No.: 24-40564

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

BROOK JACKSON,

Qui Tam Plaintiff-Appellant,

v.

VENTAVIA RESEARCH GROUP, LLC,

Defendant-Appellees,

UNITED STATES OF AMERICA,

Intervenor Plaintiff-Appellee,

PFIZER, INC., and ICON PLC,

Defendants

On Appeal from the United States District Court
for the Eastern District of Texas
No. 1:21-cv-00008-MJT
Judge Michael J. Truncale United States District Judge

APPELLANT'S OPENING BRIEF

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CERTIFICATE OF INTERESTED PARTIES

The undersigned counsel of record certifies that the following listed persons and entities as described in the fourth sentence of 5th Circuit Rule 28.2.1 have an interest in the outcome of this case. These representations are made in order that the judges of this court may evaluate possible disqualification or recusal.

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STATEMENT REGARDING ORAL ARGUMENT

Appellant requests oral argument because it will aid the decisional process in resolution of this appeal. Among other reasons, this appeal involves whether the dismissal of the entire action with prejudice to Relator should be reversed. The district court granted the DOJ's late-stage motion to intervene to dismiss this case – a *qui tam* action that aims to expose one of the biggest frauds perpetuated on the United States government and the American people. The appeal raises new, novel, important, and unprecedented issues, and Appellant seeks to address the Court regarding underlying statutory and constitutional principles.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CONSTITUTION

CASES

STATUTES

RULES

OTHER AUTHORITIES

JURISDICTIONAL STATEMENT

Subject matter jurisdiction in the U.S. District Court for the Eastern District of Texas ("district court") under the False Claims Act, 31 U.S.C. §§ 3729 *et seq.*, is predicated upon 28 U.S.C. §§ 1331 and 1345 and 31 U.S.C. §§ 3730 and 3732(a). Supplemental jurisdiction over claims under Texas Health and Safety Code § 161.134, is pursuant to 28 U.S.C. § 1359.

Jurisdiction here over the district court's judgment disposing of all remaining claims is predicated on 28 U.S.C. §§ 1291 and 1294. ROA.4935-4959.

This appeal is timely because Appellant filed a Notice of Appeal with the district court on August 29, 2024, less than 60 (sixty) days after entry of the Order of Dismissal, in compliance with Rules 3 and 4 of the Federal Rules of Appellate Procedure. ROA.4960-4961.

INTRODUCTION

Congress strengthened the False Claims Act's *qui tam* provisions in 1986, making it "the Government's primary litigative tool for combating fraud." S. Rep. No. 99-345, at 2 (1986). These amendments empowered private citizens to prosecute fraud cases even when the government declined to act, recognizing that effective fraud prevention requires both government and private enforcement.

Relator Brook Jackson's *qui tam* action alleges Defendants Pfizer, Inc. ("Pfizer"), ICON PLC ("ICON"), and Ventavia Research Group, LLC ("Ventavia") engaged in clinical trial fraud to obtain Emergency Use Authorization for its Covid-19 vaccines. After declining intervention as of right, the Department of Justice sought "later date" intervention under 31 U.S.C. § 3730(c)(3) solely to dismiss under § 3730(c)(2)(A). The U.S. Department of Justice's ("DOJ") threadbare motion provided no evidence of investigation into the merits, analysis of discovery burdens, changed circumstances since declining intervention, or legitimate government purpose served by dismissal.

The district court erred by granting intervention without requiring the DOJ to show good cause. It improperly collapsed the distinct analyses for intervention and dismissal, eliminating Rule 24's gatekeeping function. The court also failed to consider how terminating Jackson's meritorious action would chill future whistleblowers from exposing fraud. This Court should vacate the order below and

require proper application of the intervention standards that Congress designed to balance government and private enforcement of the False Claims Act.

ISSUES PRESENTED

1. Whether the district court erred in granting the DOJ's motion for permissive intervention to dismiss Jackson's *qui tam* action, where the DOJ failed to demonstrate good cause, violated constitutional principles, and the court failed to properly balance the parties' interests under Rule 24.
2. Whether the Order of Dismissal with prejudice as to Relator should be vacated on the grounds that the DOJ failed to articulate a constitutionally firm and reasonably grounded argument as to why the burdens of continued litigation at this time outweighed its benefits.
3. Whether the district court abused its discretion in entering dismissal of the *qui tam* action with prejudice as to Relator.
4. Whether, on *de novo* review, the Order dismissing Brook Jackson's retaliation claim must be vacated, where she pleaded sufficient facts stating a claim that she was unlawfully terminated from her employment because of her efforts to stop one or more violations of the False Claims Act.

STATEMENT OF THE CASE

A. Statement of the Facts

1. While Working as a Clinical Trial Director, Brook Jackson Blew the Whistle on Defendants' Fraud and Misconduct

Brook Jackson is a Clinical Research Auditor and Certified Clinical Research Professional. For over eighteen years, she worked on clinical trials supporting safe and effective medicines. Before working for defendant Ventavia, Jackson served as the Director of Operations for a multi-state clinical trial company, overseeing legal and regulatory compliance, adherence to good clinical practices, submission of required documentation, and business development. ROA.3624.

Jackson began working as a Regional Director for Ventavia on September 8, 2020, overseeing site managers, patient recruitment, training, quality assurance, enforcement of communication paths, and growth plans at her assigned test sites. Her duties included ensuring that Serious Adverse Event ("SAE") reports were timely submitted and that her assigned sites had action plans to address protocol deviations. Jackson's job duties also included daily and weekly communication with site operations managers and Ventavia's leadership team. ROA.3655-3656.

While at Ventavia, Jackson witnessed protocol violations including manipulated enrollment, subject unblinding, temperature control failures, falsified consent records, untrained staff, inadequate safety monitoring, and flawed data

collection. ROA.3656-3679. Given her training and experience, Jackson understood the cumulative violations meant the clinical trials for Pfizer's Covid-19 vaccines were not "adequate" or "well-controlled", resulting in unreliable data to assess whether "the known and potential benefits of the product, when used to … treat such disease or condition, outweigh the known and potential risks of the product" as required by the Emergency Use Authorization ("EUA") statute. 21 U.S.C. § 360bbb–3(c)(2)(B). ROA.3656.

Jackson repeatedly alerted supervisors and investigators to violations, documenting some with photos. In September 2020, Jackson recommended pausing enrollment due to audit concerns. While Ventavia briefly halted enrollment, they failed to address the data issues or implement safeguards against future violations. Her superiors later admitted compliance problems existed across multiple sites, leading her to conclude data integrity would not be addressed. ROA.3679-3687.

On September 25, 2020, Jackson reported her concerns to the FDA. She was fired hours later because she was not a "good fit." Jackson alleged she was terminated "as a direct consequence of her reports and efforts to stop fraud against the United States DoD." The next business day, Ventavia resumed enrolling subjects without completing quality control checks or remedying violations. ROA.3687-3688.

On January 8, 2021, Jackson filed a *qui tam* action under seal against Pfizer, Ventavia and ICON, the entity tasked with oversight of data management and reporting for all of the clinical trials. ROA.21-101. Concerned about public health and the pending EUA review of children's Covid-19 vaccines, Jackson spoke with journalist Paul Thacker during the government's sealed investigation, resulting in a peer reviewed BMJ article that exposed the clinical trial violations.[1]

2. In the Second Amended Complaint, Relator Details Fraud in The Design, Conduct, Data Analysis and Reporting of Pfizer's Clinical Trials to Induce FDA to Issue an EUA of Pfizer's Biologic

In her Second Amended Complaint ("SAC"), Brook Jackson detailed how Pfizer fraudulently induced the U.S. Food and Drug Administration ("FDA") to grant an EUA for the modRNA biologic. She alleged Pfizer knew it could not obtain an EUA or full approval for its Covid-19 vaccine, because the clinical trial data showed the product was ineffective and injurious to public health.

Based on its pre-clinical efforts, animal studies, and principles of immunology, Pfizer knew it could not produce a product that would give protection or immunity from a respiratory infection through blood-borne antibody responses. Worse, "experts have long understood that mass vaccination with a 'leaky vaccine' – one unable to neutralize the infection – can lead to a more severe

[1] *See* Thacker PD. Covid-19: Researcher blows the whistle on data integrity issues in Pfizer's vaccine trial. BMJ 2021; 375:n2635. Epub Nov 2 http://doi.org/10.1136/bmj.n2635.

health crisis called 'Antibody Dependent Enhancement,' or ADE." ROA.3645. Combined with other aspects of immune dysfunction, including a class switch towards non-inflammatory IgG4 antibodies, Pfizer's Covid-19 vaccinations were destined to fail any adequate, well-controlled clinical trial. ROA.3645-3648.

