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 BRIEF IN SUPPORT OF PFIZER'S MOTION TO DISMISS

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INTRODUCTION

Defendant Pfizer Inc. ("Pfizer") has moved to dismiss this case, which Plaintiff-Relator Brook Jackson ("Relator") purportedly brought under Section 3730(b)(1) of the False Claims Act ("FCA"). This "qui tam" provision empowers private parties to bring anti-fraud lawsuits "for the United States Government." But the statute was not meant for relators to "second guess decisions made by those empowered through the democratic process to shape public policy." *United States ex rel. Harman v. Trinity Indus., Inc.*, 872 F.3d 645, 668-69 (5th Cir. 2017). Second guessing the Government is precisely what Relator is attempting to do here. Through this lawsuit, she seeks to substitute her conspiratorial beliefs about Pfizer's vaccine for the science-based decision-making of the expert agencies responsible for addressing a once-in-a-century pandemic. Those agencies, which have known about Relator's concerns for two years, have rejected her views and announced as much publicly. The U.S. Food and Drug Administration ("FDA"), for example, has stated that it continues to have "full confidence in the data" underlying Pfizer's vaccine. Moreover, the Government has declined to intervene in this action while continuing to (1) purchase the vaccine, (2) recommend it as a preferred option, and (3) provide it to Americans free of charge.

Relator derides the Government daily on Twitter, demonstrating that she is in no position to represent the United States through this qui tam action. She believes "[t]he only public health emergency is the one created from the mass rollout of these killer [shots] that our govts told us were safe & effective." (Ex. A.) She is hostile to FDA and believes that "[p]rotecting the public from harm means defunding this crooked agency." (Ex. B.) She has accused the U.S. Centers for Disease Control and Prevention ("CDC") of "cri-minal fraud & willful misconduct" for recommending Pfizer's vaccine. (Ex. C.) And she has dubbed the Justice Department the "Department of Injustice" for failing to adopt her cause. (Ex. D.) This disconnect makes it impossible for Relator to maintain this case. She is not advancing the Government's interests. She

is undermining them in an improper effort to further her own anti-vaccination and anti-Government agenda. The Court should end this charade now.

In Pfizer's pending motion to dismiss (ECF 37), the company raises three compelling grounds for dismissal. First, the complaint fails to identify a false or fraudulent claim seeking Government payment, (ECF 37 at 20-23), a point Relator concedes in her opposition brief, (ECF 65 at 10). Second, none of Relator's allegations were material to the Government's decision to pay for the vaccine. (ECF 37 at 23-25.) And third, the complaint is barred because the Government never pursued the underlying claims in an administrative proceeding, a condition precedent under the relevant contract. (ECF 37 at 27-30.) Relator's counter-arguments are contrary to the statutory text, binding precedent, and contract language at the heart of this dispute. The Court should dismiss this action for all of the reasons discussed more fully below.

ARGUMENT

I. THE COMPLAINT DOES NOT PLEAD FALSE OR FRAUDULENT CLAIMS AND RELATOR'S FRAUDULENT INDUCEMENT THEORY FAILS.

To understand what the FCA requires, "we start, as always, with the language of the statute." *Universal Health Serv., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 187 (2016). The FCA imposes liability on any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment of approval," 31 U.S.C. § 3729(a)(1)(A), or 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). Both of these provisions require a "claim," which the FCA defines as "any request or demand, whether under contract or otherwise, for money or property." *Id*. § 3729(b)(2). And for liability to attach, the claim for payment itself must be "false or fraudulent." *Id*. § 3729(a)(1). That is why the FCA is "not an all-purpose antifraud statute," *Escobar*, 579 U.S. at 194, and alleged "[v]iolations of laws, rules, and regulations alone do not

create a cause of action under the FCA," *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 902 (5th Cir. 1997).

Pfizer has moved to dismiss because the complaint alleges violations of regulations rather than false claims as the statute requires. (ECF 37 at 20-22.) While the complaint contains the conclusory allegation that Pfizer's invoices for the vaccine contained "express and implied false certifications" of compliance with various regulations, (Am. Compl. ¶¶ 274, 278), Pfizer's opening brief conclusively refutes that notion by attaching the actual invoices that Pfizer submitted to the Government for payment. (ECF 37, Ex. B.) Those invoices are devoid of any false or misleading representations, as Relator's opposition brief concedes. She abandons her false certification theory, the only theory of recovery pleaded in her complaint, and admits Pfizer's invoices are "contractually justified" and "do not contain false statements." (ECF 65 at 10.) Under the plain text of the FCA, Relator's concessions are the end of the story. She acknowledges there were no false claims, and the Court should dismiss her complaint for this reason alone.

