No. 21-1052

IN THE

Supreme Court of the United States

UNITED STATES OF AMERICA, EX REL.
JESSE POLANSKY, M.D., M.P.H.,

Petitioner,

v.

EXECUTIVE HEALTH RESOURCES, INC., ET AL.,

Respondents.

On Writ of Certiorari
To the United States Court of Appeals
For the Third Circuit

BRIEF OF PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

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QUESTION PRESENTED

Whether the Government may dismiss a suit under the False Claims Act, 31 U.S.C. § 3729 *et seq.*, after initially declining to proceed with the action, and what standard applies if the Government has that authority?

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

TABLE OF AUTHORITIES *(continued)*

TABLE OF AUTHORITIES *(continued)*

Constitutional Provisions

Statutes

Regulations

TABLE OF AUTHORITIES *(continued)*

TABLE OF AUTHORITIES *(continued)*

TABLE OF AUTHORITIES *(continued)*

INTEREST OF *AMICUS CURIAE*[1]

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary, nonprofit association representing the country's leading research-based pharmaceutical and biotechnology companies. PhRMA's mission is to advocate public policies encouraging innovation in life-saving and life-enhancing new medicines. PhRMA's members invent medicines, including new cures, that allow patients to live longer, healthier, and more productive lives. Since 2000, PhRMA's members have invested more than $1 trillion in the search for new treatments and cures—including $91.1 billion in 2020 alone. PhRMA frequently participates as *amicus curiae* in cases like this one that affect is members.

Various federal healthcare programs, including Medicare and Medicaid, provide reimbursement for the cost of medicines developed by PhRMA's members. Federal spending on prescription drugs is substantial. In 2020, Medicare, Medicaid, and other federal healthcare programs paid $156.7 billion for prescription drugs. NHE Table 16: Retail Prescription Drug Expenditures, Centers for Medicare & Medicaid Services (Aug. 12, 2022), https://www.cms.gov/files/zip/nhe-tables.zip.

Because healthcare providers and pharmacies submit billions of dollars of claims for reimbursement of prescription drugs for patients covered by federal healthcare programs to the Government each year,

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[1] Pursuant to Supreme Court Rule 37.6, no counsel for a party authored this brief in whole or in part, and no person or entity other than *amicus* or its counsel made a monetary contribution to this brief's preparation. All parties have consented in writing to the filing of this brief.

companies in the pharmaceutical industry are magnets for private plaintiffs known as *qui tam* relators who allege fraud on the Government. If successful, these relators may be awarded as much as 30% of the proceeds of a False Claims Act ("FCA") action. Cases involving healthcare services and products—including prescription drugs—comprise the majority of FCA actions brought each year. In 2021, settlements and judgments in FCA healthcare cases topped $5 billion, comprising 90% of total FCA recoveries. *See* U.S. Dep't of Justice, Fraud Statistics (Feb. 1, 2022), https://www.justice.gov/opa/press-release/file/1467811/download.

In some instances, relators rightly identify fraud and abuse in the healthcare sector. However, the prospect of massive FCA proceeds and associated *qui tam* bounties incentivizes many relators to bring specious suits targeting legitimate, lawful conduct. Each year, hundreds of questionable FCA claims are filed against healthcare companies, including PhRMA's members, and declined by the Government, and these claims threaten beneficial activities by pharmaceutical companies and drive up healthcare costs. FCA claims impose significant litigation burdens on both pharmaceutical companies and the Government. PhRMA's members therefore have a substantial interest in the interpretation of the FCA, and the Government's ability to dismiss FCA actions.

SUMMARY OF ARGUMENT

The False Claims Act, 31 U.S.C. § 3729 *et seq.*, allows private *qui tam* relators to challenge alleged fraud against the Government by bringing suit on behalf of the United States and seeking treble damages and per-claim penalties for the Government, as well

as a bounty for the relator, attorneys' fees, and costs in connection with any recovery.

The FCA's plain text gives the Government virtually unfettered discretion to move for dismissal of a *qui tam* suit at any time. Petitioner in this case, Relator Jesse Polansky, argues that the Government can dismiss only when it has intervened at the outset of a suit. But his construction of the FCA has not been adopted by any court of appeals, reads verbiage into the statute, and presents problems under the Take Care Clause and separation of powers principles.

Because FCA suits can generate massive settlements and judgments, they attract both legitimate whistleblowers and opportunistic relators looking for a windfall. This is particularly true in the healthcare industry, including the pharmaceutical sector, from which the majority of FCA recoveries result. Companies in this industry must make extensive reports and certifications to federal administrators, and some relators have exploited this regulatory environment to advance extreme "implied certification" and other theories that extend beyond any traditional understanding of fraud and magnify the threat of massive damages. For any FCA claim to survive, it must pass "rigorous" materiality and scienter requirements. *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 192 (2016). But litigating these elements—which may hinge on evidence about what the Government knew and when—can require fact development beyond the pleading stage.

The Government's unfettered authority to dismiss FCA cases is vitally important in ensuring that relators do not prosecute FCA actions in the Government's name that are, or become, adverse to the Government's interests. Often the merits and burden of a *qui*

tam suit, along with its potential for interference with other Government prerogatives, will not be fully apparent at the outset of litigation, as this case illustrates. In these situations, among others, the Government must have authority to compel the dismissal of cases in which it previously declined to intervene.

Given the potential for exorbitant awards, the significant costs of discovery and litigation, and the negative public effects of being accused of fraud, there is tremendous settlement pressure on healthcare defendants. Thus, it is crucial to PhRMA's members that the Government have broad discretion to dismiss unmeritorious relator suits throughout the litigation whenever the Government determines that the litigation is no longer in the United States' interests.