Jackson alleges that, to induce an EUA for its modRNA biologic, Pfizer engaged in fraud in the design, conduct, analysis, and reporting of its clinical trials. Pfizer:

- Designed the clinical trials to avoid exposing that its product did not confer immunity from infection or transmission.
- Relied upon faulty PCR tests which it could manipulate on unblinded subjects to reach a desired result.
- Cut the trial periods short to hide negative efficacy and serious spike protein diseases.
- Destroyed the control group by unblinding and treating them.
- Lied about the durability of the modRNA material.
- Excluded pregnant women and then falsely reported there were no neonatal harms.
- Falsely manipulated inclusions and exclusions to achieve results.
- Allowed product degradation to hide adverse events in the treatment group.

- Failed to report cross-contamination in the placebo group.
- Failed to accurately report adverse events in the treatment group.
- Reported relative risk reduction instead of absolute risk reduction.
- Falsely counted vaccinated subjects as unvaccinated.
- Suppressed information about effective alternative treatments, which would have rendered an EUA unachievable.
- Reported unreliable and unethically-obtained data.

ROA.3648-3652.

The clinical trial fraud resulted in objective falsehoods material to the EUA. Jackson alleged FDA officials were unaware of the fraudulent conduct and materially false representations. But, even if FDA officials knew of the allegations, the EUA statute requires objective scientific evidence - not just the former Health and Human Services ("HHS") Secretary's judgment - for authorization. Materiality is not solely based on whether HHS, under the former administration, would have granted authorization had it known the truth, but on whether Congress required objectively true scientific evidence upon which the authorization could be granted. ROA.3653-3654.

3. Pfizer's Fraudulent Clinical Trials Contributed to a Public Health Crisis.

Brook Jackson's disclosures and the unsealing of her complaint catalyzed extensive scientific investigation into Pfizer's modRNA product. This research

revealed two critical findings: first, the vaccines failed to prevent Covid-19 transmission and showed negative efficacy. Second, data indicates the vaccines are associated with serious adverse events and immunological complications. These findings align with Jackson's original allegations about deficiencies in Pfizer's clinical trials. ROA4591-4594, 4596-4597, 4601-4682.

Had Pfizer's clinical trials been truthful, the resulting data would not have supported an EUA. An adequate and well-controlled clinical trial would have revealed that the known or potential benefits were not outweighed by the known or potential harm. For example, the data would have shown negative efficacy–the more subjects exposed to the injections, the more likely they would be infected and become seriously ill by SARS-CoV-2.

An independent study from Harvard showed no decrease of infection rates in areas with higher injection rates. The trend suggested "positive association such that countries with higher percentage of population fully vaccinated have higher COVID-19 cases per 1 million people." S. V. Subramanian, 36 Eur. J. Epidemiol. 1237-1240 (2021). This negative efficacy was hidden in the clinical trials, which falsely claimed Pfizer's product was 95% effective. Pfizer's efficacy claims were fraudulent due, in part, to the biased and manipulated categorization of subject data. ROA.4660-4669.

Similarly, an adequate and well-controlled clinical trial would have shown a rise in all-cause morbidity and mortality in subjects following their injections. In the United States and elsewhere, adverse events and deaths associated with Pfizer's product are staggering. Pfizer's products caused blood clots, neurological diseases, auto-immune disorders, increases in cancers and other life-threatening or disabling conditions. ROA.4588-4594. The Global Vaccine Data Network studied over 99 million vaccinated individuals and found significant risk periods following vaccination schedules, with observed vs. expected ratios (OE) greater than 1.5 and lower bound of the 95% confidence interval, for Guillain-Barré syndrome (2.49), for cerebral venous sinus thrombosis (3.23), for acute disseminated encephalomyelitis (3.78), for myocarditis (ranging from 6.10, 3.48 and 2.01) and for pericarditis (ranging from 6.91, 2.64 and 1.74).[2] ROA.4670-4682.

Pfizer's own inadequate and poorly controlled clinical trials reveal a connection between their Covid-19 vaccines and serious adverse events—a link that Pfizer never reported. After six months of data and a mere 60 days of control, no all-cause morbidity or mortality benefit was shown and, of those injected, more died or were injured than those given a placebo. It took 22,000 injections to purportedly avoid a single Covid-19 death but the cost was a fivefold increase in

[2] Faksova et al. "COVID-19 vaccines and adverse events of special interest: A multinational Global Vaccine Data Network (GVDN) cohort study of 99 million vaccinated individuals" Vaccine.

excess fatal cardiac arrest and congestive heart failure in injected individuals. ROA.4605. Based on the evidence now known, Pfizer's clinical trials showed its modRNA products caused more harm than any demonstrated benefit in preventing Covid-19 infection and transmission.

While the evidence already gathered demonstrates serious issues with Pfizer's clinical trials, Jackson still seeks discovery of Pfizer's internal records and communications. Through collaboration with scientists and researchers worldwide, this case has progressed further on publicly available evidence than most *qui tam* actions can achieve with full discovery.

4. Complicit in the Public Health Crisis, Former Officials in Executive Branch Agencies Protected Corporate Partners and Abandoned Public Health

In the district court below, Jackson made an offer of proof and sought an evidentiary hearing to establish the facts set forth above. Jackson was prepared to present conclusive evidence that Government medical and pharmaceutical regulatory officials were captured by corporate interests and abandoned their mission of protecting public health. These officials lost public credibility because their opinions were unsupported and unreliable and some have accepted pardons

for their actions.[3] The DOJ cited the opinions of some of these former FDA officials to explain its motion.

Official's credibility on vaccine-related matters eroded as courts repeatedly rejected their positions. Notably, when citizens sought Pfizer's clinical trial data through FOIA, the FDA claimed it needed 75 years to disclose the information. The Northern District of Texas rejected this claim, ordering the FDA to release the data at the same pace as its authorization review. ROA.4806-4810. The CDC similarly resisted transparency by releasing a fully redacted 148-page myocarditis study and withholding V-Safe data–a vaccine safety monitoring program. When citizens sued to access the V-safe data, necessary for informed consent and public health monitoring, the Northern District of Texas again ordered disclosure under FOIA. ROA.4811-4840. On an issue strikingly similar to the one raised on this appeal, the court rejected the former DOJ's representations about purported "burden" on the Government if required to comply. The court held the plaintiff could get expedited production of redaction-free text even if the burden was "heavy."

[3] https://www.nytimes.com/2025/01/20/us/politics/biden-pardons-fauci-milley-cheney-jan-6.html (accessed 2-14-2024)

And, in *Apter v. HHS*, 80 F.4th 579 (5th Cir. 2023), this Court allowed claims under the Administrative Procedures Act that the FDA acted *ultra vires* when it told consumers to avoid Ivermectin for the treatment of Covid-19. Despite plaintiff physicians' successful Ivermectin treatments and government harm to their practice, the district court dismissed on sovereign immunity grounds. This Court reversed, ruling FDA "has authority to inform, announce, and apprise – but not endorse or denounce, or advise." *Id*., 80 F.4th at 595.

At the same time the DOJ sought to dismiss Brook Jackson's case, it told the United States Supreme Court, on March 26, 2024, that the "FDA takes very seriously its responsibility to ensure the safety of drugs" and that "drug sponsors themselves remain responsible at all times." ROA.4705. The FDA cannot credibly claim a commitment to safety and that sponsors like Pfizer are "responsible at all times" while the DOJ works to dismiss Brook Jackson's *qui tam* action exposing Pfizer's clinical trial fraud influencing the EUA approval process.

Now more than ever, courts must review vaccine-related claims carefully. Many people are concerned about vaccine problems and agency misconduct. Courts have independently evaluated DOJ's vaccine claims and rejected unsupported government arguments. Even with new national leadership, judges - not politicians - must hold accountable those who obtained government funds

through fraud, regardless of the prior administration's acquiescence to their deception.

B. Procedural Posture

On January 18, 2022, over a year after this lawsuit commenced, the DOJ declined to intervene, and the action was unsealed. ROA.654-656, 659-660. Relator then filed her first amended complaint. ROA.661-740. Defendants moved to dismiss that complaint. ROA.1342-1378, 1721-1748, 1778-1812. Jackson opposed Defendants' motions to dismiss, asserting her allegations supported an unstated fraudulent inducement claim, and requested leave to amend if any claims were dismissed. ROA.1899-1944.

The DOJ filed a Statement of Interest (SOI), supporting Pfizer's motion to dismiss. It argued that the False Claims Act provided appropriate remedies when fraud was used to obtain FDA authorization or approval. But, since Jackson had not pleaded such a theory, the Government asked for dismissal. ROA.2000-2012.

On March 31, 2023, the District Court granted Defendants' motions, denying leave to amend the *qui tam* claims. ROA.2121-2168. Jackson then moved under Rule 59(e), to file a proposed second amended complaint. ROA.2179-2199. When the clerk refused to file the motion, Jackson filed a protective notice of appeal to this Court. ROA.2170-2171. Jackson then moved this Court to stay the protective appeal until the district court ruled on the Rule 59(e) motion, which this

Court granted. ROA.2877. Seven days later, the district court granted the Rule 59(e) motion, permitting Jackson to file an amended complaint. ROA.2878-2881. The first appeal was then dismissed without prejudice.

