

**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

**PFIZER'S MOTION TO DISMISS RELATOR'S SECOND AMENDED COMPLAINT
AND MEMORANDUM OF LAW IN SUPPORT**

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Defendant Pfizer Inc. (“Pfizer”) respectfully moves, pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6), to dismiss the Second Amended Complaint (“SAC”) in the above-captioned matter (ECF 118), which Plaintiff-Relator Brook Jackson (“Relator”) filed under 31 U.S.C. § 3730(b), the *qui tam* provision of the False Claims Act (“FCA”). The Government, on whose behalf Relator brings this action, has agreed this case should be dismissed, and this Court has already considered and rejected Relator’s claims that Pfizer violated the FCA. The parties thoroughly briefed the prior motions to dismiss, including the fraudulent inducement theory that Relator belatedly raised in previous briefing and now pleads for the first time in her SAC. The Court carefully considered all of Relator’s claims and theories, including fraudulent inducement, and dismissed the First Amended Complaint with prejudice because no set of facts could establish that Relator’s allegations were material to the Government. The Court has now allowed amendment solely for Relator to formally plead her fraudulent inducement theory. As with the Court’s previous decision, the Court should again dismiss Relator’s claims against Pfizer with prejudice. The SAC fails because: (1) it does not plead a false or fraudulent claim; (2) Relator’s allegations were not material to the Government; and (3) she has no standing to pursue this litigation, which the United States agrees should be dismissed.

INTRODUCTION & STATEMENT OF ISSUES

The FCA’s *qui tam* provision empowers private individuals to bring anti-fraud lawsuits “in the name of the Government” and, if successful, share in the Government’s recovery. But the statute does not empower relators to pursue *qui tam* actions in an effort to undermine important Government policies and programs. As the Supreme Court remarked earlier this year, the FCA is “unusual in authorizing private parties . . . to sue on the Government’s behalf” and, “[b]ecause the relator is no ordinary civil plaintiff, he [or she] is immediately subject to special restrictions.” *United States ex rel. Polansky v. Exec. Health Res., Inc.*, 599 U.S. 419, 423–25 (2023). Some of

these restrictions are explicit in the statutory text. Others arise from bedrock separation-of-powers values. They combine to ensure the Executive Branch retains ultimate control of civil litigation brought on behalf of the United States. *Qui tam* actions may be initiated by private relators, but “the injury they assert is exclusively to the Government.” *Id.* at 425. These cases exist solely to “vindicate the Government’s interests” and “nothing about the statute’s objectives suggests that the Government should have to take a back seat to its co-party relator.” *Id.* at 435.

It is hard to imagine a case more in conflict with the FCA’s “Government-centered purposes” than this one. *See Polansky*, 599 U.S. at 434. Since the inception of the present action, Relator has been attempting to hijack the *qui tam* process to advance an anti-vaccination agenda that the Government categorically rejects. She alleges Pfizer’s COVID-19 vaccine is “ineffective and unsafe,” and she vehemently disagrees with the Government’s decisions to authorize and purchase the product. (ECF 118, ¶ 160.) According to Relator, she obtained her information during her short tenure at Defendant Ventavia Research Group, LLC (“Ventavia”), where she was employed for eighteen days in September 2020. Ventavia owned and operated three of the 153 clinical research sites that conducted the “landmark” study of Pfizer’s vaccine. This clinical trial involved approximately 44,000 participants worldwide, approximately 1,500 of whom were enrolled by Ventavia, and showed that the vaccine was more than 90 percent effective at preventing COVID-19, with a favorable tolerability and safety profile. (ECF 118, ¶ 163.) Based on these results, the U.S. Food & Drug Administration (“FDA”) granted the initial emergency use authorization (“EUA”) for Pfizer’s vaccine on December 11, 2020 and, shortly thereafter, the U.S. Department of Defense (“DoD”) started purchasing the vaccine and providing it to Americans free of charge. (ECF 118, ¶ 21.)

Relator worked as a Regional Director at two of the three Ventavia sites while the landmark study was underway. (ECF 118, ¶¶ 262, 291.) At that time, she alleges that she witnessed “widespread” protocol noncompliance and regulatory violations that, in her view, “compromised” the “integrity of the entire clinical trial.” (ECF 118, ¶¶ 16, 335.) Relator speculates that “had the United States learned that Pfizer had engaged in [the] misconduct” alleged in her lawsuit, the FDA “would not have issued the EUA” for Pfizer’s vaccine, and “[w]ithout an EUA, the DoD would not have paid for the vaccines.” (ECF 118, ¶¶ 159, 171.) Relator has pled no facts to support these claims. To the contrary, Relator’s own complaint and the Government’s filings in this case show that the Government was well aware of her allegations, yet these concerns were not material to the Government’s decision to approve and pay for Pfizer’s vaccine.

The SAC states that, on or about September 25, 2020, Relator “called the FDA’s hotline to report the clinical trial protocol violations and patient safety concerns she witnessed” and the agency “spoke to her for several hours regarding the violations she [allegedly] saw at Ventavia.” (ECF 118, ¶ 290, 293.) Similar statements appear in Relator’s earlier pleadings, including her First Amended Complaint. (ECF 17, ¶¶ 262, 266.)¹ They establish that the Government was well aware of Relator’s concerns nearly three months before FDA first authorized Pfizer’s vaccine for emergency use, and even longer before DoD started paying the relevant invoices. Despite this knowledge, the Government’s support for the vaccine has never wavered.² The SAC notes, for

¹ The First Amended Complaint details the myriad times Relator shared her concerns not just with FDA, but also DoD, the U.S. Department of Justice (“DOJ”), and the U.S. Attorney’s Office for the Eastern District of Texas. (See ECF 17 ¶¶ 12, 38–39, 262, 266; see also ECF 93-1.)

