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

UNITED STATES OF AMERICA *ex rel*. BROOK JACKSON, Relator, vs. VENTAVIA RESEARCH GROUP, LLC, *et al*. Respondents.	Case No.: 1:21-CV-00008-MJT JUDGE MICHAEL J. TRUNCALE RELATOR BROOK JACKSON'S COMBINED RESPONSE IN OPPOSITION TO RESPONDENTS' MOTIONS TO DISMISS AMENDED COMPLAINT

RELATOR'S OPPOSITION TO RESPONDENTS' MOTIONS TO DISMISS

TO THE HONORABLE JUDGE OF THE COURT:

Relator Brook Jackson ("Relator") files this opposition as a combined response to Respondents Pfizer, Inc.'s ("Pfizer"), Icon, PLC's ("Icon"), and Ventavia Research Group, LLC's ("Ventavia") motions to dismiss [ECF No. 37, 51, and 53].

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INTRODUCTION

A national emergency birthed The False Claims Act, known as the "Lincoln Law," after contractors used the exigent circumstances of the Civil War to defraud the people, at the expense of the suffering and death of American soldiers because defense contractors sold the Army lame horses and mules, faulty rifles and ammunition, and rancid rations and provisions. Once again, we face a national emergency, where our military entrusted another defense contractor, to the tune of billions of dollars and millions of American lives. The Defense Department incorporated Food and Drug Administration ("FDA") rules and regulations into its contract by conditioning the contract on FDA compliance and authorization. Respondents ignore this critical fact when trying to claim they contracted away the False Claims Act. Don't the American people deserve to know if Pfizer lied?

Respondents seek dismissal without discovery, amendment, or trial. Their fundamental premise: even if honestly reported data showed their product caused more illness than it cured, inflicted more injury than it prevented, and took more lives than it saved, America's military would still have given them billions of dollars and mandated it be injected into America's military. Respondents claim fraudulent certifications, false statements, doctored data, contaminated clinical trials, and firing of whistleblowers can be ignored based on the theory that they contracted their way around the fraud. This ignores two legal aspects: first, fraud in the inducement is a well-recognized basis for False Claims Act qui tam actions; and second, the military wisely incorporated the FDA regulations into the contract as a precondition of any payment under the contract by conditioning payment upon FDA authorization of the product, an authorization itself dependent upon complete compliance with FDA rules and regulations governing such authorizations and approvals. In the end, the law does not belie common sense: a drug company cannot induce the taxpayers to pay billions of dollars for a product that honest data would show poses more risks than benefits to

most Americans and that ignores the actual contract and the law itself. Put differently, the alleged fraud goes "to the very essence of the bargain." *United Health Serv., Inc. v. United States ex rel. Escobar, 136 S. Ct. 1989, 2003 n. 5*. The law compels denial of Respondents' motions to dismiss.

ARGUMENT

At this pleading stage, before amendment or discovery, Respondents must cross four successive barriers to dismissal: first, that the facts, assumed to be true at this stage as alleged, cannot possibly constitute a legally cognizable claim; second, that all reasoned inferences from the facts alleged cannot possibly constitute a legally cognizable claim; third, that no set of facts that could be alleged in an amended complaint could possibly constitute a legally cognizable claim; and fourth, that no set of facts that could be discovered in the suit could possibly constitute a legally cognizable claim. Respondents fail each of these when they need to overcome all four.

This is neither about isolated instances of falsity nor whether each violation by itself could cause the FDA to refuse emergency use authorization. It is about the aggregate totality of violations, the pervasive fraudulent certifications, the routine falsification of data, and the utter, reckless disregard for even the most elemental and basic scientific standards for any clinical trial. As the evidence mounts of the undisclosed harm from this product, the logical inquiry is whether there were risks and dangers known to Pfizer at the time the vaccines were released. However, the only question that must be addressed is: did Relator allege sufficient facts, or could she amend to allege such facts upon discovery, that a jury could find Pfizer fraudulently induced the FDA to grant emergency use authorization? The answer is yes.

The False Claims Act imposes civil liability where a respondent knowingly presents to the government a "false or fraudulent claim" or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. §

3729(a)(1)(A), (B). In the FCA context, a relator, must allege that false statements were made with the requisite causation, materiality, and scienter. *See*, for example, *U.S. v. Hodge*, 933 F.3d 468, 475 (5th Cir. 2019), *as revised* (Aug. 9, 2019). These elements are typically held to the heightened pleading standard of Fed. R. Civ. P. 9(b). *See*, for example, *Health Choice Group, LLC v. Bayer Corp.*, 5:17CV126-RWS-CMC, 2018 WL 5728515, at *1 (E.D. Tex. Apr. 25, 2018). To meet this heightened pleading standard, a relator need only allege a fraudulent scheme and provide examples of specific fraudulent conduct that are "representative samples" of the scheme. *United States ex rel. Prather v. Brookdale Senior Living Cmtys., Inc.*, 892 F.3d 822, 830 (6th Cir. 2018).

Whether Pfizer was truthful to the FDA is of the utmost importance in a national emergency. The House Report on the 1986 amendments recognized "…that a false claim may take many forms, the most common being a claim for goods or services not provided, or provided in violation of a contract term, a statute, or a regulation.[1] In a national emergency, President Lincoln determined truth mattered, and it matters today.

LEGAL STANDARD

Respondents have many impediments to dismissal in this case of extraordinary public importance. They must show that no facts exist, whether alleged, possibly alleged in an amendment, or discoverable, that provide a basis for either a false claims act cause of action or a retaliation claim. "Even if it seems 'almost a certainty to the court that the facts alleged cannot be proved to support the legal claim,' the claim may not be dismissed so long as the complaint states a claim." *Clark v. Amoco Prod. Co.*, 794 F.2d 967, 970 (5th Cir. 1986) (quoting *Boudeloche v. Grow Chem. Coatings Corp.*, 728 F.2d 759, 762 (5th Cir. 1984); *see*

[1] https://www.justice.gov/jmd/ls/false-claims-amendments-act-1986-pl-99-562#:~:text=House%20Report%2099-660%2C%20False%20Claims%20Amendments%20Act%20of,1985%2C%20to%20accompany%20S.%201562%2C%20July%2028%2C%201986

also U.S. ex rel. Riley v. St. Luke's Episcopal Hosp. 355 F.3d 370, 376 (5th Cir. 2004). "A claim will not be dismissed on a Rule 12(b)(6) motion unless it appears to a certainty that no relief can be granted under any set of facts provable in support of its allegations". *Lowe v. Hearst Commc'ns, Inc.*, 414 F. Supp. 2d 669 (W.D. Tex. 2006), *aff'd,* 487 F.3d 246, fn. 1 (5th Cir. 2007).

In trying to meet that standard, Respondents cannot rely on materials outside the four corners of the pleadings as the "court does not look beyond the face of the pleadings to determine whether the plaintiff has stated a claim." *U.S. ex rel. Parikh v. Citizens Medical Center*, 977 F.Supp. 2d 654, 661 (S.D. Tex. 2013). Critically, at all times at this pleading stage of the case, all inferences, assumptions and facts, including what amendments could provide and what discovery could show, must be accepted as true against Respondents.

In cases alleging fraud, "Plaintiff is not required, however, to describe all actions, dates, participants and other details of the alleged fraud at the pleading stage. *United States ex rel. Bechtold v. Asfora,* No. CIV 16-4115, 2020 WL 5547920, at 2 (D.S.D. Sept. 16, 2020). It is sufficient for a plaintiff to plead "the time, place and contents of the false representation[], as well as the identity of the person making the misrepresentation and what that person obtained thereby." *U.S. ex rel Grubbs, v. Kanneganti*, 565 F.3d 180, 186 (5th Cir. 2009). Relator easily satisfies that burden here.

To avoid duplicative response briefs, Relator will address all Respondents' arguments by proving she pled with particularity that each Respondent made or caused to be made false statements with requisite scienter, that those statements were material to the Government's decision to pay, and those statements caused the Government to pay.

For the reasons that follow and the legal standard required for such motions as above articulated, the Respondents utterly fail their burden to compel this court dismiss Relator's Amended Complaint.

SUMMARY OF ARGUMENT

From the Department of Justice: "Fraud in clinical trials poses significant risks to the American public. The FDA relies on the veracity of clinical trial data when making drug approval determinations, with the ultimate goal of ensuring that all FDA-approved drugs are safe and effective for their approved indications. Fabricated clinical trial data can have dangerous consequences if relied upon by the FDA, drug researchers and medical doctors when making material decisions about the safety, efficacy and clinical use of drug products."[2]

Respondents Pfizer, Ventavia, and Icon conducted deeply flawed clinical trials of Pfizer's COVID-19 "vaccine," regularly deviating from the clinical trial protocol Pfizer submitted to the FDA and altering trial data to give the appearance of legitimacy.[3] Respondents' goal was to collect billions of dollars from taxpayers of the United States - the only obstacle to overcome was receiving Emergency Use Authorization (EUA) from the FDA.

