No. 25-1818

In the United States Court of Appeals for the Third Circuit

UNITED STATES OF AMERICA, ET AL., EX REL. JESSICA PENELOW AND CHRISTINE BRANCACCIO,

Plaintiffs-Appellees,

v.

JANSSEN PRODUCTS, LP,

Defendant-Appellant.

On Appeal from the United States District Court for the District of New Jersey, No. 3:12-cv-07758
The Hon. Zahid N. Quraishi

BRIEF OF *AMICUS CURIAE* THE NATIONAL ASSOCIATION OF MANUFACTURERS IN SUPPORT OF DEFENDANT-APPELLANT JANSSEN PRODUCTS, LP

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CORPORATE DISCLOSURE STATEMENT AND STATEMENT OF FINANCIAL INTEREST

Amicus curiae National Association of Manufacturers is a nonprofit, non-stock corporation. It has no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

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INTERESTS OF *AMICUS CURIAE*[1]

The National Association of Manufacturers (NAM) is the largest manufacturing association in the United States, representing small and large manufacturers in all fifty states and in every industrial sector. Manufacturing employs nearly 13 million people, contributes $2.9 trillion to the economy annually, has the largest economic impact of any major sector, and accounts for over half of all private-sector research and development in the nation, fostering the innovation that is vital for this economic ecosystem to thrive. The NAM is the voice of the manufacturing community and leading advocate for a policy agenda that helps manufacturers compete in the global economy and create jobs across the United States.

The *qui tam* system is spiraling out of control and, in the process, doing disproportionate harm to leading American companies, including members of the NAM. Although the NAM recognizes the importance of ensuring that the United States has strong, well-calibrated tools for deterring and punishing frauds against the public fisc, the *qui tam* provisions of the False Claims Act are not well-calibrated.

[1] Undersigned counsel state that no party's counsel has authored this brief in whole or in part; no party nor party's counsel contributed money that was intended to fund preparing or submitting this brief; and no person—other than amicus curiae, its members, or its counsel—contributed money that was intended to fund preparing or submitting the brief. *See* Fed. R. App. P. 29(a)(4)(E). All parties have consented to the filing of this brief.

Much of the systemic breakdown can be traced to the class of False Claims Act cases that the government does not dismiss or litigate itself, but instead allows a private relator to control. This case is one example. Janssen was hit with a *10-figure* verdict for supposedly defrauding the government when pharmacies submitted claims for allegedly off-label uses of drugs used to treat HIV. That nuclear verdict was imposed even though the government (i) does not prohibit doctors from writing prescriptions for off-label prescriptions, (ii) affirmatively recognizes that off-label treatment practices are critical for certain HIV patients, and (iii) acknowledges that Medicare Part D does not "preclude ... prescribers from prescribing drugs for off label indications, provided the drug is prescribed for a 'medically accepted indication.'" *See* Final Rule, 70 Fed. Reg. 4194, 4261 (Jan. 28, 2005). That outcome defies common sense and, as Janssen well explains, is completely out of line with precedents of the Supreme Court and this Court. The NAM writes to support Janssen's appeal and, more broadly, to emphasize the practical stakes involved for American manufacturers in this case and others like it.

INTRODUCTION AND SUMMARY

Three features of the current False Claims Act ecosystem are particularly important to understanding the real-world impact to American industry.

First, in non-intervened cases, relators often pursue claims based on theories of law that the government does not share or endorse. All too often, the relator's

theory leverages for private gain ambiguity, sometimes very slight, associated with vague or conflicting policy pronouncements. It is also commonplace that the relator's theory of the company's legal obligations has not been endorsed by the government. In some instances—like this case—government agencies and the Department of Justice have taken positions that are at odds with the "fraud" theory that the relator is nevertheless prosecuting. And yet the relators forge forward, knowing that the stakes may force companies to pay for even meritless claims.

Second, *qui tam* suits that the government declines to take over are usually meritless. By one study's account, 94 percent of non-intervened cases recover nothing. Such cases nevertheless impose heavy litigation costs on American businesses and sometimes result in settlements, which should not be surprising given the onerous financial risks of an adverse False Claims Act judgment (treble damages, civil penalties, exclusion from participation in government programs). There are other pathways to encourage whistleblowers to report wrongdoing to the government without imposing this kind of litigation drain on businesses.