² Relator has falsely suggested it was the “Biden Administration” that rejected her position. (ECF 75 at 1.) In fact, Relator brought her allegations to FDA during the Trump Administration, and it was the Trump Administration FDA that issued the initial authorization for the vaccine—the EUA—after having spoken to Relator for “several hours.” (ECF 118, ¶ 290.) The truth is that both the Trump Administration and the Biden Administration have issued approvals and purchased the vaccine despite having full knowledge of Relator’s allegations.

example, that FDA has “issued additional EUAs” for Pfizer’s vaccine for “different age cohorts” and then, on August 23, 2021, the agency fully approved the vaccine, now known as “Comirnaty,” for use in individuals ages 16 and older. (ECF 118, ¶ 21.) These approvals remain in place, and, at all relevant times, DoD continued to purchase the product. Moreover, the U.S. Centers for Disease Control and Prevention (“CDC”) continues to recommend Pfizer’s vaccine to this very day.³ These facts are fatal to Relator’s lawsuit. *See Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 195 (2016) (“[I]f 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.”).

Were there any room for doubt about the Government’s views, the Justice Department has dispelled it. First, DOJ declined to intervene in Relator’s lawsuit. (ECF 13.) Then the Justice Department took the extraordinary step of filing a “Statement of Interest Supporting Dismissal” in this case. (ECF 70.) This latter submission by the Government refutes Relator’s central claim that the alleged clinical trial violations by Ventavia “call the vaccine’s EUA into question.” (ECF 70 at 10.) The Statement of Interest recounts FDA’s public statements in response to early media coverage of Relator’s anti-vaccination crusade. Those public statements, issued more than a year after Relator first disclosed her concerns to the Government, affirmed that FDA continues to have “full confidence in the data that were used to support the Pfizer-BioNTech COVID-19 Vaccine authorization and the Comirnaty approval.” (ECF 70 at 5–6.)

³ U.S. Centers for Disease Control and Prevention, Stay Up To Date With COVID-19 Vaccines, Oct. 4, 2023, <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html> (“CDC recommends the 2023–2024 updated COVID-19 vaccines: Pfizer-BioNTech, Moderna, or Novavax” and “[e]veryone aged 5 years and older should get 1 dose of an updated COVID-19 vaccine to protect against serious illness from COVID-19.”).

As explained in the Government’s Statement of Interest, Relator has proffered no 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,” nor could she ever show that “the criteria for issuance of the EUA would not have been met without the Ventavia data.” (ECF 70 at 11.) That’s because FDA’s authorization is based on “the totality of scientific evidence available” and “Ventavia enrolled only about 3 percent” of the individuals who participated in the landmark study. (ECF 70 at 11–12.) Said another way, the Government would have authorized and purchased Pfizer’s vaccine regardless of what Relator says about the happenings at Ventavia.

Relator’s views are impossibly at odds with the Government’s. She believes COVID-19 vaccines are a “fraud.” The United States disagrees. As this Court noted in its opinion dismissing this lawsuit, “[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.” (ECF 96 at 38 (quoting *United States ex rel. Harman v. Trinity Indus., Inc.*, 872 F.3d 645, 670 (5th Cir. 2017).) The Government’s views in this regard are entitled to “substantial deference” as the “real party in interest” here. *Polansky*, 599 U.S. at 425, 437. And when the United States supports dismissal of a *qui tam* action, “a district court should think several times over before denying a motion to dismiss.” *Id.* at 437–38. That is especially so in this case, where Relator is using *qui tam* litigation as a fig leaf while she attacks a core plank of the federal government policy developed, by both Republican and Democratic administrations, in response to a global pandemic. *See Harman*, 872 F.3d at 668–69 (“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.”).

This Court heeded these important principles when it granted Pfizer’s first motion to dismiss earlier this year. (ECF 96.) The Court has since granted Relator an opportunity to amend (ECF 108), but her new pleading, the SAC, adds nothing to the fraudulent inducement allegations that this Court previously addressed and rejected. For the reasons discussed in the Court’s first opinion dismissing this case, as well as this Memorandum, Relator’s eleventh-hour invocation of the “fraudulent inducement theory” gets her nowhere, and her attempt to overcome the Court’s previous rulings on materiality are insufficient. Relator has filled her SAC with the standard tropes asserted by anti-vaccination conspiracy theorists. Among these is the obviously false assertion that Pfizer “hid information” about “alternative effective treatments” so that FDA would authorize a “historically dangerous, ineffective, gene therapy that . . . would cause death and disability of millions of people, and [Pfizer] knew it.” (ECF 118, ¶¶ 308, 314.) The SAC provides no factual basis for these wild accusations, and there is none. Such conspiracy theories may be common fodder on social media. They have no place in federal court, and they certainly cannot salvage Relator’s deficient *qui tam* lawsuit.

The Court was right to dismiss this action the first time around. It should do so again.

