No. ____

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

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

The False Claims Act ("FCA") imposes a civil penalty and treble damages on any person who presents, or causes a third party to present, a false or fraudulent claim to the United States government. Federal Rule of Civil Procedure 9(b) requires a party pleading an FCA case to "state with particularity the circumstances constituting fraud." The Relators in this FCA *qui tam* action are not insiders with a government contractor and have never submitted a claim to the government; they are two British doctors who are serving as expert witnesses in ongoing product-liability actions against DePuy. Seeking to recover the FCA's bounty, Relators have repurposed the product-liability allegations into an FCA complaint, which contains extensive detail about alleged defects in DePuy hip implants, but does not allege the details of any specific false claim submitted to the government. Instead, Relators simply allege that some hip implants were defective, that many hip-implant recipients are on Medicare and Medicaid, and that it is therefore statistically likely that at least some false claims were submitted to the government. The First Circuit held that those allegations satisfied Rule 9(b), even though Relators did not plead any particularized details about any specific false claim.

The question presented, which has divided the courts of appeals, is:

Whether a False Claims Act relator can satisfy Federal Rule of Civil Procedure 9(b)'s particularity requirement without alleging details about any specific false claim.

PARTIES TO THE PROCEEDING

Defendants-Appellees below were DePuy Orthopaedics, Inc., DePuy, Inc., and Johnson & Johnson Services, Inc. DePuy Orthopaedics, Inc., is now known as Medical Device Business Services, Inc. DePuy, Inc., is now known as DePuy Synthes, Inc. Accordingly, petitioners here are Medical Device Business Services, Inc., f/k/a DePuy Orthopaedics, Inc.; DePuy Synthes, Inc., f/k/a DePuy, Inc.; and Johnson & Johnson Services, Inc.

Plaintiffs-Appellants below, who are respondents here, are Antoni Nargol and David Langton, on their own behalf and on behalf of the United States of America, the State of Arkansas, the State of California, the City of Chicago, the State of Colorado, the State of Connecticut, the State of Delaware, the District of Columbia, the State of Florida, the State of Georgia, the State of Hawaii, the State of Illinois, the State of Indiana, the State of Iowa, the State of Louisiana, the State of Maryland, the State of Michigan, the State of Minnesota, the State of Montana, the State of Nevada, the State of New Jersey, the State of New Mexico, the State of New York, the State of North Carolina, the State of Oklahoma, the State of Rhode Island, the State of Tennessee, the State of Texas, the Commonwealth of Virginia, the State of Wisconsin, the Commonwealth of Massachusetts, the City of New York, the State of New Hampshire, the State of Missouri, and the State of Washington.

CORPORATE DISCLOSURE STATEMENT

Medical Device Business Services, Inc., is a wholly owned subsidiary of Synthes, Inc., which in turn is a wholly owned subsidiary of DePuy Synthes, Inc., which in turn is a wholly owned subsidiary of Johnson & Johnson International, which in turn is a wholly owned subsidiary of Johnson & Johnson, a publicly held company.

Petitioner DePuy Synthes, Inc., is a wholly owned subsidiary of Johnson & Johnson International, which in turn is a wholly owned subsidiary of Johnson & Johnson, a publicly held company.

Petitioner Johnson & Johnson Services, Inc., is a wholly owned subsidiary of Johnson & Johnson, a publicly held company.

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The False Claims Act strikes a careful balance between encouraging insiders with genuinely valuable information to blow the whistle on efforts to defraud the government and discouraging would-be relators without any specific information about false claims from filing opportunistic complaints in pursuit of FCA bounties. Federal Rule of Civil Procedure 9(b) plays a critical role in maintaining that balance, filtering out complaints with too little detail to assist the government's investigation and dissuading would-be relators without inside information from filing such complaints in the first place. The courts of appeals, however, disagree about how useful and how fine a filter Rule 9(b) provides when assessing an FCA complaint. In particular, the courts of appeals disagree about whether an FCA relator can satisfy Rule 9(b)'s particularity requirement by alleging information about generalized misconduct statistically likely to produce some false claims—here, allegations of defects in medical devices likely to have been implanted in Medicaid and Medicare patients—but not alleging any particularized details about specific false claims actually submitted to the government.

Relators Antoni Nargol and David Langton are not your traditional FCA plaintiffs. They are not corporate insiders with first-hand knowledge of shady billing practices or hospital administrators who were induced to submit false claims to Medicare or Medicaid. Relators are in fact British surgeons who do not even practice medicine in the United States and have never submitted claims for reimbursement to

United States healthcare programs. Their allegations derive not from any inside information about specific false claim submissions, but rather from information they gleaned in their roles as expert witnesses in two ongoing product-liability actions against Petitioners (collectively, "DePuy") concerning hip implants. Their complaint not coincidentally reads like a product-liability complaint, with extensive detail about alleged manufacturing defects in DePuy hip implants but no details linking those alleged defects to specific false claims that were submitted to the government. Instead, Relators simply assert that any claims for reimbursement for defectively manufactured implants are *ipso facto* false claims, that many hip-implant patients use government healthcare programs, and that, therefore, it is statistically likely that some such claims were submitted.

Courts in five circuits would have dismissed Relators' complaint for failing to allege the submission of false claims with the particularity required by Federal Rule of Civil Procedure 9(b). Whether Relators' statistical assertions are plausible or not, their allegations fail to identify the who, what, where, when, and how of any false claim submissions. Correctly recognizing that the *sine qua non* of an FCA violation is the submission of a false claim, the Second, Fourth, Sixth, Eighth, and Eleventh Circuits require relators without first-hand knowledge of the defendant's billing practices to allege particularized details about specific false claims that were submitted to the government—names, dates, places, amounts, and the like.

The Third, Fifth, Seventh, Ninth, Tenth, and D.C. Circuits, in contrast, apply a "relaxed" version of Rule 9(b). These circuits excuse relators from pleading the details of specific false claims as long as they describe the defendant's alleged misconduct and provide other "reliable indicia" that some false claims were actually submitted.

