No. 24-40564

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

BROOK JACKSON,
Qui Tam Plaintiff-Appellant,
v.
UNITED STATES OF AMERICA,
Intervenor Plaintiff-Appellee,

VENTAVIA RESEARCH GROUP, LLC,
Defendant-Appellees,

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 REPLY BRIEF

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases: **Page(s):**

Statutes

Other Authorities

INTRODUCTION

Brook Jackson's lawsuit exposed Pfizer's unprecedented fraud on the United States and the American people. Sparked by her whistleblowing and fueled by collective work from an army of both renowned and citizen scientists, Relator has amassed a body of evidence showing Pfizer committed multi-layered fraud in its clinical trials to induce the Food and Drug Administration (FDA) to issue an emergency use authorization (EUA) for its Covid-19 vaccines. With or without the government's knowledge or assistance, Pfizer's fraud has cost the taxpayers multiple billions of dollars for a product which, absent the fraud, could not have been authorized for use during the Covid-19 emergency.

In her second amended complaint, Jackson alleged Pfizer fraudulently designed, conducted and reported its clinical trials to avoid showing negative efficacy in preventing Covid-19 disease. Pfizer knew that injection of its modified genetic product would not stop transmission or infection, and would lead to immune dysfunction and more disease. To obtain the EUA, Pfizer designed its trial protocol to avoid measurement of immunological responses of the human subjects. Then, when conducting the study, Pfizer misclassified and excluded treatment group subjects who became symptomatic soon after their injections. Only through fraud was Pfizer able to assert a claim of 95% efficacy.

An adequate well-controlled clinical trial of the biologic would have exposed those facts and precluded issuance of the EUAs. Repeated studies now show "negative efficacy" – the more shots a person receives, the more likely that person will get sick or hospitalized for Covid-19. Had Pfizer not engaged in the clinical trial fraud exposed in this lawsuit, it would have obtained neither EUA nor federal funds on its contracts with the Government.

Similarly, Jackson alleges that Pfizer fraudulently designed, conducted and reported its clinical trials to hide significant harm caused by its vaccine. Pfizer knew the modified genetic biologic would cause some recipients to make highly-pathogenic Spike protein throughout their major organs and that, over time, devastating Spike protein diseases would take root. To suppress exposure of the serious adverse events and deaths its vaccines would cause, Pfizer lied about the distribution and persistence of the genetic material, it falsely omitted reports of serious harm to treatment subjects, it cut the observation period short prematurely before many serious adverse events could occur, and it unblinded and destroyed the control group to obfuscate data on long-term vaccine injuries.

Today, a confluence of scientific studies, medical reports, public health data (including from the CDC), federal disability statistics, and insurance actuarial calculations document alarming elevations in excess all-cause morbidity and mortality attributable to the vaccines. These include aggressive and recurring

cancers, miscarriages and fetal deaths, blood clots and cardiac arrests, neurological disorders including prion disease, auto-immune disorders, and other life-threatening or disabling conditions. Again, had Pfizer not engaged in clinical trial fraud, the truth about these harms would have been exposed as part of the scientific record, precluding authorization under the EUA statute.

Despite the critical importance of Jackson's qui tam claims – or perhaps because of it – the Government filed a motion for a "later date" intervention solely to "voluntarily" dismiss her case. In its threadbare 11-page motion, the Government departed from its own reasoned guidance regarding when circumstances might warrant the rare motion to intervene to dismiss under the False Claims Act, 31 U.S.C. §§ 3730(c)(2)(a) and (c)(3). The entirety of the "record" supporting its request for permissive intervention was reduced to one sentence: the Government's desire to have Jackson's case dismissed alone was good cause for the later date intervention.

The principal questions raised by this appeal ask whether, on the record of the Government's motion, the district court erred as a matter of law or abused its discretion when it granted leave to intervene to dismiss Jackson with prejudice. Working with its limited record below, the Government's answering brief fails to take issue with statutory and constitutional infirmities in its good cause arguments.

First, the Government's motion was based on a theory rejected by the Supreme Court in *United States ex rel. Polansky v. Exec. Health Res., Inc.*, 599 U.S. 419 (2023) – *i.e.*, that the Government has an unfettered right to dismiss any *qui tam* case under the False Claims Act whenever it wishes to do so. *Polansky* held that once the Government declines intervention during the seal period, it is the relator, not the Government, who controls the action. Before the Government can seek dismissal under § 3730(c)(2)(a), it must first become a party by showing good cause for a late intervention. The Government's stated position that its desire to dismiss alone shows good cause contravenes *Polansky*.

