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

UNITED STATES OF AMERICA ex rel. BROOK JACKSON,	)
Plaintiff,	) ) Civil Action No.: 1:21-cv-00008-MJT
v.	)
VENTAVIA RESEARCH GROUP, LLC; PFIZER, INC.; ICON, PLC,	) ) )
Defendants.	)
	)

# RELATOR'S OPPOSITION TO GOVERNMENT'S MOTIONS TO INTERVENE AND DISMISS

### TO THE HONORABLE JUDGE OF THE COURT:

Relator Brook Jackson ("Relator") opposes the United States of America's ("Government" or "DOJ") motion to intervene to dismiss [ECF No. 137].

## **TABLE OF CONTENTS**

INT	RODUCTION1
BAC	KGROUND FACTS3
A	Mass Injection with Pfizer's ModRNA Vaccines Caused Catastrophic Harms 3
В	3. United States Executive Branch Agencies have Adopted a Policy of Protecting Corporate Partners and Abandoning Public Health
С	E. In these Extraordinary Times, Courts Play an Essential Role Preserving Legitimate
	and Constitutional Functioning of Our Government
BRO	OK JACKSON'S <i>QUI TAM</i> ACTION9
APP	LICABLE LEGAL STANDARDS
ARG	EUMENT14
I.	Permissive Intervention under § 3730(c)(3) Should Be Denied Because the Only Change in Circumstances Is the DOJ's Abandonment of Its Reasoned Policy for Seeking Dismissal Under § 3730(c)(2)(A)
II.	Permissive Intervention under § 3730(c)(3) Should Be Denied Because DOJ Failed to Show Good Cause for Extreme Prejudice to Brook Jackson
III.	Permissive Intervention under § 3730(c)(3) Should Be Denied Because the DOJ's Motion Offends Fundamental Constitutional Rights
	A. The DOJ's Content-Based Proposed Termination of Brook Jackson's Right to Petition the Government for Redress Has No Compelling Justification 19
	B. The DOJ's Motion Offends the Separation of Powers
	C. The DOJ's Motion is Arbitrary and Capricious, and Based on Fraud 23
CON	ICLUSION 2

## **TABLE OF AUTHORITIES**

## **CONSTITUTION**

U.S. Const. art. I, § 7.	21
CASES	
Borough of Duryea, Pennsylvania v. Guarnieri, 564 U.S. 379 (2011)	19
Borzilleri v. Bayer Healthcare Pharms., Inc., 24 F.4th 32 (1st Cir. 2022)	13, 17
Brutus Trading, LLC v. Standard Chtd. Bank, 2023 U.S. App. LEXIS 21868 (2d Cir. Aug. 21, 2023)	17
Buckley v. Valeo, 424 U.S. 1, 17, 96 S. Ct. 612 (1976)	21
California Motor Transport Co. v. Trucking Unlimited, 404 U.S. 508 (1972)	19
Elrod v. Burns, 427 U.S. 347 (1976)	20
Gibson v. Kilpatrick, 838 F.3d 476 (5th Cir. 2016)	21
In re Nat. Gas Royalties ex rel. United States, 562 F.3d 1023 (10th Cir. 2009)	22
Int'l Soc'y for Krishna Consciousness, Inc. v. Baton Rouge, 876 F.2d 494 (5th Cir. 1989)	20
Marbury v. Madison, 5 U.S. 137 (1803)	22
McDonald v. Smith, 472 U.S. 479 (1985)	19
Polansky v. Exec. Health Res., 17 F.4th 376 (3d Cir. 2021)	12, 13
Police Department of Chicago v. Moslev	

	408 U.S. 92 (1972)	20
Burson	v. Freeman, 504 U.S. 191 (1992)	20
Regan	v. Taxation with Representation of Wash., 461 U.S. 540 (1983)	20
Rockwo	ell Int'l Corp. v. United States, 549 U.S. 457 (2007)	12
SEC v.	Chenery Corp., 332 U.S. 194 (1947)	22
Sure-T	an, Inc. v. NLRB, 467 U.S. 883 (1984)	20
United	States v. Armstrong, 517 U.S. 456 (1996)	13
United	States v. AseraCare Inc., 2012 U.S. Dist. LEXIS 136059 (N.D. Ala. Sep. 24, 2012)	12
United	States ex rel. CIMZNHCA, LLC v. UCB, Inc., 970 F.3d 835 (7th Cir. 2020)	21
United	States ex rel. Drennen v. Fresenius Med. Care Holdings, Inc., 2018 U.S. Dist. LEXIS 53978 (D. Mass. Mar. 30, 2018)	12
United	States ex rel. Hall v. Schwartzman, 887 F. Supp. 60 (E.D.N.Y. 1995)	. 12
United	States ex rel. Polansky v. Exec. Health Res., Inc., 143 S. Ct. 1720 (2023)	19
United	States ex rel. Precision Co. v. Koch Indus., Inc., 31 F.3d 1015 (10th Cir. 1994)	12
United	States ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp., 151 F.3d 1139 (9th Cir. 1998)	18
Vermoi	nt Agency of Natural Resources v. United States ex rel. Stevens, 529 U. S. 765 (2000)	19

