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

UNITED STATES OF AMERICA, *ex. rel.* BROOK JACKSON,	)	
Plaintiffs,	)	Civil Action No. 1:21-cv-00008
v.	)	
VENTAVIA RESEARCH GROUP, LLC; PFIZER, INC.; ICON, PLC,	)	
Defendants.	)	

THE UNITED STATES' STATEMENT OF INTEREST
SUPPORTING DISMISSAL OF THE AMENDED COMPLAINT

The United States submits this Statement of Interest pursuant to 28 U.S.C. § 517 addressing the allegations in the relator's amended complaint (ECF No. 17). The United States remains a real party in interest in this suit under the False Claims Act, 31 U.S.C. §§ 3729-3733, even though it has not intervened in the case. *See* 31 U.S.C. § 3730(d); *United States ex rel. Eisenstein v. City of New York*, 556 U.S. 928, 932-35 (2009). The False Claims Act is the primary statute on which the Federal Government relies to combat fraud against the public fisc and to recover taxpayer dollars lost to fraud or false claims. The Government therefore has a substantial interest in the development of the law in this area and in the correct application of that law in this and similar cases. While fraud on the Food and Drug Administration or the failure to comply with clinical trial protocols could potentially give rise to False Claims Act liability in an appropriate case, in the instant case the complaint does not plead a sufficient nexus between the alleged clinical trial violations and the alleged requests for payment from the Government to support such liability.

BACKGROUND

On January 8, 2021, the relator Brook Jackson filed a *qui tam* action under seal against Pfizer, Inc., which developed the Pfizer-BioNTech COVID-19 vaccine with BioNTech SE; Icon PLC, an Irish research organization that allegedly oversaw over 160 Pfizer-BioNTech COVID-19 vaccine clinical study sites; and her former employer, Ventavia Research Group, LLC, which allegedly contracted with Pfizer to operate three (3) Pfizer-BioNTech COVID-19 vaccine study sites.[1] Ms. Jackson, who allegedly worked as a regional director at Ventavia for less than three weeks from September 8-25, 2020, alleged violations of the False Claims Act in connection with the Pfizer-BioNTech COVID-19 vaccine clinical study.

The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic has caused over 95 million COVID-19 cases and claimed the lives of over 1 million people in the United States alone.[2] In January 2020, the Secretary of the Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19,[3] and on February 4, 2020, [4] and March 27, 2020,[5] declared that circumstances exist justifying the

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1 *See* Compl. (ECF No. 2) paras. 3-5; Am. Compl. (ECF No. 17) paras. 3-5.

2 U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, COVID Data Tracker, https://covid.cdc.gov/covid-data-tracker/#datatracker-home

3 U.S. Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Declaration of Public Health Emergency, Jan. 31, 2020, https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx

4 U.S. Department of Health and Human Services, Notice of Determination of Public Health Emergency, Feb. 4, 2020, https://www.federalregister.gov/documents/2020/02/07/2020-02496/determination-of-public-health-emergency

5 U.S. Department of Health and Human Services, Emergency Use Authorization Declaration, Mar. 27, 2020, https://www.federalregister.gov/documents/2020/04/01/2020-06905/emergency-use-authorization-declaration

authorization of emergency use of drugs and biological products during the COVID-19 pandemic.[6]

Pfizer, in partnership with BioNTech, developed a COVID-19 vaccine using mRNA vaccine technology.[7] In July 2020, the U.S. Army Contracting Command selected Pfizer as the awardee of a Project Agreement under which Pfizer would deliver 100 million doses of an FDA authorized or approved vaccine to the Government on a firm fixed price per dose basis, in accordance with a Statement of Work (SOW).[8] The introductory section of the SOW for the Project Agreement explains that the "intent" of the project is "to demonstrate that Pfizer has the business and logistics capability to manufacture 100M doses of its currently unapproved mRNA-based COVID-19 vaccine for the Government."[9] For "background and context," the SOW explains that "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."[10] The SOW expressly recognizes that the vaccine "clinical trials are regulated by the FDA and HHS," and specifies that "there is no need for separate regulation by the U.S. Army Medical Research and Materiel Command."[11]

While clinical activities are described in the background section, the scope section of the SOW states that clinical activities not related to the manufacturing of the vaccine are "out-of-

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6 *See* 21 U.S.C. § 360bbb-3 (authorizing FDA to issue an emergency use authorization under certain circumstances during a public health emergency for an unapproved medical product, such as a vaccine, to be used to prevent, diagnose, or treat serious or life-threatening diseases or conditions).