Second, the Government's argument for good cause reconstructed on appeal is unsupported on this record. Its contentions – that Jackson's claims are "not viable," that the case imposes undue discovery or litigation burdens on the executive branch, and that continued prosecution of the fraud committed by Pfizer would be inconsistent with the nation's health policies – are unsupported. Moreover, they are foreclosed by undisputed facts on the record, and by Relator's offer of proof to test the adequacy of the Government's good cause showing. Jackson's *qui tam* claims against Pfizer are overwhelmingly supported, there has been no demonstration of undue burden on the government, and this action is entirely consistent with national public health policies.

Third, the district court erred as a matter of law when it held that the Government need not satisfy the requirements of Rule 24, including balancing the extreme prejudice to Relator by permitting the intervention. Although the Government forfeited the right to raise the issue on appeal by failing to raise it below, the Government now asks the Court to hold that the Federal Rule of Civil Procedure does not apply to False Claims Act cases – a contention rejected by *Polansky*. When the proper legal standard is applied, the record demonstrates that the prejudice to Jackson – and the potential harm to the future operation of the *qui tam* statute – should have weighed heavily against granting the motion.

Fourth, the Government's motion to intervene to terminate this action does not survive strict scrutiny of viewpoint discrimination under the First Amendment. Based on her own interests as a whistleblower, and acting on the partial assignment of rights by an act of Congress, Jackson had a constitutionally protected right to remedy grievances against Pfizer for defrauding the United States, free of unjustified interference by the Government. The Government's motion was squarely predicated on the content of Jackson's allegations, as it conceded when it labelled Jackson's allegations "misinformation." The Government singled out Relator for dismissal because it did not want her to expose Pfizer's clinical trial fraud, information it tried to suppress in the general marketplace of ideas, writ large. The Government forfeited its opposition to this issue by neglecting it below,

and the Court should reject the views it expresses now on limited scope and extent of protection afforded by the First Amendment.

Fifth, the Government's motion disordered the separation of powers between government branches. Avoiding offense to the separation of powers doctrine must weigh heavily against the finding of good cause here. Executives are empowered to intervene in *qui tam* actions for legitimate purposes of prosecuting False Claims Act cases – including the purpose of dismissing actions that are truly meritless, parasitic, interfering or contrary to legitimate government interests. Such executive power is *not* vested to shield corporate partners from exposure for fraud. Nor is it vested to insulate government officials implicated in, or acquiescent of, fraud. Exercise of executive power to move to intervene is particularly pernicious in this case, given the material falsities by Pfizer and the objective criteria used by Congress in the EUA statute.

Sixth, the motion to intervene to dismiss violates the Equal Protection Clause because it fails the rational basis test, and exceeds the constitutional limits attending any exercise of executive authority. Termination of this important case – already shown to the public to be meritorious and likely to recover billions of dollars for Pfizer's fraud – is arbitrary and capricious in the constitutional sense. It shocks the conscience, represents an abuse of executive power, and perpetrates a fraud upon the Court and the American people.

Finally, it was error as a matter of law to voluntarily dismiss Jackson's case with prejudice. Relator had not previously filed an action against defendants based on the facts or theories presented here, and under the terms of Rule 41, any voluntary dismissal should be without prejudice. On appeal, the Government's insistence that dismissal be with prejudice as to Relator but not the United States merely shows its discriminatory animus against Jackson for exposing Pfizer's fraud.

Thus, while the Government has the authority to seek to make a "later date" intervention to dismiss *qui tam* actions based on good cause and legitimate government purposes, the district court's granting of the motion in this case on the present record was inconsistent with the False Claims Act, the Federal Rules of Civil Procedure, and the Constitution. The lower court's order should be reversed and remanded.[1]

[1] This Brief also replies to the answering brief of Ventavia Research Group, which terminated Jackson less than six hours after Relator reported fraud in the clinical trials to the FDA. Jackson's well-pleaded allegations show that she made good faith efforts to stop fraud on government contract funds, that Ventavia knew about such protected conduct, and that Jackson was terminated "because of" her protected activity. Ventavia's contention on appeal – that Jackson had protested mere regulatory violations – is shown to be without merit by the very nature of her *qui tam* claims, which were still pending when the Government moved to intervene on grounds that did not test the merits.