FACTUAL & PROCEDURAL BACKGROUND

Pfizer’s previous Motion to Dismiss Relator’s [First] Amended Complaint And Memorandum Of Law In Support, (ECF 37), included an extended “Factual Background” section that described, in detail, the outset of the COVID-19 pandemic, including (1) former President Trump’s decision to launch Operation Warp Speed to accelerate the development, acquisition, and distribution of COVID-19 medical countermeasures, with a particular focus on the urgent need for vaccines; (2) Pfizer’s contract to sell the first 100 million doses of the vaccine to DoD, contingent on the company first securing FDA authorization or approval; (3) the design and results of the landmark study, along with FDA’s decision to grant the EUA for Pfizer’s vaccine; and (4) the

actual invoices for the vaccine that Pfizer submitted to DoD. (ECF 37 at 5–18.) Pursuant to Federal Rule of Civil Procedure 10(c), this Memorandum adopts Pfizer’s previous motion to dismiss and its accompanying memorandum of law, including the Factual Background section, and incorporates them here by reference.⁴

Relator filed her original complaint, under seal, on January 8, 2021. (ECF 1.) DOJ declined to intervene in this action approximately one year later, and the Court unsealed the action on February 10, 2022. (ECF 13, 16.) Relator filed her First Amended Complaint, which was virtually identical to her original pleading, shortly thereafter. (ECF 17.) The First Amended Complaint made extensive allegations, encompassing 631 pages, including 29 exhibits. Pfizer moved to dismiss the First Amended Complaint on April 22, 2022 (ECF 37), and Pfizer’s co-defendants later did the same. While Pfizer’s motion was pending, Relator filed a brief opposing the motion (ECF 65), and then, on October 4, 2022, DOJ filed a 13-page Statement of Interest Supporting Dismissal of this action (ECF 70). The Court allowed all parties to be heard on the motions during an oral hearing on March 1, 2023. That hearing lasted over three hours. This Court rendered its decision on March 31, 2023, issuing a thorough, 48-page opinion that dismissed all of Relator’s claims against Pfizer with prejudice. (ECF 96 at 43–44.)

The Court set forth its rationale for dismissal in a thoughtful and well-reasoned opinion firmly rooted in Supreme Court and Fifth Circuit precedent. The opinion explains that Relator’s

⁴ Pfizer’s previous motion to dismiss argued that Relator’s lawsuit was subject to an unsatisfied condition precedent—alternative dispute resolution (“ADR”) requirements—that the Government negotiated back in July 2020 as part of its initial agreement to purchase Pfizer’s vaccine. (ECF 37 at 27–30.) As Pfizer explained at the time, those ADR requirements apply to FCA causes of action whether brought by the Government directly or by a relator on the Government’s behalf. In this case, the United States has taken no action against Pfizer, and Relator’s claims cannot proceed in federal court unless and until the Government first pursues them in an administrative proceeding. This Memorandum adopts Pfizer’s ADR-based arguments and incorporates them by reference. *See* Fed. R. Civ. P. 10(c)

First Amended Complaint failed to satisfy two of the essential elements of an FCA violation: falsity and materiality. As to falsity, the Court rejected as implausible Relator's allegation that Pfizer's claims for payment contained "express and implied false certifications" of compliance with various provisions of the Code of Federal Regulations. (ECF 96 at 19–30.) The Court also expressed skepticism about Relator's alternative argument, raised for the first time in her opposition brief, that Pfizer was liable under a "fraudulent inducement" theory. (ECF 96 at 30–32.) Relator's version of this theory, as expressed at the time, was that "Pfizer's invoices, though contractually justified, were fraudulently induced" through "lies, omissions, and fabrications" that Pfizer allegedly "made to the FDA before receiving [the] EUA." (ECF 65 at 18.)

Because Relator did not plead fraudulent inducement in her First Amended Complaint, but rather raised this theory in the briefing on Pfizer's motion to dismiss, the Court declined to decide whether the theory applied to the fact pattern alleged by Relator. (ECF 96 at 32.) The Court did, however, note that Relator's version of the fraudulent inducement theory lacked precedential support: "To the Court's knowledge, the Fifth Circuit has not expanded its recognition of the fraudulent inducement theory to situations beyond those where the *contract* under which payment is made was procured by fraud." (ECF 96 at 31–32 (emphasis in original).) Relator never argued that Pfizer procured its contract with DoD under false pretenses; she argued instead that the EUA was fraudulently procured from FDA. The Court was skeptical that the fraudulent inducement theory would apply under those circumstances.

The Court also dismissed the First Amended Complaint on materiality grounds. (ECF 96 at 32–42.) Here, the Court relied heavily on the Supreme Court's landmark decision in *Escobar*, as well as the Fifth Circuit's *Harman* decision, both of which analyzed *qui tam* allegations under the FCA's "demanding" materiality requirement. *Id.* As this Court recognized, the materiality

test looks to the “‘likely or actual behavior’ of the Government,” (ECF 96 at 33 (quoting *Escobar*, 579 U.S. at 193)), and “continued payment by the federal government after it learns of the alleged fraud substantially increases the burden on the relator in establishing materiality,” (ECF 96 at 36 (quoting *Harman*, 872 F.3d at 663)).

In light of these precedents, the Court examined the Government’s words and actions since learning about Relator’s allegations several years ago—including, in particular, the Government’s Statement of Interest Supporting Dismissal—and concluded “[t]he Government’s unbroken chain of authorization and payments in the face of Ms. Jackson’s allegations does not support an inference that the alleged misrepresentations were material.” (ECF 96 at 36–38.) As the Court put it succinctly, “[h]indsight here is 20/20,” meaning hindsight reveals that the Government’s continued approval and purchases of the vaccine after becoming aware of Relator’s concerns show their clear lack of materiality. (ECF 96 at 40.) The Court denied Relator’s request for leave to amend as well, finding the effort would be “futile.” (ECF 96 at 44 (“[T]he proposed amendments would not alter the conclusion that Defendants’ alleged fraud was not material in light of the Government’s continued authorization and purchase of the vaccine.”).) This statement by the Court would prove prescient; the newly filed SAC adds nothing that would change the Court’s prior rulings on materiality.

