No. 25-728

In the
Supreme Court of the United States

THE UNITED STATES OF AMERICA AND THE STATE OF GEORGIA EX REL. BARBARA SENTERS,

Petitioner,

v.

QUEST DIAGNOSTICS INC.,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

REPLY BRIEF FOR PETITIONER

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INTRODUCTION

Respondents acknowledge that "different circuits have offered different articulations of the Rule 9(b) standard." BIO 18. And they do not deny that those differences regularly produce opposite outcomes in materially similar cases. *See* Pet. 12-25. They nonetheless argue the split is unworthy of review, reprising the Solicitor General's 2022 arguments every other stakeholder has since rejected—including respondents' counsel when they represented the defendant petitioning this Court to review the same question in *Molina Healthcare*. They were right then, wrong now.

The panel opinion refutes the BIO's central contention (at 11-18) that no circuit applies a categorical pleading rule. "No matter which theory [petitioner] pursues," the panel held, "her FAC rises and falls with the fact that she failed to plead with particularity that a *false* claim was submitted to the government." Pet. App. 7a. That meant either identifying the billing details of specific false invoices or alleging direct knowledge of such submissions. *See id.* 7a-8a. That is the Rule 9(b) pleading requirement dividing the circuits. *See also id.* 26a n.9 (district court observing that "recent ... Eleventh Circuit authority has clarified" the "absolute requirement" to plead such details "with particularity, regardless of other indicia of reliability" (citing *84Partners LLC v. Nuflo, Inc.*, 79 F.4th 1353, 1360 (11th Cir. 2023))).

The BIO otherwise mischaracterizes petitioner's false-certification theory, offers a forfeiture argument the panel did not accept, and invokes alternative grounds the courts below haven't addressed. None of those objections warrants denial. The Court should grant the petition or CVSG.

ARGUMENT

I. The Split Is Real, Deep, and Demands Review.

A. The BIO Does Not Dispute That Divergent Pleading Standards Are Driving Conflicting Outcomes in Similar Cases.

The BIO admits that "different circuits have offered different articulations of the Rule 9(b) standard." BIO 18. And the BIO does not dispute how the petition describes any of the cases from the six circuits that reject bright-line pleading requirements, *see* Pet. 12-18, or the petition's explanation that alike cases regularly come out differently under these "different articulations," *compare* BIO 18 *with* Pet. 12-25. Nor do respondents refute that petitioner's complaint likely would have survived under the majority rule. *See* Pet. 27-28. That is an intolerable circuit conflict ripe for this Court's review.

The BIO's response (at 11-18) is to deny the split by arguing that no circuit's standard is categorical. Its citations prove otherwise.

The BIO first claims that the Eleventh Circuit applies a "nuanced, case-by-case approach" in which "other means are available" to satisfy Rule 9(b). BIO 11-15 (quoting *United States ex rel. Mastej v. Health Mgmt. Assocs., Inc.*, 591 F. App'x 693, 704 (11th Cir. 2014)). But in every case it cites, only those relators who pleaded direct knowledge of false submissions survived dismissal. Start with *Vargas*, the BIO's lead case. The relators had "audited patient files—including billing correspondence and authorizations for payment," and identified specific upcoding instances with particularity. *Vargas v. Lincare, Inc.*,

134 F.4th 1150, 1158-59 (11th Cir. 2025). The court allowed *only* the upcoding theory to proceed and dismissed three other theories for failing to connect the alleged schemes to "actual claims submitted to the government." *Id.* at 1159 n.4; *see also id.* at 1162. *Matheny* and *Walker* follow the same pattern: The relators only overcame dismissal for those claims alleging personal participation in or observation of the billing scheme in operation. *See United States ex rel. Matheny v. Medco Health Sols., Inc.*, 671 F.3d 1217, 1220-21 (11th Cir. 2012); *United States ex rel. Walker v. R&F Props. of Lake Cnty., Inc.*, 433 F.3d 1349, 1360 (11th Cir. 2005). On the other hand, the relator in *Atkins* alleged particularized details about patients, dates, and medical records, but the Eleventh Circuit dismissed because he was "a psychiatrist responsible for the provision of medical care, not a billing and coding administrator." *Atkins v. McInteer*, 470 F.3d 1350, 1359 (11th Cir. 2006). The BIO cannot cite a single Eleventh Circuit case where a relator without direct billing knowledge survived dismissal. *See also* Pet. 18-20 (collecting cases).