ARGUMENT

I. The District Court Erred As a Matter of Law and Abused its Discretion When it Granted the Government's Motion to Intervene to Terminate Brook Jackson's Case With Prejudice

Statutory and Constitutional grounds require reversal of the district court's decision to permit the Government to make a "later date" intervention to dismiss Jackson's important meritorious case.

A. The DOJ's Assertion of an Unfettered Right to Intervene Whenever it Wants Dismissal Upends Judicial Duty to Find Good Cause Shown

The Government's brief inadvertently proves Jackson's point: it made no showing of good cause to intervene. The Government provides no basis or authority showing that courts must accept unsupported assertions as legally sufficient. It lost this contention of unfettered rights in *Polansky* and this same contention must be rejected on this appeal.

As the Supreme Court clarified in *Polansky*, before the government may move to dismiss a *qui tam* action, it must first become a party by intervening. *United States ex rel. Polansky v. Exec. Health Res., Inc*., 599 U.S. 419, 433 (2023) ("once the Government becomes a party, it (alongside the relator) does what parties do: It 'proceeds with the action'"). And, in order to make a later date intervention, the Government first must show good cause. 599 U.S. at 423 ("the

Government retains certain rights, including the right to intervene later upon a showing of good cause"). *See* 31 U.S.C. § 3730(c)(3).

Even then, the Government must "offer[] a reasonable argument for why the burdens of continued litigation outweigh its benefits." *Polansky*, 599 U.S. at 438. Congress intended that False Claims Act claims be dismissed only for legitimate government purposes, and not as a result of fraud, illegality, or lack of political will. S. Rep. 99-345, at 25-26. *See United States ex rel. Sequoia v. Sunland Packing House Co.*, 912 F. Supp. 1325, 1340 (E.D. Cal. 1995) (citing Senate Report)**,** *affirmed United States ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp*., 151 F.3d 1139, 1146 (9th Cir. 1998); *In re Nat. Gas Royalties ex rel. United States v. Exxon Co., USA*, 566 F.3d 956, 963 (10th Cir. 2009) (noting the important role of relators in valid enforcement actions "even when the government should be on notice of the fraud" as the Government "could lack the resources (or, indeed, the political will) to pursue a claim").

Contrary to the DOJ's contention in this Court, no court has ever relieved the Government of the requirement to make a good cause showing for a "later date" intervention under § 3730(c)(3) simply because the Government wished to move for dismissal under § 3730(c)(2)(a). Every court which found good cause based on the Government's motion to dismiss did so because the Government had made a

showing of its reasons for seeking dismissal. The mere assertion of a desire is not the same thing as a showing of reasons or good cause. Since *Polansky* rejected the DOJ's assertion of unfettered discretion to dismiss, no Court has held that the mere assertion of the wish to dismiss, without a showing, satisfied good cause.

Polansky provides a perfect example. Although the Supreme Court did not have the good cause determination before it, the Court noted that the Third Circuit had affirmed the good cause finding based upon an actual showing by the Government: its "weighing of discovery burdens against likelihood of success." 599 U.S. at 429 n.2 (citing 17 F.4th 376, 392-393 (3d Cir. 2021)). The Supreme Court recounted the factual record for those reasons in detail: 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.

The Government argues on this appeal that this recitation of the factual record in *Polansky* was for different purposes, a post-answer dismissal under Rule 41 (DOJ Brief at 13 n.1). While it is true that the Court discussed the factual record to "give guidance" under Rule 41, it is also true, as noted, the showing of good cause was not before the Court in *Polansky*. The relevance of that record to the

contentions on this appeal does not turn on which section in the opinion where the record is discussed in *Polansky*. Good cause was found by the district court in *Polansky* and the factual record did more than simply state the Government's desire to dismiss.

Similarly, the DOJ misstated the case in *Brutus Trading, LLC v. Standard Chtd. Bank*, 2023 U.S. App. LEXIS 21868, at *5 (2d Cir. Aug. 21, 2023) and ignored the basis for the Government's motion in that case. (DOJ Br. at 14.) There, the Government showed the relator's "factual allegations were unsupported, its legal theory was not cognizable, and the continuation of the suit would waste considerable government resources." Contrary to the DOJ's position here, it was not mere assertion of an unfettered right to dismiss that established good cause. This hardly supports the Government's position that unsupported assertions suffice.

