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

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

RELATOR'S OPPOSITION TO DEFENDANTS' MOTIONS TO DISMISS

TO THE HONORABLE JUDGE OF THE COURT:

Relator Brook Jackson ("Relator") files this opposition as a combined response to Defendants Pfizer, Inc.'s ("Pfizer"), Icon, PLC's ("Icon"), and Ventavia Research Group, LLC's ("Ventavia") motions to dismiss [ECF Nos. 119, 120, and 121].

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CONSTITUTION

CASES

STATUTES

RULES

INTRODUCTION

"The right to search for truth implies also a duty; one must not conceal any part of what one has recognized to be true." - Albert Einstein

Pfizer promised a vaccine to inoculate against and prevent the infection and transmission of Covid-19, one which was shown to meet the objective standards for Emergency Use Authorization as required by Congress. Pfizer's contract with the Government required it to obtain such authorization from the FDA through honest reporting of its clinical trials. Instead, Pfizer fabricated and falsified the reports and results, obtaining the authorization through fraud. What Pfizer delivered was a dangerous, ineffective drug that did not prevent transmission, infection or even therapeutically treat Covid-19, as honest reports to the FDA would have revealed. Brook Jackson was the first to witness this directly at the clinical trial sites, raised her concerns directly with the defendants, but was fired instead. This *qui tam* claim followed.

The Pfizer "vaccines" fail to accomplish the principal benefits for which they were authorized and paid for: prevent infection with SARS-Cov-2 or stop transmission of Covid-19 from one individual to another. Data indicate the injections have "negative efficacy" -- the more doses a person receives, the more likely that person will get sick with Covid-19. Worse, Pfizer's Covid-19 vaccines have staggering "downsides." Since the biologics were authorized, they have caused an alarming increase in spike-protein diseases, including heart and blood disorders, cancers, autoimmune diseases, neurological diseases, fertility disorders, and deaths.

Relator Jackson contends that well-controlled clinical trials of Pfizer's Covid-19 vaccines would have revealed, prior to authorization, that the product failed to confer benefits and caused significant harm. Furthermore, Ms. Jackson alleges Pfizer knew this and knew it could not legitimately obtain U.S. Food and Drug Administration (FDA) approval or authorization.

Under the Emergency Use Authorization (EUA) statute, 21 U.S. Code § 360bbb–3(c), Congress required an objective basis to believe, based on the totality of scientific evidence available, that the "known and potential benefits" outweigh the "known and potential risks." Adequate and well-controlled clinical trials would have been a big part of the available scientific evidence. They would have revealed the lack of benefits for Pfizer's Covid-19 vaccines and significant potential risks– foreclosing the FDA's issuance of an EUA.

As indicated by the Albert Einstein quote above, inherent in the scientific search for truth is a duty to disclose, and not conceal, any part of what is shown to be true. Relator Jackson alleged Pfizer abandoned the scientific method and the search for truth to induce FDA's authorization of its modRNA biologic to enable it to sell the United States 100 million doses (for $1.9 billion). Ms. Jackson has alleged Pfizer engaged in fraud in the design, conduct, analysis and reporting of its clinical trials, and in statements it made to FDA.

In her Second Amended Complaint (SAC), Ms. Jackson details her knowledge of the particular circumstances in which Pfizer engaged in clinical trial fraud to induce FDA's issuance of the EUA. Among other things, this includes a trial design to avoid disclosure on immunity and transmission; short-cutting the study to conceal negative efficacy and serious adverse events; manipulation of inclusion and exclusion determinations to reach predetermined results; unblinding of subject status and then falsely reporting the occurrence or non-occurrence of adverse events based on the subject's disclosed status; and suppression of available alternatives. Ms. Jackson saw this conduct first-hand as a Regional Director at Defendant Ventavia Research Group, which ran three test sites in Pfizer's clinical trial. She pleads her own observations of material deviations from protocol as representative examples of the fraud committed by Pfizer alleged in the SAC.

Defendants now move to dismiss the SAC by challenging Ms. Jackson's "fraud on the FDA" theory of liability under the False Claims Act. However, Pfizer ignores a body of law supporting this theory, including authorities cited by the Government in its previous statement of interest (ECF Doc. 70). Pfizer also claims Relator's allegations are "implausible," but this argument misstates federal pleading requirements. It also overlooks increasing scientific evidence and respected expert opinions showing Pfizer's fraud was not only plausible, but provable. Furthermore, Ms. Jackson alleges Ventavia and Icon, contracted to manage the clinical trials, knew the trials were neither adequate nor well controlled and were designed to provide data that would achieve the issuance of an EUA. She saw that, despite her efforts to properly run a clinical trial, Ventavia and Icon ignored good clinical trial practices causing submission of unreliable data to the FDA that hid the risks of these vaccines and the lack of benefits. Finally, Pfizer poses constitutional challenges to Relator's standing under the False Claims Act, ignoring the uniform holding of the Circuits, including the Fifth Circuit, rejecting arguments based on Article II and Article III.

STATEMENT OF THE CASE AND SUMMARY OF RELEVANT FACTS

With the Court's leave, the parties are before the Court to resolve Count I of the SAC - Fraud in the Inducement and Ms. Jackson's employment claims at Counts V and VI. Counts II, III, and IV were ruled on previously and are included in the SAC to preserve those arguments for appeal. The prior briefing is incorporated by reference.

In Ms. Jackson's prior response to the first Motions to Dismiss, she reviewed the history of Pfizer's pledge to meet FDA requirements for conducting clinical trials and to seek FDA approval or authorization if the "… clinical data supports such application for approval or authorization." SAC, ¶ 126. She also demonstrated that, as defined by the project's "Statement

of Work," Pfizer's only material requirement in its DOD prototype vaccine contract was to obtain FDA approval of an EUA before claiming or receiving money from the Government under the contract. SAC, ¶ 125.

The FDA's EUAs are issued under Section 564 of the Federal Food, Drug, and Cosmetic Act. In 21 U.S. Code § 360bbb-3, Congress established objective material standards to be met by providers of medical products in emergencies and for the HHS Secretary to issue an EUA. In pertinent part, with emphasis supplied, the statute reads:

> 1. An agent referred to in a declaration under subsection (b) can cause a serious or life-threatening disease or condition;
> 2. Based on the t**otality of scientific evidence** available to the Secretary, including data from **adequate and well-controlled clinical trials**, if available, it is **reasonable to believe** that-
>
> (A) the product **may be effective** in diagnosing, treating, or **preventing**—
>
> (i) **such disease** or condition; or
>
> (ii) a serious or life-threatening disease or condition caused by a product authorized under this section, approved or cleared under this chapter, or licensed under section 351 of the Public Health Service Act [42 U.S.C. 262], for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and
>
> (B) **the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product,** taking into consideration the material [national security] threat posed by the agent or agents identified in a declaration under subsection (b)(1)(D), if applicable;
>
> 3. that **there is no adequate, approved, and available alternative to the product** for diagnosing, preventing, or treating such disease or condition.