On October 2, 2023, Jackson filed her second amended complaint ("SAC"). ROA.3612-3707. Defendants again moved to dismiss. ROA.4315-4346, 4348-4366, 4368-4387. Defendants argued, *inter alia*, that Jackson failed to state a claim because the Government was aware of her allegations, did not seek to intervene, had previously supported the motions to dismiss, and had not recalled the EUA for Pfizer's vaccines.

Jackson opposed the motions to dismiss. ROA.4406-4446. She argued that Government knowledge, acquiescence, and even complicity in the fraud did not excuse Defendants for causing or making false claims on the federal fisc– particularly in light of objective standards set by Congress in the EUA statute.

After the motions were fully briefed, just before they were to be heard, the DOJ moved to intervene and dismiss. ROA.4520-4530. Although the Government was required to make a "showing of good cause" for intervention, the DOJ's motion included no evidentiary submissions.

Jackson opposed the DOJ's motion, including an affidavit by Attorney Mendenhall describing an in-person meeting with the DOJ. At that meeting, the government raised no issues regarding the merits of the case, or resulting burdens

placed on the Government. Mendenhall attached exhibits to his declaration, including expert declarations, scientific articles, the "Granston Memo," and correspondence between Senator Grassley and DOJ officials regarding motions to dismiss. ROA.4601-4639, 4640-4659, 4660-4669, 4670-4682, 4683-4689, 4690-4805, 4806-4810, ROA.4811-4840, 4841-4849, 4850-4863, 4864-4872, 4873-4879, 4880-4886. To fulfill her role "as a check that the Government does not . . . drop the false claims case without legitimate reason," Jackson requested a hearing, setting forth the precise facts she would establish through the evidence. S. Rep. No. 99-345, at 25; ROA.4558-4587.

In its reply, the DOJ failed to address issues raised by Jackson's opposition, including application of Rule 24, the unconstitutionality of the DOJ's viewpoint-based action to terminate the action, and separation of powers concerns arising from its motion. ROA.4892-4898. Jackson then filed a Sur-Reply. ROA.4899-4907.

On May 1, 2024, the district court heard legal arguments for 2.5 hours regarding the Government's motion to dismiss and defendants' motions to dismiss. The transcript is at ROA.5094-5200. Thereafter, on June 27, 2025, Jackson filed a Notice of Supplemental Authority. ROA.4924-4930.

On August 9, 2025, the district court granted the Government's motion to intervene and to dismiss, Ventavia's motion to dismiss, and denied as moot Pfizer and Icon's motions. ROA.4935-4959. This appeal followed.

LEGAL STANDARDS

A. Standards of Appellate Review

This Court reviews the "district court's holdings on constitutional and other legal questions *de novo*, and its specific factual findings for clear error." *Sullo & Bobbitt, P.L.L.C. v. Milner*, 765 F.3d 388, 392 (5th Cir. 2014). The district court's grant of intervention is reviewed for abuse of discretion. *Newby v. Enron Corp.,* 443 F.3d 416, 423 (5th Cir. 2006); *see Gulf States Util. Co. v. Alabama Power Co.*, 824 F.2d 1465, 1476 (5th Cir. 1987).

Typically, review of the district court's dismissal under Rule 41 is also for abuse of discretion. *E.g., Welsh v. Correct Care L.L.C.*, 915 F.3d 341, 344 (5th Cir. 2019). However, unless the plaintiff previously dismissed an action based upon the same facts, Rule 41(a) dismissals are ordinarily without prejudice. In this case, the district court dismissed the *qui tam* complaint over Relator's objections and with prejudice as to Relator. "[I]in cases where the dismissal is with prejudice, [this Court's] 'examination is searching.'" *Shaw v. United Mexican States*, 2024 U.S. App. LEXIS 6166, at *5 (5th Cir. Mar. 14, 2024). As this Court explained in the context of involuntary dismissal under Rule 41(b)),

"when, as here, the dismissal was with prejudice, we apply a heightened standard of review because '[d]ismissal with prejudice . . . is an extreme sanction that deprives a litigant of the opportunity to pursue his claim.'" *Cherry v. Kroger Tex., L.P.*, 693 F. App'x 345, 345-46 (5th Cir. 2017) (quoting *Gonzalez v. Firestone Tire & Rubber Co.*, 610 F.2d 241, 247 (5th Cir. 1980)).

B. Standards Applicable to the DOJ's Motion

The DOJ's motion to dismiss presented two distinct requests under separate provisions of the False Claims Act. First, having declined to intervene during the seal period, the DOJ sought permission for "later date" intervention under 31 U.S.C. § 3730(c)(3), which provides:

> When a person proceeds with the action, the court, without limiting the status and rights of the person initiating the action, may nevertheless permit the Government to intervene at a later date upon a showing of good cause.

Second, the DOJ sought dismissal under § 3730(c)(2)(A), which states:

> The Government may dismiss the action notwithstanding the objections of the person initiating the action if the person 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.

The Supreme Court in *United States ex rel. Polansky v. Exec. Health Res., Inc.*, 599 U.S. 419 (2023) established the framework for analyzing such dual requests. The Court held that the Government cannot seek dismissal under § 3730(c)(2)(A) unless it first becomes a party through intervention. To intervene

after declining during the seal period, the Government must make "a showing of good cause." This showing requires a "legally sufficient reason" not just a desire to dismiss the case. 599 U.S. at 429 n.2.

Three key legal principles govern the analysis of the DOJ's motion:

First, courts look to Rule 24 of the Federal Rules of Civil Procedure, including the requirement under 24(b)(3) to consider prejudice to the original parties. *See* Rule 24(b)(1)(B) and (b)(2). The DOJ must satisfy the False Claims Act's good cause requirement and Rule 24's intervention standards independently. When weighing prejudice under Rule 24(b)(3), courts must consider the dramatic impact on a relator's vested rights and investment in the litigation.

Second, intervention must be justified by changed circumstances or other good cause warranting revisiting the Government's declination decision. As recognized in *Polansky*, Congress enabled post-seal intervention because "new evidence" might cause the Government to "reevaluate its initial assessment." 599 U.S. at 435. Without changed circumstances or other good cause justifying its delay, allowing intervention undermines Congress's design of the *qui tam* provisions.

Third, the DOJ's motion must satisfy constitutional requirements. Government action terminating a relator's rights must not be "arbitrary in the constitutional sense" or violate protected rights. Courts must independently

analyze whether the DOJ's action 1) respects First Amendment rights to petition; 2) maintains separation of powers; 3) provides equal protection; and 4) serves legitimate government purposes.

Only after the DOJ properly intervenes can it seek dismissal under Rule 41 principles. While courts defer to the Government's dismissal decisions once it becomes a party, such deference does not excuse compliance with these threshold requirements for intervention.

SUMMARY OF ARGUMENT

1. The district court erred when it permitted the DOJ to make a later date intervention into Brook Jackson's *qui tam* action to "voluntarily" dismiss it. The Government did not acquire the right to seek dismissal unless it first made "a showing of good cause" to intervene. While that burden is neither burdensome nor unfamiliar, it required a showing through submissions of a legally sufficient reason for intervening to dismiss.

The DOJ made no evidentiary submission. There was no enumeration of specific significant pending or future discovery obligations, no demonstration of a thorough investigation, and no detailed explanation of why it thought the action had little chance of success. Based on the Government's claim of an unfettered right to dismiss, the motion, as filed, asserted a desire to dismiss but no showing of

good cause. The district court's assumption of facts that may have supported the DOJ's desires was in error, particularly when the DOJ waived this presentation.

The district court also erred as a matter of law by refusing to consider the extreme prejudice to Relator, as required by Rule 24. Its holding that the federal rules did not apply was erroneous, as the Supreme Court clarified. Weighing that harm against the lack of prejudice if the motion was denied without prejudice, it was an abuse of discretion to grant permissive intervention.

Letting the order stand would be inconsistent with the False Claims Act and undermine its functioning. Through the 1986 amendments, Congress made the *qui tam* provisions into the most powerful litigative tool protecting the United States against fraud, by encouraging – not chilling – private enforcement. Lasting dismissal of this important case would discourage future whistleblowers from coming forward to expose fraud.

The DOJ abandoned its own internal guidance for exercising dismissal authority, and it deprived Relator of her vital role. Given the imbalanced record and Relator's unanswered offer of proof, it was an abuse of discretion to grant the motion without an evidentiary hearing.

2. Exercising *de novo* review, the DOJ's motion violated the Constitution in three respects. The Government waived its response to these claims. First, as the DOJ admitted, the motion sought to terminate Brook Jackson's First Amendment

right to petition based on her viewpoint, which former agency officials labeled "misinformation." The exercise of executive power was not content-neutral. Nor was it counter-speech designed to persuade the court on the merits of the claims. Applying strict scrutiny, the order below must be reversed.

Second, the motion disordered the separation of powers, elevating the executive branch to undo congressional enactments to save former officials from embarrassment, and hide complicity in the fraud. Congress enacted the Emergency Use Authorization statute with objective standards based on scientific evidence. The order below nullifies that law by executive action.