In *United States ex rel. Carver v. Physicians Pain Specialists of Ala., P.C.*, 2023 U.S. App. LEXIS 19592, at *11-13 (11th Cir. July 31, 2023), it was the "same grounds" supporting dismissal that also established good cause, not the mere assertion of a right. Those grounds included evidence that Carver had "failed to prosecute this action to an enforceable judgment, neglected her responsibilities as a relator, burdened the United States with discovery requests that are either irrelevant or premature, and undercut the United States' FCA enforcement efforts in this district." *Id.* The DOJ in *Carver* detailed these considerations, showing that "it did

not make the decision 'lightly,' [and] it had 'determined that the costs of continued litigation outweigh any benefits the United States could realistically obtain.'" *Id.* at 5. No such claims could be made here.

In *United States. ex rel. USN4U, LLC v. Wolf Creek Fed. Servs.*, 2023 U.S. Dist. LEXIS 217620, at *4-5 (N.D. Ohio Dec. 7, 2023), the district court found the Government had "shown good cause to intervene." It held:

> Here, for good cause the U.S. contends that discovery has cast doubt on the Relator's ability to prove any False Claims Act violations against Defendants. Many of the Relator's allegations and his expert's opinions have been challenged by the testimony of the NASA employees who were deposed in this case. For example, Relator argues that NASA employees did not adequately review Defendants' proposals, but the NASA employees described a lengthy review process for the approval of the proposals. And the U.S. correctly questions the ability of Relator's expert to refute this because he was not involved in NASA's review process. See ECF Doc. 69-1 at 7. The U.S. also shares the concerns of [*5] the Court regarding Relator's credibility; his testimony during the October 4, 2023 hearing was "vague, evasive and contradictory." Id. The U.S. does not want to devote any more resources to the case given the unlikelihood of Relator's success. [*Id*.]

The district court's decision in *Wolf Creek* supports Jackson here.

Thus, in every case cited by the DOJ where "good cause" was established, the Government provided a reasoned basis for intervention and dismissal, grounded in a valid governmental purpose as outlined in the Granston Memo. Never before has the DOJ sought to dismiss a meritorious case like this one, where the relator has shown such a strong basis to recover substantial damages for harms

caused to the United States by fraud and false claims on the public fisc. And, never before has the Government failed to articulate a legitimate reason for dismissal.[2]

This conclusion – that the Government may intervene only upon showing good cause, and not simply by expressing a desire to dismiss – is compelled by the nature of the decision on appeal. To rule upon the Government's motion, it was incumbent upon the district court to make an independent judicial decision about whether the Government showed good cause. While governments may act based on politics, courts must decide by applying law to the record before them. The questions on appeal thus involve whether the government showed good cause, and *not* simply whether the Government had expressed its desire to dismiss Jackson's case.[3]

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[2] The recent decision in *Vanderlan v. United States*, 135 F.4th 257 (5th Cir. 2025) addressed pre-answer dismissal under Rule 41(a)(1) where the government was already a party. *Id.* at 268. It did not address the "good cause" requirement for later intervention under § 3730(c)(3). *Vanderlan* involved actual interference with ongoing enforcement proceedings—absent here. *Id.* at 264. The deference in *Vanderlan* applies to dismissal decisions, not to the threshold showing of good cause required by *Polansky* for later intervention.

[3] This distinction between political decisions by the Government and judicial decisions by courts was raised by Judge Truncale himself during the May 1, 2024, oral argument. *See* ROA.5150:3-19 ("Decisions by an agency . . . to pursue an action may be political in nature. How can a court even interfere with what might have . . . a political component to it?"). As relators' counsel responded, the court's ruling on the motion would be judicial, not political. ROA.5150:14-16. While politics, unfortunately, may have contaminated the Government's decision in this case, the role of the Court is to keep politics out of it, and to determine whether the Government has made a showing of good cause consistent with the Constitution, the Federal Rules of Civil Procedure, and the policies served by the False Claims Act. ROA.5152:5-4145:7.

On the record before it, the district court erred in finding that the Government established good cause to intervene and dismiss.

B. The DOJ's Reconstructed Arguments as to Why Brook Jackson's Case Should Be Dismissed Fail to Show Good Cause to Intervene.

As pointed out in the opening brief (at 45-46), the district court below erred by *assuming* there to be a factual basis for the asserted reasons to dismiss, and by collapsing the intervention and dismissal standards. After standing on its claim to unfettered intervention authority below, the Government here recites its unsupported and unexplained reasons for wanting dismissal as a showing of good cause. However, on this factual record and procedural posture, those reasons – that Jackson's case was not meritorious, it imposed substantial discovery and litigation burden on the Government, and it was inconsistent with national health policy – cannot establish a basis for affirming the judgment.