## **STATUTES**

§ 3730(c)(2)(A)
31 U.S.C. § 3730(c)(3)
RULES
Fed. R. Civ. P. 24.
Fed. R. Civ. P. 24(b)(3)
OTHER AUTHORITIES
Good Cause, s.v. Cause, Black's Law Dictionary (4th ed. 2011)
S. Rep. No. 99-345 (1986)

#### **INTRODUCTION**

Relator Brook Jackson brings this extraordinary False Claims Act action over clinical trial fraud by Pfizer to obtain authorization for its COVID-19 vaccines, and she does so under extraordinary circumstances. Despite being paid billions of taxpayer dollars to inoculate Americans to prevent infection and transmission of SARS-Cov-2, Pfizer's genetically-modified RNA (modRNA) biologic has "negative efficacy" – the more shots people receive, the more likely they are to get seriously ill with COVID-19. Worse, Pfizer's modRNA product causes catastrophic harm. Since early 2021, mass injections have led to striking levels of excess deaths, cardiac events, strokes and other serious events in populations of the United States and other highly vaccinated countries.

In September of 2020, Jackson worked as a clinical trial director at Ventavia, a trial site hired by Pfizer in its effort to gain Emergency Use Authorization ("EUA") and approval of its modRNA vaccines. Relator was one of the first people to witness and complain about Pfizer's fraud. Within hours of her confidential disclosure to a government agency, however, she was fired. Someone within the government informed Pfizer about her disclosure of misconduct, and someone within Pfizer and Ventavia determined to silence her and prevent her from gaining further knowledge of the fraud. Now, Brook Jackson's *qui tam* action threatens to expose this cozy public-private partnership, and Pfizer's potential civil liability for one of the largest frauds perpetrated on the American people. Supported by an army of renowned and citizen scientists, Brook Jackson can prove her case with an overwhelming body of evidence, before even a single document is obtained through discovery.

The public controversy over the Government's authorization of Pfizer's modRNA vaccines exposed extraordinary regulatory failure. The FDA, CDC, and NIH are seen by many to

have abandoned their public health mission and to have entered an era of unapologetic corporate capture and protection. Stripped of public confidence, these government agencies campaign to control and suppress truthful information on the harms caused by Pfizer's vaccines and the clinical trial fraud that allowed those harms to happen. Although agency executives originally hoped their actions would be seen as a legitimate effort to protect against "vaccine hesitancy," as more and more people understood the true extent of the damage, the effort to control information has further eroded the people's trust, turning any move to reduce "vaccine hesitancy" into a self-defeating disaster.

Acting for the agencies it represents, the Department of Justice (DOJ) makes an even more extraordinary move – it seeks leave of Court to make a "later date" intervention under 31 U.S.C. § 3730(c)(3) only to terminate the case under § 3730(c)(2)(A). Until recently, the DOJ invoked § 3730(c)(2)(A) sparingly and on reasonable grounds. Statistics show that, of 1,170 *qui tam* actions filed between January 2018 and December 2019, the DOJ sought dismissal just 45 times. It did so when the Government had good reason to believe the *qui tam* action was: 1) meritless, 2) brought by opportunistic relators, 3) interfered with legitimate agency policies, 4) wasted government resources, or 5) was justified under a clear and legitimate government interest. Never before has the DOJ sought to dismiss a meritorious case likely to recover damages for harms caused to the United States by fraud and false claims on the public fisc.

Despite the circumstances surrounding this extraordinary case, denial of the DOJ's motion is on familiar grounds: no good cause exists to allow the Government to intervene solely to terminate Brook Jackson's rights under the False Claims Act. No change in circumstances justifies revisiting the Government's declination decision, and the DOJ failed to articulate a coherent government purpose to dismiss the case. Suspected unstated purposes – to discourage

industry whistleblowers, suppress the truth about vaccine injuries, protect corporate partners from being held accountable for fraud and cover up executive complicity – are all constitutionally infirm, and certainly do not constitute "legally sufficient" reasons. In May 2020, Senator Grassley told Attorney General Barr that the Government's assertion of unfettered discretion to dismiss *qui tam* actions threatens to stem the tide of whistleblowers who play a very significant role in functioning of the Act. As a prime example, dismissal here would send a chilling signal about what future Brook Jacksons can anticipate if they want to expose fraud on the United States that agency executives want kept secret.

