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 A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

BRIEF FOR AMICI CURIAE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, ADVANCED MEDICAL TECHNOLOGY ASSOCIATION, AND THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA IN SUPPORT OF PETITIONERS

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INTEREST OF AMICI CURIAE[1]

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary, nonprofit association representing the nation's leading biopharmaceutical researchers and biotechnology companies. PhRMA's member companies are dedicated to discovering medicines that enable patients to lead longer, healthier, and more productive lives. During 2016 alone, PhRMA members invested approximately $65.5 billion in efforts to discover and develop new medicines. PhRMA's mission is to advocate for public policies that encourage the discovery of life-saving and life-enhancing medicines. PhRMA closely monitors legal issues that affect the pharmaceutical industry and frequently participates as amicus in this and other courts.

The Advanced Medical Technology Association ("AdvaMed") is the world's largest medical technology association, with approximately 300 member companies that develop medical devices, diagnostic tools, and health information systems. Its members span every field of medical science and range from cutting-edge startups to multinational manufacturers, all dedicated to advancing clinician and patient access to safe, effective medical technologies in accordance with the highest ethical standards.

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[1] No counsel for a party authored this brief in whole or in part, and no entity or person, other than amicus curiae, their members, and their counsel, made a monetary contribution intended to fund the preparation or submission of this brief. Counsel of record for the parties received notice of amicus' intent to file this brief at least 10 days prior to its due date. Letters from the parties consenting to the filing of this brief are on file with the Clerk.

The Chamber of Commerce of the United States of America (the "Chamber") is the world's largest business federation. It represents 300,000 direct members and indirectly represents the interests of more than three million companies and professional organizations of every size, in every industry, from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. The Chamber regularly files amicus curiae briefs in cases raising issues of concern to the nation's business community.

The key question in this case—whether a False Claims Act relator can satisfy Rule 9(b) without alleging details about any specific false claim—is of critical importance to amici's members. The defense of specious FCA claims imposes costs on businesses across numerous industries and sectors, giving amici and their members a substantial interest in the interpretation of the FCA and application of Rule 9(b) to claims that seek to repackage public information into speculative claims of fraud. The proper application of Rule 9(b) in this context is especially important to amici's healthcare industry members because the federal government's extensive role in the healthcare market allows opportunistic relators to convert claims of consumer harm into FCA treble damages actions. Amici closely monitor developments regarding the law and have routinely participated as amici curiae in FCA cases before this Court. *E.g.*, *Universal Health Servs., Inc.* v. *United States ex rel. Escobar*, 136 S. Ct. 1989 (2016); *Kellogg Brown & Root Servs., Inc.* v. *United States ex rel. Carter*, 135 S. Ct. 1970 (2015); *Schindler Elevator Corp.* v. *United States ex rel. Kirk*, 563 U.S. 401 (2011);

Graham Cty. Soil & Water Conservation Dist. v. *United States ex rel. Wilson*, 559 U.S. 280 (2010).

SUMMARY OF THE ARGUMENT

I. Congress enacted the FCA to combat fraud on the government fisc, not serve as "'an all-purpose anti-fraud statute.'" *Universal Health Servs.*, 136 S. Ct. at 2003. The statute carefully balances the interest in encouraging whistleblowers to come forward with information that helps the government uncover fraud against the risk of opportunistic relators reaping a windfall. The relaxed Rule 9(b) standard adopted by the court below, variations of which are used in roughly half the circuits, undermines these purposes by allowing relators to repackage products-liability cases or other public allegations as FCA suits without alleging any specific claims that were submitted to the government. The resulting harm is particularly severe in the healthcare context, where the size of federal programs allows relators to almost always allege speculatively that some claims were surely submitted at some point.

The volume of *qui tam* suits has soared in the last ten years. Adoption of this relaxed standard will allow relators to draw on the wide pool of products liability cases to bring a new wave of suits. Moreover, because the government has access to information about specific claims and payments, this relaxed standard will principally benefit relators in cases where the government has declined to intervene—cases which tend to be of little value to the government.