The First Circuit straddles those two approaches: It applies the stringent standard to complaints alleging that the defendant directly submitted false claims to the government. But it applies the relaxed standard to complaints alleging that the defendant induced a third party to submit false claims. Applying the relaxed standard to the allegations of indirect fraud here, the decision below reversed the district court's dismissal and approved a complaint that undoubtedly would have been dismissed in five other circuits.

The disagreement among the circuits is widely acknowledged and, in this case and many others, outcome-determinative. It is also highly consequential, as the decision below gives a blueprint for relators with no inside information about specific false claims to turn every product-liability claim involving medical devices, pharmaceuticals, or anything else purchased by the federal government into an FCA claim. The Court should grant the petition to resolve the acknowledged split among the circuits and to clarify that Rule 9(b) requires FCA relators to do far more than suggest that a product defect makes it statistically likely that someone, somewhere, at some point, submitted a false claim.

OPINIONS BELOW

The First Circuit's opinion is reported at 865 F.3d 29 and reproduced at App.1-27. The district court's opinion is reported at 159 F. Supp. 3d 226 and reproduced at App.30-103.

JURISDICTION

The First Circuit issued its opinion on July 26, 2017, and denied rehearing on September 27, 2017. *See* App.29. Justice Breyer extended the time for filing a petition to February 5, 2018. This Court has jurisdiction under 28 U.S.C. §1254(1).

STATUTES AND RULES INVOLVED

31 U.S.C. §3729(a) provides, in relevant part:

> (1) [A]ny person who—
>
> > (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or]
> >
> > (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> * * *
>
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act … plus 3 times the amount of damages which the Government sustains because of the act of that person.

Rule 9 of the Federal Rules of Civil Procedure provides, in relevant part:

> (b) FRAUD OR MISTAKE; CONDITIONS OF MIND. In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake….

STATEMENT OF THE CASE

A. Statutory Background

Congress enacted the False Claims Act in 1863 "in order to combat rampant fraud in Civil War defense contracts." *Kellogg Brown & Root Servs., Inc. v. United States ex rel. Carter*, 135 S. Ct. 1970, 1973 (2015). The Act provides for civil liability against any person who "knowingly presents, or causes to be presented" to the United States government a "false or fraudulent claim for payment or approval." 31 U.S.C. §3729(a)(1)(A). The Act similarly provides for civil liability against any person who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim" submitted to the United States government. *Id.* §3729(a)(1)(B). A liable defendant must pay treble damages and a civil penalty of up to $21,916 for each false claim. *Id.* §3729(a)(1); 28 C.F.R. §85.5.

An FCA action may be commenced in either of two ways. *Vt. Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 769 (2000). First, "the Government itself may bring a civil action against the alleged false claimant." *Id.*; *see* 31 U.S.C. §3730(a). Second, a private party (known as a "relator") may bring an action "for the person and for the United States Government" against the defendant "in the name of the Government." 31 U.S.C. §3730(b)(1). If a relator initiates the action, he must deliver the complaint and any supporting evidence to the

Government, which then has 60 days to intervene in the action. *Id.* §§3730(b)(2), (4). If the government intervenes, it assumes primary responsibility for prosecuting the action. *Id.* §3730(c)(1). If it declines, the relator may prosecute the action on his own. *Id.* §3730(b)(4). In either case, the relator is entitled to a share of any proceeds from the action—"generally ranging from 15 to 25 percent if the Government intervenes," and "from 25 to 30 percent if it does not," plus attorney's fees and costs. *Vt. Agency of Nat. Res.*, 529 U.S. at 769-770; 31 U.S.C. §3730(d)(1)-(2).

In recognition of how enticing those bounties can be, Congress has sought to "strike a balance between encouraging private persons to root out fraud and stifling parasitic lawsuits." *Graham Cty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280, 295 (2010). For example, the FCA's first-to-file bar provides that when a private person brings an FCA action, "no person other than the Government may intervene or bring a related action based on the facts underlying the pending action." 31 U.S.C. §3730(b)(5). That provision incentivizes relators to promptly come forward with useful information while also preventing follow-on "parasitic lawsuits that merely feed off previous disclosures of fraud." *United States ex rel. Branch Consultants v. Allstate Ins. Co.*, 560 F.3d 371, 376 (5th Cir. 2009). Similarly, the public-disclosure bar requires district courts to dismiss FCA actions if the relator's allegations were previously disclosed in certain public forums, unless the relator is an "original source" of the information. 31 U.S.C. §3730(e)(4)(A).

Federal Rule of Civil Procedure 9(b) works hand-in-glove with those statutory provisions, serving as a filter in its own right and assisting district courts in assessing whether the first-to-file or public-disclosure bar applies. Rule 9(b) requires FCA plaintiffs to "state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b); *see Universal Health Servs., Inc. v. United States*, 136 S. Ct. 1989, 2004 n.6 (2016). The "circumstances" that must be pleaded with particularity include "matters such as the time, place, and contents of the false representations or omissions, as well as the identity of the person making the misrepresentation or failing to make a complete disclosure and what that defendant obtained thereby." 5A Wright & Miller, *Federal Practice and Procedure* §1297 (3d ed.). Rule 9(b) serves multiple important purposes, including "providing notice to a defendant of its alleged misconduct," "preventing frivolous suits," "eliminating fraud actions in which all the facts are learned after discovery," and "protecting defendants from harm to their goodwill and reputation." *United States ex rel. Nathan v. Takeda Pharm. N. Am., Inc.*, 707 F.3d 451, 456 (4th Cir. 2013).

B. Proceedings Below

Relators Antoni Nargol and David Langton are British doctors who are serving as expert witnesses in two product-liability multi-district litigations in which petitioners are the defendants: (1) *In re: DePuy Orthopaedics, Inc. ASR Hip Implant Prods. Liab. Litig.*, No. 1:10-md-02197 (N.D. Ohio) ("ASR MDL") and (2) *In re: DePuy Orthopaedics, Inc. Pinnacle Hip Implant Prods. Liab. Litig.*, No. 3:11-md-02244 (N.D. Tex.) ("Pinnacle MDL"). Both MDL proceedings,

which remain ongoing, involve allegations that DePuy's hip-implant devices are defective.

