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

UNITED STATES OF AMERICA *ex rel*. BROOK JACKSON,	)	Case No.: 1:21-CV-00008-MJT
Relator,	)	
vs.	)	RELATOR BROOK JACKSON'S RESPONSE TO STATEMENT OF INTEREST
VENTAVIA RESEARCH GROUP, LLC, *et al*.	)	
Respondents.	)	

INTRODUCTION

Relator Brook Jackson, through undersigned counsel, herein responds to the Statement of Interest filed October 4, 2022 by the United States, Doc. 70. The unusual pleading by the United States suggests a split of opinion between the attorneys working the case and the Biden White House. The United States has not filed any motion to dismiss the case itself. To the contrary, the government sought this court's extraordinary seal powers over this case for a substantial time period because of how seriously they took the pleadings as fully legally sufficient as plead. The Statement actually supports Relator's position that an FCA claim for fraud in the inducement can be maintained where the allegations create an inference that clinical trial violations could have "altered FDA's approval or authorization decision." *Id*., at Page ID 2056. Indeed, the Statement often supports the legal position of the Relator throughout its substantive argument section, including the essential role the drug safety, efficacy, and vaccination capability of the FDA rules played as a precondition for payment from the Defense Department. It would be nuts to suggest an unsafe, ineffective drug that vaccinated against nothing for nobody would get billions of dollars in taxpayer funds. This goes to a core reason the False Claims Act exists: Congress authorized

individual Americans to seek remedy on the behalf of the people independent of institutional support. This case proves why that was a sage principle of Congress from the inception of this law.

ARGUMENT

The Statement supports Relator's assertions that payment was contingent upon the vaccine receiving emergency use authorization ("EUA") and that the FDA in making that decision was reliant upon the accuracy of the data produced in the clinical trials. If, as Relator witnessed and alleges, the clinical trial protocol was egregiously broken, then the very basis upon which the EUA was granted would be irrelevant. The government initially recognized the merits of Relator's claims. The government made several requests to extend its deadline to either intervene or allow Relator to continue independently, ultimately deliberating for nearly a year prior to the unsealing of this action. Had the government truly believed at the time, as they now try to claim, that Relator's complaint was devoid of evidence, they would never have required such ample time to investigate. Clearly, the government had an interest in her allegations upon the initial filing of this action.

While the United States styles its Statement of Interest as supportive of Respondents' motions to dismiss, the United States agrees that a FCA claim for fraud in the inducement can be maintained if the allegations create an inference that clinical trial violations could have "altered FDA's approval or authorization decision." *Id.*, at PageID 2056. The United States claims the inference must be that the violations at the Ventavia site "actually" altered the FDA's decision, but the FCA pleading standard is not one of actuality but of materiality. *Id.*; *See* 31 U.S.C. § 3729(a)(1)(B) (imposing liability under the FCA on any person who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim"). Whether a false statement is material depends on whether the false statement has a "natural tendency to influence, or is capable of influencing, the decision of the decision making body to which it was addressed." *Neder v. United States*, 527 U.S. 1, 16, 119

S.Ct. 1827, 144 L.Ed.2d 35 (1999). Indeed, the statute expressly defines "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). As recognized in *U.S. ex rel. Longhi v. U.S.*, 575 F.3d 458 (5th Cir. 2009): "All that is required under the test for materiality, therefore, is that the false or fraudulent statements have the potential to influence the government's decisions." *Id*., at 470.

In the context of presumptions within the vaccine manufacturer immunity statute, 42 U.S. Code § 300aa–22(b)(2), the Southern District of Texas has held: "The Court cannot accept the fact that the FDA licensed the vaccines as *prima facie* evidence that Defendants complied with all regulations […]." *Blackmon v. Am. Home Products Corp.*, 328 F. Supp. 2d 659, 666 (S.D. Tex. 2004). Similarly, the United States cannot properly assert that the FDA's approval, or its continued confidence in Respondents, operates as evidence that Respondents complied with applicable regulations.

Clinical trial fraud influences the FDA's decision to grant an EUA as this authorization is always based on the "totality of the scientific evidence available." *See* Doc. 70, PageID 2057-58. The United States posits *ipse dixit* that given Ventavia's clinical trials were "only about 3 percent, or approximately 1,500 of the nearly 44,000 total clinical trial participants" and that was not enough to alter the FDA's decision to grant EUA. *Id*. This analysis, however, does not track the materiality inquiry given proper inquiry is whether the fraud has the "potential to influence the government's decision." *See Longhi*, *supra*, 575 F. 3d at 470. If, as the United States suggests, clinical trial violations may form the basis for a claim of fraudulent inducement under the FCA, then the only relevant pleading question is whether the clinical trial violations could **potentially** influence the FDA's decision to grant EUA. *See* Doc. 70, PageID 2054 (recognizing that "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.").