Indeed, the detailed unanswered factual record presented by Relator, and the offer of proof she made on the motion, preclude the Government from resting on its reconstructed arguments now. The evidence in the record – as well as the overwhelming body of scientific studies, medical reports, public health data, federal disability statistics, and actuarial calculations that continue to mount every day – document clear negative efficacy to Pfizer's Covid-19 vaccines in the prevention of infection or transmission, and alarming elevations in excess all-cause morbidity and mortality attributable to the vaccines. Rather than being "meritless,"

Jackson's lawsuit exposed unprecedented fraud by Pfizer committed through multiple layers of its clinical trials. In its brief, the Government simply ignores Relator's unrefuted showing.

Seen in context, the arguments posed by the Government now clearly fail to show a lack of merit to Jackson's lawsuit. The Government relies on two purported facts: (1) it knew of Pfizer's deviation from protocols as Jackson revealed to FDA at the time, and (2) it had access to post-marketing data and concluded that the vaccines were "effective." Even if these facts were supported by evidence, they would not undermine Jackson's claims. Government knowledge, acquiescence or even complicity in the fraud would not excuse Pfizer for its role in committing the fraud, nor allow the fraudster to retain its ill-gotten profits off American taxpayers. Moreover, the Government made no showing that the vaccine was effective in preventing either transmission or infection, and the Government no longer even tries to maintain that the injections are "safe."

Thus, the Government's argument about adequate process (Gov't Br. 22-24) completely misses the point. The issues around Jackson's request for an evidentiary hearing and her detailed offer of proof go to the one-sided factual record supporting the merits of her claims. The request and offer accomplishes exactly what was needed to defeat the Government's motion *without* an evidentiary hearing. After repeatedly being asked by the district court to respond and explain

its position assuming the proffered facts to be true, the Government simply declined. ROA.5145:9-5147:17, 5167:10-5169:22. This refusal to engage with evidence challenging the Government's position forecloses the reconstructed argument over the lack of merit now.

The Government's other reconstructed arguments are even less compelling. It made no showing of any "discovery and litigation burdens" it supposedly weighed in reaching its decision to file the motion. Similarly, the Government has not explained how this case was contrary to national health policy. Holding Pfizer accountable for its fraud, even in the face of Government acquiescence, and showing would-be whistleblowers that they can expose and remedy fraud even when the Government allows it to occur, are actions that vindicate national health policy, not defeat it.

C. The District Court Erred as a Matter of Law in Failing to Consider the Extreme Prejudice to Relator Under Rule 24.

As established in the opening brief (at 40-42), the district court's ruling Rule 24 does not apply to the False Claims Act, and its failure to consider extreme prejudice to Jackson under Rule 24(b)(3), requires reversal and remand. Although the Government forfeited the right to dispute this issue by not addressing it below, it argues here that the Court should affirm the legal error. Such a rule would be directly contrary to the Supreme Court's holding in *Polansky.*

The Government's convoluted argument that it is already a party and thus need not satisfy Rule 24 is nonsensical. Although the action is brought in the name of the Government and the United States is the real party in interest, the law is clear: until it shows good cause to make a later date intervention, it is not a party and has no control over the litigation. In making the False Claims Act "the Government's primary litigative tool for combating fraud" "in modern times," S. Rep. No. 99-345, at 2, Congress partially assigned rights directly to relators like Jackson, equipping them with authority to litigate *qui tam* claims without direct participation of the DOJ. Jackson did not need approval of the DOJ or agency executives to fulfill her role before this Court.

D. The Lower Court's Ruling Undermines the False Claims Act

As demonstrated in the opening brief (at 42-45), lasting dismissal of this case threatens to eviscerate the great gains made when Congress amended the Act in 1986. As the 1986 Senate Report makes clear, Congress strengthened the False Claims Act to ensure private enforcement even when the Government lacks "the political will" to pursue meritorious fraud cases. S. Rep. No. 99-345, at 2. The Government's position, and the district court's endorsement of it, would send a chill down the spine of every would-be whistleblower. The result says: if you know of fraud, but it is of the type that the Government allows to happen, don't bother coming forward with your information.

It is with this background that the Granston Memo, the DOJ's own guidance, recognized the need to restrict dismissals to only those circumstances where a legitimate government interest required it. The Government argues the Granston Memo does not "bind" it, but this misses Jackson's point. The arbitrariness of the Government's position in this case is shown by its failure to adhere to its own guidance. When an agency fails to follow its own reasoned policies without explanation, it acts arbitrarily and capriciously. Moreover, it's action undermines the functioning of this most important Act.

