IN THE 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 JUDGE MICHAEL J. TRUNCALE

ORDER GRANTING THE UNITED STATES' MOTION TO INTERVENE AND TO DISMISS PURSUANT TO 31 U.S.C. § 3730(c)(2)(A) AND GRANTING VENTAVIA RESEARCH GROUP, LLC'S MOTION TO DISMISS RELATOR'S SECOND AMENDED COMPLAINT

Before the Court are Defendant Pfizer, Inc. ("Pfizer")'s Motion to Dismiss Relator's Second Amended Complaint [Dkt. 119], Defendant Icon PLC ("Icon")'s Motion to Dismiss Relator's Second Amended Complaint [Dkt. 120], Defendant Ventavia Research Group, LLC ("Ventavia")'s Motion to Dismiss Relator's Second Amended Complaint [Dkt. 121], and Movant the United States' Motion to Intervene and to Dismiss Pursuant to 31 U.S.C. § 3730(c)(2)(A) [Dkt. 137]. The Court heard oral argument on the United States' Motion and the Defendants' Motions on May 1, 2024. For the following reasons, the Court **GRANTS** the United States' Motion, **DENIES AS MOOT** Pfizer's and Icon's Motions, and **GRANTS** Ventavia's Motion.

I. BACKGROUND

A. Factual Background

On May 15, 2020, the United States Government launched Operation Warp Speed, an interagency partnership between the United States Department of Defense ("DoD") and United States Department of Health and Human Services ("HHS"), in an effort to accelerate the

development, acquisition, and distribution of a COVID-19 vaccine. [Dkt. 118 at 11]. Soon thereafter, Pfizer began working to develop a COVID-19 vaccine. *See generally id.*

In July 2020, while Pfizer's vaccine was still under development, the DoD entered into a contract (the "Project Agreement") with Pfizer under which Pfizer would deliver 100 million doses of a U.S. Food and Drug Administration ("FDA") authorized or approved vaccine to the United States Government (the "Government") on a fixed price per dose basis in accordance with a "Statement of Work." [Dkt. 118-1 at 303–37]. The Statement of Work provided that if Pfizer secured FDA approval or Emergency Use Authorization ("EUA") for its vaccine, the Government would pay it $1.95 billion for 100 million doses of its vaccine. *Id.* at 319.

After executing the Project Agreement, Pfizer endeavored to launch a clinical trial in order gain FDA approval or EUA for its vaccine. [Dkt. 118 at 9–11]. Pfizer contracted with Icon, an Irish clinical research organization, and Ventavia, a testing site operator, to conduct the clinical trial. *Id.* at 10. Icon was charged with managing Pfizer's clinical trial and, in turn, was responsible for managing over 160 test sites across the globe and ensuring clinical trial protocol compliance and required information reporting. *Id.* at 14. Ventavia operated three test sites—located in Keller, Fort Worth, and Houston, Texas—as part of Pfizer's clinical trial. *Id.*

On September 8, 2020, Ventavia hired Relator Brook Jackson (the "Relator") as a Regional Director for two of its vaccine testing sites. *Id.* at 68. The Relator's direct supervisor was Director of Operations Marnie Fisher ("Fisher"). *Id.* Her other supervisors were Executive Director Olivia Ray ("Ray"), Executive Director Kristie Raney ("Raney"), and Chief Operating Officer Mercedes Livingston ("Livingston"). *Id.*

From September 8, 2020 to September 25, 2020, the Relator allegedly witnessed and "reported on a near-daily basis" numerous violations of Pfizer's clinical trial protocol. *Id.* at 68–77. Specifically, the Relator allegedly witnessed and reported the following clinical trial protocol and FDA regulatory violations to Fisher and Livingston:

> (1) enrollment and injection of ineligible trial participants; (2) falsification of data, poor recordkeeping, and the deficiency of Ventavia's documentation "quality control"; (3) deficiencies in and failure to obtain informed consent from trial participants; (4) adverse event and [Serious Adverse Event] capture and reporting; (5) failure to preserve blinding; (6) vaccine dilution errors; (7) failure to list all staff on delegation logs; (8) principal investigator oversight; (9) reporting temperature excursions; (10) patient safety issues, such as not keeping epinephrine dose information in patient charts; (11) failure to secure and record staff training required by clinical research standards; (12) use of unqualified staff as vaccinators; (13) use of biohazard bags for needle disposal; and (14) failure to properly monitor patients post-injection.

Id. at 68–69. The Relator alleges that each time she voiced her concerns to Fisher, she was instructed to send Fisher an email or make a list of affected participants. *Id.* at 69. The Relator, who claims she did not have access to the information needed to make the lists her supervisor requested, asserts that she complied with Fisher's instructions to the extent she could, but that the issues she flagged were never addressed. *Id.* The Relator also reported Ventavia's "quality checking" practices to Fort Worth Principal Investigator Dr. Mark Koch ("Dr. Koch") and Ventavia management. *Id.* at 69–70.

On both September 14, 2020 and September 16, 2020, the Relator called Ventavia's Pfizer contact, Dr. Arturo Alfaro ("Dr. Alfaro"). *Id.* She did not reach him either time. *Id.* at 70.

On September 15, 2020, the Relator informed Fisher that some patient charts had not been quality checked or sent to Pfizer. *Id.*

On September 16, 2020, the Relator took photographs of biohazard bags containing used needles; HIPAA violations, namely calendars and records containing participants' names and information that were left out in public view; and boxes labeled with participant randomization numbers that were left out in public view. *Id.* at 70–71. The Relator shared these photographs with Fisher and Livingston via text message and email. *Id.* at 72.

On September 17, 2020, the Relator spoke by phone with Lovica Downs ("Downs"), Ventavia's Houston Regional Director, and William Jones ("Jones"), Ventavia's Quality Control Director. *Id.* When asked what would happen if the FDA audited Ventavia, they allegedly both

responded that Ventavia would receive warning letters or be asked to discontinue trial enrollment. *Id.*

Later that day, during a phone call with Ray, Raney, Fisher, Downs, and Livingston, the Relator "brought up virtually all of the protocol and regulatory violations she had witnessed to date, as well as Ventavia's HIPAA violations." *Id.* The Relator explained that "the FDA would likely issue warning letters against Ventavia if it visited or audited the trial sites" and recommended that Ventavia stop enrollment. *Id.* The Relator also sent text messages to Ray, Raney, Fisher, Downs, and Livingston expressing concerns about Ventavia's quality checking of source documents and relaying concerns from the Operations Manager of Ventavia's Fort Worth site about protocol and HIPAA violations. *Id.* at 72–73.

