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

UNITED STATES OF AMERICA ex rel. Brook Jackson,

Plaintiff,

v.

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

VENTAVIA RESEARCH GROUP, LLC; PFIZER INC.; ICON PLC,

Defendants.

<u>VENTAVIA RESEARCH GROUP, LLC'S MOTION TO DISMISS</u> RELATOR'S SECOND AMENDED COMPLAINT AND BRIEF IN SUPPORT

Stacy L. Brainin
Texas Bar No. 02863075
Andrew W. Guthrie
Texas Bar No. 24078606
Taryn M. McDonald
Texas Bar No. 24088014
HAYNES AND BOONE, LLP
2323 Victory Avenue, Suite 700
Dallas, Texas 75219
Tel: (214) 651-5000
Fax: (214) 651-5940
stacy.brainin@haynesboone.com

Fax: (214) 651-5940 stacy.brainin@haynesboone.com andrew.guthrie@haynesboone.com taryn.mcdonald@haynesboone.com

TABLE OF CONTENTS

INTRO	ODUC'	FION AND STATEMENT OF ISSUES	1
ARGU	MENT	S AND AUTHORITIES	2
I.	Relator	still has not stated a viable claim for violations of the False Claims Act	2
	A.	The Court properly held that Relator failed to allege any false claims under the meaning of the FCA—and her new complaint doesn't either	2
	B.	Relator has never alleged that Ventavia caused the submission of false claims	4
II.	Relator	still has not stated a viable claim for retaliation under any statute	8
CONC	CLUSIC	N AND PRAYER	14

TABLE OF AUTHORITIES

Page(s) Cases Barron v. Cook Children's Health Care Sys., D'Agostino v. ev3, Inc., 845 F.3d 1 (1st Cir. 2016)8 Hanak v. Talon Ins. Agency, Ltd., Janaki v. C.H. Wilkinson Physician Network, In re Parkcentral Glob. Litig., 884 F. Supp. 2d 464 (N.D. Tex. 2012)4 United States ex rel. Colquitt v. Abbott Labs., United States ex rel. King v. Solvay Pharms., Inc., United States ex rel. Riley v. St. Luke's Episcopal Hosp., 355 F.3d 370 (5th Cir. 2004)5 United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah, Yates v. United States, 574 U.S. 528 (2015).......11 Statutes, Rules, and Other Authorities 31 U.S.C. § 3729......5 Tex. Health & Safety Code § 161.0001......12

TEX. HEALTH & SAFETY CODE § 161.132	10
Tex. Health & Safety Code § 161.134	passin
TEX. HEALTH & SAFETY CODE § 241.003	10
Tex. Health & Safety Code § 464.003	11
TEX. HEALTH & SAFETY CODE § 571.003	11
Tex. Senate Comm. on Health & Hum. Serv., Bill Analysis, S.B. 210 (1993)	10
FED. R. CIV. P. 9(b)	8
FED. R. CIV. P. 10(c)	1
FED. R. CIV. P. 12(b)(6)	1, 1
ANTONIN SCALIA & BRYAN A. GARNER, READING LAW: THE INTERPRETATION OF LEGAL TEXTS (2012)	11, 13

Defendant Ventavia Research Group, LLC hereby moves to dismiss Relator Brook Jackson's Second Amended Complaint (Dkt. 118) under Federal Rule of Civil Procedure 12(b)(6).

INTRODUCTION AND STATEMENT OF ISSUES

Relator's amended complaint fixes nothing, and her claims should be dismissed for good. Earlier this year, the Court properly held in a thorough order dismissing the First Amended Complaint that Relator had not sufficiently alleged any false claims for government payment, as required to state a claim under the False Claims Act; had not satisfied the FCA's demanding test for materiality; and had not engaged in the kind of protected activity that gives rise to a retaliation claim. (Dkt. 96, the "Dismissal Order.") Although the Court gave Relator one more opportunity to amend her complaint, she has not cured all (or any) of the many independent deficiencies that require dismissal. Ventavia now asks the Court to dismiss the Second Amended Complaint as it did the first—and to put an end to this baseless lawsuit once and for all.

