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

RESPONDENTS' BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

KENNETH W. STARR
5404 Point Wood Circle
Waco, TX 76710

ARTHUR R. MILLER
NEW YORK UNIVERSITY
40 Washington Square
New York, NY 10012

RICHARD J. ARSENAULT
NEBLETT, BEARD & ARSENAULT
2220 Bonaventure Court
P.O. Box 1190
Alexandria, LA 71301

JAYNE CONROY
SIMMONS HANLY CONROY
112 Madison Avenue
New York, NY 10016

W. MARK LANIER
Counsel of Record
KEVIN P. PARKER
M. MICHELLE CARRERAS
THE LANIER LAW FIRM
6180 FM 1960 Rd W
Houston, TX 77069-3804
(713) 659-5200
Mark.Lanier@LanierLawFirm.com

Counsel for Respondents

March 9, 2018

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20002

TABLE OF CONTENTS

TABLE OF CONTENTS—Continued

APPENDIX Page

TABLE OF AUTHORITIES

TABLE OF AUTHORITIES—Continued

TABLE OF AUTHORITIES—Continued

TABLE OF AUTHORITIES—Continued

TABLE OF AUTHORITIES—Continued

TABLE OF AUTHORITIES—Continued

TABLE OF AUTHORITIES—Continued

INTRODUCTION

Petitioners present the following question: "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." Pet.i. Every single circuit has answered that question affirmatively. The Petition should be denied for this reason alone. Moreover, the underlying premise of the Petition (*i.e.*, that Relators did "not allege the details of any specific false claim submitted to the government" (*id.*)) is untrue. Actually, in addition to pleading factual and statistical evidence supporting a strong inference that claims were actually submitted, Relators pled details regarding a specific claim submitted to the government in 2007. The First Circuit properly considered both this representative example and Relators' other factual and statistical evidence when it determined their Second Amended Complaint ("Complaint") satisfied the particularity requirements of Rule 9(b). Indeed, the First Circuit's decision turned on the unique set of facts at issue in this case, which are not likely to be repeated. As such, it is not worthy of this Court's review. The Petition should be denied.

COUNTER-STATEMENT OF THE CASE

A. Statutory Background

The False Claims Act ("FCA") focuses "on those who present or directly induce the submission of false or fraudulent claims" to the government. *Universal Health Services, Inc. v. United States*, 136 S. Ct. 1989, 1996 (2016). Its purpose "is to encourage private citizens who are aware of fraud against the government to expose the fraud, while preventing opportunistic suits by individuals who hear of fraud publicly but play no part in exposing it." *U.S. ex rel. Matheny v. Medco*

Health Sols., Inc., 671 F.3d 1217, 1222 (11th Cir. 2012); *see also U.S. ex rel. Presser v. Acacia Mental Health Clinic, LLC*, 836 F.3d 770, 777 n.23 (7th Cir. 2016). The FCA is construed broadly, "as it is 'intended to reach all types of fraud, without qualification, that might result in financial loss to the Government.'" *U.S. ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 899 (9th Cir. 2017) (citation omitted).

Claims under the FCA are subject to Rule 9(b), which requires parties alleging fraud to "state with particularity the circumstances constituting fraud[.]" *Universal Health*, 136 S. Ct. at 2004 n.6. This rule serves several purposes. Fraud allegations must be "specific enough to give defendants notice of the particular misconduct which is alleged to constitute the fraud charged so that they can defend against the charge and not just deny that they have done anything wrong." *United States v. United Healthcare Ins. Co.*, 848 F.3d 1161, 1180 (9th Cir. 2016) (citation and internal quotation marks omitted). Additionally, "[b]y requiring some factual basis for the claims, the rule protects against false or unsubstantiated charges." *Id.* Rule 9(b) is not the sole mechanism that serves this latter purpose; the FCA itself includes several statutory barriers to weed out frivolous claims. Pet.6.

Courts typically interpret Rule 9(b) as requiring a plaintiff to "describe the 'who, what, when, where, and how' of the fraud—'the first paragraph of any newspaper story.'" *Presser*, 836 F.3d at 776 (citation omitted). However, "this standard 'does not require absolute particularity or a recital of the evidence[.]'" *United Healthcare*, 848 F.3d at 1180 (quoting 5A Wright & Miller, *Federal Practice and Procedure* § 1298 (3d ed. 2004)). Nor does it "inflexibly dictate adherence

to a preordained checklist of 'must have' allegations." *U.S. ex rel. Heath v. AT & T, Inc.*, 791 F.3d 112, 125 (D.C. Cir. 2015); *see also U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009); *U.S. ex rel. Duxbury v. Ortho Biotech Products, L.P.*, 579 F.3d 13, 32 (1st Cir. 2009); *Shushany v. Allwaste, Inc.*, 992 F.2d 517, 521 (5th Cir. 1993). Rather, Rule 9(b) necessitates a fact-specific inquiry:

> "Rule 9(b)'s ultimate meaning is context-specific," and thus there is no single construction of Rule 9(b) that applies in all contexts. Depending on the claim, a plaintiff may sufficiently "state with particularity the circumstances constituting fraud or mistake" without including all the details of any single court-articulated standard—it depends on the elements of the claim at hand.

Grubbs, 565 F.3d at 188 (internal footnote omitted). *See also Heath*, 791 F.3d at 125; *U.S. ex rel. Chorches for Bankr. Estate of Fabula v. Am. Med. Response, Inc.*, 865 F.3d 71, 81 (2d Cir. 2017); *Presser*, 836 F.3d at 776; *U.S. ex rel. Nathan v. Takeda Pharm. N. Am., Inc.*, 707 F.3d 451, 458 (4th Cir. 2013); *E-Shops Corp. v. U.S. Bank Nat. Ass'n*, 678 F.3d 659, 663 (8th Cir. 2012); *U.S. ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1358 (11th Cir. 2006).

This is particularly true when applying Rule 9(b) in the context of FCA claims. Flexibility is required in order to effectuate the rule's purpose "without stymieing legitimate efforts to expose fraud." *Grubbs*, 565 F.3d at 190 ("[T]he rule is context specific and flexible and must remain so to achieve the remedial purpose of the [FCA]."); *see also U.S. ex rel. Thayer v. Planned Parenthood of the Heartland*, 765 F.3d 914, 918 (8th Cir. 2014). Thus, courts should consider whether some

of the relevant facts are peculiarly within the control of the defendant or third parties. *U.S. ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 229 (1st Cir. 2004) ("Rule 9(b) pleading standards may be relaxed, in an appropriate case, 'when the opposing party is the only practical source for discovering the specific facts supporting a pleader's conclusion.'") (citation omitted); 5A Wright & Miller, *Federal Practice and Procedure* § 1298 (3d ed.) ("When the pleader is asserting that third persons have been defrauded, the pleader may lack sufficient information to be able to detail the claim at the outset of the action and less particularity should be required."); *cf. Rotella v. Wood*, 528 U.S. 549, 560 (2000) (citing *Corley v. Rosewood Care Ctr., Inc.*, 142 F.3d 1041, 1050–51 (7th Cir. 1998)). Courts should also consider the reach and complexity of the fraudulent scheme and the length of time over which it occurred. 5A Wright & Miller, *Federal Practice and Procedure* § 1298 (3d ed. 2004) ("When the issues are complicated or the transactions cover a long period of time, a number of federal courts have tended to require less of the pleader.").

Importantly, Rule 9(b) does not require the plaintiff to "'*prove* his allegations.'" *U.S. ex rel. Prather v. Brookdale Senior Living Communities, Inc.*, 838 F.3d 750, 771 (6th Cir. 2016) (quoting *U.S. ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1313 (11th Cir. 2002)). *See also U.S. ex rel. Lusby v. Rolls-Royce Corp.*, 570 F.3d 849, 855 (7th Cir. 2009). As this Court has recognized, Rule 9(b) does not supersede "the flexibility provided by Rule 11(b)(3), allowing pleadings based on evidence reasonably anticipated after further investigation or discovery." *Rotella*, 528 U.S. at 560. Thus, a complaint may satisfy Rule 9(b) even though some fraud allegations are pled upon "information and belief." *Chorches*, 865 F.3d at 81–82;

Karvelas, 360 F.3d at 226 & n.8. Moreover, the complaint must be viewed in its entirety, taking into consideration all allegations. *U.S. ex rel. Lemmon v. Envirocare of Utah, Inc.*, 614 F.3d 1163, 1173 (10th Cir. 2010); *cf. Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322-23 (2007).

B. Factual Background[1]

Defendants-Petitioners manufacture and sell medical devices, including the Pinnacle metal-on-metal hip implant ("Pinnacle MoM"). Pet-App.31.[2] When Petitioners sought 510(k) clearance from the FDA to market the Pinnacle MoM, they represented in their submissions that the device was manufactured within certain specifications. Pet-App.38-39, 42, 44, 48-50, 54; Resp-App.3, 21-22, 33, 37, 46-47, 61. The FDA cleared the Pinnacle MoM for sale in December 2000; it was sold until August 2013. Pet-App.42, 54.

Plaintiffs-Respondents, *qui tam* relators Dr. Antoni Nargol and Dr. David Langton (collectively, "Relators") are two world-renowned orthopedic surgeons in England. Pet-App.34-35, 71; Resp-App.6-7, 12, 17-19. They worked closely with Petitioners for many years. Pet-App.34, 43; Resp-App.4-5, 7-10. Nargol, one of the earliest U.K. adopters of the Pinnacle MoM, was invited by DePuy to be on its Pinnacle user-group team. Pet-App.34. He was selected as one of DePuy's "key opinion leaders" for both Pinnacle and another of Petitioners'

---

[1] References to Petitioners' Appendix are cited as "Pet-App." References to Respondents' Appendix, attached, are cited as "Resp-App."

[2] The Pinnacle MoM was the metal-on-metal option for the Pinnacle Acetabular Hip System, which also provided polyethylene and ceramic options. Pet-App.40. Only the Pinnacle MoM is at issue in this case.

metal-on-metal hip implants, the ASR. Pet-App.34; Resp-App.16-17, 49. Nargol traveled to India at DePuy's request to teach surgeons to use Pinnacle hip implants. Resp-App.16-17, 49. To date, Nargol has performed over 1,200 MoM hip implant operations, many of which involved the Pinnacle MoM and ASR. Resp-App.16.

Langton has performed extensive research on Pinnacle MoM components, some of which was funded by DePuy. Pet-App.34, 46; Resp-App.9, 12, 40. He performs much of his research at the North Tees Explant Center, one of the world's largest facilities assessing failed implants. Resp-App.18. He also maintains a database containing engineering measurements of all explants collected at the Center. *Id*. Langton has analyzed over 250 Pinnacle device components, both explanted and unused. *Id*.

In 2007, Relators began voicing concerns to Petitioners regarding the risks of exposure to metal debris and ions from metal-on-metal hip implants. Resp-App.8-9. Soon thereafter Relators began raising an alarm with respect to the high failure rates of the Pinnacle MoM and the ASR. Pet-App.35, 42, 47; Resp-App.3, 7, 9. Through their own testing, Relators eventually determined that defects in the manufacture of the Pinnacle MoM were causing excessive device failures. Pet-App.43, 46, 49-51, 53; Resp-App.3, 7, 9, 11-13, 25, 37, 40-41, 49-60. Specifically, certain components in some Pinnacle MoM devices were not being manufactured within the required specifications. Pet-App.42-43, 46, 50, 52-54; Resp-App.4-6, 37, 40-42, 54-55, 59-61. These specifications related to the (i) diametrical clearance between the head and the liner, and (ii) surface roughness of the head taper. Pet-App.5, 40, 42-43, 46, 49-50, 52-53; Resp-App.11, 33-37, 40-41, 58-59. The nature of these defects was such

that an orthopedic surgeon would not realize the device was defective when implanting it into a patient. Pet-App.22, 42; Resp-App.24, 33-34, 37, 52-53. Relators repeatedly reported their findings to Petitioners, who consistently rebuffed Relators' concerns; denied the existence of any problems; and claimed any MoM failures were due to sub-optimal patient selection and surgical technique. Pet-App.43, 46-47, 49-51, 53; Resp-App.3-5, 7-13, 40-42, 48-51, 56.

Relators' concerns ultimately were proven correct. Petitioners recalled the ASR and discontinued the Pinnacle MoM. Pet-App.54, 61. Each of their MoM hip implants has been the subject of product-liability multi-district litigations against Petitioners. Pet-App.39, 54-55. Given their extensive history and experience with Petitioners' MoM hip implants, Relators were asked to testify as fact and/or expert witnesses for the plaintiffs in these litigations. Pet-App.34-35, 43; Resp-App.16-19.