Relators filed their original sealed complaint in this FCA action in May 2012, and then filed a First Amended Complaint (also under seal) in November 2013. App.2-3. The government conducted an investigation into Relators' allegations and decided not to intervene. App.3. Relators next filed a then-sealed (and now unsealed) Second Amended Complaint alleging, as relevant here, that some of DePuy's metal-on-metal hip implants were manufactured defectively. Relators alleged that "DePuy's manufacturing process fail[ed] to produce implant heads within specification 14.93% of the time and implant liners 50.41% of the time," App.5, causing the devices "to have a five-year failure rate of nearly fifteen percent, as compared to a five-year failure rate of 4.5% or lower as claimed by DePuy." App.6. Instead of providing specific details about how those alleged manufacturing defects led to the submission of particular false claims, Relators simply asserted that because the implant was widely-used, "as a matter of logic 'it follows that hundreds of thousands of Pinnacle products were implanted in government healthcare recipients and reimbursed by the government during the lifespan of the product.'" App.84-85.

Those high-level allegations that product defects made the submission of false claims statistically likely comprised essentially all of the detail that Relators provided about the supposedly false claims. Other than some incomplete allegations about one patient—which the district court found insufficient and on which the First Circuit did not rely, App.24 n.8—

Relators did not provide the details of any allegedly false claim: They did not identify any patient who received an allegedly defective implant; did not identify any doctor who submitted an allegedly false claim; did not provide the billing code or amount of reimbursement for any allegedly false claim; did not identify any hospital from which an allegedly false claim was submitted; and did not provide the date of any surgery or false claim submission. They simply alleged that many implants were sold, some were defective, some recipients were Medicare or Medicaid patients, and that, therefore, some false claims must have been submitted to the government.

DePuy moved to dismiss the Second Amended Complaint under Fed. R. Civ. P. 12(b)(6) for failure to plausibly allege a false claim and for failure to allege fraud with the particularity required by Federal Rule of Civil Procedure 9(b). The district court granted the motion to dismiss, ruling that the complaint was insufficient because it did not plead any false claims with the particularity required by Rule 9(b). The district court explained that the Relators failed to connect their allegations "to any specific claims for payment," as they did not "identify a single physician who was a target of allegedly false DePuy marketing, identify a single physician who relied on that marketing, or identify a single physician who filed a false claim for the DePuy MoM device." App.84. Moreover, the complaint's "unfocused and imprecise statistical evidence adds little to establish DePuy's fraud." *Id.*

The First Circuit reversed in relevant part, holding that Relators satisfied Rule 9(b). The court

began by acknowledging that "[t]he circuits have varied … in their statements of exactly what Rule 9(b) requires in a qui tam action." App.17. "Of most relevance here, 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." *Id*.

The court then described the First Circuit's bifurcated approach to Rule 9(b). When a relator alleges that the defendant *directly* submitted false claims, the First Circuit requires the relator "to allege the essential particulars of at least some actual false claims that were in fact submitted to the government for payment." App.19. As examples of the "types of information that may help a relator to state his or her claims with particularity," the court identified "the dates of the claims, the content of the forms or bills submitted, their identification numbers, the amount of money charged to the government, the particular goods or services for which the government was billed, the individuals involved in the billing, and the length of time between the alleged fraudulent practices and the submission of claims based on those practices." App.18.

When, however, a relator alleges that the defendant induced a third party to submit false claims—so-called "indirect" fraud—the rules are different. For such indirect claims, the First Circuit applies a "more flexible" approach, such that "a relator [can] satisfy Rule 9(b) by providing 'factual or statistical evidence to strengthen the inference of fraud beyond possibility' without necessarily providing details as to each false claim." App.19. That

evidence "must pair the details of the scheme with 'reliable indicia that lead to a strong inference that claims were actually submitted.'" *Id.*

Turning to the complaint in this case, the court ruled that Relators' allegations of indirect fraud satisfied the "more flexible" version of Rule 9(b). Based on the statistics alleged in the complaint, the court found it "very likely that every sale of a Pinnacle MoM device was accompanied by a[] … representation that the product being supplied was the FDA-approved product, rather than a materially deviant version of that product." App.22. It further found that it was "highly likely" that the cost of a hip implant was covered in part by insurance, and because "thousands of Pinnacle MoM devices" were implanted, it was "virtually certain that the insurance provider in many cases was Medicare, Medicaid, or another government program." App.22-23. Finally, there was "no reason to suspect that physicians did not seek reimbursement for defective Pinnacle MoM devices." App.22.

In light of those allegations and assumptions, the court saw "little reason for Rule 9(b) to require Relators to plead false claims with more particularity than they have done here in order to fit within [the First Circuit's] 'more flexible' approach to evaluating the sufficiency of fraud pleadings in connection with indirect false claims for government payment." App.23.[1]

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[1] The court likewise held that Relators' similar allegations with respect to false claims submitted to New York State Medicaid were sufficiently particularized to satisfy Rule 9(b). As to New York, Relators alleged: "'New York State Medicaid paid for an average of approximately 1280 claims each year for total hip

REASONS FOR GRANTING THE PETITION

The Court should grant certiorari to answer a frequently recurring question that has deeply divided the courts of appeals—namely, whether an FCA relator can satisfy the particularity requirement of Rule 9(b) without alleging the details of any specific false claim.

Fresh from their turn as expert witnesses in ongoing, contentious, and public product-liability litigation, Relators filed a complaint alleging that DePuy sold thousands of hip implants, some were manufactured defectively, some recipients are on Medicare or Medicaid, and thus it is statistically likely that some surgeons submitted some false claims somewhere at some time or another. Relators provide no specifics on the who, what, where, when, and how. They do not identify the patients who received one of the allegedly defective hip implants, or the doctors who submitted a false claim for reimbursement, let alone the date, amount, or billing code for any claim.