The American people need an honest and open adjudication of Brook Jackson's claims. Public faith in the government's processes – and of the legal system itself – depends on showing that Pfizer is not above the law against perpetrating fraud and false claims on the United States. The Court is not asked to rule on the merits but is asked to hear the relator's claims. The DOJ lacks authority to terminate the Court's adjudicatory process upon the "showing" made here. No compelling or reasoned basis exists that is legally sufficient to terminate relator's rights under the assignment made by Congress through the False Claims Act.

#### **BACKGROUND FACTS**

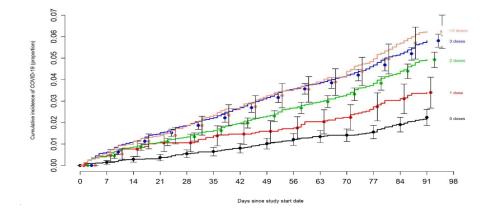
### A. Mass Injection with Pfizer's ModRNA Vaccines Caused Catastrophic Harms

Since the roll out of Pfizer's modRNA biologic, the populations of the United States and those of other highly vaccinated countries have suffered catastrophic harms. At an evidentiary hearing on the DOJ's motion, relator would present overwhelming medical evidence and respected medical opinions – subject to inspection and cross-examination – demonstrating the injections failed to stop the spread of Covid and had negative efficacy for their purpose. Worse, the evidence would show Pfizer's product exposes injected people to a barrage of immunological

dysfunction, serious disease and a risk of death. *See* Mendenhall Exhs.A-D; McCullough Decl., ¶¶ 9-13; Fraiman Decl., ¶¶ 4, 5.

Had Pfizer's clinical trials been truthful, the scientific record would not have supported an EUA under the EUA statute's objective standards. An adequate and well-controlled clinical trial would have foreclosed any *reason to believe* that the known or potential benefits outweighed the known or potential harm. For example, it 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 that, after looking at 68 countries and 2,947 counties in the United States, there was no decrease of infection rates in areas with higher injection rates. Instead, 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). Negative efficacy

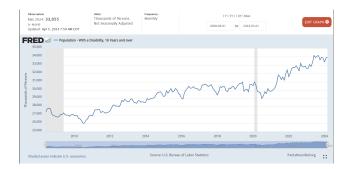
was confirmed by a study at the Cleveland Clinic, as shown by the following graph:



See Shrestha, et al., [available at <a href="https://doi.org/10.1101/2022.12.17.22283625">https://doi.org/10.1101/2022.12.17.22283625</a>]. This and an entire body of scientific evidence of negative efficacy and immune dysfunction is discussed and testified to through Dr. McCullough's declaration and article in *Cureus* (Exh. A), entitled "COVID-19 mRNA Vaccines: Lessons Learned from the Registrational Trials and Global

Vaccination Campaign." This negative efficacy was hidden in the clinical trials, which falsely claimed Pfizer's product was 95% effective. Manipulation and bias in the categorization of subject bias alone accounts for Pfizer's fraudulent efficacy claims. *See* Exh. C [Neil *et al.*, "The extent and impact of vaccine status miscategorisation on covid-19 vaccine efficacy studies."]. <sup>1</sup>

Official government statistics show alarming changes in Americans' health since the imposition of vaccine mandates. Disability rates are up<sup>2</sup>:



Cancer mortality is up 26% in younger age brackets<sup>3</sup>:



<sup>&</sup>lt;sup>1</sup> Dr. McCullough's *Cureus* paper provides significant detail on biological mechanisms that may explain the various adverse events of Pfizer's vaccines, and it refers to other papers describing mechanisms of molecular mimicry, antigen cross-reactivity, pathogenic priming, viral reactivation, immune exhaustion, and other factors related to immune dysfunction all reinforce the biological plausibility for vaccine-induced pathogenesis of malignant and autoimmune diseases. *See* Exh. A at 16. *See also* McCullough Decl.; Exh. B (Seneff *et al.*, "Innate immune suppression by SARS-CoV-2 mRNA vaccinations" *Food Chem. Toxicol*. (June 2022) (presenting evidence that vaccination induces a profound impairment in type I interferon signaling, with diverse adverse consequences to human health). These papers explain that Pfizer's modRNA vaccines trigger immune dysfunction and a host of pathophysiological effects, including chronic inflammation, thrombogenesis, prion-related dysregulation, and endotheliitis-related tissue damage.

<sup>&</sup>lt;sup>2</sup> Source: https://fred.stlouisfed.org/series/LNU00074597 accessed 4-19-2024.

<sup>&</sup>lt;sup>3</sup> Source: https://wonder.cdc.gov/mcd.html accessed 4-19-2024.

