

No. 23-2086

**UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT**

UNITED STATES OF AMERICA,

Plaintiff-Appellant,

v.

REGENERON PHARMACEUTICALS, INC.

Defendant-Appellee.

Appeal from the United States District Court for the District of
Massachusetts, No. 1:20-cv-11217, Hon. F. Dennis Saylor IV

**BRIEF OF THE CHAMBER OF COMMERCE OF THE
UNITED STATES OF AMERICA AS *AMICUS CURIAE* IN
SUPPORT OF DEFENDANT-APPELLEE AND AFFIRMANCE**

Tara S. Morrissey
Andrew R. Varcoe
U.S. CHAMBER
LITIGATION CENTER
1615 H Street NW
Washington, DC 20062
(202) 463-5337

Jeffrey S. Bucholtz
KING & SPALDING LLP
1700 Pennsylvania Avenue NW
Washington, DC 20006
(202) 737-0500
jbucholtz@kslaw.com
Matthew V.H. Noller
KING & SPALDING LLP
50 California Street, Suite 3300
San Francisco, CA 94111
(415) 318-1200

Counsel for Amicus Curiae

May 22, 2024

CORPORATE DISCLOSURE STATEMENT

The Chamber of Commerce of the United States of America (“Chamber”) is a non-profit, tax-exempt organization incorporated in the District of Columbia. The Chamber has no parent corporation, and no publicly held company has 10% or greater ownership in the Chamber.

TABLE OF CONTENTS

Corporate Disclosure Statement.....	i
Interest of <i>Amicus Curiae</i>	1
Introduction	2
Argument	4
I. Section 1320a-7b(g) requires at least but-for causation	4
II. The government’s interpretation would lead to an explosion of meritless and costly <i>qui tam</i> actions	16
Conclusion.....	21

TABLE OF AUTHORITIES

Cases

<i>AT&T Mobility LLC v. Concepcion</i> , 563 U.S. 333 (2011)	18
<i>Baker v. Smith & Wesson, Inc.</i> , 40 F.4th 43 (1st Cir. 2022)	12
<i>Buckley v. Valeo</i> , 424 U.S. 1 (1976)	20
<i>Burrage v. United States</i> , 571 U.S. 204 (2014)	<i>passim</i>
<i>Guilfoile v. Shields</i> , 913 F.3d 178 (1st Cir. 2019)	4, 5, 19
<i>Jam v. Int’l Fin. Corp.</i> , 586 U.S. 199 (2019)	12
<i>Kellogg Brown & Root Servs. v. U.S. ex rel. Carter</i> , 575 U.S. 650 (2015)	6
<i>Laaman v. Warden, N.H. State Prison</i> , 238 F.3d 14 (1st Cir. 2001)	12
<i>NLRB v. SW Gen., Inc.</i> , 580 U.S. 288 (2017)	14
<i>Paroline v. United States</i> , 572 U.S. 434 (2014)	10
<i>Reves v. Ernst & Young</i> , 507 U.S. 170 (1993)	12
<i>Schindler Elevator Corp. v. U.S. ex rel. Kirk</i> , 563 U.S. 401 (2011)	6, 7
<i>Seila Law LLC v. CFPB</i> , 591 U.S. 197 (2020)	20

Smith v. Duffey,
 576 F.3d 336 (7th Cir. 2009)..... 18

U.S. ex rel. Atkins v. McInteer,
 470 F.3d 1350 (11th Cir. 2006)..... 17

U.S. ex rel. Cairns v. D.S. Med. LLC,
 42 F.4th 828 (8th Cir. 2022) 3, 6

U.S. ex rel. Martin v. Hathaway,
 63 F.4th 1043 (6th Cir. 2023) 3, 6

U.S. ex rel. Polansky v. Exec. Health Res., Inc.,
 599 U.S. 419 (2023) 13, 20

U.S. ex rel. Schutte v. SuperValu Inc.,
 598 U.S. 739 (2023) 4, 7

United States ex rel. Hutcheson v. Blackstone Medical, Inc.,
 647 F.3d 377 (1st Cir. 2011) 15, 16