Ventavia decided to pause enrollment on September 17, 2020, although it allegedly was not honest with Pfizer or Icon about its reasons for doing so. *Id.* at 73. Despite pausing enrollment, Ventavia allegedly failed to correct documentation violations and falsified missing or incorrect data. *Id.* at 74.

On September 23, 2020, the Relator emailed Ray, Raney, Fisher, Down, Livingston, and Jones to report issues with Ventavia's quality checking process, namely outstanding queries from Icon regarding missing or inconsistent data, scheduling errors resulting in late second injections, a delay in sending a participant's chart to Icon, and missing participant charts or laboratory specimens. *Id.*

Also on September 23, 2020, the Relator emailed Livingston to report that Ventavia's emergency response protocol for allergic reactions was not being followed. *Id.* at 74–75.

On September 24, 2020, the Relator met with Fisher and Jones. *Id.* at 75. During this meeting, the Relator, Fisher, and Jones discussed the Relator's concerns regarding safety issues, HIPAA violations, unblinding, and FDA regulations as well as the Relator's photographic documentation of these issues. *Id.* The Relator alleges that Fisher "questioned repeatedly why [the]

Relator took the photographs and falsely accused [the] Relator of removing patient source documents from another Ventavia location." *Id.* The Relator suggested that Fisher and Jones "get on Google" and search for FDA warning letters if they failed to see what she saw when quality checking participants' source documents. *Id.* at 75–76.

On September 25, 2020, the Relator "called the FDA's hotline to report the clinical trial protocol violations and patient safety concerns she witnessed." *Id.* at 76.

Later that day, the Relator was terminated by Ventavia. *Id.* Ventavia's explanation was that the Relator was "not a good fit." *Id.*

After her termination, the Relator anonymously spoke with Dr. Alfaro at Pfizer about her concerns regarding unblinding, principal investigator oversight, and participant safety at the trial. *Id.* She also informed Dr. Alfaro that she had contacted the FDA. *Id.*

Shortly after her termination, the FDA contacted the Relator and spoke with her for several hours regarding the violations she witnessed while working for Ventavia. *Id.* at 77.

Ventavia lifted its enrollment pause on the following business day. *Id.* The Relator "estimates that Ventavia had neither completed quality checking nor remedied its ongoing violations by the time it resumed enrollment." *Id.*

On November 18, 2020, Pfizer announced its clinical trial results. [Dkt. 118-1 at 290–94]. Data analysis from 41,135 trial participants showed that a two-dose regimen of the vaccine was 95% effective against COVID-19. *Id.* at 290–94. Safety data showed a favorable safety profile and raised no serious safety concerns. *Id.* at 290–94. Pfizer asked the FDA to authorize its vaccine for emergency use on November 20, 2020. [Dkt. 118 at 8]. The FDA granted EUA on December 11, 2020. *Id.* On August 23, 2021, the FDA fully approved Pfizer's vaccine for individuals sixteen years of age and older by granting a Biologics License Application. *Id.* at 12.

B. Procedural Background

On January 8, 2021, the Relator filed this *qui tam* action against Pfizer, Icon, and Ventavia under seal. [Dkt. 2]. The Relator' s Original Complaint asserted presentment and false record False Claims Act (FCA) claims against all Defendants and a single FCA retaliation claim against Ventavia. *Id.*

The United States declined to intervene in this action on January 18, 2022. [Dkt. 13]. Among other things, the United States' Notice of Election to Decline Intervention specifically reserved the United States' right under 31 U.S.C. § 3730(c)(3) to intervene in this action down the road for good cause and to seek dismissal of this action. *Id.* On February 10, 2022, the Court acknowledged receipt of the United States' Notice, unsealed this action, and instructed the Relator to serve the Defendants. [Dkt. 16]. This Order also noted that the United States "is entitled to intervene in this action, for good cause, at any time." *Id.*

The Relator subsequently filed and served Defendants with her First Amended Complaint on February 22, 2022. [Dkt. 17; Dkt. 18]. Like her Original Complaint, the Relator's First Amended Complaint asserted presentment and false record FCA claims against the Defendants and one FCA retaliation claim against Ventavia. [Dkt. 17].

All three Defendants filed Motions to Dismiss under either or both Federal Rules of Civil Procedure 9(b) or 12(b)(6) and the United States filed a Statement of Interest Supporting Dismissal of the Amended Complaint. [Dkt. 37; Dkt. 51; Dkt. 53; Dkt. 70].

After hearing oral argument on Defendants' Motions, the Court granted Defendants' Motions to Dismiss on March 31, 2023. [Dkt. 96]. The Relator's two substantive FCA claims were dismissed with prejudice and the Relator's retaliation claim was dismissed without prejudice. *Id.*

On April 28, 2023, the Relator filed a Rule 59(e) Motion to Alter or Amend Order of Dismissal. [Dkt. 97]. Therein, the Relator sought leave to file a second amended complaint asserting a fraudulent inducement FCA claim against all Defendants and FCA and Texas Health

and Safety Code retaliation claims against Ventavia. *Id.* The Court granted the Relator's Motion on August 9, 2023. [Dkt. 108].

The Relator filed her Second Amended Complaint on October 5, 2023. [Dkt. 118]. Count I asserts the Relator's new fraudulent inducement FCA claim; Counts II, III, and IV assert the Relator's previously dismissed substantive FCA claims solely for appellate preservation purposes; Count V asserts the Relator's FCA retaliation claim; and Count VI asserts the Relator's Texas Health and Safety Code retaliation claim. *Id.*

The Defendants filed their underlying Motions to Dismiss on October 20, 2023. [Dkt. 119; Dkt. 120; Dkt. 121]. The United States filed its underlying Motion to Intervene and Dismiss on March 12, 2024. [Dkt. 137]. The Court heard oral argument on these motions on May 1, 2024 and is now prepared to rule on them.