Because the Court has already been through this exercise once (and so little has changed), Ventavia incorporates by reference all the prior motions to dismiss under FED. R. CIV. P. 10(c) (Dkt. 37, 51, 53) and reasserts all the same grounds for dismissal in an effort to limit unnecessary repetition. The Second Amended Complaint should be dismissed for the same reasons the Court addressed in the Dismissal Order and for other reasons that were unnecessary to reach. (*See* Dkt. 96 at 42, n.22.) This complaint should also be dismissed for the additional reasons addressed in the motions to dismiss being filed today by Pfizer and ICON, which Ventavia hereby adopts and incorporates by reference under FED. R. CIV. P. 10(c), again to avoid redundant briefing.

This motion will focus on the very few new allegations that mention Ventavia and will explain why the claims against it should be dismissed again, with prejudice. In addition to Relator's

ongoing failure to allege *any* viable FCA claim against *any* Defendant, the claims against Ventavia must be dismissed because: (1) Relator has still not sufficiently alleged that Ventavia caused the submission of false claims, as required to hold it liable under the FCA; and (2) Relator has not sufficiently alleged that Ventavia retaliated against her in violation of Texas law.

ARGUMENTS AND AUTHORITIES

I. Relator still has not stated a viable claim for violations of the False Claims Act.

The basic premise of Relator's case hasn't changed much from the one she argued at the motion-to-dismiss hearing: she still says the Defendants violated the FCA based on alleged flaws in the clinical trial that she says she observed over the 18 days she was employed by Ventavia. But Relator has now added some frankly absurd allegations in support of her fraudulent-inducement theory, asserting that Pfizer knew it could not develop a safe and effective COVID-19 vaccine, that it tricked the United States into purchasing an ineffective "gene therapy," and that the FDA's emergency authorization process was entirely unnecessary because alternative treatments already existed. (See Dkt. 118 ¶¶ 2-9, 306-19.) The good news is that the Court should never have to wade into the factual merit of those allegations—because Relator's theories have never stated a viable claim for relief under the FCA and they still don't. Dismissal on the pleadings is required again.

A. The Court properly held that Relator failed to allege any false claims under the meaning of the FCA—and her new complaint doesn't either.

In the Dismissal Order, the Court properly recognized that FCA liability turns on the existence of a false claim for government payment—and then properly rejected every theory Relator alleged for what the false claim here might have been. (See Dkt. 96 at 19, 24.) The Court

¹ See also, e.g., United States ex rel. King v. Solvay Pharms., Inc., 871 F.3d 318, 326 (5th Cir. 2017) (Proof of a "false claim against the government is the 'sine qua non' of liability under the FCA.").

held that Relator had not sufficiently alleged any "express false certifications" because the payments to Pfizer were not conditioned on compliance with federal regulations or the clinical trial protocol and because Pfizer's invoices did not contain express false certifications (Dkt. 96 at 24, 26); that Relator had not sufficiently alleged any "implied false certifications" because the invoices contained no misleading half-truths (*id.* at 27); and that Relator had not sufficiently alleged any "false record claims" because there was no underlying false claim for payment (*id.* at 29-30). Relator purports to re-assert all the same theories in Counts II-IV of her amended complaint, but she has stipulated those counts are there *only* for purposes of appeal. (Dkt. 116.) So there is no live claim in Counts II-IV for the Court to resolve. But even if there were, Relator has not offered any new factual allegations to overcome the fatal flaws that led the Court to dismiss these theories.

Instead, the focus of the Second Amended Complaint is Relator's belated attempt to allege fraudulent inducement. (*See, e.g.,* Dkt. 118 ¶¶ 135-63, 347-57.) As the Dismissal Order recognized, Relator did not allege this theory in the First Amended Complaint: she inappropriately raised it for the first time in responding to the initial motions to dismiss. (*See* Dkt. 96 at 32.) In its reply brief, Pfizer nevertheless explained why this theory failed under the text of the FCA, existing Fifth Circuit precedent, and Relator's allegations. (Dkt. 67 at 3-5.) And the Dismissal Order appeared to acknowledge that Relator's theory stretched the concept of fraudulent inducement beyond existing precedent. (Dkt. 96 at 31-32.) The fact that Relator has now formally tried to allege this misguided theory does not fix any of those flaws or state a valid claim for relief under the FCA. Count I (Fraud in the Inducement) should be dismissed as to all Defendants for the reasons stated in Pfizer's prior reply brief, in Section I of Pfizer's Motion to Dismiss the Second Amended Complaint, and in Section II of ICON's Motion to Dismiss the Second Amended Complaint.

