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

REPLY FOR PETITIONER

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REPLY FOR PETITIONER

Takeda does not dispute that the courts of appeals are divided over the standard imposed by Federal Rule of Civil Procedure 9(b) in False Claims Act cases. Nor does it deny that the issue is important, directly affecting the United States' ability to recover for fraud in *qui tam* actions. The Solicitor General has made precisely those points to this Court. See U.S. Br. as *Amicus Curiae* at 14-17, *Ortho Biotech Prods., L.P.* v. *United States ex rel. Duxbury*, No. 09-654 (U.S. May 2010) ("U.S. *Duxbury* Br."); Pet. 22-23.

Instead, Takeda's sole argument is that the Complaint in this case would have been dismissed "under any cir-

cuit's pleading standard." Br. in Opp. 1.[1] Not so. According to Takeda, "all of the circuits" require that complaints at least "plead[ ] facts in which false claims were the *necessary* result of the scheme alleged"—not plausible, not probable, but "necessary." *Id.* at 16 (emphasis added). Until the decision below, however, no court of appeals had ever articulated or applied *that* standard. It is also misconceived. Rule 9(b) requires the plaintiff to plead the facts that constitute the alleged fraud with "particularity," *i.e.*, to set forth specifics about who, what, where, and when. But it does not require a more persuasive showing of entitlement to relief than that required under Rule 8, much less require facts that, because they establish that false claims were a "necessary result," would entitle the plaintiff to judgment as a matter of law.

The Complaint here amply satisfies the standard applied by the First, Fifth, Seventh, and Ninth Circuits. The decision below acknowledged that the Complaint particularly described 98 claims actually submitted to the United States for reimbursement. But it rejected those as insufficient because the court thought allegations showing falsity were not strong enough. The law in the First, Fifth, Seventh, and Ninth Circuits, however, is that plaintiffs do not even need to identify a particular claim that was actually submitted so long as the complaint "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." *United*

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[1] Takeda also makes *ad hominem* attacks against petitioner, portraying him as a serial litigator. See Br. in Opp. 1. But Nathan has only been involved in litigation with one company—Takeda. Nathan filed this False Claims Act suit, and two related suits for adverse employment actions Takeda took against him.

States ex rel. Grubbs v. *Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009); Pet. 17-18. Here, the Complaint gives extraordinary detail regarding the scheme. It includes affidavits from physicians stating that they wrote Kapidex prescriptions in the wrong dose as a result of Takeda's sampling practices. And, rather than offer "reliable indicia" that claims "were actually submitted," it identifies with particularity 98 prescriptions that were submitted, identifying the physician who wrote them and when they were written, and alleging their falsity. See Pet. 28-33. Such allegations easily satisfy the "more relaxed construction of Rule 9(b)" the Fourth Circuit "disagree[d] with." Pet. App. 10a.

Takeda also invokes the United States' failure to intervene in this case. Br. in Opp. 1. But the United States' silence means only that—silence. See *United States ex rel. Chandler* v. *Cook Cnty.*, 277 F.3d 969, 974 n.5 (7th Cir. 2002). If the Court has any question concerning the United States' view of the issue presented, its importance, or the suitability of this case for addressing it, the Court should invite the Solicitor General to file a brief setting forth the views of the United States.

I. THE CIRCUITS ARE DIVIDED

Takeda does not dispute that the circuits are divided over the application of Rule 9(b) in False Claims Act suits. See Pet. 16-20. In cases where the plaintiff alleges a scheme to submit false claims, but cannot identify specific claims that were submitted for reimbursement, the First, Fifth, Seventh, and Ninth Circuits have held that Rule 9(b) requires pleading only the "particular details of [the] scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Grubbs*, 565 F.3d at 190; see Pet. 17-18. By contrast, the Sixth, Eighth, and Eleventh

Circuits—now joined by the Fourth Circuit—hold that Rule 9(b) requires that the complaint identify "an actual false claim" with particularity. *United States ex rel. Bledsoe* v. *Cmty. Health Sys., Inc.*, 501 F.3d 493, 504 (6th Cir. 2007); see Pet. 18-19. The conflict has been acknowledged by courts and commentators. See Pet. 20 & n.5. Takeda concedes the "divergence" in the circuits. Br. in Opp. 14.[2] And the Solicitor General has urged that the split "warrant[s] the Court's review." U.S. *Duxbury* Br. 17.