II. THE UNITED STATES' MOTION TO INTERVENE AND TO DISMISS

A. Intervention by the United States After the Seal Period

The FCA imposes civil liability on any person who presents false or fraudulent claims for payment to the federal government. *United States ex rel. Polansky v. Exec. Health Res., Inc.*, 599 U.S. 419, 423 (2023) (citing 31 U.S.C. §§ 3729–3733). FCA civil actions are unique in that they can be brought by the Government or by a private party—referred to as a relator—who sues on the Government's behalf. *Id.*; 31 U.S.C. § 3730(a), (b). When a relator files a FCA complaint, it "remain[s] under seal for at least 60 days." 31 U.S.C. § 3730(b)(2). During this time, which is often extended for "good cause," the Government receives a copy of the realtor's complaint and supporting "material evidence" and determines whether to "intervene and proceed with the action." *Id.* § 3730(b)(2), (3). "If the Government proceeds with the action, it shall have the primary responsibility for prosecuting the action, and shall not be bound by an act of the [relator]." *Id.* § 3730(c)(1). If, however, "the Government elects not to proceed with the action, the [relator] shall have the right to conduct the action." *Id.* § 3730(c)(3). But "even then, the realtor is not home free"

because the Government is a "real party in interest" and "Congress gave the Government continuing rights in the action." *Polansky*, 599 U.S. at 425–26 (quoting *United States ex rel. Eisenstein v. City of New York*, 556 U.S. 928, 930 (2009)). Most notably, "[w]hen a [relator] proceeds with the action, the court, without limiting the status and rights of the [relator], may nevertheless permit the Government to intervene at a later date upon a showing of good cause." 31 U.S.C. § 3730(c)(3); *see also Polansky*, 599 U.S. at 426 (stating that "the Government can intervene after the seal periods ends, so long as it shows good cause to do so").

The Government asserts that it has good cause to intervene at this point because it wants to dismiss the case given[1] (1) its doubt as to the case's merits, [Dkt. 137 at 7 (indicating that it has investigated and evaluated the Relator's claims and stating that "[w]hile a defendant's fraud in inducing [the] FDA to authorize or approve a product may be the basis for a viable FCA claim, here, [the] FDA was aware of [the] Relator's allegations of clinical trial protocol violations that she witnessed at Ventavia prior to the initial EUA")]; (2) its continued access to and differing assessment of the Pfizer vaccine data, *id.* at 7–8; (3) the "significant burden" that continued litigation of this case would place on it in light of "anticipated discovery and litigation obligations," *id.* at 8; and (4) its belief that it should not have "to expend resources on a case that is inconsistent with its public health policy," *id.*

The Relator argues that the Government does not have good cause to intervene because (1) there has been no showing of good cause sufficient to overcome the extreme prejudice to the Relator associated with the Government's intervention and dismissal as required by Federal Rule of Civil Procedure 24; (2) there has been no change in circumstances since the Government

[1] The portion of the Government's Motion devoted to intervention merely states that "the United States has good cause to intervene because it seeks to dismiss Relator Jackson's Second Amended Complaint." [Dkt. 137 at 6]. Because the Government's desire to dismiss the case is informed by the Government's arguments in the portion of its Motion devoted to dismissal, the Court includes those arguments here. *Id.* at 6–8.

declined to intervene; and (3) the Government's Motion offends fundamental constitutional rights. [Dkt. 145 at 16–28].

Because the parties disagree about what the "good cause" standard requires, the Court will start its analysis there. In 2023, in *United States ex rel. Polansky v. Executive Health Resources, Inc.*, the Supreme Court shed significant light on the interplay between the Government's right to intervene after the seal period ends and the Government's right to dismiss the case notwithstanding the relator's objections. *See* 599 U.S. at 423–39; *see also* 31 U.S.C. § 3730(c)(2)(A). Although it did not evaluate the good cause standard, it affirmed the Third Circuit's underlying ruling "across the board" and "in all respects." *Polansky*, 599 U.S. at 429, 439. And while the Government's satisfaction of the good cause standard was not challenged by the relator in *Polansky* and, as a result, not addressed in depth by the Supreme Court, the Supreme Court repeated the Third Circuit's explanation of the good cause standard in a neutral—if not positive—manner. *Id.* at 429 n.2. Specifically, the Supreme Court recited the Third Circuit's explanation that "showing 'good cause' is neither a burdensome nor unfamiliar obligation," but rather "a uniquely flexible and capacious concept, meaning simply a legally sufficient reason." *Id.* (quoting *Polansky v. Exec. Health Res. Inc.*, 17 F.4th 376, 387 (3d Cir. 2021)). According to the Government, this is the standard the Court should follow here.

The Relator argues that under Rule 24(b)(3), the Court must weigh the Government's good cause arguments against any prejudice the Relator would experience due to the Government's intervention. Rule 24(b)(3) applies in the context of permissive intervention and provides that "[i]n exercising its discretion, the court must consider whether the intervention will unduly delay or prejudice the adjudication of the original parties' rights." Fed. R. Civ. P. 24(b)(3). In support of this argument, the Relator cites *United States ex rel. Precision Co. v. Koch Indus., Inc.*, 31 F.3d 1015 (10th Cir. 1994); *United States ex rel. Drennen v. Fresnius Med. Care Holdings, Inc.*, No. 09-10179, 2018 U.S. Dist. LEXIS 53978 (D. Mass. Mar. 30, 2018); *United States v. AseraCare*

Inc., No. 2:12-CV-245, 2012 U.S. Dist. LEXIS 136059 (N.D. Ala. Sept. 24, 2012); and *United States ex rel. Hall v. Schwartzman*, 887 F. Supp. 60 (E.D.N.Y. 1995). Unlike *Polansky*, however, none of these cases are binding on this Court. These cases also predate *Polansky*, which did not mention Rule 24(b)(3) and therefore substantially undermines their persuasiveness.

Additionally, although the good cause requirement for intervention after the sealing period technically renders the Government's intervention permissive rather than mandatory, the Court is not convinced that Rule 24 intervention is analogous to 31 U.S.C. § 3730 intervention. Rule 24 intervention pertains to *non-parties* intervening in a lawsuit. Contrastingly, 31 U.S.C. § 3730 intervention pertains to the Government, on whose behalf the relator brings the action, intervening to prosecute the action itself. Furthermore, in the 31 U.S.C. § 3730 context, the injury asserted belongs "exclusively" to the Government, the purpose of the action is to "vindicate the Government's interests," and the relator's right to conduct the action is always subject to the Government's rights, including the right to intervene down the road. *Polansky*, 599 at 425, 427. 438. In fact, the similarities between Rule 24 intervention and 31 U.S.C. § 3730 intervention seem to begin and end with their use of the word "intervention."