When Pfizer entered its contract with the Government, and certainly when it submitted applications and information to FDA for approval and authorization, it knew well-controlled clinical trials would show the lack of benefit and overwhelming potential risks associated with its modRNA Covid-19 biologics. For example, Pfizer knew the premise of its modRNA vaccine was flawed. Blood-borne antibody responses provide little or no protection or immunity from respiratory diseases. Worse, real time clinical and epidemiological data show Pfizer's vaccines

have negative efficacy: the more shots people received of the Covid-19 vaccine, the more likely they would contract Covid-19. *See* SAC, ¶135 (discussing Harvard and Cleveland Clinic studies). This negative efficacy is explained by such immunological phenomena as "Antibody Dependent Enhancement," or ADE; antibody bridging between the virus and the cell receptors; immune tolerance caused by a class switch towards non-inflammatory IgG4 antibodies; and long term T-cell and B-Cell dysfunction leading to Vaccine Acquired Immune Deficiency Syndrome, or VAIDS. *See* SAC, ¶136.

Besides not providing immunity from Covid-19, much harm is caused by Pfizer's Covid-19 vaccines. Adverse events reported in the first 90 days following the public rollout were staggering. Since Pfizer's vaccines were introduced, there have been alarming rates of spike-protein diseases, and individuals who receive the injections suffer statistically significant higher rates of heart and blood disorders (including myocarditis, pericarditis, pleural effusion and congestive heart failure), autoimmune diseases (including rheumatoid arthritis, vasculitis, encephalitis, neuropathy and demyelination), prion like diseases (such as Creutzfeldt Jakob Disease and Alzheimer's Disease) other neurological diseases (such as strokes, seizures, multiple sclerosis, neuritis, Guillain Barre syndrome, meningitis), immune dysfunction and cancers (including IgG4 induced tolerance), and fertility, pregnancy and menstrual disorders (including spontaneous abortions, premature birth with neonatal death, fetal demises, abnormal uterine bleeding, vaginal hemorrhaging and post-menopausal bleeding, breast pain and swelling, genital pain and dysfunction, and low sperm counts and mobility). *See* SAC, ¶137.

Nine months after the rollout of the Covid-19 injection, substantial birth rate drops were seen in 13 European countries, including England, Wales, Australia, and Taiwan. Indeed, pregnant women are more likely to experience a miscarriage if they receive a Covid-19 vaccine

compared to any other vaccine. According to the Vaccine Adverse Event Reporting System (VAERS), from 1990 through March 2022, miscarriages were reported 4,693 times by women vaccinated for all diseases through March 2022. *See* SAC, ¶138. Seventy-six percent of VAERS reports of miscarriage were made since the Covid-19 vaccine rollout.[1] There are likely far more post-vaccination miscarriages than reported to VAERS. Pre-pandemic research showed adverse events following vaccination were underreported by a large margin.[2]

Given the lack of benefit and so many adverse events, how could Pfizer have obtained authorization, under Congress's objective standards, so that it could claim billions of American dollars from the Government? To understand the answer to that question, we must examine how Pfizer engaged in fraud in the design, conduct, analysis and reporting of its clinical trials and induced the FDA to issue an EUA.

Relator alleged Pfizer committed fraud on the FDA through its design, conduct, analysis and reporting of its clinical trials, and through false statements and material omissions in its applications, forms, reports, and data submissions. The particular circumstances of this fraudulent conduct are detailed in the SAC.

Pfizer designed the clinical trials to conceal that mod-RNA vaccines stop neither infection nor transmission; Pfizer used a faulty PCR test which it knew could be manipulated and would not confirm Covid-19 sickness; Pfizer cut the trials short to avoid reporting negative efficacy and serious adverse events and destroyed the control group by offering them injections

[1] https://openvaers.com/covid-data/reproductive-health

[2] Ross, Lazarus, et al. "Electronic Support for Public Health–Vaccine Adverse Event Reporting System." Harvard Pilgrim Healthcare for USHHS. 2011 (PDF); Shimabukuro, T, et al. "Safety monitoring in the Vaccine Adverse Event Reporting System (VAERS)." *Vaccine* 2015, 33;36: 4398-4405. Doi: 10.1016/j.vaccine.2015.07.035; Zhou, Weigong, et al. "Surveillance for Safety After Immunization: Vaccine Adverse Event Reporting System (VAERS) – United States, 1991—2001." *MMWR Morb Mortal Wkly Rep.* Jan 24, 2003, 52(ss01);1-24.

after only two months of study; Pfizer lied about the durability of the modified RNA material; and Pfizer purported to exclude pregnant women but the data nevertheless showed serious fetal injuries which Pfizer failed to report. *See* SAC, ¶ ¶140-145.

With respect to design and conduct, Pfizer made false, non-random inclusions and exclusions to the control and study group; Pfizer failed to protect blindness; Pfizer allowed for degradation of the product to reduce the number of injuries in the treatment group; and Pfizer failed to report contamination in the control group. *See* SAC, ¶ ¶146-149.

With respect to analysis and reports, Pfizer did not report adverse events experienced by subjects in the treatment group, including Maddie de Garay who participated in the clinical trial site at Cincinnati Children's Hospital Medical Center and Augusto Roux who participated in the trial in Argentina; Pfizer lied about whether injuries suffered more than six weeks after injection were related to the biologic; Pfizer used relative risk analysis rather than the absolute risk analysis required by the objective EUA standards; and Pfizer falsely counted "vaccinated" as "unvaccinated" when they became sick or suffered an adverse event. *See* SAC, ¶ ¶150-154.

With respect to other statutory prerequisites, Pfizer suppressed information showing that alternative remedies were known to be effective in the prevention and treatment of Covid-19; Pfizer departed from scientific protocol, rendering the data useless to establish any representation of fact; Pfizer departed from ethical requirements, including obtaining informed consent of trial subjects, rendering useless the data provided to FDA. *See* SAC, ¶ ¶155-157.

As a result of this conduct, Pfizer made false material statements to FDA regarding the known and potential benefits of its Covid-19 biologics, regarding the known and potential risks of harm, and its ability to meet the objective standards established by Congress through usable and reliable scientific data. The FDA was unaware of Pfizer's fraudulent conduct, and even after

Relator and others raised concerns, the FDA did not believe Pfizer engaged in the fraud as alleged. But, had Pfizer not engaged in the fraud as identified by Ms. Jackson, it would not have obtained EUA under Congressional standards. *See* SAC, ¶ ¶158-159.

Relator Jackson observed specific deviations from protocol at the clinical trial sites she oversaw. Most notably the unblinding of trial participants at the clinical trial site. SAC, pp. 44-47. This alone renders the data unusable and may explain statistical anomalies that underlie the data. In addition, she witnessed the false manipulation of inclusions or exclusions, the failure to report injuries and death, the false reporting of Covid-19 injections, the failure to account for product degradation and control group contamination, among other aspects of the overall fraud scheme. SAC, pp 41-62. With respect to representative examples of Pfizer's overall scheme, Jackson's allegations of protocol and regulatory violations plausibly provide the particular details on the "time, place, contents, and identity" components. 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.").

