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

SUPPLEMENTAL BRIEF FOR PETITIONER

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Four years ago, the government acknowledged a circuit conflict regarding Rule 9(b)'s application in False Claims Act cases and urged that it "warrant[s] the Court's review" 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) ("U.S. *Duxbury* Br."). The government again concedes that the "courts have reached conflicting results," U.S. Br. 11; urges that the approach taken by four courts of appeals "is unsupported by Rule 9(b) and undermines the FCA's effectiveness," *id.* at 10; and

agrees that the legal question presented is "a significant issue" warranting review, *id.* at 16.

The government nevertheless urges the Court to deny review because, in its view, some courts of appeals may be reconsidering their position. But the claim of a "self-healing" conflict does not withstand scrutiny. Nor is the government correct in urging that the conflict should be permitted to persist—leaving the lower courts with inconsistent standards for years to come—because this suit "could not go forward under the pleading standard adopted by *any* court of appeals." U.S. Br. 16 (emphasis added). The government makes that assertion, but never actually examines the Complaint's allegations under the Rule 9(b) standard adopted by the First, Fifth, Seventh, and Ninth Circuits. And its analysis of plausibility simply ignores the allegations that are the centerpiece of the case. If those critical allegations would fail under any standard, the government would have no problem explaining that in its brief. That the government instead tries to sweep them under the rug speaks volumes. Nothing about the merits or posture of this case would prevent the Court from reaching the question presented, articulating the proper standard, and applying it or remanding for its application as appropriate. Review is warranted.

I. THE LONG-ENTRENCHED CIRCUIT SPLIT OVER RULE 9(b)'S APPLICATION IN FCA CASES PERSISTS

A. The government agrees that the circuits are divided over Rule 9(b)'s application in FCA cases. U.S. Br. 10; U.S. *Duxbury* Br. 9. As the government explains, "[s]everal 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." U.S. Br. 10. By contrast, other courts of appeals "have articulated a per se rule that a relator must plead the details of particular false claims * * * to overcome a motion to dismiss." *Ibid.* The government thus observed in *Duxbury* that the "existing conflict" was "deepen[ing]." U.S. *Duxbury* Br. 9. But now it claims that the conflict may resolve itself because "those circuits that initially endorsed the per se rule" now "appear to adopt a more nuanced approach." U.S. Br. 10.

The cases do not support the government's newly minted view. The government claims that, in *In re Baycol Products Litigation*, 732 F.3d 869 (8th Cir. 2013), the Eighth Circuit retreated from its per se rule, "allow[ing] [a] *qui tam* complaint[ ] to proceed notwithstanding relators' failure to identify specific fraudulent claims for payment submitted to the government," U.S. Br. 13-14 (quotation marks omitted). Not so. The government cites the portion of *Baycol* that addresses only whether "fraud in the inducement" is "a viable theory of FCA liability." 732 F.3d at 876. In the section of *Baycol* addressing Rule 9(b), the Eighth Circuit endorsed the opposite position the government attributes to the decision. After discussing Eighth Circuit precedent, the court reaffirmed its per se rule: "[W]e agree with the district court that the pleadings in [plaintiff's] [complaint] were inadequate to state a cause of action under the FCA *because she did not include at least some representative examples of false claims* * * *." *Id.* at 878 (emphasis added). That is precisely the position the government attributed to four circuits in *Duxbuy* and characterized as incorrect. U.S. *Duxbury* Br. 15-17.

The government's reliance on *United States ex rel. Clausen* v. *Laboratory Corp. of America, Inc.*, 290 F.3d

1301 (11th Cir. 2002), cert. denied, 537 U.S. 1105 (2003), also fails. The government characterizes *Clausen* as retreating from the requirement that the complaint identify specific false claims submitted to the government, because it "stat[es] that a *qui tam* complaint must contain 'some indicia of reliability'" to "'support the allegation of an actual false claim for payment.'" U.S. Br. 14 (quoting *Clausen*, 290 F.3d at 1311). But *Clausen holds* that a complaint does not contain sufficient "indicia of reliability" *unless* it identifies "with particularity" "a false claim actually being submitted to the government." 290 F.3d at 1311-1312.