Relator tries to salvage her complaint by invoking, for the first time in her opposition brief, a "fraudulent inducement" theory.[1] According to Relator, claims that are "not literally false" can nevertheless be "actionable" under the FCA "when the contract under which payment is made was procured by fraud." (ECF 65 at 10.) But Relator does not allege that Pfizer procured its vaccine contract through false or fraudulent statements. Rather she alleges that *after* the U.S. Department of Defense ("DoD") contracted to purchase Pfizer's vaccine, the company obtained emergency use authorization ("EUA") for its product through "lies, omissions, and fabrications" submitted to

[1] This effort to change horses midstream is improper. *Roebuck v. Dothan Sec., Inc.*, 515 Fed. App'x 275, 280 (5th Cir. 2013) ("[I]t is axiomatic that the complaint may not be amended by the briefs in opposition to a motion to dismiss.").

FDA. *Id*. Relator argues these allegedly "fraudulent" submissions to FDA somehow "render[ed] the later claims for payment," which Pfizer submitted to DoD, "false under the FCA." *Id*.

Relator's new fraudulent inducement theory gets her nowhere. This cause of action has no basis in the FCA's text. The theory purports to allow FCA liability when claims are "not literally false," even though the statute requires "false or fraudulent" claims. Said another way, the theory treats true claims as false ones. This absurd result "does not naturally flow from the text of the FCA, which repeatedly refers to a 'false or fraudulent claim' and makes no mention of creating liability for bona fide claims arising from a contract [or regulatory approval] induced by fraud." *United States ex rel. Cimino v. Int'l Bus. Machines Corp.*, 3 F.4th 412, 425 (D.C. Cir. 2021) (Rao, J. concurring). As the Court is well aware, its job is to apply the statute as written. By advancing the fraudulent inducement theory, Relator asks the Court to disregard the FCA's plain language. The Court should decline that invitation.

In support of her fraudulent inducement theory, Relator cites two cases from this Circuit, *United States ex rel. Willard v. Humana Health Plan of Texas, Inc.*, 336 F.3d 375 (5th Cir. 2003) and *United States ex rel. Laird v. Lockheed Martin Eng'g & Sci. Servs. Co.*, 491 F.3d 254 (5th Cir. 2007). Neither case helps Relator because they only recognized the theory in the context of fraudulent procurement of government contracts, not fraudulent procurement of regulatory approvals as alleged here. *See Laird*, 491 F.3d at 259. And the Fifth Circuit has rejected prior attempts to expand the fraudulent inducement theory to cover claims following alleged "violation[s] of state and federal regulations." *Gonzalez v. Fresenius Med. Care N. Am.*, 689 F.3d 470, 473-78 (5th Cir. 2012) ("Although a defendant may be held liable under the FCA for engaging in a 'fraudulent course of conduct' which does not result in a false claim, this type of liability

is . . . limited to the fraudulent inducement context" where "the *contract* under which payment is made was procured by fraud.") (emphasis added).

Fraudulent procurement of FDA approvals has never been a predicate for FCA liability in this Circuit. And, even if *Willard*, *Laird*, and *Gonzalez* previously allowed FCA cases based on fraudulent procurement of government contracts, it is doubtful those historical decisions remain good law. All of them pre-date the Supreme Court's *Escobar* decision, which instructs lower courts to adhere strictly to the language of the FCA, lest it become "an all-purpose antifraud statute." 579 U.S. at 187, 194. Relator's new theory seeks to achieve a result the Supreme Court and the statutory text forbid. *United States ex rel. Yu v. Grifols USA, LLC*, No. 1:17-CV-2226-GHW, 2021 WL 5827047, at *11 (S.D.N.Y. Dec. 8, 2021) (dismissing qui tam complaint because "there is a significant dearth of support for Relator's fraud in the inducement theory regarding FDA approval," which is "difficult to square with the plain language of the FCA").

Relator's new theory is not only legally defective, it lacks factual support as well. The public record belies her assertion that Pfizer "caused the FDA to issue an EUA under false pretenses." (ECF 65 at 18.) After Relator went public with her allegations, FDA issued its own public statement that the agency continued to have "full confidence in the data" supporting the EUA. (ECF 37 at 15.) Relator's 37-page opposition brief never once mentions this statement. She ignores the FDA because the agency's position reveals that her complaint is baseless.

II. THE COMPLAINT FAILS THE FCA'S DEMANDING MATERIALITY TEST.

The Supreme Court's *Escobar* decision provides a second, independent ground for dismissal through its "rigorous" materiality standard. 579 U.S. at 181. *Escobar* teaches that "materiality looks to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation," and "if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those

requirements are not material." 579 U.S. at 193-95. Courts applying this exacting standard have rejected qui tam actions based, like this one, on alleged fraudulent procurement of FDA approvals. *See D'Agostino v. ev3, Inc.*, 845 F.3d 1, 5 (1st Cir. 2016) ("The fact that [the Government] has not denied reimbursement for [a medical product] in the wake of [the relator's] allegations casts serious doubt on the materiality of the fraudulent representations that [the relator] alleges.").

