No. 12-1349

In the Supreme Court of the United States

UNITED STATES EX REL. NOAH NATHAN, PETITIONER

v.

TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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QUESTION PRESENTED

Whether a relator in a *qui tam* action under the False Claims Act, 31 U.S.C. 3729 *et seq.*, must identify specific false claims submitted for payment in order to plead fraud with sufficient particularity to satisfy Federal Rule of Civil Procedure 9(b).

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INTEREST OF THE UNITED STATES

This brief is submitted in response to the order of the Court inviting the Solicitor General to express the views of the United States. In the view of the United States, the petition for a writ of certiorari should be denied.

STATEMENT

1. The False Claims Act (FCA), 31 U.S.C. 3729 *et seq.*, provides for the imposition of civil penalties and treble damages against any person who, *inter alia*, "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 "claims" subject to the FCA include "any request or demand * * * for money or property" that is "presented to an officer, employee, or agent of the United States," as well as certain

claims presented to entities that receive federal funds. 31 U.S.C. 3729(b)(2).[1] The Attorney General may bring a civil action if he finds that a person has violated the FCA. 31 U.S.C. 3730(a). Alternatively, a private person (known as a relator) may bring his own suit (commonly referred to as a *qui tam* action) "for the person and for the United States Government." 31 U.S.C. 3730(b)(1); see *United States ex rel. Eisenstein* v. *City of New York*, 556 U.S. 928, 930 (2009).

If a relator brings a *qui tam* action, the complaint is initially filed under seal and served upon the government, together with "substantially all material evidence and information the [relator] possesses." 31 U.S.C. 3730(b)(2). "The Government may elect to intervene and proceed with the action within 60 days after it receives both the complaint and the material evidence and information," *ibid.*, and the district court may extend the 60-day period upon a showing of good cause, 31 U.S.C. 3730(b)(3). If the government declines to intervene, the relator "shall have the right to conduct the action," but the district court "may nevertheless permit the Government to intervene at a later date upon a showing of good cause." 31 U.S.C. 3730(c)(3). If a *qui tam* action results in the recovery of damages or civil penalties, the award is divided between the government and the relator. 31 U.S.C. 3730(d).

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[1] Section 3729 was amended while the conduct at issue in this case was ongoing. See Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21, § 4(a), 123 Stat. 1621. The changes are not material to the question presented, and the parties and the courts below appear to have agreed that the amended statute governs this case. See Pet. App. 2a, 24a.

2. This *qui tam* action alleges that a pharmaceutical company caused false claims to be presented to the federal Medicare and Medicaid programs by promoting one of its drugs for uses that have not been approved by the Food and Drug Administration (FDA).

a. Under the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.*, a new drug may not be introduced into interstate commerce unless FDA has approved a new drug application based on the agency's determination that the drug is safe and effective for its intended use. 21 U.S.C. 355(a) and (d). FDA must also approve the drug's labeling, which specifies, *inter alia*, the FDA-approved uses and dosages for the drug. 21 U.S.C. 355(b)(1)(F) and (d); 21 C.F.R. 201.5(b), 201.55-201.57.

Because a drug that is safe and effective for one use may be neither safe nor effective for others, FDA approval extends only to the uses specified in a drug's approved application and labeling. 21 U.S.C. 355(d). A new drug that is distributed for an intended use that has not been approved by FDA is "misbranded," and the FDCA prohibits its distribution in interstate commerce. 21 U.S.C. 352(f); 21 C.F.R. 201.5; see 21 U.S.C. 331(a). A drug's "intended uses" are determined by the objective intent of the drug manufacturer, which may be demonstrated by the drug's "advertising" and by other "oral or written statements" by the manufacturer or its representatives. 21 C.F.R. 201.128. Accordingly, a manufacturer's promotion of a drug for unapproved uses may constitute evidence that the manufacturer has violated the FDCA's misbranding provisions by distributing a drug for an intended use that has not been approved by FDA. See

Washington Legal Found. v. *Henney*, 202 F.3d 331, 332-333 (D.C. Cir. 2000).