C. Proceedings Below

1. Relators' Allegations

Relators sued Petitioners under the FCA, alleging in relevant part: (i) the Pinnacle MoM cleared by the FDA was required to be manufactured within certain specifications; (ii) a significant percentage of Pinnacle MoMs manufactured and sold in the United States from at least 2005 to 2010 did not meet those specifications ("Nonconforming Pinnacle MoMs"); (iii) Petitioners withheld this fact from the FDA and the orthopedic community; (iv) the Nonconforming Pinnacle MoMs' deviations from approved specifications materially increased the risk of patient harm; (v) Petitioners falsely represented to the FDA and the orthopedic community that such devices were safe,

effective, and manufactured within approved specifications; and (vi) Petitioners' fraud caused medical providers to submit false claims to the government for payment under Medicare, Medicaid, and other federal or New York State-funded programs. Pet-App.4-6, 24 n.9, 35-36, 38-39, 42-44, 46, 48-56, 58-62, 71; Resp-App.3-5, 7-8, 14, 19-22, 25, 28-72.

In their Complaint, Relators identified a "representative" false claim submitted to the government involving the Nonconforming Pinnacle MoM. Pet-App.15, 56-60; Resp-App.63-67. Specifically, a patient (Mr. "F.I.") "was implanted with a DePuy Pinnacle hip implant"[3] on November 12, 2007 by Dr. "J.N.," a surgeon at Stony Brook University Medical Center ("SBUMC"). Pet-App.15, 56. Mr. F.I.'s implant was a Nonconforming Pinnacle MoM; it ultimately failed because of "manufacturing defects in the device, including nonconforming diametrical clearance dimensions." Pet-App.15, 58. At the time of implantation, "Mr. F.I. received Medicaid insurance through HealthFirst, a managed care organization that provides government-sponsored health insurance plans in New York." Pet-App.56. "On information and belief," Petitioners provided Dr. J.N. with Pinnacle MoM-related materials and surgical instructions containing materially false statements. Pet-App.56-58. Petitioners "made these fraudulent false statements with knowledge or in reckless disregard of the fact that the Pinnacle's failure rates were far greater than represented and

[3] In the Complaint, Relators define "Pinnacle" as referring to the Pinnacle MoM. Pet-App.71 (alleging "DePuy submitted false claims for payment for one of DePuy's **MoM** devices: the Pinnacle Acetabular Hip System ('Pinnacle')") (emphasis added); Resp-App.31. And Relators use "Pinnacle" to refer to the Pinnacle MoM throughout the Complaint. *See, e.g.,* Resp-App.7-8, 12, 14, 20, 33.

that the product consistently failed to conform to its diametrical clearance specifications." Resp-App.65. "Upon information and belief, on or about November 2007, [SBUMC] submitted a claim to Medicaid for Mr. F.I.'s Pinnacle hip device and implant surgery." Pet-App.15, 59. In this submission, SBUMC and Dr. J.N. certified that "Mr. F.I.'s Pinnacle device was reasonable and medically necessary for his treatment under 42 U.S.C. § 1395y(a)(1)(A)." Pet-App.59. Unbeknownst to SBUMC and Dr. J.N., this certification was false because the implantation of a defective device is not a medically reasonable treatment. Pet-App.15, 36, 58-60; Resp-App.67. Moreover, the government does not reimburse for medical devices that do not comply with specifications. Pet-App.53; Resp-App.23. Medicaid reimbursed ~$34,000 in costs for Mr. F.I.'s implant and surgery, with 50% coming from the federal government and 50% coming from New York State. Pet-App.59-60; Resp-App.67.

Relators also provided extensive factual and statistical evidence supporting their allegation that thousands of false claims involving the Nonconforming Pinnacle MoM were submitted to the government. Pet-App.56, 60-62; Resp-App.68-72. During the relevant time period, "over one million MoM hips were sold worldwide[,]" with the "United States constitut[ing] almost two thirds of the world's orthopedic device market." Pet-App.60. Petitioners' two MoM hip implants (Pinnacle MoM and ASR XL) represented 75% of the MoM hip replacement market. Pet-App.61. Prior to 2010, the Pinnacle MoM constituted roughly 50% of Petitioners' MoM hip replacement sales (37.5% of the total MoM market). Pet-App.61. After ASR was recalled in August 2010, however, the Pinnacle MoM constituted at least 70% of Petitioners' MoM hip replacement sales (53% of the total MoM market).

Pet-App.61. For example, of the 300,000+ hip replacement surgeries performed in this country in 2010, 27% (~81,000) involved MoM implants, of which an estimated 37.5 – 53% (~30,375 – 42,930) were Pinnacle MoMs. Pet-App.60-61.

Through their own testing, funded in part by a DePuy research grant, Relators discovered a significant percentage of Pinnacle MoM components were not manufactured within approved specifications. Pet-App.5-6 ("DePuy's manufacturing process fail[ed] to produce implant heads within [clearance] specification 14.93% of the time and implant liners 50.41% of the time. . . . Over fifty percent of the Pinnacle MoM devices as sold allegedly suffered from [the surface roughness] defect and were 'well outside of their required manufacturing specifications.'"), Pet-App.14 ("[B]ased on data 'representative of the outcomes of DePuy's manufacturing process,' Relators' statistical analysis suggested that DePuy's manufacturing process produced a surface-roughness defect in the taper trunnion junction in more than half of DePuy's Pinnacle MoM devices and 'fail[ed] to produce explant heads within specification 14.93% of the time and 50.41% of the time for the explant liner.'"), Pet-App.46, 61; Resp-App.7-8, 54, 59 (Langton's 2014 statistical analysis found that 87 of the 157 36mm Pinnacle heads studied (*i.e.*, 55.41%) contained the surface roughness manufacturing defect). These deviations, though material, were of a type that orthopedic surgeons would not have realized they were implanting Nonconforming Pinnacle MoMs. Pet-App.22, 42; Resp-App.24, 33-34, 37, 52-53.

Thousands of false claims involving Nonconforming Pinnacle MoMs were paid by the government. "Medicare is the primary payor for hip implants,

reimbursing between 55% and 60% of all hip implants in the United States." Resp-App.71. Between 2005 and 2009, Medicare paid for ~50,000 MoM total hip replacement devices. *Id*. Given Pinnacle MoM's market share at that time (37.5%), ~18,750 of those Medicare patients were implanted with a Pinnacle MoM. Pet-App.23 n.7. Extrapolating from Relators' own testing, ~2,799 (14.93%) of those Pinnacle MoMs failed to comply with clearance specifications for the head, ~9,452 (50.41%) failed to comply with clearance specifications for the liner, and ~10,389 (55.41%) failed to comply with surface roughness specifications for the head taper. Pet-App.5-6, 61; Resp-App.54, 59.

Similarly, Relators pled statistical evidence supporting their allegation that Medicaid paid false claims for Nonconforming Pinnacle MoMs. Pet-App.22-23, 60-62; Resp-App.68-70. On average, New York State Medicaid (funded in part by the federal government) paid ~1280 claims (totaling ~$52 million) each year for total hip replacements between 2005 and 2010. Pet-App.60. According to the FDA, 27% of all total hip replacement surgeries in 2010 involved MoM implants, which was a decline from prior years. Pet-App.61. Applying the conservative 27% to the entire six-year period indicates that between 2005 and 2010, New York Medicaid paid for ~346 MoM hip implants each year. Pet-App.60-61. Given Pinnacle MoM's market share during that time (37.5% from 2005-2009, 53% in 2010), New York Medicaid paid for a total of ~832 Pinnacle MoM devices between 2005 and 2010 (totaling ~$33.8 million). Pet-App.60; Resp-App.69. Thus, extrapolating from Relators' own testing, ~124 (14.93%) of those Pinnacle MoMs failed to comply with clearance specifications for the head, ~419 (50.41%) failed to comply with clearance specifications for the liner, and ~461 (55.41%) failed to comply with surface

roughness specifications for the head taper. Pet-App.5-6, 61; Resp-App.54, 59.

2. The District Court Dismisses Relators' Claims.

The district court dismissed Relators' Complaint, finding it failed to plead false claims with the particularity required by Rule 9(b). Pet-App.33, 86. For Relators' indirect claims, the court held, in relevant part, that the "single representative indirect claim" in the Complaint was inadequate because:

> [I]t does not identify the specific Pinnacle MoM device that is the subject of the present controversy. Put another way, the [Complaint] does not allege that the surgeon presented a claim to Medicaid for a Pinnacle MoM device, as opposed to a Pinnacle device with a ceramic head or a polyethylene liner.

Pet-App.80-81; *see also* Pet-App.97 (allegations "do not refer to the Pinnacle MoM device that is the subject of this litigation and do not raise an inference of fraud beyond mere possibility").

The court further held that the Complaint's "other factual and statistical evidence" did not satisfy Rule 9(b). Pet-App.81. The court concluded Relators failed to connect Petitioners' fraud "to any specific claims for payment" and also failed "to 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." Pet-App.84. The court found the allegations concerning Dr. "J.N." insufficient because they did "not identify the specific representations or materials that the doctor received and relied upon, nor d[id] [they] allege the specific

DePuy device for which the doctor filed a claim." Pet-App.84. The court also considered it "noteworthy" that the allegations involving that claim "are based on mere 'information and belief.'" Pet-App.84 n.8.[4]

Finally, the court rejected the Complaint's statistical analysis, finding it "not sufficiently precise or consistent as to the geographical scope, time period, or product type to maintain an inference of fraud." Pet-App.85. Notably, the court cited to only three paragraphs of the Complaint in support of its position, ignoring Relators' other statistical allegations. Pet-App.60-62; Resp-App.54, 59, 68-72. The court did acknowledge that "[a]s a matter of logic, any scheme that causes unreasonable or unnecessary purchases of a product or service will almost certainly result in the submission of some false claim, by someone, somewhere, to the federal government." Pet-App.85 n.9; *see also* Pet-App.32-33. However, it held Rule 9(b) "requires something more than conclusory allegations that false claims must have resulted from the misconduct." Pet-App.85 n.9.

3. The First Circuit Reverses in Part.

On appeal, the First Circuit vacated the dismissal of Relators' claims that Petitioners "caused physicians to submit claims to the United States and New York for payment" for Nonconforming Pinnacle MoMs, finding such claims had been pled with sufficient particularity under Rule 9(b). Pet-App.24 n.9, 27. Notably, the First Circuit rejected the district court's findings that Relators' allegations regarding patient F.I.'s claim neither alleged any specific misrepresentations or

[4] For this proposition, the court cited to ten paragraphs from the Complaint, of which four contained allegations "on information and belief." Pet-App.56-60; Resp-App.63-66.

materials relied on by Dr. J.N., nor identified the specific device for which Dr. J.N. submitted a claim:

> As to the first point, the plain, specific misrepresentation (assuming the allegations to be true) was that the device was the Pinnacle MoM device, an FDA-approved product, rather than a defectively manufactured, nonconforming variant. As to the second point, we read the complaint's description of a DePuy Pinnacle hip implant which contained use instructions for the 'Pinnacle MoM' as fairly identifying the Pinnacle MoM device.

Pet-App.15.

The court then addressed the question of "whether identifying this single exemplar false claim" was sufficient to satisfy Rule 9(b). Pet-App.16. Reaffirming its prior rulings, the court noted that in cases alleging defendants induced third parties to file false claims with the government, relators 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.'" Pet-App.19 (citations omitted). "Such evidence must pair the details of the scheme with 'reliable indicia that lead to a strong inference that claims were actually submitted.'" Pet-App.19 (citation omitted).

Analyzing the specific factual circumstances in this case, the court found the Complaint sufficiently alleged such evidence for Relators' claims that Petitioners induced third parties to submit false claims regarding the Nonconforming Pinnacle MoM "for government reimbursement from the United States

and from the state of New York." Pet-App.22-24. The court explained:

> The fraudulent scheme alleged here . . . is that DePuy knowingly palmed off, as the approved Pinnacle MoM device, devices that materially deviated from the approved specifications in a manner that materially increased the risk of patient harm. There is no suggestion in the pleadings—and no reason to infer based on the allegations—that the minute but material manufacturing defects were known to the doctors, the patients, or the government. Nor would the defects in this particular instance have manifested themselves during surgery. Unlike in our off-label marketing cases, there is therefore no reason to suspect that physicians did not seek reimbursement for defective Pinnacle MoM devices. Additionally, it is very likely that every sale of a Pinnacle MoM device was accompanied by an express or plainly implicit representation that the product being supplied was the FDA-approved product, rather than a materially deviant version of that product. Finally, given the nature of a total hip replacement, it is also highly likely that the expense is not one that is primarily borne by uninsured patients in most instances. Importantly, the complaint also alleges the sale and use of thousands of Pinnacle MoM devices, making it virtually certain that the insurance provider in many cases was Medicare, Medicaid, or another government program.