ARGUMENT

I. THE FCA'S TEXT AND HISTORY PERMIT THE GOVERNMENT TO DISMISS A RELATOR'S SUIT AT ANY TIME.

As every circuit to address the issue has concluded, the Government may move to dismiss a *qui tam* relator's FCA suit even after declining to intervene in the suit initially. The plain text and history of the FCA compels this conclusion. Furthermore, the FCA's text and history show that the Government's dismissal discretion is virtually unfettered. It serves as an important check on potential abuses by relators and helps ensure that FCA cases do not proceed against the Government's interests.

A. The Statutory Background And History Show The Importance Of Executive Control Over *Qui Tam* Suits.

First enacted in 1863, the FCA "was originally aimed principally at stopping the massive frauds perpetrated by large [military] contractors during the Civil War." *Escobar*, 579 U.S. at 181 (quoting *United States v. Bornstein*, 423 U.S. 303, 309 (1976)). "[A] series of sensational congressional investigations" revealed that "the United States had been billed for nonexistent or worthless goods, charged exorbitant prices for goods delivered, and generally robbed in purchasing the necessities of war." *United States v. McNinch*, 356 U.S. 595, 599 (1958). The original Act provided for the Government to seek civil and criminal penalties against those who submitted false claims and also allowed private plaintiffs known as relators to sue on behalf of the United States. S. Rep. No. 99-345, at 7, 10 (1986).

The FCA was amended in 1943 to prevent relators from suing or obtaining recovery based on information the Government already possessed, even if the relator was the original source of the information. *See* Pub. L. No. 78-213, ch. 377, 57 Stat. 608 (1943). The amendment was a compromise between the House and Senate after Attorney General Francis Biddle asked Congress to repeal the *qui tam* provisions, and the House voted to do just that. *See* S. Rep. No. 99-345, at 11. The ensuing jurisdictional "government knowledge" bar significantly limited the abilities of relators. *See id.* at 12.

Congress overhauled the FCA in 1986 to "encourage more private enforcement suits." S. Rep. No. 99-345, at 23-24. Congress eliminated the jurisdictional bar, increased damages from double to treble awards,

and raised the civil penalty ceiling up to approximately $25,000 per violation (after adjustments for inflation). 31 U.S.C. § 3729(a)(1); 28 C.F.R. § 85.5 (2022).

Under the amended Act, if a relator brings suit and the Government intervenes and proceeds with it, the relator may obtain 15% to 25% of the recovery. 31 U.S.C. § 3730(d)(1). If the Government does not proceed with the suit, the relator may be awarded 25% to 30% of the recovery. *Id.* § 3730(d)(2). Previously, a relator received 10% of the recovery if the Government took over, and 25% of the recovery if the relator litigated alone. *See* S. Rep. No. 99-345, at 27-28. The 1986 amendments' increased awards, combined with the treble damages provisions, allow relators to obtain sizeable bounties. For example, if actual damages before trebling were $1,000, relators could obtain up to $900.

Before the 1986 amendments, if the Government intervened in the litigation, the relator was removed, and the action was "controlled solely by the Government." S. Rep. No. 99-345, at 25. Instead of an "'all or nothing' proposition both for the person bringing the action and for the Government," the revised statute allows both relators and the Government to be involved simultaneously. *Id.* Where "the Government proceeds with the action, it shall have the primary responsibility for prosecuting the action," but the relator "shall have the right to continue as a party," subject to certain limitations. 31 U.S.C. § 3730(c)(1). Where the Government does not initially "proceed with the action," it may "intervene at a later date upon a showing of good cause." *Id.* § 3730(c)(3).

The expanded role and incentives for relators led the Department of Justice to "expres[s] concerns that

the broadening of *qui tam* provisions … might provoke a greater number of frivolous suits." S. Rep. No. 99-345, at 16. But the revised FCA also included another important protection for the Government—the provision at issue here:

> 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.

31 U.S.C. § 3730(c)(2)(A). Altogether, the "broadening [of] the government's powers of intervention," along with its expanded "supervisory powers" and dismissal authority have "increased, rather than decreased, executive control over qui tam lawsuits." *United States ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp.*, 151 F.3d 1139, 1144 (9th Cir. 1998).

B. The Plain Text And Statutory Context Give The Government Virtually Unfettered Dismissal Authority.

Polansky contends that the Government can dismiss a suit under § 3730(c)(2)(A) only when it has initially chosen to proceed with the action. *See* Pet. Br. 14-31. But this position is at odds with the statutory text, and no court of appeals has adopted it. Properly construed, § 3730(c)(2)(A) gives the Government an "unfettered" right to "dismiss [the] action notwithstanding the objections" of the person initiating the action if it complies with certain procedural requirements (notice and an opportunity to be heard). *Swift v. United States*, 318 F.3d 250, 251-52 (D.C. Cir. 2003) (citation omitted). "Regardless" of whether the United States initially proceeds with the action, "it retains

the right at any time to dismiss the action entirely." *Kellogg Brown & Root Servs., Inc. v. United States ex rel. Carter*, 575 U.S. 650, 653 (2015).

To conclude otherwise, Polansky effectively reads § 3730(c)(2)(A) as a subset of § 3730(c)(1), which applies "[i]f the Government proceeds with the action." *See* Pet. Br. 17-18. In so doing, Polansky makes two related errors.