Relator moved for reconsideration of the Court’s “futility” determination on April 28, 2023. (ECF 97.) As required by the local rules, Relator’s reconsideration motion attached a proposed amended pleading. (ECF 97-1.) The Court granted Relator’s motion for reconsideration on August 9, 2023 for a single, narrow purpose: to give Relator an opportunity to allege fraudulent inducement in an actual complaint. (ECF 108 at 2–3.) In granting this relief, the Court again expressed doubts about “whether liability can attach under the fraudulent inducement theory when

a contract was procured through truthful statements, but a condition of payment—here, FDA authorization—was subsequently obtained through misrepresentations.” (ECF 108 at 2.)

The Court also noted Relator’s new statement in the proposed SAC that “while the FDA was aware of her allegations, the agency ‘did not believe the fraud allegations.’” (ECF 108 at 3.) The Court posited that this statement “could be construed as an assertion that the FDA did not have actual knowledge of [the] alleged statutory, regulatory, or contractual violations” at the Ventavia sites. *Id.* And the Court expressed “uncertainty” as to whether “the Government’s continued authorization and/or payment after it learns of *allegations* that a defendant violated statutory, regulatory, or contractual requirements—as opposed to *actual knowledge* that such violations occurred—is strong evidence that compliance with those requirements was not material to the Government’s decision.” *Id.* (emphasis in original).

Relator filed her SAC, with the Court’s leave, on October 5, 2023. (ECF 118.) Concurrently, the parties filed a stipulation that, as to Pfizer, only a single count of the complaint—“Count I – Fraud in the Inducement”—was properly before the district court, “with the understanding that the Court previously dismissed the claims in Counts II, III, and IV with prejudice, and that those counts are included in the [SAC] only for purposes of preserving those claims for appeal.” (ECF 116.) The SAC also includes two employment-based claims, Counts V and VI, which Relator asserts against Ventavia only.

The SAC is long on anti-vaccination tropes and rhetoric, but short on well-pleaded facts. Consistent with Relator’s previous attempt to advance the fraudulent inducement theory, the SAC alleges that Pfizer “induced the issuance of the EUA . . . by breaking the clinical trial rules, covering it up when exposed, refusing to remedy violations when detailed, [and] submitting unreliable and false data to the [G]overnment.” (ECF 118, ¶ 309.) These allegations add nothing

to Relator's original allegations, and have no factual basis to boot, as the Government itself has recognized. DOJ's Statement of Interest emphatically rejected the notion that data supporting Pfizer's vaccine are "unreliable and false." (ECF 70 at 11–12.) DOJ likewise rejected the idea that the Ventavia data had any material impact on FDA's authorization of Pfizer's vaccine. *Id.*

The SAC also alleges, in conclusory fashion, that Pfizer "fooled . . . the Defense Department" and procured its contract "by fraud in the inducement." (ECF 118, ¶¶ 334, 353.) According to Relator, Pfizer "knew the premise of its modRNA vaccine was flawed," "knew that it could never gain either approval or an EUA based on truthful clinical data," "knew its product would not confer immunity," "knew that the injections would confer negative efficacy in the study group," "knew vaccine injuries would appear in the treatment subjects in the months and years after injection," and finally, "knew that the vaccines would cause injuries to pregnant women and their fetuses." (ECF 118, ¶¶ 135, 139–40, 142–43, 145.) Despite this so-called "knowledge," Pfizer allegedly entered into its contract with DoD, even though the company "never intended to, and knew it could not, deliver" a safe and effective vaccine. (ECF 118, ¶ 306.)

These allegations defy common sense and are implausible on their face. If Pfizer really knew at the outset that the vaccine it was developing would not work, (ECF 118, ¶ 306), why would the company devote billions of dollars of its own money to develop and produce the vaccine? (*See* ECF 37 at 13 (noting that "Pfizer, not the Government, was the entity footing the bill for the very significant costs of the landmark study").) Relator's allegations are simply ridiculous, and it is impossible for her to plead any factual support for her claims.

For the reasons discussed in the balance of this Memorandum, the SAC falls far short of meeting basic federal pleading standards; Relator's allegations were not material to the Government's decision to pay for the vaccine; and regardless, Relator's continued pursuit of this

litigation, after the Government itself has stated the case should be dismissed, raises intractable separation-of-powers problems.

LEGAL STANDARDS

“Motions filed under Rule 12(b)(1) of the Federal Rules of Civil Procedure allow a party to challenge the subject matter jurisdiction of the district court to hear a case.” *Ramming v. United States*, 281 F.3d 158, 161 (5th Cir. 2001). The burden of proof for a Rule 12(b)(1) motion is on the party asserting jurisdiction. *Id.* In examining a Rule 12(b)(1) motion, the district court may look outside the pleadings and consider matters of fact which may be in dispute. *Id.*

The Rule 12(b)(6) standard is different. Under this Rule, the complaint must contain “sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 555, 570 (2007)). “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* The factual allegations must be sufficient to raise the right to relief above a speculative level. *Lexington Inc. Co. v. S.H.R.M. Catering Servs., Inc.*, 567 F.3d 182, 184 (5th Cir. 2009). “[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct,” the complaint has stopped short of showing that the pleader is plausibly “entitled to relief.” *Iqbal*, 556 U.S. at 679. “When there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief.” *Id.* In doing so, the court should construe claims in the light most favorable to the plaintiff, but also “draw on its judicial experience and common sense.” *Id.*; *Doe v. MySpace, Inc.*, 528 F.3d 413, 418 (5th Cir. 2008).