> 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. In this context, 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 than they have done here in order to fit within *Duxbury's* "more flexible" approach to evaluating the sufficiency of fraud pleadings in connection with indirect false claims for government payment.

Pet-App.22-23 (internal citation and footnote omitted). Significantly, the court noted that "[w]hether the one pleaded example offered here is necessary we need not and do not decide." Pet-App.24 n.8. Rather, in making its decision, the court considered **both** the representative example **and** the statistical evidence provided in the Complaint. Pet-App.15, 22-24.

REASONS TO DENY THE PETITION

I. THERE IS NO CIRCUIT SPLIT, AS EVERY CIRCUIT RECOGNIZES THERE ARE CIRCUMSTANCES IN WHICH AN FCA RELATOR CAN SATISFY RULE 9(b) WITHOUT PLEADING A REPRESENTATIVE CLAIM.

The Petition should be denied because there is no genuine circuit split on this issue. No circuit currently applies a per se rule mandating FCA relators to plead a representative claim in all circumstances. Although previously the circuits appeared divided on this question, they have now all moved toward a case-specific approach:

> On further consideration, we conclude . . . that the reports of a circuit split are, like those prematurely reporting Mark Twain's death, "greatly exaggerated." As the various Circuits have confronted different factual variations, differences in broad pronouncements in early cases have been refined in ways that suggest a case-by-case approach that is more consistent than might at first appear.

Chorches, 865 F.3d at 89, 90-92. *See also Prather*, 838 F.3d at 772; *Heath*, 791 F.3d at 126; *Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 156 n.3 (3d Cir. 2014); Br. For United States as Amicus Curiae, *U.S. v. Takeda Pharmaceuticals North America, Inc.*, No. 12-1349 ("*Takeda* Brief"), 2014 WL 709660, at *10 (U.S. Feb. 25, 2014) ("[E]ven those circuits that initially endorsed the per se rule have issued subsequent decisions that appear to adopt a more nuanced approach.").

Indeed, every circuit now recognizes that an FCA complaint may satisfy Rule 9(b), despite not pleading a representative claim, in certain circumstances. Pet.18-21; *infra*. This includes all five of the circuits (Second, Fourth, Sixth, Eighth, and Eleventh) in which Petitioners argue Relators' complaint would have been dismissed. Petitioners even concede this is true for three of these purportedly "strict" circuits in their Petition. Pet.16-18 (acknowledging the Sixth, Eighth, and Eleventh Circuits recognize an exception for "company insiders with first-hand knowledge of the defendant's billing practices"). Of course, Petitioners' presented question is whether "a[n] [FCA] relator" can satisfy Rule 9(b) "without alleging details about any specific false claim." Pet.i. The question was not limited to relators without first-hand knowledge of the defendant's billing practices. *Id.* Even assuming such limitation is "fairly included" within the question presented,[5] none of the allegedly "strict" circuits have adopted a bright-line rule that FCA complaints lacking a representative claim can satisfy Rule 9(b) only under those limited circumstances.

First, Petitioners claim the Second Circuit has adopted the "stringent test." But the case they cite states otherwise:

> Our holding today is clearly consistent with the approach taken by the Third, Fifth, Seventh, Ninth, Tenth, and D.C. Circuits, which have overtly adopted a "more lenient" pleading standard. Those courts have allowed a

[5] U.S. SUP. CT. R. 14.1(a); *Izumi Seimitsu Kogyo Kabushiki Kaisha v. U.S. Philips Corp.*, 510 U.S. 27, 31–32 & n.5 (1993) (questions which are "merely 'complementary' or 'related' to the question presented" are "not 'fairly included therein[,]'" even if discussed in petition's text).

> complaint that does not allege the details of an actually submitted false claim to pass Rule 9(b) muster 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."

Chorches, 865 F.3d at 89 (quoting *Grubbs*, 565 F.3d at 190). The court rejected labeling its standard as either "lenient" or "stringent." *Id.* at 92.[6] Rather, it "simply appl[ied] the basic rules of Rule 9(b) to a particular set of allegations." *Id.* at 92.

Contrary to Petitioners' assertions, the court did not hold a "complaint must include 'particularized allegations of a scheme to falsify records' and must describe 'specific circumstances of the implementation of that scheme'" in order to satisfy Rule 9(b). Pet.16, 22. It merely noted the complaint at issue did contain those allegations. *Chorches*, 865 F.3d at 84-85. It ultimately held Rule 9(b) does not require every relator to plead a representative claim "so long as the relator makes plausible allegations . . . that lead to a strong inference that specific claims were indeed submitted and that information about the details of the claims submitted are peculiarly within the opposing party's knowledge." *Id.* at 93.[7] Applying this standard, the court found the complaint satisfied Rule 9(b) despite the relator not

---

[6] The court noted some courts misinterpret the "lenient" standard as "tantamount to *not* applying Rule 9(b)." *Id.* at 92 n.21.

[7] Although *Chorches* involved direct claims to the government, such that the defendant had peculiar knowledge of those claims, the court relied on the First Circuit's "persuasive" rationale for applying a flexible standard in cases involving indirect claims by third parties. *Id.* at 92 (citing *Duxbury*, 579 F.3d at 29-30).

having personal knowledge of the defendant's billing practices. *Id.* at 82-83, 89.

Petitioners similarly mischaracterize the Fourth Circuit's opinions. Rather than applying a per se rule, that court interprets Rule 9(b) "to require relators to allege that defendants **either** caused specific false claims to be submitted **or** committed actions that '*necessarily* . . . led to the submission of false claims.'" *U.S. ex rel. Szymoniak v. Am. Home Mortgage Servicing, Inc*, 679 Fed. Appx. 299, 301 (4th Cir. 2017) (unpublished) (quoting *Nathan*, 707 F.3d at 457) (emphasis added). Petitioners quote part of a sentence from *Nathan*, claiming the court held all relators must plead specific false claims. Pet.15. But the complete sentence belies that: "[W]e hold that when a defendant's actions, as alleged and as reasonably inferred from the allegations, *could* have led, but *need not necessarily have led*, to the submission of false claims, a relator must allege with particularity that specific false claims actually were presented to the government for payment." *Nathan*, 707 F.3d at 457 (complaint must contain "'some indicia of reliability' . . . to support the allegation that an actual false claim was presented") (citation omitted). Noting that whether a particular complaint's allegations "meet the required standard must be evaluated on a case-specific basis[,]" the court determined a relaxed standard was not appropriate in that particular case. *Id.* at 456–58 (distinguishing other cases in which, "[b]ased on the nature of the schemes alleged . . . , specific allegations of the defendant's fraudulent conduct necessarily led to the plausible inference that false claims were presented to the government"). *See also United States v. Triple Canopy, Inc.*, 775 F.3d 628, 640 (4th Cir. 2015) (relator's complaint containing "nothing more" than a single, conclusory sentence that claims were

paid by the government under several contracts deemed insufficient), *cert. granted, judgment vacated on other grounds sub nom. Triple Canopy, Inc. v. U.S. ex rel. Badr*, 136 S. Ct. 2504 (2016), *opinion reinstated*, 857 F.3d 174, 179 (4th Cir. 2017).

Petitioners concede the Sixth Circuit has held a relator can satisfy Rule 9(b) without identifying a specific claim, but argue this is only in cases in which the relator is a company insider with direct knowledge of the defendant's billing records. Pet.16-17. Admittedly, these are the only circumstances, to date, in which the court has found an FCA complaint to survive Rule 9(b) scrutiny without identifying a specific claim. *Prather*, 838 F.3d at 755, 769 (noting "previous cases invoking [a relaxed Rule 9(b) standard] involved facts that did not warrant its application"). But the court repeatedly has left open the possibility that there may be other circumstances in which such a complaint could satisfy Rule 9(b). *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 471-72 (6th Cir. 2011) (noting it did "not foreclose the possibility that this court may apply a 'relaxed' version of Rule 9(b) in certain situations"; a strong inference that claims were submitted may arise when a relator has "personal knowledge" that the defendant submitted the claims, and there also "may be other situations in which a relator alleges facts from which it is highly likely that a claim was submitted"); *see also United States v. Walgreen Co.*, 846 F.3d 879, 881–82 (6th Cir. 2017) (dismissing complaint in which the relator neither "allege[d] personal knowledge of Walgreen's claim submission procedures[,]" nor "otherwise allege[d] facts 'from which it is highly likely that a claim was submitted to the government'") (citation omitted); *U.S. ex rel. Bledsoe v. Cmty. Health Sys., Inc.*, 501 F.3d 493, 504 n.12 (6th Cir. 2007) ("We do not intend to foreclose the

possibility of a court relaxing this rule in circumstances where a relator demonstrates that he cannot allege the specifics of actual false claims that in all likelihood exist, and the reason that the relator cannot produce such allegations is not attributable to the conduct of the relator."); *U.S. ex rel. Eberhard v. Physicians Choice Lab. Services, LLC*, 642 Fed. Appx. 547, 553 (6th Cir. 2016) (unpublished).

The Eighth Circuit has also rejected a per se rule requiring FCA relators to plead representative claims in all cases. *Thayer*, 765 F.3d at 918 ("We agree that '[s]tating 'with particularity the circumstances constituting fraud' does not necessarily and always mean stating the contents of a bill.'") (citation omitted). Again, Petitioners argue this is only in cases in which the relator is a corporate insider with personal knowledge of the defendant's billing practices (Pet.17), which were the specific circumstances in *Thayer*. 765 F.3d at 917, 918 n.2 (distinguishing *U.S. ex rel. Dunn v. N. Mem'l Health Care*, 739 F.3d 417 (8th Cir. 2014)).[8] But the court never limited the exception to only those circumstances. *Thayer*, 765 F.3d at 918–19 (concluding "a relator can satisfy Rule 9(b) without pleading representative examples of false claims if the relator can otherwise plead the 'particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted'" and noting one way to do that is

[8] In *Dunn*, the court dismissed the complaint because the relator failed to allege a representative claim and simply relied on a conclusory assertion that, because of the defendant's misconduct, every claim it submitted for two decades was fraudulent. 739 F.3d at 419–20. There is no indication the relator alleged any other facts supporting a strong inference that false claims were actually submitted. *Id.*

by personal knowledge of the defendant's billing practices) (citation omitted).

Similarly, in the Eleventh Circuit, "there is no per se rule that an FCA complaint must provide exact billing data or attach a representative claim." *U.S. ex rel. Mastej v. Health Mgmt. Associates, Inc.*, 591 Fed. Appx. 693, 704 (11th Cir. 2014) (unpublished).[9] In *Clausen*, the court recognized that, "if Rule 9(b) is to be adhered to, some indicia of reliability must be given in the complaint to support the allegation of *an actual false claim* for payment being made to the Government." 290 F.3d at 1311. *See also United States v. HPC Healthcare, Inc.*, 16-16670, 2018 WL 526039, at *3 (11th Cir. Jan. 24, 2018) (unpublished). The court "evaluate[s] whether the allegations of a complaint contain sufficient indicia of reliability to satisfy Rule 9(b) on a case-by-case basis." *Atkins*, 470 F.3d at 1358; *see also Mastej*, 591 Fed. Appx. at 704 (court applies a "nuanced, case-by-case approach"). Although the court once mentioned thinking it "unlikely" a relator "without first-hand knowledge of the defendants' billing practices" would have a sufficient basis for asserting the defendant actually submitted false claims, it emphasized "there are no bright-line rules[.]" *Mastej*, 591 Fed. Appx. at 704.[10]

Thus, the recent decisions from these purportedly "stringent" circuits "are in fact more nuanced" than Petitioners contend, and ultimately consistent with

---

[9] *See, e.g., United States v. R&F Properties of Lake County, Inc.*, 433 F.3d 1349, 1359–60 (11th Cir. 2005); *Hill v. Morehouse Med. Associates, Inc.*, 02-14429, 2003 WL 22019936, at *5 (11th Cir. Aug. 15, 2003) (unpublished).

[10] *Matheny* is not to the contrary. 671 F.3d 1217. That case was a reverse false claim action, in which pleading the presentment of false claim is not required. *Id*. at 1224 n.12.

the flexible approach of the other circuits. *Chorches*, 865 F.3d at 90. Indeed, every circuit has adopted some variation of the test applied by the First Circuit in this case by which an FCA complaint can satisfy Rule 9(b) if it alleges the details of the fraudulent scheme along with reliable indicia leading to a strong inference that claims were actually submitted. *Supra*; Pet.18-21. This test also has been supported by the United States, the real party in interest in FCA cases. *Takeda* Brief, 2014 WL 709660, at *11-16; Br. For United States as Amicus Curiae, *Ortho Biotech Products, L.P. v. U.S.*, No. 09-654 ("*Ortho* Brief"), 2010 WL 2007742, at *14-15 (U.S. May 19, 2010).[11] Petitioners' assertion that there is a circuit split is nothing but a strained contortion of the case law.