7 Am. Compl. paras. 71, 73.

8 Am. Compl. Ex. 10.

9 *Id.* at JSN0296.

10 *Id.* at JSN0297.

11 *Id.*

scope" for the project as Pfizer and BioNTech have funded, and will continue to fund, those clinical activities "without the use of Government funding."[12] "Provided the FDA has granted approval or authorization," the payment section of the SOW states, "100M doses will be provided by Pfizer to the Government on a Firm Fixed Price per dose basis in accordance with the Milestone Payment Schedule."[13] "For clarity," the payment section of the SOW adds 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."[14]

In October 2020, FDA issued guidance regarding the data and information needed to support issuance of an Emergency Use Authorization (EUA) for COVID-19 vaccines.[15] The guidance explained that FDA may issue an EUA after FDA has determined that the following key criteria are met:

- Based on the totality of scientific evidence available, including data from adequate and well-controlled trials, if available, it is reasonable to believe that the vaccine may be effective to prevent, diagnose, or treat such serious or life-threatening disease or condition that can be caused by SARS-CoV-2.

- The known and potential benefits of the vaccine, when used to diagnose, prevent, or treat the disease or condition that can be caused by SARS-CoV-2, outweigh the known and potential risks of the vaccine.

On November 20, 2020, Pfizer submitted an EUA request to FDA for the Pfizer-BioNTech COVID-19 vaccine. The request included safety and efficacy data from the Pfizer-BioNTech COVID-19 vaccine clinical trial, in which approximately 44,000 participants were

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12 *Id.* at JSN0302.
13 *Id.* at JSN0309.
14 *Id*. at JSN0310.
15 *See* FDA Guidance for Industry, Emergency Use Authorization for Vaccines to Prevent COVID-19, Oct. 6, 2020, https://www.regulations.gov/document/FDA-2020-D-1137-0019

enrolled.[16] Data analysis from 36,621 trial participants demonstrated the vaccine's efficacy was 95 percent in preventing confirmed COVID-19 occurring at least seven days after the second dose.[17] Safety data from approximately 38,000 participants suggested a favorable safety profile and raised no specific safety concerns that would preclude issuance of an EUA.[18] Accordingly, FDA concluded that the key criteria for issuance of an EUA were met—based on the totality of the scientific evidence available, it was reasonable to believe the Pfizer-BioNTech COVID-19 vaccine may be effective to prevent the condition or disease caused by SARS-CoV-2, and the known and potential benefits of the vaccine outweighed the potential risks. FDA therefore issued the EUA on December 11, 2020. [19]

About eight months later, on August 23, 2021, FDA announced its approval of the Pfizer-BioNTech COVID-19 vaccine, marketed as Comirnaty.[20] FDA explained that the vaccine's approval was based on an "incredibly thorough and thoughtful evaluation of this vaccine," which included review of "updated data from the clinical trial which supported the EUA and included a longer duration of follow-up in a larger clinical trial population."[21] In November 2021, nearly a year after FDA granted the EUA for the Pfizer-BioNTech COVID-19 vaccine, FDA affirmed to

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16 FDA Review Memorandum, EUA for Pfizer-BioNTech COVID-19 Vaccine/BNT162b2, Dec. 11, 2020, https://www.fda.gov/media/144416/download

17 *Id.* at p. 6.

18 *Id.* at p. 6.

19 FDA News Release, FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine, Dec. 11, 2020, https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19

20 FDA News Release, FDA Approves First COVID-19 Vaccine, Aug. 23, 2011, https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine#:~:text=Today%2C%20the%20U.S.%20Food%20and,years%20of%20age%20and%20older.