Even if the EUA was a forgone conclusion - as suggested by the United States, regardless of fraud at any level given the FDA's blind faith in Respondents, the relevant inquiry remains whether the clinical trial violations as pled by Relator could **potentially** influence the decision making of an objective and unbiased FDA. Given that the EUA analysis focuses on the "totality of the scientific evidence available," and since Relator has pled that "approximately 1,500 of the nearly 44,000 total clinical trial participants" produced fraudulent data, Relator has sufficiently pled materiality. As a matter of law, a known threshold of 3% fraudulent data could have "potentially" influenced the FDA's decision to grant EUA. And, to the extent it is even necessary, Relator can add to this 3% fraud threshold given that she has since obtained data from other contracted research companies demonstrating similarly flawed clinical trial data. Such blatant fraudulent activity at one testing site should also reasonably raise suspicion over the accuracy of data produced at other sites. Further, the protocol established an end-point number of 164. Am. Comp., Ex. 6, Doc. 17-1, PageID # 1029. The date for data cut-off for the final efficacy analysis was November 14, 2020, when a total of 170 confirmed COVID-19 cases were accrued.[1] A 3% reduction in the final population studied for efficacy draws the final number of participants dangerously close to the minimum established end-point number. Thus, 3% is significant.

Clinical trial fraud is not only a sound basis for a FCA claim, it is also the basis for criminal charges.[2] The pleading standard under the FCA is plausibility. *Agema v. City of Allegan,* 826 F.3d 326, 331 (6th Cir. 2016) (holding, "To survive a motion to dismiss, a litigant must allege enough facts to make it plausible that the defendant bears legal liability.") (*citing Ashcroft v. Iqbal,* 556 U.S. 662, 678 (2009)). To meet this pleading standard, a relator need only allege a fraudulent scheme by detailing examples of

[1] Emergency Use Authorization for Pfizer-BioNTech COVID-19 Vaccine Review Memo [https://www.fda.gov/media/144416/download] (last accessed October 27, 2022).

[2] Doctor, Clinic Owner and Staff Charged with Falsifying Clinical Trial Data; tellus_indictment.pdf (justice.gov)[https://www.justice.gov/opa/press-release/file/1374741/download] (last accessed October 27, 2022).

specific fraudulent conduct that are " 'representative' samples of the scheme." *United States ex rel. Prather v. Brookdale Senior Living Cmtys., Inc.*, 892 F.3d 822, 830 (6th Cir. 2018), *cert. denied sub nom, Brookdale Senior Living Communities, Inc. v. U.S. ex rel. Prather*, 139 S. Ct. 1323 (2019).

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In the Amended Complaint, Relator detailed specific problems with the clinical trials including the unblinding of participants, all deviations from which would have significant potential to affect both the risks and benefits reported to the FDA; failure to obtain informed consent; failure to report participant deaths; and trial data that was fabricated, altered, and hidden from the FDA, easily satisfying plausibility under the FCA pleading standard. Relator witnesses numerous other clinical trial protocol violations:

1. Relator pled Ventavia failed to report "temperature excursions," which impacted benefit and risk by reducing potency and/or reducing potentially reactive agents in the injection.
2. Relator pled that doses of the frozen vaccine concentrate were required to thaw for thirty minutes before administration, but Ventavia employees were told to hold the frozen concentrate in their hand to speed up the thawing. This has the potential to change the chemistry and effects.

3. Relator pled clinical trial participants were given their second injection outside of the protocol-mandated nineteen to twenty-three day window. On at least four occasions the vaccine concentrate was over-diluted, which directly affects potency and reduces potential side-effects.
4. Relator pled Ventavia failed to report Serious Adverse Events ("SAEs") to Pfizer and Icon, though that information was available via the clinical trial participants' "electronic diary" entries. This is perhaps the most egregious violation not only of clinical trial protocol but of public trust.
5. Relator pled Ventavia's documentation practices were careless, sloppy, inaccurate, and many times falsified. Pfizer had access to this data and equally failed its oversight responsibilities which rightfully draws the presumption that data from other clinical trials is just as bad if not worse.

Each act of fraud directly impacted the risk-benefit calculation, which is a key inquiry in granting EUA. Bypassing protocol taints results, period. Respondents' failures have a clear and direct impact on the most important aspects of the FDA's decision to grant EUA.

If further detail is requested by the Court, Relator can supplement the record in an amended pleading as referenced in Relator's Combined Response in Opposition to Respondents' Motions to Dismiss Amended Complaint. *See* Doc. 65, PageID 1989-90, incorporated herein. Relator relied on thousands of pages of source documents showing clinical trial violations which contain participants' personal information and dates and times of the problematic events. Relator is also in possession of data from other contracted research companies showing similarly flawed clinical trial data and can add this detail as well if the Court so demands in permitting a Second Amended Complaint, should that be the decision of the Court.

CONCLUSION

For these reasons this Court should deny Respondents' motions to dismiss, or, in the alternative, grant Relator leave to file a Second Amended Complaint consistent with the Court's decision in order to provide the detail apparently now sought by the United States. Of note, the United States' statement has no bearing on Relator's claim for retaliation against Defendant Ventavia.

Respectfully Submitted,

/s/ Lexis Anderson

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CERTIFICATE OF SERVICE

A copy of the foregoing has been sent by the Court's Electronic Filing System to all parties of record on 10-27-2022.

/s/ Lexis Anderson
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