Universal Health Servs., Inc. v. U.S. ex rel. Escobar,
 579 U.S. 176 (2016) 3, 13

Vt. Agency of Nat. Res. v. U.S. ex rel. Stevens,
 529 U.S. 765 (2000) 11, 17

Zucker v. Rodriguez,
 919 F.3d 649 (1st Cir. 2019) 14

Statutes

21 U.S.C. § 841..... 5

31 U.S.C. § 3729..... 4, 14

31 U.S.C. § 3730..... 11, 12, 17

42 U.S.C. § 1320a-7b *passim*

Other Authorities

155 Cong. Rec. S10,853 (daily ed. Oct. 28, 2009) (statement of Sen. Kaufman)	13, 14
Bentivoglio, John T., et al., <i>False Claims Act Investigations: Time for a New Approach?</i> , 3 Fin. Fraud L. Rep. 801 (2011)	19
Brief for United States as Amicus Curiae, <i>U.S. ex rel. Flanagan v. Fresenius Med. Care Holdings, Inc.</i> , No. 23-1305 (1st Cir. Aug. 21, 2023)	8
Memo., <i>United States v. Teva Pharms. USA, Inc.</i> , No. 1:20-cv-11548 (D. Mass.), ECF No. 161.....	8
Reply, <i>United States v. Teva Pharms. USA, Inc.</i> , No. 1:20-cv-11548 (D. Mass.), ECF No. 189.....	8
U.S. Dep’t of Justice, Fraud Statistics – Overview (Oct. 1, 1986–Sept. 30, 2023) (“DOJ Fraud Statistics”), https://www.justice.gov/opa/media/1339306/dl?inline	17, 18, 19

INTEREST OF *AMICUS CURIAE*

The Chamber of Commerce of the United States of America is the world's largest business federation. It represents approximately 300,000 direct members and indirectly represents the interests of more than 3 million companies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus curiae* briefs in cases, like this one, that raise issues of concern to the nation's business community.

False Claims Act cases touch on nearly every sector of the economy, including banking, defense, education, healthcare, and technology, and exact a substantial toll on the economy. Given the combination of the FCA's draconian liability provisions—treble damages plus per-claim penalties—and enormous litigation costs, even meritless cases can be used to extract substantial settlements. As a result, cases involving the

proper application of the FCA are of particular concern to *amicus* and its members.¹

INTRODUCTION

The question presented in this appeal is straightforward. The Court accepted the appeal to decide whether 42 U.S.C. § 1320a-7b(g), which provides that “a claim that includes items or services resulting from a violation of” the Anti-Kickback Statute is a false claim under the FCA, requires but-for causation. The Supreme Court effectively resolved that question years ago when it held that “a phrase such as ‘results from’ imposes a requirement of but-for causation.” *Burrage v. United States*, 571 U.S. 204, 214 (2014). Section 1320a-7b(g)’s indistinguishable phrase “resulting from” must carry the same meaning: for an AKS violation to render a claim “false or fraudulent” under the FCA, the violation must be at least a but-for cause of the “items or services” for which the claim sought payment. *U.S. ex rel. Martin v. Hathaway*, 63 F.4th 1043, 1052-

¹ All parties to this appeal have consented to the filing of this brief. No counsel for any party authored this brief in whole or in part, and no entity or person, aside from *amicus*, its members, or its counsel, made any monetary contribution intended to fund the preparation or submission of this brief.

53 (6th Cir.), *cert. denied*, 144 S. Ct. 224 (2023) (Mem.); *U.S. ex rel. Cairns v. D.S. Med. LLC*, 42 F.4th 828, 834-35 (8th Cir. 2022).