That's especially true because Relator still has not solved her materiality problem. As an independent basis for dismissing the First Amended Complaint, this Court properly held that Relator had failed to allege any *material* misrepresentations, as required to state an FCA claim, because it is undisputed that the U.S. Government has known about the alleged protocol violations for years and has continued to authorize and purchase the Pfizer vaccine. (*See* Dkt. 96 at 32-42.) Relator tries again to allege materiality as an essential element of her fraudulent-inducement theory (*see* Dkt. 118 ¶ 349), but her allegations are not all that different and fail for the reasons addressed in Section II of Pfizer's Motion to Dismiss the Second Amended Complaint.

In short, Relator has still not alleged any viable FCA claim against any Defendant. Counts I-IV should be dismissed with prejudice in their entirety.

B. Relator has never alleged that Ventavia caused the submission of false claims.

In the alternative, and at a minimum, Relator has never sufficiently alleged that Ventavia itself violated the FCA—and the claims against it must be dismissed—because Ventavia has virtually no connection to the government and thus made no false claims for government payment. That's a problem for Relator because she has the burden to state individually viable claims for relief against *every* defendant: "It is impermissible to make general allegations that lump all defendants together; rather, the complaint must segregate the alleged wrongdoing of one from another." *In re Parkcentral Glob. Litig.*, 884 F. Supp. 2d 464, 471 (N.D. Tex. 2012); *see also United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 714 (10th Cir. 2006) ("[T]he appropriate focus of th[is] inquiry is on 'the specific conduct of the person from whom the Government [or relator] seeks to collect.'"). Relator cannot clear that bar as to Ventavia.

For one thing, it is all but undisputed that Ventavia never submitted any claims for payment to the government, much less false ones. (*See* Dkt. 65 at 10, 17.) The only defendant alleged to do

so was Pfizer (Dkt. 118 ¶ 129-30), and those claims were not false for the reasons discussed above. Because Ventavia never received any government money, Relator has not and cannot allege that it directly violated the FCA. (*See* Dkt. 53 at 18.) To hold Ventavia liable, then, Relator must necessarily rely on some sort of causal leap—by showing that Ventavia caused Pfizer to present false claims to the government or that Ventavia made or used false records or statements that caused the submission of false claims. *See* 31 U.S.C. §§ 3729(a)(1)(A), (B); *Solvay*, 871 F.3d at 328-29 (affirming summary judgment on these indirect theories for failure to show causation).

Relator cannot make that leap. These indirect theories require a "sufficient nexus between [Ventavia's] conduct and the ultimate presentation of the allegedly false claim." *United States ex rel. Colquitt v. Abbott Labs.*, No. 3:06-cv-01769, 2016 WL 80000, at *6 (N.D. Tex. Jan. 7, 2016). This is a proximate-cause standard that "demands more than mere passive acquiescence in the presentation of the claim" by someone else. *Id.* at *7 (citing *Sikkenga*, 472 F.3d at 714-15). Rather, the relator must allege some "affirmative act" on Ventavia's part that was a substantial factor in inducing Pfizer to submit claims for government payment. *Sikkenga*, 472 F.3d at 714-15; *see also United States ex rel. Riley v. St. Luke's Episcopal Hosp.*, 355 F.3d 370, 378 (5th Cir. 2004) ("The FCA applies to anyone who knowingly assists in causing the government to pay claims grounded in fraud[.]") (quotations and alterations omitted). This test "separates the wheat from the chaff, allowing FCA claims to proceed against parties who can fairly be said to have caused a claim to be presented to the government, while winnowing out those claims with only attenuated links between the defendants' specific actions and the presentation of the false claim." *Sikkenga*, 472 F.3d at 714.

Relator's indirect theories against Ventavia fall well short of that standard, including because there were no false claims in the first place as the Court found in the Dismissal Order (Dkt.

96 at 29-30), which meant the Court did not need to address causation. (*Id.* at 42, n.22.) But even if the Court were to find that Relator's fraudulent-inducement allegations satisfy the "false claim" element for purposes of her direct theory against Pfizer (and to be clear, they do not), Relator still has not alleged that Ventavia proximately caused the submission of the false claims.