Given that Rule 24 does not fit these circumstances, that the cases cited by the Relator are non-binding, and that the Supreme Court seemingly endorsed the Third's Circuit good cause standard, the Court will apply the good cause standard as outlined in *Polansky*.[2] The Government, therefore, is merely required to offer a "legally sufficient" reason to intervene. *Polansky*, 599 U.S. at 429 n.2. Courts, particularly in the wake of *Polansky*, have consistently permitted the

[2] Even if the Court were to apply Rule 24, it would find that the Government had met the good cause standard and permit the Government to intervene. In the Fifth Circuit, "Rule 24 is to be liberally construed." *Brumfield v. Dodd*, 749 F.3d 339, 341 (5th Cir. 2014). The Relator's right to conduct this action on the Government's behalf has always been subject to the Government's rights, meaning the Relator has always known that intervention was a possibility. She chose to proceed anyway. Additionally, because discovery has been stayed, the Relator's financial investment in this case has been contained. Accordingly, the Court disagrees that the Relator will face "extreme prejudice" if the Government intervenes. To the extent the Relator is prejudiced, the Court finds that the Government's good cause arguments outweigh that prejudice since it is the Government's interests that are ultimately being vindicated—not the Relator's.

Government to intervene after the seal period when the Government wants to dismiss a case because it disputes the case's merits, wants to avoid discovery and litigation costs, or finds that the case conflicts with its policies. *See e.g.*, *Polansky*, 599 U.S. at 428 n.2 (affirming the Third Circuit's decision "that the Government's request to dismiss the suit—based on its weighing of discovery burdens against likelihood of success—itself established good cause to intervene"); *Brutus Trading, LLC v. Standard Charter Bank*, No. 20-2578, 2023 WL 5344973, at *1–2 (2d Cir. Aug. 21, 2023) (affirming a lower court's decision to permit the Government to intervene and dismiss a *qui tam* action where the Government decided that "[the Relator's] factual allegations were unsupported, its legal theory was not cognizable, and the continuation of the suit would waste considerable government resources"); *United States ex rel. Carver v. Physicians Pain Specialists of Ala., P.C.*, No. 22-13608, 2023 WL 4853328, at *4, 6–7 (11th Cir. July 31, 2023) (affirming the lower court's decision to allow the Government to intervene in and dismiss a *qui tam* suit where the Relator had failed to prosecute the suit, neglected her responsibilities, burdened the Government with discovery, and "undercut the United States' FCA enforcement efforts"); *United States ex rel. CIMZNHCA, LLC v. UCB, Inc.*, 970 F.3d 835, 853–54 (7th Cir. 2020) (reversing a lower court's decision not to permit the Government to intervene in and dismiss a *qui tam* action where the Government believed the conduct being complained of by the Relators was probably lawful and complained that "[t]hese relators—created as investment vehicles for financial speculators—should not be permitted to indiscriminately advance claims on behalf of the government against an entire industry that would undermine . . . practices the federal government has determined are . . . appropriate and beneficial to federal healthcare programs and their beneficiaries" (internal quotation marks omitted)); *United States ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp.*, 151 F.3d 1139, 1142–43, 1146 (9th Cir. 1998) (affirming a lower court's decision to let the Government dismiss a meritorious *qui tam* action because the Government had determined, among other things, that (1)"further FCA litigation over prorate

violations" was "harmful to the [citrus] industry as a whole" and (2) continued litigation expenses would burden taxpayers); *United States ex rel. Vanderlan v. Jackson HMA, LLC*, No. 3:15-CV-767, at *6 (S.D. Miss. Apr. 12, 2024) (allowing the Government to dismiss a *qui tam* action because of "the potential for continued (or increased) demand on [the Government's] resources and time," among other things); *United States ex rel. Toomer v. TerraPower, LLC*, No. 4:16-cv-00226, 2018 WL 4934070, at *4–5 (D. Idaho Oct. 10, 2018) (allowing the Government to dismiss a *qui tam* case where the Relator simply "disagree[d] with the government's priorities" and where the Government doubted the case's merits, did not want to "waste substantial government time and resources" due to continued litigation, and feared that the case would impair future public-private partnerships).[3] Therefore, the Court, recognizing that the Government's interest is the predominant one, finds that the Government's desire to dismiss the case—because of its doubt as to the case's merits, differing assessment of the Pfizer vaccine data, desire to avoid discovery and litigation obligations, and belief that it should not have to expend resources in a case that is contrary to its public health policy—constitutes good cause to intervene.

The Court turns now to the Relator's other objections. First, the Court disagrees with the Relator's assertion that the Government can only intervene after the seal period "when changed circumstances warrant a change in its intervention decision." [Dkt. 145 at 19–22]. That is not what 31 U.S.C. § 3730(c)(3) states. Indeed, it unambiguously permits the Government to intervene at a later stage "upon a showing of good cause." 31 U.S.C. § 3730(c)(3). At no point does the statue indicate that good cause requires changed circumstances. *See id.* Additionally, *Polansky* merely indicates that Congress "knew that circumstances could change and new information come to light" in describing why Congress passed a provision permitting late intervention. 599 U.S. at 435 (citing S. Rep. No. 99–345, p. 26 (1986)). Nothing about that statement—or *Polansky* as a whole—

[3] The Court includes cases where only dismissal is at issue because the Government's desire to dismiss a *qui tam* case is frequently intertwined with its desire to intervene. The Court also includes dismissal-only cases because courts often construe the Government's motions to dismiss a *qui tam* case as motions to intervene.

supports requiring changed circumstances for late intervention by the Government. *See generally id.* The Relator also invokes the Department of Justice ("DOJ")'s 2018 memorandum entitled, "Factors for Evaluating Dismissal Pursuant to 31 U.S.C. § 3730(c)(2)(A)" in support of her position that a change in circumstances is required. But the memorandum's remark that "there may be cases where dismissal is warranted at a later stage, particularly when there has been a significant intervening change in the law or evidentiary record" does not in any way indicate that the Government can only move for intervention after changed circumstances. *See* U.S. Dep't of Just., Factors for Evaluating Dismissal Pursuant to 31 U.S.C. 3730(c)(2)(A) (Jan. 10, 2018). This memorandum also explicitly states that it is a "general framework." *Id.* Nothing about it binds the Government or alters 31 U.S.C. § 3730(c)(3)'s requirement for "good cause." In any case, this memorandum arguably supports the Government's position and undermines the Relator's. *Id.* (identifying eliminating meritless cases, preventing interference with agency policies and programs, and preserving government resources as factors the Government has relied upon in dismissing *qui tam* actions); *see also United States v. Eli Lilly & Co.*, 4 F.4th 255, 268–69 (5th Cir. 2021) (characterizing this memorandum as "guidance" and finding that it "cannot say that the government did not follow its own guidance when it decided to take a risk contemplated by that guidance").