E. The Government Ignores The Constitutional Violations It Failed to Address Below

The DOJ makes little effort to address the detailed constitutional arguments presented by Relator. It does not dispute that it likened Jackson's allegations to "disinformation," that the Constitution imposes strict scrutiny on such content or viewpoint discrimination, that its executive decision to move to dismiss under § 3730(c)(2)(A) is of a completely different nature from speech in a Statement of Interest, and that the separation of powers doctrine prevents the executive branch from gaining "subjective" authority to authorize vaccines when Congress imposed an "objective standard). As it did in the district court, the Government's disregard for these issues waives its right to do so on appeal.[4]

[4] The Government's claim that it did not waive these arguments (Gov't Br. 19 n.5) is without merit. Jackson raised three constitutional challenges, ROA.4558-4587, and the reply addressed none substantively. ROA.4892-4898.

To evade its obligation to stay within constitutional constraints, the DOJ suggests that Jackson may petition the government elsewhere – through some "other appropriate avenues" – to raise "concerns about federal agency decision-making." DOJ Reply, at 3. Such a claim – that Relator could choose to challenge the Government in a political forum – has no bearing on Jackson's right to bring this action against Pfizer for the fraud it committed on the United States. And such avenues – even if they existed – would not obviate the responsibility of the courts to make "good cause" determinations on the basis of the record.

The Government's admission that it sought dismissal because Jackson's allegations were "inconsistent with [government] public health policy" (Gov't Br. 12), and its demand in this Court that the voluntary dismissal must be *with prejudice* as to Jackson (*id*., 24 n.7),[5] confirm content-based discrimination requiring strict scrutiny. The Government offered no compelling interest that would survive such review.

The Government also failed to take issue with the holding in *United States ex rel. CIMZNHCA, LLC v. UCB, Inc.,* 970 F.3d 835, 847 (7th Cir. 2020), that the disordering of the branches of Government must weigh heavily in the good cause determination. The Government's own retort is to call the motives ascribed to the

[5] Other than its raw dislike of what Brook Jackson has to say in this lawsuit, the Government fails to provide a reason to overcome the presumptive rule that first dismissals under Rule 41 must be *without prejudice*.

Government as based on "speculation." And yet, that is hardly the case. Substantial proof, including the offer of proof at the hearing, included the Government's illegitimate basis for protecting Pfizer and suppressing criticisms of its vaccines.

The Government's reliance on *Polansky's* "substantial deference" language thus misses the point. That deference applies to substantive dismissal decisions, not to the threshold question of whether the Government has good cause to intervene. Here, as Jackson demonstrated, allowing intervention to dismiss protects private and former officials' personal interests, not legitimate government purposes.

Finally, the DOJ does not dispute, and therefore concedes, that substantive due process and equal protection require that its motion have a rational basis. The Government's abject failure to make a coherent explanation for dismissal means it fails even this minimal test. 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. Given this, the DOJ was unable to explain why Jackson's case contradicts national policy, or should be dismissed. Rather, dismissal of this case would be contrary to national policy.

II. Dismissal of Jackson's Retaliation Claim Should be Reversed

To establish FCA retaliation under 31 U.S.C. § 3730(h), Jackson must show: (1) she engaged in protected activity, (2) Ventavia knew of the protected activity, and (3) she was terminated because of that activity. *U.S. ex rel. Bias v. Tangipahoa*

Par. Sch. Bd., 816 F.3d 315, 323 (5th Cir. 2016). Ventavia's arguments fail on each element, particularly when viewed under the proper Rule 12(b)(6) standard that requires drawing all reasonable inferences in Jackson's favor. See *Franklin v. Regions Bank*, 976 F.3d 443, 447 (5th Cir. 2020).

A. Jackson Sufficiently Alleged She Engaged in Protected Activity

Jackson's actions went beyond complaints or criticisms about regulatory compliance. She demanded clinical trial enrollment halt until protocol violations were corrected—a direct effort to stop the generation of fraudulent data. She warned supervisors that FDA audits would result in violation notices, connecting Ventavia's conduct to government enforcement. She documented violations photographically and escalated concerns through proper channels. Finally, she reported violations directly to the FDA to prevent submission of unreliable data to federal authorities.

