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.

CASE NO. 1:21-CV-00008-MJT

ORAL ARGUMENT REQUESTED

REPLY IN SUPPORT OF PFIZER'S MOTION TO DISMISS RELATOR'S SECOND AMENDED COMPLAINT

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INTRODUCTION

Defendant Pfizer Inc. ("Pfizer" or the "Company") respectfully submits this Reply in support of the Company's motion to dismiss the Second Amended Complaint ("SAC"), which Plaintiff-Relator Brook Jackson ("Relator") filed on behalf of the United States under 31 U.S.C. § 3730(b)(1). The SAC alleges Pfizer "fraudulently induced" the Government into authorizing and purchasing the Company's COVID-19 vaccine, which, in Relator's view, is a "historically dangerous, ineffective gene therapy." (ECF 118 ¶¶ 3, 314.) This Court has previously considered and rejected Relator's fraudulent inducement claim. (ECF 96 at 30–32.) It should do so again and dismiss this case, once and for all, as the Government itself requested in its "Statement of Interest Supporting Dismissal." (ECF 70.)

Pfizer has moved to dismiss the SAC for four primary reasons: (1) Relator's "fraud-in-the-inducement" theory is contrary to Fifth Circuit precedent; (2) Relator's allegations are not plausible nor do they satisfy the heightened pleading requirements of Federal Rules of Civil Procedure 9(b); (3) Relator's allegations of fraud were not material to the Government's decision-making with respect to the vaccine, as the Government itself demonstrated in its Statement of Interest; and (4) Relator's continued pursuit of this litigation, despite the Government's objections, presents an intractable separation-of-powers problem.

In opposition, Relator provides no compelling response to Pfizer's motion, instead recycling the same unsubstantiated anti-vaccination talking points that she has continually disseminated in this litigation and on social media. Her lack of meaningful opposition merely highlights Relator's true goal: at the end of the day, she asks this Court to substitute her conspiratorial views about the COVID-19 vaccine for the evidence-based views of the U.S. Food and Drug Administration ("FDA"), which has consistently taken the position that Pfizer's vaccine is safe and effective. Relator's efforts are in direct conflict with the False Claims Act ("FCA")

and its "Government-centered purposes." *United States ex rel. Polansky v. Exec. Health Res., Inc.*, 599 U.S. 419, 434 (2023). As the Fifth Circuit has explained, "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." *United States ex rel. Harman v. Trinity Indus., Inc.*, 872 F.3d 645, 668–69 (5th Cir. 2017).

The FCA does not empower Relator to substitute her views for those of the Government on this important matter of public policy, and her SAC simply does not plead an FCA claim. The Court should once again dismiss this action with prejudice.[1]

ARGUMENT

I. Precedent Does Not Support Relator's Fraud-On-The-FDA Theory.

To succeed on her claim under the FCA, Relator must first identify a false or fraudulent claim submitted to the Government. *See United States ex rel. Hebert v. Dizney*, 295 Fed. App'x 717, 722 (5th Cir. 2008). Here, Relator does not plead that Pfizer's invoices to the Government contain false statements; rather, in an attempt to check the falsity box, Relator argues Pfizer's requests for Government payment were tainted by an upstream fraud on the FDA.

More specifically, Relator claims Pfizer made misrepresentations concerning the Company's COVID-19 vaccine to the FDA. (ECF 118 ¶¶ 306–311, 334, 353.) According to Relator, Pfizer's alleged misrepresentations "fooled" the FDA, thereby allowing Pfizer to fraudulently obtain and maintain Emergency Use Authorization ("EUA") for the vaccine. (ECF 118 ¶¶ 307–310, 334.) Under Relator's theory, this claimed fraudulent inducement of the EUA colored Pfizer's entire relationship with the Government, amounting to an FCA violation.

[1] Pursuant to Federal Rule of Civil Procedure 10(c), Pfizer joins in and incorporates by reference the arguments made in defendants Ventavia Research Group, LLC's and Icon PLC's concurrently filed replies in support of their respective motions to dismiss.

Relator's claims are implausible and frivolous, but even assuming their veracity for the purposes of this motion, they fail as a matter of law because the Fifth Circuit has expressly rejected her theory. While the Fifth Circuit has recognized a fraudulent inducement theory for certain FCA claims, it has done so only in the context of fraudulent procurement of government contracts. *Gonzalez v. Fresenius Med. Care N. Am.*, 689 F.3d 470, 476–77 (5th Cir. 2012) (explaining fraudulent inducement under the FCA arises only when "the *contract* under which payment is made was procured by fraud" (emphasis added) (quoting *United States ex rel. Longhi v. Lithium Power Techs., Inc.*, 575 F.3d 458, 467–68 (5th Cir. 2009))). In *Longhi*, for example, the relator alleged that a defense contractor, Lithium Power, made numerous misrepresentations about its qualifications in grant applications submitted to the U.S. Department of Defense ("DoD"), which subsequently awarded Lithium four government contracts. 575 F.3d at 463. According to the relator, Lithium's claims for payment under those contracts violated the FCA. *Id*. The Fifth Circuit agreed: "This type of FCA claim is characterized as fraudulent inducement. Under a fraudulent inducement theory, although the Defendants' subsequent claims for payment made under the contract were not literally false, because they derived from the original fraudulent misrepresentation, they, too, became actionable false claims." *Id*. at 468.