Moreover, the per se rule promoted by Petitioners is not supported by Rule 9(b) or the case law and "undermines the FCA's effectiveness as a tool to combat fraud against the United States." *Takeda* Brief, 2014 WL 709660, at *10. *See also Chorches*, 865 F.3d at 86 (per se rule "would discourage the filing of meritorious *qui tam* suits that can expose fraud against the government"); *Foglia*, 754 F.3d at 156.[12]

---

[11] This fact-specific approach appropriately balances the goals of the FCA and Rule 9(b). *Thayer*, 765 F.3d at 918; *Foglia*, 754 F.3d at 156-57; *Grubbs*, 565 F.3d at 190-91.

[12] A per se rule is also inappropriate because it requires relators to allege more at the pleading stage than they would have to prove at trial. *Heath*, 791 F.3d at 126–27 ("[T]o require relators to plead representative samples of claims actually submitted to the government would require relators, before discovery, to prove more than the law requires to be established at trial."); *Foglia*, 754 F.3d at 156; *Grubbs*, 565 F.3d at 190 (*qui tam* plaintiffs do "not necessarily need the exact dollar amounts, billing numbers, or dates to prove to a preponderance [at trial]

Even with a limited exception for corporate insiders with personal knowledge of the defendant's billing practices, a per se rule "takes a big bite out of *qui tam* litigation." *Lusby*, 570 F.3d at 854. The FCA "'is intended to encourage individuals who are either close observers or involved in the fraudulent activity to come forward.'" *U.S. ex rel. Joshi v. St. Luke's Hosp., Inc.*, 441 F.3d 552, 561 (8th Cir. 2006) (citation omitted). One can be a close observer of a defendant's fraud despite not working in the defendant's billing department or having been employed by the defendant at all. To the extent such an individual can provide a detailed overview of the fraudulent scheme, along with reliable indicia leading to a strong inference that false claims were submitted, there is no reason to preclude him from pursuing a *qui tam* action simply because he is unable to identify the details of a specific false claim.[13] This is precisely why the fact-specific approach applied by all the circuits is necessary.

---

that fraudulent bills were actually submitted"); *Takeda* Brief, 2014 WL 709660, at *11; *cf. Tellabs*, 551 U.S. at 328.

[13] Petitioners argue such individuals "are unlikely to have information that would assist the government if it chooses to intervene." Pet.27. On the contrary, "the government 'rarely if ever needs a relator's assistance to identify claims for payment that have been submitted to the United States. Rather, relators typically contribute to the government's enforcement efforts by bringing to light other information that shows those claims to be false.'" *Chorches*, 865 F.3d at 87 n.12 (quoting *Takeda* Brief, 2014 WL 709660, at *16); *see also Heath*, 791 F.3d at 126; *Ortho* Brief, 2010 WL 2007742, at *17.

II. THIS CASE IS NOT THE APPROPRIATE VEHICLE FOR RESOLVING THE QUESTION PRESENTED BECAUSE RELATORS PLED PARTICULARIZED DETAILS ABOUT A SPECIFIC FALSE CLAIM SUBMITTED TO THE GOVERNMENT.

Even if a circuit split existed, this case is not the appropriate vehicle by which to resolve it because, contrary to Petitioners' repeated assertions otherwise (Pet.i., 1-2, 8-9, 12), Relators pled a representative false claim in their Complaint. *Supra*, Counter-Statement of the Case ("COC") at C.1. Petitioners gloss over these allegations, dismissing them as "some incomplete allegations about one patient—which the district court found insufficient and on which the First Circuit did not rely[.]" Pet.8.[14] But although the district court found these allegations insufficient, the First Circuit rejected that court's rationale for doing so and expressly considered both the representative claim and the Complaint's other factual and statistical allegations when it determined Relators pled their indirect claims involving the Nonconforming Pinnacle MoM with sufficient particularity to satisfy Rule 9(b). Pet-App.15, 22-24. Indeed, the very question Petitioners claim this Court must resolve (*i.e.*, "[w]hether a [FCA] relator can satisfy [Rule] 9(b)'s particularity requirement without alleging details about any specific false claim") is one the First Circuit **explicitly did not decide**. Pet-App.24 n.8.

This Court "ordinarily 'do[es] not decide in the first instance issues not decided below.'" *Adarand*

---

[14] Petitioners provide no other argument or explanation for why Relators' representative claim is "insufficient" or should not be considered.

Constructors, Inc. v. Mineta, 534 U.S. 103, 109 (2001) (quoting *Nat'l Collegiate Athletic Ass'n v. Smith*, 525 U.S. 459, 470 (1999)). This is true even if the issue is considered "important." *Id.* at 110.[15] Thus, even assuming, *arguendo*, there was a circuit conflict on this issue, this Court's resolution of such a conflict would have no bearing upon this case's ultimate outcome. *Ticor Title Ins. Co. v. Brown*, 511 U.S. 117, 122 (1994) (granting certiorari not warranted when it is unclear whether the Court's resolution "will make any difference even to these litigants"); *The Monrosa v. Carbon Black Exp., Inc.*, 359 U.S. 180, 184 (1959).

---

[15] Relators do not concede the question "has immense practical importance," as Petitioners contend. Pet. 31. As explained below, there is currently no circuit split that would raise concerns of forum-shopping; rather, every circuit applies a fact-intensive, case-by-case analysis when determining this issue. *Supra*, § I. Moreover, Petitioners' assertion that the "vast majority" of recent FCA cases in which the government has not intervened "are meritless" is speculative at best and not supported by their cited authority. Pet.31-32; *Fraud Statistics-Overview*, Civil Div., U.S. Dep't of Justice (Dec. 19, 2017), *available at* http://bit.ly/2CV7dgZ (although nonintervened cases account for a fraction of the total *qui tam* settlements/judgments to date, there is no indication as to the number of nonintervened cases still pending or how any of the others were resolved); Eric Toper, *Intervention in False Claims Act Lawsuits*, Bloomberg Law (Apr. 24, 2017), *available at* http://bit.ly/2milJ8d (noting "annual recoveries for nonintervened cases have trended upwards" and the current disparity in recoveries is the result of "'a handful of extremely large settlements'" in intervened cases).

III. THE FIRST CIRCUIT CORRECTLY APPLIED ACCEPTED RULE 9(b) STANDARDS TO THE SPECIFIC FACTS OF THIS CASE.

The plain language of Rule 9(b) does not require FCA plaintiffs to plead a representative claim in order to satisfy the rule. And, as discussed above, every circuit has held that under some circumstances an FCA relator can satisfy Rule 9(b) without alleging details about a specific false claim. *Supra*, § I. This shows the contextual character of applying Rule 9(b). "The particularity demanded by [the rule] necessarily differs with the facts of each case." *Tuchman v. DSC Communications Corp.*, 14 F.3d 1061, 1067–68 (5th Cir. 1994); *supra*, COC.A. That the outcome in one case differs from the outcome in another merely speaks to the fact-intensive nature of the inquiry. *Chorches*, 865 F.3d at 89. Thus, it is unsurprising this Court has denied at least **sixteen** certiorari petitions regarding Rule 9(b)'s application in FCA cases since 2000.[16]

---

[16] *Victaulic Co. v. U.S., ex rel. Customs Fraud Investigations, LLC*, 138 S. Ct. 107 (2017); *AT&T, Inc. v. U.S. ex rel. Heath*, 136 S. Ct. 2505 (2016); *U.S. ex rel. Walterspiel v. Bayer AG*, 137 S. Ct. 162 (2016); *U.S. ex rel. Gage v. Davis S.R. Aviation, L.L.C.*, 136 S. Ct. 984 (2016); *U.S. ex rel. Mastej v. Health Mgmt. Associates, Inc.*, 135 S. Ct. 2379 (2015); *U.S. ex rel. Grenadyor v. Ukrainian Vill. Pharmacy, Inc.*, 136 S. Ct. 49 (2015); *U.S. ex rel. Nathan v. Takeda Pharm. N. Am., Inc.*, 134 S. Ct. 1759 (2014); *U.S. ex rel. Ebeid v. Lungwitz*, 562 U.S. 1102 (2010); *U.S. ex rel. Hopper v. Solvay Pharm., Inc.*, 561 U.S. 1006 (2010); *Ortho Biotech Products, L.P. v. U.S. ex rel. Duxbury*, 561 U.S. 1005 (2010); *U.S. ex rel. Fowler v. Caremark RX, L.L.C.*, 552 U.S. 1183 (2008); *U.S. ex rel. Joshi v. St. Luke's Hosp., Inc.*, 549 U.S. 881 (2006); *U.S. ex rel. Corsello v. Lincare, Inc.*, 549 U.S. 810 (2006); *Sanderson v. HCA-The Health Care Co.*, 549 U.S. 889 (2006); *U.S.*

This case similarly is not worthy of granting certiorari because it is completely fact dependent. The First Circuit applied the well-established standards of Rule 9(b) to the particular facts of this case. Pet.14-24. That Petitioners disagree with its ultimate decision is not a valid reason to grant the Petition. U.S. Sup. Ct. R. 10 (petitions "rarely granted when the asserted error consists of erroneous factual findings or the misapplication of a properly stated rule of law"); *Magnum Imp. Co. v. Coty*, 262 U.S. 159, 163 (1923); *cf. Izumi*, 510 U.S. at 34.

Regardless, the First Circuit's decision was correct, as the Complaint is sufficiently particular to satisfy the objectives of Rule 9(b). It provides extensive details with respect to Petitioners' complex, long-term fraudulent scheme to cause third parties to submit false claims to the government—the "circumstances" of the fraud. *Supra*, COC.B, C.1. Specifically, Relators alleged with particularity the who (Petitioners), what (selling Nonconforming Pinnacle MoMs to unsuspecting medical providers, causing them to submit false claims to the government for reimbursement), how (failing to manufacture a significant percentage of their Pinnacle MoMs to specifications, withholding such information from medical providers, and misrepresenting to those providers that the devices they were purchasing were safe and effective, cleared by the FDA, and manufactured within required specifications), where (to medical providers across the United States, including New York), and when (2005 to at least 2010). *Id*.

---

ex rel. Goldstein v. Fabricare Draperies, Inc., 542 U.S. 904 (2004); *U.S. ex rel. Harris v. George Washington Primary Care Associates*, 530 U.S. 1230 (2000).

Relators also pled facts supporting a reliably strong inference that false claims were actually submitted to the government. First, the Complaint provides details regarding a specific, representative false claim involving the Nonconforming Pinnacle MoM submitted to the government in 2007. *Supra*, COC.C.1. It also sets forth detailed factual and statistical evidence that leads to a strong inference that other false claims involving Nonconforming Pinnacle MoMs were submitted to the government for reimbursement, as the First Circuit concluded. *Supra*, COC.C.1, C.3. Accepting these allegations as true, as is required,[17] it is statistically certain that many claims for Nonconforming Pinnacle MoMs were submitted to, and reimbursed by, the government. *Supra*, COC.C.1, C.3.[18] And unlike in some other cases, there is no reason to think healthcare providers would have discovered the latent manufacturing defects in the Nonconforming Pinnacle MoMs and declined to submit claims for reimbursement for those devices. Pet.22, 42.[19]

---

[17] *Prather*, 838 F.3d at 761; *U.S. ex rel. Customs Fraud Investigations, LLC. v. Victaulic Co.*, 839 F.3d 242, 256–57 (3d Cir. 2016) (noting any skepticism the court may have regarding the methodology underlying the relator's statistical allegations "is misplaced at the Rule 12(b)(6) stage").

[18] *Lusby*, 570 F.3d at 854-55 ("[E]ven a requirement of proof beyond a reasonable doubt need not exclude all *possibility* of innocence; nor need a pleading exclude all possibility of honesty in order to give the particulars of fraud. . . . No complaint needs to rule out all possible defenses.").

[19] *Compare, e.g., D'Agostino v. ev3, Inc.*, 845 F.3d 1, 12 (1st Cir. 2016) (dismissing claims that defendant caused third parties to submit reimbursement claims for its defectively-manufactured medical device: "Importantly, there is no claim here of a latent manufacturing defect that manifested itself only after the

Relators are neither the typical corporate "insiders" nor the typical corporate "outsiders." Although they were never direct employees of Petitioners, Relators worked closely with Petitioners with respect to the Pinnacle MoM for over a decade. *Supra*, COC.B. Through that working relationship, Relators obtained direct, personal knowledge of Petitioners' fraudulent conduct. *Id*. Thus, they are not "parasitic" relators "who learn[ed] of the fraud through public channels and seek remuneration although they contributed nothing to the exposure of the fraud." *Graham County Soil & Water Conservation Dist. v. U.S. ex rel. Wilson*, 559 U.S. 280, 296 n.16 (2010).[20] Rather, they are exactly the type of whistleblowers the FCA was meant

---

surgery was completed and the claim for reimbursement submitted. To the contrary, the allegation is that the defect caused the device to fail as the surgeons tried to use it, and thus before any claim for reimbursement might have been submitted."); *U.S. ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 732–33 (1st Cir. 2007) (dismissing claims that defendants' off-label marketing of a drug caused the submission of false claims to the government: "[T]he complaint contained no factual or statistical evidence to strengthen the inference of fraud beyond possibility. It may well be that doctors who prescribed Genotropin for off-label uses as a result of Pharmacia's illegal marketing of the drug withstood the temptation and did not seek federal reimbursement, and neither did their patients. It may be that physicians prescribed Genotropin for off-label uses only where the patients paid for it themselves or when the patients' private insurers paid for it.").