21 *Id.* ("More than half of the clinical trial participants were followed for safety outcomes for at least four months after the second dose. Overall, approximately 12,000 recipients have been followed for at least 6 months.").

the British Medical Journal that it had "full confidence in the data that were used to support the Pfizer-BioNTech COVID-19 Vaccine authorization and the Comirnaty approval."[22]

On January 18, 2022, the United States declined to intervene in this *qui tam* action (ECF No. 13). The Court unsealed the case on February 10, 2022 (ECF No. 16). On February 22, 2022, the relator filed an amended complaint that is substantially similar to the original complaint (ECF No. 17). Defendants Pfizer, Icon, and Ventavia moved to dismiss (ECF Nos. 37, 50-51, 53). The relator filed an opposition to the motions to dismiss on August 22, 2022 (ECF No. 65). Defendants filed replies on September 20, 2022 (ECF Nos. 67-69).

DISCUSSION

The False Claims Act (FCA) permits either the Attorney General or a private party to initiate a civil action alleging fraud on the Government. *See* 31 U.S.C. §§ 3730(a), (b). A private enforcement action under the FCA is called a *qui tam* action, with the private party referred to as the "relator." *See Vermont Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 769 (2000). The FCA creates liability for one who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1)(A), as well as one who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," *id.* § 3729(a)(1)(B).

Congress intended the FCA "to reach all fraudulent attempts to cause the Government to pay out sums of money or to deliver property or services." S. REP. 99-345, 9, 1986 U.S.C.C.A.N. 5266, 5274; *see also Cook County, Ill. v. United States ex rel. Chandler*, 538 U.S. 119, 129 (2003) ("Congress wrote [the False Claims Act] expansively, meaning to 'reach all

[22] Rebecca Coombes, Rapid Response Re: COVID-19 Researcher blows the whistle on data integrity issues in Pfizer's vaccine trial, Nov. 15, 2021, https://www.bmj.com/content/375/bmj.n2635/rr-41

types of fraud, without qualification, that might result in financial loss to the Government.'" (quoting *United States v. Neifert-White Co*., 390 U.S. 228, 232 (1968))). Consistent with this broad construction of the FCA, courts have recognized multiple ways in which a defendant may violate the FCA, including by making an express or implied false certification, or engaging in fraud in the inducement.

Express false certification liability may attach when a defendant falsely and expressly certifies compliance with a condition of payment in connection with a claim for Government reimbursement. *See, e.g., United States ex rel. Thompson v. Columbia/HCA Healthcare Corp*., 125 F.3d 899, 902 (5th Cir. 1997). The Supreme Court has recognized that the implied false certification theory may apply "at least" where "the claim does not merely request payment, but also makes specific representations about the goods or services provided" and the defendant's failure to disclose noncompliance with a material requirement renders those representations "misleading half-truths." *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 190 (2016). Other courts have recognized that the implied false certification theory may also be viable when the submission of the claim implicitly represents that the claimant is legally entitled to payment and the claimant's failure to disclose noncompliance with a material payment requirement renders the claim misleading. *See United States ex rel. McBride v. Halliburton Co*., 848 F.3d 1027, 1031 n.4 (D.C. Cir. 2017) ("The Supreme Court left open the question of whether a claim that 'merely demand[s] payment,' as opposed to one that makes specific representations about the goods or services provided, can count as the requisite misleading representation."); *see also United States ex rel. Campbell v. KIC Dev*., LLC, No. EP-18-CV-193-KC, 2019 WL 6884485, at *7 (W.D. Tex. Dec. 10, 2019) ("The Court has not found any Fifth Circuit case law

that elaborates on *Escobar*'s 'specific representations' requirement—to the extent that it is an absolute requirement.").

The "fraud in the inducement" theory helps explain why a claim can be "false or fraudulent" even in situations where the underlying claim for payment is not false on its face, nor makes any 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, it may be possible to articulate a viable FCA claim 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 FCA liability could potentially attach. 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 factual allegations demonstrated how defendant's alleged misrepresentations to FDA regarding clinical study results caused FDA to approve the drug).[23]

[23] While the United States disagrees with Pfizer's arguments regarding the validity of a fraud in the inducement theory based on false or fraudulent statements to FDA, *see* ECF No. 67