The government’s contrary interpretation of § 1320a-7b(g) impermissibly “give[s] the [statutory] text a meaning that is different from its ordinary, accepted meaning.” *Burrage*, 571 U.S. at 216. If this Court were to adopt that interpretation, it would open the floodgates to a torrent of meritless FCA actions based on allegations of AKS violations. Without a requirement of but-for causation, relators will seek exorbitant *qui tam* settlements by alleging AKS violations—which are easy to allege, given the breadth of the AKS—with only an unclear or attenuated relationship to the “items or services” in claims for payment. 42 U.S.C. § 1320a-7b(g). That would impose deadweight costs on businesses and the public, and it would distort the FCA—a statute focused on *claims* that are false—into “a vehicle for punishing . . . regulatory violations” that do *not* cause any false claims. *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 579 U.S. 176, 194 (2016). This Court should reject the government’s arguments and affirm the district court’s interpretation of § 1320a-7b(g).

ARGUMENT

I. Section 1320a-7b(g) requires at least but-for causation.

When interpreting the FCA, the Court must “start . . . with [its] text.” *U.S. ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739, 749 (2023). As relevant here, the FCA imposes liability on “any person who . . . knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval.” 31 U.S.C. § 3729(a)(1)(A). The AKS, in turn, provides that “a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA].” 42 U.S.C. § 1320a-7b(g). Under these provisions, therefore, an underlying AKS “violation” renders a claim for payment “false or fraudulent” under the FCA if the claim “includes items or services *resulting from*” the AKS violation—but not if the “items or services” covered by the claim did *not* “result[] from” the AKS violation. *Id.* (emphasis added).

There can be no dispute that the phrase “resulting from” requires a “causal connection between an AKS violation and a claim submitted to the federal government.” *Guilfoile v. Shields*, 913 F.3d 178, 190 (1st Cir. 2019). This Court has so held, as shown by the preceding quote from

Guilfoile.² The government itself concedes that § 1320a-7b(g)'s "resulting from" language imposes *some* requirement of "factual causation." Gov't Br. 24. And the Supreme Court has held that the connection required by that phrase is "but-for causation." *Burrage*, 571 U.S. at 214.

Burrage involved a criminal statute imposing a mandatory minimum sentence for the sale of illegal substances when "death or serious bodily injury *results from* the use of such substance." 21 U.S.C. § 841(a)(1), (b)(1)(A)-(C) (emphasis added). The Supreme Court held that the "ordinary meaning" of "results from" requires proof "that the harm would not have occurred in the absence of—that is, but for—the defendant's conduct." 571 U.S. at 210-11 (cleaned up).

That holding resolves this appeal. As with the statute in *Burrage*, the Supreme Court has held that the FCA must be interpreted according

² Contrary to the government's argument, *Guilfoile* did not even implicitly reject a requirement of but-for causation. This Court simply held that § 1320a-7b(g) requires "a sufficient causal connection," without deciding what sort of "causal connection" would be "sufficient." 913 F.3d at 190. In fact, the Court went on to hold that the plaintiff had "plausibly alleged a sufficient causal connection" by alleging that the defendant could not have sought government benefits for its services "*if not for*" the alleged AKS violation—in other words, by alleging but-for causation. *Id.* at 191 (emphasis added). The government's brief does not mention this aspect of the Court's analysis.

to its “ordinary meaning.” *Kellogg Brown & Root Servs. v. U.S. ex rel. Carter*, 575 U.S. 650, 662 (2015); *Schindler Elevator Corp. v. U.S. ex rel. Kirk*, 563 U.S. 401, 407 (2011). And there is no meaningful difference between “results from” and § 1320a-7b(g)’s causal phrase “resulting from.” So there is no difference between the phrases’ ordinary meanings: they both unambiguously require at least but-for causation. *Burrage*, 571 U.S. at 210-11; see *Martin*, 63 F.4th at 1052 (“The ordinary meaning of ‘resulting from’ is but-for causation.”); *Cairns*, 42 F.4th at 835 (“‘Resulting,’ which is the present-participle form of the verb, has the same meaning as its present-tense cousin, ‘results.’ So we have little trouble concluding that, in common and ordinary usage, the participle phrase ‘resulting from’ also expresses ‘a but-for causal relationship.’” (citations omitted)).