[20] Nor are they asserting "repurposed" product-liability claims. Pet.i. The product-liability cases in the Pinnacle MDL are based on the harm the defective Pinnacle MoM caused the patients implanted with the device. In this case, Relators alleged Petitioners defrauded the government by causing medical providers to submit false claims for reimbursement for Nonconforming Pinnacle MoMs. *Supra*, COC.C.1. The fact that Relators are now represented by the lead plaintiff's counsel in the Pinnacle MDL has no bearing on the distinct nature of the two claims.

to encourage: "individuals with valuable knowledge of fraud unknown to the government." *U.S. ex rel. Winkelman v. CVS Caremark Corp.*, 827 F.3d 201, 210 (1st Cir. 2016); *see also Joshi*, 441 F.3d at 561. Any additional information regarding the details of specific false claims, much of which is protected by HIPAA and other privacy laws, is peculiarly within the knowledge of Petitioners and the third-party healthcare providers who unwittingly submitted claims for reimbursement for the Nonconforming Pinnacle MoMs to the government on behalf of their patients. Resp-App.26-27, 31; *Foglia*, 754 F.3d at 158.

Petitioners argue that courts in five circuits (Second, Fourth, Sixth, Eighth, and Eleventh) would have dismissed Relators' complaint. Pet.12.[21] They have no basis for this statement. To begin with, Relators pled a representative claim, which is precisely what Petitioners claim these circuits require. *Supra*, COC.C.1, C.3. Moreover, each of these circuits has held there are circumstances in which a complaint can satisfy Rule 9(b) without pleading an actual claim. *Supra*, § I. Every case necessarily differs to some extent with respect to its particular facts and circumstances. This case is no exception. But Petitioners cite no case involving facts comparable to the present case. Nor do they suggest that the particular factual circumstances of this case recur frequently. Indeed, Petitioners cite only three cases from these purportedly "stringent" circuits that even involved indirect

[21] Petitioners also insinuate Relators were forum-shopping by filing their case in Massachusetts rather than New Jersey or Indiana, where Petitioners are located. Pet.19-21, 33. Yet they ignore the fact that both the Third and Seventh Circuits apply the same "flexible approach to Rule 9(b)" as the First Circuit. Pet.19-21.

FCA claims, and each is factually distinguishable. *Thayer*, 765 F.3d at 919-20 (allegations that defendant instructed "patients who experienced abortion-related complications to give false information to medical professionals at other hospitals, causing [them] to unknowingly file claims for services performed in connection with abortions[,]" failed to satisfy Rule 9(b) because relator failed to provide any "factual basis for her knowledge" that false claims were submitted by these other hospitals); *Nathan*, 707 F.3d at 454, 457-61 (allegations that defendant's off-label promotion of its drug caused false claims to be presented to the government failed to satisfy Rule 9(b) because the reasonable inference from such allegations was merely that defendant's actions "*could* have led, but *need not necessarily* have led, to the submission of false claims[,]" as "'[i]t may be that physicians prescribed [the drug] for off-label uses only where the patients paid for it themselves or when the patients' private insurers paid for it[,]'" and, unlike in *Grubbs*, relator's claim did not "involve an integrated scheme in which presentment of a claim for payment was a necessary result") (citation omitted); *Hopper v. Solvay Pharm., Inc.*, 588 F.3d 1318, 1322, 1326-29 (11th Cir. 2009) (allegations that defendant's off-label promotion of its drug caused false claims to be presented to the government in violation of 31 U.S.C. § 3729(a)(1) failed to satisfy Rule 9(b) because complaint did "little more than hazard a guess that unknown third parties submitted false claims"; court did not decide whether a false claim in violation of 31 U.S.C. § 3729(a)(2) was sufficiently alleged because that count failed for other reasons, but did note its earlier precedent did "not necessarily foreclose the possibility that, for [such] claims . . . , general allegations of improper government payments to third parties, supported by factual or

statistical evidence to strengthen the inference of fraud, like those in the relators' Complaint, could satisfy the particularity requirements of Rule 9(b)").[22]

CONCLUSION

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

Respectfully submitted,

KENNETH W. STARR
5404 Point Wood Circle
Waco, TX 76710

ARTHUR R. MILLER
NEW YORK UNIVERSITY
40 Washington Square
New York, NY 10012

RICHARD J. ARSENAULT
NEBLETT, BEARD & ARSENAULT
2220 Bonaventure Court
P.O. Box 1190
Alexandria, LA 71301

JAYNE CONROY
SIMMONS HANLY CONROY
112 Madison Avenue
New York, NY 10016

W. MARK LANIER
Counsel of Record
KEVIN P. PARKER
M. MICHELLE CARRERAS
THE LANIER LAW FIRM
6180 FM 1960 Rd W
Houston, TX 77069-3804
(713) 659-5200
Mark.Lanier@
LanierLawFirm.com

Counsel for Respondents

March 9, 2018

[22] *Compare* Pet-App.22-23.

APPENDIX

APPENDIX

THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

[Filed 05/19/15]

Civil No. 12-10896-FDS

THE UNITED STATES OF AMERICA; AND THE STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MICHIGAN, MINNESOTA, MISSOURI, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, WASHINGTON, AND WISCONSIN; THE COMMONWEALTHS OF MASSACHUSETTS AND VIRGINIA; THE DISTRICT OF COLUMBIA; AND THE CITIES OF CHICAGO AND NEW YORK, *EX REL.* DR. ANTONI NARGOL & DR. DAVID LANGTON,

Plaintiffs,

vs.

DEPUY ORTHOPAEDICS, INC.; DEPUY, INC.; AND JOHNSON & JOHNSON SERVICES, INC.,

Defendants.

FILED UNDER SEAL PURSUANT
TO 31 U.S.C. § 3730(b)(2)

SECOND AMENDED COMPLAINT FOR VIOLATIONS OF THE FEDERAL FALSE CLAIMS ACT [31 U.S.C. § 3729 *et seq*.]; CALIFORNIA FALSE CLAIMS ACT [Cal. Govt. Code § 12650 *et seq*.]; COLORADO MEDICAID FALSE CLAIMS ACT [Colo. Rev. Stat. § 25.5-4- 305(1)(a)–(b)]; CONNECTICUT FALSE CLAIMS STATUTE [Conn. Gen. Stat. § 17b–301b(a)(1)–(2)]; DELAWARE FALSE CLAIMS AND FALSE REPORTING ACT [6 Del. C. § 1201]; FLORIDA FALSE CLAIMS ACT [Fla. Stat. Ann. § 68.081 *et seq*.]; GEORGIA FALSE MEDICAID CLAIMS ACT [Ga. Code Ann. § 49-4-168 *et seq*.]; HAWAII FALSE CLAIMS ACT [Haw. Rev. Stat. § 661-21 *et seq*.]; IOWA FALSE CLAIMS ACT [Iowa Code § 685.2(1)(a)–(b)]; ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT [740 Ill. Comp. Stat. § 175 *et seq*.]; INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT [Ind. Code Ann. § 5-11-5.5-1 *et seq*.]; LOUISIANA MEDICAL ASSISTANCE PROGRAM INTEGRITY LAW [La. Rev. Stat. § 46:437.1 *et seq*.]; MARYLAND FALSE HEALTH CLAIMS ACT [Md. Health-General Code Ann. § 2-602(a)(a)–(2)]; MASSACHUSETTS FALSE CLAIMS LAW [Mass Gen Laws ch.12 § 5 *et seq*.]; MICHIGAN MEDICAID FALSE CLAIMS ACT [Mich. Comp. Laws. § 400.601 *et seq*.]; MINNESOTA FALSE

---

* * *

indigent, military veterans and their families, and other beneficiaries of Government health insurance. Because of DePuy's fraudulent practices and false representations, the Government purchased defective medical devices which, lacking the safety and efficacy

of the devices it had bargained for, were unfit for their intended use in these vulnerable patients.

6. The total hip replacement medical devices at issue in this case generally consist of a metal cup corresponding to the socket of a human hip joint, and a metal head corresponding to the ball. Thus, they are commonly referred to as "metal-on-metal" or "MoM" total hip replacement devices. Relators Antoni Nargol and David Langton—world-renowned experts on hip-implant products—allege that DePuy submitted false claims for payment for one of DePuy's MoM devices: the Pinnacle Acetabular Hip System ("Pinnacle").

7. DePuy falsely represented to the United States Food and Drug Administration ("FDA"), surgeons, and the public that Pinnacle devices were safe and effective, failed at acceptable rates, were manufactured within their required specifications, and functioned as designed. In reliance on DePuy's false representations, the Government directly purchased or reimbursed hundreds of thousands of Pinnacle products. But unbeknownst to the Government, it subsidized a lie that placed Government healthcare recipients in grave danger.

8. DePuy's Pinnacle products were approved for sale in the United States by the FDA in 2000. The products were sold on the market between 2000 and 2013. But Relators discovered serious problems with DePuy's Pinnacle products beginning in 2009. In 2010, Relators began to voice their concerns to DePuy that the Pinnacle's elevated failure rates were related to the integrity of the device. Relators conclusively confirmed the existence of two of the primary defects that were causing the Pinnacle's escalating failure rate in 2010, and then confirmed a third in 2014. DePuy ignored and dismissed Relators' warnings, however,

and continued to sell the Pinnacle throughout the United States.

9. DePuy marketed the Pinnacle hip replacement to medical practitioners—including Government doctors and hospitals—as virtually invulnerable to failure; DePuy's marketing materials consistently described Pinnacle as "99.9 percent" effective. Yet Relators provided DePuy with substantial evidence belying these representations. In fact, the Pinnacle suffered abnormally high failure rates far exceeding established industry standards. While most non-defective hip implants remain functional twenty years after implantation, Pinnacle implants failed at far greater rates and far sooner after implantation than other products.

10. DePuy's internal studies and data revealed the high failure rate of its products, but the Company deliberately concealed this information from the public, the medical community, and the Government. The "99.9 percent" success figure touted by Pinnacle had no basis in any testing data and was entirely fabricated.

11. DePuy misrepresented to the FDA and the public by no later than June 2012 that the Pinnacle's failure rate at five years after implantation was 4 to 4.5%, even after its own internal analysis (completed by April 2012) showed a five-year failure rate of greater than 14%.

12. Furthermore, no later than 2010, DePuy possessed evidence indicating both that it was consistently manufacturing Pinnacle components outside of their approved specifications, and that the Pinnacle was defective in its design. The most persistent and compelling reports of these defects came from Relators

Langton and Nargol, who made their reports directly to DePuy's executive personnel.

13. DePuy privately acknowledged the serious implications of Relators' findings to the functioning of DePuy's MoM products. In one June 2010 email, a top DePuy executive admitted to Dr. Langton that, were DePuy to conclude from Relators' research that its MoM parts "were out of specification," the Company would "need to notify patients if we have made a serious manufacturing error."

14. As Relators' independent research confirmed in 2010, the Pinnacle products that DePuy sold—and the Government purchased—did suffer from serious manufacturing errors, and therefore differed greatly from those that DePuy had advertised and submitted to the FDA for approval. Indeed, these differences were so material that the products that the Government received were effectively not the same products that it had intended to purchase.

15. Relators had also by 2010 confirmed and reported to DePuy that a design defect in DePuy's Pinnacle device was increasing both the incidence and the degree of its manufacturing defects. They urged the Company to advise the public of the device failures caused by these interrelated defects. While some of these defects were shared by DePuy's earlier discredited ASR device, collectively they were unique to the Pinnacle device.

16. The importance of Relators' findings has also been corroborated by at least two statements made by FDA, both now available to the public. In 2005, five years after the FDA had approved the product for sale in the United States, FDA acknowledged that DePuy had prematurely brought the Pinnacle to the market

without adequately conducting clinical trials to test whether one of the device's most important physical dimensions could be manufactured safely and effectively.