The Sixth and Eleventh Circuits have declined to "foreclose the possibility" that they "may" not require identification of particular false claims in one circumstance, *Chesbrough* v. *VPA, P.C.*, 655 F.3d 461, 471-472 (6th Cir. 2011)—where the relator has "alleged personal knowledge of the defendant's billing practices" that could itself "g[i]ve rise to a well-founded belief that the defendant submitted actual false or fraudulent claims," *Hopper* v. *Solvay Pharms., Inc.*, 588 F.3d 1318, 1326 (11th Cir. 2009), cert. denied, 130 S. Ct. 3465 (2010) (discussing *United States ex rel. Walker* v. *R&F Props. of Lake Cnty., Inc.*, 433 F.3d 1349 (11th Cir. 2005), cert. denied, 549 U.S. 1027 (2006)). But a narrow (potential) exception for relators with personal knowledge of the defendant's billing practices does little to bridge the circuit conflict. Indeed, it fails to alleviate the primary defect the government identified with the requirement (in the Fourth, Sixth, Eighth, and Eleventh Circuits) that the Complaint identify specific false claims: It still precludes relators who "may be privy to detailed information indicating that their employers are engaged in fraud against the United States," and who are "well-positioned to provide valuable

assistance to the government's anti-fraud efforts," from bringing suit simply because they are not "privy to the details of the defendants' billing activities." U.S. Br. 15; see U.S. *Duxbury* Br. 17.

B. Far from self-healing, the circuit conflict is self-cementing. The government does not dispute that the Fourth Circuit's decision below deepens the conflict further by articulating a "pleading standard" that "differs" from that adopted by "other circuits." U.S. Br. 17. Nor does the government suggest that the standard adopted by the Fourth Circuit is correct.

The government urges that the decision below did not adopt a "per se rule requiring relators to plead specific false claims." U.S. Br. 12. But it did so for the lion's share of cases, offering only a limited exception to that rule. The *only* time a relator is excused from "alleg[ing] with particularity that specific false claims actually were presented * * * for payment," the Fourth Circuit announced, is when the relator can establish, before discovery, that the defendant's actions "*necessarily* * * * led to the submission of false claims." Pet. App. 10a. Requiring a complaint to establish that false claims "necessarily" were submitted is a far cry from the Rule 9(b) standard adopted by the First, Fifth, Seventh, and Ninth Circuits, which 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." *United States ex rel. Grubbs* v. *Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009); see Pet. 17-18.

Finally, the government claims that the decision below "endorsed the results" in certain First and Fifth Circuit cases. U.S. Br. 12. But the Fourth Circuit itself noted its "disagree[ment]" with the *standard* adopted by other

circuits, which it calls "a more relaxed construction of Rule 9(b)." Pet. App. 10a. The Fourth Circuit's decision does not diminish the conflict; it exacerbates the division. Review is warranted.

II. THIS CASE SQUARELY PRESENTS THE QUESTION

Conceding the "significan[ce]" of the question presented, the government nevertheless urges that the Court deny review because "[p]etitioner's suit * * * could not go forward under the pleading standard adopted by any court of appeals." U.S. Br. 16. That assertion is unfounded. The government identifies nothing that would prevent this Court from articulating the proper standard in this case and either applying the standard or remanding for its proper application.

A. As an initial matter, the government never actually applies the standard adopted by the First, Fifth, Seventh, and Ninth Circuits to the facts of this case. In those circuits, an FCA complaint is sufficient if it provides 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. The Complaint amply satisfies that standard. It has never been disputed that the Complaint alleges "particular details of [Takeda's] scheme to submit false claims." As for "reliable indicia * * * that claims were actually submitted," the Complaint identifies 98 specific prescriptions, written by 16 primary-care physicians, as "specific examples" of "false claims." Pet. App. 123a (¶ 379). For each prescription, the Complaint (using Takeda's own data) identifies the treating physician; provides the dates the physician received 60-mg Kapidex samples from Takeda; specifies when the prescription was written; and alleges that it was submitted

to Medicare. *Id.* at 105a-109a (¶¶286-301). No one denies those prescriptions were submitted to Medicare.[1]

The Complaint also demonstrates why those prescriptions were false claims—written for GERD (rather than EE) at 60 mg (rather than 30 mg) and thus ineligible for reimbursement. 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. *Id.* at 166a (¶¶4-5). The most reasonable inference is that those primary-care physicians were treating GERD, a common condition they regularly treat. The contrary supposition, that they were treating a rarer condition that primary-care physicians do not ordinarily treat and that cannot be diagnosed without a procedure primary-care physicians do not perform, borders on absurdity.