Similarly, an adequate and well-controlled clinical trial would have shown a stark rise in all-cause morbidity and mortality in injected subjects following their injections. Adverse events and deaths associated with Pfizer's product are staggering. As explained by McCollough and demonstrated in data analysis by several experts, Pfizer's products caused blood clots, neurological diseases, auto-immune disorders, increases in cancers and other life-threatening or disabling conditions. A recent study by the Global Vaccine Data Network of over 99 million vaccinated individuals 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). 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*. [Exh. D].

This connection between Pfizer's COVID vaccines and serious adverse events went unreported by Pfizer, but it can be seen in the sponsor's own inadequate and uncontrolled clinical trials. After 6 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. The data showed it took 22,000 injections to purportedly avoid a single Covid death but the cost was a fivefold increase in excess fatal cardiac arrest and congestive heart failure in injected individuals. Pfizer's own adulterated study showed its product killed five individuals from cardiac conditions in the first three months for every Covid death supposedly avoided. *See* Exh. A, at 4. It was obvious to Pfizer then, and it is clear to the rest of us now, that Pfizer's modRNA

biologics cause devastating harm to the health of the people, by far in excess of any promised benefit of preventing the infection and contraction of COVID-19.

# B. United States Executive Branch Agencies have Adopted a Policy of Protecting Corporate Partners and Abandoning Public Health

At an evidentiary hearing on the motion, relator is also prepared to present conclusive evidence that United States officials who regulate the nation's medical and pharmaceutical industries have been captured by corporate interests and have abandoned their mission of protecting public health. These officials have lost legitimacy and their opinions are unsupported and unreliable. Primary among them are the FDA executives upon whom the DOJ relies.

Examples abound of the lost confidence and credibility of agency officials on vaccine related topics. For example, the CDC recently, finally, released a report on the incidents of myocarditis following COVID-19 vaccinations. The agency redacted all 148 pages of the report. [https://www.documentcloud.org/documents/24463984-cdc-moving-foia.] To satisfy itself whether the Government has good cause to intervene to end Brook Jackson's *qui tam* action, the Court should consider requiring production of the unredacted report.

Another example of lost agency credibility is seen in the recent complaint filed by Rolf Hazlehurst, demonstrating the DOJ committed perjury to hide the causal link between childhood vaccines and the rising tide of autism in our nation's children. *See* Exh. E (Letter of Rolf Hazlehurst) A similar lack of credibility is apparent in the DOJ's representations to this Court. While the DOJ seeks to dismiss this case that attempts to hold Pfizer accountable for its fraud in the EUA authorization and approval process, the same agency told the United States Supreme Court on March 26, 2024, that "FDA takes very seriously its responsibility to ensure the safety of drugs" and that "drug sponsors themselves remain responsible at all times." Exh. F, at 14 (argument in FDA v. Alliance for Hippocratic Medicine *et al.*, No. 23-235). It is not credible the

FDA takes its safety mission seriously or believes sponsors like Pfizer "remain responsible at all times" while the DOJ simultaneously seeks to dismiss Brook Jackson's important *qui tam* action.

# C. In these Extraordinary Times, Courts Play an Essential Role Preserving Legitimate and Constitutional Functioning of Our Government

In these extraordinary times of widespread public interest in the inefficacy and injuries from Pfizer's product, and the manifest failures of the nation's administrative agencies, the Courts' role is essential. As the last check on abusive executive power, federal courts have repeatedly exercised independent judgment over claims about the vaccine raised by the DOJ, and they have not hesitated to reject the Government's assertions when not based on facts or inconsistent with the law.

For example, when concerned citizens sought release of Pfizer's clinical trial data through FOIA, the FDA told the federal district court in the Northern District of Texas that those data could not be disclosed for 75 years. The court took argument on the matter, and rejected the FDA's assertion, ordering the data released in at least the amount of time the Agency had the data before authorizing its use. *See* Exh. G (1/6/22 Order in Public Health and Medical Professionals for Transparency, v FDA, No. 4:21-cv-1058-P.)

Similarly, when the CDC refused to release the data from "V-safe," its massive vaccine data monitoring program, the court in the Northern District of Texas granted the plaintiff summary judgment under FOIA. *See* Exh. H (1/5/24 Order in Freedom Coalition of Doctors for Choice v. Centers for Disease Control and Prevention, *et al.*, No. 2:23-cv-102-Z.) Rejecting the DOJ's representations about the purported "burden" on the Government, the court held the plaintiff could get expedited production of redaction-free text, even if the burden was "heavy."

And, in *Apter v. HHS*, 80 F.4th 579 (5th Cir. 2023), the Fifth Circuit 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. Although the plaintiff physicians prescribed Ivermectin to thousands of patients with excellent results and the Government had injured their practice through its actions, the district court dismissed the action under sovereign immunity.

The Fifth Circuit reversed, holding that FDA "has authority to inform, announce, and apprise—but not to endorse, denounce, or advise."