II. The relaxed standard also undermines the core purposes of Rule 9(b). First, by relieving relators of the obligation to identify specific false claims, it limits defendants' ability to respond meaningfully to allega-

tions of fraud. In particular, many FCA defenses depend on a close analysis of the timing and content of the claims submitted to the government. The relaxed Rule 9(b) standard prevents a defendant from effectively raising these defenses until summary judgment. Second, by deeming general allegations sufficient, the relaxed standard limits courts' ability to control the scope of discovery. When relators make sweeping allegations of long-running, nationwide fraud—but only have firsthand knowledge of claims submitted in a specific location in a defined period—district courts can initially limit the scope of discovery to those specific claims, allowing assessment of the merits of the case before opening the door to unrestricted discovery. The relaxed standard's acceptance of complaints that fail to allege any particular false claims deprives district courts of the ability to implement such a prudent, staged approach.

ARGUMENT

I. RELAXING THE APPLICATION OF RULE 9(b) ALLOWS OPPORTUNISTIC RELATORS TO MISUSE THE FCA

The relators in this case are two British doctors who based their complaint on information from two pending products-liability MDLs in which they serve as expert witnesses, and layered on statistical allegations hypothesizing that some unknown number of allegedly defective devices were paid for by the government. App. 60. The First Circuit sanctioned this approach, finding it sufficient that the complaint alleged facts showing that it is "statistically certain" that "many" false claims were submitted. App. 23.

This decision illustrates the hazards of "relaxing" Rule 9(b) to allow relators to avoid their burden to al-

lege particularized details about specific false claims submitted to the government. The circuits that follow this approach encourage claims that depart from the purpose of the FCA. Congress did not want opportunistic relators to wield the severe penalties authorized by the FCA outside of their intended context, leveraging them to extract settlements for claims that do little to advance the government's goals of deterring and detecting fraud.

A. The Decision Below Undermines The Purpose Of The FCA And Invites Opportunistic Suits

Enacted in 1863, the FCA "was originally aimed principally at stopping the massive frauds perpetrated by large contractors during the Civil War." *United States* v. *Bornstein*, 423 U.S. 303, 309 (1976). Although Congress has since extended the FCA's scope beyond the defense industry, "its focus remains on those who present or directly induce the submission of false or fraudulent claims." *Universal Health Servs., Inc.* v. *United States ex rel. Escobar*, 136 S. Ct. 1989, 1996 (2016).

In furtherance of its goal of preventing fraud on the government fisc, the FCA includes generous *qui tam* provisions that are intended to encourage private whistleblowers to expose wrongdoing by allowing relators to receive 15 to 30 percent of the government's award, including treble damages and civil penalties. 31 U.S.C. § 3730(d)(1)-(2). These very same provisions, however, provide a powerful incentive for parasitic relators to bring suits that simply repackage available information.

As a result, Congress has structured the FCA with the goal of "'[s]eeking the golden mean between ade-

quate incentives for whistle-blowing insiders with genuinely valuable information and discouragement of opportunistic plaintiffs who have no significant information to contribute of their own.'" *Graham Cty. Soil & Water Conservation Dist.* v. *United States ex rel. Wilson*, 559 U.S. 280, 294 (2010) (quoting *United States ex rel. Springfield Terminal Ry. Co.* v. *Quinn*, 14 F.3d 645, 649 (D.C. Cir. 1994)). Likewise, courts have sought to interpret the FCA to encourage suits by knowledgeable insiders and discourage "'opportunistic' litigation." *Schindler Elevator Corp.* v. *United States ex rel. Kirk*, 563 U.S. 401, 413 (2011) ("[A]nyone could identify a few regulatory filing and certification requirements, submit FOIA requests until he discovers a federal contractor who is out of compliance, and potentially reap a windfall in a qui tam action under the FCA"); *see also United States ex rel. Kinney* v. *Stoltz*, 327 F.3d 671, 674 (8th Cir. 2003) ("The False Claims Act 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.").

In order to reach this "golden mean," the statute includes a series of jurisdictional bars to weed out individuals without information to contribute, *see* 31 U.S.C. § 3730(e), and requires that the plaintiff allege that the defendant either presented, caused to be presented, or made a statement material to "a false or fraudulent claim for payment or approval," *id.* § 3729(a)(1)(A)-(B). In other words, it is not enough to allege a fraudulent scheme related to a government program. The scheme must be connected to the actual submission of a false or fraudulent claim. This claim-submission element requires that would-be relators have direct knowledge about the nature of the fraud on the government, and

ensures that the FCA is not used as "'an all-purpose antifraud statute.'" *Universal Health Servs.*, 136 S. Ct. at 2003.