Third, the motion departed from the DOJ's own internal guidance. It was arbitrary in a constitutional sense in violation of the Equal Protection clause.

3. It was an abuse of discretion to enter a "voluntary" dismissal with prejudice as to Relator. The Government offered no reasonable argument for why the burdens of continued litigation outweighed its benefits. Under the federal rules, dismissal must be without prejudice.

4. On de novo review, the order dismissing Relator's retaliation claim must be reversed. She pleaded lawful efforts to stop one or more violations of the Act, the employer knew of such protected activity, and she was terminated because of it. These allegations are enough as a matter of law to state a claim.

This Court should vacate the Order below and remand for further proceedings.

ARGUMENT

I. The District Court Erred in Permitting DOJ to Make a "Later Date" Intervention in Order to Dismiss this *Qui Tam* Action

A. The DOJ Lacked Authority to Dismiss Under § 3730(c)(2)(A) Because it Made No Showing of Good Cause to Intervene

As the Supreme Court resolved in *Polansky*, the DOJ could not acquire the right to seek dismissal under § 3730(c)(2)(A) without first showing good cause to intervene. *Polansky*, 599 U.S. at 426 ("the Government can intervene after the seal period ends, so long as it shows good cause to do so") and 430 (§ 3730(c)(2)(A) "applies only if the Government has intervened").

The Supreme Court did not construe what constitutes "a showing of good cause" under § 3730(c)(3), but it recited what the Third Circuit had to say: "showing 'good cause' is neither a burdensome nor unfamiliar obligation," but is instead "a uniquely flexible and capacious concept, meaning simply a legally sufficient reason." 599 U.S. at 429 (quoting *Polansky v. Exec. Health Res*., 17 F.4th 376, 387 (3d Cir. 2021)). *See also United States ex rel. CIMZNHCA, LLC v. UCB, Inc.*, 970 F.3d 835, 846-47 (7th Cir. 2020) (quoting Good Cause, s.v. Cause, Black's Law Dictionary (4th ed. 2011)).

In the context of § 3730(c)(3) and the holding in *Polansky*, meeting the

threshold requirement of a "showing of good cause" for later date intervention into a non-intervened *qui tam* action requires more than the mere assertion of a desire to dismiss. The Government must establish something more than "cause" – it must establish "good cause." That means providing specific justification in the context of the legal standards being applied. *See*, *e.g.*, *Winters v. Teledyne Movible Offshore*, 776 F.2d 1304, 1306 (5th Cir. 1985) ("Without attempting a rigid or all-encompassing definition of 'good cause,' it would appear to require at least as much as would be required to show excusable neglect, as to which simple inadvertence or mistake of counsel or ignorance of the rules usually does not suffice, and some showing of 'good faith on the part of the party seeking an enlargement and some reasonable basis for noncompliance within the time specified' is normally required").

Similarly, the Government must make *a showing* – i.e., it must provide the court with evidence, affidavits or some other submission to establish the good cause for intervention. This flows logically from the statutory text. What § 3730(c)(3) requires is a showing of good cause for intervention when the Government delayed intervention until after the seal period expired. Under § 3730(b)(3), the Government may, "for good cause shown, move the court for extensions of the time during which the complaint remains under seal," and any such motion may be "supported by affidavits or other submissions in camera." In

context, the statute contemplates that "a showing of good cause" for later date intervention would be made by motion and supported by affidavits or submissions.

In the district court below, the DOJ made no *evidentiary* submissions to establish good cause for intervention. Indeed, only one sentence of the thin 11-page motion purports to state the reason for permitting intervention:

> In this case, the United States has good cause to intervene because it seeks to dismiss Relator Jackson's Second Amended Complaint. [ROA.4525].

In other words, rather than making a showing of legally sufficient reasons for the Government to intervene, the DOJ asserted its desire to seek dismissal as the basis for satisfying § 3730(b)(3).

A mere assertion that the Government has legally sufficient reasons to intervene is not a showing. Indeed, if the Government's mere assertion that it had a legally sufficient basis for dismissal of a *qui tam* action constituted a showing of good cause to intervene, the Supreme Court in *Polansky* would not have rejected the Government's assertion of an unfettered right to dismiss under § 3730(c)(2)(A) at any time. Instead, the Court held the Government has discretion to dismiss under Rule 41 if it "offers a reasonable argument for why the burdens of continued litigation outweigh its benefits," 599 U.S. at 438, but *first* it must make a showing of good cause to intervene. Equating the threshold intervention requirement with the reasonable argument requirement would endorse the former position of the

DOJ which the Supreme Court rejected.

The failure by the DOJ to show good cause distinguishes this appeal from other cases where intervention was justified. No cases cited by the DOJ hold that a desire to dismiss automatically establishes good cause for intervention. For example, in *Polansky*, the Court noted that the Third Circuit found good cause based on the government's "weighing of discovery burdens against likelihood of success," showed good cause, but this described specific factual findings, not a universal rule. Indeed, in the interest of providing guidance, the Supreme Court in *Polansky* identified the specific reasons established in that record, where the Government 1) enumerated significant costs of discovery, including possible disclosure of privileged documents; 2) a thorough investigation of costs and potential benefits of the action; 3) a detailed explanation of why it believed the suit had little chance of success on the merits; and 4) clear evidence that discovery demands on the Government were becoming onerous. *Polansky*, 599 U.S. at 438.

Similarly, in *Brutus Trading, LLC v. Standard Chtd. Bank*, 2023 U.S. App. LEXIS 21868 (2d Cir. 2023), the government showed the relator's "factual allegations were unsupported, its legal theory was not cognizable, and continuation of the suit would waste considerable government resources." And, in *Borzilleri v. Bayer Healthcare Pharms., Inc.*, 24 F.4th 32 (1st Cir. 2022), the government demonstrated it "carefully investigated Relator's claims" concluding they lacked

support while requiring "substantial expenditure of government resources."

Here, the DOJ provided no evidence of any investigation of the merits, analysis of discovery burdens, assessment of government resources required, changed circumstances since declining intervention, or legitimate government purpose served by dismissal.

Instead, the DOJ offered an unsupported assertion that exposing clinical trial fraud was "inconsistent with national health policy." This vague claim is not good cause, particularly given that the DOJ never advised Jackson of any deficiencies in the meetings and the DOJ did not explain how exposing clinical trial fraud conflicted with FDA policy.

Indeed, Jackson's *qui tam* action upholds national health policy, as demonstrated by the complaint's factual allegations and the grounds for this appeal. Jackson's *qui tam* lawsuit vindicates national health policy. In no way does this action undermine the nation's true health policies. It was Pfizer's fraud in the design, conduct, analysis and reporting of its clinical trials that led to the current national health crisis, and it was the former administration's effort to suppress Pfizer's clinical trial data and dismiss Brook Jackson's case that undermined public health and public trust in former health officials.

It was thus an abuse of discretion for the court to find good cause based on the DOJ's motion, as submitted. The motion should have been denied, with leave

for it to be renewed in the future if good cause appeared.

B. The District Court Erred as a Matter of Law by Ignoring Prejudice to Relator as Original Party and By Holding Rule 24(b)(3) Does Not Apply to Permissive Intervention

In exercising its discretion to permit a later date intervention, courts look to Rule 24, including subparagraph (b)(3), which requires consideration of prejudice to the original parties. That parallels the False Claims Act's intervention provisions which "invites reference to Rule 24 . . . and the body of case law that accompanies it." *United States ex rel. Drennen v. Fresenius Med. Care Holdings, Inc*., 2018 U.S. Dist. LEXIS 53978, at *4-5 (D. Mass. Mar. 30, 2018) (citations omitted). The Government waived any argument against application of Rule 24, as it failed to address the argument in its reply. The district court erred as a matter of law when it held that Rule 24 was not "persuasive" on the DOJ's motion. ROA.4943-4944.

The district court held that cases which consistently applied Rule 24 to the Government's motions for later date interventions were not binding, and they pre-dated *Polansky*. *Id*. To the court below, the fact that *Polansky* did not mention Rule 24 meant that the federal rule did not apply to motions under § 3730(c)(3). Additionally, the court thought that Rule 24 was not analogous to § 3730(c)(3) because the rule applied to non-parties and the court thought the Government was a party, even in an action where it did not intervene.

This legal reasoning was in error. Rule 24(b)(1)(A) and (b)(2) expressly

refer to the circumstances alleged to be present here, where a federal statute gives a conditional right to intervene, and where the Government seeks to intervene on a party's claim which is based upon a statute. The holding that the Government is a party to a non-intervened case contradicts the holdings in *Polansky*, and in *United States ex rel. Eisenstein v. City of New York*, 556 U. S. 928 (2009), where the Supreme Court made clear that the Government is *not* a party unless and until it formally intervenes. Moreover, no authority exists for the proposition that the Federal Rules of Civil Procedure do not apply to the *qui tam* statute. *Polansky* made clear the Act's "many cross-references to the Rules suggest that their application is the norm." 599 U.S. at 933-34. As with Rule 41 and its application to § 3730(c)(2)(A), "nothing in the FCA suggests Congress meant to except *qui tam* actions from the usual" permissive intervention rule in motions under § 3730(c)(3).