Seeking to downplay the conflict's significance, Takeda urges that the Fourth Circuit merely construed Rule 9(b) to demand "some basic threshold of reliability * * * consistent with the legal conclusion of every circuit that has approached this question." Br. in Opp. 15 (invoking the Fourth Circuit's statement that complaint needs "some indicia of reliability * * * to support the allegation that an actual false claim was presented to the government," Pet. App. 8a); see also *id.* at 18-19. But that underscores the need for review. The text of Rule 9(b) requires only that a party "state with *particularity* the circumstances constituting fraud." Fed. R. Civ. P. 9(b) (emphasis added). It says nothing about demanding heightened "*reliability*"—*i.e.*, increasing the burden of proof—beyond the general pleading standard in Rule 8(a). See Pet. 28. Under Rule 8(a), a complaint need only "contain sufficient factual matter, accepted as true, to

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[2] Although Takeda urges that the decision below "[d]oes [n]ot '[d]eepen'" the conflict, Br. in Opp. 14, it clearly does: The Fourth Circuit "disagree[d]" with "other cases" that "apply a more relaxed construction of Rule 9(b)." Pet. App. 10a. As the petition notes (at 19), and Takeda nowhere disputes, district courts have "no doubt" that the Fourth Circuit "chose a side in the controversy." *United States ex rel. Palmieri* v. *Alpharma, Inc.*, — F. Supp. 2d —, 2013 WL 821965, at *13 (D. Md. Mar. 5, 2013).

'state a claim for relief that is *plausible* on its face.'" *Ashcroft* v. *Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp.* v. *Twombly*, 550 U.S. 544, 570 (2007)) (emphasis added). Rule 9(b)'s "specificity requirements" do not "abrogate" Rule 8(a)'s standard. 2 James Wm. Moore, *Moore's Federal Practice* § 9.03[7], at 9-48.2 (3d ed. 2010).

The decision below turns those principles on their heads. In the name of requiring "indicia of reliability," Pet. App. 8a, the Fourth Circuit held that a complaint is insufficient under Rule 9(b) unless it (1) "allege[s] with particularity that specific false claims actually were presented * * * for payment," or (2) alleges facts that "*necessarily*" would have "led to the submission of false claims," *id.* at 10a. Under that standard, Rule 8 "plausibility" is not enough—the complaint must show with *certainty* both that claims were submitted and that they were false. See *Webster's Third New Int'l Dictionary* 1510 (2002) ("necessarily" means "in such a way that it *cannot* be otherwise" (emphasis added)). "[S]urely a procedural rule ought not be read to insist that a plaintiff plead the level of detail required to prevail at trial." *Grubbs*, 565 F.3d at 189. But the Fourth Circuit's "indicia of reliability" standard does just that, imposing a heightened burden of proving falsity. See pp. 6-7, *infra.* To the extent other courts of appeals have misconstrued Rule 9(b) similarly, see Br. in Opp. 15-16, that underscores the need for review.

II. THE ISSUE IS IMPORTANT AND RECURRING

The pleading standard for False Claims Act cases is profoundly important—the United States' ability to recover billions of dollars for fraud is at stake. See Pet. 22-24. The Solicitor General has explained that the standard adopted by the Sixth, Eighth, and Eleventh Circuits "would * * * disable[ ]" many relators from filing suit

under the FCA," even where they possess "detailed knowledge" of a "fraudulent scheme." U.S. *Duxbury* Br. 15, 17. Yet identical suits could proceed in the First, Fifth, Seventh, and Ninth Circuits, which hold that a "complaint may be sufficiently detailed and particularized to satisfy [Rule 9(b)] even though it does not identify false claims." *Id.* at 15; see Pet. 25-28. The "uncertainty" created by that conflict "hinders the ability of *qui tam* relators to perform the role that Congress intended." U.S. *Duxbury* Br. 16. Takeda does not contend otherwise. Nor does it dispute that the issue arises routinely throughout the federal courts. See Pet. 24-25 & nn.8-9.

III. THIS CASE IS AN APPROPRIATE VEHICLE

Takeda's sole argument is that this case is an inappropriate vehicle for resolving the question presented. Br. in Opp. 20. Takeda does not identify a jurisdictional barrier to review. Contrast U.S. *Duxbury* Br. 17-18 (jurisdictional defect). Instead, attempting to litigate the merits at the petition stage, Takeda claims that the Complaint here would have been dismissed under any of the standards it identifies. Br. in Opp. 1. Until this Court identifies the correct standard, however, that remains to be seen. Moreover, notwithstanding Takeda's claim that the Complaint would fail "under any circuit's standard," *id.* at 18, Takeda never evaluates the Complaint under the Rule 9(b) standard applied by the First, Fifth, Seventh, and Ninth Circuits. Instead, Takeda argues that the Complaint cannot meet a standard of its own invention, which it erroneously attributes to those circuits. The complaint amply meets the standard the First, Fifth, Seventh, and Ninth Circuits actually apply.