Jackson's report to the FDA represents the clearest form of protected activity under any interpretation of the FCA's retaliation provision. Ventavia's argument against protected activity argues only that Jackson's internal complaints were not protected activity. Ventavia does not dispute that Jackson's complaint to the FDA was protected, but disputes only whether it had knowledge of her FDA complaint – a fact stated in briefing, not part of the factual record, and inappropriate to consider at this stage. Reporting regulatory violations to a government agency is protected

conduct, regardless of the terminology used. This external reporting goes beyond internal complaints and is direct communication with federal authorities about potential misconduct—activity squarely within the "in furtherance of" and "efforts to stop" categories of protection.

Relator's efforts were to prevent fraud on the government and were not passive reports of general misconduct. *Josey v. Impulse Dynamics* correctly recognized that pre-submission efforts to prevent FDA fraud fall squarely within the "efforts to stop" category. 371 F. Supp. 3d 603 (D. Ariz. 2019). The connection between clinical trial fraud and government payment is direct: fraudulent trial data enables fraudulent EUA applications, which trigger government vaccine purchases. Jackson's efforts to halt enrollment, demand corrections, and alert federal authorities were designed to prevent this exact causal chain. *Miniex v. Houston Hous. Auth.* recognized that reports of regulatory violations to government authorities is protected activity under the FCA's retaliation provision. 400 F. Supp. 3d 620 (S.D. Tex. 2019)

Ventavia argues that clinical trial violations are merely "regulatory compliance" issues ignoring the government fraud nexus and the nature of Jackson's FDA report. When a company knowingly submits unreliable clinical trial data to obtain FDA authorization that enables government payment, that conduct is fraud even if the underlying violations are characterized as "regulatory." See *Josey*

v. Impulse Dynamics (USA) Inc., 371 F. Supp. 3d 603 (D. Ariz. 2019). Jackson's efforts to stop such conduct, culminating in her direct report to federal authorities, fall within statutory protection.

B. Ventavia Had Notice of Jackson's Protected Activity

1. The Fifth Circuit Does Not Require "Magic Words" To Put The Employer on Notice of Protected Activity.

Regarding Relator's internal complaints, Ventavia explicitly argues that the Fifth Circuit requires "magic words" like "illegal," "unlawful," or "fraud" to establish employer notice of protected activity. This position contradicts the statutory text and the remedial purpose of FCA retaliation protection. The statute protects efforts to stop violations, not efforts to use particular words to describe those violations. *Nichols v. Baylor Research Institute* rejected this formalistic approach, finding that "no magic words—such as illegal or unlawful—are needed to put the employer on notice of protected activity."[6] 418 F. Supp. 3d 143 (N.D. Tex. 2019)

However, Ventavia does not argue that Jackson's complaints were insufficient to notify them that she was potentially investigating fraud. If

[6] Ventavia claims the holding of *Robertson v. Bell Helicopter Textron, Inc.*, 32 F.3d 948, 951 (5th Cir. 1994), is that "there can be 'no protected activity where plaintiff failed to use words such as *illegal*, *unlawful*, or *qui tam* in characterizing concerns." Appellee Brief at p. 46, citing *United States ex rel. Toledo v. HCA Holdings, Inc.*, 2023 WL 2823899 (5th Cir. Apr. 7, 2023) at *3. However, *Robertson*, a decision affirming judgment as a matter of law following a jury trial, found that the relator's "reporting was qualitatively different than the reporting that occurred in the cases he cites." *Robertson*, at 951.

Ventavia's interpretation of the law were correct, Jackson's identical conduct would be protected activity simply by adding "This is illegal" to her communications—elevating form over substance.

The critical question for notice is whether the employer reasonably understood that the employee was concerned about fraud on the government, not whether particular phrases appeared in internal communications. Even *Patton*, which Ventavia heavily relies on, recognized that courts must examine "the substance of his complaints" rather than merely the presence or absence of specific terminology. *U.S. ex rel. Patton v. Shaw Services*, L.L.C., 418 Fed.Appx. 366, 372 (5th Cir. 2011).[7] In *United States ex rel. Toledo v. HCA Holdings, Inc.*, 2023 WL 2823899 (5th Cir. Apr. 7, 2023), the relator asked whether certain billing practices were appropriate, but there was no indication she asked in a way implying that she believed they were not. Further, the *Toledo* Court reached this conclusion only on consideration of a fully developed record on summary judgment. Jackson's communications provided clear notice of fraud concerns.