It is thus misleading at best for the government to say that “§ 1320a-7b(g)’s ‘resulting from’ language is silent as to the appropriate standard of factual causation.” Gov’t Br. 24-25. “Resulting from” is the statutory standard, and it requires at least “but-for causation.” *Burrage*, 571 U.S. at 214. Nor can the government identify any plausible reason to give the FCA’s “text a meaning that is different from its ordinary,

accepted meaning.” *Id.* at 216; see *Schindler Elevator*, 563 U.S. at 410 (explaining that the Court has “cautioned . . . against” giving the FCA’s text “a different, somewhat special meaning” instead of its “primary meaning” (quotation marks omitted)). The government suggests that *Burrage* does not apply to different “statutory scheme[s],” Gov’t Br. 20, but *Burrage* did not depend on anything specific to the statute at issue.³ Because that statute did “not define the phrase ‘results from,’” the Supreme Court “g[a]ve it its ordinary meaning.” 571 U.S. at 210. And the phrase’s “common understanding”—not some specialized, statute-specific meaning—reflects a “but-for requirement.” *Id.* at 211. It could not be clearer that the Court understood its interpretation of “results from” to apply generally as a matter of plain English: “[I]t is one of the *traditional background principles* against which Congress legislates that a phrase such as ‘results from’ imposes a requirement of but-for

³ The government’s citation to *Schutte* is misplaced. Gov’t Br. 21. There, the Supreme Court found that the meaning of “willfully” in one statute should not be applied to *different* terms in the FCA. 598 U.S. at 754. The Court also held that its earlier decision had not interpreted “willfully” in the way the defendants claimed. *Id.* at 754-55. *Burrage*, in contrast, undeniably interpreted language indistinguishable from § 1320a-7b(g)’s phrase “resulting from” to require but-for causation.

causation.” *Id.* at 214 (emphasis added) (cleaned up). That background principle applies with full force to the FCA and the AKS.

Indeed, as noted above, the government concedes that § 1320a-7b(g) requires *some* “appropriate standard of factual causation” between an AKS violation and the items or services in a claim for payment. Gov’t Br. 24; *accord* Gov’t Br. 20 (“*some* requirement of causation in fact”). But the government has long struggled to explain what it thinks that causal connection *is*. The government typically has relied on unhelpful labels: there must be a “sufficient causal connection”; the claim must be “tainted” by a kickback; a patient must be “exposed to” an AKS violation; and so on. Memo. at 5-8, *United States v. Teva Pharms. USA, Inc.*, No. 1:20-cv-11548 (D. Mass.), ECF No. 161 (emphasis omitted); Reply at 5-8, *Teva Pharms.*, No. 1:20-cv-11548, ECF No. 189; Brief for United States as Amicus Curiae at 9-15, *U.S. ex rel. Flanagan v. Fresenius Med. Care Holdings, Inc.*, No. 23-1305 (1st Cir. Aug. 21, 2023). But what does any of that *mean*? What kind of “causal connection” is “sufficient” or “appropriate”? What constitutes an actionable “taint”? How, and how far, does the “taint” spread? *See* Gov’t Br. 23 (suggesting services are “tainted by a kickback” “regardless of whether the kickback actually altered

medical decisionmaking” (quotation marks omitted)). More fundamentally, what do any of those inquiries have to do with the statutory phrase “resulting from”? The government has never been able to answer these questions coherently.

It still can't. In this case, the government at least purports to offer a test, but—belying its acknowledgment of a “factual causation” requirement, Gov't Br. 24—its proposal imposes *no causation requirement at all*. According to the government, a “claim ‘includes items or services resulting from’ the kickback within the meaning of § 1320a-7b(g)” whenever “the claimed items or services are those that the kickback was given to induce,” even if the kickback did not *in fact* induce those items or services because they would have been provided in the absence of the kickback. Gov't Br. 22, 27-28.

