No. 17-1108

In the
Supreme Court of the United States

MEDICAL DEVICE BUSINESS SERVICES, INC., F/K/A DEPUY ORTHOPAEDICS, INC.; DEPUY SYNTHES, INC., F/K/A DEPUY, INC.; JOHNSON & JOHNSON SERVICES, INC.,

Petitioners,

v.

UNITED STATES EX REL. ANTONI NARGOL AND DAVID LANGTON, *et al.*,

Respondents.

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

REPLY BRIEF FOR PETITIONERS

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Other Authorities

REPLY BRIEF

Respondents devote most of their opposition to denying the existence of a circuit split on the question presented. That is a curious strategy, given that the decision below expressly recognized that "a consensus has yet to develop on whether, when, and to what extent a relator must state the particulars of specific examples of the type of false claims alleged," and the United States has twice advised that the conflict is real and should be resolved "in an appropriate case." Pet.14-15, 21-22. The simple and widely acknowledged reality is that the Second, Fourth, Sixth, Eighth, and Eleventh Circuits require company outsiders, like respondents, to plead details about specific false claims, while the Third, Fifth, Seventh, Ninth, Tenth, and D.C. Circuits do not. And if all that were not enough, respondents concede that the First Circuit has its own unique approach requiring the pleading of specific false claims only when the relator alleges direct, rather than indirect, fraud. The division among the circuits is real, entrenched, and outcome-determinative here.

Respondents contend that the split is not implicated because their 800-paragraph complaint describes a single hip-implant procedure that, "upon information and belief," resulted in a claim to Medicaid. While acknowledging that the district court found those skeletal allegations insufficient, respondents insist that the First Circuit relied on that lone claim, and not their generalized statistical allegations, in allowing the suit to proceed. But the decision below squarely refutes that contention. The First Circuit made crystal clear that it was embracing

an "exception" to the rule that relators must plead specific examples of false claims, and it expressly stated that it was making its decision based on respondents' statistical allegations alone.

The importance of the question presented is undeniable—and respondents do not really deny it. FCA litigation has exploded in recent years, and the FCA's generous venue provision gives relators near-total control over whether their complaints will be subject to a stringent or lenient standard. Picking a circuit with a lenient standard allows relators to turn product-liability allegations into FCA claims, thereby converting the FCA from a specialized vehicle to prevent fraud on the government into an alternative means for litigating product-liability cases with generous remedial provisions. The United States has warned against the proliferation of meritless FCA actions, and the decision below is a blueprint for making a bad situation worse. This Court should grant certiorari to restore uniformity in the circuits, rein in relators without inside information, and clarify that Rule 9(b) requires plaintiffs to do more than suggest that it is statistically likely that someone, somewhere, at some point, submitted a false claim.

I. The Circuits Are Divided.

Respondents' assertion that "there is no genuine circuit split" cannot be squared with decision below, let alone the reality of the decided cases. The First Circuit acknowledged: "The circuits have varied … in their statements of exactly what Rule 9(b) requires in a qui tam action," and "a consensus has yet to develop on whether, when, and to what extent a relator must state the particulars of specific examples of the type of

false claims alleged." Pet.App.17. The First Circuit had it right: As the United States has twice acknowledged, the circuits are deeply divided.

Respondents begin by mischaracterizing the Second Circuit's opinion in *United States ex rel. Chorches v. American Medical Response, Inc.*, 865 F.3d 71 (2d Cir. 2017). Its nod to Twain aside, that opinion leaves no doubt that the long-entrenched circuit split persists. The court divided its sister circuits into the exact same "lenient" and "stricter" categories described in the petition, *id.* at 89, expressly disclaimed the test applied by the "lenient" circuits, *id.* at 92 n.21, and adopted its own relatively stringent standard, holding that although relators need not provide invoice numbers of claim submissions, they must "provide details about *specific instances* of alleged fraud." Pet.16 (emphasis added); *see Chorches,* 865 F.3d at 82, 87. The relator in *Chorches* alleged that an ambulance company falsified the details of ambulance runs to obtain reimbursement from Medicare; his complaint satisfied Rule 9(b) because it "detail[ed] many specific runs—providing information such as the date, patient name, and original reason for the transport." 865 F.3d at 75-76, 83-84.