The decision below, like others that relax the application of Rule 9(b), renders meaningless the need to plead the submission of a false claim. This approach encourages plaintiffs with nothing to offer the government—like Relators in this case—to file opportunistic suits in hopes of reaping a windfall. Opportunistic suits threaten businesses in a range of industries. *See, e.g.*, *United States ex rel. Shea* v. *Cellco P'ship*, 863 F.3d 923, 934 (D.C. Cir. 2017) (FCA suit against telecommunications provider, where relator's complaint was based on information gathered from "public databases" of government contracts); *United States ex rel. Lee* v. *Corinthian Colls.*, 2013 WL 12114015, at *4 (C.D. Cal. Mar. 15, 2013) (FCA suit against for-profit college and its auditor, noting that relators' counsel had filed five other *qui tam* suits with substantially identical allegations against other colleges and auditors), *aff'd*, 652 F. App'x 503 (9th Cir. 2016); *In re Natural Gas Royalties*, 562 F.3d 1032, 1037 (10th Cir. 2009) (FCA suit against dozens of natural gas pipelines, brought after relator learned of Senate report on industry-wide fraud).

The risk is particularly acute in the healthcare context. Because government programs like Medicare and Medicaid are responsible for a major share of overall healthcare expenditures, a would-be relator can almost always use general statistics to allege that some claims must have been submitted. Under the relaxed standard, relators lacking personal or even secondhand knowledge of claims that were submitted to the government will bring FCA cases against healthcare industry defendants premised on little more than allegations that their products are medically ineffective, have

manufacturing defects, or have undisclosed or unanticipated risks or side effects—and probably were paid for by the government at some point. Instead of being the core component that makes an alleged fraudulent scheme an actionable FCA case, the claim-submission element is reduced to an afterthought.

The possibility of parasitic suits is not a hypothetical concern. Other courts have previously rejected, under Rule 9(b), FCA claims grounded in products liability theories that failed to allege specific false claims. *See, e.g.*, *United States ex rel. Roop* v. *Hypoguard USA, Inc.*, 559 F.3d 818, 822-823 (8th Cir. 2009) (in FCA case involving defective blood glucose monitoring systems, allegations of consumer injury and noncompliance with regulations insufficient under Rule 9(b) in the absence of allegations of representative claims); *In re Darvocet*, 2015 WL 2451208, at *8 (E.D. Ky. May 21, 2015) (in FCA and products liability case alleging defendants failed to disclose that their drugs were causing heart problems, summary judgment granted due to failure to identify specific false claims).

This very case provides a clear example of the potential for abuse: Relators' complaint was not filed until May 18, 2012, nearly a year after the Judicial Panel on Multidistrict Litigation consolidated *57* products liability actions alleging defects in the same Pinnacle hip replacement devices at issue in relators' complaint. *See* MDL Transfer Order, *In re DePuy Orthopaedics, Inc., Pinnacle Hip Implant Prods. Liab. Litig.*, No. 3:11-md-02244, Dkt. 1 (N.D. Tex. May 24, 2011); App. 31. In such a case, the government is perfectly capable of initiating its own FCA investigation. Allegations of pervasive defects in a widely used or high-profile medical device or drug inevitably attract public attention, and are even advertised by attorneys seeking potential

plaintiffs. In addition, the government has a legal right to notice of such claims by Medicare beneficiaries and their insurers, who must report payouts received as result of settlements, judgments, or awards, so that the government has the opportunity to seek reimbursement. *See* 42 U.S.C. § 1395y(b)(2), (8); 42 C.F.R. pt. 411.

In short, the government does not need relators to alert it to the possibility that the FCA may bear on allegedly defective medical devices or drugs. However, under the decision below, opportunistic relators would be free to file similar FCA suits based on any of the dozens of other pending pharmaceutical and medical device MDLs, or any other products liability action involving an industry where the government is a significant customer. This is not what Congress intended in passing the FCA, and such a rule only serves to reduce the government's share of any recovery and bar other relators with bona fide inside information.