FDA does not, however, attempt to regulate the practice of medicine. Once a drug is approved for one use at one dosage, doctors are free to prescribe it for unapproved uses or at other dosages—a practice that is sometimes called "off-label" prescribing. See 59 Fed. Reg. 59,820, 59,821 (Nov. 18, 1994); *Washington Legal Found.*, 202 F.3d at 332-333; cf. *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 350-351 (2001) (discussing the similar statutory scheme governing medical devices).

b. Although prescriptions for unapproved uses are not prohibited by the FDCA, they may be ineligible for reimbursement under the federal Medicare and Medicaid programs. "Medicare is a federally funded health insurance program for the elderly and disabled." *Thomas Jefferson Univ.* v. *Shalala*, 512 U.S. 504, 506 (1994). Medicaid is a cooperative federal-state program that funds medical care for needy individuals. *Arkansas Dep't of Health & Human Servs.* v. *Ahlborn*, 547 U.S. 268, 275 (2006). Both programs provide coverage for certain prescription drugs. See 42 U.S.C. 1395w-102 (2006 & Supp. V 2011) (Medicare); 42 U.S.C. 1396r-8 (2006 & Supp. V 2011) (Medicaid). To be eligible for reimbursement, however, a drug generally must be prescribed for an FDA-approved use or for another "medically accepted indication" listed in one of several statutorily specified compendia. 42 U.S.C. 1395w-102(e)(1) (2006 & Supp. V 2011); 42 U.S.C. 1395w-102(e)(4) (Supp. V 2011); 42 U.S.C. 1396b(i)(10), 1396r-8(k)(3) and (6); see 42 U.S.C. 1396r-8(g)(1)(B)(i) (identifying compendia).

c. Petitioner Noah Nathan is a sales manager employed by respondent Takeda Pharmaceuticals. Pet. App. 2a. Respondent manufacturers and sells a drug known as Kapidex, which suppresses the production of stomach acid. *Id.* at 3a.[2] FDA has approved Kapidex for three indications: (1) for the healing of erosive esophagitis (EE), a condition in which refluxed stomach acid causes ulcers in the throat, with a recommended dose of 60 milligrams daily; (2) for the maintenance of healed EE, with a recommended dose of 30 milligrams daily; and (3) for the treatment of non-erosive gastroesophageal reflux disease (GERD), commonly known as heartburn or acid reflux, with a recommended dose of 30 milligrams daily. *Id.* at 4a. Petitioner alleged that the relevant compendia do not specify any other medically accepted indications for Kapidex, and that these three FDA-approved uses are therefore the only ones eligible for reimbursement under Medicare and Medicaid. *Id.* at 77a.

Petitioner contended that respondent had violated the FCA by knowingly causing Kapidex prescriptions written for unapproved uses to be presented to Medicare and Medicaid for reimbursement. Specifically, petitioner alleged that respondent had urged doctors to prescribe 60-milligram doses of Kapidex to GERD patients because respondent believed that a 60-milligram dose was more effective in treating GERD than the 30-milligram dose specified in the FDA-approved labeling. Pet. App. 3a-4a. For example, petitioner alleged that respondent had offered samples of Kapidex exclusively in the 60-milligram dose and had provided those samples to primary care phy-

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[2] Kapidex is now known as "Dexilant." Pet. App. 3a n.3. Like the decisions below, this brief refers to the drug as Kapidex.

sicians and other doctors who treat GERD but generally do not treat active EE, the only condition for which a 60-milligram dose is approved. *Id.* at 4a. Petitioner alleged that respondent's actions had caused doctors to write prescriptions for unapproved uses; that some of those prescriptions had gone to patients covered by Medicare and Medicaid; and that false claims had resulted when those patients or their health care providers sought reimbursement from the federal health care programs. *Id.* at 41a, 44a-45a.