In *D'Agostino*, the relator alleged a medical device manufacturer "made three fraudulent representations to the FDA in seeking approval to market Onyx," a device to treat malformed blood vessels in the brain. *Id*. at 4. The relator further alleged the defendant's misrepresentations "could have influenced the FDA to grant that approval," which was a "precondition" to reimbursement of Onyx by Medicare and Medicaid. *Id*. Applying *Escobar*, the First Circuit affirmed dismissal of the complaint, focusing on the Government's actual behavior in response to the allegations. *Id*. at 6 ("The FDA's failure actually to withdraw its approval of Onyx in the face of D'Agostino's allegations precludes D'Agostino from resting his claims on a contention that the FDA's approval was fraudulently obtained."); *see also United States ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29, 35 (1st Cir. 2017) (holding "it is not plausible that the conduct of the manufacturer in securing FDA approval constituted a material falsehood capable of proximately causing the payment of a claim" when "an agency armed with robust regulatory powers to protect the public health and safety is told what Relators have to say, yet sees no reason to change its position").

Pfizer has moved to dismiss Relator's complaint because, like those in *D'Agostino* and *Nargol*, the complaint alleges FDA was the victim of "fraud" even though the agency has known about Relator's allegations for years, has not withdrawn the approvals in question, and continues to express confidence in the data underlying those approvals. (ECF 37 at 22-25.) Complaints like

these cannot satisfy the FCA's "demanding" materiality standard. *Escobar*, 579 U.S. at 194. Relator resists this conclusion by making several arguments, none of which is persuasive.

Relator first asserts "[a]ll that is required under the test for materiality . . . is that the false or fraudulent statements have the *potential* to influence the [G]overnment's decisions." (ECF 65 at 19 (emphasis added).) She also argues an "objective FDA, without conflicts of interest" never would have authorized Pfizer's vaccine. (ECF 65 at 9, 20.) In this way, Relator urges the Court to turn a blind eye to FDA's actual response to her allegations. She argues, in effect, that her own views—and those of her lawyers—should supersede FDA's scientific judgment concerning the efficacy and safety of Pfizer's vaccine.[2]

Relator's position is absurd, and both the Supreme Court and the Fifth Circuit have rejected it. "Under any understanding of the concept, materiality looks to the likely or actual behavior of the recipient of the alleged misrepresentation," *Escobar*, 579 U.S. at 193, and courts "should not ignore what actually occurred" when they "have the benefit of hindsight," *Harman*, 872 F.3d at 667-68. Hindsight here is 20/20. FDA has been aware of Relator's concerns since September 2020, as stated in her complaint. (Am. Compl. ¶¶ 262, 266.) That agency, which has "robust regulatory powers to protect the public health and safety," *Nargol*, 865 F.3d at 35, authorized Pfizer's vaccine for emergency use, and later granted full approval for the product. Then, when Relator went to the media with her allegations, the agency issued the following public statement: "FDA has full confidence in the data that were used to support the Pfizer-BioNTech [v]accine authorization and the [vaccine's full] approval." (ECF 37 at 15.) Those regulatory decisions

[2] Relator also seeks to overrule DoD's decision to exercise "other transaction" authority to purchase Pfizer's vaccine. (ECF 65 at 32.) Needless to say, the FCA does not empower Relator to veto DoD's judgments concerning mission effectiveness during a national emergency. *See Harman*, 872 F.3d at 668-69. And because DoD purchased the vaccine under an OTA contract, the Federal Acquisition Regulation ("FAR") does not apply as a matter of black letter law. (ECF 37 at 7.) Relator's insistence that "Pfizer's deal with the Government is subject to FAR," (ECF 65 at 33), is simply wrong.

remain in place and, accordingly, the Government continues to purchase the vaccine. All of this proves Relator's claims are not material to the Government. *See Escobar*, 579 U.S. at 195.

Despite the clear language of *Escobar* and *Harman*, Relator argues the Government's "ongoing payments" for the vaccine are "irrelevant" because, in her view, the Government has "virtually no power to withhold payment under the DoD contract with Pfizer." (ECF 65 at 21.) Here she is referring to a provision of the contract requiring the Government to pay for "delivered doses" unless and until FDA withdraws "approval or authorization of the vaccine." *Id*. Relator's argument flies in the face of reality. The Government itself, through DoD, negotiated the contract provisions in question, and the Government itself, through FDA, controls the vaccine's regulatory status. When it comes to the vaccine, the Government holds all of the cards, and its continued authorization, approval, and purchases of the vaccine are unquestionably relevant to materiality.[3]

Finally, Relator asks the Court to disregard the Government's continued payments because there are "numerous reasons unrelated to materiality why the [G]overnment might continue doing business with a contractor despite allegations of fraud." (ECF 65 at 23.) Among the reasons she posits is that the Government may have been "forced to rely on [Pfizer] for essential goods and services." (ECF 65 at 22.) Relator speculates that, in this case, "the significant resources already expended" on the landmark trial, along with "the likely lack of other sponsors who could undertake the operation," may explain why the Government "could not divert course" once Relator came forward with her concerns. (ECF 65 at 23-24.)