In sum, every claim for payment submitted to the United States required the FDA's EUA. To obtain FDA's authorization, Pfizer had to submit a totality of scientific evidence upon which a reasonable belief could be formed that the known and potential benefits outweighed the known and potential harms. As alleged with particularity by Relator, Pfizer and the other Defendants committed clinical trial fraud to induce the FDA to authorize the ineffective and unsafe Covid-19 biologic. Such "upstream fraud" on the FDA taints every claim for payment by Pfizer under the contracts, rendering each claim a violation of the False Claims Act. Through this *qui tam* action,

relator seeks to recover for the United States treble damages and the maximum penalty for each false claim.

LEGAL STANDARDS

Defendants 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 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, Defendants 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 Defendants.

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.

A False Claims Act violation occurs when a defendant knowingly presents a false claim for payment or approval. See 31 U.S.C. § 3729. In *United States ex rel. Longhi v. Lithium Power Techs., Inc.*, the Fifth Circuit imposed False Claims Act liability on a payee for fraudulently inducing the Government to pay a claim. 575 F.3d 458 (5th Cir. 2009). The *Longhi* test for fraudulent inducement under the False Claims Act is: (1) a false statement or fraudulent course of conduct; (2) made with scienter; (3) that was material; (4) that caused the government to pay out money (i.e., that involved a claim). Id. at 467. In *Longhi*, like here, the defendant's claims for payment were preceded by false statements in grant proposals and did not submit false claims for payment. *Id.* Rather, the *Longhi* defendant submitted false statements in grant proposals submitted to the Department of Defense. *Id.* at 470-72. The DOD awarded the defendant grants based on the false statements and paid money for work the defendant performed. *Id*. The Fifth Circuit found a violation of the FCA under the test it established, while emphasizing the principle that "FCA liability may be imposed 'when the contract under which payment is made was procured by fraud.'" *Id*. at 467-68.

For the following reasons under the above-stated legal standards, Defendants fail their burden to compel this Court to dismiss Relator's second amended complaint.

ARGUMENT

I. Relator Adequately Pleads a Claim of Fraud on the FDA

In its motion to dismiss the SAC, Pfizer challenges the viability of Relator's theory of liability based on fraud on the FDA to induce issuance of the EUA. According to Pfizer, the "Fifth Circuit has only recognized the fraudulent inducement theory in the context of fraudulent procurement of Government contracts, not fraudulent procurement of regulatory approvals, as alleged here." ECF No. 119, PageID #: 5165**.** Pfizer does not show the Fifth Circuit would abandon the approach adopted by courts recognizing "fraud on the FDA" as a basis of liability, including the authorities cited by the Government in its previous statement of interest in this case. *See* ECF 70, at 8. Nor does Pfizer address the crux of Relator's claim: since the EUA was a material condition for getting paid on the contract with the United States, fraud on the FDA to obtain the EUA is fraud in the inducement of the contract's material component.

Pfizer's narrow view of the scope of the False Claims Act is mistaken. "The False Claims Act is the primary law on which the federal government relies to recover losses caused by fraud." *McNutt ex rel. United States v. Haleyville Med. Supplies, Inc*., 423 F.3d 1256, 1259 (11th Cir. 2005). Known originally as "Lincoln's Law," the Act was passed during the Civil War, providing for damages and penalties against those who falsely or fraudulently claim federal funds. The Act imposes treble damages and penalties on any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" to the United States, § 3729(a)(1)(A). "Knowingly" is defined as "actual knowledge," "reckless disregard," or "deliberate ignorance" as to the truth of the information, and the Act expressly requires "no proof of specific intent to defraud," § 3729(b)(1).

As drafted in 1863, the False Claims Act "was intended to reach all types of fraud, without qualification, that might result in financial loss to the Government." *United States v. Neifert-White Co*., 390 U.S. 228, 232 (1968).

> The Act was [] broadly phrased to reach any person who makes or causes to be made 'any claim upon or against' the United States, or who makes a false 'bill, receipt, [or] claim,'[] for the purpose of 'obtaining or aiding to obtain the payment or approval of' such a false claim. In the various contexts in which questions of the proper construction of the Act have been presented, the Court has consistently refused to accept a rigid, restrictive reading, even at the time when the statute imposed criminal sanctions as well as civil. *See, e.g.*, *United States ex rel. Marcus v. Hess*, 317 U.S. 537 (1943). [*Id.*]

See Rainwater v. United States, 356 U.S. 590, 592 (1958) (the original Act was worded "broadly to protect the funds ... from fraudulent claims, regardless of the particular form, or function, of the government instrumentality upon which such claims were made"). In 1986, the Act was amended to make it "the Government's primary litigative tool for combating fraud" "in modern times." S. Rep. No. 99-345, at 2, 1986 U.S.C.C.A.N. 5266. *See also* H. Rep. No. 99-660, at 18 (1986) (Act "used as the primary vehicle by the Government for recouping losses suffered through fraud" and it is "important that it be an effective tool for recouping these losses").

Relator's "fraud in the inducement" theory explains why a claim can be "false or fraudulent" even where the underlying claim for payment is not false on its face, nor makes a false certification. *See United States ex rel. Laird v. Lockheed Martin Eng'g & Sci. Servs. Co.*, 491 F.3d 254, 259 (5th Cir. 2007) (recognizing the fraud in the inducement theory under the FCA in a bid-rigging case). Consistent with this theory, a viable False Claims Act claim may be based on materially false or fraudulent statements made to FDA related to a drug or vaccine authorization or approval. For example, if a manufacturer makes false statements to FDA about its product, and those false statements actually cause FDA to authorize or approve the product (*i.e.*, where FDA would not have taken those actions had it known the truth), then the Act may be violated. That is, liability is possible if the Defendant's fraud actually induced FDA to authorize or approve a product, thereby improperly rendering it eligible for subsequent payment by the Government. *See United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 902-04 (9th

Cir. 2017) (holding defendant's alleged misrepresentations to FDA rendered each subsequent claim for payment for the drug false or fraudulent under a fraud in the inducement or promissory fraud theory); *United States ex rel. Brown v. Pfizer, Inc.*, No. CV 05-6795, 2017 WL 1344365, at *9-10 (E.D. Pa. Apr. 12, 2017) (holding complaint stated a claim under fraud in the inducement theory where facts alleged demonstrated how defendant's alleged misrepresentations to FDA regarding clinical study results caused FDA to approve the drug); *United States ex rel. Higgins v. Bos. Sci. Corp.*, 2017 U.S. Dist. LEXIS 138767, at *24-25 (D. Minn. Aug. 29, 2017) ("the Eighth Circuit Court of Appeals has applied the fraudulent inducement theory to False Claims Act claims, and has given no indication that the theory would not apply to such claims where the allegedly false representations were made to the FDA as a link in the causal chain to the extension of Medicare or other government benefits") (citation omitted).