[7] *Patton* does not hold "if there is no clear report about government fraud, as opposed to just an internal complaint about misconduct, an employer 'could not possess the retaliatory intent necessary to establish a violation of § 3730(h).'" See Appellee Brief at 48. The full quote is, "Without knowledge that Patton was investigating fraud, Shaw 'could not possess the retaliatory intent necessary to establish a violation' of § 3730(h)." *U.S. ex rel. Patton v. Shaw Services, L.L.C.*, 418 Fed.Appx. 366, 372 (5th Cir. 2011), citing *Robertson,* 32 F.3d at 952. This merely reiterates the employer knowledge standard, but does not add a specific reporting requirement.

2. Jackson's Communications Provided Clear Notice of Fraud Concerns

Jackson consistently connected Ventavia's conduct to potential government enforcement. When she asked supervisors what would happen if the FDA audited Ventavia, the response was violation notices or enrollment suspension. She told supervisors to "Google FDA warning letters," specifically in the context of discussing protocol violations. Her demand to halt enrollment addressed her concerns of continuing violations that would trigger FDA sanctions.

These communications clearly signaled concern about Ventavia's reluctance to correct wrongful conduct that would result in government enforcement action—the essence of fraud. Jackson was not merely suggesting process improvements or raising general compliance concerns.

Most critically, Jackson reported violations to the FDA on September 25, 2020, and was terminated that same day.

3. Jackson's FDA Report Provides an Independent Basis for Protected Activity and Notice.

Even if Jackson's internal communications were somehow insufficient to establish protected activity or notice (they are not), her report to the FDA creates independent grounds for both elements. Reporting regulatory violations to a federal agency is protected activity under any reasonable interpretation of the FCA, regardless of specific terminology used. This external reporting represents direct

communication with government authorities about potential misconduct affecting federal interests.

Ventavia's argument that it lacked knowledge of the FDA report misunderstands the factual allegations and the applicable legal standard. The same-day timing creates a reasonable inference that Ventavia learned of Jackson's external reporting before terminating her employment. Finding otherwise infers facts in the moving party's favor. Whether this knowledge came through internal communications, regulatory contacts, or other channels is the type of factual question requiring discovery..

Appellee cannot rely on *Patton's* finding that the relator's complaints to government authorities were unknown to the defendant because *Patton*, like the other cases Appellee relies on, was decided on summary judgment.[8] *See U.S. ex rel. Patton v. Shaw Services, L.L.C.*, 418 Fed.Appx. 366, 367 (5th Cir. 2011). Tellingly, Ventavia's compulsion to assert in briefing that it "did not know about this call" – an unpled factual assertion – admits a factual dispute that cannot be resolved on the pleadings. Jackson has alleged facts creating a plausible inference of employer knowledge based on temporal proximity. Ventavia's contrary assertion

[8] Appellant refers to footnote 4 in her Appellant Brief to reiterate that the cases Appellee relies on were decisions under a fully developed factual record and are thus not appropriate to compare. See Appellant's Brief at 61, fn 4. Here, Jackson has had no opportunity to develop evidence of what Ventavia actually understood from her communications or whether the company knew of her FDA report before terminating her.

confirms that material factual issues exist regarding the company's knowledge and decision-making process—issues that preclude Rule 12(b)(6) dismissal.

C. The Temporal Proximity Between Jackson's FDA Report and Termination Establishes But-For Causation.

While Ventavia does not appear to dispute the Fifth Circuit law on but-for causation, Jackson reiterates that the temporal proximity between her report to the FDA and her termination creates such a strong inference of retaliation that dismissal at the pleading stage is inappropriate under the Rule 12(b)(6) standard. Jackson was terminated within hours of reporting violations to the FDA, during an enrollment pause she demanded due to protocol violations.

The same-day timing between Jackson's FDA report and termination creates an inference that Ventavia learned of her external reporting before making the termination decision. This inference must be drawn in Jackson's favor at the Rule 12(b)(6) stage and requires factual development to resolve.

CONCLUSION

For the foregoing reasons, the judgment entered by the district court should be reversed, and the case should be remanded for further proceedings consistent with the Court's opinion.

Date: July 3, 2025

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the 6,500 word type-volume limit of FRAP 32(a)(7)(B)(i) because, excluding the parts of the document exempted by FRAP 32(g) and, this document contains 6,452 words.

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Dated: July 3, 2025

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CERTIFICATE OF SERVICE

I, Robert E. Barnes, certify that on July 3, 2025, I served the attached **APPELLANT'S REPLY BRIEF**, by electronically filing the foregoing with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit by using the CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the CM/ECF system.

/s/ Robert E. Barnes
Robert E. Barnes