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

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

REPLY IN SUPPORT OF MOTION TO CONTINUE DISCOVERY DEADLINES

Defendant Pfizer Inc. ("Pfizer" or the "Company") has moved to dismiss this action, which Plaintiff-Relator Brook Jackson ("Relator") filed under Section 3730(b)(1) of the False Claims Act ("FCA"). This "*qui tam*" provision empowers private individuals to bring anti-fraud lawsuits "for the United States Government," which would receive at least 70 percent of any recovery were the case successful. 31 U.S.C. § 3730(d). Despite these financial incentives, the Government has disavowed Relator's lawsuit by filing a Statement of Interest Supporting Dismissal. (ECF 70.) This unprecedented filing urges the Court to grant Pfizer's motion to dismiss, (ECF 37), because the Amended Complaint fails to identify any "false or misleading" claims, its allegations are "implausible," and the United States continues to have "full confidence" in Pfizer's COVID-19 vaccine. (ECF 70 at 6, 11–12.) In other words, the Government has concluded there was no fraud here and it stands behind its policy choices concerning the vaccine. *See United States ex rel. Harman v. Trinity Indus., Inc.*, 872 F.3d 645, 668–69 (5th Cir. 2017) ("Congress enacted the FCA to vindicate fraud on the federal government, not second guess decisions made by those empowered through the democratic process to shape public policy.").

These exceptional circumstances provide good cause to further delay discovery, as explained in Pfizer's pending motion for continuance. (ECF 87 at 2–4.) Relator opposes this motion and, in her opposition brief, she notes that the Court has agreed twice previously that it would be inefficient to launch discovery while motions to dismiss remain undecided. (ECF 92 at 1–2.) Nothing has changed: (1) the Court has not ruled on Pfizer's dispositive motion; (2) the Company's earlier arguments for deferring discovery, (ECF 40, 78), apply with equal force today; and (3) Relator's latest opposition brief only repeats arguments that the Court has already rejected twice over, (*compare* ECF 92 *with* ECF 49, 80). The Court should maintain the status quo for the relatively short time needed to draft a written opinion regarding Pfizer's 12(b)(6) motion.

The "strength of the dispositive motion" is a key consideration for district judges weighing motions to postpone discovery. *Bowman v. Wells Fargo Bank, N.A.*, No. 13-389, 2014 WL 12791068, at *1 (E.D. Tex. Apr. 4, 2014). Pfizer's dispositive motion here provides several compelling grounds for dismissal, including that the Amended Complaint fails to plead the "indispensable element" of any FCA lawsuit: submission of a "false or fraudulent" claim. (ECF 37 at 20–23.)[1] Although Relator initially alleged Pfizer's invoices for the vaccine contained "express and implied false certifications" of compliance with various federal regulations, (Am. Compl. ¶¶ 274, 278), she later admitted the invoices were "contractually justified" and "do not contain false statements." (ECF 65 at 10.) That is because the invoices simply certified that "the amounts invoiced [were] for costs incurred in accordance with the agreement, the work reflected ha[d] been performed, and prior payment ha[d] not been received." (ECF 37 at 22.)

This certification was a truthful one, lacking any nexus to the regulatory provisions cited in the Amended Complaint, none of which are listed in Pfizer's contract with the U.S. Department of Defense ("DoD"). As explained in Pfizer's motion to dismiss, that agreement "specifies the number of doses the Government would buy and the price the Government would pay, *but it does not impose any requirements relating to Pfizer's clinical development activities, FDA regulations, or [the Federal Acquisition Regulation]*." (ECF 37 at 22 n.24 (emphasis added).) Several express provisions of the contract support this conclusion. For example, the contract states Pfizer's clinical development activities were "described solely for background and context." Am. Compl., Ex. 10,

[1] Pfizer has advanced two other arguments, either of which on its own provides adequate grounds for dismissal. First, the Amended Complaint fails to satisfy the "demanding" materiality requirement announced in *Universal Health Serv., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 194 (2016). (ECF 37 at 23–25.) And second, Relator may not pursue the claims against Pfizer because they are subject to an unsatisfied condition precedent—mandatory ADR procedures—that the Government negotiated as part of its initial agreement to purchase Pfizer's vaccine. (ECF 37 at 27–30.)

§ 1.1.2. The contract also states there was "no need for separate regulation" of Pfizer's clinical trials in the contract because "these clinical trials are regulated by FDA and HHS." *Id.* § 1.1.2(A). Elsewhere the contract provides that "[w]hile pre-clinical [and] clinical . . . activities are described in the Background section of this Statement of Work," the parties agree "such activities" are "out-of-scope for this prototype project" and Pfizer "will continue to fund these activities, without the use of Government funding." *Id.* § 1.2. To remove any doubt, the agreement states "[f]or clarity" that "the Government will have no right to withhold payment in respect of any delivered doses, unless the FDA has withdrawn approval or authorization of the vaccine." *Id.* § 5.0. Thus regulatory compliance was not a condition of payment under the plain terms of the contract.[2]

Both parties to the contract—Pfizer and the Government—are in complete agreement on this point. The Government's Statement of Interest puts it this way:

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

(ECF 70 at 10.)