Third, frivolous *qui tam* suits are bad for the economy and raise healthcare costs. The constant drumbeat of *qui tam* litigation is a significant and expensive distraction to American businesses. In the healthcare industry, FCA sanctions are now comparable to medical malpractice in terms of annual liability. For ordinary

Americans, overzealous FCA enforcement has meant higher healthcare costs, diverted tax dollars, and little to show in the way of improved care.

These features of today's False Claims Act environment are symptoms of an unconstitutional system in which financially motivated private parties, appointed by no one and unaccountable to the President and the public alike, have pushed aggressive legal theories at odds with the law and the public good. The Court should reverse, both because the verdict cannot be squared with the FCA's settled limits and because the *qui tam* provisions of the FCA are unconstitutional under Relator's expansive view.

ARGUMENT

I. Feature one: relators often pursue fraud claims based on theories of law that the Government does not share or endorse.

A. Relators routinely exploit legal and policy ambiguities.

An unavoidable fact of dealing with the modern administrative state is that much of the relevant law – whether it stems from statute, regulation, sub-regulatory guidance, order, contract, or some combination of the above – is "subject to multiple interpretations." *United States v. AseraCare, Inc.,* 938 F.3d 1278, 1299 (11th Cir. 2019).

The legal instruments that private parties must navigate in their relations with the federal government have been called "byzantine" (Agricultural Marketing Agreement Act of 1937) (*United States ex rel. Sequoia Orange Co. v. Sunland*

Packing House Co., 912 F. Supp. 1325, 1329 (E.D. Cal. 1995)), "onerous, "intricate" and "almost unintelligible" (the Social Security Act) (*Schweiker v. Gray Panthers*, 453 U.S. 34, 43 (1981) (citation omitted)), and "onerous and impenetrable" and "byzantine to the point of incomprehensibility" (government procurement rules) (Steven R. Koltai, *How the Healthcare.gov Mess Happened and How To Fix It*, Brookings Inst. (Nov. 25, 2013), https://brook.gs/3oaOkdr (referencing "onerous and impenetrable procurement rules"); David Freeman Engstrom, *Agencies as Litigation Gatekeepers*, 123 Yale L.J. 616, 672 n.180 (2013) (referencing "byzantine" two-thousand-page Federal Acquisition Regulations governing federal government procurement).

The False Claims Act's draconian damage and penalty provisions raise the stakes for companies facing those byzantine legal requirements by making liability "essentially punitive in nature." *Universal Health Servs., Inc. v. United States*, 579 U.S. 176, 182 (2016). An "army of whistleblowers, consultants, and, of course, lawyers" has descended into this target-rich environment. John T. Boese, *Civil False Claims and Qui Tam Actions*, at xxi (4th ed. 2011).

Examples are everywhere. In *United States ex rel. Health Choice Alliance, L.L.C. v. Eli Lilly & Co.*, for example, a for-profit, private investment group filed 11 substantially similar complaints against 38 pharmaceutical companies alleging defendants violated federal law by providing free patient education programs about

pharmaceuticals. 4 F.4th 255, 259 n.1 (5th Cir. 2021). As the Seventh Circuit held in a related case, the profit-driven litigation theory was contrary to "nine cited agency guidances, advisory opinions and final rulemakings" in which federal officials had "consistently held" that such patient support services were "[n]ot only lawful, but beneficial to patients and the public." *United States ex rel. Cimznhca, LLC v. UCB, Inc.*, 970 F.3d 835, 852 (7th Cir. 2020). The government declined to intervene and ultimately sought dismissal of the cases after determining that "further litigation ... will undermine practices that benefit federal healthcare programs by providing patients with greater access to product education and support." *Eli Lilly*, 4 F.4th at 267. And while the government's dismissal motion ultimately did end these cases, such meritless FCA cases can drag on for years at great expense.

In a similar vein, companies often face litigation stemming from statutory or contractual ambiguities when the relevant administrative agencies have not provided guidance about how the government itself understands the law. In *United States ex rel. Sheet Metal Workers International Ass'n, Local Union 20 v. Horning Investments, LLC*, 828 F.3d 587, 594 (7th Cir. 2016), a roofing subcontractor was sued under the False Claims Act for knowingly "violat[ing] the Davis-Bacon Act by deducting Trust contributions from the paychecks of employees whose rights to fringe benefits had not yet vested," even though the agency manual addressed only insurance plans, not trust contributions. Likewise, in *United States ex rel. Marshall*

v. Woodward, Inc., 812 F.3d 556, 562 (7th Cir. 2015), a helicopter manufacturer was sued over whether its brazed sensor joints met requirements over which there was a reasonable "difference in interpretation." And in *United States v. Sodexho, Inc.*, No. 03-6003, 2009 WL 579380, at *17 (E.D. Pa. Mar. 6, 2009), the case asked whether a contractor was required to credit supplier rebates to the government, even though the Office of Management and Budget and the relevant Office of Inspector General had "differing opinions" on the issue.