The Second Amended Complaint certainly does not plead facts establishing any "affirmative acts" by Ventavia that assisted or induced Pfizer's alleged conduct related to the negotiation of its contract with the United States, the development and execution of the clinical trial protocol, or the so-called effectiveness of alternative treatments—the allegations at the heart of Relator's fraudulent-inducement theory. (*E.g.*, Dkt. 118 ¶¶ 1-9, 37-49, 135-63.) Nor does Relator allege that Ventavia did anything to help procure a government contract through false statements, as explained in Section II of ICON's Motion to Dismiss the Second Amended Complaint.

At best, and as in the prior complaint, Relator asserts in a conclusory fashion that Ventavia's alleged violations of the clinical trial protocol—over 18 days, at two test sites out of hundreds in the Phase 3 trial—caused the FDA to approve the Pfizer vaccine under false pretenses. (*E.g.*, Dkt. 118 ¶¶ 169-72.) Even this is an overly generous reading of the Second Amended Complaint, as Relator's FDA allegations focus more on the general conduct of the clinical trial than the conduct at Ventavia's sites specifically.² But regardless, Relator's allegations aren't good enough as a matter of law because they suggest only "but for" causation—and but-for causation is not the same thing as proximate causation. *See Sikkenga*, 472 F.3d at 714 (rejecting "broad 'but for' test" under the FCA). Because Relator has not even tried to allege that Ventavia's conduct

² See, e.g., Dkt. 118 ¶ 159 ("Had Pfizer not engaged in the clinical trial fraud as alleged herein, it would not have obtained an EUA based on the totality of the scientific evidence and the objective facts showing that the harm far outweighed any potential benefit.").

proximately caused the FDA to approve the vaccine—much less the submission of false claims—Relator fails to state a claim against Ventavia for this reason alone.

That said, Relator hasn't sufficiently alleged but-for causation either. She has admitted that in approving Pfizer's vaccine, the FDA relied on data from roughly 44,000 Phase 3 trial participants. (*See* Dkt. 17 ¶ 80; Dkt. 118 ¶ 163.) She alleges Ventavia enrolled 1,500 of those participants (only 3%), though the real number (1,126) is lower than that. (Dkt. 53 at 16, n.6.) Whatever the precise percentage, the participants at Ventavia's sites were a small piece of the overall trial, Relator's "allegations only implicate a fraction of" that percentage (Dkt. 96 at 42), and Relator has not sufficiently alleged that the Ventavia data was the deciding factor in the FDA's approval decision. On the contrary, the United States explained in its Statement of Interest that:

[E]ven if the allegations were sufficient to show that Ventavia's safety and efficacy data was 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 about 3 percent, or approximately 1,500 of the nearly 44,000 total clinical trial participants.

(Dkt. 70 at 11-12, emphasis added.) That means Relator has not even alleged a but-for causal link between the violations she alleges at Ventavia and the FDA's approval of the vaccine.

Relator's conclusory allegations in the Second Amended Complaint do not overcome that fatal shortcoming. She vaguely asserts that the alleged protocol violations caused the trial data to be unreliable and inadequate (*see, e.g.,* Dkt. 118 ¶¶ 170, 309-10), but that argument fails as a matter of pleading (because it's not supported by anything), particularity (because it doesn't connect the dots to Ventavia's data), and basic logic (because the FDA had roughly 42,000 other data points to go on). Relator purports to confront this flaw in one superficial paragraph that says "with a data endpoint of 170 people, Ventavia's errors . . . easily push the number of endpoints below statistical

significance." (*Id.* ¶ 163.) That allegation is as incoherent as it is irrelevant. Relator offers no explanation for what "data endpoint" she's talking about or how/why Ventavia's so-called errors would be statistically significant to that calculation—and she certainly does not support her allegation with the well-pleaded facts necessary to pass muster under Rule 9(b) or the *Twombly/Iqbal* standard of Rule 8(a). (*See* Dkt. 53 at 6-7.)

For all those reasons, Relator has not sufficiently alleged that any false records or statements by Ventavia proximately caused the FDA to authorize the Pfizer vaccine—and that's still a step removed from what Relator actually has to show (that Ventavia proximately caused Pfizer to make false claims for government payment). See D'Agostino v. ev3, Inc., 845 F.3d 1, 7-10 (1st Cir. 2016) (affirming dismissal of fraudulent inducement claims because relator could not establish a "causal link" between misrepresentations to get FDA approval for medical device and submission of claims to CMS by healthcare providers). Such a "generalized daisy chain of causation" between the target defendant and the alleged false claims does not meet the pleading requirements of Rule 9(b) or the legal requirements of the FCA. See Sikkenga, 472 F.3d at 728 n.34.3 So, at a minimum, the Court should dismiss Relator's FCA claims against Ventavia.