A. Takeda Misconstrues The First, Fifth, Seventh, And Ninth Circuits' Standard

As Takeda notes, a False Claims Act complaint is sufficient in any circuit if it provides "representative examples of *actual* false claims." Br. in Opp. 18. And Takeda agrees that identification of a specific false claim is not required in the First, Fifth, Seventh, and Ninth Circuits. Like the court of appeals below, however, Takeda claims that those circuits will overlook the absence of a specifically identified, submitted claim only where the "fraudulent scheme" alleged "would '*necessarily* result' in the submission of false claims." *Ibid.* (emphasis added); see Pet. App. 17a (requiring "an *integrated scheme* in which presentment of a [false] claim for payment was a *necessary* result" (emphasis added)).

That is incorrect. See Pet. 20-21 n.6. The First, Fifth, Seventh, and Ninth Circuits are clear: A False Claims Act complaint is sufficient 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*." *Grubbs*, 565 F.3d at 190 (emphasis added); see Pet. 17-18. Never have those courts suggested that, in requiring a "*strong inference* that claims were actually submitted," they *really* meant that a complaint must allege an "'integrated scheme'" (whatever that means) in which "'presentment of a [false] claim for payment was a *necessary result*.'" Br. in Opp. 19 (quoting Pet. App. 17a). Nor did the Solicitor General interpret their decisions that way. See U.S. *Duxbury* Br. 14-15. That is because Takeda invented the distinction: While Takeda invokes the supposed "necessary result" and "integrated scheme" standard repeatedly, it never grounds that language in a decision of the First, Fifth, Seventh, or Ninth Circuits. See Br. in Opp. 9, 11, 12, 13,

16, 18, 19. Takeda's refusal to confront the standard actually adopted by those circuits speaks volumes.

B. The Complaint Satisfies The First, Fifth, Seventh, And Ninth Circuits' Standard

The Complaint amply satisfies the actual standard applied in the First, Fifth, Seventh, and Ninth Circuits. See Pet. 28-33. While Takeda invokes Rule 9(b), its argument has nothing to do with "particularity." The Complaint identifies 98 specific prescriptions, written by 16 primary-care physicians, and alleges that those prescriptions are "specific examples of certain false claims." Pet. App. 123a (¶ 379). For each, the Complaint identifies the treating physician; provides the dates the physician received 60-mg Kapidex samples from Takeda; specifies the month the prescription was written; and alleges that it was submitted to Medicare. *Id.* at 105a-109a (¶¶ 286-301). Greater specificity is hard to imagine (short of violating federal privacy laws). See *id.* at 10a (agreeing that "privacy laws may pose a barrier to obtaining" additional "information without court involvement").

Takeda instead urges that those "allegations do not support a plausible inference that false claims were submitted for reimbursement." Br. in Opp. 17. The Complaint, however, specifically alleges that the 98 prescriptions were "submitted to Medicare for reimbursement," and Takeda does not contend otherwise. Pet. App. 105a-109a (¶¶ 286-301). Instead, Takeda disputes whether the submitted claims were *false*. In particular, Takeda claims that the Complaint does not "definitively" preclude the possibility that the physicians were treating EE (the only condition for which 60-mg doses are reimbursable). Br. in Opp. 9, 17. But the Complaint's allegations show precisely why those prescriptions are for GERD (for which the 60-mg dose is not reimbursable),

not EE. The prescriptions were written by primary-care physicians, who treat GERD but not EE. Pet. App. 84a-85a(¶¶206-209). Diagnosing EE requires an endoscopy, something primary-care physicians do not perform. *Id.* at 43a-44a(¶7). And GERD is relatively common, while EE is rare: GERD cases outnumber EE cases 10-to-1. See *id.* at 166a(¶¶4-5). So Takeda's contention can be accepted only if one speculates that those 16 primary-care physicians were, in those 98 cases, treating a much rarer condition; one that primary-care physicians do not ordinarily treat; and doing so without performing the necessary diagnosis.[3] Such speculation is no basis for holding that the Complaint falls short on falsity—at least not in the First, Fifth, Seventh, and Ninth Circuits.