The government should and often does refrain from litigating False Claims Act cases like these. But the *qui tam* provisions allow relators to pursue enforcement for private profit even when the federal government has decided, in the exercise of its prosecutorial discretion, not to pursue an enforcement claim on its own.

That is what happened here. The United States and several states declined to intervene. *See* Appx19. That decision made sense in light of the government's own guidelines on HIV treatment. The Department of Health and Human Services (HHS) publishes the most influential, consensus-based HIV treatment guidelines in the country, reflecting the government's position on the standard of care. *See* Janssen Br. 7; Dkt. No. 187-1 at 9. The HHS guidelines not only included the two drugs at the center of this case, Prezista and Intelence, but also referenced data *supporting* their use in each of the ways that Relators claimed to be *unlawful*. Janssen Br. 7.

More than that, Relators have pressed a legal theory that is at odds with DOJ positions. Relators claim that Janssen's reimbursement claims were false because they misrepresented Janssen's compliance with laws prohibiting "off-label" marketing. Janssen Br. 18-19. But DOJ has previously taken a contrary position before this Court and the Ninth Circuit—arguing that off-label marketing does *not* automatically render reimbursement claims false. *Id.* at 22. This case thus demonstrates well an unfortunate feature of modern FCA litigation: private relators pushing legal theories that the government itself neither supports nor endorses.

B. This ecosystem creates perverse incentives and, as a result, has become overrun with professional relator suits.

The lure of big-dollar FCA verdicts has also spawned a sophisticated industry of professional relators. "*Qui tam* provisions were intended to expand the government's ability to prosecute wrongdoing directed at the government by rewarding informers; they were not primarily for the benefit of the informer." *Yates v. Pinellas Hematology & Oncology, P.A.*, 21 F.4th 1288, 1313 (11th Cir. 2021) (citation omitted). The proliferation of professional relators has undermined this traditional purpose and understanding—treating the whole *qui tam* system as a virtual casino, taking one spin of the wheel after another in pursuit of private investment gain.

Relators sometimes even form special purpose corporate entities for the purpose of organizing ownership shares and administering and funding False Claims

Act litigation. *UCB, Inc.*, 970 F.3d at 839. And, unlike traditional whistleblowers (who may bring to light information that would be otherwise inaccessible to the government), professional relators often bring claims based on data that has been mined from publicly available sources. *See*, *e.g.*, *Eli Lilly*, 4 F.4th at 259 & n.1 (collecting cases brought by affiliated professional relator entities based largely on public-source data mining operations). The False Claims Act's public disclosure bar provides important protection against derivative claims such as these, but it does not entirely resolve the concern, as companies must still pointlessly incur defense costs even when the public disclosure bar ultimately shuts down such relator-driven claims.

The financial incentives created by the *qui tam* device also promote misconduct. In one instance, a federal district court concluded that a relator's legal team "devised and implemented an elaborate scheme of misrepresentation and deceit under the guise of a legitimate medical research study … solely for the purpose of ensuring that the complaint survived a motion to dismiss." *Leysock v. Forest Labs., Inc.*, No. 12-11354, 2017 WL 1591833, at *12–13 (D. Mass. Apr. 28, 2017). In another, the Second Circuit held that a company's former general counsel used confidential information to bring a *qui tam* action against his former employer in violation of the ethical rule against "side-switching." *United States v. Quest Diagnostics Inc.*, 734 F.3d 154, 157–58, 161 (2d Cir. 2013). And the Fifth Circuit

dismissed a *qui tam* claim brought by an attorney who was attempting to use information he had obtained through another litigation matter as the basis of his claim. *United States ex rel. Holmes v. Northrop Grumman Corp.*, 642 F. App'x 373, 375–76 (5th Cir. 2016) (per curiam).

None of this should be allowed, much less incentivized. Reversing the runaway verdict here would be a step in the right direction.

II. Feature two: most non-intervened suits lack merit.

Some people say that non-intervened *qui tam* suits are worth the costs because False Claims Act defendants sometimes settle them, resulting in recovery for the government. But this ignores the government's loss of prosecutorial discretion in choosing which cases to bring to best serve the interests of good governance. And of course, as noted above, settlements do not imply that the underlying claims had merit; defendants often have incentives to settle meritless claims.