Those failures should have doomed their complaint—and would have if the complaint had been filed in the Second, Fourth, Sixth, Eighth, or Eleventh

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replacement devices,' … that [metal-on-metal] 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 [metal-on-metal] device, 'nearly 425 Pinnacle devices bearing the diametrical-clearance manufacturing defect would have been paid for by New York State Medicaid … between 2005 and 2010.'" App.26. The court affirmed the dismissal of Relators' allegations about false claims submitted to other states and municipalities. App.25.

Circuit. Although those courts vary in their precise formulations, they all correctly require relators without first-hand knowledge of the defendant's billing practices (like Relators here) to allege particularized details about specific false claims that were submitted to the government—names, dates, places, amounts, and the like. In contrast, the Third, Fifth, Seventh, Ninth, Tenth, and D.C. Circuits hold that Rule 9(b) is satisfied as long as the relator describes the details of the defendant's generalized misconduct and then adds enough other "reliable indicia" to raise an "inference that claims were actually submitted." The First Circuit applies this same lenient standard to allegations of "indirect fraud" (as in this case), while applying the strict standard to allegations of direct fraud. This division among the circuits is entrenched, widely acknowledged, and often outcome-determinative, as it was here.

Review is particularly warranted because the relaxed standard employed by numerous circuits, including the First Circuit here, is unfaithful to the FCA and Rule 9(b). The FCA is not an all-purpose wrongdoing statute, but rather is concerned only with the submission of false or fraudulent claims to the government. It follows that a relator cannot plead an FCA case by pleading a product-liability case and adding that the government is a significant purchaser, so there must have been false claims. Instead, both Rule 9(b) and the FCA demand specific allegations concerning particular false or fraudulent claims. Requiring particularized details about specific false claims helps courts apply FCA requirements and the

federal government decide whether to join such suits or move to dismiss them as abusive.

Resolution of this important issue is particularly important in light of the explosion in FCA litigation over the past decade, with ever-increasing numbers of opportunistic relators attracted by the FCA's bounties. Indeed, a dozen new FCA cases are now filed *every week*. Given the enormous time, expense, and burden of defending FCA cases, defendants invariably file motions to dismiss, but those motions are currently governed by different standards depending on where the case was filed. Making matters worse, the FCA's generous venue provision makes it particularly easy for relators to file in favorable forums, making the circuit split one that not only creates disuniformity, but provides obvious incentives for forum-shopping. The decision below is particularly problematic because it provides a blueprint for turning any product-liability case concerning a product the federal government purchases into an FCA case, even when the relator knows nothing about any specific false claim. The Court should review this well-developed, entrenched, and consequential split of authority.

I. The Circuits Disagree About How Rule 9(b)'s Particularity Requirement Applies To False Claims Act Complaints.

Courts, commentators, and the federal government all agree: "[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." App.17; 5A Wright & Miller, *Federal Practice & Procedure* §1298 (3d ed.) ("In the context of the FCA, the degree of particularity

required at the pleading stage has yet to find consensus among the various Courts of Appeals."); Br. for United States as Amicus Curiae at 10, *United States ex rel. Nathan v. Takeda Pharm. N. Am., Inc.*, No. 12-1349 (U.S. Feb. 25, 2014) ("[L]ower courts have reached inconsistent conclusions about the precise manner in which a *qui tam* relator may satisfy the requirements of Rule 9(b)."). Every regional circuit has now addressed the question, with two principal approaches emerging: a stringent pleading standard in about half and a relaxed pleading standard in the other half. The distinctions among the circuits are often outcome-determinative, as they were here. Indeed, at least five circuits would have joined the district court in dismissing Relators' complaint for failing to allege fraud with the particularity required by Rule 9(b), while others would have joined the court of appeals in reinstating the complaint.

1. Two circuits apply a stringent Rule 9(b) pleading standard to all FCA complaints. In the Fourth Circuit, for example, all relators "must allege with particularity that specific false claims actually were presented to the government for payment." *Nathan*, 707 F.3d at 457. Thus, in the Fourth Circuit, "an FCA plaintiff must, at a minimum, describe the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby." *United States v. Triple Canopy, Inc.*, 775 F.3d 628, 634 (4th Cir. 2015). When it adopted this standard, the Fourth Circuit expressly "disagree[d]" with the First Circuit's "more relaxed" approach to cases involving indirect claims. *Nathan*, 707 F.3d at 457-58.

The Second Circuit applies a similarly stringent test, albeit with a slightly different focus. Unlike the Fourth Circuit, the Second Circuit does not require relators to "provide details of actual bills or invoices submitted to the government." *United States ex rel. Chorches for Bankr. Estate of Fabula v. Am. Med. Response, Inc.*, 865 F.3d 71, 93 (2d Cir. 2017). But unlike the circuits that apply a relaxed version of Rule 9(b), *see infra*, the Second Circuit *does* require relators to provide details about specific instances of alleged fraud: The complaint must include "particularized allegations of a scheme to falsify records" and must describe "specific instances of the implementation of that scheme." *Id.* at 84. The Second Circuit noted that its standard "is distinguishable from" the "lenient" standards applied by several other circuits, which do not require relators to allege particularized instances of fraud. *Id.* at 92 & n.21.

2. Three circuits apply a stringent Rule 9(b) standard to relators who are company outsiders—*i.e.*, those who lack first-hand knowledge of the defendant's billing practices—but apply a more permissive version of Rule 9(b) to relators who are company insiders with first-hand knowledge of the defendant's billing practices.

In the Sixth Circuit, for example, company outsiders cannot satisfy Rule 9(b) "without alleging which specific false claims constitute a violation of the FCA." *United States ex rel. Bledsoe v. Cmty. Health Sys., Inc.*, 501 F.3d 493, 505 (6th Cir. 2007). For those outsiders, "[t]he identification of at least one false claim with specificity is 'an indispensable element of a complaint that alleges a [False Claims Act] violation.'"

United States ex rel. Hirt v. Walgreen Co., 846 F.3d 879, 881 (6th Cir. 2017). In contrast, company insiders with first-hand knowledge of the defendant's billing practices are not required to plead the specifics of any particular false claim. The Sixth Circuit recently summarized its approach as follows: "[We have adopted] a doctrine that (1) requires the pleading of representative false claims in the majority of cases, while (2) recognizing that a relator may nonetheless survive a motion to dismiss by pleading specific facts based on her personal billing-related knowledge that support a strong inference that specific false claims were submitted for payment." *United States ex rel. Prather v. Brookdale Senior Living Communities, Inc.*, 838 F.3d 750, 773 (6th Cir. 2016).