The BIO next argues (at 15-16) that neither the Sixth nor Eighth Circuit "categorically requires relators to plead firsthand knowledge of specific false claims." But it does not dispute anything the petition said about those circuits. The Eighth Circuit in *Strubbe* dismissed despite allegations of a "wide-ranging fraudulent scheme" because the relators lacked "personal knowledge of the billing system or the submission of false claims." *United States ex rel. Strubbe v. Crawford Cnty. Mem'l Hosp.*, 915 F.3d 1158, 1165 (8th Cir. 2019). And the Sixth Circuit's sole exception exists in theory; in practice, only "*Prather* itself" has ever satisfied it. *United States ex rel. Ibanez v. Bristol-Myers Squibb Co.*, 874 F.3d 905, 915 (6th Cir.

2017); *see also United States ex rel. VIB Partners v. LHC Grp., Inc.*, 2025 WL 1103997, at *3 (6th Cir. Apr. 14, 2025) (dismissing under purportedly relaxed standard). The petition invited respondents to identify another; they did not. An exception that has produced exactly one survivor cannot eliminate the conflict with circuits that regularly let such claims proceed.

As for the three circuits that require relators to plead the details of actual false claim submissions by default, the BIO agrees with how petitioner describes the Second and Fourth Circuits' rules. *Compare* BIO 17-18 *with* Pet. 23-25. Respondents argue that the First Circuit's exception needs more time to percolate. *See* BIO 16-17 (citing *United States ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29 (1st Cir. 2017)). But *Nargol* was announced in 2017, and respondents identify no development since. *See also United States ex rel. Flanagan v. Fresenius Med. Care Holdings, Inc.*, 142 F.4th 25, 37 (1st Cir. 2025) (dismissing for failing to allege "actually submitted" false claims).

Finally, the BIO suggests that even the six circuits that apply a flexible standard sometimes require particularized allegations of false claims. *See* BIO 18 (citing one Seventh Circuit case). That those circuits might require more "in at least some circumstances," *ibid.*, is the point. That describes a context-specific standard, under which those circuits consistently permit claims like petitioner's to proceed, Pet. 12-18, 27-28—claims that are dismissed at the threshold in the First, Second, Fourth, Sixth, Eighth, and Eleventh Circuits, *id.* 18-23.

B. Fourteen Prior Petitions Confirm the Question's Importance.

The BIO reproduces the Solicitor General's 2022 recommendation, predicting that this Court would not

need to resolve the conflict because the circuits had been converging. *Compare* BIO 18 *with* U.S. *Amicus Curiae* Br. 22, *United States ex rel. Owsley v. Fazzi Assocs., Inc.*, No. 21-936 (U.S. 2022). As respondents' counsel argued then, when representing the defendant petitioner in *Molina Healthcare*: "Bluntly put, no, they haven't." Petr. Second Supp. Br. 2, *Molina Healthcare of Illinois, Inc. v. Prose*, No. 21-1145 (U.S. 2022). "Different results based on the application of the same rule to different facts are how law is supposed to work. Different results based on the application of different rules to the same facts are not." *Id.* at 1.[1]

The split has only calcified since. This case and at least *84Partners* (11th Cir. 2023), *Vargas* (11th Cir. 2025), *Flanagan* (1st Cir. 2025), *VIB Partners* (6th Cir. 2025), and *Olsen* (6th Cir. 2025)[2] have all reaffirmed those circuits' categorical approach. The BIO points to no case from any of these circuits applying the majority's context-specific standard. At minimum, the Solicitor General should be invited to address what has happened since it last weighed in four years ago.

This Court regularly grants review on questions like these even if they "could not reasonably be expected to produce a bright-line rule or otherwise eliminate all disuniformity." *Cf.* BIO 2 (quoting U.S.

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[1] Molina Healthcare's petition was supported by the U.S. Chamber of Commerce, *see Amicus* Br. 2 (split has "far-reaching consequences"), the Washington Legal Foundation, *see Amicus* Br. 3 (split "cries out for this Court's review"), and America's Health Insurance Plans, *see Amicus* Br. 5-6 & n.3 (split "acknowledged and deep").

[2] *United States ex rel. Olsen v. Tenet Healthcare Corp.*, 2025 WL 1166894 (6th Cir. Apr. 22, 2025), *cert. denied*, 2026 WL 80010 (U.S. Jan. 12, 2026).

Amicus Br. 21-22, *Owsley*).[3] Fourteen denials, including the recent denial in *Olsen* (6th Cir.), do not counsel otherwise. *Contra* BIO 1, 3, 10-11. Those cases left room for the Solicitor General's prediction that the circuits were converging. In the recent *Olsen* petition, the relators were emergency physicians who lacked access to billing records; a court considering that petition could reasonably have thought that a relator *with* such access might fare differently under the Sixth Circuit's *Prather* exception, for example. *See supra* pp.3-4. This case eliminates that possibility. As Quest's Business Unit Compliance Officer, petitioner's job was to ensure that tests billed to government payors were eligible for payment. FAC ¶¶26, 31. If even this relator cannot satisfy the Eleventh Circuit's pleading requirement, the rule is categorical and the question is squarely presented.