Under Federal Rule of Civil Procedure 8(a)(2), a complaint must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." As the Supreme Court held in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), a complaint survives a motion to dismiss if it contains enough facts, accepted as true, "to state a claim to relief that is plausible on its face." *Id.* at 570. Facial plausibility requires that the plaintiff "plead[ ] factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "Where the well-pleaded facts of a complaint do not permit a court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not 'show[n]'—'that the pleader is entitled to relief.'" *Walker v. Beaumont Indep. Sch. Dist.*, 938 F.3d 724, 734 (5th Cir. 2019) (quoting *Iqbal*, 556 U.S. at 678); *see Cuvillier v. Taylor*, 503 F.3d 397, 401 n.4 (5th Cir. 2007) (noting, in the past, the court frequently used the expression that a case will not be dismissed "unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief," however, the Supreme Court retired the "no set of facts" language in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007)).

In this case, the relator's complaint alleges that Pfizer's claims for payment from the Government were "false and/or fraudulent by express and implied false certifications" of compliance with the clinical trial protocol and regulations.[24] However, the complaint fails to allege facts sufficient to support an express or implied false certification theory. The complaint does not plead facts indicating how any express or implied representations in connection with

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at pp. 3-5, the Court need not determine the validity of the fraud in the inducement theory to resolve the motions to dismiss as the complaint lacks factual allegations that would support the theory, assuming its validity.

[24] *See* Am. Compl. paras. 274-75.

Pfizer's claims for payment were false or misleading in light of Ventavia's alleged clinical trial violations.[25] The complaint does not identify any provision in the SOW for the Project Agreement between Pfizer and the Army that conditioned Government payment for the vaccine on Pfizer's compliance with the clinical trial protocol or regulations.[26] The SOW, which is attached to the complaint, further specifies that the Army did not regulate the conduct of the clinical trial, which is "out-of-scope" for the purchase agreement between the Army and Pfizer.[27] In short, the complaint does not plead factual content to support a conclusion that compliance with the clinical trial protocol or regulations was necessary under the contract between Pfizer and the Army such that clinical trial violations would give rise to a claim for express or implied certification liability.

As the complaint notes, the contract did condition payment between Pfizer and the Army on FDA approval or authorization of the vaccine. This provision in the contract could support a claim for fraud in the inducement if the complaint had pleaded facts supporting an inference that the alleged clinical trial violations at the Ventavia sites actually altered FDA's approval or authorization decision. However, while the complaint generally contends that the alleged clinical trial violations by Ventavia "call[] the vaccine's EUA into question," there are no allegations in the complaint that the data from the Ventavia sites caused FDA to authorize the vaccine or that FDA would have revoked authorization had it known about the alleged clinical

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[25] *See id.* para. 138 ("Under the contract, Pfizer sends monthly invoices to DoD at $19.50 per dose for each delivery of vaccines, which are paid within thirty days"), para. 278 ("Defendant Pfizer certified in its claims for payment that they were true and correct, prepared from Pfizer's books and records, and in accordance with the Pfizer-DoD contract.").

[26] *See id.* para. 135 ("DoD contracted to pay Pfizer $1.95 billion for the vaccines ($19.50 per dose) after FDA approval or Emergency Use Authorization ('EUA').").

[27] *Id.* Ex. 10 at JSN0297, 0302.

trial violations by Ventavia.[28] Also absent from the complaint are factual allegations indicating that the alleged violations at the Ventavia sites resulted in FDA receiving fabricated, inaccurate, or misleading data about the safety or efficacy of the vaccine. The complaint does not, for example, identify any safety risk that was hidden from FDA in the data from the Ventavia sites, or any symptomatic participants who Ventavia did not properly test for COVID-19 infection, or any COVID-19 infections in vaccinated participants that Ventavia falsely reported to have occurred in the placebo group.[29] In other words, the complaint does not plead facts that would allow the Court to reasonably infer that the alleged protocol deviations at the Ventavia sites would have affected the safety or efficacy data generated at those sites.[30] Moreover, even if the allegations were sufficient to show that Ventavia's safety and efficacy data was unreliable, a conclusion that the criteria for issuance of an EUA would not have been met without the Ventavia data is implausible considering that authorization is based on "the totality of scientific

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[28] *See id.* para. 287.