"The FCA is designed to protect the Government from fraud by imposing civil liability and penalties upon those who seek federal funds under false pretenses" such as those here. *United States ex rel. Lesinski v. S. Fla. Water Mgmt. Dist.*, 739 F.3d 598, 600 (11th Cir. 2014). This "vaccine" is currently in the bodies of hundreds of millions of Americans who were repeatedly told that the testing was comprehensive and the end product was "safe and effective." While information continues to be released showing the shots are neither safe nor effective, Americans are beginning to wonder what went wrong. The original promises were

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[2] Prepared remarks from Deputy Assistant Attorney General Arun G. Rao at the Food and Drug Law Institute's 2021 Enforcement, Litigation and Compliance Conference, December 9, 2021 accessed at: [https://www.justice.gov/opa/speech/deputy-assistant-attorney-general-arun-g-rao-delivers-remarks-food-drug-law-institute-s], last accessed August 18, 2022.

[3] In 2019, the U.S. Department of Justice highlighted fraudulent data in clinical research trials as a "major concern." Gustav Eyler, Dir. Consumer Prot. Branch, Dep't of Justice, Remarks at the Food and Drug Law Institute's Advertising and Promotion Conference (Oct. 18, 2019).

not fulfilled. Individuals who are fully vaccinated for COVID-19 are now shown to be at a higher risk of dying from COVID-19 compared to unvaccinated individuals.[4] In children, the Pfizer vaccine's effectiveness plummets after mere weeks, and actually has a negative efficacy for young children just 8 weeks after receiving the second dose.[5] Even former White House COVID response coordinator, Dr. Deborah Birx, recently admitted the vaccine's failure, stating that she "knew these vaccines were not going to protect against infection."[6] Meanwhile, in record time, the COVID-19 vaccines have accumulated a higher number of reported deaths and adverse events *greater than all cumulative adverse reports for any vaccine for the prior thirty years* - an alarming statistic. Recent estimates suggest that the rate of injury for vaccinated individuals is 5.1%.[7]

Information revealed in FDA documents obtained via FOIA request show warning signals in Pfizer's early data following the administration of the vaccine that by any reasonable measure would have halted the vaccine rollout in its tracks. The concerns about

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[4] *See* Manitoba Provincial Respiratory Surveillance Report, August 3, 2022, available at https://www.gov.mb.ca/health/publichealth/surveillance/covid-19/2022/week_30/index.html.

[5] Vajeera Dorabawila, PhD, Dina Hoefer, PhD, Ursula E. Bower, PhD et al., "Effectiveness of the BNT162b2 Vaccine among Children 5-11 and 12-17 years in New York after the Emergence of the Omicron Variant," medRxiv, Feb. 28, 2022, https://www.medrxiv.org/content/10.1101/2022.02.25.22271454v1.full.pdf; Vajeera Dorabawila, PhD, Dina Hoefer, PhD, Ursula E. Bower, PhD et al., "Risk of Infection and Hospitalization among Vaccinated and Unvaccinated Children and Adolescents in New York After the Emergence of the Omicron Variant," JAMA (2022), www.doi.org/10.1001/jama.2022.7319; *see also* Vaccine effectiveness of two-dose BNT162b2 against symptomatic and severe COVID-19 among adolescents in Brazil and Scotland over time: a test-negative case-control study - The Lancet Infectious Diseases; Effectiveness of BNT162b2 vaccine against SARS-CoV-2 infection and severe COVID-19 in children aged 5–11 years in Italy: a retrospective analysis of January–April, 2022 - The Lancet

[6] Dr. Deborah Birx says she 'knew' COVID vaccines would not 'protect against infection," *Fox News*, July 22, 2022, available at https://www.foxnews.com/media/dr-deborah-birx-knew-covid-vaccines-not-protect-against-infection.

[7] Horowitz: German insurance claims hint at millions of unreported COVID vaccine injuries, August 15, 2022, available at https://www.conservativereview.com/horowitz-german-insurance-claims-vaccine-injury-2657863726.html.

the vaccine were suppressed, labeled as anti-vaccine rhetoric (as Respondents attempt to do here), and largely ignored. Yet, the grave predictions regarding the vaccine have largely come true: the "vaccine" is neither safe nor effective and the benefits don't outweigh the risks. As Florida Governor Ron DeSantis aptly put it: "They lied to us about the mRNA shots."[8] Respondents lied to the government and they lied to the American people. Relator Brook Jackson provided the starting point for uncovering how deep that lie goes, as discussed below and in the Amended Complaint.

On January 19, 2021, the FDA announced an EUA for Pfizer's COVID-19 vaccine based "on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials." 86 F.R. 5200 - 5219. This EUA triggered a condition in a contract between the Department of Defense ("DOD") and Pfizer, obligating the DOD to purchase 100 million doses for $1.95 billion. Prior to this approval, the FDA stated in its October 2020 guidance, reissued in March 31, 2022, titled "Emergency Use Authorization for Vaccines to Prevent COVID-19," there must be "adequate manufacturing information to ensure its quality and consistency, issuance of an EUA would require a determination by FDA that the vaccine's benefits outweigh its risks based on data from at least one well-designed Phase 3 clinical trial that demonstrates the vaccine's safety and efficacy in a clear and compelling manner."[9] Pfizer's Phase 3 clinical trial data was the basis for the FDA's decision to issue the EUA, which was necessary for DOD to pay Pfizer for the vaccines. Thus, Pfizer's Phase 3 clinical trial data was the basis of the Government's decision to pay Pfizer $1.95 billion for 100 million doses.

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[8] T. Boone on Twitter: "“They lied to us about the mRNA shots.” - Gov. Ron DeSantis https://t.co/3EM7HbH8aE" / Twitter

[9] Emergency Use Authorization for Vaccines to Prevent COVID-19, March 31, 2022, at p. 4 [https://www.fda.gov/media/142749/download], last accessed August 18, 2022.

To ensure the Phase 3 clinical trial data was generated in a manner that would scientifically ensure quality and accuracy of produced data, the FDA required Pfizer, the sponsor, to submit an Investigational New Drug Application ("IND") before commencing the trial. *See* 21 C.F.R. § 312.23(a). In the IND, the sponsor commits to conduct the trial "in accordance with all [] applicable regulatory requirements." 21 C.F.R. § 312.23(a)(v). Pfizer also submitted a clinical trial protocol alongside its IND. Am. Comp. at ¶ 147, PageID 731.

Since Pfizer utilized contract investigators Icon and Ventavia to administer the clinical trial, Pfizer must also ensure that each investigator is qualified, provide them with the information needed to properly conduct the clinical trial, ensure proper monitoring of the clinical trial, ensure that the clinical trial complies with the IND and clinical trial protocol, and ensure "that FDA and all participating investigators are promptly informed of significant new adverse effects or risks" with respect to the drug under investigation. 21 C.F.R. § 312.50. "A sponsor who discovers that an investigator is not complying" with those requirements "shall promptly either secure compliance or discontinue shipments of the investigational new drug to the investigator and end the investigator's participation in the [clinical trial]." 21 C.F.R. § 312.56(b).

Contract investigators are bound by the same regulations as the sponsor, to the same degree, with regard to any obligation the sponsor delegates to them. *See* 21 C.F.R. § 312.52. Icon and Ventavia submitted Form FDA-1572s, certifying they will conduct the trial under Pfizer's clinical trial protocols and the same regulations. To produce clinical trial data on which the FDA could rely to determine the risks and benefits of the vaccine, Respondents must abide by the regulations and clinical trial protocols they certified they would follow in the IND and Form FDA-1572. To grant emergency use authorization, the law requires that "the known and potential benefits of the product . . . outweigh the known and potential risks of the product." 21 U.S.C. § 360bbb-3(c)(2)(B). That determination is made based on "the

totality of the evidence . . . including data from adequate and well-controlled clinical trials." Id. § 360bbb-3(c)(2). Respondents' false certifications rendered the clinical data necessary for the FDA to make its EUA approval decision scientifically flawed and therefore undeserving of EUA. The EUA triggered the DOD's obligation to pay, and therefore the Government's decision to pay. The false certifications by Pfizer and its subcontractors in the IND and Forms-1572 constitute false statements to the Government material to the Government's decision to grant the EUA, a precondition to payment and, therefore, false claims.