II. Relator still has not stated a viable claim for retaliation under any statute.

The Second Amended Complaint similarly fails to resuscitate Relator's retaliation claim against Ventavia. In the Dismissal Order, the Court properly dismissed Relator's FCA retaliation claim because she did not engage in "protected activity" prior to her termination and because

³ If nothing else, Relator has failed to allege the particularized details necessary to satisfy Rule 9(b) for her indirect theories, including because she fails to allege specific facts regarding *what* the relevant false records and statements were, *who* made those records or statements, *when* they were submitted to the government, or *how* they were material in causing the submission or payment of false claims. (*See* Dkt. 53 at 20-21; *see also* Section II of ICON's Motion to Dismiss.)

Ventavia did not know she was engaged in protected activity. (Dkt. 96 at 46, 48.) The Court left open the possibility that Relator "may be able" to bring a proper retaliation claim under another statute. (*Id.* at 48, n.23.) And Relator tries to do just that in her Second Amended Complaint, by asserting a new claim for retaliation under Texas Health and Safety Code § 161.134 while also reasserting her failed retaliation claim under the FCA. (Dkt. 118 ¶¶ 261-95, 337-46.) Both theories fail to state a viable claim for relief and should be dismissed with prejudice.

To quickly address the restated retaliation claims under the FCA: Relator's factual allegations have not changed on this claim, and it should be dismissed again for the same reasons. Relator continues to generally say she engaged in protected activity through internal complaints "about participant safety and regulatory, protocol, and HIPAA violations," which—as the Court held—are "not protected activity under the FCA's retaliation provision." (*See* Dkt. 96 at 46; Dkt. 53 at 21-23; Dkt. 118 ¶¶ 261-95.) Nor has Relator made any effort to cure the second independent basis for dismissing her FCA retaliation claim—her failure to allege that Ventavia *knew* she was engaged in protected activity. (Dkt. 96 at 48.) Count V must be dismissed all over again.

Relator's new retaliation claim under Texas law fails just the same and must be dismissed as well. (*See* Dkt. 118 ¶¶ 341, 380.) Section 161.134 of the Texas Health and Safety Code provides that a "hospital, mental health facility, or treatment facility may not . . . terminate the employment of . . . an employee for reporting . . . a violation of law, including a violation of this chapter, a rule adopted under this chapter, or a rule of another agency." Tex. Health & Safety Code § 161.134(a). To prevail under that provision, a plaintiff must show, among other elements, that she: (1) was an employee of a "hospital, mental health facility, or treatment facility," (2) reported a "violation of law" under Section 161.134, and (3) was terminated by the covered entity for making

that report. See, e.g., Janaki v. C.H. Wilkinson Physician Network, 624 S.W.3d 623, 628 (Tex. App.—Corpus Christi 2021, no pet.). Because Relator has not sufficiently alleged any of those elements, her claim under Section 161.134 must be dismissed.

Most fundamentally, Section 161.134 does not apply to Relator or to Ventavia as a matter of statutory text or context—because Ventavia is not the kind of health care facility governed by this provision. Section 161.134 appears in a relatively narrow subchapter related to "Abuse, Neglect, and Unprofessional or Unethical Conduct in Health Care Facilities." Tex. Health & SAFETY Code, Ch. 161, Subchapter L. That chapter defines "abuse" and "neglect" by reference to a federal "Protection and Advocacy for Individuals with Mental Illness Act" and addresses misconduct against patients receiving chemical dependency, mental health, or rehabilitation services. *See id.* §§ 161.131(1), (8), 161.132(a); *see also* Tex. Senate Comm. on Health & Hum. Serv., Bill Analysis, S.B. 210 (1993) (impetus for these provisions was a "study of private psychiatric and substance abuse services in Texas" and "complaints relating to the abuse and neglect of patients and to the administration of excessive, unusual, and potentially harmful 'therapy'").4

With that context in mind, the retaliation provision in Section 161.134 protects only the employees of three kinds of healthcare facilities: "hospitals, mental health facilities, and treatment facilities." Tex. Health & Safety Code § 161.134(a). Relator does not allege which of those categories she believes applies to Ventavia—but none of them do. Hospitals are generally defined as establishments that offer services, facilities, and beds for individuals requiring diagnosis, treatment, or care for illness, injury, or other medical conditions. *See id.* §§ 161.131(3), 241.003(5), (15). Mental health facilities provide diagnosis, treatment, and care for people with mental illness.