With respect, the government's proposal does not make sense. Whatever “nexus” the government thinks exists between an AKS violation and items or services that would have been provided even in the absence of the violation, *id.* at 22, it is not a *causal* nexus. If a manufacturer tries to “induce the purchase of particular items or services” with a kickback but the actual purchase is not at all influenced

by the kickback, then the manufacturer’s “intended result[]” may have “materialize[d],” *id.* at 30—but the manufacturer plainly did not *cause* that result. An act cannot cause an event “when the event would have occurred without it.” *Burrage*, 571 U.S. at 215-16 (cleaned up).⁴

The upshot is that, far from offering a “natural interpretation of ‘resulting from,’” Gov’t Br. 24, the government reads that language out of the statute. If Congress had meant § 1320a-7b(g) to make a claim for payment a “false” claim under FCA anytime remuneration was “given to induce the provision of the items or services” in the claim, Congress would have just *said that*, using the same language it used in the AKS. Gov’t Br. 21-22. Likewise, if Congress had intended to make any claim *occurring after* an AKS violation a “false” claim, it would have said so. Instead, it chose the phrase “resulting from,” along with its “ordinary,

⁴ The only potential caveat is that an act sometimes may be deemed a sufficient “cause” of an event “when multiple sufficient causes independently, but concurrently, produce a result.” *Burrage*, 571 U.S. at 214-15 (describing hypothetical where A stabs B at the same time as X shoots B, where both the stab wound and the gunshot wound would be independently fatal); *Paroline v. United States*, 572 U.S. 434, 451 (2014). While requiring “strict but-for causality” may be unworkable in such unusual situations, *Burrage*, 571 U.S. at 214-15, that is irrelevant here. Not even the government suggests that it is unworkable to assess whether items or services contained in a claim for payment would have been provided even in the absence of an alleged AKS violation.

accepted meaning” that “imports but-for causality.” *Burrage*, 571 U.S. at 216. Courts must honor that choice.

The government’s contextual arguments fare no better. The government relies on other AKS provisions, *e.g.*, Gov’t Br. 21-22, but this case is about the scope of *the FCA*, not the AKS. There is nothing “inconsistent” about interpreting § 1320a-7b(g) to require a but-for causal connection between an AKS violation and a claim for payment even if no such causal relationship is required under the AKS itself. Gov’t Br. 18. The AKS and the FCA are distinct statutes that prohibit different conduct; the False *Claims Act* is focused on claims for payment and is not implicated if an AKS violation does not result in a claim for payment. In addition, the AKS is a criminal statute enforceable only by the United States, while the FCA, by virtue of its *qui tam* provisions, may be enforced by anyone. 31 U.S.C. § 3730(b). Because third-party “informer” actions are “highly subject to abuse,” *Vt. Agency of Nat. Res. v. U.S. ex rel. Stevens*, 529 U.S. 765, 775 (2000), Congress subjected them to multiple restrictions that do not apply to suits brought by the government. *E.g.*, 31 U.S.C. § 3730(b)(5) (first-to-file bar); *id.* § 3730(e)(3) (government action bar); *id.* § 3730(e)(4)(A) (public disclosure bar); *see*

also id. § 3730(c)(2)(A)-(B) (authorizing government to dismiss or settle FCA action over relator’s objections). Section 1320a-7b(g), by limiting a private relator’s ability under the FCA to rely on AKS provisions that the government can always enforce directly in appropriate cases, serves the same purpose.

Without statutory text or context on its side, the government resorts to speculation about congressional purpose. *E.g.*, Gov’t Br. 18-19, 23-24. As an initial matter, of course, a statute’s “purpose is expressed by the ordinary meaning of the words used.” *Jam v. Int’l Fin. Corp.*, 586 U.S. 199, 209 (2019) (cleaned up); *see Laaman v. Warden, N.H. State Prison*, 238 F.3d 14, 16 (1st Cir. 2001). Because the Supreme Court has already decided the ordinary meaning of “resulting from,” the government’s suppositions about congressional intent have no legitimate role to play. *E.g.*, *Reves v. Ernst & Young*, 507 U.S. 170, 177 (1993); *Baker v. Smith & Wesson, Inc.*, 40 F.4th 43, 48 (1st Cir. 2022).