The Eighth Circuit likewise distinguishes between outsiders and insiders. Company outsiders cannot satisfy Rule 9(b)'s particularity requirement unless they "plead such facts as the time, place, and content of the defendant's false representations, as well as the details of the defendant's fraudulent acts, including when the acts occurred, who engaged in them, and what was obtained as a result." *United States ex rel. Thayer v. Planned Parenthood of the Heartland*, 765 F.3d 914, 916-17 (8th Cir. 2014); *accord United States ex rel. Dunn v. N. Mem'l Health Care*, 739 F.3d 417, 420 (8th Cir. 2014). By contrast, company insiders with "personal, first-hand knowledge" can satisfy Rule 9(b) by simply "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." *Thayer*, 765 F.3d at 917.

The Eleventh Circuit draws the same distinction. Company outsiders must provide specific allegations, "stated with particularity, of a false claim actually being submitted to the Government" in order to satisfy Rule 9(b)." *United States ex rel. Clausen v. Lab. Corp. of Am.*, 290 F.3d 1301, 1312 (11th Cir. 2002); *accord United States ex rel. Matheny v. Medco Health Sols., Inc.*, 671 F.3d 1217, 1225 (11th Cir. 2012) ("[A] relator must identify the particular document and statement alleged to be false, who made or used it, when the statement was made, how the statement was false, and what the defendants obtained as a result."). In contrast, "a relator with direct, first-hand knowledge of the defendants' submission of false claims gained through her employment with the defendants may have a sufficient basis for asserting that the defendants actually submitted false claims" without alleging the details about any particular claims. *United States ex rel. Mastej v. Health Mgmt. Assocs., Inc.*, 591 F. App'x 693, 704 (11th Cir. 2014).

In short, the Second, Fourth, Sixth, Eighth, and Eleventh Circuits unequivocally require corporate outsiders, like Relators here, to plead particularized details about specific instances of fraud in order to satisfy Rule 9(b). Thus, while the decision below held that Relators satisfied Rule 9(b) by providing generalized statistical allegations that raised a plausible inference of fraud, at least five other circuits would have dismissed the complaint for failure to plead fraud with particularity.

3. By contrast, six circuits apply an "across-the-board permissive" standard to all FCA claims, under which a relator need not plead with particularity the

submission of false claims. *Prather*, 838 F.3d at 772. In the Third Circuit, a relator satisfies Rule 9(b) as long as he provides "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 157-58 (3d Cir. 2014). In *United States ex rel. Customs Fraud Investigations, LLC. v. Victaulic Co.*, 839 F.3d 242 (3d Cir. 2016), for example, the relator alleged that the defendant failed to pay marking duties on imported pipe fittings. The court acknowledged that the relator did not allege "which shipments, during which time periods, at which ports, were supposedly unlawful." *Id.* at 258. Instead, the relator provided "ten years of raw import data," and, without identifying which ones, broadly alleged that the defendant must have failed to pay duties on some imports. *Id.* at 260 (Fuentes, J., dissenting in part). Despite the lack of detail about particular shipments or specific false claims, the Third Circuit held that the complaint satisfied Rule 9(b). *Id.* at 258.

The Fifth Circuit applies the same standard. An FCA plaintiff who "cannot allege the details of an actually submitted false claim" can still satisfy Rule 9(b) "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." *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009). The Fifth Circuit has explained that while "Rule 9(b) generally requires the plaintiff to plead the time, place, and contents of the false representation and the identity of the person making the representation," an "FCA claim can meet Rule 9(b)'s standard if it alleges

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 States v. Bollinger Shipyards, Inc.*, 775 F.3d 255, 260 (5th Cir. 2014).

The Ninth Circuit has expressly "join[ed] the Fifth Circuit" and held that an FCA relator need not always plead "representative examples." *Ebeid ex rel. United States v. Lungwitz*, 616 F.3d 993, 998 (9th Cir. 2010). While acknowledging that this "requirement has been adopted by some of our sister circuits," the Ninth Circuit rejected the "approach that would, as a matter of course, require a relator to identify representative examples of false claims." *Id.* Instead, in the Ninth Circuit, "a complaint need not allege a precise time frame, describe in detail a single specific transaction, or identify the precise method used to carry out the fraud." *United States v. United Healthcare Ins. Co.*, 848 F.3d 1161, 1180 (9th Cir. 2016).

The Seventh, Tenth, and D.C. Circuits have adopted the same standard, holding that "claims under the FCA need only show the specifics of a fraudulent scheme and provide an adequate basis for a reasonable inference that false claims were submitted as a part of that scheme." *United States ex rel. Lemmon v. Envirocare of Utah, Inc.*, 614 F.3d 1163, 1172 (10th Cir. 2010); *see United States ex rel. Heath v. AT&T, Inc.*, 791 F.3d 112, 126 (D.C. Cir. 2015) ("We accordingly join our sister circuits in holding that the precise details of individual claims are not, as a categorical rule, an indispensable requirement of a viable False Claims Act complaint."); *United States ex rel. Lusby v. Rolls-Royce Corp.*, 570

F.3d 849, 854 (7th Cir. 2009) (relator need not plead "the specific request for payment").

4. The First Circuit straddles the foregoing "stringent" and "relaxed" approaches, adopting the former for certain types of claims and the latter for others. In the First Circuit, when a relator alleges that the defendant itself submitted false claims—so-called "direct" fraud—the stringent standard employed by five other circuits applies: "[A] relator must provide details that identify particular false claims for payment that were submitted to the government." *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 232 (1st Cir. 2004). But where, as here, the relator alleges that the defendant induced a third party to submit false claims—so-called "indirect" fraud—the First Circuit applies the "more flexible" version of Rule 9(b) utilized by six other circuits, under which a relator can "satisfy Rule 9(b) by providing 'factual or statistical evidence to strengthen the inference of fraud beyond possibility' without necessarily providing details as to each false claim." App.19 (quoting *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 29 (1st Cir. 2009)). Applying that "more flexible" framework to this case, the court below held that Relators pleaded their case with the requisite particularity. App.23-24. But not only would the complaint here have been dismissed in five other circuits, it would have been dismissed in the First Circuit as well if it alleged false claims made directly by Petitioners.