Takeda urges that the Complaint does not conclusively establish that the prescriptions were for 60-mg doses. But Takeda does not deny that 93% of Kapidex prescriptions are for 60 mg. Pet. App. 88a(¶228). More important, PPIs like Kapidex are prescribed through a "PPI trial" in which the physician gives the patient free samples, given to him by the drug company, together with a prescription to fill if the patient finds the samples effective. Pet. 8-9; Pet. App. 82a-83a(¶¶191-194); 96a-97a(¶¶265, 269); 98a-99a(¶¶271, 278). As a result, physicians prescribe only in the sampled dose. *Id.* at 102a(¶281(d)). And the Complaint alleges that Takeda sampled only 60-mg doses, and that the 16 prescribing doctors received only 60-mg samples. *Id.* at 105a-108a(¶¶285-301). The Complaint, moreover, incorpor-

[3] Takeda's assertion that physicians might be treating "suspected" EE (and not GERD) without performing the necessary diagnosis, Br. in Opp. 8, is rank speculation. Regardless, the FDA did not approve 60-mg Kapidex for "suspected" EE. Takeda nowhere suggests that such a prescription would be reimbursable.

ates the affidavits of three doctors—including a former president of the American Medical Association—who aver that, because Takeda exclusively sampled Kapidex at 60 mg, *they personally* had prescribed off-label 60-mg doses for GERD. *Id.* at 44a (¶ 10); 98a-103a (¶¶ 273-281).

Takeda can respond only by ignoring the effect of PPI trials, by urging that the affidavits should be disregarded (even though they were incorporated in the Complaint), or by going beyond the Complaint with further unsubstantiated speculation. The physicians' "allegations alone," Takeda asserts, "are insufficient" because the Complaint does not identify specific prescriptions written by those doctors. Br. in Opp. 18. But the affidavits do not stand "alone"; they demonstrate that, because Takeda provides only 60-mg samples for PPI trials, physicians write prescriptions for GERD at the non-reimbursable 60-mg dose. Despite Takeda's claim that such affidavits "cannot be used to bolster or inform [p]etitioner's other allegations," *ibid.*, the Complaint's allegations—even under Rule 9(b)—must be considered "as a whole," *United States ex rel. Lemmon* v. *Envirocare of Utah, Inc.*, 614 F.3d 1163, 1173 (10th Cir. 2010).[4]

Takeda claims it is "illogical" to think that the 16 identified primary-care physicians prescribe 60-mg Kapidex doses consistent with the overall 93% rate, because primary-care physicians do not treat EE, "'the condition for which the higher 60 mg dose is indicated.'" Br. in Opp. 17-18 (quoting Pet. App. 14a). But that assumes the

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[4] Takeda urges that the Complaint does not allege Takeda made false statements to physicians. Br. in Opp. 8. But it does allege the prescriptions resulted from misleading sampling practices. Besides, "false statements" to third parties are not an element of a claim under 31 U.S.C. § 3729(a)(1)(A). See *United States ex rel. Wilkins* v. *United Health Grp., Inc.*, 659 F.3d 295, 307 (3d Cir. 2011).

proposition Takeda purports to prove—that primary-care physicians do not write prescriptions at the 60-mg dose for GERD. It ignores the effect of PPI trials—that physicians prescribe in the sampled 60-mg dose. And it assumes, contrary to the Complaint, that physicians know FDA-approved doses. The Complaint alleges and cites studies confirming that physicians generally do not read drug labels or inserts and are unaware of FDA standards. See Pet. App. 93a (¶252), 94a (¶¶253-254), 95a (¶258). Takeda cannot challenge those well-pleaded facts on a motion to dismiss. See *Scandinavian Satellite Sys., AS* v. *Prime TV Ltd.*, 291 F.3d 839, 845 (D.C. Cir. 2002).[5] But even if one indulges Takeda's speculation that the 16 physicians were outliers who prescribe 60-mg doses at "much lower" than the general 93% rate (despite the impact of sampling), Br. in Opp. 17—say, 50%—it is still "plausible" that each of the 98 prescriptions was for 60 mg.

The Complaint provides both ample particularity and more than enough "factual [and] statistical evidence to strengthen the inference of fraud beyond [mere] possibility." *Duxbury*, 579 F.3d at 29. It is more than sufficient under any proper application of Rule 9(b), and certainly sufficient under the standard applied by the First, Fifth, Seventh, and Ninth Circuits.

CONCLUSION

The petition for a writ of certiorari should be granted.

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[5] Takeda likewise errs in invoking "cards" with "dosing information" that Takeda claims to have distributed. Br. in Opp. 4. That improperly goes beyond the Complaint, assuming such cards were distributed. It also improperly assumes, contrary to the Complaint, that physicians read them. *Makor Issues & Rights, Ltd.* v. *Tellabs Inc.*, 513 F.3d 702, 705 (7th Cir. 2008) (court must "treat the pleaded facts as true and draw all reasonable inferences in favor of the plaintiff").

Respectfully submitted.

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