Moreover, circumstances *have* changed since the Government declined to intervene. For example, the Relator's First Amended Complaint was dismissed with the Government's support. [Dkt. 70; Dkt. 96]. The Relator filed a Second Amended Complaint, which the Government clearly also wants dismissed. [Dkt. 137]. The Government has also expended resources monitoring the case since it declined to intervene and faces the prospect of expending further resources should the case survive and discovery begin. *Id.* The Government has also received additional data on the Pfizer vaccine since it declined to intervene that seemingly supports its position that the Relator's case lacks merit and undermines its public health policy. *Id.* at 7–8.

Second, contrary to the Relator's assertions, the Court finds that the Government's Motion does not offend fundamental constitutional rights. *See Polansky*, 599 U.S. at 436 n.4 (noting the Third Circuit's statement that the Government's efforts to dismiss a *qui tam* action "rest atop the foundation of bedrock constitutional constraints on Government action," but not "consider[ing] the circumstances in which, or procedures by which, a court should find the Constitution to prevent the Government from dismissing a *qui tam* action"). The Relator first claims that the Government's motion runs afoul of her First Amendment right to petition the government. [Dkt. 145 at 24–26]. But the First Amendment does not give the Relator the right to petition the government on the United States' behalf—only her own. *See* U.S. Const. amend. I. Additionally, to the extent that the FCA gives her the right to petition the government on the United States' behalf, that right is, as previously discussed, substantially limited by the United States' own rights over a *qui tam* action. *See* 31 U.S.C. § 3730.

The Relator's separation of powers argument likewise falls short because it ignores *Polansky* and is based on pure speculation. In *Polansky*, the Supreme Court explicitly stated that "the Government's views are entitled to substantial deference" when it comes to dismissal of a *qui tam* action.[4] 599 U.S. at 437. It further stated that "a district court should think several times over before denying a motion to dismiss" and that [i]f the Government offers a reasonable argument for why the burdens of continued litigation outweigh its benefits, the court should grant the motion"—"even if the relator presents a credible assessment to the contrary." *Id.* at 437–38. Given this binding precedent, Congress's inclusion of a late intervention provision in the FCA, and case law permitting the Government to intervene in similar situations, the Court is unclear how allowing to the Government to intervene here violates separation of powers principles and constitutes an abdication of judicial power. *See* [Dkt. 145 at 27]. In any case, the Relator offers nothing but

[4] *See infra* note 3 (describing why the Court relies on cases regarding dismissal when discussing intervention).

speculation in support of this argument. The Government has offered frequently cited and reasonable grounds for intervening and dismissing this case. The Relator has hardly shown that these reasons are a façade for protecting executive officials' personal interests.

The Relator's argument that the Government's motion to intervene should be denied on substantive due process and equal protection grounds because it is arbitrary, capricious, and perpetrates a fraud on this Court also fails. Although the Supreme Court did not touch on this matter in *Polansky*, the Third Circuit did. It stated that "[o]nly the most egregious official conduct can be said to be arbitrary in the constitutional sense" and that in this context "the constitutional question would not be whether the Government adequately weighed the costs and benefits of its actions, but whether there was 'executive abuse of power' that 'shocks the conscience.'" *Polansky*, 17 F.4th at 390 n.17 (quoting *Cnty. of Sacramento v. Lewis*, 523 U.S. 833, 846 (1998)). The Government provided multiple reasons for its desire to intervene in this case. As outlined above, courts have frequently permitted intervention and dismissal for the reasons identified by the Government here, even when a relator believes the case has merit. Contrary to the Relator's assertions, the Government's reasons are also consistent with the factors identified in the DOJ's memorandum. Finally, there is no indication beyond the Relator's conjecture that the Government's desire to intervene is due to "fraud, illegality, or lack or political will." *See* [Dkt. 149 at 2]. The Relator's differing perspective on the Pfizer vaccine data and the merits of this action are insufficient to establish that the Government's reasons for intervening and seeking dismissal are arbitrary, capricious, and fraudulent. *See Toomer*, 2018 WL 4934070, at *5; *see also Sequoia Orange Co.*, 151 F.3d at 1146–47.

Accordingly, the Court holds that the Government has good cause to intervene in this case pursuant to 31 U.S.C. § 3730(c)(3) and **GRANTS** the Government's Motion to Intervene.

B. Dismissal

The Court turns now to the Government's Motion to Dismiss. 31 U.S.C. § 3730(c)(2)(A) provides that "[t]he Government may dismiss [a *qui tam*] action notwithstanding the objections of the [relator] if the [relator] has been notified by the Government of the filing of the motion and the court has provided the person with an opportunity for a hearing on the motion." 31 U.S.C. § 3730(c)(2)(A). *Polansky* held that Federal Rule of Civil Procedure 41 applies to the Government's efforts to dismiss a *qui tam* action subject to 31 U.S.C. § 3730(c)(2)(A)'s procedural requirements for notice and a hearing. 599 U.S. at 435–36. The Supreme Court stated that 31 U.S.C. § 3730(c)(2)(A) motions to dismiss "will satisfy Rule 41 in all but the most exceptional cases." 559 U.S. at 437. It further explained that "the Government's views are entitled to substantial deference" in this context and that "a district court should think several times over before denying a motion to dismiss." *Id.* at 437–38. In fact, the Supreme Court instructed that "[i]f the Government offers a reasonable argument for why the burdens of continued litigation outweigh its benefits, the court should grant the motion." *Id.* at 438. This is so "even if the relator presents a credible assessment to the contrary." *Id.*

Both the Government and the Relator agree that Defendants have not filed answers or motions for summary judgment and that, as a result, Rule 41(a)(1)(A)(i) applies. Rule 41(a)(1)(A)(i) states that "the plaintiff may dismiss an action without a court order by filing . . . a notice of dismissal before the opposing party serves either an answer or a motion for summary judgment." Fed. R. Civ. P. 41(a)(1)(A)(i). When dismissal is sought before an answer or motion for summary judgment are filed, Rule 41(a)(1)(A)(i) "entitles the [Government] to a dismissal" and "the district court has no adjudicatory role." *Polansky*, 599 U.S. at 436 n.4.