First, he assumes that because § 3730(c)(1) references the "right" "of the person bringing the action … to continue as a party to the action, subject to the limitations set forth in paragraph (2)," paragraph (2) only applies when paragraph (1) has been triggered—*i.e.*, when the Government has "proceed[ed]" with the action. But, as a structural matter, each of the numbered paragraphs under subsection (c), which sets forth the "[r]ights of parties to qui tam actions," stands alone. 31 U.S.C. § 3730(c). Tellingly, Polansky does not argue that paragraph (3) of subsection (c), which governs when "the Government elects not to proceed with the action," applies only when the Government has "proceed[ed] with the action" under paragraph (c)(1)—that would make no sense. *Id.* And logically, paragraph (c)(1)'s reference to paragraph (c)(2) does not mean that (c)(2) is limited only to the circumstances of (c)(1). Because of their structural independence, there is good reason to conclude—as the D.C., Ninth, and Tenth Circuits have done—that intervention is not necessary for the Government to dismiss the action. *See Ridenour v. Kaiser-Hill Co.*, 397 F.3d 925, 934-35 (10th Cir. 2005); *Swift*, 318 F.3d at 252; *Sequoia Orange Co.*, 151 F.3d at 1145.[2]

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[2] Nonetheless, whether the Government must intervene before moving to dismiss a suit is "largely academic." *Swift*, 318 F.3d

But even if intervention is required, as the Third Circuit held, Polansky mistakenly assumes that the Government "proceeds with the action" only when it *initially* proceeds with the action, not when it later intervenes. This is Polansky's second error. As the Third Circuit rightly concluded, there is no such limitation in the text. *See* Pet. App. 15a-16a. The statute allows the Government to "intervene and proceed with the action within 60 days" after receiving the complaint, 31 U.S.C. § 3730(b)(2), and allows "the Government to intervene at a later date upon a showing of good cause," *id.* § 3730(c)(3). Regardless of when the Government intervenes, it is beyond serious dispute that once it has done so, the Government is *proceeding* with the action. *See Sequoia Orange Co.*, 151 F.3d at 1145.

Polansky puts great weight on the language in paragraph (c)(3) providing that a court should not "limi[t] the status and rights of the person initiating the action" when it allows the "Government to intervene at a later date." 31 U.S.C. § 3730(c)(3); *see* Pet. Br. 15-16. But especially considering that the statute's prior version removed the relator entirely when the Government intervened, it is most natural to read this requirement as a counterpart to paragraph (c)(1)—*i.e.*, when the Government "proceeds with the action," the person initiating the action "shall have the right to continue as a party to the action, subject

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at 252. As the Third Circuit concluded below, and the D.C. and Seventh Circuits have recognized, a separate intervention motion is unnecessary because a motion to dismiss can be construed as a motion for intervention. *See* Pet. App. 28a; *United States ex rel. CIMZNHCA, LLC v. UCB, Inc.*, 970 F.3d 835, 849 (7th Cir. 2020); *Swift*, 318 F.3d at 252. Where the Government has reason to dismiss, there will almost certainly be "good cause" for intervention. Pet. App. 28a.

to the [Government's dismissal authority] set forth in paragraph (2)." Stated differently, where the Government intervenes at a later date, the relator "retains the same status and rights as if the Government originally intervened." Pet. App. 16a-17a; *see also UCB, Inc.*, 970 F.3d at 854 ("The better reading is that § 3730(c)(3) instructs the district court not to limit the relator's 'status and rights' as they are defined by §§ 3730(c)(1) and (2).").

Notably, under Polansky's reading, if a relator's right to continue with the suit cannot be limited when the Government intervenes at a later date, then the other "limitations" in paragraph (c)(2) would not apply either. The Government could not settle the action or ask the court to limit the relator's ability to present evidence or participate in the litigation because of repetition, irrelevance, "harassment," "undue burden or unnecessary expense." 31 U.S.C. § 3730(c)(2)(B)-(D). But "[n]othing" "purports to limit" the Government's authority under § 3720(c)(2) "based upon the manner of intervention." *Sequoia Orange Co.*, 151 F.3d at 1145.

Moreover, if a relator has an unbounded right to prosecute the action when the Government intervenes at a later date, it is unclear what the Government could do. Normally, under the Federal Rules of Civil Procedure, an "intervenor is treated as if the intervenor were an original party and has equal standing with the original parties." 7C Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 1920 (3d ed. 2022). For example, "[t]he intervenor may move to dismiss the proceeding and may challenge the subject-matter jurisdiction of the court." *Id.* (footnote omitted); *cf. SEC v. U.S. Realty & Improvement Co.*, 310 U.S. 434, 458-60 (1940) (holding that

Securities and Exchange Commission could intervene and move to dismiss Chapter XI bankruptcy proceeding). And there are many other actions an intervenor could take under the Rules—including requests to limit discovery—that could impinge on a relator's ability to conduct a suit. It would be passing strange to deny these rights to the party (the United States) in whose name the litigation was brought and whose injury is the basis for the suit.

Preventing the Government from exercising default party rights under the Federal Rules of Civil Procedure—in addition to limiting its statutory rights under § 3730(c)(2)—also would raise serious concerns under the Take Care Clause and separation of powers principles, as Respondent Executive Health Resources, Inc. has explained. *See* U.S. Const. art. II, § 1, cl. 1; *id.* art. II, § 3; EHR Br. 23-35; *cf. Ridenour v. Kaiser-Hill Co.*, 397 F.3d 925, 934 (10th Cir. 2005). If the Government, which unquestionably remains "the real-party-in-interest in any False Claims Act suit," *United States v. Health Possibilities, P.S.C.*, 207 F.3d 335, 341 (6th Cir. 2000) (citation omitted), cannot even exercise the normal rights of a party intervening under Rule 24, it is not at all apparent that the President can "take Care that the Laws be faithfully executed," U.S. Const. art. II, § 3; *see also id.* art. II, § 1, cl. 1 (vesting "executive Power" in the President). For this reason, under the canon of constitutional avoidance, the Court should reject Polansky's argument that a relator's rights to maintain a suit are unbounded—by either statute or rule—when the Government intervenes at a later date. *Cf. Swift*, 318 F.3d at 253 (discussing Government's discretion to bring or continue suit under the Take Care Clause).

