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.*,

Respondents.

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

BRIEF IN OPPOSITION

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QUESTION PRESENTED

Whether the Fourth Circuit properly affirmed the dismissal of Petitioner's Third Amended Complaint for failing to plead fraud with particularity where Petitioner does not identify an actual false claim or provide specific facts creating some indicia of reliability that a false claim was presented to a federal program, and instead relies on generalized allegations that a false claim must have been presented for federal reimbursement.

CORPORATE DISCLOSURE STATEMENT

Takeda Pharmaceuticals America, Inc.

Parent Corporations: Takeda Pharmaceuticals North America, Inc.; Takeda Pharmaceutical Company Limited

10% or more of the stock of the party is owned by the following corporations: Takeda Pharmaceuticals North America, Inc., Takeda Pharmaceutical Company Limited

Takeda Pharmaceuticals North America, Inc.

Parent Corporations: Takeda Pharmaceutical Company Limited

10% or more of the stock of the party is owned by the following corporations: Takeda Pharmaceutical Company Limited

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INTRODUCTION

Petitioner Noah Nathan is a pharmaceutical sales representative employed by Takeda Pharmaceuticals America, Inc. ("Takeda"). He is also a serial unsuccessful litigant against Takeda. In addition to this case, Nathan filed sex discrimination and defamation claims against Takeda which have, to date, failed, and his *qui tam* action has fared no better. The United States and nineteen States' Attorneys General declined to intervene in this case at the district court level, and the court dismissed Petitioner's Second Amended Complaint. Having been granted leave to amend, Petitioner filed a Third Amended Complaint, which the district court dismissed again, this time with prejudice. Petitioner appealed to the United States Court of Appeals for the Fourth Circuit, and the United States reviewed Petitioner's arguments and again declined to intervene or file a brief as *amicus curiae* in support of Petitioner's position.[1] The Court of Appeals unanimously affirmed the district court's dismissal for failure to plead with particularity a plausible basis for relief.

Petitioner characterizes the Court of Appeals' decision as "deepening" an existing split among the circuits. That characterization is inaccurate. As the Court of Appeals emphasized, the shortcomings in the Third Amended Complaint would have resulted in its dismissal under any circuit's pleading standard. Petitioner concedes his failure to identify an actual false claim and, as two courts

1. *See* Notice that the United States Will Not File a Brief as Amicus Curiae, *United States ex rel. Nathan v. Takeda Pharmaceuticals North America Inc., et al.*, 707 F.3d 451 (4th Cir. 2013) (Dkt. No. 30).

have already held, the assorted statistics and generalized allegations included in his Complaint do not offer sufficient "indicia of reliability" to demonstrate that a false claim was presented to the government for payment. At best, Petitioner has alleged that Takeda's actions might have led to the submission of a false claim. Such allegations are inadequate under any standard or any reasonable application of Rule 9(b).

COUNTERSTATEMENT OF FACTS

A. Facts Alleged in the Third Amended Complaint

The following is drawn from Petitioner's Third Amended Complaint, documents incorporated therein, and additional materials Petitioner presented to the district court.

Takeda manufactures and markets Kapidex,[2] a medication classified as a proton pump inhibitor ("PPI") that is indicated for conditions treated by suppressing the secretion of gastric acid. Kapidex is marketed and sold in 30 mg and 60 mg strengths. The 60 mg dose is approved by the United States Food & Drug Administration ("FDA") for use in the healing of erosive esophagitis ("EE") caused by gastroesophageal reflux disease ("GERD") and, therefore, is indicated for that treatment. The 30 mg dose is approved by the FDA for use in the treatment of GERD

2. Following the approval and initial marketing of Kapidex, Takeda and the FDA agreed that its name should be changed to avoid confusion with other prescription medications. As a result, Kapidex is now marketed as Dexilant. (FDA News Release, *FDA Approves Name Change for Heartburn Drug Kapidex*, Mar. 4, 2010 *available at* http://www.fda.gov/NewsEvents/Newsroom/Pressannouncements/2010/ucm203096.htm.)

as well as the maintenance of healed EE. Kapidex's FDA-approved "label," or package insert, which is included with any sale of the drug as well as every packet given out as a sample, specifically describes its dosing instructions. Third Amended Complaint, Ex. 3 at 4, 6, 9, *United States ex rel. Nathan v. Takeda Pharmaceuticals North America, Inc., et al.*, No. 1:09 Civ. 1086 (E.D. Va. 2011) (Dkt. No. 73-3). While both strengths were tested for all indications for which Kapidex is approved, clinical trials demonstrated that the 60 mg dose provided no additional benefit to patients diagnosed with only GERD or for the maintenance of healed EE. Accordingly, the FDA approved the 30 mg strength for these conditions and the 60 mg dose for the healing of EE caused by GERD. Pet. App. 65a (¶ 115), 77a (¶ 170).