After setting out the contours of the circuit split, the Second Circuit acknowledged that courts on different sides of that split might reach different results on the same facts—*i.e.*, that a relator's choice of forum can be outcome-determinative. While the court was confident that the relator's complaint would satisfy the "lenient" tests applied by the Third, Fifth, Seventh, Ninth, Tenth, and D.C. Circuits, *see id.* at 89 n.15, it was less sure whether the complaint would

satisfy the "stricter" tests applied by the Fourth, Sixth, Eighth, and Eleventh Circuits, *id.* at 89-90. After some reflection, the court concluded that "[i]t is far from clear that Circuits that have adopted the stricter pleading standard … would disagree with our decision in this case." *Id.* at 90. Thus, while the circuit split turned out to be "not particularly meaningful" to the outcome of *Chorches*, *id.*, the Second Circuit's opinion unquestionably recognizes the continuing circuit split over how to apply Rule 9(b) to FCA complaints.

Respondents make the baffling claim that the Second Circuit actually adopted the "lenient" test. Opp.18-19. The language they quote, however, says only that the *result* the Second Circuit reached is consistent with the *result* the "lenient" circuits would reach on the same facts—an obvious point, as any complaint that satisfied the Second Circuit's stringent standard would satisfy the more lenient test *a fortiori*. *See Chorches*, 865 F.3d at 89 n.15 ("We simply express our view that a complaint that satisfies our pleading standard also satisfies that of the Third, Fifth, Seventh, Ninth, Tenth, and D.C. Circuits."). In reality, the court expressly disclaimed the "lenient" test. *Id.* at 92 n.21 ("[T]he standard we apply in this case is distinguishable from that of *Grubbs*."). Respondents similarly claim that the Second Circuit "did not hold" that a complaint must allege specific instances of fraud. Opp.19. That is wrong: The court repeatedly emphasized that a relator must do more than allege a generalized fraudulent scheme; he must "identif[y] particular cases in which that scheme was carried out." *Chorches*, 865 F.3d at 87; *see id.* at 84-85.

Moving beyond the Second Circuit, respondents assert that "*none* of the allegedly 'strict' circuits" requires company outsiders to plead details about specific false claims. Opp.18 (emphasis added). But respondents utterly fail to support that assertion. They do not identify *a single case* from the Second, Fourth, Sixth, Eighth, or Eleventh Circuit in which an outsider's complaint survived a motion to dismiss without pleading details about specific false claims, and admit no such case exists. *See, e.g.*, Opp.21. Moreover, many of those circuits go out of their way to distinguish outsider and insider complaints and apply a more demanding standard to the former, *see* Pet.16, which makes respondents' optimism that those circuits will change course inexplicable. But in all events, respondents' hope that strict circuits will become more lenient if they see just the right complaint is no answer to the present reality that the circuits are split and the strict circuits would have dismissed their complaint for noncompliance with Rule 9(b). *See* Pet.15-18.

Indeed, for all their insistence that the circuit split is illusory, respondents never explain how their statistical allegations could actually survive a motion to dismiss in the Second, Fourth, Sixth, Eighth, or Eleventh Circuit. To be sure, they point out (as did petitioners, Pet.16) that three of those circuits relax their standard when the relator is a company insider with first-hand knowledge of the defendants' billing practices. Opp.20-23, 32 (citing, *e.g.*, *United States ex rel. Mastej v. Health Mgmt. Assocs., Inc.*, 591 F. App'x 693 (11th Cir. 2014)). But, of course, respondents are not insiders and have no such first-hand knowledge; at most, they have knowledge only of supposed

product defects, which is precisely why they are paid experts in the product-liability litigation. *See* Opp.5-7. Accordingly, respondents could not benefit from the "company insider" aspect of the Sixth, Eighth, and Eleventh Circuits. In those three circuits—and in the Second and Fourth to boot—respondents' product-defect allegations and statistical assertions would not satisfy Rule 9(b). *See* Pet.18. The circuit split is thus not just real and entrenched, but outcome-determinative here.