Instead, it should hold that the relator's right to maintain the action—regardless of when the Government becomes involved—is subject to all of the limitations "set forth in paragraph (2)." 31 U.S.C. § 3730(c)(1).

For similar reasons, the Court also should hold that the Government's power of dismissal is virtually "unfettered," *Swift*, 318 F.3d at 252, subject only to the procedural requirements spelled out in the statute, *see* 31 U.S.C. § 3730(c)(2)(A). The FCA contains no language substantively limiting the Government's dismissal authority, and there is no basis to infer any limitations here.[3] EHR Br. 16, 47-48. The Ninth Circuit has invented a two-step analysis for dismissal under which the Government must (1) identify a "valid government purpose," and (2) show "a rational relation between dismissal and accomplishment of the purpose," before the burden shifts to the relator "to demonstrate that dismissal is fraudulent, arbitrary and capricious, or illegal." *Sequoia Orange Co.*, 151 F.3d at 1145 (citation omitted); *see also Ridenour*, 397 F.3d at 936 (adopting this standard). The Court should reject that rational-relation test, which lacks textual support or foundation. Consistent with the Government's broad authority under § 3730, buttressed by separation of powers principles, the Court should hold that where the Government has provided notice to the relator and the opportunity for a hearing,

[3] Of course, there may be constitutional and judicial limits to the Government's dismissal authority in extreme factual scenarios not presented here. *See Borzilleri v. Bayer Healthcare Pharms., Inc.*, 24 F.4th 32, 42-43 (1st Cir. 2022) (discussing Equal Protection and fraud on the court).

it may dismiss the case. *See* 31 U.S.C. § 3730(c)(2)(A).[4]

II. THE GOVERNMENT'S DISMISSAL AUTHORITY PROTECTS AGAINST MERITLESS AND UNDULY BURDENSOME FCA LITIGATION.

The 1986 revisions to the FCA have led to a "drastic increase in qui tam actions." Christina Orsini Broderick, Note, *Qui Tam Provisions and the Public Interest: An Empirical Analysis*, 107 Colum. L. Rev. 949, 955 (2007). In 1987, relators filed 31 *qui tam* suits; in 2021, they filed nearly twenty times as many (598). U.S. Dep't of Justice, Fraud Statistics, https://www.justice.gov/opa/press-release/file/1467811/download. With the explosive growth of *qui tam* suits, spurred by the potential for high-dollar recoveries, spurious litigation also has increased. Against this backdrop, the Government's dismissal authority has been an important—albeit carefully exercised—protection. In recent years, the Government has moved to dismiss only approximately 3.85% of *qui tam* cases.[5]

To protect against meritless and burdensome litigation, the Government must be able to exercise this dismissal authority throughout the litigation, not just

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[4] *Amicus* takes no position on whether the requirements of Federal Rule of Civil Procedure 41(a) also apply to such dismissal, as the Third Circuit concluded. Pet. App. 25a-27a. Although the Rules generally apply to FCA actions, Rule 41 does not neatly map onto the dismissal authority codified in § 3730(c)(2)(A). *See, e.g.*, *Borzilleri*, 24 F.4th at 41.

[5] *See* U.S. Dep't of Justice Letter to The Honorable Charles E. Grassley at 1 (Dec. 19, 2019) (explaining that from January 1, 2018 through October 25, 2019, 1,170 *qui tam* actions were filed, and the Department moved to dismiss 45 of them).

at the outset. The Government has specified its criteria for exercising this authority; these criteria often do not become clear until after discovery. For example, the suit's merit (or lack thereof), costs to the Government, and public policy often are not apparent until later in the litigation. The potential for abuse is particularly pronounced in healthcare-related FCA actions where ongoing protection of the public interest is paramount. Unnecessary litigation distracts the Government from its overarching goal of protecting and promoting public health, and it bleeds resources from private healthcare providers and pharmaceutical companies that would otherwise help ensure that patients receive lifesaving care and treatment. It also potentially puts into the hands of a lay relator decisions about complex clinical regulatory matters that underlie the FCA allegations. In this context, the Government has repeatedly dismissed suits in which it initially chose not to intervene, and it should be allowed to continue to do so.

A. An FCA Suit's Viability May Not Be Apparent Until Discovery Commences.

In 2018, Michael Granston, then the Director of the Fraud Section of the Civil Division of the Department of Justice, issued a memo setting forth a "general framework" for "when to seek dismissal under section 3730(c)(2)(A)." Michael D. Granston, U.S. Dep't of Justice, Factors for Evaluating Dismissal Pursuant to 31 U.S.C. 3730(c)(2)(A), at 2 (Jan. 10, 2018) ("Granston Memo"). The Granston Memo set forth seven factors—with specific case examples—for when Department attorneys should consider dismissal. *See id.* These factors, which the Government had already been employing after decades of litigation,

were subsequently incorporated into the Justice Manual. *See* U.S. Dep't of Justice, Justice Manual, § 4-4.111 (2021).[6]

The first factor is "[c]urbing [m]eritless *[q]ui [t]ams*," and the Granston Memo urges dismissal whenever a "*qui tam* complaint is facially lacking in merit—either because [the] relator's legal theory is inherently defective, or the relator's factual allegations are frivolous." Granston Memo at 3. But the Granston Memo further explains that "[i]n certain cases, even if the relator's allegations are not facially deficient, the government may conclude after completing its investigation of the relator's allegations that the case lacks merit," and it should consider dismissal at that point. *Id.* Moreover, "[i]f the Department is concerned that a case lacks any merit, but elects to afford the relator an opportunity to further develop the case, the Department … may consider advising the relator that dismissal will be considered if the relator is unable to obtain additional support for the re-

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[6] The factors are:

> 1. Curbing meritless qui tams that facially lack merit …. 2. Preventing parasitic or opportunistic qui tam actions that duplicate a pre-existing government investigation and add no useful information to the investigation. 3. Preventing interference with an agency's policies or the administration of its programs. 4. Controlling litigation brought on behalf of the United States, in order to protect the Department's litigation prerogatives. 5. Safeguarding classified information and national security interests. 6. Preserving government resources, particularly where the government's costs … are likely to exceed any expected gain. 7. Addressing egregious procedural errors that could frustrate the government's efforts to conduct a proper investigation.