3. Petitioner filed his *qui tam* complaint in September 2009. The government declined to intervene, and petitioner amended his complaint twice after it was unsealed. The district court dismissed the complaint without prejudice, finding it deficient in several respects. Pet. App. 17a-18a & n.10. Petitioner then filed a third amended complaint, which the district court dismissed with prejudice on two alternative grounds. *Id.* at 19a-31a.

a. The district court first held that the complaint failed to satisfy Federal Rule of Civil Procedure 9(b), which provides that a complaint alleging fraud "must state with particularity the circumstances constituting fraud." See Pet. App. 22a-28a. The court noted that petitioner's complaint "failed to identify any specific instances in which [respondent] caused a pharmacist or other healthcare provider to submit a claim for reimbursement to the government based on a non-reimbursable prescription." *Id.* at 24a. Instead, the complaint relied on "a combination of statistics and general allegations." *Ibid.*

The district court held that this "statistics-based" approach failed to satisfy Rule 9(b). Pet. App. 24a. In particular, the court rejected petitioner's reliance on

98 Kapidex prescriptions written by 16 primary care physicians. Petitioner's complaint identified the 16 doctors by name, listed the month in which each prescription was written, and further alleged that each of the 98 prescriptions was submitted to Medicare for reimbursement. *Id.* at 26a-27a; see *id.* at 105a-109a. Petitioner did not, however, "allege that the prescriptions issued were in fact for 60 milligram doses." *Id.* at 26a. Instead, petitioner argued that it was reasonable to infer that more than 90% of the 98 prescriptions were for 60-milligram doses because the 16 doctors had received 60-milligram samples of Kapidex, and because more than 90% of respondent's overall sales of Kapidex are at the 60-milligram dose. *Ibid.* The district court rejected that inference as too speculative, concluding that petitioner had not "allege[d] any basis on which to assume that the overall level of 60 milligram doses, as a percentage of overall Kapidex sales, corresponds to the prescriptions that were actually issued by these [16] primary care physicians." *Id* at 26a-27a.[3]

b. The district court also held, in the alternative, that petitioner's complaint lacked plausible allegations that respondent had "caused" the presentation of false claims within the meaning of Section 3729(a)(1)(A). Pet. App. 28a-29a. The court concluded that, even if Kapidex prescriptions for unapproved uses were submitted to Medicare and Medicaid for reimbursement, petitioner had failed to plead facts supporting a plau-

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[3] In the lower courts, petitioner unsuccessfully argued that other, more general allegations in his complaint independently satisfied Rule 9(b). Pet. App. 11a-16a, 24a-28a. His petition for certiorari, however, relies only on the 98 prescriptions written by 16 primary care physicians. See Pet. 9-10, 30-31.

sible inference that those prescriptions were caused by respondent's actions rather than by the independent judgment of the prescribing physicians. *Id.* at 29a.

4. The court of appeals affirmed. Pet. App. 1a-18a. The court held that petitioner's complaint did not satisfy Rule 9(b) and the plausibility standard set forth in *Ashcroft* v. *Iqbal*, 556 U.S. 662, 678 (2009), because petitioner had "failed to plausibly allege that any false claims had been presented to the government for payment." Pet. App. 2a.

The court of appeals first addressed the pleading standards governing FCA complaints, which must satisfy Rule 9(b) and must "state a claim to relief that is plausible on its face," *Iqbal*, 556 U.S. at 678. See Pet. App. 5a-6a. The court held that, because "liability under the Act attaches only to a claim actually presented to the government for payment," a relator must "plead plausible allegations of presentment." *Id.* at 8a. The court further held that, under both Rule 9(b) and "the general plausibility standard of *Iqbal*," "'some indicia of reliability' must be provided in the complaint to support the allegation that an actual false claim was presented to the government." *Id.* at 8a-9a (quoting *United States ex rel. Clausen* v. *Laboratory Corp. of Am.*, 290 F.3d 1301, 1311 (11th Cir. 2002), cert. denied, 537 U.S. 1105 (2003)).