Respondents dispute the circuit split by claiming that "every circuit" really just applies the same "fact-intensive, case-by-case analysis." Opp.27 n.15; *see* Opp.29, 32-34. That would come as a surprise to the courts of appeals, which, in case after case, have confirmed the widespread disagreement about the applicable legal standard, and then chosen one side or the other before applying that standard to the facts. *See, e.g.*, *Chorches*, 865 F.3d at 92 n.21 ("[T]he standard we apply in this case is distinguishable from that of [the Fifth Circuit]."); *United States ex rel. Heath v. AT&T, Inc.*, 791 F.3d 112, 126 (D.C. Cir. 2015) ("We accordingly join our sister circuits…."); *United States ex rel. Nathan v. Takeda Pharm. N. Am., Inc.*, 707 F.3d 451, 456 (4th Cir. 2013) ("We agree with the Eleventh Circuit[]…."); *Ebeid ex rel. United States v. Lungwitz*, 616 F.3d 993, 998 (9th Cir. 2010) ("We join the Fifth Circuit…."). Courts would not be going out of their way to acknowledge a circuit split and then to pick sides if there were no divide.

In the end, the truth is exactly as petitioners have described it. The Second and Fourth Circuits require all relators to allege particularized details about

specific false claims. Pet.15-16. The Sixth, Eighth, and Eleventh Circuits apply that same standard to company outsiders, but a more permissive standard to company insiders. Pet.16-18. The Third, Fifth, Seventh, Ninth, Tenth, and D.C. Circuits apply a lenient standard to all FCA claims. Pet.18-21. And the First Circuit, applying its own unique standard, requires details about specific false claims in cases alleging "direct" fraud, but not in cases like this one alleging "indirect" fraud. Pet.21. The United States, for its part, has acknowledged that a circuit split exists and should be resolved in an appropriate case. As shown next, this is an appropriate case.

II. The Question Is Squarely Presented Here.

Respondents claim that the question presented is not implicated here because the First Circuit relied not on their generalized statistical allegations, but on the complaint's description of a single hip-implant procedure performed on patient "F.I." by Dr. "J.N." at Stony Brook Hospital. Opp.8-9, 16, 26-27. The First Circuit did no such thing, and respondents grossly mischaracterize the decision below.

To be sure, the First Circuit acknowledged that respondents had pleaded "one actual sale of a defectively manufactured product to a provider that sought government reimbursement" and found that some of the district court's criticism of these allegations was unfounded. Pet.App.15. But the First Circuit never concluded that the skeletal allegations about this one incident were sufficient under circuit precedent that demanded "details concerning the dates of the claims, the content of the forms or bills submitted, their identification numbers," and "the

individuals involved in the billing." Pet.App.18. Rather than test the relatively skeletal F.I./J.N./Stony Brook allegations against that demanding standard, the court recognized and applied an "exception" to that general rule for indirect claims, like those alleged by respondents here. Pet.App.18-19. It is that "more relaxed" standard for indirect claims, and not any conclusion that the skeletal F.I./J.N./Stony Brook allegations met the demanding standard for direct claims, that caused the First Circuit to conclude that the complaint here was sufficient.[1]

That conclusion is underscored by how the First Circuit described respondents' allegations that *did* satisfy Rule 9(b). The First Circuit did not mention F.I., J.N., or Stony Brook, but spoke *exclusively* of respondents' generalized statistical allegations:

> To summarize, Relators allege that, over a five-year period, several thousand Medicare and Medicaid recipients received what their doctors understood to be Pinnacle MoM device implants; that more than half of those implants fell outside the specifications approved by the FDA; and that the latency of the defect was such that doctors would have had no reason not to submit claims for reimbursement for noncompliant devices.

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[1] The United States has recognized that in the First Circuit, "specific false claims need not be identified when the relator alleges that the defendant induced third parties to file false claims." Br. for United States as Amicus Curiae at 14 n.5, *United States ex rel. Nathan v. Takeda Pharm. N. Am., Inc.*, No. 12-1349 (U.S. Feb. 25, 2014) (emphasis omitted).

Pet.App.23. "*In this context*," the court continued, "where the complaint essentially alleges facts showing that it is statistically certain that DePuy caused third parties to submit many false claims to the government, we see little reason for Rule 9(b) to require Relators to plead false claims with more particularity." *Id.* (emphasis added). Conspicuously absent is any reference to F.I., J.N., or Stony Brook. The decision thus makes clear that the court's holding relied *solely* on respondents' generalized statistics, and not on respondents' passing reference to a single submitted claim.