> As a practical matter, the Federal Rules apply in FCA litigation in courts across the country every day. There is no reason to make an exception for the one about voluntary dismissals. [599 U.S. at 436.]

Correcting for this legal error, this Court should find the lower court abused its discretion in its alternative finding that the good cause standard was met. ROA.4944 n.2. The district court failed to consider prejudice to the Relator as the original party in her pursuit of this action on behalf of the United States. Permitting intervention would undeniably prejudice her adjudicatory rights which Congress assigned to her to pursue, even when the Government lacks the political will to do

so. *See United States v. AseraCare Inc.*, 2012 U.S. Dist. LEXIS 136059, at *5 (N.D. Ala. Sep. 24, 2012).

In balancing the prejudice to Relator against the prejudice to the Government on the record of the motion, as filed, there is only one conclusion. Allowing intervention of the former DOJ caused dismissal of Brook Jackson's meritorious case *with prejudice* as to her. This deprived Relator of the right to pursue the lawsuit and meant that the statutory scheme created by Congress in the *qui tam* provisions would go unfulfilled. In contrast, the Government in its motion failed to offer any actual evidence of any burdens imposed on by the lawsuit if permitted to go forward. Relator specifically requested that the motion be denied without prejudice, meaning that the Government could renew the motion at a later date if circumstances change and good cause appears. As such, there is only extreme prejudice to Relator on one side of the scale, and no prejudice on the other.

C. It Was Inconsistent with the Purpose of 3730(c)(3) to Allow Later Intervention to Dismiss this Action, and It Would Undermine the Functioning of the Act to Allow the Ruling Below to Stand

The district court erred in allowing the government to intervene because the only changed circumstance since the Government's declination decision was the former DOJ's abdication of its reasoned policy for seeking dismissal under § 3730(c)(2)(A). As the Court in *Polansky* recognized:

> Congress decided not to make seal-period intervention an on-off switch. It knew circumstances could change and new information could come to light. So Congress enabled the Government, in the protection of its own interests, to reassess *qui tam* actions and change its mind. *See* S. Rep. No. 99-345, p. 26 (1986) (explaining that the Government should have a continuing chance to intervene because "new evidence" might cause it to "reevaluate its initial assessment"). [*Polansky,* 599 U.S. at 435]

This connection between changed circumstances and a showing of good cause was previously recognized by the DOJ itself. *See* "Factors for Evaluating Dismissal Pursuant to 31 U.S.C. 3730(c)(2)(A)" (Granston Memo), ROA.4872 ("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").

The Granston Memo was the DOJ's effort to protect its constitutional authority to act as a non-arbitrary arm of the Government. It is a challenge to maintain this image in the face of the former DOJ's repeated assertion that it had unfettered discretion under § 3730(c)(2)(A) – a contention it lost in *Polansky*. In the guidance, Director Granston set forth a "general framework for evaluating when to seek dismissal under section 3730(c)(2)(A) and to ensure a consistent approach to this issue across the Department." ROA.4866. Significantly, the Granston Memo reviewed and expounded upon the limited instances where the Government sought dismissal under § 3730(c)(2)(A), listing the reasoned grounds on which it did so. These included curbing meritless *qui tam* actions, preventing

parasitic actions, preventing interference with valid agency policies or programs, controlling litigation already brought by the Government, safeguarding classified information, preserving Government resources, and addressing egregious procedural errors. ROA.4867-4871. Each stated ground is exemplified by review of applicable case decisions.

Upholding reasoned agency action was important to retention of constitutional authority, just as it was necessary to hold off loss of that authority through legislative action. This was made clear in the written exchange between the DOJ and Senator Grassley, author and principal protector of the False Claims Act amendments. ROA.4873-4879, 4880-488. As Senator Grassley explained and underscored himself in the last paragraph of his letter: "Having unfettered dismissal authority will create a chilling effect on future whistleblowers that will ultimately end up costing the taxpayers a lot more." ROA.4886.

Ensuring that potential future relators will effectively combat fraud was the premise of the 1986 amendments, which turned the False Claims Act into "the Government's primary litigative tool for combating fraud" "in modern times." S. Rep. No. 99-345, at 2, 1986 U.S.C.C.A.N. 5266. *See id*., at 5 ("The most frequently cited reason given (53 percent) [for why employees chose to not report fraud] was the belief that *nothing would be done* to correct the activity even if reported") (emphasis supplied). The DOJ's ungrounded request for permissive

intervention here contradicted the premise of the False Claims Act and undermined its functioning. The effect of allowing the Government's motion to intervene to stand and to allow it to dismiss this case would end important *qui tam* enforcement.

Whistleblowers may be deterred from reporting fraud after observing the Jackson case and the previous administration's stance that Pfizer was immune from fraud claims regarding its Covid-19 vaccines. Allowing this precedent to stand could undermine public confidence in equal application of the law.

D. The District Court Improperly Collapsed the Intervention and Dismissal Standards

The district court abused its discretion allowing the DOJ's Rule 41 dismissal argument to satisfy the good cause requirement for intervention. By accepting the DOJ's assertion that its wish to dismiss itself establishes good cause to intervene, the court rendered § 3730(c)(3)'s requirements meaningless. This circular reasoning - that wanting to dismiss inherently provides good cause to intervene to dismiss - eliminated Rule 24's distinct gatekeeping function.

Failing to make "a showing" of good cause in the motion, as presented, means the DOJ waived its right to prevail on that particular motion. Finding good cause despite the waiver, the district court *assumed* a factual basis for the DOJ's assertions – *i.e.,* the unexplained reasons for why the action lacked merit, the unelucidated items of potential future discovery burdens – even though such facts were not "shown." It was both a legal error for the district court to alleviate the

Government's burden of showing good cause, and an abuse of discretion to assume facts not established in the record.

As the DOJ may waive its right to satisfy the good cause standards on that particular motion, it was improper for the district court to find those requirements satisfied on its own. As the Supreme Court has reasoned:

> [A]s a general rule, "[o]ur adversary system is designed around the premise that the parties know what is best for them, and are responsible for advancing the facts and arguments entitling them to relief." . . . "[Courts] do not, or should not, sally forth each day looking for wrongs to right. We wait for cases to come to us, and when they do we normally decide only questions presented by the parties." [*Greenlaw v. United States*, 554 U.S. 237, 244 (2008) (citation omitted).]

In a passage particularly appropriate here, the Court went on:

> Counsel almost always know a great deal more about their cases than we do, and this must be particularly true of counsel for the United States, the richest, most powerful, and best represented litigant to appear before us. [*Id*. (citation omitted).]

E. It was an Abuse of Discretion to Deny Relator an Evidentiary Hearing Given the Imbalance of Evidence and Offer of Proof

As explained by the Senate committee when Congress enacted the 1986 Amendments, "[s]ubsection (c)(1) provides *qui tam* plaintiffs with a more direct role not only in keeping abreast of the Government's efforts and protecting his financial stake, but also in acting as a check that the Government does not neglect evidence, cause unduly delay, or drop the false claims case without legitimate reason." S. Rep. 99-345, at 25-26. To that end, in cases where the Government

intervenes, the Act requires service on the relator and an opportunity to object to any motions to dismiss or proposed settlements by the Government. Under these provisions, Congress did not intend that the relator would have an automatic right to an evidentiary hearing. Rather, "evidentiary hearings should be granted when the *qui tam* relator shows a 'substantial and particularized need.'" *Id*.

> Such a showing could be made if the relator presents a colorable claim that the settlement or dismissal is unreasonable in light of existing evidence, that the Government has not fully investigated the allegations, or that the Government's decision was based on arbitrary and improper considerations. [*Id*.]

In this case, Relator offered substantial evidence opposing the DOJ's motion, and such evidence supported the basis for challenging dismissal on these very grounds. Existing evidence overwhelmingly supports Brook Jackson's claim that Pfizer engaged in fraud in the design, conduct, analysis and reporting of its clinical trials. That evidence also established that the executive agencies of the former administration acquiesced, and were even complicit, in allowing that fraud to take place. Indeed, at oral argument, the district court received an offer of proof on that exact set of facts, and it asked the DOJ to respond assuming the facts would be established at an evidentiary hearing. *See* ROA.5145:9-5147:17. Despite repeating its request for a response, the DOJ declined to respond to the court's request. ROA.5167:10-5169:22.

On this record, it was an abuse of discretion for the district court to grant the

DOJ's motion without providing Relator with an evidentiary hearing. *See United States v. Acad. Mortg. Corp*., 2018 U.S. Dist. LEXIS 109489, at *10-11 (N.D. Cal. June 29, 2018) (denied the Government's motion where the relator provided "'some evidence' that the Government's decision to dismiss was unreasonable, not a result of a full investigation, or based on arbitrary or improper considerations," and the DOJ declined to present any evidence to the contrary), *appeal dismissed United States v. United States ex rel. Thrower*, 968 F.3d 996, 1010 (9th Cir. 2020).