That aside, the government’s arguments lack merit. The government focuses on the purpose of *the AKS*, arguing (for example) that “[t]he point of the AKS is that financial conflicts are so inherently corrupting that they are punishable as felonies regardless of whether

they can be shown to have produced a concrete change in medical decisionmaking.” Gov’t Br. 14. But, again, this is not an AKS case—it’s an *FCA* case. Although the AKS may forbid “financial conflicts” even if they do not affect “medical decisionmaking,” *id.*, the FCA prohibits only “false or fraudulent claims for payment” that are “meant to appropriate government assets,” *U.S. ex rel. Polansky v. Exec. Health Res., Inc.*, 599 U.S. 419, 423-24 (2023). The FCA is not “a vehicle for punishing garden-variety breaches of contract or regulatory violations.” *Escobar*, 579 U.S. at 194. So while an unsuccessful kickback scheme might violate the AKS, Gov’t Br. 11, 21, it does not violate *the FCA*. The FCA is not implicated unless the kickback scheme *results in* the provision of items or services for which a person seeks payment from the government.

When the government addresses § 1320a-7b(g)’s legislative history, it cites two lone floor statements by individual legislators that § 1320a-7b(g) would “strengthen[] whistleblower actions based on medical care kickbacks.” Gov’t Br. 3 (quoting 155 Cong. Rec. S10,853 (daily ed. Oct. 28, 2009) (statement of Sen. Kaufman)). To the extent individual floor

statements could be considered,⁵ they are irrelevant to the causation question here. According to the statements, and as the government itself emphasizes, § 1320a-7b(g) was meant to permit liability for claims that “result[] from illegal kickbacks” but are “not submitted directly by the wrongdoers themselves.” 155 Cong. Rec. at S10,853 (Sen. Kaufman); Gov’t Br. 3, 19. All that means is that a claim can be false even if *the submitter* did not violate the AKS, as long as some other actor in the causal chain leading to the submission of the claim *did* violate the AKS. *See also* 31 U.S.C. § 3729(a)(1)(A) (creating FCA liability for anyone who “knowingly presents, *or causes to be presented*, a false or fraudulent claim” (emphasis added)). The items or services included in the claim still must “result[] from” an AKS violation, 155 Cong. Rec. at S10,853, and nothing in the legislative history suggests that Congress intended § 1320a-7b(g)’s “resulting from” requirement to demand anything less than but-for causation.

⁵ Because “[f]loor statements by individual legislators rank among the least illuminating forms of legislative history,” courts should “not attribute to Congress as a whole the views expressed in individual legislators’ floor statements.” *Zucker v. Rodriguez*, 919 F.3d 649, 660 (1st Cir. 2019) (quoting *NLRB v. SW Gen., Inc.*, 580 U.S. 288, 307 (2017)).

The government’s discussion of *United States ex rel. Hutcheson v. Blackstone Medical, Inc.*, 647 F.3d 377 (1st Cir. 2011), reflects the same confusion. Gov’t Br. 13. For one thing, *Hutcheson* explicitly declined to “address” whether “AKS compliance is, without more, a precondition of Medicare payment.” 647 F.3d at 392. The court held only that the defendants could be held liable for violating an express “contract term” that conditioned payment on “the underlying transaction complying with . . . the Federal anti-kickback statute.” *Id.* at 381-82, 392-94 (quotation marks omitted).