[3] Relator's analogy to the Volkswagen ("VW") emissions scandal, (ECF 65 at 20), makes no sense. There the U.S. Environmental Protection Agency ("EPA") initiated an enforcement action against VW upon learning about the misconduct. FDA, on the other hand, has taken no action against Pfizer in the two years since Relator first notified the agency about her concerns. In both cases, the Government's response to the allegations demonstrates whether they were actually material. They were in the VW case; they are not here.

None of this speculation appears in her complaint, of course. *See United States ex rel. Foreman v. AECOM*, 19 F.4th 85, 115 (2d Cir. 2021) ("There may be circumstances where the [G]overnment's payment of a claim . . . will not be particularly probative of lack of materiality. . . . But the plaintiff must plausibly plead facts to support such possible alternative explanations in the complaint[.]"). In any event, her allegations are implausible. Pfizer funded the landmark trial, not the Government, and it is preposterous to think the Government would purchase an ineffective or unsafe vaccine simply because Pfizer spent a lot of money developing it. It is similarly implausible to suggest a "lack of other sponsors" forced the Government's hand, especially when many manufacturers besides Pfizer were attempting to develop their own vaccines at the time, and two of them—Moderna and J&J—did so successfully. Relator can't have it both ways. She cannot claim Pfizer's vaccine is "neither safe nor effective," (ECF 65 at 5), while at the same time arguing the product was "essential" and the Government was forced to purchase it, (ECF 65 at 22-23).

"Continued payment by the federal government after it learns of the alleged fraud substantially increases the burden on the relator in establishing materiality," even at the pleading stage. *United States ex rel. Porter v. Magnolia Health Plan, Inc.*, 810 Fed. App'x 237, 242 (5th Cir. 2020). Relator has clearly failed to shoulder that burden. Dismissal is required.

III. THE COMPLAINT IS SUBJECT TO AN UNSATISFIED CONDITION PRECEDENT.

Pfizer also moved to dismiss Relator's complaint because its claims against Pfizer are subject to alternative dispute resolution ("ADR") procedures that the Government negotiated with Pfizer as part of the initial contract to purchase the vaccine. (ECF 37 at 27-30.) Under the contract, the Government must exhaust these ADR requirements before it—or any qui tam relator acting on its behalf—may initiate litigation against Pfizer "arising from or in connection with" the agreement. *Id*. at 28. Relator's lawsuit fits easily within the scope of the ADR provision.

Relator argues the ADR provision "does not encompass FCA causes of action" because her lawsuit "arises from [Defendants'] clinical trial protocol violations and the false claims those violations caused." (ECF 65 at 26.) This conclusory statement ignores the fact that Pfizer submitted the allegedly "false claims" in this case "in connection with" the Government's contract to purchase Pfizer's vaccine, and the contract's ADR provision applies "whether or not" a breach of contract claim is at issue. (ECF 37 at 28.) There is no reason to read this language to exclude statutory causes of action like Relator's FCA lawsuit.

She also argues the ADR provision is "permissive," not "mandatory," because it includes the word "may." *Id*. at 25. This frivolous argument cherry-picks a single word from the contract and takes it out of context. Here's what the ADR provision really says: "Any disagreement, claim or dispute among the Parties concerning questions of fact or law arising from or in connection with this Agreement and whether or not involving an alleged breach of the Agreement, may be raised *only* under this article." (ECF 37, Ex. A, § 7.02 (emphasis added).) This is mandatory language—especially the adverb "only," which Merriam-Webster defines as "solely" or "exclusively." It is impossible to read this provision as permissive without striking "only" from the agreement. This is not how courts interpret contracts. *See*, *e.g.*, *In re Texas Pig Stands, Inc.*, 610 F.3d 937, 944 (5th Cir. 2010) ("Contracts are to be read as a whole, and an interpretation that gives effect to every part of the agreement is favored so that no provision is rendered meaningless or as surplusage."). Relator's argument is a desperate attempt to circumvent the agreement's clear text, which requires the Government to exhaust the ADR procedures before a case can proceed.

CONCLUSION

For all of these reasons, and those discussed by Defendants ICON and Ventavia in their respective reply briefs, incorporated here by reference, Pfizer respectfully asks the Court to dismiss Counts I and II of Relator's complaint with prejudice.

Date: September 20, 2022

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on September 20, 2022 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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