When reviewing a complaint, courts “are not bound to accept as true a legal conclusion couched as a factual allegation.” *Twombly*, 550 U.S. at 678. “[A] plaintiff must plead specific

facts, not mere conclusional allegations, to avoid dismissal for failure to state a claim.” *Kane Enterprises v. MacGregor (USA), Inc.*, 322 F.3d 371, 374 (5th Cir. 2003). “A pleading that offers ‘labels and conclusions’ or ‘a formulaic recitations of the elements of a cause of action will not do.’” *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 555). “Nor does a complaint suffice if it tenders ‘naked assertion[s]’ devoid of ‘further factual enhancement.’” *Id.* (quoting *Twombly*, 550 U.S. at 557).

Complaints filed under the FCA must also satisfy the “heightened” pleading standards of Rule 9(b). *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 185 (5th Cir. 2009). Under this Rule, a party alleging fraud or mistake “must state with particularity the circumstances constituting fraud or mistake.” Fed. R. Civ. P. 9(b). This requires, at a minimum, that a *qui tam* plaintiff set forth the “who, what, when, where, and how of the alleged fraud.” *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 903 (5th Cir. 1997). The Fifth Circuit has instructed lower courts to apply the Rule 9(b) requirements “with bite and without apology.” *Grubbs*, 565 F.3d at 185.

ARGUMENT

I. RELATOR HAS NOT PLED A FALSE OR FRAUDULENT CLAIM.

It is often said in FCA litigation that a false or fraudulent claim is the “*sine qua non*” of a *qui tam* action. *Grubbs*, 565 F.3d at 188. To satisfy this “indispensable element” of an FCA violation, *United States ex rel. Hebert v. Disney*, 295 Fed. App’x 717, 722 (5th Cir. 2008), a relator must identify a claim requesting money or property from the United States that is either factually or legally false. *United States ex rel. Ruscher v. Omnicare, Inc.*, 663 Fed. App’x 368, 373 (5th Cir. 2016). Factually false claims are those representing that a claimant has provided goods or services that the Government never received. *Id.* Relator has not tried to plead factually false claims. Rather, in her First Amended Complaint, Relator alleged that Pfizer made legally false

claims because Pfizer's invoices to DoD contained "express and implied false certifications" of compliance with various federal regulations. (ECF 17 ¶¶ 274, 278.) This Court dismissed these false certification claims with prejudice. (ECF 96.)

With respect to falsity, the only issue remaining for this Court is Relator's assertion that Pfizer violated the FCA under a theory of fraudulent inducement. (ECF 116.) According to Relator, Pfizer's claims for payment to the Government were not literally false, but they were actionable nonetheless because of misrepresentations that Pfizer allegedly submitted to FDA and DoD. (ECF 118 ¶¶ 306–311, 334, 353.) Relator first articulated her "fraud-on-the FDA" theory in opposition to Pfizer's first motion to dismiss, but the Court—expressing skepticism that Relator could plead such a claim—declined to resolve this issue. (ECF 96 at 30–32.) Relator has not previously pled "fraud-on-the DoD," but her allegations on this score are equally unavailing.

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

Applying current Fifth Circuit precedent, Relator's fraudulent inducement claim as to FDA must fail. The Fifth Circuit has only recognized the fraudulent inducement theory in the context of fraudulent procurement of Government contracts, not fraudulent procurement of regulatory approvals, as alleged here. *See Gonzalez v. Fresenius Med. Care N. Am.*, 689 F.3d 470, 476 (5th Cir. 2012) (explaining fraudulent inducement under the FCA arises where "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))); *see also United States ex rel. Willard v. Humana Health Plan of Texas, Inc.*, 336 F.3d 375, 384 (5th Cir. 2003); *United States ex rel. Laird v. Lockheed Martin Eng'g & Sci. Servs. Co.*, 491 F.3d 254, 259 (5th Cir. 2007). In fact, 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*, 689 F.3d at 473–78 ("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)).

Fraudulent procurement of FDA approvals has never been a predicate for FCA liability in this Circuit. *See id.* This Court previously recognized as much, explaining in its prior decision: “[t]o the Court’s knowledge, the Fifth Circuit has not expanded its recognition of the fraudulent inducement theory.” (ECF 96 at 31–32.) Other courts have expressly rejected the theory’s application in the FDA context. *See 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”). Although the Court declined to reach this issue previously, the Court should now dismiss Relator’s fraud-on-the-FDA claim as inconsistent with Fifth Circuit law.

Additionally, Pfizer maintains the fraudulent inducement theory is always invalid because the theory has no basis in the FCA’s statutory text. Although the Court previously disagreed with Pfizer on this point, (ECF 96 at 31), Pfizer respectfully notes that other judges have questioned whether fraudulent inducement remains a viable theory following the Supreme Court’s instruction in *Escobar* that lower courts must adhere strictly to the plain language of the FCA, lest it become “an all-purpose antifraud statute.” 579 U.S. at 187, 194. These judges have noted the fraudulent inducement theory “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).

Pfizer incorporates by reference its prior text-based arguments, (ECF 67 at 2–5), and respectfully notes that the Court could dismiss the SAC with prejudice for this reason alone.

B. Relator’s Latest Fraud Allegations, As To FDA And DoD, Defy Common Sense And Are Implausible.

Relator’s fraudulent inducement theory is not only legally defective, it lacks factual support as well. To adequately plead a claim under the FCA, Relator “must meet the heightened pleading standard of Rule 9(b).” *Grubbs*, 565 F.3d at 185. And under Rule 8’s more liberal pleading standard, Relator must state a claim that is plausible when viewed through the lens of ordinary experience and common sense. *Iqbal*, 556 U.S. at 679. As the Government noted its Statement of Interest supporting dismissal, Relator’s First Amended Complaint lacked “factual allegations that would support a plausible claim.” (ECF 70 at 12.) The allegations in Relator’s SAC are even less plausible and rise to the point of absurdity.