II. The BIO's Vehicle Arguments Fail.

A. The Eleventh Circuit Applied a Categorical Pleading Rule.

The BIO claims "the Eleventh Circuit neither announced nor enforced any categorical legal rule for pleading an FCA claim." BIO 14. The opinion says otherwise. The panel identified petitioner's "three theories of liability: (1) express false certification

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[3] *See, e.g.*, *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009) ("Determining whether a complaint states a plausible claim for relief" is "a context-specific task."); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 553 (2007) (deciding "proper standard for pleading an antitrust conspiracy"); *see also Fifth Third Bancorp v. Dudenhoeffer*, 573 U.S. 409, 414-15 (2014) (deciding question about ERISA breach-of-duty-of-prudence pleading standard); *Texas Dep't of Hous. & Communities Affs. v. Inclusive Communities Project, Inc.*, 576 U.S. 519, 543 (2015) (no bright-line rules for pleading disparate impact).

theory, (2) implied false certification theory, and (3) fraudulent inducement theory." Pet. App. 6a-7a. "No matter which theory she pursues," it held, "her FAC rises and falls with the fact that she failed to plead with particularity that a *false* claim was submitted to the government." *Id.* 7a.

The Eleventh Circuit's reasoning proves the nature of its categorical rule. Petitioner reviewed thousands of Medicare and Medicaid claims as a Quest compliance officer, comparing physicians' original paper orders with the tests Quest performed and billed. FAC ¶¶24, 198-99, 209, 211-12. She found that Quest billed for tests the physicians never authorized, meaning no valid physician order met Medicare's reimbursement requirements. FAC ¶¶200, 212; 42 C.F.R. § 410.32(a). Yet the panel held that pleading her "access and knowledge" could not satisfy Rule 9(b) because petitioner alleged neither "'specific details regarding either the dates on or the frequency with which the defendants submitted false claims, the amounts of those claims, or the patients whose treatment served as the basis for the claims,'" nor her participation in or observation of such submissions. Pet. App. 8a (quoting *United States ex rel. Sanchez v. Lymphatx, Inc.*, 596 F.3d 1300, 1302 (11th Cir. 2010) (per curiam); citing *Matheny*, 671 F.3d at 1230); *see also id.* 26a n.9 (district court recognizing Eleventh Circuit's "absolute requirement" to plead such details "regardless of other indicia of reliability").

B. The BIO Does Not Refute Petitioner's Theories on the Merits.

The BIO devotes most of its vehicle argument to mischaracterizing how petitioner pleads falsity while offering no substantive response on fraudulent inducement. Neither strategy works.

1. Respondents misrepresent the false-certification claims.

The BIO clams the panel rejected only a theory that Quest's certifications were "false" because Quest "did not know if the services were medically necessary." BIO 9, 14, 21-22. From that premise, it asserts that petitioner "abandoned any argument that Quest had submitted claims for medically unnecessary tests." *Id.* 22 (citing Petr. C.A. Br. 27). That conflates two propositions. The BIO isolates petitioner's passing observation that Quest certified medical necessity without knowing whether doctors intended to prescribe any of the tests included in a custom panel and recasts that as the whole of petitioner's falsity theory. Not so.

Petitioner's theory is that Quest's certifications were *legally false*: Quest certified compliance with Medicare's requirement of a valid physician order for each billed test when no such order existed. *See* Petr. C.A. Reply Br. 17 ("Falsity stems from certifying compliance with Medicare regulations ... despite no valid orders ... ."). Medicare reimburses lab tests only when "ordered by the physician who is treating the beneficiary." 42 C.F.R. § 410.32(a). Yet Quest certified on every claim that it had complied with Medicare's reimbursement requirements and that each billed test was "medically indicated and necessary," even though no valid physician order existed for the individual component tests in Quest's Care360 panels, because Quest's scheme kept physicians from knowing what those components were and from independently authorizing them. *See* FAC ¶161 (Quest bypassed compliance procedures to create electronic panels); ¶¶173-74, 182 (Quest sales reps trained to build panels in Care360 without physician authorization,

and took "no steps" to verify physicians knew what tests were included); ¶180 (Quest concealed panel contents from physicians); ¶¶39-40, 175 (Quest phlebotomists converted paper panel selections into electronic requisitions automatically ordering every component test); ¶¶185-86 (Quest then unbundled each panel and billed every test individually to the Government).[4]

Quest acknowledges it must have a physician's order. *See* BIO 5. And although a laboratory may usually rely on a doctor's order as a safe harbor for clinical necessity (*see* BIO 4-5), Quest does not dispute that this protection is lost when the lab's own conduct prevents physicians from independently deciding what to prescribe. *See United States ex rel. Omni Healthcare, Inc. v. MD Spine Sols. LLC*, 160 F.4th 248, 261 n.14 (1st Cir. 2025) (when a laboratory's "own actions have made a medical service unnecessary, [it] should not be shielded by the independent determination of a physician, who never took—who was never asked to take—the laboratory's subsequent conduct into account" (quoting *United States v. Bertram*, 900 F.3d 743, 750 (6th Cir. 2018))). The parties agree that falsity and scienter are distinct elements. *See* BIO 21. Whether Quest knew of, deliberately ignored, or recklessly disregarded Medicare's reimbursement conditions goes to scienter, which the complaint alleges in detail.