17. Additionally, an FDA Inspection in 2011 questioned whether DePuy may have been improperly producing Pinnacle components below these very same untested engineering dimensions. In its Inspection Report, the FDA concluded that DePuy's manufacturing process required review. In response, DePuy denied that any such review was necessary.

18. As further detailed herein, DePuy had thus admitted in 2005 that manufacturing

* * *

Massachusetts and the Attorneys General of Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Washington, and Wisconsin, as well as the District of Columbia, City of Chicago, and City of New York, in compliance with the False Claims Act, 31 U.S.C. § 3730(b)(2), and relevant State, District, and local statutes.

II. INTRODUCTION

23. Relators Dr. Antoni Nargol and Dr. David Langton are two of the most prominent experts in MoM surgical technique and engineering technology, respectively. Together, Relators Dr. Nargol and Dr. Langton have been published eighteen times in peer-reviewed journals on MoM hips. Relators have given

several dozen national and international presentations on topics including, without limitation, the Pinnacle and other MoM hips, the dangers of metal ions in relation to MoM hips, the mechanisms by which Pinnacle and other MoM hips were prone to failure, and the findings from implant retrievals, which they themselves performed in many cases. The orthopaedic industry worldwide has adopted the diagnostic term coined by the Relators, "Adverse Response to Metal Debris ("ARMD"), used to describe the detrimental effects of metal ions on MoM patients.

24. Relators reported their concerns about the high failure rates of the Pinnacle with great urgency throughout the relevant period. Beginning in 2008, Relators originated and then led a growing international consensus of critics of DePuy's ASR device, another MoM device system similar to the Pinnacle. They began to likewise criticize the Pinnacle in 2009. Relators learned of the defects in these devices primarily through their own work with these and other similar MoM implants, as well as through frequent communication with many of DePuy's principals and key decision-makers.

25. Through a long series of formal and informal meetings and presentations between 2009 and 2013, Relators presented evidence directly to DePuy's highest level executives that the Pinnacle was experiencing high failure rates, and, beginning in 2010, that these failures were caused by device abnormalities. During this period, Relators also described high Pinnacle failure rates and device abnormalities at prominent international orthopaedic meetings, including gatherings of the American Association of Hip and Knee Surgeons and the American Academy of Orthopaedic Surgeons.

26. Relator Nargol was one of the first to show that DePuy was improperly blaming surgeons, including himself, for the Pinnacle's failure rates. DePuy concocted a false relationship between device failure and surgical technique—specifically, the angle of the hip's implantation. Dr. Nargol waged a campaign, directed principally at DePuy itself, to scientifically refute DePuy's representations in this regard. Dr. Nargol ultimately found that, because of defects in the manufacture and design of the Pinnacle, there was no possible surgical angle (or "angle of inclination") that could have prevented device failure.

27. The Relators were the first individuals outside of DePuy to discover the high failure rates of the Pinnacle, and they determined the causes of failure in 2010, three and one-half years prior to DePuy's removal of the product from the market. By then, it had become clear to Relators that DePuy was withholding critical information that could have provided surgeons and regulatory authorities worldwide—including the FDA—with the means to take corrective action to prevent further device failures and patient injuries.

28. Beginning in early 2010, Relators' concerns focused increasingly on manifest failures in DePuy's manufacturing process and a defective design in the Pinnacle that exacerbated those failures. In 2014, Relators confirmed a second critical manufacturing defect in the Pinnacle. Relators were the first to discover and report all three of these defects.

A. Relators Warned of Metal Ion Exposure in MoM Patients By 2007

29. As early as 2007, DePuy was made aware that its MoM hip replacement devices were apt to fail—in

a manner highly detrimental to patient health and safety. Relators' disclosures to DePuy during this period emphasized that MoM failures carried grave consequences for patients. In particular, MoM devices undergo surface wear which generates metal debris. When this process occurs, debris and metal ions are released into the soft tissue surrounding the hip joint. As a result, patients experience painful and debilitating necrosis (tissue death) and metallosis (metallic staining of tissues next to the hip). Metallosis, in turn, can cause osteolysis (resorption or degradation of the bone).

30. In his surgical practice, Relator Nargol encountered numerous examples of patients whose DePuy MoM devices had caused metallosis in their tissue. Among these surgeries are those depicted below:

* * *

34. Dr. Langton used his research, data, and clinical studies in an effort to help DePuy isolate the root cause of the device failures. DePuy nevertheless continued to falsely blame the failings of its MoM devices on sub-optimal patient selection and surgical technique.

B. Relators Warned DePuy of the Pinnacle's Abnormally High Failure Rates and Device Defects Beginning in 2009

35. By 2009, Dr. Nargol's and Dr. Langton's relationship with DePuy began to deteriorate as they developed evidence of the astronomical failure rates of DePuy's MoM implants and demanded that the ASR device be removed from the international marketplace. Relators themselves discontinued use of the Pinnacle at North Tees in October 2009. Despite hav-

ing relied upon Relators' expertise in the past, DePuy claimed that Relators' findings were without basis.

36. In particular, DePuy claimed that the failures of its MoM devices were caused by surgical error—improper positioning of the cup or angle of inclination. Relator Nargol reported to DePuy that its Pinnacle devices were experiencing failures even at perfect cup placement. But, despite their having previously relied upon Dr. Nargol to demonstrate his MoM surgical technique to other surgeons internationally, DePuy responded simply by telling Dr. Nargol that he was an outlier and that he must be implanting the device incorrectly.[3] The Company's assertions were baseless; DePuy fabricated a phony defense to avert responsibility for the defects in its products.

* * *

London Hip Meeting Presentation"). DePuy was in attendance. Relators concluded their presentation with the statement that "Pinnacle MoM and Pinnacle CoM systems are failing at a higher than expected rate at our centre."

---

[3] DePuy then suddenly changed the Pinnacle's surgical instruction manual, which had recommended that surgeons implant the device at a 45-degree angle of inclination. Now, DePuy warned that an angle of less than 45 degrees could increase the risk of device failure. After DePuy's edit to their manual, Relator Nargol compared hips implanted in line with this new instruction and those implanted in a position outside of the instruction. He found that following DePuy's instructions for implanting the Pinnacle actually led to a higher failure rate, making it clear that the Pinnacle's failures did not result from surgeons straying from instructions. Many surgeons around the world, including Relator Nargol, reported to DePuy that Pinnacle devices were failing despite following DePuy's instructions exactly.

42. DePuy blamed those failures on surgical error in their statements to regulators and the public, but DePuy knew better. As alleged herein, beginning in 2010, Relators repeatedly placed DePuy on notice of two critical device defects Relators had confirmed were contributing to failures in both the ASR and the Pinnacle. Relators referred to these defects as the "diametrical clearance" and "taper trunnion" defects. Relators disclosed both of these related defects, and rigorous scientific evidence of their causes, to DePuy long before DePuy ceased production of the Pinnacle line of implants in 2013. But even in the face of this evidence, DePuy consistently disregarded Relators' warnings.

43. Additionally, by as early as 2010, DePuy knew or recklessly disregarded the existence of an additional manufacturing defect Relators refer to as the "surface roughness" defect. This defect, unique to the Pinnacle, was discovered by Relators in 2014. To Relators' knowledge, they were the first to confirm the existence of the surface roughness defect in the Pinnacle outside of DePuy.

44. Despite extensive information and warnings from Relators, however, DePuy neglected to address the failure rates or defects evident in its Pinnacle product. DePuy ignored and even tried to blame Relators for the Pinnacle's failures, all in an effort to maintain sales of the device.

C. Relators Warned the FDA of the Pinnacle Device's Manufacturing Defects and High Failure Rates in 2011

45. Relator Nargol reported concerns about DePuy's medical devices to the FDA as early as 2007. In 2007, Relator Nargol determined that his ASR Resurfacing

patients were suffering femoral neck fractures after implantation at rates greater than applicable standards in the industry permitted. Relator Nargol reported these findings to the FDA after the agency had appointed him as a Chief Investigator studying DePuy's ASR Resurfacing product in connection with FDA's Investigational Device Exemption ("IDE") regulation.[4]

46. Relator Langton has also served as a consultant to the FDA and has presented his findings regarding the failure rates and dimensions of MoM products sold in the United States, including the Pinnacle. Most recently, on September 23, 2014, Dr. Langton was retained by the FDA to provide to provide his assessment of the causes of irregularities found in explanted total hip replacement devices.

47. In January 2011, the MHRA convened a meeting with a group of prominent members of the UK orthopaedic community. The FDA and Canadian MHRA participated in the meeting by teleconference. During this meeting, the Relators disclosed their findings regarding the rising failure rates of both the ASR and the Pinnacle. Relators also conveyed the evidence they had developed up to and including that date that DePuy's MoM implants suffered from both design

[4] During the IDE Study, Dr. Nargol performed a revision surgery on one of his patients in which an ASR head component had collapsed, resulting in failure of the device and injury to the patient. Notably, when Dr. Nargol asked that DePuy inform the FDA that the device had failed due in part to a defect in the implant itself, a DePuy representative asked Dr. Nargol to make a written statement confirming that he had not discovered any problems with the device. Dr. Nargol refused to go along with this misrepresentation.

and manufacturing defects (the "January 2011 Disclosure").

48. Following the meeting, Susan Ludgate from the MHRA asked Relator Nargol if his presentation could be shared with the FDA. Several months later, Relator Nargol met with an FDA representative at the American Academy of Orthopaedic Surgeons. The representative thanked Relator Nargol for the slides that he had provided.

D. DePuy Attempted to Avoid Poor Sales Results by Blaming Device Failure on Surgical Technique and Patient Selection

49. Instead of acknowledging and attempting to solve the manifest problems with its products, DePuy put together a four-pronged strategy to evade responsibility and maintain sales. First, DePuy baselessly attributed Pinnacle's failures to surgeons' implantation techniques. This is the same strategy that DePuy utilized when it blamed Relator Nargol for his Pinnacle patients' poor results.

50. Second, DePuy blamed "patient selection," claiming that the issues with Pinnacle arose from surgeons' choice of patients.

51. Third, DePuy asserted that, despite certain failures, its "global results" were good. In reality, this defense was a way to scour the world and cherry-pick positive outcomes to tout.

52. Finally, DePuy determined to develop a "soft landing strategy" that would avoid a major product recall. Unfortunately, DePuy was never able to face reality and reckon with the problems associated with its devices.

E. DePuy's MoM Devices' Defects and High Failure Rates Ended Sales of Both the Pinnacle and the ASR.

53. After years of insisting that its products were safe and ignoring numerous pleas by Relators about the defective devices, the dam finally broke. Despite DePuy's continued efforts at concealment, the facts eventually came to light and the Company was finally forced to stop selling its harmful products.

54. DePuy's ASR and Pinnacle products fell so far below acceptable standards of care so as to render them effectively worthless to patients. The metallic debris released from the Pinnacle and ASR systems inflicted substantial damage to muscles, tendons, and other soft tissue. This damage consistently resulted in early device failure, causing debilitating pain and immobility and necessitating revision surgery.

55. Within three years of the recall of the ASR product from the market in 2010, DePuy found itself once again forced to publicly admit failure in regard to the Pinnacle.[5] In May 2013, DePuy announced that it

---

[5] DePuy had previously been forced to acknowledge the alarming failure rates of the ASR device on March 6, 2010 due to data from Australia and England demonstrating the high failure rates. DePuy sent a letter to healthcare providers noting the high failure rate and signaling a recall of the product in the United States. On August 24, 2010, DePuy announced a world-wide "voluntary recall" due to the high number of patients who required a revision surgery after their ASR implant. The FDA Regulatory Procedures Manual notes that the "FDA may conduct informal discussions with a manufacturer or distributor that includes voluntary recall as an option." DePuy's "voluntary" recall notice for the ASR represented that the recall was precipitated by "new, then-unpublished data." DePuy did not publicly disclose in that notice any of the evidence of the underlying

would cease sales of its MoM Pinnacle products as of August 2013. Even at this point, with full knowledge that Pinnacle products were unsafe, DePuy decided to leave the device on the market for four more months, to the harm of even more patients.

56. As the evidence of device failures emerged, DePuy also found itself embroiled in product liability cases starting in 2010. In a trial in March 2013, a California state court jury awarded $8.3 million dollars to Loren Kransky, a Vietnam veteran and retired prison guard who had been implanted with an ASR device. The panel ruled that DePuy was negligent and that the ASR device was defective. Mr. Kransky was awarded $338,000 for his medical expenses alone. DePuy also settled several cases for undisclosed amounts.

57. On November 19, 2013, it was announced that DePuy would pay over $2.5 billion dollars to resolve 8,000 lawsuits to ASR recipients who required revision surgeries. DePuy was also forced to set aside funds to reimburse Medicare and other insurers. In total, DePuy faces 10,000 suits filed in federal and state courts in California, Ohio, and New Jersey. The enormous

* * *

62. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) because DePuy can be found in and transacts—or has transacted—significant business in the District of Massachusetts.