The only question remaining is whether 31 U.S.C. § 3730(c)(2)(A)'s procedural requirements have been satisfied. The Relator received notice of the Government's Motion to Dismiss when it was filed. Whether the hearing requirement has been satisfied is a tougher question

because neither the statute nor *Polansky* specify the type of hearing required. *See* 31 U.S.C. § 3730(c)(2)(A) (stating only that "an opportunity for a hearing on the motion" is required); *Polansky*, 599 U.S. 436 n.4 (indicating that "a hearing, whether pre- or post-answer, *might* inquire into allegations that a dismissal 'violate[s] the relator's right to due process or equal protection,'" but opting not to consider the contours of the hearing requirement since that issue was not raised by the relator (alteration in original) (emphasis added)). The Fifth Circuit considered this question, albeit without the benefit of *Polansky*. *See Eli Lilly & Co.*, 4 F.4th at 262–63. Specifically, it "construe[d] the term 'hearing' in 31 U.S.C. § 3730(c)(2)(A) to require something more than a forum for a relator to convince the government not to dismiss" and noted that "[i]t includes judicial involvement and action." *Id.* at 262–64. The Fifth Circuit stopped short, however, of requiring an evidentiary hearing. *Id.* at 265–67 (finding that the relator's right to a hearing was satisfied without determining that an evidentiary hearing was required because the relator opted not to present evidence at the hearing held). Additionally, while not binding precedent, several courts have found 31 U.S.C. § 3730(c)(2)(A)'s hearing requirement satisfied by briefing alone or by non-evidentiary hearings, particularly in *Polansky*'s wake. *See Brutus Trading, LLC*, 2023 WL 5344973, at *2 (interpreting *Polansky* as requiring a district court to "exercise some degree of scrutiny in evaluating the government's motion to dismiss" and, in turn, finding that the district court satisfied the hearing requirement by "carefully considering the parties' written submissions"); *Borzilleri v. Bayer Healthcare Pharms., Inc.*, 24 F.4th 32, 39–40 (1st Cir. 2022) (holding that the hearing requirement "contemplates a judicial judgment of some kind, providing a level or protection for the relator's interest in the suit"); *Vanderlan*, No. 3:15-CV-767, at *5, 7–8 (reasoning that the hearing required by 31 U.S.C. § 3730(c)(2)(A) in the Rule 41(a)(1) context cannot be more onerous than the hearing required in the Rule 41(a)(2) context; noting that neither *Polansky* or 31 U.S.C. § 3730(c)(2)(A) support requiring an evidentiary hearing; and finding that a hearing to consider whether the Government had provided a reasonable basis for dismissal satisfied the

hearing requirement);[5] *United States ex rel. Sargent v. McDonough*, No. 1:23-cv-00328, 2024 WL 809902, at *2 (D. Maine Feb. 26, 2024) (finding that a hearing is not necessary because "there is no actual prospect that [the relator] would reveal at a further hearing how dismissal of Count I will expose him to a constitutional injury"); *Toomer*, 2018 WL 4934070, at *6 (denying a relator's request for discovery and a hearing because the relator's constitutional arguments are speculative and because allowing the relator to present this evidence "may amount to an unjustified 'mini-trial' on the merits of this case").

Although evidence was not put on during the May 1, 2024 hearing, the Court finds that an evidentiary hearing is not required by 31 U.S.C. § 3730(c)(2)(A). In any case, the Government cited a Journal of the American Medical Association editorial in its Motion [Dkt. 137 at 8] and the Relator submitted affidavits in support of its Response [Dkt. 145-1; Dkt. 145-2], so there was at least some evidence before the Court. At the hearing, the Court heard arguments from the Government, the Relator, and the Defendants. It also asked counsel numerous questions regarding their positions, including on the Government's reasons for wanting to intervene and dismiss the case and on the Relator's opposition to the Government's motion and constitutional arguments. The hearing was certainly more than a forum in which the Relator could try to convince the Government not to dismiss its FCA lawsuit and involved "judicial involvement and action." *See Eli Lilly & Co.*, 4 F.4th at 262–64. Additionally, both before and after the hearing, the Court spent significant time considering the Government and the Relator's briefs and the cases cited therein. The Court holds that this is sufficient to satisfy 31 U.S.C. § 3730(c)(2)(A)'s hearing requirement.

Because 31 U.S.C. § 3730(c)(2)(A)'s and Rule 41(a)(1)(A)(i)'s requirements are satisfied and because the Government offers a reasonable explanation for its desire to dismiss the action,

[5] In *Vanderlan*, the court also noted that 31 U.S.C. § 3730(c)(2)(A)'s legislative history did not support construing the hearing requirement as mandating an evidentiary hearing. No. 3:15-CV-767, at *8 (describing how an earlier, unpassed version of the FCA permitted relators to file objections and request an evidentiary hearing without guaranteeing such hearings). The Court finds this argument particularly compelling since, as the *Vanderlan* court points out, the enacted version of 31 U.S.C. § 3730(c)(2)(A) "dropped all reference to an evidentiary hearing right or the right to object." *Id.*

dismissal is warranted. The reasons proffered by the Government for dismissal are amply supported by case law and, pursuant to *Polansky*, are entitled to substantial deference. The Government's Motion to Dismiss is therefore **GRANTED**. As a result, Counts I through IV in the Relator's Second Amended Complaint are **DISMISSED WITH PREJUDICE** as to the Relator and **DISMISSED WITHOUT PREJUDICE** as to the Government.[6] As no claims remain against Defendants Pfizer and Icon, their Motions to Dismiss are **DENIED AS MOOT**.

III. VENTAVIA RESEARCH GROUP LLC'S MOTION TO DISMISS

Although the Government's dismissal of Counts I through IV eliminates the substantive FCA claims against Ventavia, the Relator's FCA and state-law retaliation claims against Ventavia remain. Ventavia argues that the Relator has failed to state claims upon which relief can be granted under the FCA or the Texas Health and Safety Code. The Court address the Relator's retaliation claims in turn.