The Fifth Circuit has since rejected attempts to extend this theory to cover claims arising from a "fraudulent course of conduct" without a nexus to the procurement of a government contract. *Gonzalez*, 689 F.3d at 73–78 ("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)). Relator's fraud-on-the FDA claims are thus contrary to existing Fifth Circuit precedent, and they can be dismissed on this basis alone.

See Universal Health Servs., Inc. v. United States ex rel. Escobar, 579 U.S. 176, 194 (2016) ("The False Claims Act is not an all-purpose antifraud statute or a vehicle for pushing garden-variety breaches of contract or regulatory violations." (quotation omitted)).

In response, Relator argues the "distinction between a regulatory fraud and the fraudulent inducement of a contract is a red herring" because here "Relator indeed alleges the fraudulent procurement of government contracts, the mechanism of which was fraudulent procurement of regulatory approval." Relator thus claims "[i]t is not necessary to expand recognition of the fraudulent inducement theory because this case fits the existing theory." (Opp. at 14.)

No Fifth Circuit precedent supports this argument. Instead, Relator cites several out-of-circuit cases in support of the notion that fraud-on-the-FDA can result in the submission of false claims to the Government. (Opp. at 12–13.) In this Circuit, however, the distinction between a regulatory fraud and the fraudulent inducement of a contract is not a "red herring," but rather a line the Fifth Circuit itself has drawn in recognizing a more circumscribed version of the fraudulent inducement theory. Indeed, the Court has expressly rejected the notion that claims for payment can be "per se tainted" simply because they are "grounded in fraud" perpetrated on a federal regulator outside of the contract procurement process.

In *Gonzalez*, the Fifth Circuit affirmed the pre-trial dismissal of an FCA claim based on a "fraudulent course of conduct," where the allegedly fraudulent conduct did not involve fraudulent inducement of a contract. 689 F.3d at 477–78. The relator in *Gonzalez* claimed the defendant engaged in Medicare fraud by offering dialysis services under a referral scheme that violated a host of federal and state laws and regulations. *Id.* at 475. Central to this claim was defendant's submission of Medicare "cost reports," which falsely certified that defendant was in compliance with the relevant legal and regulatory requirements. *Id.* at 475–76. Just as the EUA was a

requirement of Pfizer's contract with the Government here, the cost reports in *Gonzalez* were required as "a condition of Medicare participation." *Id.* But like Pfizer's EUA application materials, the cost reports did not include a request for payment and could not, on their own, establish an FCA violation. *Id.* Although the *Gonzalez* relator argued the submission of allegedly false cost reports amounted to a fraudulent course of conduct that "per se tainted" defendants' subsequent claims seeking payment from the Government, the Fifth Circuit refused to adopt this broad interpretation of the FCA. In rejecting this argument, the Court explained the "fraudulent inducement" theory only applies "when *the contract under which payment is made* was procured by fraud." *Id.* at 476–77 (emphasis added) (quoting *Longhi*, 575 F.3d at 467).

Despite Relator's protestations to the contrary, her claims do not fit the existing fraudulent inducement theory that the Fifth Circuit articulated in *Gonzalez*. Here, Relator alleges the "mechanism" by which Pfizer fraudulently procured its contract with DoD (signed in July 2020) was the fraudulent procurement of the EUA, which Pfizer sought and the FDA granted approximately six months *after* the contract was signed. This theory makes no sense. Pfizer's statements to the FDA six months after inking its contract with DoD have no bearing on whether Pfizer made knowingly false statements to DoD during the contract negotiation process. Relator cannot allege that any statement made during the EUA approval process fraudulently induced a contract with DoD that was already finalized and signed many months earlier.

To the extent Relator asks this Court to stretch the existing fraudulent inducement theory to cover alleged regulatory fraud, this Court should decline to do so. The Fifth Circuit has already rejected attempts to expand the fraudulent inducement theory in this way, *Gonzalez*, 689 F.3d at 473–78, and for reasons discussed in Pfizer's moving brief, the plain text of the FCA does not support any expansion of the fraudulent inducement theory, (*see* ECF 67 at 2–5).