Like the fraudulent inducement of the underlying contract, "subsequent claims are false because of an *original fraud*," even if the subsequent claim for payment is not false on its face. *United States ex rel. Hendow v. University of Phx.*, 461 F.3d 1166, 1173 (9th Cir. 2006). *See also In re Baycol Prods. Litig.*, 732 F.3d 869, 876 (8th Cir. 2013) ("[A] claim alleging fraud in the inducement of a government contract . . . focus[es] on the false or fraudulent statements which induced the government to enter into the contract at the outset."); *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 787-88 (4th Cir. 1999) (explaining that there may be instances in which claims for payment are "not in and of themselves false," but False Claims Act liability attaches "because of the fraud surrounding the efforts to obtain the contract or benefit status, or the payments thereunder").

In this case, Relator alleges fraud at the most crucial step in obtaining payment under the contract with the Government – the FDA's grant of Emergency Use Authorization. When a

material condition of a contract is procured by a fraud on the Government, fraudulent inducement has occurred. Pfizer argues "other judges have questioned whether fraudulent inducement remains a viable theory following the Supreme Court's instruction in *Escobar*" but cites only one judge's concurring opinion in *United States ex rel. Cimino v. Int'l Bus. Machines Corp.*, 3 F.4th 412 (D.C. Cir. 2021), a post-*Escobar* decision upholding fraudulent inducement as viable under the FCA. Further, as explained in *U.S. ex rel. Bid Solve, Inc. v. CWS Mktg. Group, Inc.*, 567 F. Supp. 3d 59 (D.D.C. 2021), *Escobar* involved "a false presentment theory of liability, not a fraudulent inducement theory." *Id*., at 74, citing *Cimino*, supra, distinguishing *Escobar*. Regardless, Pfizer acknowledges that fraudulent inducement in the FCA context is a viable claim in the Fifth Circuit. See Pfizer MTD, Doc. 119, PageID # 5165, citing *Gonzalez v. Fresenius Med. Care N. Am.*, 689 F.3d 470, 476 (5th Cir. 2012) (quoting *United States ex rel. Longhi v. Lithium Power Techs., Inc.*, 575 F.3d 458, 467–68 (5th Cir. 2009)); *United States ex rel. Willard v. Humana Health Plan of Texas, Inc.*, 336 F.3d 375, 384 (5th Cir. 2003); *United States ex rel. Laird v. Lockheed Martin Eng'g & Sci. Servs. Co.*, 491 F.3d 254, 259 (5th Cir. 2007).

Pfizer asserts that fraudulent inducement is only recognized where a contract is induced by fraud, not regulatory approval. The distinction between a regulatory fraud and the fraudulent inducement of a contract is a red herring. The FCA does not distinguish between a fraud committed on one agency of the United States Government over another. Here, Relator indeed alleges fraudulent procurement of government contracts, the mechanism of which was fraudulent procurement of regulatory approval. It is not necessary to expand recognition of the fraudulent inducement theory because this case fits the existing theory.

Pfizer has argued that a fraud on the FDA which led to the grant of an EUA does not matter as the contract with the DOD only demanded an EUA be granted. Relator alleges fraudulent inducement on the Government, however, and for purposes of the FCA there is no meaningful distinction between a fraud on the FDA and a fraud on the DOD.

The FDA is not an independent federal agency, but one under HHS. Only the Secretary of HHS is authorized to make rules under the Food Drug and Cosmetic Act. 21 USC 371. "[B]efore a rule can be proposed or promulgated by FDA it must be reviewed and approved first by the Secretary of HHS and then by OMB." *Wolfe v. Dept. of Health and Human Services*, 839 F.2d 768, 770 (D.C. Cir. 1988). Both the DOD and HHS are executive departments of the United States. 5 USC § 101. A fraud on the FDA, under the control of HHS, inducing a material condition for payment on the contract with the DOD, is a fraud on the United States Government. Summarily, upstream fraud inducing the FDA to grant EUA as a material condition for claiming payment on the contract results in False Claims Act violations every time Pfizer makes a downstream claim for payment.

II. Relator Pleads a Plausible Claim of False Claims Act Violations, Including Facts Establishing Materiality

A. Relator Has Sufficiently Plead Plausible Claims

Pfizer argues that the claim for fraudulent inducement is not a viable theory and that the facts alleged are implausible. ECF No. 119 at 119-120. Pfizer paints Relator's 386-paragraph second amended complaint as devoid of plausible or common-sense allegations. It contends that it is implausible the Government would fast-track a vaccine product, purchase hundreds of millions of vaccines, and make continued purchases, if Relator's allegations were true.

To survive a motion to dismiss, the Supreme Court has established that "a complaint must contain sufficient factual matter, accepted as true, to "state a claim to relief that is plausible

on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S. Ct. 1937, 1949, 173 L. Ed. 2d 868 (2009) (quoting *Bell Atlantic Corp. v. Twombly,* 550 U.S. 544, 570m 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007)). The Court in *Iqbal* held that "[a] claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* at 678. "When there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." *Id.*, at 679. Finding plausibility does not require a finding of probability as to whether a relator will prove the truth of her allegations, but only whether the non-conclusory facts alleged, liberally construed in favor of the relator, plausibly state a claim for relief. *See Innova Hosp. San Antonio, Ltd. P'ship v. Blue Cross & Blue Shield of Ga., Inc.,* 892 F.3d 719, 729 (5th Cir. 2018) ("we adhere to the Supreme Court's admonition that "[t]he plausibility standard is not akin to a 'probability requirement') (quoting *Iqbal*, 556 U.S. at 678, and *Twombly*, 550 U.S. at 556)). Plausibility on Defendants' Rule 12(b)(6) motions cannot become a vehicle to weigh evidence or determine which party may win at trial.

Plausibility of claims is established through the well-pleaded facts in the Relator's SAC. Those facts establish that Pfizer knew risks of potential harm far outweighed the non-existent benefits of the COVID-19 biologics, and that Pfizer could only obtain the EUA through clinical trial fraud. These allegations, accepted as true and liberally construed in favor of Relator, are sufficient to establish both plausibility and materiality at the pleading stage.