Justice Manual § 4-4.111.

lator's claims by a specified date." *Id.* at 4. The Government's ability to dismiss unmeritorious cases both protects against wasteful litigation and allows it to avoid the development of potentially unfavorable precedent, which could hinder its enforcement efforts elsewhere.

In some factually intensive FCA cases the action's viability might not become clear until there has been some discovery. For one thing, the Act has "demanding" scienter and materiality requirements, which may hinge on initially unknown facts relating to the Government's knowledge and activities. *Escobar*, 579 U.S. at 194. As this Court has explained, "materiality 'look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.'" *Id.* at 193 (brackets in original; citation omitted); *see also* 31 U.S.C. § 3729(b)(4) (defining "material" to mean "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property").

Further, in recent years relators have advanced increasingly creative and expansive theories of FCA liability, including so-called "implied certification" theories, which treat submission of a claim to the Government for reimbursement as containing an implied certification of compliance with a host of contractual, regulatory, and statutory requirements. *See Escobar*, 579 U.S. at 187. Any arguable noncompliance with these requirements purportedly renders the certification "false"; the relator frequently seeks to recover all funds paid by the Government in connection with the claims. In this context, the FCA's materiality element has taken on critical significance. If the relator cannot show that the certification was material to the

Government's decision to pay, then the claim fails. *Id.* at 192.

In *Escobar*, the Court clarified that "[a] misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment." 579 U.S. at 194. "Nor is it sufficient for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant's noncompliance." *Id.* Instead, "proof of materiality can include … evidence that … the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement." *Id.* at 194-95. Alternatively, "if the Government pays a particular claim [or type of claim] in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material." *Id.* at 195.

After *Escobar*, defendants who can show that the Government continued paying claims after knowing of the alleged "fraud" often can convince courts to rule in their favor. But uncovering this type of evidence—regarding whether the Government has paid claims, notwithstanding its knowledge of noncompliance, as well as what the defendant knew about the Government's payment of these claims—often requires discovery. One study of defendants' use of the materiality defense between 2019 and 2021 found that district courts dismissed FCA complaints on this basis in 37% of the decisions on motions to dismiss and 40% of the decisions on summary judgment or judgment as a matter of law. Brenna Jenny et al., *Analyzing FCA Materiality Defense Outcomes Under Escobar*,

Law360 (Dec. 13, 2021), https://www.law360.com/articles/1447443/analyzing-fca-materiality-defense-outcomes-under-escobar.

This case illustrates the potential difficulties in assessing the viability of claims and the existence of materiality at the outset of litigation. Polansky filed suit in 2012 alleging that Respondent Executive Health Resources, Inc. and other healthcare entities (collectively, "Executive Health") improperly caused claims for outpatient medical services to be billed as inpatient, "exploit[ing] the difference in reimbursement rates" between the two. Pet. 32a-33a. The Government investigated Polansky's complaint for two years before deciding not to proceed with the action. Pet. App. 5a. After the complaint was served on Executive Health and litigation began, the district court denied Executive Health's motion to dismiss in July 2016, finding the complaint facially plausible. Pet. App. 32a; *see United States ex rel. Polansky v. Exec. Health Res., Inc.*, 196 F. Supp. 3d 477, 493 (E.D. Pa. 2016). In February 2019, in the midst of discovery, the Government announced that it planned to dismiss the case. Pet. App. 37a. After hearing from the parties, the Government agreed not to seek dismissal if Polansky narrowed the scope of his claims, but reserved its "right to evaluate whether dismissal is warranted in the future based on further developments, including arguments raised by the parties, further factual and evidentiary developments, and associated discovery burdens." *Id.*

Polansky then filed an amended complaint that purportedly narrowed his claims, although the Government disputed the extent of narrowing. Pet. App. 37a-38a. Thereafter, Executive Health deposed Po-

lansky, and the Government participated in the deposition. Pet. App. 39a. Additionally, a Special Master recommended that the Government produce documents previously withheld as privileged and documents "for additional custodians." Pet. App. 38a.

According to the district court, these three events led to the Government's renewed motion to dismiss in August 2019. *See* Pet. App. 55a-56a. Among other things, "[i]nformation learned during [Polansky's] deposition was considered in evaluating dismissal and evidently changed the Government's calculation." Pet. App. 56a. In support of its motion, the Government "cite[d] genuine concerns regarding the likelihood that Relator will successfully establish FCA liability," because of "his inability to access 'medical records'" to determine whether submitted claims were false, "his failure to demonstrate that Defendant 'caused the submission of false claims to CMS,'" and "his credibility given prior behavior in this case." Pet. App. 51a. In short, after years of litigation and discovery, the Government now had serious concerns about the viability of Polansky's case.