While the credibility of our nation's executive agencies are in free-fall, the federal courts are the last bastion of hope for a governmental system of laws and policies working in the interest of the People. Now, more than ever, this nation's body politic needs a fair and lawful adjudication of Brook Jackson's claims that Pfizer must account for its fraud on the federal fisc and on the people of the United States.

### BROOK JACKSON'S QUI TAM ACTION

Brook Jackson's *qui tam* action exposes one of the largest frauds on federal funds, and perhaps the greatest threat to the health of the American people. As demonstrated on this record, she was the first to expose misconduct by Pfizer and its contractors during clinical trials of the COVID-19 vaccines. When she could not correct the clinical trial misconduct on her own, she reported the problems to the government. Within hours, she was fired. Rather than being seen as a hero for scientific integrity, she was one of the first victims of an unaccountable corrupt public-private partnership.

Relator discovered she could bring a *qui tam* action in the name of the United States to seek redress for the financial damages caused by Pfizer's fraud. As required by the Act, she filed her action under seal where it remained while Pfizer was alerted to the action and while the Government purported to conduct its own investigation. But seeing the overriding public interest in the underlying information on Pfizer's misconduct, Brook Jackson offered an interview to the

British Medical Journal, becoming the first person to publicly disclose the lack of scientific integrity in Pfizer's clinical trials.

Since then, an army of world-renowned and citizen scientists, along with medical practitioners, health freedom advocates and their attorneys have amassed overwhelming evidence and analysis supporting Brook Jackson's claim that Pfizer engaged in material fraud in the design, conduct, analysis, and reporting of the clinical trials. Before even a single document is obtained from Pfizer through formal discovery, Relator stands able to establish that Pfizer lied about its clinical trials to induce the FDA's authorization. Not only can she show that the modRNA products have no known or potential benefits, the evidence of known harms is staggering, and the potential for future harms is terrifying.

The evidence gathered by relator and her supporting band of researchers proves the specifics of her primary cause of action. Although Pfizer would have likely dragged its feet before producing its underlying clinical trial data, the courts expedited its release to the people, and that data has been subjected to a collective analysis. For example, as shown by the Cureus article (Exh. A), McCollough and his co-authors confirmed relator's allegations of specific ways the trials' design and conduct hid the truth. The study by Neil and colleagues at the University of London (Exh. C) confirms how the arbitrary categorizations, exclusions and inclusions revealed by Brook Jackson were the product of bias, and were responsible for the false reports of vaccine efficacy. And when Joseph Fraiman and his co-authors obtained and analyzed the trial data directly from NEJM, they found statistically significant higher serious adverse events in the vaccinated group as compared to the placebo group, demonstrating that Pfizer lied when it reported the events were "similar." *Compare* Fraiman Decl.; Exh. I (Fraiman *et al.*, "Serious adverse events of special interest following mRNA COVID-19 vaccination in randomized trials

in adults between vaccinated and placebo groups," *Vaccine*); *with* Exh. J (Polack et al., "Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine" *NEJM* (December 2020)).

Relator still desires and is entitled to discovery of Pfizer's own records and communications. However, in this extraordinary case, the immeasurable hard work of the People has advanced it to a point never before attained in a False Claims Act case, whether initiated under the *qui tam* provisions or by the Government itself.

### APPLICABLE LEGAL STANDARDS

In its motion, the DOJ seeks intervention here solely to move to dismiss triggering two False Claims Act provisions. First, under § 3730(c)(2)(A), the Act provides:

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 other provision of the statute is § 3730(c)(3), which provides for permissive intervention after the Government declines intervention in the case during the seal period. In relevant part, it 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.

Case law in this area is still developing. Some important questions were recently addressed and resolved by the Supreme Court in *United States ex rel. Polansky v. Exec. Health Res., Inc.*, 143 S. Ct. 1720, 1734 & n. 4 (2023), but others are unsettled. Applying existing case law and using normal rules of statutory and constitutional construction, this much can be said about legal standards applicable to the DOJ's motion:

<u>First</u>, the Government may not move to dismiss a *qui tam* action unless and until it intervenes and becomes a party. *See Polansky*, 143 S. Ct. at 1730 (§ 3730(c)(2) "applies only if the Government has intervened").

Second, the Government may request permissive intervention after passing on its "as-of-right" intervention during the seal period, but only upon a "showing of good cause." *See id.*, S. Ct. at 1728 ("the Government can intervene after the seal period ends, so long as it shows good cause to do so").

The Supreme Court in *Polansky* had no reason to construe what constitutes "showing of good cause" under § 3730(c)(2)(A), as that relator did not challenge that aspect of the lower courts' ruling. It did, however, recite what the Third Circuit had to say: "showing 'good cause' is neither a burdensome nor unfamiliar obligation," but instead "a uniquely flexible and capacious concept, meaning simply a legally sufficient reason." *Id.*, 143 S. Ct. at 1729 n. 2 (quoting *Polansky v. Exec. Health Res.*, 17 F.4th 376, 387 (3d Cir. 2021)). *And, see 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)).