---

defects that caused the device failures such as that Relators had provided DePuy.

IV. PARTIES

63. Relator Dr. Antoni Nargol is an orthopedic surgeon residing in North Tees, UK. Dr. Nargol studied medicine at Newcastle University, performed his Fellowship at the Royal College of Surgeons at Edinburgh, and completed a six-year training program in orthopaedics. Dr. Nargol specializes in MoM hips, particularly the screening, surveillance, investigation, and revision of MoM hips.

64. The University Hospital of North Tees ("North Tees"), where Dr. Nargol practices as a consultant orthopaedic surgeon and the clinical lead for lower limb surgery, was one of the earliest centers to use the ASR, beginning in April 2004. In 2004, the North Tees hospital was also selected as a site for the aforementioned FDA Investigational Device Exemption ("IDE") study of DePuy's ASR Resurfacing product,[6] for which Dr. Nargol was the Chief Investigator.

65. Dr. Nargol is one of the highest volume revision THR surgeons in the United Kingdom and was the highest volume revision surgeon with respect to the ASR and Pinnacle devices. To date, Dr. Nargol has performed over 1,200 MoM hip implant operations and over 500 revisions at North Tees, many of which involved the ASR and Pinnacle Hip systems. Dr. Nargol has implanted approximately 500 ASR and ASR Hip Resurfacing systems.

66. Dr. Nargol was selected as a key opinion leader (KOL) for DePuy for both the ASR and the Pinnacle

---

[6] The "ASR Hip Resurfacing System" is another hip implant device manufactured by DePuy. Hip resurfacing, an alternative procedure to total hip replacement, removes less bone than an arthroplasty because the metal cap is placed on the patient's natural femur bone instead of on a metal stem.

total hip replacement systems. In 2003 he became one of the earliest U.K. adopters of the Pinnacle, and was invited by DePuy to be on its Pinnacle user group team. Dr. Nargol was invited by DePuy to travel around India to demonstrate surgical methods to Indian surgeons during live Pinnacle surgeries.

67. Dr. Nargol has been invited to speak at numerous meetings on MoM hips, with groups such as the Hospital for Special Surgery in New York City (2010), the British Hip Society (2011 and 2012), and the Dutch Hip Society (2011). Dr. Nargol's research has been published in prominent orthopedic journals, including *Bone and Joint Research, American Clinics of North America,* and the *Journal of Bone and Joint Surgery*.

68. Dr. Nargol served as a testifying expert for plaintiff in *Strum v. DePuy Orthopaedics, Inc. and Premier Orthopaedic Sales, Inc.,* No. 2011 L 009352 2404 (Cir. Ct. of Cook Cnty., Ill.) (the "Strum Litigation"). Dr. Nargol also provided expert assistance to the Plaintiff Executive Committee in *Kransky, et al. v. DePuy, Inc., et al*., No. BC 456086 (Superior Ct. of the State of Cal.) (the "Kransky Litigation"), in which the plaintiffs' allegations focused on perceived design defects in the ASR. Finally, Dr. Nargol served as a fact witness in *Herlihy-Paoli v. DePuy Orthopaedics, Inc., et al.*, No. 3:11-CV-04975-K (N.D. Texas) (the "Herlihy-Paoli Litigation").

69. Relator Dr. David Langton is a surgeon residing in Gateshead, UK, with several years of experience in orthopaedic surgery. Dr. Langton received a PhD at Newcastle University in metal hip arthroplasty. Since August 2007, he has been a researcher at the University Hospital of North Tees and Newcastle University, where he focuses on functional, tribological (the science of interacting moving surfaces), and

biochemical results of MoM hip arthroplasty. He has written extensively about the deficiencies of MoM hips and the dangerous implications for patients who have been exposed to MoM hip arthroplasties.

70. The North Tees Explant Center, at which Dr. Langton performs much of his research, is one of the largest facilities assessing failed implants in the world, hundreds of which are failed Pinnacle MoM explants. In all, Relator Langton has analyzed over 250 Pinnacle device components, both explanted and unused ("sterile") components, including over 100 mated Pinnacle implants. Dr. Langton maintains a database containing, among other data, engineering measurements of all of the explants collected at the Center (the "Retrieval Database"). Dr. Langton also leads PXD ("Progression from Explanted Devices"), an independent research company that offers analyses of failed hip explants at no cost to patients and or surgeons. PXD is funded in part by an FDA grant.

71. Dr. Langton has received numerous awards and recognitions related to his research, including the McKee Prize for Best Research at the British Hip Society in 2009 for his presentation with Relator Dr. Nargol on the design flaws of the ASR, as well as an award from the British Orthopaedic Association in 2009.

72. Dr. Langton has served as a consultant to FDA to present his findings regarding the failure rates and dimensions of MoM products sold in the United States, including the Pinnacle. Most recently, on September 23, 2014, Dr. Langton was retained by the FDA to provide to provide his assessment of the causes of irregularities found in explanted total hip replacement devices. Dr. Langton served as an expert witness for the plaintiffs in the Strum Litigation, among other

litigations involving the ASR device. He served as a fact witness in the *Herlihy-Paoli* Litigation.

73. DePuy Orthopaedics, Inc. ("DePuy Orthopaedics") has its principal place of business in Warsaw, Indiana. DePuy Orthopaedics is in the business of designing, licensing,

* * *

126. DePuy violated TRICARE provisions by inducing surgeons, hospitals, and other medical providers to present claims which included false certifications stating that Pinnacle hip procedures were medically necessary and reasonable.

VI. FDA REGULATIONS GOVERNING MEDICAL DEVICES

127. The FDA is tasked with protecting and promoting public health through the regulation of medical devices. CMS defines a medical device as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals." 21 U.S.C. § 321(h).

A. "High Risk" or Class III Medical Devices

128. Following the passage of the Medical Device Amendments of 1976 to the Food, Drug, and Cosmetics Act of 1938 ("FD&C Act" or "Medical Device Amendments"), the FDA established three risk-based classifications for medical devices. Classes I, II, and III represent low, moderate, and high-risk categories, respectively, based on the intended use of the device. The level of regulatory review necessary to provide

assurance of the device's "safety and effectiveness" determines the class of a particular device. 21 U.S.C. §§ 360c(a)(1)(A)(i), 360c(a)(1)(B), 360c(a)(1)(C)(i).

129. Class III devices are those that have uses purported or represented to support or sustain human life, are of substantial importance in preventing impairment of human health, or present a potential unreasonable risk of illness or injury. 21 U.S.C. § 360c(a)(1)(C). Class III devices are generally subject to a premarket approval process ("PMA"), which is the most stringent level of device regulation imposed by the FDA. PMA usually requires the manufacturer to conduct costly clinical studies to demonstrate the safety and effectiveness of the device. *See* 21 U.S.C. § 360e.

130. Metal-on-Metal ("MoM") Total Hip Replacement systems, like the Pinnacle and ASR, qualify as Class III medical devices under the FD&C Act.

B. FDA Approval of Class III Medical Devices Through Means of 510(k) Substantial Equivalence

131. Under FDA regulations, there are two avenues by which a manufacturer can seek approval of a new medical device for marketing in the United States: the PMA process and the "510(k)" clearance process. The more onerous PMA process requires, among other things, a full report of all information known to the applicant regarding investigations into the device's safety and efficacy. This report is referred to as the pre-market approval application. *See* 21 U.S.C. § 360e(c)(1)(A).

132. In contrast, under the 510(k) process, the applicant is required to demonstrate only that the device is substantially equivalent in terms of safety

and effectiveness to an existing FDA-approved device. 21 C.F.R. § 807.92(a)(3). Class III devices, which usually require premarket approval, may receive a 510(k) based on a substantially equivalent prior device. If the FDA determines under section 510(k) that a new device is substantially equivalent to a predicate device, the new device is placed into the same class and subject to the same requirements as its predicate device.

133. A device is substantially equivalent if, when comparing it to the predicate, it has both the same intended use and the same technological characteristics as the predicate. A device with different technological characteristics can be considered substantially equivalent only if the information submitted to FDA does not raise new questions of safety and effectiveness and demonstrates that the device is at least as safe and effective as the legally marketed predicate device.

134. Under the 510(k) certification process, a manufacturer must submit to the FDA a premarket notification submission, commonly known as a 510(k) notice, before a device may be introduced into interstate commerce. 21 U.S.C. § 360(k); 21 C.F.R. § 807.81 (2010). The 510(k) notice must include, among other things, proposed labeling sufficient to describe the device, its intended use, and the directions for its use; a statement indicating whether the device is similar to or different from other products of comparable type in commercial distribution; and a statement that the submitter believes, to the best of the submitter's knowledge, that all information in the 510(k) notice is truthful and accurate and that no material fact has been omitted. 21 C.F.R. § 807.87(e)-(h), (k).

135. Along with the 510(k) notice, a manufacturer must submit a "510(k) summary," which "shall be in sufficient detail to provide an understanding of the basis for a determination of substantial equivalence [to previously cleared devices]." 21 C.F.R. § 807.92(a). Among the information that must be contained in a 510(k) summary is "[a] description of the device . . . including . . . the significant physical and performance characteristics of the device, such as device design, material used, and physical properties." 21 C.F.R. § 807.92(a)(4). The 510(k) summary must also include "[a] statement of the intended use of the device . . . including a general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate." 21 C.F.R. § 807.92(a)(5).

C. Quality System (QS) Regulation

136. Manufacturers of medical devices, regardless of class, are subject to Quality System (QS) regulations. 21 C.F.R. § 820. This set of regulations covers, among other things, quality management and organization, device design, buildings, equipment, purchase and handling of components, production and process controls, packaging and labeling control, device evaluation, distribution, installation, complaint handling, servicing, and records. Regulations require that domestic or foreign manufacturers have a quality system in place for the design and production of medical devices intended for commercial distribution in the United States.

1. Current Good Manufacturing Practices (cGMP): *What Are the Minimum Manufacturing Requirements Necessary in Order to Assure a Given Device's Safety and Efficacy?*

137. The FDA's current Good Manufacturing Practices ("cGMP") contain the minimum requirements that device manufacturers must meet to "assure that the device will be safe and effective," among other things. 21 U.S.C. § 360j(f). A device that has not been manufactured in accordance to cGMP standards is considered "adulterated," and such adulterated products may not be sold to the United States Government. 21 U.S.C. § 351(h). Process Controls, such as Process Validation and proper treatment of nonconforming product, are essential to a proper quality management system and to assuring fitness for use.

138. Part 820.70 of Chapter 21 of the Code of Federal Regulations describes the requirements for process controls to ensure that a device conforms to its specifications. In general, whenever "deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures." 21 C.F.R. § 820.70(a). These procedures can involve personnel, buildings, equipment, environmental controls, inspection of products, and, in some cases, process validation.

139. Manufacturing process controls prevent the production of adulterated products by ensuring the conformity of output to device specifications Included among the most significant

specification. This total inspection would require the manufacturer to perform and record a complete set of dimensional measurements for each and every component in a lot.

144. If such 100% inspection or other methods of full verification are impractical or impossible—such as where there is a large volume of output—the manufacturing process must be validated. Accordingly, process validation is often a necessary step to ensure an acceptably low risk of device adulteration. As another example, if a device defect manifested itself only after the product had been placed in distribution, then process validation would necessary to assure conformity to specifications. The manufacture of hip implants is a good example, as defects could conceivably become apparent only after—even years after—the device is surgically implanted in patients.

145. In such circumstances, it is not possible for the manufacturer to verify the product's fitness for use through inspection alone. Rather, the manufacturer would be required by 21 C.F.R. § 820.75(a) and the GHTF industry standards to implement Process Validation controls in order to ensure its capability of consistently delivering quality product.

3. Process Validation: *Are Proper Controls in Place to Assure Consistent Delivery of Devices of Adequate Manufacturing Quality?*

146. Process Validation, as defined by the FDA, is "the collection and evaluation of data, from the process design stage through commercial production, which

established scientific evidence that a process is capable of consistently delivering quality product."[7]

147. Among FDA's several codified methods for medical device manufacturers to validate their manufacturing operations is to perform statistical analysis to assess trending. 21 C.F.R. § 820.250. As Relators allege more fully below, Relators' own statistical analyses and their expert's statistical analyses indicate that, had DePuy performed an appropriate trending analysis, it would have revealed that the Pinnacle hip implants did not conform to specifications and were failing at alarming rates.

148. Without proper verification, manufacturers are not able to certify truthfully that their manufacturing process consistently delivers a product of a quality fit for its intended purpose. When a manufacturer fails to validate its production processes and consequently sells defective products to the Government, the Government is deprived of the benefit of its bargain. The manufacturer's shortfalls are material to the Government's decision to pay for the devices.