Although it did not need to address the issue given its grant of the dismissal motion, the district court offered its own views on whether Polansky likely would be able to demonstrate materiality in the event of a future reversal and summary judgment. At least for certain claims, under this Court's decision in *Escobar*, the district court "doubt[ed]" that Polansky could "establish that [Executive Health's] alleged noncompliance was material to the Government's decision to pay." Pet. App. 74a. The district court pointed to the Government's own actions in the case—both in "declining to intervene and moving for dismissal"—as "probative of the lack of materiality" of Polansky's

claims. Pet. App. 74a-75a. "The Government's apparent view that [Polansky's] claims are not worthy of even private enforcement is relevant because it underscores the conclusion that [Executive Health's] alleged fraud was not material in the eyes of the payor and ultimate beneficiary of Relator's claims—the Government." Pet. App. 75a.

The district court also relied on the lack of evidence that the Government ever refused to pay a claim certified by Executive Health even though Polansky alleged that the "scheme" was ongoing. Pet. App. 76a. This was "'strong evidence' that the noncompliance was not material." *Id.* Accordingly, although the district court refused to grant summary judgment on this basis due to unfinished discovery, it concluded that Polansky "likely falls short of [*Escobar*'s] demanding materiality standard." Pet. App. 74a n.23; *see* Pet. App. 77a.

As this case amply illustrates, any attempt to limit the Government's dismissal authority to the outset of the case would prevent the Government from terminating burdensome litigation that is likely to be unmeritorious. As the real party in interest, the Government undoubtedly has a stake in preventing the entry of judgment in cases that could set poor precedent and potentially intrude on its ability to prosecute meritorious cases.

B. The Burdens And Costs Of *Qui Tam* Litigation Often Are Not Apparent At The Outset.

Most of the other Granston Memo factors relate to the burden of *qui tam* litigation on the Government and interference with its policy prerogatives and the

public interest. For example, the Government considers potential "[i]nterference with [a]gency [p]olicies and [p]rograms," its "litigation prerogatives," the need to [s]afeguard[] [c]lassified [i]nformation and [n]ational [s]ecurity [i]nterests," and "[p]reserv[ation of] [g]overnment [r]esources." Granston Memo at 4-6. While some of these issues may be evident at the outset of an FCA suit, many become apparent only after the parties begin discovery. As the following examples illustrate, the Government has repeatedly dismissed suits against healthcare companies based on these factors after declining to intervene initially. It is important that the Government retain this authority.

1. Preserving Government Resources.

The Granston Memo recommends dismissal whenever the "government's expected costs are likely to exceed any expected gain." Granston Memo at 6. In many ways, this is the factor that undergirds—and is frequently intertwined with—all of the other factors. But the Government often cannot conduct a full cost-benefit analysis until suit has progressed and some discovery has occurred.

This case is again illustrative. When the Government sought dismissal, not only was the Government concerned about Polansky's ability to succeed on the merits of his claims, it also cited the "costs of continued litigation." Pet. App. 51a. Even though it had declined to intervene, the Government had significant ongoing burdens related to the case: "internal staff obligations," "anticipated costs related to the document production recommended by the Special Master, expected attorney time associated with preparing depositions of CMS personnel and monitoring the litiga-

tion, including filing statements of interest," all in addition to "the concern that material it deems as privileged has been produced and will be used." Pet. App 53a-54a (footnotes omitted). Obviously, many of these burdens only arose as a result of discovery and were not evident at the outset of the case. Therefore, the Government's conclusion that the "costs outweigh the benefits of continued litigation" also was not apparent from the start. Pet. App. 54a.

This scenario is not uncommon. The First and Second Circuits recently affirmed courts in Rhode Island and New York that dismissed FCA cases where the same relator made sweeping allegations that pharmaceutical manufacturers colluded with pharmacy benefit managers to drive up the cost of drugs by paying kickbacks disguised as service fees. *Borzilleri*, 24 F.4th at 37; *United States ex rel. Borzilleri v. AbbVie, Inc.*, 837 F. App'x 813, 815 (2d Cir. 2020). The Government initially declined to intervene but later moved to dismiss these cases because "(1) [they] would likely require significant expenditure of government resources; (2) the relator's claims were unlikely to result in any material recovery for the United States; and (3) the relator was not an appropriate advocate for the government." *Borzilleri*, 837 F. App'x at 815.

If the litigation continued, "attorneys from multiple offices would be required to monitor the litigation and likely coordinate third-party discovery, rather than pursue other (and in the Government's view, more meritorious) cases," while "program staff from the Centers for Medicare and Medicaid Services ('CMS') … would likely have to divert time and resources to respond to discovery requests." *United States ex rel. Borzilleri v. AbbVie, Inc.*, No. 15-CV-

7881, 2019 WL 3203000, at *2 (S.D.N.Y. July 16, 2019). Moreover, after a multi-year investigation that included "review of tens of thousands of documents, interviews with more than thirty witnesses, consultations with regulatory experts within the U.S. Department of Health and Human Services, and the retention of expert consultants," the Government "concluded that many key aspects of [relator's] allegations [were] not supported." *Borzilleri*, 24 F.4th at 38, 45.

As these examples illustrate, the Government's ongoing dismissal authority is crucial in preserving the Government's resources. *See also, e.g.*, *United States ex rel. Nicholson v. Spigelman*, No. 10 C 3361, 2011 WL 2683161, at *2 (N.D. Ill. July 8, 2011) (dismissing at Government's request where costs to Government far exceeded any potential recovery).

2. Preventing Interference with Agency Policies and Programs.

According to the Department of Justice, "[d]ismissal should be considered where an agency has determined that a *qui tam* action threatens to interfere with an agency's polices or the administration of its programs." Granston Memo at 4. Dismissal is also appropriate "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." *Id.* at 5.