That aside, *Hutcheson* held that a device manufacturer that violated the AKS could be liable under the FCA for “causing” hospitals to submit false claims, even if the hospitals themselves were not aware of the manufacturer’s AKS violation. *Id.* at 388-91. The hospitals’ innocence had nothing to do with whether the AKS violation was the but-for cause of the hospitals’ services. The *Hutcheson* plaintiff alleged that the defendant “paid kickbacks to doctors” and that “*as a result of the kickbacks*, doctors across the country had performed spinal surgeries on Medicare and Medicaid patients using [its] devices.” *Id.* at 380-81 (emphasis added). If kickbacks caused the doctors to perform surgeries

and the doctors' hospitals billed the government for those surgeries, then the kickbacks *were* the but-for cause of the items and services in the hospitals' claims even if the hospitals did not know about them. *See also id.* at 393 (holding that because the “underlying transaction’ violated the AKS,” “*resulting claims* were ineligible for payment” (emphasis added)).

The bottom line is that the “ordinary meaning” of § 1320a-7b(g)’s phrase “resulting from” requires but-for causation, and the government identifies no genuine “textual or contextual indication” that Congress intended a different meaning. *Burrage*, 571 U.S. at 212. Congress could have written § 1320a-7b(g) to impose some other standard, but “[i]t chose instead to use language that imports but-for causality.” 571 U.S. at 216. This Court should honor that choice and hold that a claim is “false or fraudulent” under § 1320a-7b(g) only if an AKS violation was, at a minimum, the but-for cause of the “items or services” in the claim.

II. The government’s interpretation would lead to an explosion of meritless and costly *qui tam* actions.

Although the United States filed this case, the vast majority of FCA actions—70 percent of them since 1986—are initiated by private

relators.⁶ And § 1320a-7b(g) applies equally to both government-initiated and *qui tam* actions. By relieving FCA plaintiffs from any obligation to plead and prove but-for causation, the government’s interpretation of § 1320a-7b(g) would expose government contractors to a flood of *qui tam* actions based on allegations of AKS violations.

The FCA’s *qui tam* provisions create strong incentives for relators to bring even extraordinarily weak claims. Those provisions authorize private citizens who have suffered no injury to bring actions for treble damages and per-claim penalties of \$13,508–\$27,018—remedies that “are essentially punitive in nature.” *Stevens*, 529 U.S. at 784. If the United States intervenes, a relator keeps 15 to 25 percent of any recovery, as well as attorneys’ fees and costs; if the United States declines to intervene, a relator keeps up to 30 percent of any recovery, as well as fees and costs. 31 U.S.C. § 3730(d)(1)-(2). Even if a *qui tam* suit is doomed to fail, defendants face tremendous pressure to settle because the costs of litigating are so high and the potential downside so great. *U.S. ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1359-60 (11th Cir. 2006). These

⁶ U.S. Dep’t of Justice, *Fraud Statistics – Overview* (Oct. 1, 1986–Sept. 30, 2023) (“DOJ Fraud Statistics”) at 3, <https://www.justice.gov/opa/media/1339306/dl?inline>.

potential remedies, along with the ability to extract *in terrorem* settlements from innocent defendants, have led to an explosion in *qui tam* litigation, with 712 new cases filed in fiscal year 2023 alone. DOJ Fraud Statistics at 2.

If § 1320a-7b(g) is interpreted to require only some amorphous non-causal connection between an alleged AKS violation and claims for payment, those numbers will only go up. Because of the costs of litigating FCA actions, a motion to dismiss is often a defendant's only chance to defeat a meritless *qui tam* claim; once a claim survives a motion to dismiss, the costs of discovery and risks of trial leave little choice but to settle even "questionable claims." *AT&T Mobility LLC v. Concepcion*, 563 U.S. 333, 350 (2011); *see Smith v. Duffey*, 576 F.3d 336, 340 (7th Cir. 2009) (recognizing that discovery costs "can be so steep as to coerce a settlement on terms favorable to the plaintiff even when his claim is very weak"). By rejecting but-for causation as a requirement under § 1320a-7b(g), the government's interpretation would reduce the facts a relator must plead under that section to survive a motion to dismiss, making § 1320a-7b(g) claims particularly attractive for enterprising relators. That is even more true in Circuits, like this one, that have held that

§ 1320a-7b(g) “obviate[s] the need for a plaintiff to plead materiality.” *Guilfoile*, 913 F.3d at 190.