In his Complaint, Petitioner alleges that Takeda is "promoting" Kapidex for off-label use by providing physicians only with 60 mg samples of the drug rather than both 60 mg *and* 30 mg samples. *Id.* at 43a (¶ 6), 78a–79a (¶¶ 177, 179). According to the Complaint, because GERD is more common than EE and most PPI prescriptions are written for GERD, and because sampling practices "have a strong influence on physician prescribing practices," Takeda's sampling of Kapidex is purportedly causing physicians to write off-label 60 mg prescriptions for patients for whom a 30 mg dose is indicated. *Id.* at 96a (¶ 262), 98a (¶ 272). In other words, Petitioner alleges that Takeda has a legal obligation to supply 30 mg samples as well as 60 mg samples; otherwise, Takeda is purportedly engaging in illegal off-label promotion. Petitioner does not and cannot allege that Takeda had a direct profit motive to promote the 60 mg dose over the 30 mg dose because both doses cost the same. *Id.* at 89a (¶ 230).

Petitioner acknowledges that Kapidex's FDA-approved label and other materials Takeda supplied to physicians clearly advise them of the availability of both 30 mg and 60 mg doses and the approved indications for each. But he alleges that Takeda sales representatives did not always verbally provide the same information provided in writing and that several representatives gave misleading answers when questioned about why only 60 mg samples were available. *Id.* at 91a–93a (¶¶ 237–51). These vague allegations must be viewed against the materials Takeda provides to physicians that offer explicit dosing information, which Petitioner incorporates by reference into the Complaint. *Id.* at 79a (¶ 183). Specifically, promotional documents intended to be left behind with a physician after a sales call include, among other things, a "Dosing Card" and a "Magnum P[roduct] I[nsert]," both of which offer clear guidance to physicians on dosing. *See* Brief of Appellees at 12–13, *United States ex rel. Nathan v. Takeda Pharmaceuticals North America, Inc. et al.*, 707 F.3d 451 (4th Cir. 2013) (Dkt. No. 40).

The dosing card is a 4 by 6-inch card providing dosing information for each approved indication. *Id.* at 12. The card contains a large, clear chart showing that 30 mg is the appropriate dose for symptomatic non-erosive GERD and maintenance of healed EE, and that 60 mg is the appropriate dose for the healing of EE. The chart is pictured here:

INDICATION	RECOMMENDED DOSE	FREQUENCY
Healing of EE	60 mg	Once daily for up to 8 weeks
Maintenance of healed EE	30 mg	Once daily*
Symptomatic non-erosive GERD	30 mg	Once daily for 4 weeks

Id. at 13. The dosing card also contains an image of a prescription for 60 mg Kapidex, accompanied by the bold-letter caption "**For patients with EE**." *Id.*

The "Magnum PI" is a larger version of the Kapidex packet insert, which representatives use to promote Kapidex to physicians and which also contains dosing information. The front page of the Magnum PI, and each page thereafter, includes the Kapidex "logo lock" disclosing that Kapidex comes in 30 mg and 60 mg capsules. *Id.* The logo lock is pictured here:

Id. Significantly, Petitioner does not allege that sales representatives provided inaccurate dosing information or failed to distribute these dosing materials. Moreover, as the materials attached to the Complaint disclose, Takeda's sampling of Kapidex at 60 mg conforms to physicians' practice of prescribing PPIs at the highest available dose. Third Amended Complaint, Ex. 12 at 8, *United States ex rel. Nathan v. Takeda Pharmaceuticals North America, Inc., et al.*, No. 1:09 Civ. 1086 (E.D. Va. 2011) (Dkt. No. 73-12) ("Research and market history has shown a willingness by doctors to prescribe the highest marketed dose . . . .").