If the Government cannot exercise discretion over which cases should and should not be pursued in its name, private individuals will exercise power to make policy decisions on the Government's behalf. The Government may determine that certain activities by healthcare entities arguably violate broadly worded

statutes or regulations that allegedly support FCA liability, but nevertheless should not be subject to enforcement action because they benefit the public on balance. The Government must continue to have the prerogative to make those policy decisions.

In a notable string of cases, the National Health Care Analysis Group, a for-profit, private investment group, filed eleven nearly identical complaints through various affiliates against thirty-eight pharmaceutical companies in district courts across the country. *See United States v. Eli Lilly & Co.*, 4 F.4th 255, 259 & n.1 (5th Cir. 2021) (collecting cases). The Group alleged that patient educational programs and nurse support provided by the companies constituted illegal kickbacks under the FCA and the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), which prohibits remuneration given willfully in return for referrals for items or services covered by federal programs. After declining to intervene, the Government subsequently moved to dismiss most of these cases (the other cases were jointly dismissed by the parties, or in one instance by the defendant). *See Eli Lilly*, 4 F.4th at 259 n.1

After extensive consideration, the Government determined that "further litigation ... will undermine practices that benefit federal healthcare programs by providing patients with greater access to product education and support." *Eli Lilly & Co.*, 4 F.4th at 267 (ellipsis in original). "[A]cross nine cited agency guidances, advisory opinions, and final rulemakings," the Government had "consistently held that the conduct complained of"—product support services—was "[n]ot only lawful, but beneficial to patients and the public." *UCB, Inc.*, 970 F.3d at 852; *see also Eli Lilly & Co.*, 4 F.4th at 268 (similar).

As a result, the Government concluded that "the allegations ... lack sufficient merit to justify the cost of investigation and prosecution." *Eli Lilly & Co.*, 4 F.4th at 267 (ellipsis in original). The scope of the claims was massive—the Group "alleged violations spanning a six-year period involving Medicare, Medicaid, and TRICARE." *Id.* "For Medicare Part D alone," the allegations against one company "involve[d] more than 32,000,000 prescriptions, from more than 400,000 physicians, for more than 1,000,000 Medicare beneficiaries." *Id.* For another company, the Medicare Part D allegations involved "nearly 500,000 prescriptions, from more than 10,000 physicians, for 'tens of thousands' of Medicare beneficiaries." *Id.* at 267-68. Given these claims' breadth, which became clear as discovery loomed, the Government was concerned about the "'substantial litigation burdens' on the United States as it monitors the cases, responds to discovery requests, prepares agency employees for depositions, *et cetera*." *Id.* at 268.

In all but one of the cases, the district court granted the Government's motions to dismiss. *See Eli Lilly & Co.*, 4 F.4th at 269; *United States v. EMD Serono, Inc.*, 370 F. Supp. 3d 483, 491 (E.D. Pa. 2019); *United States ex rel. NHCA-TEV, LLC v. Teva Pharm. Prods. Ltd.*, No. 17-CV-2040, 2019 WL 6327207, at *6 (E.D. Pa. Nov. 26, 2019); *United States ex rel. SCEF, LLC v. AstraZeneca PLC*, No. 17-CV-1328, 2019 WL 5725182, at *4 (W.D. Wash. Nov. 5, 2019). The one exception was swiftly reversed by the Seventh Circuit, which labelled the relators "investment vehicles for financial speculators" and endorsed the Government's argument that the Group's claims would jeopardize

practices that the Government had found "appropriate and beneficial to federal healthcare programs and their beneficiaries." *UCB, Inc.*, 970 F.3d at 852.

In another instance, the Government sought dismissal where allowing a relators' suit to proceed would "impinge on agency decisionmaking and discretion." *United States v. Gilead Scis., Inc.*, No. 11-cv-941, 2019 WL 5722618, at *3 (N.D. Cal. Nov. 5, 2019). In *Gilead Sciences*, the relators contended that the pharmaceutical company had violated the FCA by seeking Medicare and Medicaid payment for HIV drugs that was contingent on FDA approval of the drugs. The relators alleged that the company had distributed drugs that were partly manufactured at a facility in China that was not FDA-approved. *Id.* at *1-2. The United States declined to participate in the case at the outset but filed multiple statements of interest and *amicus* briefs before the district court, Ninth Circuit, and Supreme Court that were favorable to the relators without taking "a position on the ultimate merits." *Id.* at *2-3.

Notwithstanding these statements, the Government later moved to dismiss the litigation. The FDA had engaged in its own investigation of the alleged conduct before the relators ever filed suit, and the Government was concerned that if the litigation continued, it would "undermin[e] the considered decisions of FDA and CMS about how to address the conduct at issue." 2019 WL 5722618, at *5. The FDA had already "taken into account [the relators'] claims in its regulatory oversight of [the company] and taken actions it deemed appropriate," short of further enforcement. *Id.* at *5-7. Accordingly, the Government wanted "to avoid the additional expenditure of government resources on a case that it fully investigated and

decided not to pursue," especially since continued litigation could lead to "burdensome discovery" and "requests for FDA documents and FDA employee discovery (and potentially trial testimony)," which "would distract from the [FDA's] public-health responsibilities." *Id.* at *3, *5 (citation omitted).

3. Controlling Government Litigation Brought on Behalf of the United States.

The Granston Memo also recommends "dismissing cases when necessary to protect the Department's litigation prerogatives." Granston Memo at 5. The potential for a *qui tam* action to interfere with separate Government litigation may not become fully apparent until later in the suit.

