Ms. Downs, and Quality Control Director, Mr. Jones, about what would happen if the FDA audited Ventavia, both expressed concern that Ventavia would receive warning letters or be asked to discontinue trial enrollment. *Id.* at 65. Ms. Jackson reiterated this message to other members of Ventavia management, explaining that "the FDA would likely issue warning letters against Ventavia if it visited or audited the trial sites" and recommended that Ventavia stop enrollment. *Id.*

On September 24, 2020, Ms. Jackson met with Mr. Jones and Ventavia's Director of Operations, Ms. Fisher. *Id.* at 68. During the meeting, Ms. Jackson again noted her concerns about safety issues, HIPAA violations, unblinding, and FDA regulatory violations. *Id.* at 68–69. At some point during the meeting, she told Mr. Jones and Ms. Fisher to "get on google and search for FDA warning letters." *Id.* at 69.

The next day, Ms. Jackson called the FDA's hotline and reported "the clinical trial protocol violations and patient safety concerns that she witnessed." *Id.* Ventavia fired Ms. Jackson later that day. *Id.* Shortly after her termination, the FDA reached out to Ms. Jackson and "spoke to her for several hours regarding the violations she witnessed at Ventavia." *Id.* at 70.

The well-pleaded facts in the Amended Complaint do not support a conclusion that Ms. Jackson engaged in protected activity. At no point does she allege that she was concerned about, or alerted Ventavia or the FDA to, potential "fraud against the government." *Thomas*, 517 F. App'x at 262. Rather, she alleges that she complained about participant safety and regulatory, protocol, and HIPAA violations. But that is not protected activity under the FCA's retaliation provision—internal complaints about patient safety, or protocol and regulatory violations, are not the same thing as complaining about defrauding the Government. *Patton*, 418 F. App'x at 372.

In her Response to Ventavia's Motion to Dismiss, Ms. Jackson asks the Court to rely on out-of-circuit authorities that impose different standards for protected activity than the Fifth Circuit. [Dkt. 65 at 36–37]. It would be improper, however, to go outside the Fifth Circuit because its caselaw is clear: for internal reports to be protected under the FCA, the relator must have raised concerns about fraud on the government—not merely criticized the company's business practices. *Patton*, 418 F. App'x at 372.

Ms. Jackson also argues that her conduct amounted to protected activity in light of FERA's

2009 revisions to the FCA. [Dkt. 65 at 38–39]. The Court disagrees. Pre-FERA, the FCA's antiretaliation provision prohibited retaliation against an employee "because of lawful acts done by the employee . . . in furtherance of an *action* under this section." 31 U.S.C. § 3730(h) (2009) (emphasis added). FERA broadened the scope of protected activity to include "lawful acts done by an employee . . . in furtherance of an action under this section *or other efforts* to stop 1 or more violations of this subchapter." *Id.* § 3730(h) (emphasis added).

The amendment clarifies that a relator need not have acted with the purpose of bringing a *qui tam* lawsuit for her activity to be protected. *See Melchior v. Apple Homecare Med. Supply, Inc.*, No. A-16-CV-1301-RP, 2018 WL 1876287, at *3 (W.D. Tex. Jan. 8, 2018) ("[W]hile the court agrees that the law *does require* an internal whistleblower's complaints to clearly convey that the concerns focus on fraud against the federal government, the law *does not require* that acts be in furtherance of an actual qui tam action . . . .") (emphasis added). As a matter of text, the amended statute still requires an effort to stop "violations of this subchapter." 31 U.S.C. § 3730(h).

The Fifth Circuit addressed the amended statute in *Thomas* and still noted that the protected activity must be "motivated by a concern regarding fraud against the government." 517 F. App'x at 262; *see also Reddell*, 2019 WL 12875471, at *16 (applying the amended statute and holding that internal reports are protected only "if they raise concerns about fraud instead of merely criticizing the underlying subject"); *Guerrero v. Total Renal Care, Inc.*, No. EP-11-CV-449-KC, 2012 WL 899228, at *5 (W.D. Tex. Mar. 12, 2012) (observing that even post-FERA, "in order to constitute protected conduct, an employee's internal report must specifically allege fraudulent claims for federal funds and not merely address concerns about general misconduct"); *United States ex rel. Ligai v. ETS-Lindgren Inc.*, Civil Action No. H-112973, 2014 WL 4649885, at *17 (S.D. Tex. Sept. 16, 2014) (same), *aff'd sub nom. United States ex rel. Ligai v. ESCO Techs., Inc.*,

611 F. App'x 219 (5th Cir. 2015).

In conclusion, Ms. Jackson did not engage in protected activity. Further, her claim also fails because nowhere in the Amended Complaint does she allege the second element of a FCA retaliation claim—that Ventavia knew she was engaged in protected activity. Accordingly, the Court dismisses Ms. Jackson's retaliation claim under 31 U.S.C. § 3730(h) without prejudice.[23]

V. CONCLUSION

It is therefore **ORDERED** that Defendants Pfizer, Inc., ICON, PLC, and Ventavia Research Group, LLC's Motions to Dismiss [Dkt. 37; Dkt. 51; Dkt. 53] are hereby **GRANTED**.

It is **FURTHER ORDERED** that Relator Brook Jackson's presentment claim under 31 U.S.C. § 3729(a)(1)(A) and false record claim under 31 U.S.C. § 3729(a)(1)(B) are hereby **DISMISSED WITH PREJUDICE**.

It is **FURTHER ORDERED** that Relator Brook Jackson's retaliation claim under 31 U.S.C. § 3730(h) is hereby **DISMISSED WITHOUT PREJUDICE**.

SIGNED this 31st day of March, 2023.

Michael J. Truncale
United States District Judge

[23] The Court observes, however, that while Ms. Jackson has failed to state a claim for retaliation under the FCA, she may be able to bring her claim under another statute. The Court does not opine on the likelihood of success with respect to asserting retaliation under a different statute.