Because the 60 mg dose and 30 mg dose are the same price, Petitioner does not and cannot allege that Takeda is "attempting to seek greater profits from the spread between the cost of a 30 mg versus 60 mg Kapidex prescription (*as there generally is none*)." Pet. App. 89a (¶ 230) (emphasis added). He alleges instead that Takeda "believes that patients are more likely to be successful on Kapidex 60 than Kapidex 30, and therefore more likely to fill those prescriptions." *Id.* at 89a (¶ 230), 118a (¶ 353). A document attached to the Third Amended Complaint explains the rationale for sampling Kapidex exclusively at 60 mg as, among other reasons, "[w]e want patients to have the greatest opportunity for success especially since physicians may not know what they are treating initially (*i.e.* EE)." Third Amended Complaint, Ex. 12 at 8, *United States ex rel. Nathan v. Takeda Pharmaceuticals North America, Inc., et al.*, No. 1:09 Civ. 1086 (E.D. Va. 2011) (Dkt. No. 73-12). Therefore, physicians who cannot rule out EE in patients without an invasive endoscopy (Pet. App. 84a (¶ 204)) can prescribe Kapidex in a 60 mg dose to ensure all possible conditions are treated.

Petitioner alleges that the sales representatives provided Kapidex samples to physicians and were "coached" to give misleading answers if asked why Takeda was sampling in only a 60 mg dose and to compare Kapidex to Prevacid, another PPI sold by Takeda that went off patent in 2009. *Id.* at 42a–43a (¶ 3), 91a (¶¶ 238, 242), 93a (¶ 250). There is no allegation that these allegedly misleading answers resulted in off-label prescriptions or claims for reimbursement from a federal program. In fact, not a single off-label prescription is identified. Further, the Complaint identifies only one sales representative who called on physicians who wrote prescriptions presented to Medicare and Medicaid, and it is not clear that the representative was actually providing samples or whether any such activities resulted in actual claims for government payment. *Id.* at 92a (¶ 247). Nor does the Complaint allege that doctors receive any financial benefit from Takeda (such as kickbacks) or participate in some fraudulent scheme concocted by Takeda.

Petitioner identifies four physicians—described in the Complaint and in attached affidavits—who opine that doctors are unlikely to write prescriptions for PPIs unless a sample is available, that the availability of a sample in a certain dose makes it more likely that a doctor will write a prescription at that dose, and that the high percentage of Kapidex prescriptions at the 60 mg strength is a function of the market created by Takeda. *Id.* at 99a–101a (¶ 278), 101a–103a (¶ 281), 103a–104a (¶ 283). Neither the Complaint nor the doctors' affidavits indicate that affirmative misrepresentations were made to these four physicians, nor does Petitioner allege that any of their prescriptions were filled and resulted in claims for government reimbursement. Indeed, the four identified

physicians attest that PPI prescriptions are generally *only* filled when a patient has success with a given sample, but they do not state whether their patients achieved such success. *Id.* at 96a (¶ 262), 99a (¶ 278 (a)-(c)), 102a (¶ 281(c)-(f)), 103a–104a (¶ 283(a)-(d), (t)). Petitioner does not identify any prescription by these doctors—off-label or otherwise—or any claim that was actually presented to a federal health care program as a result of off-label promotion.

The Complaint also identifies sixteen primary care doctors who received Kapidex samples and wrote ninety-eight Kapidex prescriptions that led to claims being submitted for reimbursement to Medicare, and twenty-five doctors of unknown specialties who received samples and wrote Kapidex prescriptions that were presented to Medicare Part D. *Id.* at 104a–109a (¶¶ 284–301), 111a–116a (¶¶ 315–40). Petitioner provides the month and year in which each doctor received samples and wrote Kapidex prescriptions that were purportedly presented to a federal program. *Id.* at 105a–109a (¶¶ 286–301), 111a–116a (¶¶ 315–40). Notably absent from these allegations, though, is any information regarding the condition for which the prescriptions were written, the dose of the prescriptions submitted for reimbursement, or any false statement by Takeda that led to the prescriptions. No allegations at all are made regarding the patients who were treated—*e.g.*, whether they showed symptoms of GERD or whether EE was diagnosed or suspected. Petitioner alleges that 93% of *all* Kapidex prescriptions are at the 60 mg dose (*Id.* at 67a (¶ 128)) and that primary care physicians do not "regularly" treat the condition for which a 60 mg dose is approved. *Id.* at 84a–85a (¶¶ 208–09). But he does not offer any comparable statistic focused on Kapidex prescriptions

written by primary care physicians generally, or the physicians specifically named in the Complaint.