5. The division among the circuits is not just deep, but entrenched. Indeed, in response to this Court's requests for its views in similar cases, the United

States has twice acknowledged a "circuit conflict" resulting from the courts of appeals' "inconsistent conclusions about the precise manner in which a *qui tam* relator may satisfy the requirements of Rule 9(b)." Br. for United States as Amicus Curiae at 10, *Nathan*, No. 12-1349 (U.S. Feb. 25, 2014); *see* Br. for United States as Amicus Curiae at 9, *Ortho Biotech Prods., L.P. v. United States ex rel. Duxbury*, No. 09-654 (U.S. May 19, 2010). The government recommended denial of certiorari in those two cases because neither was a suitable vehicle for review, but agreed with petitioners that the Court's review likely would be "warranted in an appropriate case." Br. for United States as Amicus Curiae at 10, *Nathan*, No. 12-1349 (U.S. Feb. 25, 2014). This is just such a case. Unlike *Duxbury* and *Nathan*, there are no barriers interfering with the Court's ability to resolve the circuit split, and the First Circuit's application of the lenient standard here was outcome-determinative.

Moreover, the need for review has only intensified in the four years since the United States submitted its brief in *Nathan*. Neither the Second Circuit nor the D.C. Circuit had entered the fray at the time of the *Nathan* petition, but those two courts have now staked out conflicting positions that add to the deep, yet even, division of authority. The D.C. Circuit expressly adopted the Fifth Circuit's lenient *Grubbs* standard, *see Heath*, 791 F.3d at 126, while the Second Circuit adopted a more stringent standard, expressly noting that its own standard "is distinguishable from that of *Grubbs*," *Chorches*, 865 F.3d at 92 n.21. *Compare id.* at 84 (complaint must describe "specific instances of the implementation of [fraudulent] scheme"), *with Heath*, 791 F.3d at 126 ("[T]he precise details of

individual claims are not … an indispensable requirement.").[2]

In sum, every regional circuit has now taken a position on whether and to what extent an FCA relator must plead particularized details about specific instances of fraud. The division among the circuits is deep, even, entrenched, and outcome-determinative here.

II. The Decision Below Is Incorrect.

The existence of a longstanding, acknowledged circuit split is sufficient to warrant certiorari on its own. But certiorari is all the more critical because the decision below is wrong. Since the essence of an FCA violation is the submission of a false claim, it follows that, to satisfy Rule 9(b), a relator must allege particularized details of false claim submissions. Allegations about the defendant's generalized misconduct, without detail about how that misconduct connects to specific false claims, do not and should not suffice. Faithful application of Rule 9(b) ensures that

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[2] The Second and D.C. Circuits tried to minimize the importance of the circuit split to the outcome of the particular cases they were confronting, but neither suggested that the circuits have coalesced around the same standard or that the division among the circuits has otherwise diminished. The Second Circuit, for example, opined that the circuits applying "the relaxed pleading standard of *Grubbs*" and the circuits "that have adopted the stricter pleading standard" all would reach the same result in that particular case. *Chorches*, 865 F.3d at 89-90 & n.15. At the same time, however, it expressly disclaimed the "relaxed" pleading standard: "[W]e are neither bound by, nor do we adopt wholesale, either the announced pleading standard purportedly adopted in those cases or the particular results reached in each of them." *Id.* at 89 n.15.

the government and the defendant have the information they need to investigate the allegations, and that courts are in a position to apply FCA requirements designed to ensure that those who file *qui tam* actions are the whistleblowers Congress sought to encourage, not parasitic relators seeking to exploit windfall recoveries.

1. Rule 9(b) requires a plaintiff to "state with particularity the circumstances constituting fraud." Fed R. Civ. P. 9(b). Under Rule 9(b), the "circumstances" that must be pleaded with particularity include "matters such as the time, place, and contents of the false representations or omissions, as well as the identity of the person making the misrepresentation or failing to make a complete disclosure and what that defendant obtained thereby." 5A Wright & Miller, *Federal Practice and Procedure* §1297 (3d ed.); *accord Nathan*, 707 F.3d at 456. This is often referred to as the "who, what, where, when, and how" of fraud. *Hopper v. Solvay Pharm., Inc.*, 588 F.3d 1318, 1327 (11th Cir. 2009).

Under the FCA, the "circumstances constituting fraud" are not the circumstances of the defendant's generalized misconduct, but rather the circumstances of the submission of false claims. "The False Claims Act is not an all-purpose antifraud statute." *Universal Health Servs.,* 136 S. Ct. at 2003; *see Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 672 (2008). The FCA does not attach liability for failing to comply with government regulations, for breach of contract, or—as here—for manufacturing a defective product. Instead, it attaches liability only for "knowingly ask[ing]," or causing others to ask, "the

Government to pay amounts it does not owe." *Clausen*, 290 F.3d at 1311; *see id.* ("The submission of a claim is … the *sine qua non* of a False Claims Act violation."). The "central question" in any FCA case is therefore "whether the defendant ever presented" or caused to be presented "a false or fraudulent claim to the government." *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 785 (4th Cir. 1999).

Accordingly, in an FCA case, Rule 9(b)'s directive that "the circumstances constituting fraud or mistake shall be stated with particularity" refers to the circumstances surrounding the actual submission of false claims—not just the circumstances related to the underlying misconduct. To use a concrete example, if a hip-implant patient filed a standard state-law fraud claim alleging that she was defrauded into purchasing a defective hip implant, she would be required to plead with particularity the "who, what, where, when, and how" of the allegedly false representations on which she relied. An FCA relator alleging that the same patient's doctor then submitted a false claim to the government for reimbursement should have to supply comparable detail about how the *government* was defrauded—*i.e.*, about the false claim submission.