Relator alleges, from personal knowledge, the many false claims Pfizer and its subcontractors made about the Phase 3 clinical trials by providing Ventavia's Form-1572 as a representative example. In just 18 days with Ventavia, Relator witnessed alarming departures from FDA regulations and the clinical trial protocol that destroyed data integrity making the clinical trial data unreliable. Pfizer, as sponsor, ignored evidence of falsity and knowingly submitted unreliable clinical trial data to the FDA anyway, failing to monitor the trial as required. Taking the allegations in the Amended Complaint as true, the multitude of these false certifications distorted the clinical data such that the FDA would not have issued the EUA, and the Government would not have paid Pfizer.

Despite Respondents' spurious and rhetorical arguments, Relator met all pleading requirements necessary under the False Claims Act, and respectfully asks this Court to deny Respondents' Motions to Dismiss so this case may proceed to discovery to answer key factual questions such as: (1) Did Respondents' faked Phase 3 clinical trial data destroy the study's reliability, thus fraudulently inducing the FDA to grant EUA?; and (2) If Relator's allegations were proven correct to the FDA, would an objective FDA, without conflicts of interest, have refused to grant EUA?

Section 1: Falsity - Respondents fraudulently induced the FDA to grant EUA by submitting fabricated, altered, and compromised clinical trial data in support of the EUA application.

FCA liability may be imposed "when the contract under which payment is made was procured by fraud." *United States ex rel. Willard v. Humana Health Plan of Texas, Inc.*, 336 F.3d 375, 384 (5th Cir.2003), citing *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 787 (4th Cir. 1999). In *United States ex rel. Marcus v. Hess*, the Supreme Court recognized that FCA liability can be based on a fraudulent premise that caused the United States to enter into a contract. See 317 U.S. 537, 543-44 (1943). This type of FCA claim is characterized as fraudulent inducement. Under a fraudulent inducement theory, although the Respondents' "subsequent claims for payment made under the contract were not literally false, [because] they derived from the original fraudulent misrepresentation, they, too, became actionable false claims." *United States ex rel. Laird v. Lockheed Martin Eng'g & Science Servs. Co.*, 491 F.3d 254, 259 (5th Cir. 2007), citing *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 543–44, 63 S.Ct. 379, 87 L.Ed. 443 (1943).

Where the government has conditioned payment of a claim upon a claimant's certification of compliance with, for example, a statute or regulation, a claimant submits a false or fraudulent claim when he or she falsely certifies compliance with that statute or regulation. *U.S. ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 902 (5th Cir. 1997). Pfizer is liable under the FCA for fraudulent inducement. Pfizer's invoices, though contractually justified, were fraudulently induced via prior false certifications Pfizer, Ventavia, and Icon made to the FDA before receiving EUA. Although its invoices do not contain false statements, Pfizer's lies, omissions, and fabrications in their EUA application, whether by Pfizer directly or caused by Ventavia and Icon, render the later claims for payment false under the FCA as Respondents fraudulently induced the EUA.

Under Fed. R. Civ. P. 9(b) standards, Relator alleged representative samples of clinical trial protocol violations she personally observed at Ventavia. To Relator's knowledge the patient data affected was not excluded from the trial. These clinical trial protocol violations render Ventavia and Pfizer's certifications of compliance false. Relator alleged in detail Ventavia's protocol violations, for example:

i. Inclusion and exclusion criteria: Ventavia enrolled and injected ineligible clinical trial participants, including pregnant women and people potentially infected with COVID-19 at the time they received the shot. Am. Comp. at ¶¶ 148-54, PageID 731-4. Ventavia altered patient records to hide ineligibility violations, creating false source documents. *Id*. Pfizer and Icon included ineligible participants' data in the clinical trial.

ii. Blinding: Trial participants received randomized numerical identifiers that identified whether the patient was in the vaccine or placebo group; the randomization scheme was placed in every participant's chart which unblinded anybody who saw it, including the participants. Am. Comp. at ¶ 157, PageID 734-5. Pfizer was presented with red flags regarding this issue but failed to take any action. *Id.* This corrupts the data as to infection, adverse events, and the patient safety and monitoring protocols generally mentioned below in section vii.

iii. Temperature control: Ventavia failed to report "temperature excursions," i.e., significant temperature changes in temperature-controlled vaccine storage units (freezers), to Pfizer. Am. Comp. at ¶¶ 162-3, PageID 737.

iv. Informed consent: Ventavia routinely screened and injected clinical trial participants before obtaining informed consent in direct violation of the clinical trial protocol. Am. Comp. at ¶ 164, PageID 737. Ventavia falsely changed the time informed consent was

given during "quality control." *Id.* at ¶¶ 165-7, PageID 737-8. Ventavia never reported informed consent violations to the IRB. Id. at ¶ 170, PageID 739.

v. Dose preparation: Frozen vaccine concentrate was required to thaw for thirty minutes before administration, but to maximize the number of participants injected and increase per-patient payments from Pfizer, Ventavia employees warmed the frozen concentrate in their hand to speed up thawing. Am. Comp. at ¶ 171, PageID 739.

vi. Administration: Many clinical trial participants were given the second injection outside of the protocol-mandated nineteen to twenty-three days. Am. Comp. at ¶ 176, PageID 740-1. Further, improperly trained vaccinators were utilized in administering the shots such as a medical assistant "trained" over the phone, an office assistant with no medical background. Am. Comp. at ¶¶ 173-5, PageID 739-40.

vii. Safety and patient monitoring: Participants had to remain under medical supervision for thirty minutes post-injection, but in order to inject as many patients as possible patients were told to wait in a hallway where they were periodically checked on by non-medical staff. Am. Comp. at ¶ 179, PageID 741-2. Ventavia also failed to report Serious Adverse Events ("SAEs") to Pfizer and Icon, but Pfizer and Icon were on notice of this because that information was available via the clinical trial participants' "electronic diary" entries. *Id*. at ¶¶ 183-6, PageID 743-4.

viii. Accuracy and completeness of data: The most egregious data and documentation failure concerned blood samples used as a baseline prior to injection; the failure to timely process or record data from the first blood sample affects the baseline which hides subsequent changes and side effects of the vaccine that could be slow to develop. Am. Comp. at ¶ 189, PageID 744-5. Errors in blood draw data or processing go to the heart of the clinical trial – attempting to prove the vaccine's effectiveness. *Id*. Relator attached to the Amended Complaint an example blood draw log from

Ventavia's Fort Worth, Texas location which shows a host of problems with blood draw data and processing. Am. Comp. ¶ 190, PageID 745-6; Ex. 25, PageID 1268-1295. Further, Relator witnessed quality control personnel fabricating data such as blood pressure readings during "quality checking." Am. Comp. at ¶ 194, PageID746.

ix. Adherence to protocol: Ventavia failed to maintain principal investigator oversight leading to creation of false records indicating that principal investigators examined patients when they did not. Ventavia failed to report clinical trial protocol deviations to Pfizer and Icon, instead opting to bury issues as "notes to the file" if they were reported at all. Am. Comp. at ¶¶ 198-205, PageID 747-50.

x. Privacy law compliance: Ventavia failed to maintain the privacy of patient health information in violation of HIPAA. Am. Comp. at ¶¶ 206-10.

Relator relayed concerns about Ventavia's "quality checking" in an email dated September 23, 2020. Am. Comp. at ¶ 254, PageID 762-3; Ex. 2, PageID 789-92.

Clinical trial protocol violations constitute false certifications, but many also directly violate FDA regulations. Icon and Ventavia are bound by FDA regulations to the same extent as Pfizer.[10] Respondents failed to report to the Institutional Review Board additional clinical trial participant compensation, failure to follow clinical trial protocols, and informed consent violations. Am. Comp. at ¶ 212, PageID 751; 21 C.F.R. §§ 312.66, 312.53(c). Respondents violated FDA regulations when they failed to investigate and report all adverse event

[10] A Technical Direction Letter from the U.S. Army Contracting Command - New Jersey to Advanced Technology International stated, "**Pfizer will meet the necessary FDA requirements for conducting ongoing and planned clinical trials**, and with its collaboration partner, BioNTech, will seek FDA approval or authorization for the vaccine, assuming the clinical data supports such application for approval or authorization. **Given that these clinical trials are regulated by the FDA** and HHS, there is no need for separate regulation by the U.S. Army Medical Research and Materiel Command." (emphasis added). [https://www.keionline.org/misc-docs/DOD-ATI-Pfizer-Technical-Direction-Letter-OTA-W15QKN-16-9-1002-21July2020.pdf] at p. 3, Section 1.1.2(A), last accessed August 18, 2022.

information received in the clinical trial at issue and failed to notify the FDA of all potential serious risks and adverse reactions. Am. Comp. at ¶ 213, PageID 751; 21 C.F.R. §§ 312.32, 312.50. Ventavia and Icon violated 21 C.F.R. § 312.64(b) when they failed to immediately report all adverse events to Pfizer. Am. Comp. at ¶ 213, PageID 751. Pfizer violated 21 C.F.R. § 312.50 and 21 C.F.R. § 312.56 when it failed to properly oversee Respondents Ventavia and Icon and failed to ensure compliance with the clinical trial protocol. Relator details several other FDA regulatory violations in her Amended Complaint. See Am. Comp. at ¶¶ 211-22, PageID 751-2.