A. Legal Standard

Federal Rule of Civil Procedure 12(b)(6) authorizes dismissal of a complaint for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). In reviewing a Rule 12(b)(6) motion, the Court "accepts all well-pleaded facts as true, viewing them in the light most favorable to the plaintiff." *Sonnier v. State Farm Mut. Auto. Ins. Co.*, 509 F.3d 673, 675 (5th Cir. 2007). While the Court must accept the well-pleaded facts in the complaint as true, it will "not accept as true conclusory allegations, unwarranted factual inferences, or legal conclusions." *Gentilello v. Rege*, 627 F.3d 540, 544 (5th Cir. 2010).

To survive a Rule 12(b)(6) motion to dismiss, a complaint must contain enough well-pleaded facts "to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S.

[6] Rule 41(a)(1)(B) provides that "[u]nless the notice or stipulation state otherwise, the dismissal is without prejudice." Fed. R. Civ. P. 41(a)(1)(B). The Government's proposed order requests that the substantive FCA claims be dismissed with prejudice as to the Relator and without prejudice as to the Government, so the Court structures its dismissal accordingly. *See* [Dkt. 137-1].

662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)); *see* Fed. R. Civ. P. 8(a)(2) ("A pleading that states a claim for relief must contain: . . . a short and plain statement of the claim showing that the pleader is entitled to relief . . . ."). A claim is "plausible on its face" when the well-pleaded facts allow the Court to "draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. "Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of entitlement to relief.'" *Id.* (quoting *Twombly*, 550 U.S. at 557). Determining whether a complaint states a plausible claim for relief is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id.* at 679.

B. The Relator's False Claims Act Retaliation Claim

The Relator alleges that Ventavia retaliated against her in violation of 31 U.S.C. § 3730(h) "because of her efforts to stop Defendants from committing violations of the False Claims Act." [Dkt. 118 at 68, 92]. Specifically, she asserts that Ventavia retaliated against her for engaging in protected activity through harassment, termination, and slander. *Id.* at 92.

"The 'whistleblower' provision of the [FCA] prevents the harassment, retaliation, or threatening of employees who assist in or bring *qui tam* actions." *Robertson v. Bell Helicopter Textron, Inc.*, 32 F.3d 948, 951 (5th Cir. 1994). The statute provides:

> Any employee, contractor, or agent shall be entitled to all relief necessary to make that employee, contractor, or agent whole, if that employee, contractor, or agent is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of lawful acts done by the employee, contractor, agent or associated others in furtherance of an action under this section or other efforts to stop 1 or more violations of this subchapter.

31 U.S.C. § 3730(h)(1). "To establish a claim under § 3730(h), a party must show (1) that she was engaged in protected activity with respect to the [FCA]; (2) that her employer knew she was engaged in protected activity; and (3) that she was discharged because she was engaged in

protected activity." *Thomas v. ITT Educ. Servs., Inc.*, 517 F. App'x 259, 262 (5th Cir. 2013) (citing *Robertson*, 32 F.3d at 951).

"A protected activity is one motivated by a concern regarding fraud against the government." *Id.*; *United States ex rel. Johnson v. Kaner Med. Grp., P.A.*, 641 F. App'x 391, 395 (5th Cir. 2016) ("To qualify as protected activity under the whistleblower provision, the activity must be 'in furtherance of' uncovering fraud or potential fraud against the Government." (citing 31 U.S.C. § 3730(h)(1))). Mere criticism by an employee of the employer's methods of conducting business, "without any suggestion that the [employee] was attempting to expose illegality or fraud within the meaning of the FCA, does not rise to the level of protected activity." *United States ex rel. Patton v. Shaw Servs., L.L.C.*, 418 F. App'x 366, 372 (5th Cir. 2011).

The Court previously dismissed the Relator's FCA retaliation claim because she failed to allege that she complained to Ventavia or the FDA about fraud against the government as opposed to participant safety and regulatory, protocol, and HIPAA violations and, thus, failed to allege that she engaged in protected activity. [Dkt. 96 at 46, 48]. The Court also dismissed the Relator's FCA retaliation claim on the grounds that she failed to allege that Ventavia knew she engaged in protected activity. *Id.* at 48. Although the Court allowed the Relator to replead her FCA retaliation claim and fix these issues, she has not done so. *See* [Dkt. 108]. *Compare* [Dkt. 17 at 60–70, 78], *with* [Dkt. 118 at 68–77, 92]. In fact, the Relator's retaliation allegations in her First Amended Complaint and Second Amended Complaint are nearly identical. *Compare* [Dkt. 17 at 60–70, 78], *with* [Dkt. 118 at 68–77, 92]. Although she rewords certain sentences, none of her wordsmithing changes the substance of her allegations. She does not include any new factual allegations indicating that she complained to Ventavia or the FDA about fraud against the government. She also does not include any new factual allegations suggesting that Ventavia was aware of any alleged protected activity.

In her Response to Ventavia's Motion to Dismiss, the Relator claims that "there should be no question that [she] alleges a good faith belief that her efforts were to stop a violation" because her FCA fraud-in-the-inducement theory is that "the departure from protocol and violation of scientific methods was to fraudulently induce the FDA to issue the EUA, which in turn, was a material condition for payment on the contract." [Dkt. 127 at 31]. She also argues that her motivations cannot properly be determined at the pleadings stage because the issue requires that a record be built. *Id.* Finally, she asserts that her Second Amended Complaint makes it clear that Ventavia knew about her protected activity because she consistently voiced her concerns about clinical trial and FDA regulatory violations and because Ventavia acknowledged that an FDA audit "would be bad for the company because . . . Ventavia knew a fraud was being committed on the Government in order to acquire the EUA." *Id.* at 31–32.

As Ventavia points out in its Reply, a "complaint may not be amended by the briefs in opposition to a motion to dismiss." *Energy Coal v. CITGO Petroleum Corp.*, 836 F.3d 457, 462 n.4 (5th Cir. 2016) (quoting *Roebuck v. Dothan Sec., Inc.*, 515 F. App'x 276, 280 (5th Cir. 2013)). In any case, none of the Relator's rationalizations cure the shortcomings of her Second Amended Complaint. The Fifth Circuit's requirements regarding protected activity and employer knowledge of protected activity are very clear. This Court was very clear with the Relator as to the problems with her FCA retaliation claim. For whatever reason the Relator made no substantive changes to her FCA retaliation allegations. As a result, she once again has not plausibly plead that she engaged in protected activity or that Ventavia was aware of her protected activity. The Court therefore **GRANTS** Ventavia's Motion to Dismiss and **DISMISSES** Count V, the Relator's FCA retaliation claim, **WITH PREJUDICE**.