The court of appeals identified some prior judicial decisions holding that "Rule 9(b) can be satisfied in the absence of particularized allegations of specific false claims." Pet. App. 9a. In the view of the court below, those cases involved circumstances in which "specific allegations of the defendant's fraudulent conduct necessarily led to the plausible inference that

false claims were presented to the government." *Id.* at 9a-10a (citing *United States ex rel. Grubbs* v. *Kanneganti*, 565 F.3d 180, 192 (5th Cir. 2009); *United States ex rel. Duxbury* v. *Ortho Biotech Prods., L.P.*, 579 F.3d 13, 30 (1st Cir. 2009), cert. denied, 130 S. Ct. 3454 (2010)). The court concluded, however, that where the defendant's alleged conduct "*could* have led, but *need not necessarily* have led, to the submission of false claims, a relator must allege with particularity that specific false claims actually were presented to the government." *Id.* at 10a. The court of appeals added that, "[t]o the extent that other cases apply a more relaxed construction of Rule 9(b)," the court "disagree[d] with that approach." *Ibid.*

The court of appeals then applied this standard to petitioner's allegation that 16 primary care physicians had written 98 Kapidex prescriptions that were submitted to Medicare. The court explained that, although petitioner "allege[d] that these [98] claims were presented to the government for payment," he did not "plausibly allege that the prescriptions were written for off-label uses." Pet. App. 13a. The court of appeals rejected as too "speculative" petitioner's contention that, because more than 90% of *all* Kapidex prescriptions are for the 60-milligram dose, a comparable percentage of these 98 specific prescriptions likely were for that dose. *Id.* at 13a-14a. The court also noted that, even if some of the 98 prescriptions had been for the 60-milligram dose, those prescriptions were not necessarily ineligible for reimbursement because they could have been written to treat

active EE, a condition for which the 60-milligram dose is approved. *Id.* at 14a.[4]

DISCUSSION

Although the disagreement is not as clearly defined as petitioner contends, lower courts have reached inconsistent conclusions about the precise manner in which a *qui tam* relator may satisfy the requirements of Rule 9(b). Several courts of appeals have correctly held that a *qui tam* complaint satisfies Rule 9(b) if it contains detailed allegations supporting a plausible inference that false claims were submitted to the government, even if the complaint does not identify specific requests for payment. Other decisions, however, have articulated a per se rule that a relator must plead the details of particular false claims—that is, the dates and contents of bills or other demands for payment—to overcome a motion to dismiss.

This per se rule is unsupported by Rule 9(b) and undermines the FCA's effectiveness as a tool to combat fraud against the United States. Indeed, even those circuits that initially endorsed the per se rule have issued subsequent decisions that appear to adopt a more nuanced approach. The disagreement among the circuits therefore may be capable of resolution without this Court's intervention. If that disagreement persists, however, this Court's review to clarify the applicable pleading standard may ultimately be warranted in an appropriate case.

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[4] Because it affirmed the dismissal of petitioner's complaint based on the failure to plausibly allege that false claims were presented to the government, the court of appeals did not consider the district court's alternative holding that petitioner had failed adequately to allege causation. Pet. App. 5a.

This case, however, is not a suitable vehicle for resolving the question presented. The court below correctly held that petitioner's complaint failed to satisfy the requirements of both Rule 9(b) and *Ashcroft* v. *Iqbal*, 556 U.S. 662 (2009), because it did not plausibly allege that false claims were presented to the government. Because the complaint failed not merely for lack of specificity, but also for lack of plausibility, this suit could not go forward even under the pleading standard most favorable to relators. Particularly because the issue continues to percolate in the lower courts, this Court's consideration of the question presented should await a case in which it would be outcome-determinative.