Pfizer is also required to comply with Federal Acquisition Regulation requirements (FAR) but did not disclose violations of the FCA to the DOD nor monitor its subcontractors. See 48 C.F.R. §§ 42-202(e)(2), 52.023-13. These protocol and regulatory violations were plausibly pled by providing details on the "time, place, contents, and identity" components of each. See *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009) (stating "[T]he 'time, place, contents, and identity' standard is not a straitjacket for Rule 9(b). Rather, the rule is context specific and flexible and must remain so to achieve the remedial purpose of the False Claim Act.").

Each protocol and regulatory violation by Ventavia resulted in a false statement because Ventavia certified in its Form FDA-1572 it would abide by those protocols and regulations. Form FDA-1572 was submitted to the FDA as part of Pfizer's overall EUA application. The false certifications therein are false statements to the government.

Pfizer also certified in its IND that it would monitor its subcontractors and ensure they abided by the protocols and regulations. Relator alleged that for each of Ventavia's protocol and regulatory violations, Pfizer failed to do this. Therefore, the false certifications therein constitute false statements to the government as well. The 9(b) standard is a heightened pleading standard, but 12(b)(6) still entitles Relator to have all reasonable inferences drawn in

her favor. Relator's representative examples of Ventavia's protocol and regulatory violations plausibly and sufficiently cover the fraudulent scheme for pleading purposes.

Icon contends Relator did not particularly plead it made false statements to the government like she did for Ventavia and Pfizer, yet Relator alleged the following:

i. Pfizer delegated some management of the clinical trial to Icon, though Pfizer remained responsible for managing and quality checking all data for the entire trial per the trial's protocol. Am. Comp. at ¶¶ 4, 137, PageID 702, 729.

ii. Icon had access to all trial data from clinical trial participants' source documents via the "Complion" Clinical Trial Management System database. Am. Comp. at ¶¶ 26, 51, PageID 707, 712.

iii. Icon had access to electronic diary data used by participants to record any adverse events. Am. Comp. at ¶ 100, PageID 723.

iv. Icon and Pfizer are responsible for data management of the study, including quality checking. Am. Comp. at ¶ 115, PageID 725; Ex. 7, at 120, PageID 1037.

v. Icon ignored numerous red flags apparent from the clinical trial data source documentation as well as participant diary entries, and failed to remove compromised clinical trial data. Am. Comp. at ¶ 151, PageID 732 (ineligible participants), ¶ 158, PageID 735-6 (unblinding), ¶ 169, PageID 738 (informed consent), ¶ 176, PageID 741-2 (administration), ¶ 177, PageID 741 (administration), ¶ 178, PageID 741 (administration), ¶ 186, PageID 744 (safety and patient monitoring), ¶ 187, PageID 744 (accuracy and completeness off data), 191, PageID 746 (accuracy and completeness off data), ¶ 196, PageID 747 (accuracy and completeness off data), ¶ 200, PageID 748 (adherence to protocol).

vi. Icon violated 21 C.F.R. § 312.64(b) by failing to immediately report all adverse events to Pfizer. Am. Comp. at ¶ 213, PageID 751.

vii. Icon (and Pfizer) violated 21 C.F.R. § 312.56(b) by electing not to promptly secure compliance or discontinue shipments of the vaccine and end Ventavia's participation in the clinical trial when it learned of Ventavia's regulatory and protocol violations. Am. Comp. at ¶ 215, PageID 751.

viii. Icon (and Ventavia) violated 21 C.F.R. § 312.64 by failing to furnish all required reports to Pfizer, including reports of adverse events, temperature excursions, and clinical trial protocol deviations. Am. Comp. at ¶ 216, PageID 752.

ix. Icon failed to follow up on one hundred outstanding inquiries about missing or inconsistent data. Am. Comp. at ¶ 254, PageID 762-3.

As a Phase 3 clinical trial subcontractor, Icon certified in its Form FDA-1572 it would abide by those protocols and regulations. The Form FDA-1572 was a document it submitted to the FDA as part of Pfizer's overall EUA application and therefore the falsified certifications therein constitute numerous false statements to the government. Am. Comp at ¶ 277, PageID 768. Thus, Relator plausibly pled enough representative samples of Icon's protocol and regulatory violations for Icon to be included in the overall fraud scheme.

Relator went above and beyond the falsity requirements by offering a deluge of representative examples alleging Ventavia's and Icon's violations of clinical trial protocols and regulations, which resulted in Respondents' false statements to the government. Further, Relator plausibly pled Respondents participated in a broad fraudulent scheme that extended beyond these representative samples. Since Relator satisfied its requirement to plead Respondents made false statements to the government with particularity, she is entitled to discovery on how pervasive these protocol and regulatory violations were and to what degree they jeopardized the scientific reliability of the Phase 3 clinical trial.

Section 2. Causation - Respondents' false certifications caused the FDA to issue an EUA under false pretenses, and caused the DOD to pay for a product that was not subject to scientifically reliable testing.

Causation in the FCA context only requires the Relator to plead that the Respondent's false statement or false record was "submitted to the U.S. government causing it to pay the claim." *U.S. ex rel. Prather v. Brookdale Senior Living Communities, Inc.*, 892 F.3d 822, 830 (6th Cir. 2018). When applying for the EUA, Pfizer had to submit its INP and its subcontractors' Form FDA-1572 to the FDA so the Phase 3 clinical trial data could be considered. Without the Respondents' certifications in the INP and Form FDA-1572 that they conducted the clinical trial in accordance with protocols and regulations, the FDA would not have an objective basis to determine the safety and efficacy of the vaccine. A study is valid only if it follows the process it purports to follow. The clinical trial protocol and FDA regulations exist to ensure the clinical trial data is produced using the correct process. Therefore, the FDA relied on Pfizer as sponsor and its subcontractors as administrators to ensure the clinical trial proceeded in strict adherence to the protocols and regulations, and each Respondent certified the same.

In this case, the FDA relied on Respondents' certifications regarding the Phase 3 clinical trial data to find the vaccine was "safe and effective," the benefits outweigh the risks, and to issue the EUA. This triggered an obligation for the DOD to pay Pfizer. But-for the emergency use authorization, the government would have never paid Pfizer for the vaccines. Further, but-for the favorable, albeit manipulated clinical trial data, an objective FDA would not have issued Pfizer the EUA. Finally, but-for Respondents INP and Form FDA-1572 certifications, the FDA would have never considered the clinical trial data in the first place. Thus, Respondents' INP and Form FDA-1572 certifications are the but-for cause of Pfizer's receipt of $1.95 billion for the 100 million vaccines

Respondents' regulatory and protocol violations destroyed the scientific value of the clinical trial data. Their false certifications caused the FDA to issue an EUA under false pretenses. The vaccine is also thus misbranded, and Respondents caused the FDA to issue an EUA for a misbranded drug. Am Comp. ¶¶ 2, 12, PageID 701, 704. *See*, for example, *U.S. v. Aerodex, Inc.*, 469 F.2d 1003, 1007 (5th Cir. 1972) (stating, "The mere fact that the item supplied under contract is as good as the one contracted for does not relieve defendants of liability if it can be shown that they attempted to deceive the government agency."). Discovery is necessary because Relator's allegations justify an inquiry into whether Respondents caused the FDA to issue the EUA under false pretenses.

Section 3. Materiality - Respondents' falsehoods were material to the grant of the EUA and the DOD's decision to pay.

The False Claims Act imposes civil liability where a respondent knowingly presents to the government a "false or fraudulent claim" or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A), (B). The Act defines "material" broadly as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." *Id.* § 3729(b)(4).

In light of the Act's broad definition—which covers not just falsehoods with a "natural tendency" to influence the government payment decision, but those "capable" of doing so—the Sixth Circuit and the Supreme Court have recognized that "[t]he analysis of materiality is 'holistic.'" *United States ex rel. Prather v. Brookdale Senior Living Cmtys., Inc.*, 892 F.3d 822, 831 (6th Cir. 2018). No one factor is "automatically dispositive." *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2003 (2016). The Supreme Court considered a variety of factors to be relevant—including whether the falsehood went to the "essence of the bargain," whether the "noncompliance is minor or insubstantial," whether the falsehood involved an "express[] … condition of payment," and

whether "the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated." *Id.* at 2003 & n.5.