Regarding dosage, the Complaint does not merely allege that 93% of all Kapidex prescriptions are for 60 mg (making it the most likely dosage for *any* particular prescription). Pet. App. 88a (¶228). Critically, the Complaint also explains that PPIs like Kapidex are prescribed through a "PPI trial" in which the physician gives the patient free samples provided by the drug company,

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[1] The government's statement that there is a "conceded absence of any allegations of a specific false claim" in this case, U.S. Br. 17-18, overlooks the record. The Complaint alleged that those 98 specific prescriptions submitted to Medicare are "specific examples" of "false claims." Pet. App. 123a (¶379). And they were prominently discussed both in the petition, Pet. 10, 30-33; Pet. Reply 8-11, and in briefing below, C.A. Br. 21-22, 39-45; C.A. Reply 4-11. It is hard to see how the government missed them.

together with a prescription to fill if the samples are effective in alleviating symptoms. Pet. App. 82a-83a (¶¶191-194); 96a-97a (¶¶265, 269); 98a-99a (¶¶271, 278). Physicians prescribe in the sampled dose. *Id.* at 102a (¶281(d)). Here, Takeda sampled only 60-mg doses, and the 16 prescribing doctors received only 60-mg samples. *Id.* at 105a-108a (¶¶285-301). It is hard to imagine more "reliable indicia" that the 16 primary-care physicians wrote the 98 prescriptions in the same 60-mg dose that was sampled. Nowhere does the government offer any reason to accept the bizarre notion that those physicians used the sampled 60-mg dose for the PPI trial, but inexplicably wrote a 30-mg dose for the prescription.

The Complaint thus meets the standard of the First, Fifth, Seventh, and Ninth Circuits, providing "factual [and] statistical evidence to strengthen the inference of fraud beyond [mere] possibility." *Duxbury*, 579 F.3d at 29. The government's failure to analyze the Complaint's allegations under that standard belies its assertion that "[p]etitioner's suit" would fail "under the pleading standard adopted by any court of appeals." U.S. Br. 16.

B. The government urges that, "as to the 98 Kapidex prescriptions," Rule 9(b) is not "implicated" because the Fourth Circuit's "analysis indicates that its decision rested chiefly on the complaint's lack of *plausibility*, not its lack of *particularity*." U.S. Br. 18. That is hard to reconcile with the decision below, which expressly stated that it was "[e]mploying" the "pleading standard" it had adopted for Rule 9(b) in rejecting the Complaint. Pet. App. 11a. Had the court simply affirmed the dismissal based on a lack of plausibility under the Rule 8(a) standard in *Ashcroft* v. *Iqbal*, 556 U.S. 662, 678 (2009), there would have been no need for the court to survey Rule 9(b) decisions, to announce its own Rule 9(b) stand-

ard, or to express its "disagree[ment]" with circuits that have adopted a different approach to Rule 9(b). Pet. App. 6a-11a.

The government's argument does illuminate another flaw in its position: While the Fourth Circuit sprinkled the word "plausible" throughout its opinion, see, *e.g.*, Pet. App. 13a-17a, it ultimately construed Rule 9(b) to require far more than plausibility. On its face, Rule 9(b) requires only additional "particularity" in pleading the "circumstances constituting fraud"—*i.e.*, it requires greater *detail* in the allegations. Fed. R. Civ. P. 9(b). Rule 9(b) does not require that those detailed allegations meet a standard more exacting than the "plausibility" standard applicable to Rule 8(a) under *Iqbal*. See 2 James Wm. Moore, *Moore's Federal Practice* § 9.03[7] (3d ed. 2013). The Fourth Circuit thus erred in reading Rule 9(b) to require "'indicia of reliability'"—more persuasive *proof* beyond mere plausibility—"in the complaint to support the allegation that an actual false claim was presented to the government." Pet. App. 8a.