II. The DOJ's Motion to Intervene and Dismiss Violated the Constitution

As a government agency, the DOJ must not act inconsistent with constitutional limits. *See Polansky*, 143 S. Ct. at 1734 n. 4 (citing Third Circuit *Polansky* decision, 17 F.4th at 390 n.16 (the DOJ's motion must "rest atop the foundation of bedrock constitutional constraints on Government action")); *Borzilleri,* 24 F.4th at 42-43 (1st Cir. 2022) (citing *CIMZNHCA, LLC v. UCB, Inc.*, 970 F.3d at 835). As the First Circuit stated, citing *United States v. Armstrong*, 517 U.S. 456, 464 (1996): "It is axiomatic that constitutional limitations attend any exercise of executive authority." *Borzilleri,* 24 F.4th at 42. Constitutional constraints apply to the DOJ's motion to dismiss, and also to the motion to intervene. *See CIMZNHCA*, 970 F.3d at 847 (the claim that a "good cause" requirement would "tend to fetter the executive unconstitutionally" neglects, "at minimum, the possibility that avoiding offense to the separation of powers in a

case that actually risks it would itself weigh heavily in any 'good cause' determination").

In the district court below, relator raised several constitutional challenges in opposition to the motion. The DOJ failed to reply to these contentions, thereby waiving any claim before this Court.

A. The DOJ Motion Failed Strict Scrutiny as Content/Viewpoint Based Termination of Right to Petition

The DOJ's motion to intervene to dismiss the *qui tam* action was based upon the content of the claims and Jackson's viewpoint regarding clinical trial fraud for Pfizer's vaccines. The DOJ admitted this in its motion, where it likened her allegations to "misinformation available on social media and the internet." *See* ROA.4527. It is one thing for the DOJ to file a Statement of Interest and use the force of its ideas to persuade the court that the views expressed by a litigant are wrong or dangerous, but it is quite another to "use the power of the State to punish or suppress disfavored expression." *NRA of Am. v. Vullo*, 602 U.S. 175, 188 (2024). As the Supreme Court stated: "the First Amendment prohibits government officials from wielding their power selectively to punish or suppress speech." *Id*., at 198.

Congress partially assigned to relators the right to petition to redress injury to the Government arising from violation of its laws and injury to its proprietary interests resulting from a fraud. *Polansky*, 599 U.S. at 425. The DOJ's motion

interfered with Relator's adjudicatory rights in an extreme way. By filing the motion, the DOJ used the power of its agency to terminate Brook Jackson's right to be a *qui tam* plaintiff. It did so not by persuading the court the action lacked merit, but by exercise of its authority under the Act.

The First Amendment protects the right of individuals "to petition the Government for a redress of grievances." U.S. Const, amend. I. The Right to Petition "is cut from the same cloth as the other guarantees of [the First] Amendment," and operates as "an assurance of a particular freedom of expression." *McDonald v. Smith*, 472 U.S. 479,482 (1985). Broad in scope, the right extends to all departments of the Government, *California Motor Transport Co. v. Trucking Unlimited*, 404 U.S. 508, 510 (1972), and guarantees, at a minimum, the right to seek redress from a federal decision-maker based on a well-pleaded claim for relief. *See Sure-Tan, Inc. v. NLRB*, 467 U.S. 883, 896-897 (1984) ("the right of access to courts for redress of wrongs is an aspect of the First Amendment right to petition the government"). Government actions that "significant[ly] impair[]" this right must, like all substantial constitutional burdens, survive "exacting scrutiny." *See Elrod v. Burns*, 427 U.S. 347, 362 (1976).

The right to petition may be restricted only in the face of compelling state interests. *See Giboney v. Empire Storage Co.*, 336 U.S. 490, 502 (1949). The level of scrutiny is initially tied to whether the restriction distinguishes between

prohibited and permitted speech based on content. "Content-based regulation must be necessary to serve a compelling state interest and be narrowly drawn to achieve that end; content-neutral regulations of time, place, and manner of expression are enforceable if they are narrowly tailored to serve a significant government interest, and leave open ample alternative channels of communication." *Int'l Soc'y for Krishna Consciousness, Inc. v. Baton Rouge*, 876 F.2d 494, 497 (5th Cir. 1989) (citation omitted). In regulating the exercise of First Amendment rights, the government may not pick and choose what views may be heard. *Police Department of Chicago v. Mosley*, 408 U.S. 92, 95-96; (1972); *Burson v. Freeman*, 504 U.S. 191, 198 (1992)).

The DOJ's motion failed this test. Rather than regulating the time, place and manner of expression, the DOJ sought to end Brook Jackson's assigned right based on the content of her expression in her court case. It was a speaker-based regulation which demanded strict scrutiny because it reflected the Government's aversion to what she has to say. *See Regan v. Taxation with Representation of Wash*., 461 U.S. 540, 548 (1983); *Buckley v. Valeo*, 424 U.S. 1, 17, 96 S. Ct. 612, 634 (1976).

Claims brought under the First Amendment's free speech and petition clause are analyzed in the same way. *Gibson v. Kilpatrick*, 838 F.3d 476, 481 (5th Cir. 2016. The DOJ could not, consistent with the First Amendment, silence

Jackson from talking about Pfizer's clinical trial fraud – or the former administration's complicity in the fraud – based on the content of her speech. The DOJ's motion to terminate Brook Jackson's petitioning activity because of the content and viewpoints expressed in her lawsuit fails constitutional scrutiny.

B. The DOJ Motion Offended Separation of Powers

A disordering of the separation of powers would weigh heavily in any "good cause" determination. *CIMZNHCA*, 970 F.3d at 847. As an example of where such concerns would be determinative, the Seventh Circuit posited "a case where the government seeks to dismiss on the eve of trial of meritorious claims only to protect a high-ranking executive official's private business interests." *Id*, at 847 n.3. Although Jackson's *qui tam* case was not on the literal "eve" of trial, she amassed overwhelming proof of its merits. More significant is the need for heightened scrutiny of the DOJ's "good cause" assertion, given its purported aim of protecting former executive officials' personal interests.

Deference to the former officials' interests in this context violated the separation of powers. Those officials could not impose binding obligations upon our citizenry or legislate, through a process vastly less difficult and less subject to democratic scrutiny than the legislative process prescribed in the Constitution. *See* U.S. Const. art. I, § 7. Deference to the former officials' determination in this context effected an abdication of "judicial power" vested in Article III

courts, as the judicial branch may not cede to the Executive the "emphatic[] . . . province and duty of the judicial department to say what the law is." *Marbury v. Madison*, 5 U.S. 137 (1803).

Here, Congress enacted the EUA statute to protect the nation's public health in an emergency and did so using objective standards. Authorization for Covid-19 vaccines was lawful only if there were *reason to believe*, based on the totality of scientific evidence, that known and potential benefits may be outweighed by known and potential harms. Former FDA executives may have wanted Congress to give it authority to grant authorization even when such reasons failed, but the law vested the executive with power to act based only on objective reasons. The DOJ's motion to terminate the action effectively re-wrote the statute to fit the former officials' own purposes.

Congress amended the False Claims Act in 1986 to remove the "government knowledge" defense, not only because the government might lack the resources, but might lack "indeed, the political will" to pursue meritorious claims of fraud on federal funds. *In re Nat. Gas Royalties ex rel. United States*, 562 F.3d 1023, 1030 (10th Cir. 2009); *United States ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp.*, 151 F.3d 1139, 1149 (9th Cir. 1998). As shown in this case, government knowledge, acquiescence, or complicity in the clinical trial fraud did not negate defendants' knowing material falsities. In this context,

separation of powers concerns required close scrutiny and independent judgment of the DOJ's motion, and upon such inspection, the district court's order granting permissive intervention and dismissal must be vacated.

C. The DOJ's Motion Offends the Equal Protection Clause

Even if, contrary to the above, the DOJ's motion escaped strict scrutiny, the order granting the intervention to dismiss failed the rational-basis test of the Equal Protection Clause. As explained by the First Circuit, "constitutional limitations attend any exercise of executive authority." *Borzilleri,* 24 F.4th at 42.

> This is the case even for a government decision not to institute an enforcement action – a decision roughly analogous to the government's decision to dismiss a *qui tam* suit – where the government is entitled to the greatest discretion. *See Heckler v. Chaney*, 470 U.S. 821, 838 (1985) (holding that agency decisions not to institute enforcement proceedings are unreviewable under the APA but reserving the question of the reviewability of a claim that an agency decision not to institute proceedings 'violated any constitutional rights"). [*Id*.]