Finally, the Complaint includes what is described as "District-wide data" showing that Kapidex prescriptions were submitted for federal reimbursement in the territory that Petitioner covers and one other territory. *Id.* at 109a–111a (¶¶ 302–13). This data provides the number of Kapidex prescriptions in Petitioner's territory that were presented to federal health care programs in seven individual months between June 2010 and March 2011, and the total number of Kapidex prescriptions in two districts presented to federal reimbursement programs from April 1, 2010 through March 31, 2011. *Id.* But Petitioner does not identify the names or specialties of the physicians who wrote these prescriptions, the conditions for which Kapidex was prescribed, the breakdown of doses in which the drug was prescribed, or whether the prescribing doctors received samples of the drug. Nonetheless, he claims that "one may deduce that more than 90% of these prescriptions were written at the 60 mg dose." *Id.* at 110a (¶ 310), 111a (¶ 314). Petitioner does not specifically identify any actual claim for federal reimbursement that he can state is definitively false, and does not provide statistical evidence showing that false claims were necessarily submitted for payment.

B. Proceedings Below

1. Nathan's Initial Complaint and First Two Amendments

Petitioner filed four complaints in this case over a three-year period. During this time, Petitioner was—

and continues to be to this day—a sales representative at Takeda with access to the sales data and marketing materials at issue in this case.

The original complaint, First Amended Complaint, and Second Amended Complaint were filed under seal on September 14, 2009, October 20, 2009, and January 13, 2010, respectively. On December 13, 2010, the United States, nineteen states, and the District of Columbia declined to intervene. The district court unsealed the case four days later, on December 17, 2010.

2. Dismissal of the Second Amended Complaint

On March 21, 2011, Takeda moved to dismiss the Second Amended Complaint for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6), and for failure to plead fraud with particularity under Rule 9(b). That motion was granted on May 5, 2011. The court found that the Second Amended Complaint lacked "facts regarding how claims for reimbursement came to be submitted to the government, or why those claims for reimbursement were false or fraudulent" and therefore failed to meet the pleading requirements of Rule 9(b). Memorandum Opinion and Order Granting Takeda's Motion to Dismiss Relator's Second Amended Complaint at 5, *United States ex rel. Nathan v. Takeda Pharmaceuticals North America, Inc., et al.*, No. 1:09 Civ. 1086 (E.D. Va. 2011) (Dkt. No. 66). The court further held that the Second Amended Complaint did not provide "a plausible, fact based explanation for its conclusion that Takeda, rather than the prescribing physicians, caused any off label Kapidex prescriptions to be issued." *Id.* (internal citations omitted). Indeed,

the court observed that Takeda's alleged conduct was not inherently fraudulent, highlighting that the Second Amended Complaint did not contain "allegations regarding kickbacks, the provision of improper incentives to physicians such as trips, grants, honoraria, or similar inducements, and has not alleged that Takeda engaged in nefarious attempts to seed medical literature with articles favorable to Kapidex, which are typical in these types of cases." *Id.* at 4–5 (internal citations omitted). The court allowed Petitioner to amend his complaint to attempt to resolve these pleading deficiencies.

3. Dismissal of the Third Amended Complaint

On May 18, 2011 Petitioner filed a Third Amended Complaint. After further briefing and oral argument, the district court again dismissed Petitioner's Complaint, holding that Petitioner failed to plead fraud with particularity under Rule 9(b), as he did not plead any actual false claim or facts demonstrating that false claims were necessarily submitted. Pet. App. 26a–28a. The district court held that "Petitioner's statistical and general allegations concerning what ailments are treated by what physicians, and the general nature of Takeda's promotional activities, do not supply the needed specificity under Rule 9(b), do not satisfy *Iqbal* and *Twombly*, and do not raise an inference of fraud beyond mere possibility." *Id.* at 31a. As the district court noted, "Petitioner has failed to identify any false claims, or plead facts that would establish 'beyond possibility' that false claims were in fact submitted." *Id.* at 28a.

The district court also dismissed Petitioner's complaint on causation grounds. The court held that

the Third Amended Complaint "fail[ed] to plead facts sufficient to make plausible Petitioner's claim that Takeda 'caused' any off-label prescriptions to be issued." *Id.* In the absence of any improper payments, benefits, inducements, or misrepresentations, the court found it implausible that physicians prescribed Kapidex because of Takeda's allegedly unlawful marketing practices, and not because of their independent medical judgment. *Id.* at 28a–29a.