[4] Only claims for tests ordered through Quest's Care360 custom panels would be false. Tests individually ordered by physicians with valid orders would not be false.

2. Respondents do not contest the merits of the fraudulent-inducement claim.

Respondents' claim that petitioner's fraudulent inducement theory was "never raised" below and thus forfeited, BIO 20, is contradicted by both the briefing and the panel's decision. Petitioner pressed the theory in her briefing. Petr. C.A. Br. 19-20; Petr. C.A. Reply Br. 18-21. Respondents argued forfeiture. Resps. C.A. Br. 33-35. Rather than accept respondents' forfeiture claim, the panel identified fraudulent inducement as one of petitioner's "three theories of liability" and rejected all three for the same reason. Pet. App. 6a-8a.

The complaint speaks for itself. Quest enrolled as a Medicare provider by "agree[ing] to abide by [Medicare's] laws, regulations, and program instructions" governing claims for payment, including that it would "not knowingly present" false claims nor "submit claims with deliberate ignorance or reckless disregard of their truth or falsity." FAC ¶¶64, 68. Quest had an ongoing duty to notify Medicare if enrollment information became untrue, FAC ¶69, and re-enrolled multiple times while acquiring additional laboratories, FAC ¶168. Yet Quest violated those requirements and dismantled the physician authorization safeguards it was forced to adopt under its DOJ settlement and Corporate Integrity Agreement following Operation LabScam, while certifying compliance to enroll. *See* FAC ¶¶152-61, 173-74, 186, 189-96. "[E]ach and every claim submitted under" the false enrollment "constitutes a false claim." *See* S. Rep. No. 99-345, at 9 (1986); *see, e.g.*, *United States ex rel. Hendow v. University of Phoenix*, 461 F.3d 1166, 1170-71 (9th Cir. 2006) (same).

Respondents offer no response on the merits, underscoring this case's value as a vehicle. Because

the fraudulent-inducement claim does not depend on individual invoices, the Eleventh Circuit's bright-line pleading rule necessarily derived the outcome.

C. Alternative Grounds Unaddressed Below Are Not Reasons to Deny Review.

The BIO invokes alternative grounds for affirmance (at 21-22) but concedes the panel did not reach them, confirming that the question is cleanly presented. As the United States often argues, "when an issue resolved by a court of appeals warrants review, the existence of a potential alternative ground to defend the judgment is not a barrier to review—particularly where, as here, that ground ... was not addressed by the court of appeals." *See, e.g.*, U.S. Pet. Reply 9, *Comm'r Internal Revenue v. Estate of Jelke*, No. 07-1582 (U.S. 2008).[5]

Aside from asserting unaddressed merits arguments, respondents pretend that this case "languished" under seal. *See* BIO 6. Federal and state authorities spent those nine years issuing document subpoenas, interviewing witnesses, and coordinating across agencies, even pursuing parallel criminal inquiries.[6] Nearly a decade of sustained criminal and

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[5] *See also, e.g.*, *United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739, 757-58 (2023) (granting certiorari to resolve legal questions and remands for lower courts to address remaining arguments); *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 196 (2016) (same). Pending constitutional challenges likewise do not counsel against review. *Cf.* BIO 4 n.2. The Court granted the petitions and reached the merits in *SuperValu* and *United States ex rel. Polansky v. Executive Health Resources, Inc.*, 599 U.S. 419 (2023), despite those lurking concerns.

[6] *Cf. United States ex rel. Purcell v. MWI Corp.*, 209 F.R.D. 21, 26-27 (D.D.C. 2002) (relator's voluntary disclosures to the Government are protected by joint-prosecutorial privilege).

civil government scrutiny shows merit, not grounds to dismiss. *Cf. United States ex rel. Chandler v. Cook Cnty.*, 277 F.3d 969, 974 n.5 (7th Cir. 2002) ("The Justice Department may have myriad reasons for permitting the private suit to go forward including limited prosecutorial resources and confidence in the relator's attorney."), *aff'd*, 538 U.S. 119 (2003).

CONCLUSION

The Court should grant the petition or call for the views of the Solicitor General.

Respectfully submitted,

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