[29] *See, e.g., id.* para. 153 (alleging that Ventavia did not test Subject 11281302 for COVID-19 until after the vaccine was administered without alleging that Subject 11281302 was COVID-19 positive and should have been excluded from the study), paras. 183-186 (alleging Ventavia failed to report adverse events to Pfizer and Icon without describing or identifying any particular adverse event that was not properly reported), Ex. 12 (reporting that an adverse event report had been completed and faxed to Pfizer for Subject 10961031 on account of a positive pregnancy test prior to vaccination), Ex. 17 (indicating the protocol for reporting adverse events was unclear and recommending that QC look for potential adverse events not caught during study visits and flag them for correction).

[30] *See, e.g., id.* para. 165 (alleging that Ventavia likely mispresented the time that participants' vital signs were taken to conceal the fact that vitals were taken before or during the informed consent process without alleging that informed consent was never obtained or providing any factual basis to conclude that the timing of informed consent could impact the study's evaluation of the vaccine's safety or efficacy), para. 190 (alleging deviations in blood sample clotting, centrifuge, and freezing times without pleading facts indicating whether or how those alleged deviations could affect the evaluation of the blood samples or the measure of safety or efficacy of the vaccine), para. 194 (alleging that a Ventavia employee changed a participant's blood pressure reading without explaining how the reading was changed or what impact, if any, the change could have on the safety or efficacy results).

evidence available"[31] and the complaint alleges that Ventavia enrolled only about 3 percent, or approximately 1,500 of the nearly 44,000 total clinical trial participants.[32]

In sum, the relator's complaint lacks factual allegations that would support a plausible claim that Ventavia's clinical trial violations masked problems with the vaccine that were so serious that FDA would have withheld or withdrawn its authorization of the vaccine had it known the truth, such that Pfizer's subsequent claims for Government payment for the vaccine could be rendered "false or fraudulent" under the FCA.[33]

CONCLUSION

For the reasons stated above, the United States supports dismissal of the relator's complaint.

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[31] *See* FDA Guidance for Industry, Emergency Use Authorization for Vaccines to Prevent COVID-19, Oct. 6, 2020, https://www.regulations.gov/document/FDA-2020-D-1137-0019 (explaining that FDA may issue an EUA when, based on "the totality of scientific evidence available," it is "reasonable to believe" the vaccine "may be effective" and the "known and potential benefits" of the vaccine "outweigh the known and potential risks"); *see also* FDA Review Memorandum, EUA for Pfizer-BioNTech COVID-19 Vaccine/BNT162b2, Dec. 11, 2020, at pp. 6-8 (recommending issuance of an EUA based on "the totality of scientific evidence available," which includes data from over 36,000 clinical trial participants, which showed the vaccine to be 95 percent effective and raised no safety concerns that would preclude issuance of an EUA).

[32] *See* Am. Compl. para. 4 (alleging that Icon oversaw over 160 clinical trial sites worldwide), para. 5 (alleging that Pfizer contracted with Ventavia to provide three (3) test sites), para. 80 ("A total of 43,998 participants were enrolled in Phase 3 of the trial at issue, per Pfizer's reporting on clinicaltrials.gov. Approximately 1,500 of those were enrolled at Defendant Ventavia's facilities.").

[33] The Court need not consider whether the relator's claims are subject to dismissal for noncompliance with a dispute resolution provision in the vaccine purchase agreement between Pfizer and the Army. *See* ECF No. 37 at pp. 27-30. The United States does not concede that the dispute resolution provision would apply to an FCA claim brought by the United States premised on clinical trial fraud on FDA. *See* Am. Compl. Ex. 10 at JSN0302 (specifying that the conduct of the clinical trial is outside the scope of the purchase agreement). In any event, it is unnecessary for the Court to address the dispute resolution provision as the pending motions may be resolved on other grounds.

Respectfully submitted,

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ATTORNEYS FOR THE UNITED STATES OF AMERICA

CERTIFICATE OF SERVICE

I hereby certify on this 4th day of October 2022, I caused copies of the foregoing document to be served on all counsel of record through the Court's electronic filing system.

/s/ Michael W. Lockhart
MICHAEL W. LOCKHART