4. The Court of Appeals' Decision Affirming Dismissal of the Third Amended Complaint

Petitioner appealed and the Court of Appeals affirmed the district court's decision that the Third Amended Complaint failed to satisfy Rule 9(b). The Court of Appeals did not reach the issue of causation. Based on Petitioner's allegations, the Court of Appeals concluded that this was not a case in which Takeda's actions *necessarily* would have led to the submission of false claims. Instead, it found that "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 (emphasis in original). In such instances, the Court of Appeals held that Petitioner did not plead with particularity that specific false claims actually were presented to the government for payment. *Id.*

The Fourth Circuit reviewed case law from other circuits including those that Petitioner cites as offering a more "flexible" standard for Rule 9(b). Pet. at 17 (citing *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180 (5th Cir. 2009); *United States ex rel. Duxbury v. Ortho Biotech Prods.*, 579 F.3d 13, 31 (1st Cir. 2009)). The Fourth Circuit noted that its conclusion to affirm the dismissal

of Petitioner's Complaint was "not altered" by cases "in which courts have held that the requirements of Rule 9(b) can be satisfied in the absence of particularized allegations of specific false claims." Pet. App. 9a. The court recognized that in such cases, "specific allegations of the defendant's fraudulent conduct necessarily led to the plausible inference that false claims were presented to the government." *Id.* In contrast to the facts in those cases, the Fourth Circuit found that Petitioner's "claim does not involve an integrated scheme in which presentment of a claim for payment was a necessary result." *Id.* at 17a. Rule 9(b) requires that "some indicia of reliability" be provided to support "the allegation that an actual false claim was presented to the government." *Id.* at 8a. Because Petitioner had merely offered allegations that are speculative in nature, the court held that Petitioner "failed to plead with particularity a plausible claim that any off-label prescriptions were presented to the government for payment." *Id.* at 17a.

REASONS TO DENY THE PETITION

I. Statutory Background: The False Claims Act

The False Claims Act ("FCA") is an anti-fraud statute, subject to the heightened pleading requirements of Rule 9(b). *See Schindler Elevator Corp. v. United States ex rel. Kirk*, 131 S. Ct. 1885, 1898 (2011) (Ginsburg, J. dissenting); *United States ex rel. Totten v. Bombardier Corp.*, 286 F.3d 542, 551–52 (D.C. Cir. 2002) (noting uniform agreement among circuit courts that Rule 9(b) applies to FCA suits). As such, a plaintiff is required to plead the details of the purported fraud on the government with particularity. *See Ashcroft v. Iqbal*, 556 U.S. 662, 686–87 (2009); *United*

States ex rel. Willard v. Humana Health Plan of Texas, Inc., 336 F.3d 375, 384 (5th Cir. 2003) ("Rule 9(b) requires that the plaintiff allege the particulars of time, place, and contents of the false representations as well as the identity of the person making the misrepresentation and what that person obtained thereby, otherwise referred to as the who, what, when, where, and how of the alleged fraud.") (internal citations omitted).

Like all claims, FCA suits are also subject to the pleading standards of Rule 8(a), as applied and articulated by this Court in *Ashcroft v. Iqbal*, 556 U.S. 662 (2009) and *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007). As this Court has noted, "[t]he need at the pleading stage for allegations plausibly suggesting (not merely consistent with) [liability] reflects the threshold requirement of Rule 8(a)(2) that the 'plain statement' possess enough heft to 'show that the pleader is entitled to relief.'" *Twombly*, 550 U.S. at 557 (quoting FED. R. CIV. P. 8(a)(2)). "A pleading that offers labels and conclusions or a formulaic recitation of the elements of a cause of action will not do." *Iqbal*, 556 U.S. at 678. To plead an FCA violation under Rules 8 and 9, therefore, a plaintiff must plead facts that plausibly suggest that the defendant defrauded the government, and must plead the "who, what, when, where, and how" of how the defendant did so. *Willard*, 336 F.3d at 384.