Although Relator generally asserts that “Pfizer induced the issuance of the EUA” by engaging in a host of alleged fraudulent behaviors, the SAC does not plead facts supporting Relator’s theory. (ECF 118 ¶ 309.) For example, Relator claims Pfizer “knew that alternative effective treatments” for COVID-19 existed in the early days of the pandemic, and then “falsely represented to the FDA that such treatments were still investigational.” (ECF 118 ¶ 155.) But the SAC does not contain any supporting factual allegations establishing the who, what, when, where, and why of this incendiary claim. *See Grubbs*, 565 F.3d at 186 (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”). More to the point, Relator’s conclusory allegations are completely implausible. Had effective, alternative treatments existed back in 2020, there would have been no need for former President Trump to

launch Operation Warp Speed, and expend billions of taxpayer dollars, to develop and purchase a safe and effective vaccine. *See Iqbal*, 556 U.S. at 679.

Similarly, Relator avers throughout the SAC that Pfizer knew, but did not tell the Government, including both FDA and DoD, “that [Pfizer’s] vaccines were ineffective and unsafe.” (ECF 118 ¶¶ 160, 314, 316, 319, 361.) Again, Relator pleads nothing beyond accusatory rhetoric to support her claims about the vaccine’s benefit/risk profile. And, again, Relator’s assertions are clearly implausible. The notion that Pfizer somehow “knew” from the outset that the company could never successfully develop an effective and safe vaccine makes no sense when: (1) the company ultimately secured FDA authorization and approval, as did other companies like Moderna and J&J; (2) the Government continued to promote and pay for Pfizer’s vaccine; and (3) 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 70 at 5–6.)

On a common-sense level, it simply defies logic that Pfizer would invest the billions of dollars required to develop and produce a COVID-19 vaccine if the company knew, on the front end, that there were effective alternatives already in existence and Pfizer “knew” it could not deliver a vaccine of its own. (*See* ECF 118, ¶ 306.) Relator’s nonsensical allegations do not come close to meeting the plausibility requirements of Rule 8. *See Iqbal*, 556 U.S. at 679 (“Determining whether a complaint states a plausible claim for relief will . . . be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense.”).

To highlight the nonsensical nature of Relator’s case, it is helpful to consider two of the SAC’s allegations side-by-side. First, Relator avers that Pfizer “sought an EUA by engaging in fraudulent conduct in the design” of the landmark trial, (ECF 118, ¶¶ 139–45), and then Relator faults Pfizer for “departure[s] from the scientific protocol” because “[d]eparture from the protocols

renders the data useless,” (ECF 118, ¶ 156). In other words, Relator says Pfizer committed “fraud” on FDA and DoD by designing a bogus protocol, but she also says it was “fraud” to deviate from that bogus protocol. If Pfizer designed a bogus protocol to secure the EUA, why would Pfizer need to commit fraud to comply with that bogus protocol? Relator’s claims simply defy common sense. When it comes to incoherent allegations like these, “implausible” is too kind a word, and the requirements of *Iqbal* and Rule 8 cannot be satisfied.

II. RELATOR FAILS TO SATISFY THE FCA’S DEMANDING MATERIALITY REQUIREMENT.

Materiality is another insurmountable hurdle for Relator. To be actionable under the FCA, a “misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government’s payment decision.” *Escobar*, 579 U.S. at 181. This materiality standard is a “demanding” one—not “too fact intensive” to decide on a motion to dismiss—that “looks to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.” *Id.* at 194, 195 n.6.

In granting the prior motion to dismiss, this Court held the allegations in the First Amended Complaint “cannot support a conclusion that Defendants’ alleged fraud was material.” (ECF 96 at 42.) In particular, the Court relied on the Government’s continued authorization and payment for the Pfizer vaccine, explaining “continued payment by the federal government after it learns of the alleged fraud substantially increases the burden on the relator in establishing materiality.” (ECF 96 at 36–40 (quoting *Harman*, 872 F.3d at 663).) The Court also explained that “materiality ‘cannot be found where noncompliance is minor or insubstantial,’” noting “Ventavia only enrolled about 3%...of the total clinical trial participants [and] Ms. Jackson’s allegations only implicate a fraction of that 3%.” (ECF 96 at 42 (quoting *Harman*, 872 F.3d at 660).) Indeed, the Court originally denied Relator leave to amend because her “proposed amendments would not alter the

conclusion that Defendants’ alleged fraud was not material in light of the Government’s continued authorization and purchase of the vaccine.” (ECF 96 at 44.)

This Court’s materiality analysis of the First Amended Complaint was correct, and other courts have cited this Court’s decision with approval. *See State ex rel. Harman v. Trinity Indus., Inc.*, No. M2022-00167-COA-R3-CV, 2023 WL 3959887, at *14 (Tenn. Ct. App. June 13, 2023) (adopting the Court’s materiality analysis in ECF 96 in a state-court action related to the federal *Harman* case). That analysis applies in exactly the same way to the SAC, and the Court should dismiss Relator’s new pleading, with prejudice, for the same reasons.