Each factor listed in *Escobar* is discussed below.

Natural Tendency and Capability to Influence

"A false statement is material if it has a 'natural tendency to influence, or [is] capable of influencing, the decision of the decision making body to which it was addressed.'" *Neder v. United States*, 527 U.S. 1, 16, 119 S.Ct. 1827, 144 L.Ed.2d 35 (1999) (quotation omitted) (insertion in original); see also *United States v. Southland Mgmt. Corp.* (*Southland II*), 326 F.3d 669, 679 (5th Cir.2003) (en banc) (Jones, J., concurring); *United States v. Southland Mgmt. Corp.* (*Southland I*), 288 F.3d 665, 676 (5th Cir.2002), vacated by grant of reh'g en banc, 307 F.3d 352 (5th Cir.2002) (quoting *United States v. Wells*, 519 U.S. 482, 489, 117 S.Ct. 921, 137 L.Ed.2d 107 (1997)).

The "'natural tendency to influence or capable of influencing' test requires only that the false or fraudulent statements either (1) make the government prone to a particular impression, thereby producing some sort of effect, or (2) have the ability to affect the government's actions, even if this is a result of indirect or intangible actions on the part of the Respondents. All that is required under the test for materiality, therefore, is that the false or fraudulent statements have the potential to influence the government's decisions." *U.S. ex rel. Longhi v. U.S.*, 575 F.3d 458, 470 (5th Cir. 2009)

The safety and quality of the resulting product, which relies upon scientifically acceptable testing, has the natural tendency to influence the Government's decision to pay for the end product. Section 21.12 of the "Base Agreement" highlights the importance of adhering to current Good Manufacturing Practices as defined by FDA guidance. Section 21.12 of the Agreement, "Compliance with current Good Manufacturing Processes (cGMP)," states:

> Manufacturing Standards as appropriate for the level of prototype Material used for clinical trials, pivotal nonclinical studies, consistency lots, and other uses as defined in regulatory plans should be compliant with current Good Manufacturing Processes (cGMP) as defined by FDA guidance (21 CFR Parts 210-211). If at any time during the life of the award, the PAH [Project Agreement Holder] fails to comply with cGMP in the manufacturing, processing and packaging of this product and such failure results in a material adverse effect on the safety, purity or potency of the product (a material failure) as identified by the FDA, the PAH shall have thirty (30) calendar days from the time such material failure is identified to cure such material failure. See Doc. 37-1, PageID 1467.

False trial data leading to the FDA's grant of an EUA unquestionably has the natural tendency and capability to influence the Government's payment decision. The grant of the EUA by itself is not enough of an inquiry to determine what is capable of influencing the Government's decision to pay. Though the EUA is the express condition in the Agreement, knowledge that the EUA was obtained by fraud and deception would cause any reasonable taxpayer to reconsider taking the shot let alone pay for it. During its emissions scandal, Volkswagen, for example, was not able to argue that all it had to do was pass emissions testing to avoid liability for tampering with its emission control systems. Pfizer attempts a similar argument, however, claiming Respondents' falsified test data does not matter because they got the EUA. If an objective FDA saw the fraud leading to the EUA, it would have determined material conditions were not honestly met, and the DOD would not have purchased the shots. The fraud alleged by Relator has the natural tendency and capability to influence the Government's payment decision as pled in Relator's Amended Complaint.

Essence of the Bargain and Express Condition of Payment

EUA approval encompasses two factors identified by the Supreme Court in a FCA materiality determination, i.e., whether the falsehood went to the "essence of the bargain" and whether the falsehood involved an "express[] … condition of payment." *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2003 & n.5 (2016). Pfizer argues EUA was the **only** condition of payment. It logically flows, then, that EUA also goes

to the essence of the bargain, which at its core was the delivery of a vaccine that is "safe and effective." By bypassing scientifically significant processes in the clinical trials, Respondents guaranteed tainted results. Inadequate testing destroys the very essence of the bargain.

Payment despite knowledge

The FDA's ongoing payments to Respondents is an irrelevant factor because the government had virtually no power to withhold payment under the DOD's contract with Pfizer.[11] The contract stated 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."[12] Nor did the government have the power to halt Respondents' activities: "except as required by applicable law or regulation, or judicial or administrative order, the Government shall not have the authority to issue a Stop-Work Order to halt the work contemplated under this Statement of Work."[13]

Furthermore, knowledge of allegations is not the same as knowledge allegations are true and violations have actually occurred. *See United States ex rel. Escobar v. Universal Health Servs., Inc.*, 842 F.3d 103, 112 (1st Cir. 2016) ("[M]ere awareness of allegations concerning noncompliance with regulations is different from knowledge of actual noncompliance."). As courts have recognized, the government may choose to continue doing business with a contractor for a variety of reasons unrelated to the materiality of the alleged fraud. *See, e.g., United States ex rel. American Sys. Consulting, Inc. v. ManTech Advanced Sys. Int'l*, 600 F. App'x 969, 977-78 (6th Cir. 2015) ("[W]e do not agree with the district court's reasoning that [the government's continued business with the contractor] necessarily precludes a finding of materiality."); *United States ex rel. Prose v. Molina Healthcare of*

[11] https://www.keionline.org/misc-docs/DOD-ATI-Pfizer-Technical-Direction-Letter-OTA-W15QKN-16-9-1002-21July2020.pdf
[12] *Id.* at 19.
[13] *Id.* at 21.

Illinois, Inc., 10 F.4th 765, 777 (7th Cir. 2021) (rejecting respondent's argument that the relator had failed to plead materiality because "the government continued to contract with [the respondent]"); *United States ex rel. Cimino v. International Bus. Machs. Corp.*, 3 F.4th 412, 423 (D.C. Cir. 2021) (rejecting similar argument); *Campie.*, 862 F.3d at 906-07 (noting similar concerns); *Harrison* II, 352 F.3d at 917 (same).

Given the difference between alleged fraud and actual fraud, the Government may not want to prematurely end a relationship with a contractor over unproven allegations. In addition, the Government may not have other feasible procurement options and may be forced to rely on the contractor for essential goods or services even after becoming aware of a plausible fraud claim. For example, the government might have made "operational changes or investments in reliance on the agreement." *ManTech*, 600 F. App'x at 977-78. It might be too "costly for the government to find a replacement" for the time being—for example, due to supply limitations or "[t]he costs associated with implementing another bidding process." *Id.* at 977; *Harrison II*, 352 F.3d at 917. Alternatively, the 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. The government might also have investigated and found past violations but have privately conferred with the respondent and believed the respondent would comply going forward. Further, perhaps the government investigated the allegations but incorrectly concluded that no violation occurred. *See Cimino*, 3 F.4th at 423 ("It is … plausible that the [government] could have later learned of [the respondent's] fraud and continued to pay for the licenses for any number of reasons that do not render [the] fraud immaterial."). In *United States ex rel. Harrison v. Westinghouse Savannah River Co.*, the Fourth Circuit also set forth reasons why "a government entity might choose to continue funding the contract despite earlier wrongdoing by the contractor." 352 F.3d 908, 917 (4th Cir. 2003).

In short, there are numerous reasons unrelated to materiality why the government might continue doing business with a contractor despite allegations of fraud. Accordingly, "contractors who make … misrepresentations are not" automatically "protected by the government's subsequent decision to continue working with them, for whatever reason." *ManTech*, 600 F. App'x at 977-78 (citing *Harrison II*, 352 F.3d at 917). "To find otherwise could lead to perverse outcomes; the more dependent the government became on a fraudulent contractor, the less likely it would be to terminate the contract (and the less likely the contractor would be held liable)." *ManTech*, 600 F. App'x at 978. The Government's continued business with the contractor does not automatically make false representations immaterial.

Here, it is unreasonable to assume that, even if knowledge can be imputed to the Government from Relator's call to the FDA's hotline, the project would be immediately abandoned. According to Pfizer's timeline: Operation Warp Speed was launched May 15, 2020; Pfizer contracted with the DOD on July 21, 2020; Pfizer launched the study on July 27, 2020; Relator reported the fraudulent conduct to the FDA on September 25, 2020; the FDA granted the first EUA December 11, 2020. Pfizer Brief, Doc. 37 at 18, Page ID 1403. The study was underway for nearly two months when Relator reported the conduct, and the EUA was granted just over two months after Relator's report. As though even an hours long call with one person is going to cause the FDA to immediately change course and deny what was already set in motion by high-ranking officers of the United States Government and high level multinational corporate executives, this knowledge imputed to the Government which precedes its decision to pay is not dispositive of the materiality inquiry here. As explained above, the significant resources already expended at the time of Relator's report, and the likely lack of other sponsors who could undertake the operation, constitute strong evidence that the Government did not consider the fraud immaterial but rather that it could not divert

course, during a national emergency, based on the allegations of one whistleblower. That is why Relator continues to litigate this action absent Government intervention, as is Relator's right under the FCA.