II. The Court of Appeals' Decision Does Not "Deepen" a Purported Circuit Split

Petitioner's Third Amended Complaint would have been dismissed in any circuit regardless of whether there is some divergence in how circuits analyze FCA claims. The Fourth Circuit explained that "Rule 9(b) requires

that 'some indicia of reliability' must be provided in the complaint to support the allegation that an actual false claim was presented to the government," and found that such "indicia of reliability" were absent in this case. Pet. App. 8a (quoting *United States ex rel. Clausen v. Lab. Corp. of Am.*, 290 F.3d 1301, 1311 (11th Cir. 2002)). The same conclusion would have been reached by the other courts of appeal. The Fourth Circuit's demand for some basic threshold of reliability is consistent with the legal conclusion of every circuit that has approached this question. *See United States ex rel. Duxbury v. Ortho Biotech Prods.,* 579 F.3d 13, 31 (1st Cir. 2009) (holding that Petitioner satisfied Rule 9(b) where he alleged "facts that false claims were . . . filed by the medical providers he identified"); *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 184–85, 190 (5th Cir. 2009) (holding that Petitioner satisfied Rule 9(b) by pleading a conspiracy to defraud Medicare and "at least one overt act of false billing for each doctor," thereby establishing the "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted"); *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 471 (6th Cir. 2011) (dismissing complaint and holding that Petitioner must plead "facts which support a strong inference that a claim was submitted"); *United States ex rel. Lusby v. Rolls-Royce Corp.*, 570 F.3d 849, 853–54 (7th Cir. 2009) (holding that Petitioner pled the "who, what, when, where, and how" of the alleged fraud by alleging "the promise, the intent not to keep that promise, and the details of non-conformity" in a defense contract which "narrate, with particularity, the circumstances that violate 31 U.S.C. § 3729(a)(1)"); *United States ex rel. Joshi v. St. Luke's Hosp., Inc.*, 441 F.3d 552, 557 (8th Cir. 2006) (dismissing complaint because allegations regarding

fraudulent scheme lacked "sufficient indicia of reliability" that false claims were actually submitted); *United States ex rel. Cafasso v. General Dynamics C4 Sys., Inc.*, 637 F.3d 1047, 1055–56 (9th Cir. 2011) (emphasizing that "[a]n actual false claim is the *sine qua non* of an FCA violation" and reasoning that, in the absence of specific false claims, a complaint may satisfy Rule 9(b) only where the "complaint warrants an inference that false claims were part of the scheme alleged"); *Hopper v. Solvay Pharmaceuticals, Inc.*, 588 F.3d 1318, 1325 (11th Cir. 2009) ("[S]ome indicia of reliability must be given in the complaint to support the allegation of *an actual false claim* for payment being made to the Government.") (emphasis in original, internal citations omitted).

As all of the circuits have held, a plaintiff must plead facts that support a reliable inference that false claims were submitted to the government to satisfy Rule 9(b), either by providing representative examples of false claims or by pleading facts in which false claims were the necessary result of the scheme alleged. Petitioner's complaint does neither.

In his Third Amended Complaint, Petitioner identifies sixteen primary care physicians who received 60 mg samples of Kapidex from Takeda and collectively wrote ninety-eight prescriptions for Kapidex that were submitted to the government for payment. As the Court of Appeals noted, however, Petitioner does not allege the dose in which these prescriptions were written, or that they were written for off-label purposes. Instead, Petitioner makes the following series of generalized allegations, wholly lacking in specificity, from which the Court is asked to infer that a false claim was submitted: (1) primary care physicians typically do not treat active cases of EE (the

only condition for which a 60 mg dose is indicated); (2) Takeda distributed samples of Kapidex only in a 60 mg dose; (3) physicians tend to prescribe drugs in the same dose as the sample the patient has received; and (4) 93% of Kapidex sales nationwide are for the 60 mg dose even though GERD is more common than EE in the general population. Therefore, according to Petitioner, some of these prescriptions must have been for the off-label treatment of GERD. Petitioner then extrapolates that each of the prescriptions he identifies is 93% likely to be off-label. Pet. App. 105a–110a (¶¶ 285–310). But Petitioner does not allege any facts connecting the overall 93% prescription rate to either the ninety-eight prescriptions he specifically identifies or to prescriptions written by *primary care physicians*, as opposed to prescribing physicians generally. *Id.* at 13a–14a.