1. The lower courts have reached conflicting results about the application of Rule 9(b) in the FCA context. Recent decisions, however, create some uncertainty about the extent of the disagreement.

a. Although a plaintiff "must state with particularity the circumstances constituting fraud," Fed. R. Civ. P. 9(b), several courts of appeals have correctly recognized that pleading the details of a specific false claim presented to the government is not an indispensable requirement of a viable FCA complaint. Even at trial, "a plaintiff does not necessarily need the exact dollar amounts, billing numbers, or dates to prove to a preponderance that fraudulent bills were actually submitted." *United States ex rel. Grubbs* v. *Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009). To demand those details to survive a motion to dismiss is "significantly more than any federal pleading rule contemplates." *Ibid.* Accordingly, several courts have held that a relator's complaint satisfies Rule 9(b) if it "alleg[es] particular details of a scheme to submit false

claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Ibid.*; see *Ebeid* v. *Lungwitz*, 616 F.3d 993, 998-999 (9th Cir.) (same), cert. denied, 131 S. Ct. 801 (2010); *United States ex rel. Lusby* v. *Rolls-Royce Corp.*, 570 F.3d 849, 854 (7th Cir. 2009) (Easterbrook, C.J.) ("We don't think it essential for a relator to produce the invoices (and accompanying representations) at the outset of the suit.").

The First and Fourth Circuits have also declined to adopt a per se rule requiring relators to plead specific false claims. The First Circuit has held that where—as in this case—a *qui tam* complaint alleges that "the defendant induced *third parties* to file false claims with the government," the complaint can "satisfy Rule 9(b) by providing 'factual or statistical evidence to strengthen the inference of fraud beyond possibility' without necessarily providing details as to each false claim." *United States ex rel. Duxbury* v. *Ortho Biotech Prods., L.P.*, 579 F.3d 13, 29 (2009) (quoting *United States ex rel. Rost* v. *Pfizer, Inc.*, 507 F.3d 720, 733 (1st Cir. 2007)), cert. denied 130 S. Ct. 3454 (2010). In the decision below, the Fourth Circuit endorsed the results in *Grubbs* and *Duxbury* and indicated that a relator need not identify particular false claims when "specific allegations of the defendant's fraudulent conduct necessarily [lead] to the plausible inference that false claims were presented to the government." Pet. App. 9a.

b. By contrast, the Sixth, Eighth, Tenth, and Eleventh Circuits have issued decisions finding that particular *qui tam* complaints should be dismissed under Rule 9(b) because the relators failed to identify specific requests for payment. See, *e.g.*, *United States ex*

rel. Bledsoe v. *Community Health Sys., Inc.*, 501 F.3d 493, 504 (6th Cir. 2007) ("We hold that pleading an actual false claim with particularity is an indispensable element of a complaint that alleges a FCA violation in compliance with Rule 9(b)."); *United States ex rel. Joshi* v. *St. Luke's Hosp., Inc.*, 441 F.3d 552, 560 (8th Cir.) (requiring a relator to plead "some representative examples" of false claims), cert. denied, 549 U.S. 881 (2006); *United States ex rel. Sikkenga* v. *Regence BlueCross BlueShield*, 472 F.3d 702, 727-728 (10th Cir. 2006) (affirming dismissal of a complaint that failed "to identify any specific [false] claim"); *Hopper* v. *Solvay Pharm., Inc.*, 588 F.3d 1318, 1326 (11th Cir. 2009) (holding that a relator must plead a specific false claim to avoid dismissal), cert. denied, 130 S. Ct. 3465 (2010).

These courts, however, have not consistently adhered to this rigid understanding of Rule 9(b). The Sixth Circuit recently left open the possibility "that the requirement that a relator identify an actual false claim may be relaxed when, even though the relator is unable to produce an actual billing or invoice, he or she has pled facts which support a strong inference that a claim was submitted." *Chesbrough* v. *VPA, P.C.*, 655 F.3d 461, 471 (2011). The Tenth Circuit has likewise stated that an FCA complaint "need only show the specifics of a fraudulent scheme and provide an adequate basis for a reasonable inference that false claims were submitted as part of that scheme." *United States ex rel. Lemmon* v. *Envirocare of Utah, Inc.*, 614 F.3d 1163, 1172 (2010) (citing *Duxbury*, 579 F.3d at 29; *Lusby*, 570 F.3d at 854-855; *Grubbs*, 565 F.3d at 190). And both the Eighth and Eleventh Circuits have allowed *qui tam* complaints to proceed notwithstand-