Conclusion on Materiality

"[A]t this stage of the case," Relator's allegations suggest "more than the mere possibility" that gross misrepresentations in the testing data would have the natural tendency or capacity to influence the FDA's EUA decision and the DOD's payment decision. *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 907 (9th Cir. 2017). Relator plausibly pled that Respondents' wrongdoing was material to the acquisition of the EUA as well as DOD's payment decision.

Section 4. Scienter - Respondents knew the data was flawed but used it in applying for and receiving the EUA.

The scienter requirement comes from § 3729(b)'s definition of the terms "knowing" and "knowingly." *U.S. ex rel. Longhi v. U.S.*, 575 F.3d 458, 468 (5th Cir. 2009). Relator may demonstrate scienter in one of three alternative methods; Relator may demonstrate Respondents: (1) had actual knowledge of falsity, (2) acted with deliberate ignorance of the truth or falsity of the information provided, or (3) acted with reckless disregard of the truth or falsity of the information provided. *Id*.

Here, Relator sufficiently pled that Pfizer and Icon acted, at minimum, with reckless disregard of the falsity of the information provided by Ventavia. As sponsor, Pfizer had a duty to monitor the clinical trial. Icon also had a monitoring duty by agreement with Pfizer. Since Ventavia violated Pfizer's clinical trial protocol in so many ways with no objection or correction from Pfizer or Icon: Pfizer and Icon abdicated their duty. Though Pfizer and Icon actually knew of the wrongdoing in the clinical trials, their behavior also meets the lesser thresholds of deliberate ignorance or reckless disregard of Ventavia's consequential and material deviations from the clinical trial protocol.

Section 5. The Agreement does not mandate ADR; regardless, Relator's retaliation claim cannot fall under the Agreement.

Pfizer suggests Article VII of the Agreement commits this action to some form of alternative dispute resolution. This argument raises three questions which Pfizer fails to answer: (1) is the provision permissive rather than mandatory; (2) if mandatory, are FCA causes of action contemplated within the provision; and (3) if the provision is mandatory and FCA causes of action are mandated to ADR under the provision, is Relator's retaliation claim committed to ADR as well?

The relevant language in Article VII is ambiguous. Article VII, Section 7.02 states "Any disagreement, claim or dispute among the Parties concerning questions of fact or law arising from or in connection with this Agreement and whether or not involving an alleged breach of this Agreement, **may be raised only under this Article**." (emphasis added). It is apparent that this section utilized the permissive "may" rather than the mandatory "shall," "will," or "must." Undoubtedly the lawyers that drafted the Agreement understand the critical implications of using "may" rather than "shall." Further still, nowhere does this "Article" mention arbitration or otherwise invoke the Federal Arbitration Act, lending further weight to the likelihood that Section 7.02 was not meant to mandate ADR for any and all disputes conceivably related to anything involved in the contract, but only to certain disputes specifically related to the text of the Agreement. Further, the sole fact that the provision at issue here says nothing about arbitration and is not a mandatory arbitration provision easily distinguishes this case from *U.S. v. Bankers Ins.*, 245 F.3d 315 (4th Cir. 2001), primarily relied upon by Respondent. Further still, the very last sentence of Section 7.02 appears to suggest the entire Section is permissive. Section 7.02 ends, "Alternatively, the parties may agree to explore and establish an Alternative Disputes Resolution procedure to resolve this dispute." All signs suggest Section 7.02 is a permissive provision and, should it be invoked,

its procedures followed. Section 7.02 does not constitute a condition precedent to bringing this FCA action.

Alternatively, even if the clause is not permissive, it relates only to issues relevant to the Agreement itself and does not encompass FCA causes of action. Case law suggests this provision only relates to disagreements arising out of and relevant to the language of the Agreement and does not pertain to anything else like this FCA case. Though the relevant portion of Section 7.02 uses "arising from or in connection with this Agreement," the Supreme Court has stated that even the broader term "relate to," if "taken to extend to the furthest stretch of its indeterminacy," would not have much limiting power because "really, universally, relations stop nowhere." *N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655, 115 S.Ct. 1671, 131 L.Ed.2d 695 (1995). "Arising from or in connection with this Agreement" cannot be read to include this FCA cause of action because this case arises from Respondents' clinical protocol violations and the false claims those violations caused.

Courts have found that agreements between employee and employer mandating arbitration, though the Agreement here is not one, failed to contemplate FCA causes of action even if the cause of action arguably relates to the employee's employment. See, for example, *Mikes v. Strauss*, 889 F. Supp. 746, 754 (S.D.N.Y. 1995). It follows, then, that "arising from or in connection with this Agreement" refers only to disputes over the Agreement, not any dispute in which the Agreement may be referred to tangentially such as this FCA action. Under the ADR provision in the Agreement, the dispute must arise from or connect with the Agreement. Here, the dispute arises from the failed clinical trials and the falsities in connection therewith; to that end Respondent merely attempts to use the Agreement to argue it was not obligated to do anything but gain EUA regardless of fraud. Thus, the Agreement is

only relevant to this dispute as a type of affirmative defense. The defense fails, however, due to Respondents' bad clinical practices and falsities underlying their submissions to the FDA.

Alternatively, if the provision is mandatory and it encompasses FCA causes of action, it certainly does not cover Relator's retaliation claim. Courts have found FCA retaliation claims not subject to ADR provisions even in contracts between the relator and the relator's employer mandating ADR. "[...] Congress must have intended that whistleblower retaliation actions brought under 31 U.S.C. § 3730(h) be heard in a district court rather than before an arbitrator." See, for example, *Nguyen v. City of Cleveland*, 121 F. Supp. 2d 643, 647 (N.D. Ohio 2000). Here, however, the ADR provision does not include Relator as a signatory. Thus, even if the Court interprets the provision as a mandatory ADR provision that includes FCA causes of action, Relator's retaliation claim is not and cannot be contemplated by the provision.

The Agreement does not mandate ADR for anything other than Agreement-specific disputes. This is a case alleging fraud on the United States Government and the taxpayers duped by Respondents' falsities. Pfizer's condition precedent argument fails.

Section 6. Ventavia retaliated against Relator for exposing Ventavia's wrongdoing; Relator stated a claim for retaliation under § 3730(h).

This Fifth Circuit applies the "*McDonnell Douglas* framework to the False Claims Act's anti-retaliation provision." *Diaz v. Kaplan Higher Educ., L.L.C.*, 820 F.3d 172, 175 n.3 (5th Cir. 2016). Under this framework, the employee must first establish a prima facie case of retaliation by showing: (1) that she engaged in protected activity; (2) that the employer knew about the protected activity; and (3) retaliation because of the protected activity. *United States ex rel King v. Solvay Pharms., Inc.*, 871 F.3d 318, 332 (5th Cir. 2017); *see also United States ex rel. Bias v. Tangipahoa Par. Sch. Bd.*, 816 F.3d 315, 323 (5th Cir. 2016). Once an employee establishes a prima facie case, "the burden shifts to the employer to state a legitimate, non-retaliatory reason for its decision." *Solvay Pharms.*, 871 F.3d at 332 (citation

omitted). After the employer provides that benign reason, "the burden shifts back to the employee to demonstrate that the employer's reason is actually a pretext for retaliation." *Garcia v. Prof. Contract Services, Inc.*, 938 F.3d 236, 240–41 (5th Cir. 2019).

Relator Brook Jackson was terminated in retaliation for her reports of misconduct to the FDA. Ventavia states "Relator was fired for violating company policy and patient confidentiality, not for raising red flags about the clinical trial." Ventavia Brief, Doc 53 at 5, PageID 1834. First, this allegation is not properly asserted in a motion to dismiss. Second, Relator directly challenges the validity of the claimed reasons for her termination in the Amended Complaint. Am. Comp. at ¶¶ 256-63, Page ID 763-4. Ventavia's assertion by motion, outside of a responsive pleading, cannot be considered, though at minimum the basis for Relator's termination is a contested issue that, at this stage, must be decided for the Relator.