Moreover, the data shows that cases the government pursues are far more likely to lead to significant recoveries. As an initial matter, government intervention results in settlement or recovery around 90 percent of the time, while only 10 percent of non-intervened cases result in recovery. *United States ex rel. Hunt v. Cochise Consultancy, Inc.*, 887 F.3d 1081, 1087–88 (11th Cir. 2018) (citing David Freeman Engstrom, *Public Regulation of Private Enforcement: Empirical Analysis of DOJ Oversight of Qui Tam Litigation Under the False Claims Act*, 107 Nw. U. L. Rev.

1689, 1720–21 (2013)), *aff'd*, 587 U.S. 262 (2019). Indeed, "[t]he DOJ's failure to dismiss non-meritorious qui tam actions more frequently has resulted in 94% of non-intervened qui tam suits (more than 3,000 in all over the last twenty years) recovering no funds." Michael Rich, *Prosecutorial Indiscretion: Encouraging the Department of Justice to Rein in Out-Of-Control Qui Tam Litigation Under the Civil False Claims Act*, 76 U. Cin. L. Rev. 1233, 1236 (2008).

Other studies suggest that the strong correlation between government intervention and recovery has persisted for many years. *See, e.g.*, David Kwok, *Evidence From the False Claims Act: Does Private Enforcement Attract Excessive Litigation?*, 42 Pub. Cont. L.J. 225, 237 (2013) ("DoJ's published data demonstrate that relators and their law firms do not have a good track record in successfully litigating nonintervened cases."); Christina Orsini Broderick, *Qui Tam Provisions and the Public Interest*, 107 Colum. L. Rev. 949, 971 (2007) (demonstrating "much support for the assumption that the Attorney General will intervene when a suit has merit"); Tiffany Li, *Government Control over Qui Tam Suits and Separations of Powers*, 42 Yale J. on Reg. 383, 434 (2025) (recommending ways for DOJ to ensure fewer meritless *qui tam* suits proceed in the name of the government).

The disparities between intervened and non-intervened cases have not stopped the *qui tam* suits from coming. The 979 *qui tam* actions brought in 2024 represent a 61 percent increase over the 598 actions brought in 2021. U.S. Dep't of Just., *Fraud*

Statistics—Overview: Oct. 1, 1986-Sept. 30, 2024 at 2 (2025), https://tinyurl.com/5xrdk868. Meanwhile, the total fraud recovery by the government in 2024 was barely half of the 2021 all-time-high of $5.6 billion. *Id.*

This case has many of the hallmarks of meritless cases that have become a feature of the FCA ecosystem. The government has been aware of relators' allegations for more than a decade. Janssen Br. 25. Yet the government continues to pay for lifesaving Preszista and Intelence prescriptions. *Id*. The FDA has not instituted any adverse proceedings against Janssen for its promotion of the drugs at issue in this case, nor has it otherwise limited the medically accepted indications for those drugs. *Id*. Even still, a private relator has taken the case all the way to an unprecedented $1.64 billion judgment.

III. Feature three: frivolous qui tam suits are bad for the economy and raise healthcare costs.

Frivolous *qui tam* litigation is "downright harmful" to legitimate business interests. *Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280, 298 (2010).

The reasons why are well known, but worth repeating. Such suits are expensive and time-consuming to defend. Relators know that even meritless allegations can "be used to extract settlements." Sean Elameto, *Guarding the Guardians: Accountability in Qui Tam Litigation Under the Civil False Claims Act*, 41 Pub. Cont. L.J. 813, 824 (2012). That is so because even the most tenuous False

Claims Act allegations "can do great damage to a firm," *United States ex rel. Grenadyor v. Ukrainian Vill. Pharmacy, Inc.*, 772 F.3d 1102, 1105–08 (7th Cir. 2014), thereby creating settlement leverage. *See* Dayna Bowen Matthew, *The Moral Hazard Problem with Privatization of Public Enforcement: The Case of Pharmaceutical Fraud*, 40 U. Mich. J.L. Reform 281, 314 (2007) (observing this trend in federal False Claims Act litigation).

The resulting constant drumbeat of qui tam litigation distracts corporations across a wide array of industries from innovating, serving their customers, and returning profits to their shareholders.