For example, in *United States ex rel. Piacentile v. Amgen, Inc.*, No. 04 CV 3983, 2013 WL 5460640, at *1 (E.D.N.Y. Sept. 30, 2013), the Government dismissed a relators' suit after the Government reached a $780 million settlement with a company based on allegations arising from multiple complaints that the company had engaged in fraudulent marketing, provided unlawful kickbacks, and promoted off-label use of its drugs. The settlement was the culmination of an eight-year investigation in which the Government reviewed over 9 million documents and interviewed over 250 witnesses. *Id.* at *3. The Government offered relators $1.8 million of the settlement. *Id.* at *1. After they refused the offer, the Government declined to intervene in and moved to dismiss their particular suit, citing the cost to the Government in continuing the case, the weakness of the relators' claims, and the unlikelihood of further recovery. *Id.* at *1-4.

* * *

As these examples illustrate, the Government's ability to dismiss *qui tam* suits throughout litigation in accordance with its own dismissal factors is necessary to protect the Government's interests.

C. Broad Dismissal Authority Is Needed To Protect Against Frivolous Litigation That Hinders Lifesaving Treatments.

FCA claims can generate massive recoveries. Last year settlements and judgments in FCA cases topped $5.6 billion; 90% of this—over $5 billion—came from the healthcare industry. *See* U.S. Dep't of Justice, Fraud Statistics, https://www.justice.gov/opa/press-release/file/1467811/download. And most of that amount stemmed from cases involving pharmaceutical companies. *See* U.S. Dep't of Justice, Justice Department's False Claims Act Settlements and Judgments Exceed $5.6 Billion in Fiscal Year 2021 (Feb. 1, 2022), https://www.justice.gov/opa/pr/justice-department-s-false-claims-act-settlements-and-judgments-exceed-56-billion-fiscal-year. Statistical analysis of unsealed FCA settlements between 2004 and 2014 revealed that pharmaceutical companies are the most likely of any industry to have FCA 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).

The vast reach of the Anti-Kickback Statute often drives significant FCA settlements with pharmaceutical companies. *See, e.g.*, U.S. Dep't of Justice, Justice Department's False Claims Act Settlements and Judgments Exceed $5.6 Billion, *supra* (discussing

$400 million in settlements paid by generic pharmaceutical manufacturers in 2021 to resolve kickback claims). As amended in 2010, the Anti-Kickback Statute provides that a claim for an item or service "resulting from" a violation of the statute is false for purposes of the FCA. 42 U.S.C. § 1320a-7b(g). Because relators and the Government typically request the total value of items or services billed as damages in kickback cases—on the theory that the kickback "tainted" the judgment of the healthcare provider who selected the product or service for a patient—and since damages under the FCA are trebled, FCA cases involving kickbacks have the potential to generate especially large recoveries. *See, e.g.*, *United States v. Rogan*, 517 F.3d 449, 453 (7th Cir. 2008) (affirming $64 million damages award). And the seeming possibility of a massive recovery provides an enormous incentive for would-be relators.

In appropriate cases, relators can play a beneficial role in ferreting out and driving accountability for true fraud. PhRMA's members invest many resources in preventing fraud and abuse affecting Government healthcare programs. Too often, however, the prospect of exorbitant bounties incentivizes opportunistic relators to pursue aggressive theories and legal fictions to establish "fraud" on the Government.

Historically, Government intervention has been correlated with the likelihood of recovery in FCA litigation. *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."); 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, 1264 (2008) (finding that fewer than 10% of relator suits in which the Government does not intervene result in monetary recovery); Broderick, *Qui Tam Provisions and the Public Interest*, 107 Colum. L. Rev. at 971 (finding "much support for the assumption that the Attorney General will intervene when a suit has merit"). Most FCA awards and settlements typically have come from cases where the Government either brings suit directly or intervenes in a relator's suit. *See* U.S. Dep't of Justice, Fraud Statistics, https://www.justice.gov/opa/press-release/file/1467811/download (In 2021, $3.9 billion of FCA recoveries came from non-*qui tam* suits; $1.2 billion came from *qui tam* suits in which the Government intervened; and only $479 million came from *qui tam* suits in which the United States declined to intervene).

Nevertheless, the overwhelming majority of FCA cases are brought by private relators. *See id.* (598 *qui tam* suits filed in 2021, compared to 203 filed by the Government). In approximately 75% of these, the Government does not intervene. *See* U.S. Dep't of Justice, False Claims Act Cases: Government Intervention in Qui Tam (Whistleblower) Suits (June 12, 2012), https://www.justice.gov/sites/default/files/usao-edpa/legacy/2012/06/13/InternetWhistleblower%20update.pdf; *see also* Broderick, *Qui Tam Provisions and the Public Interest*, 107 Colum. L. Rev. at 971 (between 1987 and 2004, the United States intervened in only 22% of *qui tam* suits). Although most of these FCA suits are unlikely to succeed, the threat of crushing damages and negative public perception pushes defendants to settle even unmeritorious cases. *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). Additional settlement pressure occurs because companies found to have violated the FCA or Anti-Kickback Statute face mandatory or discretionary exclusion from federal healthcare programs, including Medicare and Medicaid—the death knell to a healthcare company. *See* 42 U.S.C. § 1320a-7. This settlement pressure has "resulted in billions of dollars in settlements" "without any clear finding of fault or liability." Matthew, *supra*, at 285. Accordingly, even unmeritorious FCA cases impose substantial societal costs.

Biopharmaceutical companies offer lifesaving treatment and care. These treatments often are available to the public through federal healthcare programs, and the Government has a clear interest in ensuring that such treatments remain available. Unmeritorious and burdensome FCA litigation can interfere with that mission by diverting time and resources away from drug development. Especially in the context of FCA suits in which the Government has not intervened, the Government's ability to later dismiss unmeritorious suits is a crucial protection for both the Government, healthcare defendants, and society.

CONCLUSION

The Court should affirm the judgment of the court of appeals.

Respectfully submitted.

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