⁴ Available at: https://lrl.texas.gov/LASDOCS/73R/SB210/SB210 73R.pdf#page=51.

See id. §§ 161.131(7), 571.003(12). And treatment facilities are designed to promote a person's chemical-free status or ensure the person is free of illegal drugs. See id. §§ 161.131(10), 464.001(5).⁵ Ventavia is a testing site operator that conducts clinical research trials. (See Dkt. 118 ¶¶ 33-34, 166.) It does not fall into any of those categories and, more importantly, Relator does not even argue as much or offer well-pleaded allegations in support. Because Relator has not sufficiently alleged that she was an employee of a covered facility under Section 161.134, she has no retaliation claim. See Janaki, 624 S.W.3d at 633 (affirming summary judgment because plaintiff's former employer was not a hospital, mental health facility, or treatment facility); Barron, 218 S.W.3d at 810-11 (same).

But Relator's retaliation claim fails for a second independent reason as well—because she has not sufficiently alleged the kind of reported "violation of law" that triggers the protections of Section 161.134(a). Though that term appears broad at first glance, the statute implies a narrower meaning by listing three specific categories of violations that are included: "a violation of this chapter, a rule adopted under this chapter, or a rule of another agency." *Id.* Under the associated-words canon, *noscitur a sociis*, "words grouped in a list should be given related meanings." Antonin Scalia & Bryan A. Garner, Reading Law: The Interpretation of Legal Texts 195 (2012); *see also Yates v. United States*, 574 U.S. 528, 543 (2015) (*noscitur a sociis* "avoid[s] ascribing to one word a meaning so broad that it is inconsistent with its accompanying words" or has "unintended breadth"). So, Section 161.134 applies only to "violations" of the laws listed in those three categories or something similar. Relator does not allege any such violations.

⁵ See also Barron v. Cook Children's Health Care Sys., 218 S.W.3d 806, 809 (Tex. App.—Fort Worth 2007, no pet.) (limiting retaliation provision to treatment facilities that "ha[ve] a 'planned, structured, and organized program designed to initiate and promote a person's chemical-free status or to maintain the person free of illegal drugs").

For one thing, Relator does not sufficiently allege that she reported a violation of the "chapter" in which Section 161.134 appears, *i.e.*, the provisions of Subchapter L related to abuse and neglect of patients with mental illnesses or chemical dependencies. But even if the term "this chapter" were expanded to include all of Chapter 161, Relator has not cleared that bar either. In attempting to do so, Relator mischaracterizes the law by suggesting that Section 161.0001 "requires every 'health care provider who administers a vaccine'" to record "'any adverse or unexpected events for a vaccine.'" (Dkt. 118 ¶ 343.) That's not quite right.

Section 161.0001 is a *definition* provision, not an affirmative legal requirement. It merely defines the term "data elements," for purposes of another subchapter, as "the information a health care provider who administers a vaccine is required to record in a medical record under 42 U.S.C. Section 300aa-25." Tex. Health & Safety Code § 161.0001(1)(A)(iii). No court has ever construed this definitional provision to impose the kind of affirmative legal requirement that might amount to a "violation of law" under Chapter 161. But even if it did impose such a requirement, its terms apply only to "health care providers," not clinical testing facilities like Ventavia. And even if Ventavia were a health care provider, the incorporated federal law only requires records for vaccines on the federal "Vaccine Injury Table." *See* 42 U.S.C. § 300aa-25(a). Pfizer's COVID-19 vaccine is not listed on the Vaccine Injury Table, meaning even the incorporated federal law does not require reporting of adverse events. So, in short, Relator has not alleged a violation of the definition provision in Section 161.0001 (or anything else in Chapter 161).

⁶ See Health Resources & Services Administration, Vaccine Injury Table (Jan. 3, 2022), available at: https://www.hrsa.gov/sites/default/files/hrsa/vicp/vaccine-injury-table-01-03-2022.pdf.

⁷ Relator also has not alleged that she "report[ed]" any such violations to Ventavia, as is required to support her retaliation claim. Tex. Health & Safety Code § 161.134(a). She certainly does not support any such allegation with well-pleaded facts. (*See* Dkt. 53 at 6-7.)