Additional overwhelming evidence is coming to light every day from multiple experts who have analyzed data – including data from Pfizer's clinical trials that was pried loose from FDA – exposing Pfizer's clinical trial fraud. For example, with only 170 of the 44,000 trial participants as the study endpoint, it is easy to see that small errors as to infections could result in large

changes in the final estimate of vaccine efficacy and safety. Eliminating seven people would put the numbers below the final analysis efficacy endpoint which accrued after 164 Covid-19 cases–meaning there would not be enough data to conclude the clinical trial.[3] Safety signals were similarly sensitive to small changes in numbers as evidenced by the adverse events reported in Pfizer's Vaccines and Related Biological Products Advisory Committee (VRBPAC) briefing document.[4]

Table 8. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020) – Phase 2/3 (All Subjects) – Safety Population

	Vaccine Group (as Administered)	
Adverse Event	BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	Placebo (N[a]=21631) n[b] (%)
Any event	5770 (26.7)	2638 (12.2)
Related[c]	4484 (20.7)	1095 (5.1)
Severe	240 (1.1)	139 (0.6)
Life-threatening	21 (0.1)	24 (0.1)
Any serious adverse event	126 (0.6)	111 (0.5)
Related[c]	4 (0.0)	0
Severe	71 (0.3)	68 (0.3)
Life-threatening	21 (0.1)	23 (0.1)
Any adverse event leading to withdrawal	37 (0.2)	30 (0.1)
Related[c]	16 (0.1)	9 (0.0)
Severe	13 (0.1)	9 (0.0)
Life-threatening	3 (0.0)	6 (0.0)
Death	2 (0.0)	4 (0.0)

Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event", n = the number of subjects reporting at least 1 occurrence of any event.
c. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (16:29) (Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s091_all_p23_saf

Adding only the severely injured examples of DeGaray (Cincinnati) and Roux (Argentina) to the case analysis could dramatically shift the risk/benefit ratio. SAC, ¶ 150.

This Court may take judicial notice of such documents, not for the truth of the statements contained therein, but to support a finding of plausibility. *See, e.g.*, *Brooks v. Menifee*, 2010 U.S. Dist. LEXIS 19736, at *15 (W.D. La. Mar. 4, 2010) (taking judicial notice of a report issued by the United States Surgeon General, "which catalogues and analyzes various scientific findings regarding exposure to secondhand smoke"); *In re Bayer Corp. Combination Aspirin Prods.*

[3] PFIZER-BIONTECH COVID-19 VACCINE (BNT162, PF-07302048) VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE BRIEFING DOCUMENT MEETING DATE: 10 December 2020. Accessed 12-17-2023 at https://www.fda.gov/media/144246/download, p. 21.
[4] Id.

Mktg. & Sales Practices Litig., 701 F. Supp. 2d 356, 367-68 (E.D.N.Y. 2010) (taking judicial notice of information published on FDA website pursuant to Rule 201(b)); *Barnes v. City of El Paso,* 2023 U.S. Dist. LEXIS 109091, at *17 n.7 (W.D. Tex. June 12, 2023) (taking judicial notice of government reports on police training to determine plausibility of plaintiff's claims).

Judicial notice for such purposes is consistent with the federal pleading requirement for plausibility. *See, e.g., In re Bayer Corp*., 701 F.Supp.2d at 367 ("Although the purpose of a motion to dismiss is to test the legal sufficiency of a plaintiff's claims, taking all the allegations as true and reading them in the light most favorable to the plaintiff, the court is not required to reason in a vacuum"); *Gavin v. Medtronic, Inc.*, 2013 U.S. Dist. LEXIS 101216, at *31-32 & n.111 (E.D. La. July 19, 2013) ("The court must not evaluate the likelihood of the claim's success, but instead ascertain whether the plaintiff has stated a legally cognizable claim that is plausible. In deciding a motion to dismiss, a court may consider ... matters of which judicial notice may be taken").

B. Relator Sufficiently Pleads Facts of Materiality

Pfizer argues that the government's continued payment for modRNA injections, and the absence of any withdrawal of the EUA by the FDA, negates any showing by relator as to materiality. As this Court recognized in granting relief under Rule 59(e), however, Relator's allegations that the Government did not know of the fraud alleged in the second amended complaint, and did not believe the allegations by relator to be true, reasonably gives rise to the inference that "FDA did not have actual knowledge of Defendants' alleged statutory, regulatory, or contractual violations." ECF 108, at 3. Thus, it is "unclear whether the Government's continued authorization and/or payment" is "strong evidence" negating a showing of materiality at the pleading stage. *Id*.

Perhaps even more important, the scope and scale of Pfizer's clinical trial fraud is still emerging. What can be seen so far, and what relator alleges in her second amended complaint, is that Pfizer engaged in fraud in the design, conduct, analysis and reporting of its clinical trials to conceal the truth about the modRNA product: they do not prevent disease, infection or transmission, they actually make people more vulnerable to COVID-19, and they pose a staggering risk of serious medical harm. As addressed above, the EUA statute imposes objective criteria on what is material to the issuance of the EUA. Relator's allegations that Pfizer's clinical trial fraud impacted the totality of scientific evidence, and that it upset the balance of benefits and harm, establish as a matter of law that fraud in the clinical trials was material to the FDA's decision to issue the EUA. Pfizer's fraud was thus material to its claim for payment.

Whether or not the Government was fully aware of the fraud, and whether or not it has recalled or stopped payment under the contract, Relator alleges Pfizer's conduct could influence, and indeed was determinative, of the right to payment according to the objective criteria established by Congress in the EUA statute.

III. Relator Has Standing To Pursue This Case Under *Qui Tam* Provisions of the False Claims Act

Relying on the dissenting opinions of a minority of Supreme Court justices, Pfizer argues that the *qui tam* provisions of the FCA violate the "Appointments Clause" and "Take Care Clause" of the U.S. Constitution's Article II, depriving Ms. Jackson of standing to continue this suit under Article III. *See United States ex rel. Polansky v. Exec. Health Res., Inc.*, 599 U.S. 419, 143 S. Ct. 1720, 1737 (2023) (JUSTICE THOMAS, dissenting). These constitutional arguments lack merit, and should be rejected by the Court.

Pfizer's Article II contentions have been unanimously rejected by every Circuit Court of Appeals to consider them, including the Fifth Circuit. *See United States ex rel. Stone v. Rockwell*

Int'l Corp., 282 F.3d 787, 804-05 (10th Cir. 2002); *Riley v. St. Luke's Episcopal Hosp.*, 252 F.3d 749, 757-58 (5th Cir. 2001) (en banc); *United States ex rel. Taxpayers Against Fraud v. Gen. Elec. Co.*, 41 F.3d 1032, 1041 (6th Cir. 1994); *United States ex rel. Kelly v. Boeing Co.*, 9 F.3d 743, 757-59 (9th Cir. 1993); *see also Yates v. Pinellas Hematology & Oncology, P.A.*, 21 F.4th 1288, 1312 (11th Cir. 2021). Subsequent to dissent in *Polansky*, one district court also determined these Article II arguments to be without merit, in a thorough, well-reasoned opinion supported by the United States. *See United States ex rel. Wallace v. Exactech, Inc.,* 2023 U.S. Dist. LEXIS 207881 (N.D. Ala. Nov. 20, 2023).

And, in *Vermont Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765 (2000), the Supreme Court confirmed that *qui tam* False Claims Act litigants have Article III standing. *Stevens* expressly did not reach Article II arguments, but the Supreme Court's decision under Article III compels a similar conclusion under Article II. Indeed, it is undeniable that the First Congress enacted multiple *qui tam* statutes, indicating the framer's original intent to confer standing on private citizens consistent with Article II. Thus, "[historical] evidence, together with the evidence that private prosecutions were commonplace in the 19th century, . . . is . . . sufficient to resolve the Article II question [before] the Court. . . ." *Wallace*, 2023 U.S. Dist. LEXIS 207881 at *17 (quoting *Stevens*, 529 U.S. at 801 (Stevens, J., dissenting) (citation omitted)).