This is a problem because most *qui tam* actions—including those based on alleged AKS violations—are meritless. The government intervenes in a small minority of *qui tam* actions, but the vast majority of the over \$75 billion obtained under the FCA since 1986 has come from that small subset of intervened cases. DOJ Fraud Statistics at 3. The much larger universe of declined cases has produced just 6.9 percent of the total recovery. *Id.* These meritless *qui tam* actions impose enormous financial costs. Many of *amicus*’s members are in industries where businesses interact with the government and therefore invest substantial resources in efforts to ensure compliance and avoid FCA exposure. Meritless *qui tam* litigation only adds to those costs.⁷

Relaxing the pleading burden for *qui tam* claims based on alleged AKS violations will also exacerbate constitutional concerns with the “*qui*

⁷ These costs are particularly severe for healthcare defendants like Regeneron. Every year, FCA claims cost healthcare companies “billions.” John T. Bentivoglio et al., *False Claims Act Investigations: Time for a New Approach?*, 3 Fin. Fraud L. Rep. 801, 801 (2011). Of the nearly 16,000 *qui tam* suits filed between 1986 and 2023, over 60 percent related to healthcare. DOJ Fraud Statistics at 3, 6.

tam device.” *Polansky*, 599 U.S. at 442 (Kavanaugh, J., joined by Barrett, J., concurring); *id.* at 449 (Thomas, J., dissenting). The tension between allowing uninjured private citizens to sue on the United States’ behalf and Article II of the U.S. Constitution—under which “[t]he entire ‘executive Power’ belongs to the President alone,” *Seila Law LLC v. CFPB*, 591 U.S. 197, 213 (2020), and “civil litigation . . . for vindicating public rights” may be conducted “only by persons who are ‘Officers of the United States,’” *Buckley v. Valeo*, 424 U.S. 1, 138-40 (1976) (*per curiam*)—has “been noticed for decades.” *Polansky*, 599 U.S. at 449-50 (Thomas, J., dissenting). Although this government-plaintiff case does not directly implicate the constitutionality of the FCA’s *qui tam* provisions, those constitutional concerns counsel against dramatically increasing the number of *qui tam* suits through an unnatural interpretation of § 1320a-7b(g).

CONCLUSION

The Court should affirm the district court's decision and hold that 42 U.S.C. § 1320a-7b(g) requires but-for causation.

Respectfully submitted,

/s/ Jeffrey S. Bucholtz

Tara S. Morrissey
Andrew R. Varcoe
U.S. CHAMBER
LITIGATION CENTER
1615 H Street NW
Washington, DC 20062
(202) 463-5337

Jeffrey S. Bucholtz
KING & SPALDING LLP
1700 Pennsylvania Avenue NW
Washington, DC 20006
(202) 737-0500
jbucholtz@kslaw.com

Matthew V.H. Noller
KING & SPALDING LLP
50 California Street, Suite 3300
San Francisco, CA 94111
(415) 318-1200

Counsel for Amicus Curiae

May 22, 2024

CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(g), I hereby certify that this brief complies with the type-volume limitations of Fed. R. App. P. 29(a)(5) and 32(a)(7)(B) because it contains 4,172 words, excluding the parts exempted by Fed. R. App. P. 32(f). I further certify that this brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because the brief was prepared in 14-point Century Schoolbook font using Microsoft Word ProPlus 365.

Dated: May 22, 2024

/s/ Jeffrey S. Bucholtz
Jeffrey S. Bucholtz
Counsel for Amicus Curiae

CERTIFICATE OF SERVICE

I hereby certify that on May 22, 2024, I electronically filed the foregoing amicus brief with the Clerk of Court for the United States Court of Appeals for the First Circuit by using the appellate CM/ECF system, thereby serving all persons required to be served.

/s/ Jeffrey S. Bucholtz

Jeffrey S. Bucholtz

Counsel for Amicus Curiae