2. Requiring relators to plead the details of false claims with particularity helps maintain the "golden mean" between encouraging "whistle-blowing insiders with genuinely valuable information" and discouraging "opportunistic plaintiffs who have no significant information to contribute of their own." *Graham Cty.*, 559 U.S. at 294. The substantial financial bounty promised to relators and the "essentially punitive" nature of the damages the FCA

authorizes, *Vt. Agency of Nat. Res.*, 529 U.S. at 784, encourage profit-seeking actors without any inside information to file vague complaints in the hopes that the government will intervene or that they can survive a motion to dismiss and force their way into a favorable settlement.

This is a case in point. Relators here are British doctors who are not DePuy insiders, have never practiced medicine in the United States, and have never submitted claims to government healthcare programs. By no stretch of the imagination are they the types of whistleblowers whom the FCA's bounty provisions are meant to encourage. But because of the lenient pleading standard applied below, they were able to survive a motion to dismiss simply by layering statistics and assumptions atop a product-liability complaint. And since Medicare and Medicaid are responsible for a significant percentage of overall healthcare expenditures, the decision below creates a blueprint for converting any medical device or pharmaceutical-based product-liability case into an FCA claim. Relators can almost always repeat the same steps, using general allegations of product defects and statistical likelihood to convert product-liability actions into parasitic FCA complaints.

Indeed, underscoring that the decision below obliterates the line between product-liability litigation and FCA litigation, the lead plaintiff's counsel in the product-liability MDL over DePuy's hip implants recently entered an appearance in this FCA case—and has now taken the extraordinary step of trying to transfer this FCA case into the MDL proceeding. *See* Notice of Potential Tag-Along Action, *In re DePuy*

Orthopaedics, Inc. Pinnacle Hip Implant Prods. Liab. Litig., MDL No. 2244 (J.P.M.L. Jan. 31, 2018), Doc. 1926. False Claims Act cases should be focused on whether false claims were submitted to the government; they should not become alternative forums to leverage state product-liability claims into federal FCA windfalls.

Rule 9(b), properly understood and applied, plays a critical role in filtering out opportunistic actions like these. Relators who lack sufficient information to allege the details of particular false claims are unlikely to have information that would assist the government if it chooses to intervene. *See Hirt*, 846 F.3d at 882 ("If Hirt lacked the information to do even this, he was not the right plaintiff to bring this *qui tam* claim."). Discouraging those opportunists from filing *qui tam* actions is critically important, as the FCA's first-to-file bar prohibits anyone from filing "a related action based on the facts underlying [a] pending action." 31 U.S.C. §3730(b)(5). Thus, a relator who survives a motion to dismiss because of a lenient pleading standard prevents other possible relators with "genuinely valuable information" from filing their own lawsuits and providing the government with the information it needs to uncover fraud. *Graham Cty.*, 559 U.S. at 294.

In addition to serving as a filter in its own right, Rule 9(b) enables courts to apply the FCA's own filters. Without particularized allegations of specific false claims, defendants and district courts lack the information they need to determine whether a relator's claims are derived from public disclosures or whether the relator qualifies as an original source.

See 31 U.S.C. §3730(e)(4)(A). Requiring relators to plead fraud with particularity thus "not only respects Civil Rule 9(b), but … also helps in determining whether the public-disclosure bar applies." *Hirt*, 846 F.3d at 881; *see also Bellevue v. Universal Health Servs. of Hartgrove, Inc.,* 867 F.3d 712, 720 (7th Cir. 2017) ("[S]uch conclusory allegations fail to meet the particularity standards required by Rule 9(b), and therefore are insufficient to evade the public-disclosure bar.").

3. Requiring relators to plead the details of false claims with particularity furthers the "overarching purpose" of Rule 9(b), which "is to ensure that a defendant possesses sufficient information to respond to an allegation of fraud." *United States ex rel. SNAPP, Inc. v. Ford Motor Co.*, 532 F.3d 496, 504 (6th Cir. 2008); *see Harrison*, 176 F.3d at 784 ("[T]he rule ensures that the defendant has sufficient information to formulate a defense by putting it on notice of the conduct complained of."). When courts appropriately require FCA relators to allege particular details about particular claims for payment, defendants can investigate those specific instances and formulate their defenses accordingly. But when relators do not allege any particularized details about any specific claims, defendants have nothing to guide them as they evaluate the allegations and develop their legal defenses—for example, that a particular patient was not enrolled in a government healthcare program, so that there was no false claim submitted. *See Bledsoe*, 501 F.3d at 510.

Similarly, if a relator can survive a motion to dismiss by alleging wrongdoing but not details about

particularized claims, the district court "will be presented with the dilemma of allowing an unlimited fishing expedition or no discovery at all because of the difficulty in fashioning logical and principled limits on what has to be produced." *United States ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1359-60 (11th Cir. 2006). A complaint that alleges specific instances of fraud, by contrast, allows for reasonable and targeted discovery into those specific instances. *See, e.g.*, *United States ex rel. Spay v. CVS Caremark Corp.*, 2013 WL 4525226, at *4, *6, *7 (E.D. Pa. Aug. 27, 2013) (limiting discovery to specific instances of fraud alleged with particularity).

4. The particular irony about the lenient standard applied below is that the First Circuit agrees with all of the above when it comes to allegations of *direct* fraud. In that context, the First Circuit recognizes that "an actual false claim is the *sine qua non* of a False Claims Act violation," and that requiring particularized allegations of fraud helps "prevent parasitic lawsuits" and maintain the "fine line between encouraging whistle-blowing and discouraging opportunistic behavior." *Karvelas*, 360 F.3d at 224-25; *see id.* at 231 ("[A] *qui tam* relator may not present general allegations in lieu of the details of actual false claims in the hope that such details will emerge through subsequent discovery."). When it comes to *indirect* fraud, however, the First Circuit inexplicably abandons those principles, allowing relators to proceed on the basis of generalized allegations wholly lacking in particularity.