A. The *Qui Tam* Provisions Are Constitutional Under The Appointments Clause

FCA *qui tam* provisions do not violate the Appointments Clause because Relators are not considered "officers" under Article II. The Appointments Clause specifies the permissible means of appointing "Officers of the United States" to public offices "established by Law." U.S. Const. art. II, § 2, cl. 2. Pfizer argues that the FCA's *qui tam* provisions violate the Appointments

Clause, but that argument has been rejected by the courts cited above, because the assignment to the relator is not an appointment to a federal office. *See e.g.*, *Wallace*, at *10-12 ("*[q]ui tam* relators are not officers under the Appointments Clause"). Where a relator's authorization to litigate is only temporary, they do not wield government power and enjoy no governmental benefits. Moreover, under the False Claims Act, the Government has diverse power to intervene and control the litigation, initially at its own decision, and subsequently for good cause. Relators are not officers under the Appointments Clause, and therefore the FCA does not violate Article II on those grounds. *Id.*

Furthermore, Pfizer's argument is inconsistent with the Supreme Court's decision in *Stevens,* which held that a Relator's statutory entitlement to any share of an ultimate recover can be seen as providing her a "partial assignment of the Government's damages claim" and giving her a concrete personal stake in the disposition of the suit. After addressing standing, the *Stevens* Court held that the FCA does not authorize relators to pursue *qui tam* actions against States because, among other things, actions pursued by relators are "private suit[s]" brought by "private parties." Id. at 780-81 n.9, 786 n.17. The core premise of Pfizer's Appointments Clause argument is inconsistent with the *Stevens* Court's emphasis on relator's personal, private stake. Moreover, the historical evidence of *qui tam* statutes enacted by the First Congress bears directly on the Appointments Clause question presented here. *See Wallace*, *supra.* Relator's personal stake in the litigation inherently means that she is not an "agent" or "officer" of the Government, and thus historic *qui tam* provisions cannot offend Article II's Appointments Clause.

B. The *Qui Tam* Provisions of the FCA Are Not Violative of the Take Care Clause

Similarly, the FCA *qui tam* provisions do not violate the Take Care Clause of Article II. The Take Care Clause provides that the President "shall take Care that the laws be faithfully

executed." U.S. Const. art. II, § 3. The assessment hinges on whether the FCA "disrupts the proper balance between the coordinate branches, the proper inquiry focuses on the extent to which it prevents the Executive Branch from accomplishing its constitutionally assigned functions." *Nixon v. Adm'r of Gen. Servs*., 433 U.S. 425, 443 (1977). Simply put, the FCA does not authorize any action by a *qui tam* Relator that would impede these functions. Regardless of whether the United States intervenes in a given suit, relators' conduct of *qui tam* litigation does not prevent the President from carrying out his constitutional functions—a point on which courts have long agreed. *See Stone*, 282 F.3d at 805-07; *Riley*, 252 F.3d at 752-57; *Taxpayers Against Fraud*, 41 F.3d at 1041; *Kelly*, 9 F.3d at 749-57; *see also United States ex rel. Kreindler & Kreindler v. United Techs. Corp.*, 985 F.2d 1148, 1154-55 (2d Cir. 1993).

Indeed, the Executive Branch has substantial control over False Claims Act cases, and *qui tam* cases do not interfere with those powers. The Attorney General may intervene initially in a *qui tam* case and assume control over the litigation. 31 U.S.C. §3730(b)(4)(A). The Government may settle or dismiss the action "notwithstanding the objections of the person initiating the action," and may elect to pursue the allegations in an alternative forum. *Id.,* § 3730(c)(2)(A), (B); *Id.,* § 3730(c)(5). Even when the Government does not intervene, it retains executive authority in connection with the Act's provisions. It must be kept informed of any major developments, and it may seek to restrict the relator's discovery if it would interfere with a criminal investigation or prosecution by the Government. *Id.,* § 3730(c)(4). The Government may even intervene at a later point in the case for "good cause," or otherwise request that a *qui tam* case not be settled or dismissed without the Attorney General's consent. *Id.* § 3730(c)(3).

In sum, the *qui tam* provisions of the False Claims Act pose no interference to the "Take Care Clause" of Article II. The Government has ample measures to control and involve itself in

qui tam litigation, and the assignment Congress perfected to *qui tam* plaintiffs leaves those measures intact. For these reasons, the Executive's constitutional authority is not impaired by a relator's pursuit of litigation on behalf of her own interests along with those of the Government.

C. Relator Has Article III Standing

Because Pfizer's Article II arguments fail for the aforementioned reasons, Pfizer's claim that Relator lacks Article III standing also fails. Moreover, regardless of the Article II analysis, *qui tam* plaintiffs independently satisfy Article II standing as an assignee of the Government's claim under the controlling authority of *Stevens*, which found history "well nigh conclusive" on that question. 529 U.S. at 776-77. Indeed, the Supreme Court in *Stevens* concluded that there is "no room for doubt that a *qui tam* relator under the FCA has Article III standing." *Id.* at 778. *See Wallace*, 2023 U.S. Dist. LEXIS 207881, at *17.

D. Pfizer's Contention that the Action is Contrary to the Government's Interest is Based on a Misunderstanding of the Government's Statement

Mixed into its constitutional arguments is Pfizer's wishful thinking regarding the Government's interest in this litigation. According to Pfizer, the fact that the Government filed a statement of interest in support of its earlier motion to dismiss Jackson's first amended complaint (ECF 70) demonstrates that the Government is opposed to this lawsuit. Pfizer misunderstands the nature of the Government's statement and it misconstrues its substance. In fact, the Government's statement of interest *supports* the very theory of "fraud on the FDA" presented by Jackson's second amended complaint. *See* ECF 70, at 8 & n.23 (noting the Government's disagreement with Pfizer's legal contentions but saying that the Court need not address them because Jackson had not pleaded a fraudulent inducement claim at that time). Relator suspects that the Government would similarly dispute the Article II contentions put forth by Pfizer here.

At any rate, Jackson's standing in this action is not dissolved by the Government's filing of its previous statement of interest in this case.

IV. Relator States Claims of Unlawful Retaliation

A. Relator States A Claim Under 31 U.S.C. § 3730(h)

Ms. Jackson states a claim for FCA retaliation under 31 USC § 3730(h). The Court dismissed Ms. Jackson's first amended complaint because the allegations of departure from scientific protocol were, in the Court's opinion, insufficient to state a claim under the Act. After granting leave to amend, Ms. Jackson now pleads a viable theory of False Claims Act violations - the departure from protocol and violation of scientific methods was to fraudulently induce the FDA to issue the EUA, which in turn, was a material condition for payment on the contract. Now that relator pleads a viable theory under the Act, there should be no question that Jackson alleges a good faith belief that her efforts were to stop a violation. This is sufficient to afford protection against retaliation under § 3730(h).