The healthcare industry is a frequent target of FCA claims, and healthcare cases have dominated the largest awards. *See* Benjamin J. McMichael et al., *A Constitutional False Claims Act*, 102 Wash. U. L. Rev. 677, 701 (2025). Since the mid-2010s, for example, FCA sanctions have been comparable to medical malpractice damages in the healthcare system, and they even exceeded malpractice damages in one year. *Id*. at 703–04. Overzealous FCA enforcement has thus added "a huge cost burden to the American health care system." U.S. Chamber of Com. Inst. for Legal Reform, *An Easy Way to Reduce Health Care Costs: Fix FCA Lawsuits* (Aug. 16, 2022). That affects everyone in the industry: FCA penalties can have devastating effects, for example, on "rural physician practices, nonprofit

hospitals, and other providers that may not have sufficient compliance staff to avoid lawsuits or the funds to defend against them." *Id*.

In the pharmaceutical industry, FCA liability has similarly meant that less time and fewer resources are available to develop and seek regulatory approval for life-saving and life-altering treatments. Indeed, relator claims are a persistent problem for pharmaceutical companies, who, by virtue of operating in an industry in which expanding government programs have established government entities as large purchasers and payors, have become more likely than their counterparts in any other industry to face *qui tam* settlements exceeding $10 million. Tammy W. Cowart et al., *Carrots and Sticks of Whistleblowing: What Classification Trees Say about False Claims Act Lawsuits*, 17 ALSB J. Emp. & Lab. L. 1, 13, 15 (2019) (analyzing claim data for the decade ending 2014).

All Americans share in the cost of frivolous *qui tam* suits. Sometimes, the cost to taxpayers is borne directly, as Federal Acquisition Regulations allow cost-based government contractors to pass up to 80% of their legal expenses back to the government when they successfully defend against non-intervened *qui tam* claims. See 48 C.F.R. § 31.205-47(a)(3), (e). In addition, "significantly increasing competitive firms' cost of doing federal government business[] could result in the government's being charged higher, not lower, prices." *United States v. Data Translation, Inc.*, 984 F.2d 1256, 1262 (1st Cir. 1992) (Breyer, C.J.). Or, the threat

of *qui tam* suits may discourage firms from doing business with the government at all, leading to decreased competition, higher prices, and fewer options for service provision in critical areas like healthcare and defense. *See, e.g.*, U.S. Dep't of Just., *Memorandum from Michael D. Granston, Dir., Com. Litig. Branch, Fraud Section,., to Atty's, Com. Litig. Branch, Fraud Section* at 5 (Jan. 10, 2018), https://tinyurl.com/3r546ten ("[T]here may be instances where an action is both lacking in merit and raises the risk of significant economic harm that could cause a critical supplier to exit the government program or industry.")

All of this is, as the Supreme Court put it, "downright harmful" to the NAM's members and to the U.S. economy. *Graham Cnty.*, 559 U.S. at 298.

CONCLUSION

For the foregoing reasons, and those stated by Janssen, the Court should reverse or, at a minimum, vacate and remand for a new trial.

Date: July 21, 2025

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitations of Federal Rules of Appellate Procedure 29(a)(5) and 32(a)(7)(B) and the Rules of this Court, because it contains 3414 words (as determined by the Microsoft Word word-processing system used to prepare the brief), excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f).

This brief complies with the typeface and type style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6). The brief has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Times New Roman font.

Pursuant to Local Rule 31.1(c), the undersigned also certifies that the text of the electronic brief is identical to the text in the paper copies.

Date: July 21, 2025

/s/ Kwaku A. Akowuah
Kwaku A. Akowuah

CERTIFICATE OF SERVICE

I hereby certify that on July 21, 2025 a true and correct copy of the foregoing was timely filed with the Clerk of the Court using the appellate CM/ECF system, which will send notifications to all counsel registered to receive electronic notices.

Date: July 21, 2025.

/s/ Kwaku A. Akowuah
Kwaku A. Akowuah

CERTIFICATE OF VIRUS SCAN

I hereby certify, pursuant to Local Rule 31.1(c), that a virus scan detection program has been run on the file of the electronic version of this brief and that no virus was detected. The virus detection program is CrowdStrike v7.26.

Date: July 21, 2025.

/s/ Kwaku A. Akowuah
Kwaku A. Akowuah

CERTIFICATE OF BAR MEMBERSHIP

Pursuant to Local Rule 28.3(d), I hereby certify that I am a member in good standing of the Bar of this Court. Pursuant to 28 U.S.C. § 1746, I certify under penalty of perjury that the foregoing is true and correct.

Date: July 21, 2025.

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