Further, Relator engaged in protected activity and Ventavia knew it. To engage in protected activity under the Act, an employee need not "have filed an FCA lawsuit or [ ] have developed a winning claim at the time of the alleged retaliation." *United States ex rel. Karvelas v. Melrose–Wakefield Hosp.*, 360 F.3d 220, 236 (1st Cir.2004) (citing *United States ex rel. Yesudian v. Howard Univ.*, 153 F.3d 731, 741 (D.C.Cir.1998)); *accord Schuhardt v. Washington Univ.*, 390 F.3d 563, 567 (8th Cir.2004). Instead, an employee's actions must be aimed at matters that reasonably could lead to a viable claim under the Act. *See Harrington v. Aggregate Indus.–Ne. Region, Inc.*, 668 F.3d 25, 32 (1st Cir.2012); *Mann v. Heckler & Koch Defense, Inc.*, 630 F.3d 338, 344 (4th Cir.2010); *Hoyte v. Am. Nat'l Red Cross*, 518 F.3d 61, 66 (D.C.Cir.2008); *Schuhardt*, 390 F.3d at 567; *Moore v. California Inst. of Tech. Jet Propulsion Lab'y*, 275 F.3d 838, 845 (9th Cir. 2002); *McKenzie v. BellSouth Telecomms., Inc.*, 219 F.3d 508, 515–16 (6th Cir.2000); *United States ex rel. Gray v. Lockheed Martin Corp.*, Civ. A. No. 05–4201, 2010 WL 672017, at *2 (E.D.La. Feb. 19, 2010); *Velazquez v.*

LandCoast Insulation, Inc., Civ. A. No. 06–0174, 2007 WL 902297, at *4 (W.D.La. Mar. 22, 2007); *United States ex rel. Dyson v. Amerigroup Tex., Inc.*, No. Civ. A. H–03–4223, 2005 WL 2467689, at *2 (S.D.Tex. Oct. 6, 2005). The employee's actions must be aimed at matters demonstrating a "distinct possibility" of False Claims Act litigation. *See United States ex rel. Sanchez v. Lymphatx, Inc.*, 596 F.3d 1300, 1303–04 (11th Cir.2010) (per curiam); *Fanslow v. Chicago Mfg. Ctr., Inc.*, 384 F.3d 469, 479 (7th Cir.2004); *Dookeran v. Mercy Hosp. of Pittsburgh*, 281 F.3d 105, 108 (3d Cir.2002); *United States ex rel. Gonzalez v. Fresenius Med. Care N. Am.*, 748 F.Supp.2d 95, 104 (W.D.Tex.2010). Whether the test is stated as the "reasonably could lead" standard or the "distinct possibility" standard, four circuits find the standard satisfied when "(1) the employee in good faith believes, and (2) a reasonable employee in the same or similar circumstances might believe, that the employer is committing fraud against the government." *Hoyte*, 518 F.3d at 71 (internal quotation marks omitted); *accord Schuhardt*, 390 F.3d at 567; *Fanslow*, 384 F.3d at 480; *Moore*, 275 F.3d at 845.

Respondent relies on *U.S. ex rel. Patton v. Shaw Services, L.L.C.*, 418 Fed. Appx. 366 (5th Cir. 2011), to contend that internal complaints must specifically refer to the False Claims Act, but for several reasons *Patton* is distinguishable. In *Patton*, an unpublished case, the relator-employee worked as a carpenter for Shaw Services, a construction company. He alleged that he complained repeatedly to on-site Shaw supervisors, off-site management, and to state and federal authorities about fraudulent construction mistakes. *Id.* Unlike Relator's complaints, none of the *Patton* relator's complaints referred to any contractual provision or federal regulation that Shaw allegedly violated. *Id*., at 370 (stating, "There is no indication, for instance, that Shaw falsely certified compliance with the contract provisions or construction methods that [relator] alleges Shaw violated; nor has he shown that compliance with those provisions or methods was a condition to payment under the contract.").

Summarily, *Patton* involved complaints about faulty construction unrelated to certifications or contractual provisions required for Government payments. Since the *Patton* relator's claims did not show the contractor violated promises made to the Government, it was easy to dismiss the retaliation claim.

Patton appears not to have acknowledged the 2009 and 2010 Congressional FCA amendments perhaps because the complaint was deficient. Respondents also rely upon *Robertson v. Bell Helicopter Textron, Inc.*, 32 F.3d 948, 951 (5th Cir. 1994), which predates these FCA amendments. As explained in *Melchior v. Apple Homecare Med. Supply, Inc.*, A-16-CV-1301-RP, 2018 WL 1876287, at *2–3 (W.D. Tex. Jan. 8, 2018), discussing *Robertson*, "The Fifth Circuit did not reject the possibility that internal reporting alone could constitute protected activity; it merely found that Robertson's actions did not rise to the level of protected activity." The whistleblower provision in *Robertson* was limited to relief for "'lawful acts done by the employee on behalf of the employee or others in furtherance of an action under this section, including investigation for, initiation of, testimony for, or assistance in an action filed or to be filed under this section.'" *Melchior*, supra, (referring to the previous version of 31 U.S.C. § 3730(h)). In 2009, Congress amended the FCA "to provide relief to any employee discharged for acting 'in furtherance of other efforts to stop [one] or more violations of this subchapter.'" *Thomas v. ITT Educ. Servs., Inc.*, 517 Fed.Appx. 259, 262 (5th Cir. 2013). The language now reads:

> Any employee, contractor, or agent shall be entitled to all relief necessary to make that [individual] whole if that [individual] 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 [individual] in furtherance of an action under this section or other efforts to stop [one] or more violations of this subchapter.
> 31 U.S.C. § 3730(h)(1).

"The Fifth Circuit has not yet issued a published opinion interpreting the new language, but the unpublished *Thomas* opinion broadly stated '[a] protected activity is one motivated by a

concern regarding fraud against the government.'" *Melchior*, supra, citing *Thomas*, 517 Fed.Appx. at 262. See also *U.S. ex rel. Reed v. KeyPoint Govt. Sols.*, 923 F.3d 729, 764–65 (10th Cir. 2019) (discussing *Robertson*, supra, and explaining that the 2009 and 2010 FCA amendments expanded the scope of protection for whistleblowers).

Relator stated a claim for retaliation. Relator repeatedly alerted Ventavia to violations of Pfizer's clinical trial protocol and FDA regulations, warning that should the FDA become aware of their practices Ventavia would be shut down. See, for example, Am. Comp. at ¶¶ 33, 259, PageID 709-10, 764; Ex. 3 at 14, PageID 807. The Ventavia representative that interrogated Relator prior to termination admitted that the photographs Relator took documenting protocol and regulatory violations were "proof that […] this is a problem**.**" Am. Comp. Ex. 3, PageID 802. The same day Relator called the FDA hotline to report violations, Ventavia fired her. Am. Comp. at ¶¶ 262-3.

For these reasons the Court should deny Ventavia's arguments against Relator's well-pled retaliation claim.

Section 7. The Agreement is not properly authorized under 10 U.S.C. § 2371b ("OTA") and should be treated as a traditional acquisition and subject to FAR.

"Title 10, Chapter 139 of the United States Code provides the authority for the Department of Defense to conduct acquisitions pertaining to research and development. *See* 10 U.S.C. ch. 139 ('Research and Development'). […] Section 2371 of Title 10 states that the respective leader of each military department 'may enter into transactions (other than contracts, cooperative agreements, and grants) under the authority of this subsection.' 10 U.S.C. § 2371(a). This authority applies only to 'basic, applied, and advanced **research projects**.' 10 U.S.C. § 2371 (emphasis added). In 2015, Congress amended Title 10 to provide additional authority to the Department of Defense, adopting Section 2371b. *See* National Defense Authorization Act for Fiscal Year 2016, Pub. L. No. 114-92, § 815, 129 Stat. 726, 893.

The authority for the Agreement, claimed under 10 U.S.C. § 2371b, now known as 10 U.S.C.A. § 4022, reads:

> (a) Authority.--(1) Subject to paragraph (2), the Director of the Defense Advanced Research Projects Agency, the Secretary of a military department, or any other official designated by the Secretary of Defense may, under the authority of section 4021 of this title, carry out **prototype projects** that are directly relevant to enhancing the mission effectiveness of **military personnel** and the supporting platforms, systems, components, or materials proposed to be acquired or developed by the Department of Defense, or to improvement of platforms, systems, components, or materials in use by the armed forces (emphasis added).