C. The Relator's Texas Health and Safety Code Retaliation Claim

The Relator alleges that Ventavia retaliated against her in violation of Texas Health and Safety Code § 161.134 "because of her efforts to stop Defendants from committing violations of

Federal Acquisition Regulations and Texas state law." [Dkt. 118 at 92]. Specifically, she asserts that Ventavia retaliated against her for engaging in protected activity through harassment, termination, and slander. *Id.* at 92.

Because the Court has dismissed all claims over which it has original jurisdiction, the Court must first decide whether to exercise supplemental jurisdiction over the Relator's Texas Health and Safety Code retaliation claim. 28 U.S.C. § 1367(a) provides that "district courts shall have supplemental jurisdiction over all other claims that are so related to claims in the action within such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution." 28 U.S.C. § 1367(a). The Court, however, may decide not to exercise its powers of supplemental jurisdiction if: (1) "the claim raises a novel or complex issue of State law"; (2) "the claim substantially predominates over the claim or claims over which the district court has original jurisdiction"; (3) "the district court has dismissed all claims over which it has original jurisdiction"; or (4) "in exceptional circumstances, there are other compelling reasons for declining jurisdiction." *Id.* § 1367(c). In determining whether to exercise supplemental jurisdiction, courts "must consider the provisions of 28 U.S.C. § 1367(c) and 'weigh in each case, and at every stage of the litigation, the values of judicial economy, convenience, fairness, and comity.'" *Hanak v. Talon Ins. Agency, Ltd.*, 470 F. Supp. 2d 695, 707 (E.D. Tex. 2006) (*Carnegie-Mellon Univ. v. Cohill*, 484 U.S. 343, 350 (1988)).

Where, as here, all federal claims have been dismissed before trial, the Supreme Court has counseled that a court should decline jurisdiction. *Robertson v. Neuromedical Ctr.*, 161 F.3d 292, 296 (5th Cir. 1998) (quoting *United Mine Workers of Am. v. Gibbs*, 383 U.S. 715, 726 (1966)). Within the Fifth Circuit, the "general rule is to dismiss state claims when the federal claims to which they are pendant are dismissed." *Parker v. Parsley Petroleum Co. v. Dresser Indus.*, 972 F.2d 580, 585 (5th Cir. 1992) (citing *Wong v. Stripling*, 881 F.2d 200, 204 (5th Cir. 1989)); *see also Smith v. Amedisys Inc.*, 298 F.3d 434, 446–47 (5th Cir. 2002). "[T]his rule is neither

mandatory nor absolute," though. *Smith*, 298 F.3d at 447 (quoting *Batiste v. Island Records, Inc.*, 179 F.3d 217, 227 (1999)).

All of the Relator's federal claims have been dismissed. Additionally, this case is still at the pleading stage, no discovery has been conducted, and trial is not scheduled until December 8, 2025. Because the federal claims have been dismissed well before trial, the factors of judicial economy, convenience, fairness, and comity suggest that this Court should decline to exercise jurisdiction over the Relator's state-law retaliation claim. Accordingly, the Court **GRANTS** Ventavia's Motion to Dismiss and **DISMISSES** the Relator's Texas Health and Safety Code retaliation claim **WITHOUT PREJUDICE** for lack of subject matter jurisdiction.

IV. LEAVE TO AMEND

The Relator requests leave to amend if the Court finds any deficiencies in the Relator's Second Amended Complaint as well as leave to amend to add a common law tort of wrongful discharge. [Dkt. 127 at 35, 39]. Because the Government has intervened and dismissed Counts I through IV with prejudice as to the Relator, the Court will not permit the Relator to amend her complaint as to those claims. Because the Relator did not even remotely utilize her previous opportunity to amend her FCA retaliation claim and because the Relator has already amended her complaint, including her FCA retaliation claim, twice, the Court will not allow the Relator to amend her complaint as to that claim. *See Jack v. Evonik Corp.*, 79 F.4th 547, 564–65 (5th Cir. 2023) (stating that leave to amend is governed by Federal Rule of Civil Procedure 15(a)(2) and should be "freely given" unless there is (1) "undue delay," (2) "bad faith or dilatory motive on the part of the movant," (3) "repeated failure to cure deficiencies by amendments previously allowed," (4) "undue prejudice to the opposing party by allowing the amendment," or (5) "futility of amendment"); *Herrmann Holdings Ltd. v. Lucent Techs Inc.*, 302 F.3d 552, 566–67 (5th Cir. 2022) (finding that the district court did not abuse its discretion in denying leave to amend where plaintiffs had already amended their complaint twice). Finally, because there are no remaining

federal claims and the Court has declined to exercise supplemental jurisdiction over the Relator's Texas Health and Safety Code retaliation claim, the Court will not permit the Relator to amend Count VI or to amend her complaint to add a state common law tort of wrongful discharge claim.

V. CONCLUSION

It is therefore **ORDERED** that Movant the United States' Motion to Intervene and to Dismiss Pursuant to 31 U.S.C. § 3730(c)(2)(A) [Dkt. 137] is **GRANTED**. As a result, the claims outlined in Counts I through IV of Relator Brook Jackson's Second Amended Complaint are **DISMISSED WITH PREJUDICE** as to the Relator and **DISMISSED WITHOUT PREJUDICE** as to the United States.

It is further **ORDERED** that Defendant Pfizer, Inc.'s Motion to Dismiss Relator's Second Amended Complaint [Dkt. 119] is **DENIED AS MOOT**.

It is further **ORDERED** that Defendant Icon PLC's Motion to Dismiss Relator's Second Amended Complaint [Dkt. 120] is **DENIED AS MOOT**.

It is further **ORDERED** that Defendant Ventavia Research Group, LLC's Motion to Dismiss Relator's Second Amended Complaint [Dkt. 121] is **GRANTED**. The claim outlined in Count V of Relator Brook Jackson's Second Amended Complaint is **DISMISSED WITH PREJUDICE**. The claim outlined in Count VI of Relator Brook Jackson's Second Amended Complaint is **DISMISSED WITHOUT PREJUDICE**.

It is further **ORDERED** that all Court dates and deadlines are hereby **VACATED**. The Clerk is **INSTRUCTED** to close this matter.

SIGNED this 9th day of August, 2024.

Michael J. Truncale
Michael J. Truncale
United States District Judge