Ms. Jackson's motivations cannot be determined at the pleading stage. Ms. Jackson was, however, motivated to stop the fraud being committed on the Government and was thus engaged in a protected activity. Previously the Court found otherwise. See Opinion, Doc. 96, PageID # 2339, citing *Thomas v. ITT Educ. Servs., Inc.*, 517 F. App'x 259, 262 (5th Cir. 2013); *United States ex rel. Johnson v. Kaner Med. Grp., P.A.*, 641 F. App'x 391, 395 (5th Cir. 2016). *Thomas* and *Johnson* were decided on summary judgment. Similarly, Ms. Jackson's motivations for voicing her concerns cannot be conveyed completely in a pleading. The issue demands that a record be built before deciding the fact. For these reasons the Court should not similarly determine Ms. Jackson's motivations in ruling on Ventavia's motion.

Finally, the SAC makes clear that Ventavia knew Ms. Jackson engaged in a protected activity since Ms. Jackson consistently voiced her concerns, including clinical trial violations and

violations of FDA regulations. Ventavia acknowledged that an FDA audit would be bad for the company because, as discovery will show, Ventavia knew a fraud was being committed on the Government in order to acquire the EUA. Ventavia cannot claim ignorance in this situation.

For these reasons Ms. Jackson states a claim for retaliation under 31 USC 3730(h).

B. Relator States a Claim Under Texas Health and Safety Code § 161.134

Texas is an at-will employment state meaning employers and employees may "terminate their relationship at any time for any reason unless they contractually agree otherwise." *Ritchie v. Rupe*, 443 S.W.3d 856, 885 (Tex. 2014). There are exceptions when statues protect workers from retaliatory discharge *Word v. N. Jones Reg'l Health Sys*., No. 05-06-00881-CV, 2007 WL 2421500, at *4 (Tex. App.—Dallas Aug. 28, 2007, no pet.). One such exception is found in the Texas Health and Safety Code; Title 2. Health; Subtitle H. Public Health Provisions; Chapter 161. Public Health Provisions; Subchapter L. Abuse, Neglect, and Unprofessional or Unethical Conduct in Health Care Facilities that states:

> A hospital, mental health facility, or treatment facility may not suspend or terminate the employment of or discipline or otherwise discriminate against an employee for reporting to the employee's supervisor, an administrator of the facility, a state regulatory agency, or a law enforcement agency a violation of law, including a violation of this chapter, a rule adopted under this chapter, or a rule of another agency. Tex. Health & Safety Code § 161.134(a).

A covered entity that retaliates against an employee is liable to the employee for injunctive relief, damages, or both. *Id*. § 161.134(b).

Section 161.134 applies to retaliation for reporting violations of federal law, such as the complaints Brook Jackson voiced to her superiors and to the FDA. *See id*. § 161.134(a) (prohibiting a hospital, mental health facility, or treatment facility from retaliating or discriminating against an employee for reporting "a violation of law [...] or a rule of another agency."); *see also U.S. ex rel. Smart v. Christus Health*, 626 F. Supp. 2d 647, 657 (S.D. Tex.

2009). The elements of a retaliatory discharge claim under § 161.134 are: (1) the plaintiff was an employee of a hospital, mental health facility, or treatment facility; (2) the plaintiff reported a violation of law; (3) the plaintiff reported the violation to a supervisor, an administrator, a state regulatory agency, or a law enforcement agency; (4) the report was made in good faith; and (5) the plaintiff was suspended, terminated, disciplined or otherwise discriminated against by the covered entity. Tex. Health & Safety Code § 161.134.

Ventavia is a qualifying "Treatment facility" under § 161.134 as it offered vaccination and post-vaccination care services. While some courts have found that "treatment facility" as defined in § 161.131 applies only to addiction recovery centers, there is good reason to doubt those decisions. *See*, *Nichols v. HealthSouth Corp.*, No. CIV.A.3:00-CV-1487-P, 2001 WL 1081288, at *3–4 (N.D. Tex. Sept. 12, 2001); *Barron v. Cook Children's Health Care System*, 218 S.W.3d 806, 809 (Tex. App.--Fort Worth 2007). Importantly, § 161.134 applies not only to "treatment facilities" but to a "Hospital" as defined in § 241.003, which includes general hospitals and special hospitals. In the *Mendez* case under the subsequent section § 161.135, covering non-employees, the court permitted a retaliation lawsuit to proceed against a community hospital. *Sweeny Community Hosp. v. Mendez*, 226 S.W.3d 584, 596 (Tex. App. 2007). The inclusion of hospitals within § 161.134 demonstrates the legislative intent that this section reaches any facility where medical care of some type is provided. The definition of "Treatment facility" also includes "a public or private hospital" suggesting the meaning of "Treatment facility" is intended to be broad and encompassing rather than limiting. See § 464.001, incorporated in § 161.131.

Tex. Health & Safety Code § 161.131 incorporates the definition of "Treatment facility" from § 464.001, but does not incorporate the definition of "Treatment." Nor does "Treatment

facility" as found in § 464.001 incorporate the definition of "Treatment" at § 464.001(4). There is no explicit statutory indication "Treatment facility" is intended to be limited to addiction rehabilitation facilities. In addition to what was previously argued, "Treatment facility" as defined in Sec. 464.001(5) also includes an "ambulatory care facility" as well as " any other facility that offers or purports to offer treatment." See § 464.001(K) and (L). Further still, if "Treatment facility" applied only to detoxification centers, it would make little sense to separately list "a detoxification facility" or "recovery center" in defining "Treatment facility" under Health & Safety Code § 464.001(5), as incorporated in § 161.131. It would make less sense to include "health maintenance organization" in the definition of "treatment facility" if it applied only to facilities offering addiction treatment or recovery services. Thus, there is reason to believe that "Treatment facility" includes a broad range of facilities offering medical treatment, not merely addiction recovery or rehabilitation services.

Under Tex. Health & Safety Code § 161.134(f), Ms. Jackson has the burden of proof, except there is a rebuttable presumption her employment was terminated for making a report related to the violations she alleged because her termination occurred before the 60th day after the date she reported Ventavia to the FDA in good faith. Here, Ms. Jackson clearly was terminated within 60 days of her report. Thus, the presumption is she was terminated in retaliation for reporting her violations, though other facts suggest this as well. For instance, Ms. Jackson was terminated hours after she reported Ventavia's violations to the FDA. SAC, ¶¶ 290-91, PageID # 4519. Further, Ventavia withdrew the enrollment pause the day after they terminated Ms. Jackson. SAC, ¶ 294, PageID # 4520.