The Court of Appeals properly held that these generalized allegations do not support a plausible inference that false claims were submitted for reimbursement. "To the contrary, drawing on the language in the amended complaint, it is logical to assume that a much lower-than-average percentage of the 98 prescriptions were written for 60 mg doses, given that P[rimary] C[are] P[hysicians] purportedly do not treat the condition for which the higher 60 mg dose is indicated." *Id.* at 14a. The court further observed that Petitioner failed to allege that any of the identified prescriptions were for off-label uses, therefore requiring an "implausible inference" that the general statistics equally apply to these ninety-eight prescriptions. *Id.* The court held that the allegations in the complaint do not support such inferences, and do not plead with particularity that any false claims were submitted for government payment.

The Complaint also identifies individual physicians who allegedly wrote 60 mg prescriptions for GERD and were unaware that Kapidex was available in a 30 mg dose due to Takeda's sampling practices. *Id.* at 99a–103a (¶¶ 278–81). As the Fourth Circuit correctly observed, however, the Complaint "does not include any details about the particular prescriptions these physicians wrote for Medicare patients, such as approximate dates or patient information, nor does the amended complaint contain allegations that the Medicare patients ever 'filled' these prescriptions or that corresponding claims for reimbursement were ever submitted to the government." *Id.* at 15a–16a. These allegations alone are insufficient to establish the existence of false claims under any circuit's pleading standard, and cannot be used to bolster or inform Petitioner's other allegations concerning the general statistical prevalence of GERD or 60 mg Kapidex sales.

As the Court of Appeals held, Petitioner's broad allegations and illogical attempts to apply generalized statistics to specific facts do not satisfy the requirement that FCA relators plead fraud with particularity. Petitioner's complaint does not identify any actual false claims submitted for federal reimbursement and does not allege facts that would permit the inference that false claims were necessarily presented for government payment. Absent allegations of a fraudulent scheme that would "necessarily result" in the submission of false claims or representative examples of *actual* false claims, the Complaint does not provide the required "indicia of reliability" that a false claim was presented for payment. This failure is fatal under any circuit's standard for pleading FCA claims. *Id.* at 8a; *see also Ebeid ex rel. United States v. Lungwitz*, 616 F.3d 993, 999 (9th Cir.

2010) ("[E]ven under a relaxed standard, [Plaintiff] must provide enough detail to give [Defendant] notice of the particular misconduct which is alleged to constitute the fraud charged" and "supply reasonable indicia that false claims were actually submitted."); *Grubbs*, 565 F.3d F.3d at 190 (holding that, in the absence of details of actual false claims, an FCA relator's complaint may survive only "by alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted").

In contrast to cases where FCA claims survived on the basis of specific facts supporting a strong inference that claims were submitted, such as *Grubbs*, Petitioner's claim does not involve an "integrated scheme in which presentment of a claim for payment was a necessary result." Pet. App. 17a. Therefore, the court appropriately observed that Petitioner "essentially has alleged that some claims must have been presented to the government for payment, because prescriptions of that kind frequently and routinely are obtained by persons who participate in health care programs sponsored by the federal government" but concluded that "allegations of this type are insufficient because they are inherently speculative in nature." *Id.* at 16a–17a.

The Court of Appeals' decision to uphold the dismissal of the Third Amended Complaint was thus not contingent on the adoption of a "strict" interpretation of Rule 9(b); the result would have been the same had this case been heard in any other circuit. Despite four successive attempts, Petitioner has been unable to allege any facts that would reliably indicate that actual false claims were presented to the government for payment, much less that Takeda's

marketing practices caused the submission of false claims. This case therefore does not present an appropriate vehicle for this Court's review of the Rule 9(b) pleading standard in FCA cases. The existence or non-existence of a purported "circuit split" is immaterial to the disposition of this case, as no court has ever held that a plaintiff can satisfy Rule 9(b) through the sorts of attenuated chains of inference that Petitioner relies on here.

In its brief as Amicus Curiae in *Ortho Biotech Products, L.P. v. United States ex rel. Duxbury*, the United States urged the Court to review the application of Rule 9(b) to the FCA in an "appropriate case." Brief for the United States as *Amicus Curiae* at 17, *Ortho Biotech Prods., L.P. v. United States ex rel. Duxbury*, No. 09-654 (U.S. May 2010). That case is not before this Court here. Petitioner has not alleged any actual false claims submitted for government payment, has not provided any information that supports the inference that false claims were submitted, and has not alleged facts that satisfy any court's standard for pleading fraud under Rule 9(b).

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be denied.

Respectfully submitted.

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