The Fourth Circuit's standard makes that error patent: It held that Rule 9(b) requires a complaint to establish "that specific false claims *actually were* presented," or to allege facts that "*necessarily*" would have "led to the submission of false claims." Pet. App. 10a (emphasis added). That displaces the plausibility standard—a plaintiff can allege facts making it "plausible" that false claims were submitted to the government, but still fall short of establishing that such claims "necessarily" or "actually were" presented. The fact that the Fourth Circuit interpreted Rule 9(b)'s particularity requirement to heighten the burden of proof at the pleading stage underscores the need for review.

C. Finally, the government claims the Complaint fails under any standard because it is "implausible" that even one of the 98 prescriptions, written by the 16 primary-care physicians and submitted to Medicare, was a false claim. U.S. Br. 19. That is both irrelevant and incorrect. It is irrelevant because this Court need only decide the proper standard for Rule 9(b), and then either apply that standard or remand to the court of appeals for application; this Court should be indifferent to which side wins. And it is incorrect, because the government ignores precisely why it is not merely plausible, but almost certain, that the 98 prescriptions were false claims. See pp. 6-8, *supra*; Pet. 28-33; Pet. Reply 8-11.

The government asserts that "the complaint does not provide a plausible basis for inferring that the 98 prescriptions were for 60-milligram doses." U.S. Br. 20. The government, however, *completely ignores* petitioner's primary explanation for why the prescriptions were for 60 mg—the role of drug-company-provided samples in PPI trials. Even apart from the fact that 93% of all prescriptions are written at 60 mg, the Complaint, the briefing below, and the petition all explain that physicians write prescriptions for PPIs in the dose that is sampled. Pet. 8-9; Pet. App. 82a-83a (¶¶191-194); 96a-97a (¶¶265, 269); 98a-99a (¶¶271, 278); 102a (¶281(d)). Here, Takeda sampled *only* 60-mg doses of Kapidex, and the 16 prescribing doctors received *only* 60-mg samples. *Id.* at 105a-108a (¶¶285-301). Indeed, the Complaint included affidavits from three physicians, including a former President of the American Medical Association, who explained that *they* wrote 60-mg doses for GERD, unaware that it was a double-dose, because Takeda had provided only 60-mg samples. *Id.* at 44a (¶10); 98a-103a (¶¶273-281).

Rather than address PPI sampling, or the physicians' affidavits, the government ignores them. The government does not explain how it could be implausible that the identified 16 physicians, having received 60-mg samples for GERD, would write 60-mg prescriptions for GERD when the President of the American Medical Association (and others) did precisely that. The government's refusal to address the allegations for which it has no answers, despite their being extensively briefed, speaks loudly to the credibility of its position.

Finally, the government asserts that the "complaint does not provide a plausible basis for inferring that the 98 prescriptions were written to treat GERD rather than EE." U.S. Br. 20. But the Complaint alleges that the prescriptions were written by primary-care physicians, who treat GERD but not EE, Pet. App. 84a-85a (¶¶206-209), and who do not perform the endoscopies necessary to diagnose EE, *id.* at 43a-44a (¶7). And GERD is relatively common, while EE is rare: GERD cases outnumber EE cases 10-to-1. *Id.* at 166a (¶¶4-5). It is more plausible that the prescriptions were written for GERD, a common condition that primary-care physicians regularly treat, than that they were written for EE, a rare condition that such doctors typically do not treat and do not perform the necessary procedures to diagnose.

The government's riposte that the Complaint "did not allege that primary care physicians *never* treat EE," U.S. Br. 20, shows only how far the train has gone from the rails. Under Rule 9(b), plaintiffs need not exclude every speculative theory the defendants may offer, showing it could "never" be the case that the physician was treating a rare disorder he would not often treat. Plaintiffs need only provide sufficient particularity such that falsity is "plausible"—provide a foundation for a "reasonable ex-

pectation" that the allegations may prove true, even if "a savvy judge" may believe "that actual proof of those facts is improbable." *Twombly*, 550 U.S. at 556-557. That the courts below dismissed based on implausible speculation of the sort endorsed by the government underscores the need for review. The government may worry that the Court will not adopt its chosen standard. But that is not a principled reason to deny review.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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