Third, in exercising its discretion to permit a late intervention, courts look to Fed. R. Civ. Pro. 24, including subparagraph (b)(3), which requires consideration of prejudice to original parties. That is because parallels with the False Claims Act's intervention provisions "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) (citing *Rockwell Int'l Corp. v. United States*, 549 U.S. 457, 478 (2007)); *United States ex rel. Precision Co. v. Koch Indus., Inc.*, 31 F.3d 1015, 1017 (10th Cir. 1994); and *United States ex rel. Hall v. Schwartzman*, 887 F. Supp. 60, 62 (E.D.N.Y. 1995)).

The DOJ's motion should be denied under § 3730(c)(3) and Rule 24(b)(3) where permitting intervention will prejudice the relator's adjudicatory rights. *See United States v. AseraCare Inc.*, 2012 U.S. Dist. LEXIS 136059, at \*5 (N.D. Ala. Sep. 24, 2012) ("In deciding whether to allow a party to intervene, the court 'must consider whether the intervention will unduly delay *or* prejudice the adjudication of the original parties' rights'") (citing Rule 24(b)(3)) (emphasis supplied). Any good cause shown by the Government must be measured against the extreme prejudice to the relator's action should the DOJ be permitted to intervene.

Finally, the DOJ must not act inconsistently with the constitutional limits on Government action. *See Polansky*, 143 S. Ct. at 1734 n. 4 (citing Third Circuit *Polansky* decision, 17 F.4th at 387); *Borzilleri v. Bayer Healthcare Pharms., Inc.*, 24 F.4th 32, 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.

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.*]

Applying constitutional constraints, the Court must determine whether the Government's action would be "arbitrary in the constitutional sense," *i.e.*, whether it "violate[s] a right otherwise protected by the substantive Due Process Clause" and "shock[s] the conscience," or when government officials abuse their power and "employ[] it as an instrument of oppression" to the extent that it "shocks the conscience;" or when the Government "is attempting to perpetrate a fraud on the court." *Borzilleri*, 24 F.4th at 42-43 (citations omitted).

Courts always "possess[] the inherent power to deny the court's processes to one who defiles the judicial system by committing a fraud on the court." [*Id.* (citations omitted).]

Strict scrutiny applies when constitutional standards require it, for it is "beyond debate that the government could not dismiss a *qui tam* action if its decision to seek dismissal is based on an unjustifiable standard such as race, religion, or other arbitrary classification in violation of equal protection principles." *Id.* (citations and internal marks omitted). These constitutional principles apply not only to a motion to dismiss pursuant to § 3730(c)(2)(A) if the Government becomes a party, but also to a motion to intervene to dismiss under § 3730(c)(3). *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").

#### **ARGUMENT**

I. Permissive Intervention under § 3730(c)(3) Should Be Denied Because the Only Change in Circumstances Is the DOJ's Abandonment of Its Reasoned Policy for Seeking Dismissal Under § 3730(c)(2)(A)

The DOJ's motion to intervene should be denied because the only changed circumstances since the Government's declination decision is the DOJ's abdication of its reasoned policy for seeking dismissal under § 3730(c)(2)(A). As the Court in *Polansky* recognized, Congress enabled the Government to seek leave of Court to make a permissive post-seal period intervention when changed circumstances warrant a change in its intervention decision.

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*, 143 S. Ct. at 1733.]

This connection between a change in circumstances and a showing of good cause is recognized by the DOJ itself. In its January 10, 2018, internal guidance on "Factors for Evaluating Dismissal Pursuant to 31 U.S.C. 3730(c)(2)(A)" (the "Granston Memo"), the DOJ noted that "there may be cases where dismissal is warranted at a later stage, particularly when there has been a significant intervening change in the law or evidentiary record." (*See* Exh. K, at 8). The Granston Memo recognized that courts will be more "receptive" to requests for permissive intervention when made upon "significant intervening change," and when made in a way that does not undercut the DOJ's contentions regarding litigation discovery burdens. *Id*.

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 its repeated assertions it has 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." *Id*, at 2. Significantly, the Granston Memo reviewed 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. *See id.*, at 3-7. Each stated ground is exemplified by review of applicable case decisions.

Appearing to be a reasoned agency actor was important to retain constitutional authority in Article III courts and to hold off any loss of that authority through legislative action. This is made clear in the written exchange between the DOJ and Senator Grassley, author of the False Claims Act amendments and principal protector of the Act's functioning. *See* Exhs. L and M. 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." Exh. M, at 6.