ing relators' failure to identify "specific fraudulent claims for payment submitted to the government." *In re Baycol Prods. Litig.*, 732 F.3d 869, 875-877 (8th Cir. 2013); see *United States ex rel. Walker* v. *R&F Props. of Lake Cnty., Inc.*, 433 F.3d 1349, 1360 (11th Cir. 2005), cert. denied, 549 U.S. 1027 (2006); see also *United States ex rel. Clausen* v. *Laboratory Corp. of Am.*, 290 F.3d 1301, 1311 (11th Cir. 2002) (stating that a *qui tam* complaint must contain "some indicia of reliability * * * to support the allegation of an actual false claim for payment") (emphasis omitted), cert. denied, 537 U.S. 1105 (2003).[5]

c. The current extent of the disagreement among the lower courts is thus uncertain, and the courts of appeals that have previously articulated a per se rule requiring relators to plead the details of specific false claims may have retreated from a rigid application of that rule. There is, however, at least some continuing uncertainty as to whether a *qui tam* complaint satisfies Rule 9(b) if it contains detailed allegations giving rise to a reasonable inference that false claims were submitted to the government, but does not identify specific requests for payment.

As the government explained when the Court sought the views of the United States on another petition raising the same question, a rigid rule that

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[5] The First Circuit, too, has shifted its approach to this question. In 2004, that court appeared to adopt a per se rule that "a relator must provide details that identify particular false claims for payment." *United States ex rel. Karvelas* v. *Melrose-Wakefield Hosp.*, 360 F.3d 220, 232, cert. denied, 543 U.S. 820 (2004). But the court later narrowed that holding, making clear that specific false claims need not be identified when the relator alleges that "the defendant induced *third parties* to file false claims with the government." *Duxbury*, 579 F.3d at 29.

such complaints are inadequate would hinder the ability of *qui tam* relators to perform the role that Congress intended them to play in the detection and remediation of fraud against the United States. See U.S. Amicus Br. at 16-17, *Ortho Biotech Prods., L.P.* v. *United States ex rel. Duxbury*, No. 09-654 (May 19, 2010). *Qui tam* complaints are often filed by the defendants' current and former employees. Such relators may be privy to detailed information indicating that their employers are engaged in fraud against the United States, and may be well-positioned to provide valuable assistance to the government's anti-fraud efforts, even if they are not privy to the details of the defendants' billing activities.

In *Lusby*, for example, an engineer who had worked for a government contractor alleged that his former employer had falsely represented that its aircraft engines met the government's specifications. See 570 F.3d at 853-854. And in *Grubbs*, a physician alleged that other doctors at his hospital had sought to recruit him into a scheme to bill the government for services they had not provided. See 565 F.3d at 191-192. Both relators came forward with detailed, plausible allegations of fraud. Yet under a per se rule requiring *qui tam* complaints to identify specific false claims, both suits would have been dismissed because neither relator was familiar with the minutiae of his employer's billing. Because a prospective relator is unlikely to be privy to such details unless she "works in the defendant's accounting department," a rule demanding the details of specific false claims would "take[] a big bite out of *qui tam* litigation." *Lusby*, 570 F.3d at 854.

Subjecting *qui tam* relators to a per se rule requiring the identification of specific false claims is especially unwarranted because it attaches dispositive significance to the relator's awareness of details that in most instances are already known to the government. The government rarely if ever needs a relator's assistance to identify claims for payment that have been submitted to the United States. Rather, relators typically contribute to the government's enforcement efforts by bringing to light other information that shows those claims to be false. Requiring *qui tam* complaints to identify specific false claims thus would not meaningfully assist the government's enforcement efforts. To the contrary, the likely effect of such a requirement would be to discourage the filing of *qui tam* suits by relators—like those in *Grubbs* and *Lusby*—who would otherwise have the means and the incentive to expose frauds against the United States.