That two-track approach has nothing to recommend it. Indeed, the very concept of a two-track

approach to Rule 9(b) is incoherent, as there is only one Rule 9(b) and one FCA. If the Rule requires details about specific instances of fraud in one type of case, it necessarily requires the same details in all other cases, as "neither the Federal Rules nor the Act offer any special leniency" to any class of relators. *Clausen*, 290 F.3d at 1314. Courts "have no more authority to 'relax' the pleading standard" in certain circumstances "than [they] do to increase it." *Hirt*, 846 F.3d at 881. Moreover, because all relators are suing on behalf of the government, there is no justification for holding any category of relator to a different standard than would apply to the government itself. *See United States ex rel. Robinson v. Northrop Corp.*, 149 F.R.D. 142, 145 (N.D. Ill. 1993).

The First Circuit has suggested that its "more flexible" standard is necessary because a relator pleading indirect claims is less likely to have access to claim submissions. *See United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 732-33 (1st Cir. 2007). But that gets matters exactly backwards. The FCA "is intended to encourage individuals who are either close observers or involved in the fraudulent activity to come forward, and is not intended to create windfalls for people with secondhand knowledge of the wrongdoing." *United States ex rel. Joshi v. St. Luke's Hosp., Inc.*, 441 F.3d 552, 561 (8th Cir. 2006). Making it easier for those far removed from the submission of claims to plead FCA violations gives special treatment to those who are *least* likely to provide the government with useful information, thereby encouraging exactly the wrong people to file FCA lawsuits.

III. The Question Presented Is Important And Frequently Recurring.

The question presented has immense practical importance because it is often determinative of whether a relator's claim will survive a motion to dismiss. *See* Br. for United States as Amicus Curiae at 16, *Nathan*, No. 12-1349 (U.S. Feb. 25, 2014) (deeming "[t]he proper application of Rule 9(b) in the FCA context" a "significant issue"). By dispensing with the requirement that FCA relators allege the details of specific false claims, the circuits applying a lenient standard not only disregard the statutory language of the FCA and the purpose of Fed. R. Civ. P. 9(b), but allow meritless cases to proceed to costly and intrusive discovery, often resulting in settlements entered only to avoid the risk of the FCA's "essentially punitive" damages provisions. *Vt. Agency of Nat. Res.*, 529 U.S. at 784. As this Court noted in a similar context, "extensive discovery and the potential for uncertainty and disruption in a lawsuit could allow plaintiffs with weak claims to extort settlements from innocent companies." *Stoneridge Inv. Partners, LLC v. Scientific-Atlanta*, 552 U.S. 148, 149 (2008).

The question presented frequently recurs. Indeed, recent years have seen an explosion in FCA cases, the vast majority of which have lacked merit and should be filtered out on motions to dismiss or deterred altogether. In the first decade of the 2000s, only 373 *qui tam* complaints were filed each year. *Fraud Statistics-Overview*, Civil Div., U.S. Dep't of Justice (Dec. 19, 2017), http://bit.ly/2CV7dgZ. This decade, that average has nearly doubled, with 670 *qui tam* complaints filed each year, *id.*, which works out to

an average of more than 12 new cases every week. The government intervenes in only about 25% of those cases, *see* Eric Topor, *Intervention in False Claims Act Lawsuits*, Bloomberg Law (Apr. 24, 2017), http://bit.ly/2milJ8d, and the vast majority of the remaining 75% are meritless: Over the past five years, the 75% of cases in which the government did not intervene produced just 8% of the total recovery in *qui tam* actions. *See Fraud Statistics*, *supra*. But without Rule 9(b) serving as a reliable deterrent to opportunistic relators, the number of meritless complaints will continue to grow.

Indeed, the issue recurs frequently enough that every regional circuit has now weighed in on the question presented, and new opinions applying the various standards are issued regularly. *See, e.g.*, *United States ex rel. Roycroft v. Geo Group, Inc.*, No. 17-3521, 2018 WL 266782 (6th Cir. Jan. 3, 2018); *United States ex rel. Tessler v. City of New York*, No. 17-178, 2017 WL 4457141 (2d Cir. Oct. 5, 2017); *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890 (9th Cir. 2017). The frequency with which the issue arises in the courts of appeals is particularly striking given that orders denying motions to dismiss—of which there are many—are not immediately appealable.

And while no circuit split is ideal, this one is particularly unfair, because the FCA makes it easy for a relator to steer a lawsuit to a friendly circuit. The FCA's exceedingly broad venue provision allows suit "in any judicial district in which the defendant, or in the case of multiple defendants, any one defendant can be found, resides, transacts business, or in which any

[violation] occurred," 31 U.S.C. §3732(a). That expansive provision gives every incentive to relators who lack sufficient information to identify particularized instances of fraud to direct their cases to circuits that apply Rule 9(b) more leniently. This case is a good example—two relators from England represented by attorneys from New York filed a lawsuit against Indiana and New Jersey companies in *Massachusetts*, within the comfortable confines of the First Circuit's flexible approach to Rule 9(b). The forum shopping that the circuit split invites is precisely the kind of "opportunistic and parasitic behavior that the FCA seeks to preclude," *Bailey v. Shell W. E&P, Inc.*, 609 F.3d 710, 721 n.3 (5th Cir. 2010), but it is the inevitable result of the current state of affairs in the circuits.

This problem will only worsen, as the decision below provides a blueprint for converting any product-liability claim into an FCA claim. The government is a ubiquitous purchaser of all manner of products, especially medical devices and pharmaceuticals. If all it takes to survive a motion to dismiss is a product-liability complaint and the bare statistical likelihood that the government paid for some of the defective products at some point, it will be the rare product-liability case that does not spawn an FCA facsimile. That is not how the FCA is supposed to work. The FCA encourages insiders to unearth fraudulent claims against the government. When it is interpreted to encourage expert witnesses who have never submitted a claim to the government and have no knowledge of any specific claim to file a lawsuit based on nothing more than statistical probabilities that some false

claim was submitted somewhere, the need for this Court's intervention is clear.

CONCLUSION

For the foregoing reasons, this Court should grant the petition.

Respectfully submitted,

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