The court made the same point with respect to respondents' state-law allegations. The court described the allegations that, in its view, satisfied Rule 9(b) with respect to respondents' state-law claims as follows:

> Relators … allege that between 2005 and 2010, New York State Medicaid paid for an average of approximately 1280 claims each year for total hip replacement devices, fifty percent of each of which the United States paid; that MoM hip-replacement devices made up a large percentage of devices being prescribed and installed during that time; and that given both DePuy's general market share and the specific market share of the Pinnacle MoM device, nearly 425 Pinnacle devices bearing the diametrical-clearance manufacturing defect would have been paid for by New York State Medicaid, and the United States, between 2005 and 2010.

Pet.App.26. Once again, the court made no reference to F.I., J.N., or Stony Brook (even though that hospital is *in New York*) and did not state or even suggest that those allegations had any bearing on its conclusion. Instead, the court made clear that respondents' generalized statistics, standing alone, were "enough for Relators' manufacturing-defect-based indirect claims under New York's analogue to the FCA to satisfy Rule 9(b)'s particularity requirement." *Id.*

III. The Question Presented Is Important And Frequently Recurring.

Respondents barely dispute the importance of the question presented or the frequency with which it arises, *see* Pet.31-34, saying only that they "do not concede the question has immense practical importance" and rehashing their denial of the circuit split. Opp.27 n.15. The reality, as *amici* describe, is that faithful and uniform application of Rule 9(b) is immensely important to "businesses across numerous industries and sectors," especially as relators have grown more active and more aggressive in their willingness "to file opportunistic suits in hopes of reaping a windfall." PhRMA/Chamber Br.2, 7.

Frivolous FCA claims are on the rise, and they are harmful to the government, commerce, and the public. As the Department of Justice recently explained, "the government expends significant resources in monitoring [non-intervened] cases and sometimes must produce discovery or otherwise participate" at great expense. Memorandum from Michael D. Granston, Dir. of Commercial Lit. Branch, Fraud Section at 1 (Jan. 10, 2018), http://bit.ly/2BHOhRl. Furthermore, when FCA complaints "lack substantial

merit, they can generate adverse decisions that affect the government's ability to enforce the FCA." *Id.* The threat of severe economic harm from meritless actions likewise can "cause a critical supplier to exit the government program," thereby harming the government procurement process and, accordingly, the public fisc. *Id.* at 5; *see* Gov't Contractor Br.12-16. Rule 9(b) plays a critical role in filtering out meritless FCA actions, *see* Pet.27-29, but that gatekeeping function is undermined by the lax approach that six circuits have endorsed and respondents advocate.[2]

Finally, respondents' recent effort to transfer the FCA case into the product-liability/MDL proceedings, *see* Pet.26-27, dramatically illustrates the tendency of the decision below to blur the line between product-liability litigation and the special office of the FCA. Respondents have argued that transfer is appropriate because "[t]he core issues in this [FCA] case—manufacturing defects in the Pinnacle hip implant—are being litigated in the Pinnacle Hip MDL." Mem. In Support Of Mot. To Transfer at 1, ECF 279 (Mar. 9, 2018). "[M]anufacturing defects in the Pinnacle hip implant" may well be at the core of *this* complaint, but

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[2] Respondents assert that "annual recoveries in nonintervened cases have trended upwards." Opp.27 n.15. But as their own cited article explains, those recoveries have trended upwards only in *absolute* terms, not as compared to recoveries in intervened cases, which also have increased in recent years. *See* Pet.31-32. Indeed, "[t]he bulk of the $2.4 billion recovered by the federal government in 2016 from health-care [FCA] settlements and judgments came from cases in which the Justice Department intervened." Eric Toper, *Intervention in False Claims Act Lawsuits*, Bloomberg Law (Apr. 24, 2017), available at http://bit.ly/2milJ8d.

the "core issues" in an FCA case should be whether identified false claims were submitted to the government, not whether a product was defective. The fundamental problem here is that the First Circuit approved a complaint that was long on product-liability allegations and statistical probabilities, but bereft of details on specific false claims. Respondents' approach would not suffice in five circuits, and the difference in approach is critical, especially given FCA plaintiffs' latitude in selecting a forum. The split in the circuits is deep, entrenched, and consequential; certiorari is warranted.

CONCLUSION

This Court should grant the petition.

Respectfully submitted,

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