In the few cases where OTA prototype authority has been mentioned, a stark difference presents itself. *MD Helicopters Inc. v. U.S.*, 435 F. Supp. 3d 1003, 1005 (D. Ariz. 2020), involved production of a prototype advanced attack helicopter. *Space Expl. Techs. Corp. v. U.S.*, 219CV07927ODWGJSX, 2020 WL 7344615, at *2 (C.D. Cal. Sept. 24, 2020), involved proposals to increase the pool of satellite launch vehicles to meet the Air Force needs. Both cases involved prototype projects directly relevant to the mission effectiveness of military personnel. A contract to produce and distribute hundreds of millions of vaccine doses to the general public is not "directly relevant" to enhancing the military's mission effectiveness. See 10 U.S.C.A. § 4022, mandating the "prototype project" be "directly relevant" to enhancing the mission effectiveness of military personnel.

This Agreement was not, in truth, to develop a prototype; it was to acquire a vaccine for distribution to the general public. How will the general public react to learning safeguards for the injection they received were bypassed because government bureaucrats decided to label an agreement in an obscure way? Is protection and enrichment of big pharma more important than the safety of American citizens? The Agreement is subject to FAR despite superficial labels. The contract states "An OTA is being proposed with the purpose of conducting Research and Development into medical, pharmaceutical, and diagnostic technologies to enhance mission effectiveness of military personnel." See Doc. 37-1, PageID 1425. Somehow still this shot ended up in many more people than just military personnel.

Courts "have long looked to the *contents* of the agency's action, not the agency's self-serving *label*." *Azar v. Allina Health Services*, 139 S. Ct. 1804, 1812 (2019). OTA cannot be used to skirt requirements imposed by the FAR. Pfizer's deal with the Government is subject to FAR. This was a traditional acquisition and intended for distribution to the American people. For this reason Pfizer's OTA argument fails.

Section 8. Relator's Twitter posts do not warrant dismissal.

No court has ever dismissed a qui tam claim because a Relator disclosed its existence after the government had formally announced the end of its pre-intervention investigation. This is because courts focus on the purpose of a seal–to protect the government's pre-intervention investigation. Yet, that is precisely what the unharmed Respondents demand this court do.

Relator disputes the claimed seal breach. At this stage, it is irrelevant because it is a disputed factual claim outside the four corners of the pleadings. Equally, the seal only protects the existence of the suit, not the underlying facts. Furthermore, the seal solely exists for the government to have time to investigate and make an intervention decision; the lawsuit itself was never publicly disclosed and Respondent's disputed, outside-the-record claim concerns a vague tweet that only occurred after the reason for the seal no longer existed–after the government formally announced the end of its pre-intervention investigation and formally declined intervention.

Regardless, the seal exists solely to protect the government's interests, not Respondents' interests. To the contrary, unsealing the suit benefits the Respondents because the seal is to keep Respondents in the dark. The idea that unsealing, which profits Respondents, would be grounds for dismissal is absurd. No court has ever supported such a claim.

A seal violation that does not prejudice the government can never mandate dismissal of a relator's complaint. *State Farm Fire and Cas. Co. v. U.S ex rel. Rigsby*, 580 U.S. 39 (2016); *United States v. Montalvo–Murillo*, 495 U.S. 711, 718 (1990). Cognizant of this purpose, Congress deliberately excluded unsealing as grounds for dismissal. See *Marx v. General Revenue Corp.*, 568 U.S. 371, 384, 133 S. Ct. 1166, 185 L.Ed.2d 242. This is because the sealing requirement was not implemented to prevent whistleblowers from exposing fraudulent schemes against the government; indeed "the sealing requirement was added to the False Claims Act in 1986 as part of Congress's overall effort to reinvigorate the private bar to take on False Claims Act cases." *U.S. ex rel. Bibby v. Wells Fargo Home Mortg. Inc.*, 76 F. Supp. 3d 1399, 1410 (N.D. Ga. 2015). "A rule mandating dismissal for any seal violation would not . . . further the statutory purpose of the 1986 amendments." *Id.*

The seal provision serves several purposes: "(1) to permit the United States to determine whether it already was investigating the fraud allegations (either criminally or civilly); (2) to permit the United States to investigate the allegations to decide whether to intervene; (3) to prevent an alleged fraudster from being tipped off about an investigation; and, (4) to protect the reputation of a respondent in that the respondent is named in a fraud action brought in the name of the United States, but the United States has not yet decided whether to intervene." *Am. C.L. Union v. Holder*, 673 F.3d 245, 250 (4th Cir. 2011). How absurd would it be for an alleged fraudster who profits from unsealing to then use the very fact of unsealing to preclude the people from ever obtaining their day in court and a trial by jury!

When contemplating a seal violation, the district court focuses on "whether the Government was actually harmed" by the disclosure. *U.S. ex rel. Lujan v. Hughes Aircraft Co.*, 67 F.3d 242, 245 (9th Cir. 1995). The delay in the release of the existence of the suit is meant to provide the government with the opportunity to investigate. When Relator allegedly

violated the seal, the government knew of the suit for more than twelve months and had already declined to intervene. The release did not "incurably frustrate[]" the purpose of the seal nor cause "irreparable harm" to the government. *United States ex rel. Pilon v. Martin Marietta Corp.*, 60 F.3d 995, 1000 (2d Cir. 1995).

Compare this case to *U.S., ex rel., Rigsby v. State Farm Fire & Cas. Co*, where the Fifth Circuit held, and the Supreme Court affirmed, that relators' violations of the seal requirements did not warrant dismissal of relators' qui tam action. *U.S., ex rel., Rigsby v. State Farm Fire & Cas. Co.*, 794 F.3d 457, 471 (5th Cir. 2015), *aff'd sub nom. State Farm Fire & Cas. Co. v. U.S ex rel. Rigsby*, 580 U.S. 39, 137 S. Ct. 436, 196 L. Ed. 2d 340 (2016). In *Rigsby,* relators and their attorneys committed far more serious violations of the seal provision than alleged here. Following filing of the sealed complaint in April 2006, the *Rigsby* relators "disclosed the existence of the lawsuit to several news outlets" by emailing copies of evidence that included the case caption, sat for interviews regarding the action, and informed a state congressman of the lawsuit. *Id.* at 471. These activities occurred before the seal was lifted more than a year after the suit was filed. *Id.* Although the court held the Rigsbys violated the seal, it found the government was not harmed because relators did not "imperil[]" a "fundamental purpose of the seal requirement - allowing the government to determine whether to join the suit without tipping off a defendant." *Id.* at 472. Additionally, the court found the violations were "considerably less severe" because they "did not involve a complete failure to file under seal or serve the government." *Id.*

In *Smith v. Clark/Smoot/Russell,* although the relator violated the seal by notifying a respondent of the filing of the complaint while the complaint was under seal, the court held that the breach did not "incurably frustrate" the purpose of the seal requirement, and thus did not support dismissal of the relator's claim with prejudice, where the "government was still

able to investigate the alleged fraud and determine whether it was already investigating the same issue." 796 F.3d 424, 430 (4th Cir. 2015).

No harm to the Government came from Relator's Twitter posts. As such, Relator's Twitter posts are not deserving of the sanction of dismissal, nor is the sanction supported by law.

Section 9. Relator requests leave to amend if the Court is inclined to grant any motion to dismiss.

Should the Court find any of Respondent's arguments persuasive to the extent the Amended Complaint, or any claim, or party may be dismissed, but also find any alleged defect may be cured, Relator requests the opportunity to submit a Second Amended Complaint consistent with Fed. R. Civ. P. 15 and this Court's decision.

If necessary, Relator's areas of personal knowledge to expand the detail of the Complaint are as follows:

1. Relator can add Pfizer's interference with medical charting as indicated in the electronic Case Report Form (eCRF) audit trials;
2. Relator can expand on widespread unblinding violations that irreparably tainted the study;
3. Relator can submit additional outcome data on mRNA injection benefits, or lack thereof, and additional allegations as to misbranding of the end product;
4. Relator can cite individual patient data or source documents which show clinical trial data was falsified such as inclusion and exclusion criteria;
5. Relator can demonstrate violation of record retention protocols due to records destruction (spoliation) to hide problems like unblinding.

Despite the ability to make numerous additions, Relator cannot anticipate where the Court may find the Amended Complaint lacking, if at all. Relator asserts the Amended Complaint

sufficiently states the claims pled. However, Relator respectfully requests the opportunity to amend if the Court is inclined to grant any of Respondents' motions.

CONCLUSION

Relator's Amended Complaint sufficiently pleads the necessary elements under the False Claims Act. This case should proceed to discovery as it is in the interests of the taxpayers of the United States and the interest of justice.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 22 day of August 2022 a true and correct copy of the foregoing document was filed electronically in compliance with Local Rule CV-5. All counsel of record consented to electronic service and are being served with a copy of this document through the Court's CM/ECF system under Local Rule CV-5(a)(3)(A).

Respectfully submitted,

/s/ Lexis Anderson
Lexis Anderson