Nor has Relator sufficiently alleged a violation of any "rule adopted under this chapter, or a rule of another agency." Tex. Health & Safety Code § 161.134(a). The only thing Relator appears to allege here is the so-called "major protocol deviations in violation of Federal Acquisition Regulations." (Dkt. 118 ¶ 343.) But as this Court pointed out in its Dismissal Order, Pfizer's agreement with the Department of Defense was not subject to the FAR and neither was its clinical trial. (*See* Dkt. 96 at 20–22.) That flaw aside, there is no indication that this Texas state statute was designed to capture reported violations of *federal* regulations. Again, the term "another agency" must be read in the context of this provision as a reference to state agencies—those with the power to enforce the provisions of Texas Health & Safety Code Chapter 161—not federal agencies. *See* SCALIA & GARNER, READING LAW at 195. So Relator's misguided allegations of federal regulatory violations would not trigger Section 161.134 in any event.

The bottom line here: for several reasons, Relator does not have a viable retaliation claim under Section 161.134. Her state-law claim must be dismissed just like her federal claim.

Alternatively, and even if the Court finds that Relator has a plausible claim under Section 161.134, the Court can and should decline to exercise supplemental jurisdiction over this standalone state-law claim. A federal court can "decline to exercise supplemental jurisdiction over" a state-law claim when, among other things, the court "has dismissed all claims over which it has original jurisdiction." 28 U.S.C. § 1367(c)(3). Although this is a discretionary decision, in this Court and "the Fifth Circuit, the 'general rule is to dismiss state claims when the federal claims to which they are pendent are dismissed." Hanak v. Talon Ins. Agency, Ltd., 470 F. Supp. 2d 695, 708 (E.D. Tex. 2006) (quoting Parker & Parsley Petroleum Co. v. Dresser Indus., 972 F.2d 580, 585 (5th Cir.1992)); see also id. ("The Supreme Court has counseled that a court should

decline jurisdiction if the federal claims are dismissed before trial.") (quotations omitted).

The general rule applies here, and the Court should decline to exercise supplemental jurisdiction, because its original jurisdiction is based exclusively on federal question jurisdiction under the FCA—and because all of Relator's FCA claims should again be dismissed. There is no reason for the Court to hang on to Relator's state-law retaliation claim because trial is years away and discovery has not even begun. *See id.* (declining supplemental jurisdiction "because the federal claims are being dismissed well before trial"). Further, "the factors of judicial economy, convenience, fairness, and comity suggest that this court should decline to exercise jurisdiction over the remaining state law claim[]" (*see id.*) because, among other things, resolving this claim may require *Erie* guesses of first impression about the scope of the retaliation provision in Section 161.134 and those questions are better left for Texas state courts. Plus, the Court should not stretch to extend any further lifeline to a relator who has so consistently flouted the federal rules and this Court's instructions throughout this litigation. (*See, e.g.*, Dkt. 53 at 21; Dkt. 81 at 3-4.)

In short, the last thing this Court needs is a strained, standalone state-law claim crowding its docket unnecessarily. So, in the event the Court does not dismiss Relator's state-law retaliation claim under Rule 12(b)(6)—and it should do just that—the Court can and should decline to exercise supplemental jurisdiction and dismiss this claim regardless.

CONCLUSION AND PRAYER

Ventavia respectfully requests that this Court grant its Motion and dismiss with prejudice all claims asserted against it in Relator's Second Amended Complaint (Dkt. 118). Ventavia also requests that this Court grant any other relief to which it may be justly entitled.

Respectfully submitted,

/s/ Stacy L. Brainin

Stacy L. Brainin
Texas Bar No. 02863075
Andrew W. Guthrie
Texas Bar No. 24078606
Taryn M. McDonald
Texas Bar No. 24088014
HAYNES AND BOONE, LLP
2323 Victory Avenue, Suite 700
Dallas, Texas 75219
Tel: (214) 651-5000
Fax: (214) 651-5940
stacy.brainin@haynesboone.com
andrew.guthrie@haynesboone.com

COUNSEL FOR VENTAVIA

taryn.mcdonald@haynesboone.com

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing document was served upon all counsel of record on October 20, 2023, pursuant to the Court's ECF filing system and the Federal Rules of Civil Procedure.

/s/ Andrew W. Guthrie
Andrew W. Guthrie