Now, as executive agencies are losing credibility with the American people (and the courts) over the disastrous COVID-19 vaccination policies, they no longer act with the authority they had when the Granston Memo was issued. The only way those executives can protect themselves from future Brook Jacksons is to deter them from coming forward. If the Government can end Brook Jackson's clearly meritorious lawsuit over billions of taxpayer dollars, other brave and principled insiders will have no possible avenue to combat fraud when it undermines agency narratives, including the public health consequences of the forthcoming onslaught of experimental modRNA technology.

Ensuring potential future relators can effectively combat fraud was the premise of the 1986 amendments, which turned the False Claims Act into the "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 contradicts the premise of the False Claims Act, and would undermine its effective functioning. The suspected motive behind the request, and its unquestionable effect if

granted, would end important *qui tam* enforcement enacted to protect the federal fisc. And it would end the faith and hope in the American people who believe no one, including Pfizer backed by captured agencies, is above the law.

# II. Permissive Intervention under § 3730(c)(3) Should Be Denied Because DOJ Failed to Show Good Cause for Extreme Prejudice to Brook Jackson

The DOJ fails to articulate a coherent reason for dismissal of Brook Jackson's *qui tam* action, let alone make a "showing" of good cause. Unlike the other cases where intervention and dismissal was warranted, here the DOJ failed to put in *any* evidence or even a description of efforts to assess merits of the case or investigate its costs.

For example, in *Polansky*, the district court found that, after declination, actual "discovery burdens mounted and weighty privilege issues emerged," and the Government had "thoroughly investigated the cost and benefits of allowing [Polansky's] case to proceed and ha[d] come to a valid conclusion based on the results of its investigation." 143 S. Ct. at 1729 (emphasis supplied). Before the Supreme Court, Polansky did not even challenge the finding of "good cause" on that showing.

In *Brutus Trading, LLC v. Standard Chtd. Bank*, 2023 U.S. App. LEXIS 21868, at \*5 (2d Cir. Aug. 21, 2023), the government showed that the relator's "factual allegations were unsupported, its legal theory was not cognizable, and the continuation of the suit would waste considerable government resources." Relator's opposition presented "nothing more than a 'subjective disagreement' with the government's investigation and its ultimate decision as to Brutus's claims." *Id.*, at 7-8.

In *Borzilleri*, the Government showed that it had "carefully investigated Relator's claims" and "concluded that many key aspects of his allegations are not supported," that "continued litigation" was "likely to require substantial expenditure of government resources," and that the

relator "used the *qui tam* process to leverage his financial interests through securities trading." 24 F.4th at 38.

And, in *United States ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp.*, 151 F.3d 1139, 1142 (9th Cir. 1998), the government had already intervened on the basis of a representation that "it would litigate the *qui tam* actions . . . if a settlement could not be reached," and later moved to dismiss because it decided to "end the divisiveness in the citrus industry" and "to terminate protracted and burdensome litigation." Even there, the district court held a four-day evidentiary hearing on the request.

Not one factor is present here. There is no logic to the DOJ's incoherent contention that exposthe DOJ met with Relator but never advised her of any perceived deficiencies or burdens caused by her action. ing clinical trial fraud or holding Pfizer accountable for that fraud is "inconsistent with national health policy." Contrary to the guidance of the Granston Memo, Exh. K, at 8, the DOJ met with Relator but never advised her of any perceived deficiencies or burdens caused by her action. *See* Mendenhall Decl., ¶¶ 3-9. Indeed, it could not even explain how exposing fraud in the clinical trials was inconsistent with FDA policy, and clearly it is not. The opinions cited in the JAMA article – asserting demonstrably false facts that the vaccines have saved lives rather than stolen them – rely on the non-existent integrity of the clinical trials.

Plenty of suspected unstated and invalid reasons back the DOJ's effort: to deter future whistleblowers, to suppress truth about the harmful and ineffective Pfizer product, to protect Pfizer from accountability, and to save agency officials from embarrassment, financial loss or even criminal liability. Whether any of these motives are true, each would unquestionably result from the DOJ's action.

And, under considerations required by Rule 24(d)(3), none of the DOJ's "showing" can overcome the extreme prejudice to relator from intervention and dismissal. Under the good cause requirement of § 3730(c)(3) and the express requirement of Rule 24, the DOJ's motion must be denied.

# III. Permissive Intervention under § 3730(c)(3) Should Be Denied Because the DOJ's Motion Offends Fundamental Constitutional Rights

To show "good cause," the DOJ's motion to intervene and dismiss this *qui tam* action must pass constitutional muster. Here, the DOJ's motion survives neither strict scrutiny nor rational basis tests of the constitutional protection of equal protection, due process, the right to petition the government for redress of grievances, or the separation of powers.