Ms. Jackson met the requirements of Tex. Health & Safety Code § 161.134 when she reported Ventavia's clinical trial violations and violations of FDA regulations, which were

reports of violations of law and the rules of another agency, i.e., the FDA. Ventavia argues the FDA is not contemplated as "another agency" under § 161.134 but there is no support for that argument. Section 161.143 is intended to protect whistleblowers from retaliation. That the whistleblower might not cite Texas law or the rules of a Texas state agency makes no difference if the whistleblower was, as Ms. Jackson was, attempting to prevent or halt violations of the law or the rules of a regulatory agency to which the violating organization is bound.

Ms. Jackson has sufficiently stated a claim under § 161.134.

C. Relator Should Be Permitted to Plead a Claim for Common Law Tort of Wrongful Termination

Ms. Jackson should be given leave to amend her complaint to plead a common law claim for wrongful termination, based on the facts already pleaded. In *Sabine Pilot Serv., Inc. v. Hauck*, 687 S.W.2d 733 (Tex. 1985), the Supreme Court of Texas found a narrow exception to the employment-at-will doctrine covering "the discharge of an employee for the sole reason that the employee refused to perform an illegal act." *Id*., at 735. Under 18 U.S.C. § 1001 it is a violation of federal law to conceal or make false statements of material facts or make fraudulent representations regarding matters within the jurisdiction of one of the branches of Government.

Ms. Jackson refused to continue on Ventavia's course of clinical trial fraud that Ventavia was concealing, falsifying, and misrepresenting to the FDA. Ms. Jackson called the FDA to report the violations and was terminated hours later. Ventavia apparently did not take issue with Ms. Jackson's numerous internal complaints, perhaps believing she would continue without further incident, but retaliated after Ms. Jackson called the FDA, *i.e.*, after Ventavia knew Ms. Jackson was not going to "play along." Due to Ms. Jackson's refusal to perform illegal acts for Ventavia, she was terminated. Thus, Ms. Jackson may state a claim for wrongful termination under Texas common law and herein requests leave to amend in order to state that claim.

V. Defendants' Other Contentions are Without Merit

Both Icon and Ventavia rely upon the same asserted bases for dismissal as those made by Pfizer regarding fraud in the inducement and sufficiency of relator's allegations. Their motions are defeated for the same reasons stated above.

In addition, Icon contends Relator did not particularly plead facts showing that Icon made, or caused to be made, false statements to the Government. Yet, as explained above, Pfizer submitted claims for payment that were false based upon the upstream fraud on the FDA, and both Ventavia and Icon were the instruments through which that fraud was perpetrated. Moreover, Relator alleges 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. SAC at ¶¶ 13, 128, PageID 4453, 4475.

ii. Icon had access to all trial data from clinical trial participants' source documents via the "Complion" Clinical Trial Management System database. SAC at ¶¶ 35, 269, PageID 4458, 4512-3.

iii. Icon had access to electronic diary data used by participants to record any adverse events. SAC at ¶ 84, PageID 4467.

iv. Icon and Pfizer are responsible for data management of the study, including quality checking. SAC at ¶ 99, PageID 4469; Ex. 7, at 120, PageID 4801.

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. SAC at ¶ 176, PageID 4489 (ineligible participants), ¶ 184, PageID 4492 (unblinding), ¶ 200, PageID 4496 (informed consent), ¶ 206, PageID 4498

(administration), ¶ 207, PageID 4498 (administration), ¶ 208, PageID 4499 (administration), ¶ 216, PageID 4501 (safety and patient monitoring), ¶ 217, PageID 4501-2 (accuracy and completeness off data), ¶ 221, PageID 4503 (accuracy and completeness off data), ¶ 226, PageID 4504 (accuracy and completeness of data), ¶ 230, PageID 4505 (adherence to protocol).

vi. Icon violated 21 C.F.R. § 312.64(b) by failing to immediately report all adverse events to Pfizer. SAC at ¶ 242, PageID 4508.

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. SAC at ¶ 244, PageID 4508.

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. SAC at ¶ 245, PageID 4508.

ix. Icon failed to follow up on one hundred outstanding inquiries about missing or inconsistent data. SAC at ¶ 282, PageID 4517.

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 representations to the Government. Sec. Am. Comp at ¶ 323, PageID 4525. Thus, Relator plausibly pled enough examples of Icon's protocol and regulatory violations for Icon to be included in the overall fraud scheme.

In addition, Icon asserts that Relator fails to allege it acted "knowingly" under the False Claims Act, asserting that Relator's own allegations demonstrate that the clinical trial fraud was *hidden* from Icon. Defendant, however, misunderstands Ms. Jackson's allegations as well as the scienter requirement of the Act. Section 3729(b)'s definition of the terms "knowing" and "knowingly" makes this clear. *See 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: she may demonstrate defendant (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*.

Ms. Jackson sufficiently pleads 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, and Icon shared that 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. Indeed, as alleged in the second amended complaint, the departure from scientific protocol was not mere sloppiness; it was designed and conducted to conceal the negative efficacy and substantial risk of physical harm that adequate and well-controlled clinical trials would have revealed. Icon suggests that the wrongdoing was hidden from it, but Icon had access to all trial data from clinical trial participants' source documents via the "Complion" Clinical Trial Management System database. SAC at ¶¶ 35, 269, PageID 4458, 4512-3. And, Icon had a duty to monitor the conduct of the trials to ensure compliance with its regulatory standards. That Icon chose not to cross reference the source data is at minimum reckless disregard. It is in fact more appropriately categorized as deliberate ignorance, given the numerous red flags evident during the clinical trials. Finally, it

does not matter whether Relator alleged exactly who at Icon was responsible for reviewing the source documents or electronic diary entries "for the more than 40,000 clinical participants and comparing them to documents provided by Ventavia." Icon MTD, Doc. 120, PageID # 5195. Ms. Jackson was able to do this by herself and find obvious problems. Icon either admits it failed in its obligation to provide the necessary oversight – after committing to provide it – or Icon did indeed deliberately bury its head in the sand. Any reasonable oversight would have disclosed the red flags and would have caused Icon to verify Ventavia's information. Whether or not Icon chooses to rest on the contention that that was too much work, Relator's allegations are adequate to establish reckless disregard for the truth of the data's accuracy.

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.

VI. Relator Requests Further Leave to Amend

In addition to the request for leave to amend to add a common law tort of wrongful discharge, Relator requests further leave to amend in the event that the Court find any deficiencies in the pleading of Relator's second amended complaint. Such leave is consistent with Rule 15 of the Federal Rules of Civil Procedure and Fifth Circuit law. *See Great Plains Tr. Co. v. Morgan Stanley Dean Witter & Co.*, 313 F.3d 305, 329 (5th Cir. 2002) ("our cases support the premise that "granting leave to amend is especially appropriate . . . when the trial court has dismissed the complaint for failure to state a claim []") (citations omitted).

CONCLUSION

For the foregoing reasons, Defendants' motions to dismiss the second amended complaint should be denied; and to the extent defendants' motions are sustained in any part, the Court should grant leave to file a third amended complaint.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 19th day of December 2023 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).

/s/Warner Mendenhall