The Court held an oral hearing on Pfizer's motion to dismiss on March 1, 2023. During the hearing, the Court asked several questions about Pfizer's contract with DoD, including whether

[2] Even though Pfizer's clinical development activities were "out-of-scope" for the Company's contract with DoD, FDA undertakes a rigorous evaluation of the scientific information submitted through all phases of clinical trials. This evaluation continues even after the Agency authorizes a product for emergency use or grants full approval. As FDA has stated publicly with respect to Pfizer's COVID-19 vaccine, "the public can be very confident that this vaccine meets the high standards for safety, effectiveness, and manufacturing quality the FDA requires of an approved product" (ECF 37 at 14.)

it might contain "implied terms" conditioning payment on the Company's compliance with FDA clinical trial regulations.[3] The contract's *express* terms, which manifest the unmistakable intent of the parties, provide a straightforward answer to the Court's question: the agreement contains no terms—implied or otherwise—that condition payment on regulatory compliance.

As a matter of black-letter law, a court's "only function" when construing a contract is to "discover the intention of the parties as found within the agreement, and give effect to it." *Koontz v. Thomas*, 333 S.C. 702, 708 (Ct. App. 1999).[4] "It has long been held that to ascertain the intention of an instrument, the court must first look to its language, and if it is perfectly plain and capable of legal construction, then that language alone determines the instrument's force and effect." *Id.* at 708–09. "The court must enforce an unambiguous contract according to its terms regardless of its wisdom or folly, apparent unreasonableness, or the parties' failure to guard their rights carefully." *Id.* at 708. While contracts can sometimes contain implied promises designed to "protect the spirit of the agreement," those promises "*cannot contravene the parties' express agreement* or be used to forge a new agreement beyond the written language." *In re Hovis*, 325 B.R. 158, 166 (D.S.C. 2005) (emphasis added). Moreover, courts must interpret each contract as "a harmonious whole," giving effect "if practicable, to every clause and word in it." *Atlantic Am. Life Ins. Co. v. Peoples Life Ins. Co. of S.C.*, 267 F. Supp. 441, 444 (D.S.C. 1967).

[3] The Court also asked for record citations concerning Relator's many interactions with the Government before the United States declined to intervene in this action. Attachment 1 to this Reply provides those record citations, in chronological order, to aid the Court's consideration of Pfizer's materiality arguments.

[4] The contract in question contains a choice-of-law provision stating that the agreement "shall be governed by the laws of the state of South Carolina." (ECF 37, Ex. A at 2.) For this reason, Pfizer has cited South Carolina precedents in this Reply, but the interpretive principles announced in those cases are uncontroversial and should be familiar to practitioners nationwide.

These fundamental canons of contract interpretation dictate the result here. This Court's "only function" for present purposes is to effectuate the "intention of the parties" to the contract. *Koontz*, 333 S.C. at 708. That contract is crystal clear: DoD did not intend to "separately regulate" Pfizer's clinical trials, but rather deferred to FDA's expertise in this area. Am. Compl., Ex. 10, § 1.1.2(A). For this reason, the agreement contains a single prerequisite to payment—the provision of 100 million doses of an FDA-authorized or approved COVID-19 vaccine to the Government. *Id*. § 5.0. Pfizer satisfied this condition, FDA continues to have "full confidence" in the vaccine, and the Government continues to purchase it. Were there any room for doubts about the parties' intentions, the Government's Statement of Interest resolves them in Pfizer's favor. As that document says, "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." (ECF 70 at 10.) There can be no implied terms in the contract that "contravene" this express understanding. *In re Hovis*, 325 B.R. at 166. Nor would an implied term conditioning payment on regulatory compliance "protect the spirit of the agreement." *Id*. Rather, it would read numerous express terms out the contract altogether. That is something courts must never do. *Atlantic Am. Life Ins.*, 267 F. Supp. at 444.

* * *

Pfizer's motion to dismiss is uncommonly strong and—remarkably—supported by the United States, the named plaintiff in this action. The Court should consider the strength of Pfizer's dispositive motion when deciding the Company's pending motion to continue discovery deadlines. *Bowman*, 2014 WL 12791068, at *1. Unless the Court acts quickly, discovery will start one week from today, on March 15, 2023. (ECF 86.) For the reasons discussed in this Reply, good cause exists for the Court to maintain the status quo and enter another short continuance of discovery until the Court has an opportunity to issue its written decision on Pfizer's motion to dismiss.

Date: March 8, 2023

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on March 8, 2023 a true and correct copy of the foregoing document was served upon all counsel of record via the Court's CM/ECF system in accordance with this Court's Local Rules.

/s/ Meagan D. Self
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