In granting Relator leave to amend, the Court noted Relator’s allegation that FDA “did not believe [her] fraud allegations,” and asked the question whether this could be “construed as an assertion that the FDA did not have actual knowledge” of the alleged fraud. (ECF 108 at 3.) Citing *Harman*, the Court raised the question of whether the Government’s continued payment and authorization after learning of mere *allegations* of fraud can support a finding of immateriality at the motion to dismiss stage. *Id.*

The Fifth Circuit precedent in *Harman* is exactly on point and controls the result here. In this case, as in *Harman*, the Government thoroughly vetted Relator’s fraud allegations, speaking with her for “several hours,” and nevertheless the Government concluded it was appropriate to issue the EUA. (ECF 118, ¶ 290); *see also Harman*, 872 F.3d at 667 (noting relator presented information concerning the alleged fraud to the Government, but the Government “was not persuaded by the allegations”). And, as the *Harman* court noted, deference to the Government’s conclusion concerning fraud allegations is particularly appropriate in situations, like this one, where the Government’s decision involved an issue of exceptional “gravity.” *Id.* at 663.

Immateriality is particularly clear in this case due to the Government's Statement of Interest, which explained why Relator's information was not significant from FDA's perspective.

(ECF 70.) The Government put it this way:

[E]ven if the allegations were sufficient to show that Ventavia's safety and efficacy data were 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 evidence available" and the complaint alleges that Ventavia enrolled only 3 percent, or approximately 1,500 of the nearly 44,000 total clinical trial participants.

(ECF 70 at 11–12.) In other words, this is not a case in which the Government was merely aware of allegations but never followed up on them. Rather the United States here carefully evaluated Relator's allegations and found that—even if those allegations were assumed to be true—the alleged fraud would not have altered the Government's decision-making in terms of authorizing and purchasing Pfizer's COVID-19 vaccine.

DOJ's Statement of Interest in the present case is akin to the "official memorandum" of the Federal Highway Administration in *Harman*. (See ECF 96 at 37.) In that case, as here, "the court did not even need to infer the Government's approval from continued payment because the Government's memorandum explicitly stated approval." (ECF 96 at 37 (citing *Harman*, 872 F.3d at 663–64).) The Statement of Interest in this case does the same, highlighting that Relator's allegations about the Ventavia sites simply did not move the needle when it comes to the Government's decision-making with respect to Pfizer's vaccine.

Even if the United States had never filed a Statement of Interest explaining why the Government continues to have "full confidence" in Pfizer's vaccine despite Relator's concerns, her complaint would still come up short from a materiality perspective. The reason lies in the Government's "unbroken chain of authorization and payments in the face of Ms. Jackson's allegations." (ECF 96 at 37.) "[T]hough not dispositive, continued payment by the federal

government after it learns of the alleged fraud substantially increases the burden on the relator in establishing materiality.” *Harman*, 872 F.3d at 663; *see also United States ex rel. Porter v. Magnolia Health Plan, Inc.*, 810 Fed. App’x 237, 242 n.7 (5th Cir. 2020) (affirming dismissal of *qui tam* complaint for lack of materiality where relator “made no allegations that . . . continued approval persisted for reasons other than non-materiality”).

The SAC proffers a single reason for the Government’s continued payments in this case—namely, “both the DOD and FDA . . . did not believe the fraud allegations against Pfizer.” (ECF 118, ¶ 334.) This statement comes nowhere close to satisfying Relator’s “substantially increase[d]” burden for establishing materiality. *Porter*, 810 Fed. App’x at 242. If anything, to the extent the Government disbelieved Relator’s claims, this would confirm their immateriality, as well as their implausibility. *See Escobar*, 579 U.S. at 193 (“Under any understanding of the concept, materiality looks to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.”); *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 investigatory powers to protect the public health and safety is told what [r]elators have to say, yet sees no reason to change its position”).

The Government is the real party in interest in this case, and Relator is bringing this action on the Government’s behalf. *See* 31 U.S.C. § 3730(b). Where, as here, the Government was made aware of potential fraud, assessed the allegations, and concluded the case should be dismissed because Relator’s concerns would not have changed the relevant regulatory and payment decisions of the United States, the Court should defer to the Government’s assessment. *See Harman*, 872 F.3d at 669 (“[The] 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.”). For all of these reasons, dismissal of Relator’s SAC, with prejudice, is required; she simply cannot clear the FCA’s high bar for pleading materiality.

III. RELATOR HAS NO STANDING TO PURSUE THIS CASE AGAINST THE GOVERNMENT’S WISHES.

While the falsity and materiality questions are dispositive, the Court can also dismiss the SAC for the independent reason that Relator’s continued prosecution of this case, over the Government’s crystal-clear objections, violates Article II of the Constitution, which in turn undercuts Relator’s standing to sue “for the United States Government” as provided under the FCA. *See* 31 U.S.C. § 3730(b)(1).

The conflict between the FCA’s grant of authority to relators, on the one hand, and the requirements of Article II, on the other, were noted recently by three Supreme Court justices who acknowledged there are “substantial arguments” that “Congress cannot authorize a private relator to wield executive authority to represent the United States’ interests in civil litigation.” *Polansky*, 599 U.S. at 449–50 (Thomas, J. dissenting); *see id.* at 442 (Kavanaugh, J., and Barrett, J. concurring) (agreeing with Justice Thomas on this point). In the words of Justice Thomas, the FCA’s *qui tam* provisions “have long inhabited something of a constitutional twilight zone,” and there is “good reason to suspect that Article II does not permit private relators to represent the United States’ interests in FCA suits.” *Id.* at 449–51.