2. The proper application of Rule 9(b) in the FCA context is thus a significant issue. If one or more courts of appeals continue to adhere to the rigid view that petitioner attributes to the court below (but see pp. 13-14, *supra*), this Court's intervention may be warranted in a case where application of that approach appears to be outcome-determinative. This case, however, is not a suitable vehicle in which to take up the question. The court below correctly held that petitioner's complaint failed to satisfy Rule 9(b) and *Iqbal* because it does not plausibly allege that false claims were presented to the government. Petitioner's suit therefore could not go forward under the pleading standard adopted by any court of appeals.

a. Petitioner contends (Pet. 19-20; Reply Br. 3-4 & n.2) that the court of appeals found his complaint

insufficient only because that court adopted an inflexible rule requiring *qui tam* relators to identify specific false claims. But the court of appeals did not adopt that per se rule. To the contrary, it required only "'some indicia of reliability' * * * to support the allegation that an actual false claim was presented to the government." Pet. App. 8a (quoting *Clausen*, 290 F.3d at 1311). The court stated that a relator must identify specific false claims only where the "defendant's actions, as alleged and as reasonably inferred from the allegations, *could* have led, but *need not necessarily* have led, to the submission of false claims." *Id.* at 10a. Although this articulation of the pleading standard differs from the phrasing used by other circuits, it does not require that every *qui tam* complaint plead the details of specific false claims.[6]

The court of appeals' rejection of a per se rule is further confirmed by the balance of its opinion. If the court had followed the decisions demanding that a relator plead "representative examples" of specific

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[6] Petitioner contends (Reply Br. 5) that, by requiring a relator to identify specific false claims whenever a defendant's conduct would not "necessarily" have led to the submission of false claims, the court of appeals improperly elevated *Iqbal*'s plausibility requirement to a demand that relators "prov[e] falsity." But the court below did not require such proof; rather, it rejected petitioner's complaint because petitioner had failed to "plausibly allege" the presentation of false claims. Pet. App. 2a, 13a. The court of appeals explained, moreover, that a relator's complaint is sufficient if the defendant's actions "as alleged *and as reasonably inferred from the allegations*" would "necessarily have led[] to the submission of false claims." *Id.* at 10a (emphasis altered). That formulation suggests that petitioner's complaint would have satisfied the court's standard if petitioner had alleged facts sufficient to support a reasonable inference that false claims were submitted.

false claims, *Joshi*, 441 F.3d at 557, or the "dates, times, or amounts of individual false claims," *Hopper*, 588 F.3d at 1326, it would have rejected petitioner's complaint out of hand, because there is no dispute that petitioner failed to allege the details of any request for payment made to the federal government. See Pet. 29-30.[7] Despite the conceded absence of any allegation of a specific false claim, however, the court of appeals carefully examined the complaint to determine whether it provided a plausible basis for inferring that false claims were presented. Pet. App. 11a-17a. And as to the 98 Kapidex prescriptions on which petitioner now relies, the court's analysis indicates that its decision rested chiefly on the complaint's lack of *plausibility*, not its lack of *particularity*. The court characterized petitioner's allegation regarding those 98 prescriptions as resting on "speculative" and "implausible" assertions, and the court framed its holding as a conclusion that petitioner had not "plausibly allege[d] that the [98] prescriptions were written for off-label uses." *Id.* at 13a-14a.

This lack of plausible allegations that respondent's conduct led to the presentation of false claims would have doomed petitioner's complaint before every court of appeals, even those that apply the most relator-friendly pleading standards. See, *e.g.*, *Duxbury*, 579 F.3d at 29 (requiring "factual or statistical evidence to