B. The Decision Below Provides A Blueprint For FCA Actions Piggybacking On Products Liability Claims

The decision below applies the "relaxed" approach to Rule 9(b) in a manner that invites derivative FCA cases based on alleged product defects, including with respect to pharmaceuticals and medical devices. For amici's members, such claims will further increase the costs of developing and delivering innovation and life-saving drugs and devices. The health care industry has already proven to be a popular target for relators, with health care cases now comprising over 70% of new FCA *qui tam* cases, with 492 filed in FY 2017. *See Fraud Statistics - Overview: Oct. 1, 1986-Sept. 30, 2017*, at 2, 4

(2018).[2] And the universe of new products liability suits to mine for allegations is substantial: In the federal district courts alone, 21,517 new health care or pharmaceutical products-liability cases were filed in 2016, making up over 7% of the civil cases filed.[3] There are even more cases in the state courts, which are where most products liability suits are filed, and which handle far more cases than the federal courts.[4] For example, one of the defendants in this case, Johnson & Johnson, alone faces more than 100,000 pending products-liability cases related to its products. *See* Johnson & Johnson, 2017 Annual Report, SEC Form 10-K, at 75.

Even before this case, the number of *qui tam* suits has nearly doubled in the past ten years. *See Fraud Statistics* 2. Opening the door to copycat products-liability suits could result in an exponential increase in the volume of cases.

This new wave of FCA claims will be of little value to the government. Healthcare payors already have access to detailed claims information about specific devices and drugs. Where concerns about a defective product support a *bona fide* FCA action, the government will either initiate its own investigation or intervene, and bring to bear that trove of payment data. As a result, relaxing the application of Rule 9(b) in this context only benefits relators where the government

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[2] https://www.justice.gov/civil/page/file/1025711/download

[3] http://www.uscourts.gov/sites/default/files/data_tables/jb_c2a_0930.2016.pdf

[4] Court Statistics Project, *Examining the Work of the State Courts: An Analysis of 2010 State Court Caseloads* 3 (Dec. 2012) (incoming civil caseload in state courts totals 19 million per year), http://www.courtstatistics.org/other-pages/~/media/Microsites/Files/CSP/DATA%20PDF/CSP_DEC.ashx

declines to intervene—cases which tend to be groundless strike suits or fishing expeditions that do not advance the purposes of the FCA and that Rule 9(b) is generally meant to prevent. *See Fraud Statistics* 2 (in the past 10 years, qui tam cases in which the United States declined resulted in less than 7% of qui tam settlements and judgments).

Allowing such claims to proceed under a "relaxed" Rule 9(b) will compel government suppliers to expend significant resources to defend or settle speculative claims that often lack merit. For example, in 2009, the Seventh Circuit applied its relaxed standard to allow a relator to proceed with a claim based on allegedly defective engine parts, even though the government declined to intervene and the relator failed to plead a "specific request for payment." *United States ex rel. Lusby* v. *Rolls-Royce Corp.*, 570 F.3d 849, 854 (7th Cir. 2009). More than three years later and after "extensive discovery," the district granted summary judgment to the defendant because the relator had "no individualized knowledge that a particular part that failed to meet contract specifications was ever sold to the government." *United States ex rel. Lusby* v. *Rolls-Royce Corp.*, 2012 WL 4357438, at *11 (S.D. Ind. Sept. 24, 2012).

II. THE DECISION BELOW UNDERMINES THE CRITICAL ROLE RULE 9(b) PLAYS IN PROTECTING DEFENDANTS

Since their adoption in 1937, the Federal Rules of Civil Procedure have required a party alleging fraud to "state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). This heightened pleading standard—which applies to FCA cases—demands that plaintiffs provide more than the "short and plain statement of the claim" that suffices in other cases. Fed. R.

Civ. P. 8(a)(2). As this Court has noted, this requirement is meant to protect defendants from the "high risk of abusive litigation" resulting from fraud claims. *Bell Atl. Corp.* v. *Twombly*, 550 U.S. 544, 569 n.14 (2007).