# A. The DOJ's Content-Based Proposed Termination of Brook Jackson's Right to Petition the Government for Redress Has No Compelling Justification

In the *qui tam* provisions of the False Claims Act, Congress partially assigned 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*, 143 S. Ct. at 1727 (citing *Vermont Agency of Natural Resources v. United States ex rel. Stevens*, 529 U. S. 765, 771 (2000)). The DOJ's motion to intervene and dismiss the relator's case interferes with the right to petition—a right protected by the First Amendment to the United States Constitution. Because the motion is based on the content of Brook Jackson's case and is not justified by a compelling government interest, the motion must be denied.

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 Borough of Duryea*, *Pennsylvania v. Guarnieri*, 564 U.S. 379, 387 (2011) ("the Petition Clause protects the right of individuals to appeal to courts and other forums established by the government for resolution of legal disputes"). *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).

A 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 government's ability to permissibly restrict expressive activity in a public forum is very limited. 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 to intervene and terminate Brook Jackson's case fails this test. Rather than regulating the time, place and manner of expression, the DOJ seeks to end her assigned right to petition based on the content of her expression in her court case. Such "viewpoint" discrimination does not survive strict scrutiny. It is a speaker-based regulation which demands strict scrutiny because it reflects 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).

The DOJ could not, consistent with the First Amendment, silence Brook Jackson from talking about Pfizer's clinical trial fraud in the public square based on the content of her speech. 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). Its motion to terminate her petitioning activity based on content and viewpoints expressed in her lawsuit fails constitutional scrutiny.

### B. The DOJ's Motion Offends the 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 Brook Jackson's *qui tam* case is not on the literal "eve" of trial, she has amassed overwhelming proof of the merits of her claim that Pfizer engaged in clinical trial fraud material to issue an EUA under statutory standards. More importantly, the purpose to protect executive officials' personal interests cries out for close scrutiny of the DOJ's assertion of "good cause."

Deference to the executive agencies' interest to terminate this *qui tam* action would violate the separation of powers. These agencies may 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. And, deference to the agencies' determination to terminate this action would effect 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 passed the EUA statute with objective standards. Authorization for the vaccines could be lawful only if there was *reason to believe*, based on the totality of scientific evidence, that known and potential benefits may be outweighed by known and potential harms. FDA executives may have wanted Congress to give it authority to grant authorization even when such reasons failed, the law wisely invested the executive with power to act only based on objective reason. Combined with Pfizer's flawed contention on the motion to dismiss, the DOJ's motion to terminate the action would essentially retroactively re-write the statute to fit the agency's own purposes.

To protect against this disorder, the Court should make its own determination of "good cause" for the DOJ's motion. "After all, agency decisionmakers aren't insulated from politics and policymaking in the way Article III judges are." *De Niz Robles v. Lynch*, 803 F.3d 1165, 1175 (10th Cir. 2015) (citations omitted). To the extent the FDA wants the EUA statute to provide unfettered authority to authorize experimental drugs, it could try to gain such power through rule promulgation. "The function of filling in the interstices of the Act should be performed, as much

as possible, through this quasi-legislative promulgation of rules in the future." SEC v. Chenery Corp., 332 U.S. 194, 202 (1947)."

The same could be said about the False Claims Act. Congress amended the 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 the claim. *In re Nat. Gas Royalties ex rel. United States*, 562 F.3d 1023, 1030 (10th Cir. 2009). As shown by this case, government knowledge, acquiescence, or complicity in the fraud does not negate knowing material falsities committed by Pfizer. In this context, separation of powers concerns require close scrutiny and independent judgment of the DOJ's motion, and upon such inspection, permissive intervention should be denied.

### C. The DOJ's Motion is Arbitrary and Capricious, and Based on Fraud

Even if these more exacting constitutional standards are inapplicable, the motion should be denied based on substantive due process and equal protection grounds. The DOJ may not take such arbitrary and capricious actions, or perpetrate a fraud upon the Court. Its inability to articulate a coherent basis to dismiss Brook Jackson's meritorious and important *qui tam* action alone demonstrates the lack of a rational basis for its action. Moreover, to move to dismiss based upon a request for judicial notice of an opinion piece that falsely declares the vaccines saved millions of lives – contrary to true facts of devastating harm – is no less than an attempt to commit a knowing fraud upon the Court, and the People. Even if the Government was a party, its § 3730(c)(2)(A) motion would be denied.

#### CONCLUSION

For the foregoing reasons, the DOJ's motion to intervene to dismiss Brook Jackson's *qui* tam case should be denied.

### Respectfully submitted,

/s/ Lexis Anderson

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## **CERTIFICATE OF SERVICE**

I hereby certify that on this 19th day of April 2024 a true and correct copy of the foregoing document was filed electronically in compliance with Local Rule CV-5. All counsel of record consented to electronic service and are being served with a copy of this document through the Court's CM/ECF system under Local Rule CV-5(a)(3)(A).

/s/ Lexis Anderson