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[7] Petitioner provided some details concerning 98 Kapidex prescriptions, including the names of the prescribing doctors and the months in which the prescriptions were written. Pet. App. 105a-109a. He also generally alleged that all 98 prescriptions were submitted to Medicare for reimbursement. *Ibid.* He provided no dates, amounts, or other details, however, about the circumstances under which reimbursement was sought. See *ibid.*

strengthen the inference of fraud beyond possibility" (quoting *Rost*, 507 F.3d at 733)); *Lusby*, 570 F.3d at 854-855 (complaint need not "exclude all possibility of honesty," but must contain more than "vague and unsubstantiated allegations of fraud"); *Grubbs*, 565 F.3d at 190 (requiring "reliable indicia that lead to a strong inference that claims were actually submitted"); *Ebeid*, 616 F.3d at 998-999 (same). Because the deficiencies in petitioner's complaint would have resulted in dismissal in any circuit, the disagreement about the application of Rule 9(b) in FCA cases is not implicated here.

b. Petitioner contends (Pet. 28-33) that the court of appeals was wrong to find his allegations implausible. But the question whether this particular complaint plausibly alleged the presentation of false claims to the government is a factbound issue that would not warrant this Court's review even if the court of appeals had erred. In any event, the decision below is correct.

Petitioner relies on the allegation that 16 primary care physicians wrote 98 Kapidex prescriptions that were ultimately submitted to Medicare for reimbursement. Petitioner did not, however, directly allege that those prescriptions were ineligible for reimbursement. Instead, petitioner argues that general allegations and nationwide statistics about Kapidex prescriptions support an inference that these 98 prescriptions were for 60-milligram rather than 30-milligram doses, and a further inference that the prescriptions were for GERD rather than for the healing of active EE (an indication for which a 60-milligram dose is approved). As the court of appeals correctly

held, the allegations in petitioner's complaint do not support either inference.

First, the complaint does not provide a plausible basis for inferring that the 98 prescriptions were for 60-milligram doses. Petitioner contends (Pet. 31) that "there is a 'more than 90%' certainty" that these prescriptions were for 60-milligram doses because the 16 doctors received 60-milligram samples and because 93% of *all* Kapidex prescriptions are written for 60-milligram doses. As the court of appeals observed, however, the complaint fails to "connect[] these general statistics to the 98 prescriptions identified." Pet. App. 14a. Although petitioner's theory of the case assumes that these 98 prescriptions were representative of Kapidex prescriptions nationwide, "it is logical to assume that a much lower-than-average percentage of the 98 prescriptions were written for 60 mg doses" given the complaint's allegation that primary care physicians generally "do not treat the condition for which the higher 60 mg dose is indicated." *Ibid.*

Second, the complaint does not provide a plausible basis for inferring that the 98 prescriptions were written to treat GERD rather than EE. Pet. App. 14a-15a. Petitioner alleged that, in general, primary care physicians "do not regularly treat EE." *Id.* at 84a. But he did not allege that primary care physicians *never* treat EE, and he also did not allege anything about the patient populations or practices of the 16 specific primary care physicians who wrote the prescriptions at issue here. *Id.* at 14a.

As the First Circuit explained in rejecting an analogous FCA action against a manufacturer that had allegedly marketed one of its drugs for unapproved uses, "it is a possible but not a necessary or even

strong inference that doctors" wrote prescriptions for Kapidex for unapproved uses and that "some false claims for [Kapidex] reimbursement were submitted to the government" as a result. *Rost*, 507 F.3d at 732. Like the complaint in *Rost*, petitioner's pleading "contained no factual or statistical evidence to strengthen the inference of fraud beyond possibility." *Id.* at 733. Accordingly, petitioner's suit would fail under the pleading standard adopted by any court of appeals.[8]

[8] It is also unclear whether petitioner's complaint would ultimately survive respondent's motion to dismiss even if this Court granted certiorari and reversed the court of appeals' judgment. The district court dismissed petitioner's complaint on the independent ground that petitioner had failed adequately to plead causation. Pet. App. 28a-29a. The court of appeals found it unnecessary to address that alternative holding. See *id.* at 5a; note 4, *supra*. Even if this Court granted certiorari and held that petitioner had pleaded facts sufficient to create an inference that false claims were submitted, petitioner's suit could not go forward if the court of appeals on remand were to agree with the district court on the issue of causation.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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