Relaxing the pleading standard with respect to the submission of particular false claims undermines this protection in at least two critical ways: first, it limits defendants' ability to prepare a meaningful defense, and second, it limits courts' ability to control discovery and weed out deficient cases. If some circuits continue to relax Rule 9(b) in this context, relators without information about any specific false claims may survive motions to dismiss, and the threat of treble damages and "discovery expense will push cost-conscious defendants to settle even anemic cases before reaching [summary judgment or trial]." *Twombly*, 550 U.S. at 559. The Court should grant certiorari to reiterate and restore the proper protections of Rule 9(b).

A. Relaxing Rule 9(b) Limits Defendants' Ability To Respond Meaningfully To Allegations Of Fraud

A core purpose of Rule 9(b) is to "'guarantee all defendants sufficient information to allow for preparation of a response.'" *United States ex rel. Williams* v. *Martin-Baker Aircraft Co.*, 389 F.3d 1251, 1256 (D.C. Cir. 2004); *accord United States ex rel. Nunnally* v. *West Calcasieu Cameron Hosp.*, 519 F. App'x 890, 892 n.2 (5th Cir. 2013) ("The heightened pleading standard for fraud claims supplies defendants with the information they need to prepare responses."). An FCA complaint is subject to a range of potential defenses at the motion to dismiss stage, including absence of a false statement, lack of scienter, non-materiality, and the public disclosure bar. These defenses, however, often turn on the

specifics of the claims submitted to the government, and, in a products-liability case like this one, the specifics of a given patient's medical condition. Allowing relators to plead FCA cases with only general statistics about submitted claims hamstrings a defendant's ability to assert these defenses effectively, opening the door to discovery to the very plaintiffs least likely to have meritorious cases.

One of the most basic defenses in an FCA action is that the defendant made no false statements to the government. This may be because the device or drug at issue worked as expected, or because the risk of side effects or failure was appropriate in light of the patient's circumstances. *See United States ex rel. Nowak* v. *Medtronic, Inc.*, 806 F. Supp. 2d 310, 354-355 (D. Mass. 2011) (FCA complaint alleging misrepresentation of safety and efficacy of medical device "would require an individual claim-by-claim review of medical necessity"). Or a defendant may argue that an allegedly defective product was compliant with applicable government regulations when the claim was submitted. *See United States ex rel. Gage* v. *Davis S.R. Aviation, L.L.C.*, 623 F. App'x 622, 627 (5th Cir. 2015) (dismissing FCA complaint alleging that contractor's parts caused aircraft crash, on grounds that "post hoc product failure is not enough, standing alone, to create an inference that the product was non-compliant at the time of sale."). Without particularized allegations about specific claims, defendants have no way to argue, on a claim-by-claim basis, that the claims were not false.

Particularized allegations are also critical if a defendant is to meaningfully respond to a FCA case based on a theory of implied certification—*i.e.*, a case premised on the theory that the defendant impliedly certified compliance with some material contractual or regu-

latory provision in submitting claims for payment. In *Universal Health Services*, the Court approved of this theory, but only when two conditions are met: "first, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths." 136 S. Ct. at 2001. When the submission of claims is pleaded generally, defendants have no way to argue that the claims did not make specific representations. Nor are defendants able to explain how any specific representations were not misleading half-truths. Without the protections of Rule 9(b), a defendant's implied certification defense is all but foreclosed at the pleading stage.

Scienter and materiality defenses are also compromised without particularized allegations. A common defense to FCA liability is that any defects were disclosed to the government, showing that the defendant was not intending to perpetrate a fraud and that the defects were not material to the government. For example, in *United States ex rel. Booker* v. *Pfizer, Inc.*, 188 F. Supp. 3d 122, 132 (D. Mass. 2016), *aff'd*, 847 F.3d 52 (1st Cir. 2017), which addressed allegations of fraudulent off-label marketing of pharmaceuticals, the court found that the scienter element was negated because state Medicaid programs knowingly chose to reimburse for the off-label use. This type of defense may be difficult to assert without particularized details about the circumstances of specific claims, especially where there are factual disputes about what exactly the government knew and when it acquired that knowledge. Moreover, in the pharmaceutical and medical device context, the knowledge and independent medical judgment of pre-

scribing or treating doctors must also be considered. If a medical provider determines that the device or drug remains medically reasonable or necessary despite latent defects, the materiality standard is not satisfied. Without representative sample claims for payment or particularized details about specific categories of claims, a defendant cannot present concrete arguments that go to these elements.