On *de novo* review, the Court must determine whether the DOJ's motion was "arbitrary in the constitutional sense" – *i.e.,* whether it "violate[d] a right otherwise protected by the substantive Due Process Clause" and "shock[ed] the conscience," or when the former government officials abused their power and "employ[ed] it as an instrument of oppression" to the extent that it "shocks the conscience;" or when the Government attempted "to perpetrate a fraud on the

court." *Borzilleri*, 24 F.4th at 42-43 (citations omitted)." *Borzilleri*, 24 F.4th at 42-43.

The former administration's failure to coherently explain its desire to dismiss this action shows it failed this minimal test. There is no doubt that protection of whistleblowers is a principal policy of the United States. So too is prevention of fraud in the design, conduct, analysis and reporting of clinical trials. Adhering to the "Granston Memo," the DOJ historically sought to intervene to dismiss only when cases were meritless, parasitic, interfered with agency policies, wasted resources, or clearly lacked government interest. Jackson's case fits none of these established categories. The DOJ could not explain to the court, or the people, why Brook Jackson's prosecution of this action was inconsistent with national health policy. And, indeed, it was the former officials who acted in contravention of that policy. No legitimate, rational basis existed for interfering with her meritorious case.

III. It Was an Abuse of Discretion to Dismiss the *Qui Tam* action with Prejudice as to Brook Jackson

In addition to the statutory, constitutional and rule-based reasons for overturning the Order granting the DOJ's motion to intervene to dismiss this action, the Order of dismissal with prejudice must be vacated on this record. Under *Polansky*, to obtain a dismissal, the Government must "offer[] a reasonable argument for why the burdens of continued litigation outweigh its benefits." The

district court abused its discretion by granting the DOJ's motion, which failed to meet the required showing for the reasons detailed above. The motion should have been denied without prejudice, and the DOJ should now be required to renew its motion and offer such a "reasonable argument," if one can be made.

Moreover, Brook Jackson had not previously filed and dismissed an action predicated on the same facts. By the express terms of Rule 41(a)(1)(A) and (2), the dismissal should have been without prejudice to the relator. The district court offered no grounds for entering a dismissal with prejudice to Jackson. Given the Rule's requirements and the transition in national administrations, this Court should vacate the Order and remand to the district court to determine whether dismissal is warranted—without prejudice or not at all.

IV. On De Novo Review, the District Court Erred in Dismissing Jackson's Retaliation Claim

A. Standard of Review for Retaliation Claim

Section 3730(h) creates an entitlement to be made whole for employees, contractors, or agents who are "discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of lawful acts done … 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). Rule 8(a) applies to Jackson's retaliation claims. *Thomas v.*

ITT Educ. Servs., Inc., No. CIV.A. 11-544, 2011 WL 3490081, at *3 (E.D. La. Aug. 10, 2011).

To survive a motion to dismiss, a plaintiff alleging injury under Section 3730(h)(1) must show (1) she engaged in protected activity, (2) her employer, or the entity with which she has contracted or serves as an agent, knew about the protected activity, and (3) she was retaliated against because of his protected activity. *U.S. ex rel. Bias v. Tangipahoa Par. Sch. Bd.*, 816 F.3d 315, 323 (5th Cir. 2016).

B. Jackson Was Engaging in Protected Activity

Jackson pleaded: "Defendant Ventavia Research Group, LLC (Ventavia) retaliated against Relator in response to her reports of, and efforts to stop, Defendants' fraud against the United States DoD." ROA.3679. The district court acknowledged the same. ROA.4954. Yet, the district court did not analyze Jackson's claims as an effort to stop fraud. Instead, it cited *United States ex rel. Johnson v. Kaner Med. Grp., P.A.*, 641 F. App'x 391, 395 (5th Cir. 2016) for the proposition, "To qualify as protected activity under the whistleblower provision, the activity must be 'in furtherance of' uncovering fraud or potential fraud against the Government" and dismissed her retaliation claim. ROA.4955. Under the standard of plausible pleading, the SAC raises more than a mere possibility that Jackson engaged in protected activity. In addition to internal complaints and

complaints to the FDA, Jackson tried to stop the fraud by halting enrollment in the clinical trial.

Other circuits have addressed the language, i.e., "efforts to stop 1 or more violations of" the False Claims Act. "[T]he statute's protection of 'efforts to stop' False Claims Act violations suggests Congress aimed to protect efforts not merely to expose existing fraud, but to prevent future violations as well. See 31 U.S.C. § 3730(h)(1)." *Josey v. Impulse Dynamics (USA) Inc.*, 371 F. Supp. 3d 603, 609 (D. Ariz. 2019). "To that end, the Ninth Circuit has recognized as protected activity an employee's reports of acts antecedent to the submission of an actual claim for payment, provided a nexus exists between those acts and the prospect of government compensation." *Id.*, *citing Moore v. California Inst. of Tech. Jet Propulsion Lab'y*, 275 F.3d 838, 846 (9th Cir. 2002) (reporting laboratory's lies used to increase government compensation for project's early completion is protected activity).

The *Josey* court determined the relator plausibly pleaded protected activity and denied a motion to dismiss. The *Josey* relator alleged she engaged in protected activity by reporting protocol violations during clinical testing of an investigational medical device for treating chronic heart failure. 371 F. Supp. 3d 603, 605. The protocol violation was a verbal, instead of a required written, administration of a heart failure questionnaire. *Id.*, at 606-07. Jackson argued the uncorrected protocol

violations "could reasonably be expected to result in ill-gotten gains—first in the form of FDA approval, then as government payment made possible by that approval." Id. The court agreed, stating:

> The submission of inaccurate data to the FDA could reasonably be linked to an False Claims Act violation. *See [United States ex rel.] Campie [v. Gilead Sciences]*, 862 F.3d [890] at 907 [(9th Cir. 2017)]. Indeed, the connection seems all too obvious. FDA approval unlocks a host of coveted government funding, including Medicare and Medicaid. *Id.* at 897, 905…. Should Defendants rely on that data to obtain FDA approval and become eligible for government funds, subsequent claims for reimbursement would plausibly be considered false. *See Id*., at 904, 907. *Josey*, at 608-09.

In *Miniex v. Houston Hous. Auth.*, 400 F. Supp. 3d 620, 642 (S.D. Tex. 2019), judgment entered, No. CV 4:17-00624, 2019 WL 10892215 (S.D. Tex. Sept. 16, 2019), the court declined to enter judgment as a matter of law, finding a jury could reasonably believe the relator engaged in an effort to stop one or more violations of the False Claims Act by reporting HCPV's lack of effective internal controls to the Houston Housing Authority's Board of Commissioners, HUD-OIG, and the FBI. *Id.*, at 640-44. That relator argued ineffective internal controls could mask ongoing financial fraud and lead to future fraud. Id. The *Miniex* court stated, "By reporting fraud, regardless of the fact that HUD-OIG requested the information, Miniex still engaged in an "effort[ ] to stop" a False Claims Act violation. *See* 31 U.S.C. § 3730(h)(1)." *Id.*, at 644.

Here, Jackson saw and reported serious clinical trial violations and demanded trial enrollment stop. Like the *Josey* relator, Jackson believed faulty clinical trial data would be submitted to the FDA for an EUA without disclosing protocol violations. Jackson went further than the *Josey* relator by reporting the violations to the FDA. Like the *Miniex* relator, Jackson's reports were protected activity. Though her efforts were pre-EUA, under *Josey, Miniex*, and 3730(h), these pre-submission efforts to stop one or more violations of the False Claims Act are protected.

Jackson's retaliation claim should not have been dismissed because she plausibly pled her internal and external complaints of clinical trial protocol violations are protected activity under 3730(h). Further, Jackson plausibly pled her activity was motivated by a concern regarding fraud against the government.

C. Jackson's Actions Were Motivated by a Concern Regarding Fraud Against the Government

The Fifth Circuit "has confirmed the overarching principle that '[a] protected activity is one motivated by a concern regarding fraud against the government.'" *United States ex rel. Johnson v. Raytheon Co*., 395 F. Supp. 3d 791, 798 (N.D. Tex. 2019) (quoting *Thomas v. ITT Educ. Servs., Inc.,* 517 F. App'x 259, 263 (5th Cir. 2013)). *Thomas* was a summary judgment decision, after a

factual record was developed and submitted for review.[4] The Rule 12(b)(6) standard for reviewing a pleading, however, is less demanding. It "'simply calls for enough fact to raise a reasonable expectation that discovery will reveal evidence of' the necessary claims or elements." *In re S. Scrap Material Co., LLC*, 541 F.3d 584, 587 (5th Cir. 2008) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 127 S.Ct. 1955, 1965, 1974, 167 L.Ed.2d 929 (2007)).

Since the SAC raised a reasonable expectation that discovery would reveal Jackson was motivated by a concern over fraud against the government, it should not have been dismissed. Jackson explicitly alleged an effort to halt enrollment in the clinical trial after expressing many times that an FDA audit would yield warning letters or an order to stop trial enrollment. Jackson knew Ventavia might ignore the violations and submit its clinical trial data supporting an application for an EUA without disclosing the violations, thus committing fraud against the government.