II. Relator's Latest Fraud Allegations Defy Common Sense And Are Implausible.

Relator's only argument that Pfizer fraudulently obtained its contract with the Government, thus satisfying falsity, is based on the SAC's conclusory allegations that Pfizer knew from the outset—but did not tell FDA or DoD—that it could never deliver a safe and effective vaccine, (ECF 118 ¶¶ 160, 314, 316, 319, 361), and that "alternative effective treatments" for COVID-19 already existed, (ECF 118 ¶ 155). As explained in Pfizer's opening motion, the SAC does not plead sufficient facts to satisfy Rule 9(b)'s requirement of pleading the who, what, when, where, and why of this claimed fraud. *See United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 186 (5th Cir. 2009) (explaining to satisfy Rule 9(b), a relator must allege "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"). Indeed, Relator does not plead a single fact supporting her bogus claims that Pfizer hid information from the FDA and DoD to obtain a government contract, and they are belied by reality and common sense. (*See* ECF 119 at 16–18.)

In opposition to Pfizer's motion, Relator does not identify any factual support for her assertions that Pfizer defrauded the Government. Instead, Relator argues "overwhelming evidence is coming to light every day" that supports her baseless claims that the Pfizer COVID-19 vaccine is ineffective and harmful. (Opp. at 16–17.) This is no opposition at all. The so-called "new" evidence is a single, conclusory statement that, after Pfizer entered into its contract with DoD, the Company failed to report two adverse events to FDA and that the clinical trial results were "sensitive to small changes in numbers." (Opp. at 7, 17.) Even if true, the mere allegation that Pfizer's clinical trial results were "sensitive to small changes in numbers," is not sufficient to establish a clam of fraud. As explained in Pfizer's opening motion, Relator does not plead actual facts supporting her assertion that Pfizer hid information from the Government, and the SAC

simply does not contain the particularized allegations necessary to support an inference of fraud. *See* Fed. R. Civ. P. 9(b); *Grubbs*, 565 F.3d at 186.

Regardless, the conclusory assertion that "overwhelming new evidence" exists does not add credibility to Relator's claims of fraud. Relator has claimed without factual support that Pfizer *knew* it could never deliver on the promise of a safe and effective vaccine. (ECF 118 ¶¶ 160, 314, 316, 319, 361.) As discussed in Pfizer's moving brief, this claim is completely implausible; if Pfizer knew at the outset that the vaccine would not work, why would the Company spend billions of dollars of its own money trying to develop it? Moreover, Relator's reference to "new" information says nothing about Pfizer's knowledge or intent at the time it negotiated its contract with DoD, designed its clinical trials, or submitted information to the FDA in support of the EUA. At bottom, the SAC contains nothing beyond nonsensical rhetoric, and the opposition simply doubles down on these conclusory, unsupported claims.

III. Relator Fails To Satisfy The FCA's Demanding Materiality Requirement.

Setting aside Relator's failure to plead an actionable false statement under the FCA, the SAC can and should be dismissed for the independent reason that Relator cannot establish that any alleged misrepresentations by Pfizer were material to the Government. This Court has already concluded that Relator cannot satisfy the FCA's materiality requirement. (ECF 96 at 42.) The Government's continued payment for the COVID-19 vaccine, even after learning of Relator's claims, shows that Relator's allegations are not material to the Government's payment decision. (ECF 96 at 36–40 ("[C]ontinued payment by the federal government after it learns of the alleged fraud substantially increases the burden on the relator in establishing materiality." (quoting *Harman*, 872 F.3d at 663).) This is not surprising given that Relator's claims of clinical trial irregularities impact, at most, a tiny portion of Pfizer's clinical trials. (ECF 96 at 42.) To the extent there could remain any doubt as to materiality, the Government itself resolved it through its

Statement of Interest expressing the Government's view that, *even if we assume Relator's allegations are true*, the alleged fraud here would not have impacted the Government's decisions to authorize and purchase Pfizer's COVID-19 vaccine. (ECF 70 at 11–12).

Faced with these facts undermining materiality, Relator clings to her assertion that the Government did not believe her claims of fraud, leaving open the possibility that the Government lacked "actual knowledge" of the alleged fraudulent activity. (Opp. at 18.) But as Pfizer explained in its motion, the Government need not believe Relator to make an informed decision as to whether her claims were sufficiently material to stop payment. Here, as in *Harman*, the Government reviewed Relator's allegations and made the public policy determination that, based on the totality of the scientific evidence, continued authorization and purchasing of the COVID-19 vaccine was warranted. (ECF 118 ¶ 290); *see also Harman*, 872 F.3d at 663–67 (finding no materiality where the Government "was not persuaded" by the relator's allegations of fraud).