Finally, a relaxed pleading standard undermines the jurisdictional bars of the FCA. In assessing whether a claim is barred by prior public disclosure, courts often use the formulation "X + Y = Z" to assess whether either the allegation of fraud itself (Z) or its component parts (X + Y) were publicly disclosed. *See, e.g.*, *United States ex rel. Mateski* v. *Raytheon Co.*, 816 F.3d 565, 573 (9th Cir. 2016); *Springfield Terminal*, 14 F.3d at 654. Those component parts are a "misrepresented state of facts and a true state of facts." *Springfield Terminal*, 14 F.3d at 655. When a complaint fails to allege specific false claims—the who, what, when, where, and how of the alleged fraud—a court may be unable to identify the specific false misrepresentations presented to the government and determine whether they had been publicly disclosed prior to the complaint. *See United States ex rel. Hirt* v. *Walgreen Co.*, 846 F.3d 879, 881 (6th Cir. 2017) ("Adherence to this requirement [for pleading of specific false claims] not only respects Civil Rule 9(b), but it also helps in determining whether the public-disclosure bar applies.")

B. Relaxing Rule 9(b) Diminishes Courts' Ability To Control The Scope Of Discovery

Rule 9(b) also serves as a tool for courts to weed out meritless or speculative cases at the pleading stage, and to narrow overbroad cases before proceeding to

summary judgment and trial. The need to prevent fishing expeditions is especially important in the FCA context, given "that a qui tam plaintiff, who has suffered no injury in fact, may be particularly likely to file suit as 'a pretext to uncover unknown wrongs.'" *United States ex rel. Karvelas* v. *Melrose-Wakefield Hosp.*, 360 F.3d 220, 231 (1st Cir. 2004). Defendants should not be forced to bear the enormous costs of discovery in cases where relators cannot allege that any actual false claims were submitted.

Even in cases where a relator is able to plead certain claims with particularity, Rule 9(b) can be used effectively to control the scope of discovery and limit litigation costs for defendants and courts. *United States ex rel. Clausen* v. *Laboratory Corp. of Am.*, 198 F.R.D. 560, 564 (N.D. Ga. 2000), *aff'd*, 290 F.3d 1301 (11th Cir. 2002) ("The particularity requirement of Rule 9(b), if enforced, will not only protect defendants against strike suits, but will result in claims with discernable boundaries and manageable discovery limits."). For example, in *United States ex rel. Spay* v. *CVS Caremark Corp.*, 2013 WL 4525226, at *1 (E.D. Pa. Aug. 27, 2013), the relator sought discovery, on a nationwide basis over the course of seven years, of an alleged practice by a pharmacy benefit manager of fraudulently adjudicating and submitting prescription drug event claims to Medicare and Medicaid. The court rejected this effort, ordering that discovery be limited to the time periods, types of activity, and locations alleged in the complaint. *Id.* at *2, *4, *6, *7; *see also, e.g.*, *United States ex rel. Rost* v. *Pfizer, Inc.*, 253 F.R.D. 11, 15, 17 (D. Mass. 2008) (where relator supported complaint alleging nationwide off-label marketing scheme with details about more than 200 false claims submitted in Indiana, court limited discovery to conduct in Indiana).

As illustrated by the decision below, however, the relaxed pleading standard forecloses the possibility of any such case management effort. In their complaint, Relators allege a five-year course of nationwide misconduct without identifying a single false claim with particularity. *See* App. 23. Lacking any details about the nature of the individual false claims, and how they may have varied over time, by region, or in substance, a district court on remand would simply not have enough factual material to meaningfully limit discovery in any way. *See, e.g.*, *United States ex rel. Rigsby* v. *State Farm Fire & Cas. Co.*, 2014 WL 691500, at *5 (S.D. Miss. Feb. 21, 2014) ("Were the Court to grant Relators' request, discovery would necessarily be overly broad because the Amended Complaint lacks enough detail to permit the Court to craft reasonable discovery parameters."). Instead of a reasonably staged approach, the doors of discovery are opened in full, allowing the kind of speculative, burdensome fishing expedition that Rule 9(b) has traditionally guarded against.

CONCLUSION

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

Respectfully submitted.

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