[4] The district court relies on several decisions decided against Relator's on post-pleading motions with an evidentiary record, not some pleading deficiency. ROA.4954-4955; citing *Robertson v. Bell Helicopter Textron, Inc.*, 32 F.3d 948, 952 (5th Cir. 1994) (granting judgment as a matter of law when plaintiff "failed to present sufficient evidence to support a finding that Bell was aware that his investigations were in furtherance of a qui tam action"); *Thomas v. ITT Educ. Servs., Inc.*, 517 F. App'x 259, 263 (5th Cir. 2013) (affirming summary judgment based on "finding that Thomas did not submit evidence establishing any of the three required elements of a prima facie case"); *United States ex rel. Patton v. Shaw Servs., L.L.C.*, 418 F. App'x 366, 372 (5th Cir. 2011) (affirming summary judgment); and *United States ex rel. Johnson v. Kaner Med. Grp., P.A.*, 641 F. App'x 391, 395 (5th Cir. 2016) (also reviewed under the summary judgment standard).

In *Nichols v. Baylor Rsch. Inst.*, No. 3:19-CV-1883-B, 2020 WL 1158456 (N.D. Tex. Mar. 10, 2020), the court denied respondent's motion to dismiss a retaliation claim because it determined the relator's complaint to the FDA alleging noncompliance with NIH protocols was protected activity and relator alleged her concern was based on fraud against the government.

Jackson's knowledge of clinical trials enabled her to identify Ventavia's protocol violations. The SAC shows that, knowing these trials involved government funding, she recognized that Pfizer's EUA submission would fraudulently conceal its deficient trial practices from federal authorities. Because the SAC plausibly alleges Jackson was motivated by concerns about government fraud, the district court's ruling should be reversed

D. Relator's Actions Were in Furtherance of an Action Under the False Claims Act

The SAC plausibly alleged that Jackson engaged in protected activity by attempting to stop False Claims Act violations and that her actions were in furtherance of a False Claims Act action. The district court's dismissal of the SAC concluded there were no material changes to the retaliation allegations in the SAC. Opinion Dismissing SAC, R. 158, pp. 20-22, Page ID # 5893-95. However, the district court erred by not fully analyzing Jackson's claim under § 3730(h).

The district court cited *Guerrero v. Total Renal Care, Inc.* No. EP-11-CV-449-KC, 2012 WL 899228 (W.D. Tex. Mar. 12, 2012) for the principle that

3730(h) still requires internal reports to "specifically allege fraudulent claims for federal funds and not merely address concerns about general misconduct." Opinion Dismissing FAC, Doc. 96, at 47, Page ID # 2341. Yet, *Guerrero* found internal reports of Medicare/Medicaid fraud met the "in furtherance of" standard and sustained the retaliation claim. *Id.*, at *6. Moreover, *Guerrero* recognized the 2009 amendments protected conduct "whether or not such steps [were] clearly in furtherance of a potential or actual *qui tam* action." 155 Cong. Rec. E1295–03, E1300, 2009 WL 1544226 (daily ed. June 3, 2009). *Id.*, at *4..

In *United States ex rel. Reddell v. DynCorp Int'l, LLC*, No. 1:14-CV-86, 2019 WL 12875471 (E.D. Tex. Mar. 20, 2019) that court found relator's claims failed under the "in furtherance of" standard but the relator's conduct likely satisfied the "efforts to stop" standard, as he "continued to object to the settlement of oversize charges and to insist that DynCorp recover payments that were in accordance with the contractual pricing approved by the Government." *Reddell*, at *16.

The SAC plausibly alleged Ventavia anticipated Jackson would report its fraudulent conduct to authorities or pursue False Claims Act litigation, given her knowledge of unreported clinical trial violations in the pursuit of an EUA requiring "adequate and well controlled clinical trials." 21 USC § 360bbb(c)(2). On September 17, 2020, Jackson questioned Ventavia about what the FDA would do if

they audited Ventavia. ROA.2980. The response was that it would issue a violation notice or stop clinical trial enrollment. *Id.* Later that day Jackson stated in a group text message that they needed to approach the clinical trial violations from the perspective of an FDA auditor. ROA.2980.

During a meeting with Ventavia management on September 24, 2020, Jackson suggested they google FDA warning letters. ROA.2983. Ventavia, aware of its clinical trial violations and Jackson's intentions to report those violations, suddenly determined she "was not a good fit" and terminated her the same day she reported the clinical trial violations to the FDA. ROA.2984. Like the *Redell* relator, Jackson repeatedly warned Ventavia about potential FDA audit failures. The day she told the FDA about the violations she was fired.

Jackson raised concerns about the flawed clinical trials to prevent Ventavia from concealing deficiencies in its EUA application, showing her intent to stop fraud against the government and the public. Her reports of clinical trial violations were protected efforts to prevent False Claims Act violations and fraud against federal authorities.

E. Ventavia had Knowledge of Protected Activity

The district court found Jackson failed to allege Ventavia knew of her protected activity. ROA.4955. However, the Court did not consider that protected activity encompasses more than explicit complaints about fraud against the

government. As stated in *Nichols v. Baylor Rsch. Inst.*, No. 3:19-CV-1883-B, 2020 WL 1158456 (N.D. Tex. Mar. 10, 2020), no magic words—such as illegal or unlawful—are needed to put the employer on notice of protected activity. *Id.*, at *6, citing *Jamison v. Fluor Fed. Sols.*, 2017 WL 3215289, at *9 (N.D. Tex. July 28, 2017).

The district court's finding rests on its erroneous conclusion that Jackson failed to allege protected activity. Since her internal complaints constituted protected activity, Ventavia was on notice. When Jackson escalated those complaints to the FDA, Ventavia terminated her. The SAC's allegations create a reasonable expectation that Ventavia knew of her FDA complaint.

F. But-for Relator's Protected Activity, She Would Not Have Been Retaliated Against

While but-for causation was not addressed by the district court, Jackson plausibly alleged but-for causation. The SAC raises a reasonable expectation that discovery will show a causal connection between Relator's protected activity and her retaliatory termination.

Meeting the default "but-for" cause requirement is hardly onerous following the Supreme Court's decision in *Bostock v. Clayton Cty.*, 590 U.S. 644, 656-667 (2020). There, the Supreme Court held that to meet but-for causation in the employment setting, an employee must show protected activity was *a* "but-for" reason for the employer's intentional act, but she need not prove it was the "sole,"

"main," "primary" or even the "most important" reason for the adverse decision. The Court held there may be, and often are, multiple but-for reasons. It is irrelevant whether non-retaliatory factors also motivated the decision, even if other factors played a more important role. *Id.*

The Fifth Circuit has held that "the combination of suspicious timing with other significant evidence of pretext[ ] can be sufficient to survive summary judgment." *U.S. ex rel. Dyson v. Amerigroup Texas, Inc.*, No. CIV.A. H-03-4223, 2005 WL 2467689, at *4 (S.D. Tex. Oct. 6, 2005), quoting *Shackelford v. Deloitte & Touche, LLP*, 190 F.3d 398, 409 (5th Cir.1999).

In her 2AC, Relator alleges that she was terminated from her employment at Ventavia because of her efforts to stop 1 or more violations of the False Claims Act. Moreover, the timing of Jackson's termination is suspicious because she was terminated during the period when her employer had paused enrollment in the clinical trials to correct for her multiple internal complaints about protocol violations. And, she was fired within hours of reporting those violations to the FDA. She further alleged that, during her meeting on September 24, 2020, after presenting photographic evidence of clinical trial protocol violations, she was harassed by Fisher and repeatedly questioned why she took photographs. ROA.3686. Fisher also falsely accused Jackson of removing patient source documents from another trial site. *Id*. The SAC pleads a direct causal nexus

between her efforts and her termination, as well as close proximity and evidence of pretext. These allegations are sufficient at the pleading stage.

Since Relator's SAC raises a reasonable expectation that discovery will reveal evidence of a causal connection between Relator's protected activity and her retaliatory termination, it meets the requirements for alleging but-for causation.

CONCLUSION

For the foregoing reasons, this Court of Appeals should vacate and reverse the district court's Order granting the DOJ's motion to intervene to dismiss.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the 13,000 word type-volume limit of FRAP 32(a)(7)(B)(i) and 6 Cir. 32(a) because, excluding the parts of the document exempted by FRAP 32(f) and 6 Cir. R. 32(b)(1), this document contains 12,109 words.

This brief complies with the typeface requirements of FRAP 32(a)(5) and the type style requirements of FRAP 32(a)(6) because this document has been prepared in a proportionally spaced typeface using 14-point Times New Roman style font.

Dated: February 14, 2025

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CERTIFICATE OF SERVICE

I certify that, on February 14, 2025, the foregoing Brief of Appellants was served on all parties or their counsel of record through the CM/ECF system if they are registered users or, if they are not, by placing a true and correct copy in the United States mail, postage prepaid, to their address of record as reflected in the Court's CM/ECF system.

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