In opposition, Relator now argues "the EUA statute imposes objective criteria on what is material to the issuance of the EUA." (Opp. at 19.) According to Relator, her allegations are material "as a matter of law," (*id.*), because, if proven true, Pfizer's vaccine would not have satisfied the "objective criteria" enumerated in the EUA statute, regardless of any public policy determination the Government made regarding the significance of her allegations, (*id.*). But Relator distorts the statutory text in making this argument by cherry-picking some of the language and ignoring the rest. In quoting 21 U.S.C. § 360bbb-3—the statute setting forth the criteria for issuance of an EUA—Relator conveniently omits the most critical language. (Opp. at 4.) Immediately before the language Relator quotes, in a section entitled "Criteria for Issuance of Authorization," the statute provides:

> ***The Secretary*** may issue an authorization under this section with respect to the emergency use of a product ***only if***, after consultation with the Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the applicable circumstances described in subsection (b)(1)), ***the Secretary concludes***—….

21 U.S.C. § 360bbb-3(c) (emphasis added).

Accordingly, Congress has not merely identified "objective criteria" for issuing an EUA, but rather Congress also identified an appropriate decision maker: the Secretary of the U.S. Department of Health & Human Services ("HHS").[2] Despite the Government's full knowledge of Relator's concerns, the Secretary continues to urge Americans to get vaccinated to this very day. *See*, *e.g.*, Statement from HHS Secretary Xavier Becerra Following CDC's Recommendation of Updated COVID-19 Vaccines, Sept. 12, 2023, http://tinyurl.com/4tuea5sj ("Following the . . . launch of the largest adult vaccination program in our nation's history, COVID-19 vaccines saved millions of lives, kept countless people out of the hospital, and provided peace of mind for the country. As fall and winter approach, I encourage everyone six months and older to get an updated COVID-19 vaccine to protect themselves and their loved ones.").

There is no statutory basis for Relator to substitute her judgment for the Secretary's on this critical question of public policy. Nor does a jury have a role to play here. *See Harman*, 872 F.3d at 669 ("We can assume that this and contrary views are debatable, but we must accept that the choice among them lies beyond the reach of seven citizens of Marshall, Texas, able though they

[2] The FDA is the agency within HHS empowered to make determinations about the safety and efficacy of drugs and vaccines and to issue EUAs in coordination with the HHS Secretary. *See* Authorizations of Emergency Use of Two Biological Products During the COVID-19 Pandemic; Availability, 86 F.R. 5200, 5201 (Jan. 19, 2021) (explaining the FDA is empowered to issue an EUA "when the Secretary of HHS has declared that circumstances exist justifying the authorization of emergency use" and only "after consultation with the HHS Assistant Secretary for Preparedness and Response").

may be. As revered as is the jury in its resolution of historical fact, its determination of materiality cannot defy the contrary decision of the [G]overnment, here said to be the victim, absent some reason to doubt the [G]overnment's decision as genuine.").

Congress entrusted the EUA decision to the HHS Secretary's discretion; Relator's allegations have not prompted the Secretary to withdraw the EUA; and the SAC provides no basis to doubt the sincerity of the Secretary's determination—in the face of Relator's persistent objections—that Pfizer's vaccine is safe and effective. As the Fifth Circuit has explained, "[w]hen the [G]overnment, at appropriate levels, repeatedly concludes that it has not been defrauded, it is not forgiving a found fraud—rather it is concluding that there was no fraud at all." *Id.* at 670. *Harman*, which is conspicuously absent from Relator's opposition brief, controls the materiality analysis here. As both a factual and statutory matter, it is crystal clear that Relator's allegations were not material to the Government's decision to purchase the COVID-19 vaccine. Under the principles set forth in *Harman*, the SAC should be dismissed. *See id*.

CONCLUSION

For the reasons discussed in this Reply and in Pfizer's motion to dismiss, Pfizer respectfully asks the Court to dismiss Counts I, II, III, and IV of the SAC, with prejudice, under Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6).[3]

[3] In Pfizer's moving brief, the Company argued Relator's continued pursuit of this action is unconstitutional. (ECF 119 at 22–25.) Although Relator's opposition brief cites some case law upholding the constitutionality of *qui tam* proceedings generally, she does not identify a single Fifth Circuit case in which the Court considered the Article II implications of allowing a relator to proceed with a *qui tam* action like this one, in which the Government has affirmatively announced that it wants the case dismissed. (*See* ECF 70.) Permitting this action, which is purportedly brought on behalf of the Government, to proceed against the Government's wishes would raise serious separation-of-powers concerns. *See Polansky*, 599 U.S. at 442, 449–51 ("The FCA's *qui tam* provision has long inhabited something of a constitutional twilight zone. There are substantial arguments that the *qui tam* device is inconsistent with Article II and that private relators may not represent the interests of the United States in litigation." (Thomas, J. dissenting).)

Respectfully submitted,

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