Article II vests the executive power—including the power to litigate in the Government’s name—in the President alone. “[O]nly . . . persons who are ‘Officers of the United States,’” and over whom the President has significant control, may exercise the power to “conduct[] civil litigation in the courts of the United States for vindicating public rights.” *Buckley v. Valeo*, 424 U.S. 1, 140 (1976); *see Morrison v. Olson*, 487 U.S. 654, 696 (1988). Yet the FCA allows private

citizens to take the “lead role” when it comes to litigating fraud claims on the Government’s behalf in cases where the DOJ has declined to intervene. *Polansky*, 599 U.S. at 423. This dynamic raises serious questions under Article II, which requires individuals who take “primary responsibility” for litigation on behalf of the United States to be appointed in accordance with the Appointments Clause. U.S. Const., art. II, § 2, cl. 2; *Buckley*, 424 U.S. at 140. Relator in this case was never appointed to federal office.

There is also a conflict with the Take Care clause, which entrusts the President with the power to “take care that the Laws are faithfully executed.” U.S. Const., art. II, § 3; *see Free Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, 484 (2010). The President cannot satisfy the Take Care clause “if he cannot oversee the faithfulness” of his subordinates. *Free Enter. Fund*, 561 U.S. at 484. Nor may Congress properly transfer litigating authority from the President to individuals over whom the President does not exercise “sufficient control.” *Morrison*, 487 U.S. at 695–96. The FCA’s *qui tam* provision seems to do just that; it deputizes private relators to enforce the federal government’s primary anti-fraud statute, thereby outsourcing a significant measure of prosecutorial discretion that more properly resides in the Executive Branch. *In re Wild*, 994 F.3d 1244, 1260 (11th Cir. 2021) (en banc).

To the extent Relator lacks authority to prosecute this action under Article II of the Constitution, she lacks Article III standing as well. “In this case, as with every False Claims Act *qui tam* lawsuit, the ‘real party in interest’ is the United States.” *United States ex rel. Health Choice Alliance, LLC v. Eli Lilly and Co., Inc.*, 4 F.4th 255, 262 (5th Cir. 2021). And the Relator in this action, like all *qui tam* plaintiffs, has no claims or injury separate from the Government’s; she is considered, for standing purposes, a “partial assignee” of the Government’s rights under the FCA. *Vermont Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 773–74 n.4

(2000); *see also Little v. Shell Expl. & Prod. Co.*, 690 F.3d 282, 285 (5th Cir. 2012) (“[A] *qui tam* relator is, in effect, suing as a partial assignee of the United States['] claim for damages.”).

If the FCA’s *qui tam* provision is unconstitutional under Article II, then there has been no valid “assignment” of the Government’s damages claim, in whole or in part, to Relator. And in the absence of a valid assignment, Relator lacks the injury-in-fact necessary for Article III standing. *See Texas Life, Accident, Health & Hosp. Serv. Ins. Guar. Ass’n v. Gaylord Ent. Co.*, 105 F.3d 210, 214, 216–17 (5th Cir. 1997) (holding that if there was “no valid assignment,” then the assignee cannot have “derivative standing”); *see also MSPA Claims I, LLC v. Tenet Fla., Inc.*, 918 F.3d 1312, 1318 (11th Cir. 2019) (holding that a purported assignee “only has standing if it was validly assigned the right to sue”).

The serious separation-of-powers concerns raised by Justices Thomas, Kavanaugh, and Barrett are particularly heightened in this case. Here, the Government not only declined to intervene in the *qui tam* lawsuit—a relatively common occurrence—but the Government also filed an unprecedented Statement of Interest supporting *the defendants’* motions to dismiss. (ECF 70.)

The Fifth Circuit has not previously considered the Article II implications of a case like this one, in which a *qui tam* relator is continuing to pursue FCA litigation after the United States has gone on record supporting dismissal. This is not surprising; the United States, to Pfizer’s knowledge, has never before filed a “Statement of Interest Supporting Dismissal” as the Government did in this case. Twenty-two years ago, a split panel of the Fifth Circuit held, as a general matter, that *qui tam* relators may continue litigating FCA cases, after the Government simply declines to intervene, without violating Article II. *Riley v. St. Luke’s Episcopal Hosp.*, 252 F.3d 749, 751 (5th Cir. 2001). It is questionable whether the Supreme Court would agree with that decision today. Regardless, the facts of *Riley* are distinguishable from the present action; here the

United States did not merely decline to intervene, but rather took affirmative steps, over Relator's objection, to urge the Court to dismiss her lawsuit outright. (ECF 70.)

Riley does not control the result here, but the dissent in *Riley* is highly persuasive under the circumstances presented by this lawsuit:

[T]he Constitution is pellucid on separation of powers. It does not permit Congress to vest executive power in one of Congress's agents. The question presented in this case is whether the Constitution also forbids Congress from vesting the executive power in a self-appointed agent who answers to no one. The answer to this question must be no, because the Constitution is violated both when one branch of government aggrandizes itself at the expense of another and when one branch impermissibly undermines the constitutionally granted powers and functions of another, even if there is no aggrandizement.

Riley, 252 F.3d at 759–60 (Smith, J., dissenting).

It would be an inappropriate invasion of the Executive Branch's prerogatives to allow Relator to continue with this lawsuit, against the wishes of DOJ, DoD, and FDA. *Qui tam* litigation is supposed to vindicate the Government's interests. This lawsuit does anything but. It is a vehicle for Relator to advance a personal, anti-vaccination agenda that runs contrary to policy choices that the federal government, under both Republican and Democratic administrations, has made in response to a once-in-a-century public health emergency. This is improper: "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." *Harman*, 872 F.3d at 668–69.

CONCLUSION

For all of the reasons discussed in this Memorandum, Pfizer respectfully asks the Court to follow Fifth Circuit precedent and its prior ruling in this case and dismiss Counts I, II, III, and IV of Relator's Second Amended Complaint under Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). Pfizer also requests oral argument on this motion.

Respectfully submitted,

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/s/ Meagan D. Self _____

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