4. Complaint Handling and Adverse Event Reporting: *Are Device Failures Implicating Patient Safety and/or Efficacy Being Adequately Tracked and Reported to FDA?*

149. In order to help monitor the performance and fitness of devices that have been released into the marketplace, manufacturers must investigate and

[7] U.S. Department of Health and Human Services, et al., Guidance for Industry, Process Validation: General Principles and Practices, 4 (Jan. 2011), http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070336.pdf.

advise FDA of any and all complaints of device failures. A complaint refers to any written, electronic, or oral communication that alleges that a device exhibits deficiencies. Complaints can be related to any aspect of the device that indicates a failure to meet customer or user expectations or performance specifications, such as the quality, durability, safety, efficacy, or reliability of a device.

150. As a medical device distributor, DePuy has a duty to report deaths and serious injuries that a device has or may have caused or contributed to; it must establish and maintain adverse event files and submit annual reports to the FDA. *See* 21 C.F.R. § 803. Manufacturers and importers are required to report an adverse event to the FDA if the device (1) has or may have caused or contributed to a death or serious injury, or (2) has malfunctioned and the device or a similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

151. The Medical Device Reporting ("MDR") regulation requires manufacturers and importers of medical devices to report serious injury or malfunction to the FDA, using Form 3500A, within 30 calendar days of becoming aware of the event.

152. Quality System Regulation requires *all* complaints to be addressed, whether or not it is clear that the device has failed. 21 C.F.R. § 820.198(b). Manufacturers are required to investigate possible failures to confirm the failure and/or determine their causes. 21 C.F.R. § 820.198(c).

153. Once the failure is confirmed, the Corrective and Preventive Actions (CAPA) section of the QS

Regulation (21 CFR § 820.100) takes effect. Then manufacturers are required to process and analyze failed devices and to take corrective action, directed toward the elimination of the causes of nonconformity. 21 C.F.R. § 820.100(a)(1).

154. CAPA consists of the following steps: (1) collect and analyze data to identify nonconforming product and other quality problems; (2) investigate the cause; (3) identify and implement corrective and preventive action; (4) verify and validate actions and effectiveness; (5) communicate information on the quality problems and the necessary actions to appropriate staff; (6) forward information to management review. Trending or continual monitoring of complaints for specific failures can also be a corrective and preventive action, especially when a manufacturer cannot determine the cause of the failure.

155. CAPA investigations and analyses of such failures must be conducted by appropriately trained and experienced personnel. The manufacturer must adopt a written procedure to assure that the process of device handling and analysis will not compromise the

* * *

> including a determination of any adverse effect from the rework upon the product, shall be documented in the DHR [Device History Record].

161. When a company is faced with a nonconforming product, it must determine whether its validation process needs to be corrected. If the company had no validation procedures in place, then nonconforming product proves the need to create validation procedures.

6. Misbranding: *Does the Product Label, Including All Marketing Materials and Other Manufacturer Communications, Accurately Represent the Safety and Efficacy of the Device?*

162. A manufacturer must advise healthcare providers and the medical community of any known facts regarding the safety and/or efficacy of its products, including by updating the product label information if necessary.

163. Misbranded devices may not be marketed in the United States or sold to federally funded insurance programs, such as Medicare, Medicaid, TRICARE, and the Veteran's Administration. 21 U.S.C. § 352(a) (deeming a drug or device misbranded "unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use . . .").

164. As defined by 21 U.S.C. § 352, misbranded devices are "dangerous to health when used in the . . . manner or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof." This means that a device that is dangerous even when used as directed is misbranded. Thus, a manufacturer who is aware that its product routinely causes injury, but does not advance adequate warnings is knowingly causing the sale of misbranded products.

165. A medical device is misbranded if "its labeling is false or misleading in any particular." A device's labeling includes marketing materials and other information issued by the distributor about the device, including correspondence with providers, FDA, and the public. Manufacturers that make false and misleading statements regarding the device's safety or

efficacy in marketing materials and other communications render the device "misbranded."

166. When manufacturers learn that their products create a risk to health or safety, they must revise their labels and issue corresponding warnings to providers and the public.

VII. THE DEVICES AND DEFECTS AT ISSUE

A. MoM Total Hip Replacement Medical Devices

167. A hip joint consists of a ball (the femoral head) and socket (acetabulum), covered with cartilage and lubricated by fluids. The femoral head, a ball-like structure on top of the thigh bone, rotates within the surface of the acetabulum. In a healthy hip, the femur and acetabulum are cushioned by interposed cartilage that acts to distribute the forces generated during motion.

168. Over time, the cartilage sometimes degenerates. As a result, the bone of the femur rubs directly against the bone of the acetabulum, causing pain and disability. Hip joint deterioration can lead to pain, stiffness, or difficulty walking. When these symptoms do not respond to conservative treatment, such as physical therapy, patients may be advised to undergo total hip replacement or hip resurfacing.

169. Hip implants replace the bone components of a hip joint: with MoM devices, metal parts replace both the ball and socket. A metal ball is inserted onto the femur and fits into a metal cup, which is surgically implanted into the hip socket. Surgeons perform total hip replacement ("THR"), also known as total hip arthroplasty, to treat serious medical conditions, such as late-stage degenerative hip disease, hip joint

damage, osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, aseptic necrosis, and bone fractures. During a total hip replacement, an orthopaedic surgeon replaces a body's natural, degenerative hip joint (the acetabulum and the femoral head) with an artificial one, known as a prosthesis.

170. A total hip system typically includes components referred to as (1) a femoral stem, (2) a femoral head ("head"), (3) a liner, and (4) an acetabular shell ("shell"). These components essentially represent the artificially reconstituted joint, ball, and socket. Sometimes the liner and shell are manufactured together as one component, referred to as a "monoblock."

171. In MoM total hip replacement devices, both the head and the cup are made of metal. Because of the durability of metal, MoM devices were expected to last longer than other hip implants.

172. In order for the components of a MoM hip replacement device to satisfy minimum standards of care to the patients in whom they are implanted, their dimensions must be manufactured within a range of error acceptable to the FDA and the medical device industry. The accuracy of these dimensions is critical to the success or failure of the device.

173. The dimensions of MoM hip components are measured using a precision tool called a Coordinate Measuring Machine ("CMM"). The CMM, a standard means of measuring the dimensions of MoM hip components during the manufacturing process, measures both the physical dimensions and geometrical characteristics of an object by recording its coordinates.

174. The CMM is typically operated and controlled by certain software, which dictates the number of the data points gathered on each component. The CMM

measures, among other things, radius or diameter of each cup. The accuracy of these measurements is of critical importance to manufacturers' efforts to satisfy FDA and industry quality standards. In order to produce accurate measurements and ensure that device components come within specified tolerances, the CMM must be properly calibrated and maintained in a tightly temperature-controlled environment.

175. Generally, when an MoM hip replacement component, such as the head, the cup, or the liner, is manufactured at a manufacturing plant, the component is measured in the factory to ensure it is within the stated size range, and a printed record is be generated for every component. Any component that is outside of the tolerance range should be removed from the manufacturing process and destroyed.

B. The Pinnacle Acetabular Cup System

176. The DePuy Pinnacle Acetabular Cup System ("Pinnacle") is an example of a MoM total hip system. The Pinnacle has a modular design, which includes a metal cup, head, and liner. The Pinnacle device utilizes a larger head than many similar total hip systems. The Pinnacle also includes an ULTAMET metal liner as part of its total hip system. The liner is surgically affixed to the cup, referred to as the "shell."

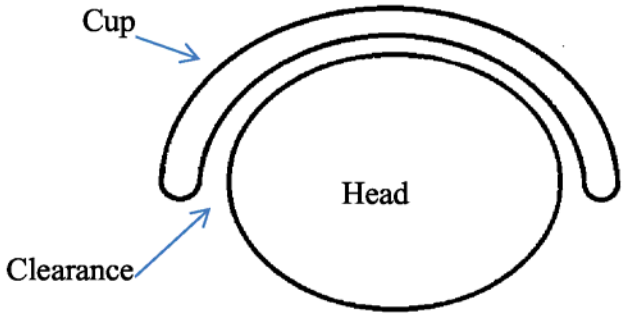
177. The Pinnacle ULTAMET metal liner, part of the Pinnacle total hip system, was designed at the time of Pinnacle's 510(k) approval, or FDA "clearance," for use with metal Pinnacle shells, and metal heads. Metal heads are made in different sizes; 28mm, 32mm, 36mm, 40mm, and 44mm in diameter. They also fit on certain variations of stems and "tapers." On December 13, 2000, the FDA approved the Pinnacle ULTAMET 36mm metal liner, based on substantial equivalence

with the DePuy Ultima Unipolar Adapter Sleeves ("Ultima"), cited as the ULTAMET's predicate device.

178. DePuy released a statement announcing the discontinuation of the ULTAMET metal liner used in the Pinnacle on May 16, 2013, with a discontinuation date of August 31, 2013.

C. The Pinnacle's Diametrical Clearance Dimensions

179. The space between the femoral head and acetabular cup of a MoM device is referred to as diametrical clearance. Diametrical clearance is calculated as the difference between the diameter of the cup and the head: written arithmetically: (Cup diameter) – (Head diameter) = Diametrical clearance.



180. Bodily fluid fills in the clearance between cup and head, ideally preventing the two pieces from contacting each other. When these adjacent components do contact each other in DePuy's MoM hips, it can create friction, which may in turn causes surface wear and the release of small metal particles into the body. When this occurs, these metal particles often decompose further, resulting in the release of metal ions into the bloodstream. The components of the MoM hip may also loosen, creating additional risk to the patient.

181. The diametrical clearance for the Pinnacle, as set forth in the ULTAMET's 510(k) application, is measured as the amount of space between the liner and the head. When the Pinnacle was approved by the FDA in 2000, DePuy's 510(k) application listed the device's diametrical clearance dimensions as falling within a 40–80 micron tolerance band.

182. DePuy purports to manufacture Pinnacle liners and Pinnacle heads at a specified "nominal" size. Along with a nominal size, each component is assigned an upper and lower tolerance. These upper and lower tolerances denote the range of permissible diametrical clearance measurements of the manufactured component.

The acceptable range of diameter measurements for each component is ± 10 microns (± 0.010 millimeters) from the nominal size. Therefore the complete range of acceptable deviation is 20 microns for each component.

183. DePuy has represented in its marketing materials that, as diametrical clearance decreases, the volume of fluid lubricating the joint increases. Lower clearances, on this theory, would be beneficial because lubrication of the joint is essential for reducing the force transmitted to each part of the joint.

184. As reflected in their respective applications for approval in the United States, DePuy designed the Pinnacle and ASR MoM devices with clearance dimensions far lower than those specified for other hip replacement devices. DePuy heavily marketed this feature of its MoM devices, claiming—albeit with insufficient scientific support—that low clearance made the product subject to less wear over time than its counterparts in the medical device marketplace.

185. When the clearance is small, however, the consequences of any deformation of the cup, even if slight, are dire for the patient. The clearance could become so small that fluid cannot enter and lubricate the surface between the cup and head.

186. A lack of such fluid, along with accompanying friction between the cup and the head, can cause increased wear on the device and/or cause premature loosening of the cup. This, in turn, can cause increased pain, decreased range of motion, and more frequent need for revision surgery. All of these consequences of low diametrical clearance ultimately result in patient injury. When the 36mm cup liner was added to DePuy's Pinnacle product line in 2005, DePuy advised the FDA that the diametrical clearance dimensions of the 36mm liner was not 40–80 microns, but was in fact 80–120 microns.

187. Upon learning of this inaccuracy, FDA specifically advised DePuy that, had it known that the 36mm liner's dimensions were not as DePuy had represented, the device would not have been granted a "substantial equivalence" waiver. Instead, DePuy would have had to make a full application for PMA.

D. The Pinnacle's "Taper Trunnion" Design

188. MoM hip implants are designed with a taper junction where the femoral head meets the femoral stem. The term "trunnion" is applied to the end of the stem, and the term "taper" refers to the area affixed within the head that is intended to receive the trunnion.

189. The taper trunnion is not meant to move and thus should not generate any wear. However the bearing (*i.e.* the surface of contact between the head and liner) can be expected to wear. In ASR devices, the

trunnion was inserted into a sleeve in the femoral head; in Pinnacle devices the trunnion was simply inserted into an internal cone in the head. The following image shows the components of an ASR XL Head System, which contains a taper trunnion mechanism similar to that of the Pinnacle:

* * *

surgery and a new metal head simply hammered onto the taper trunnion, there will remain further risk of implant failure.

193. Relators' research revealed that these complications result in part from DePuy's production of tapers and trunnions that are defectively designed. In particular, DePuy had stated an improper tolerance band for the taper angle at the time it applied for 510(k) clearance for the device.

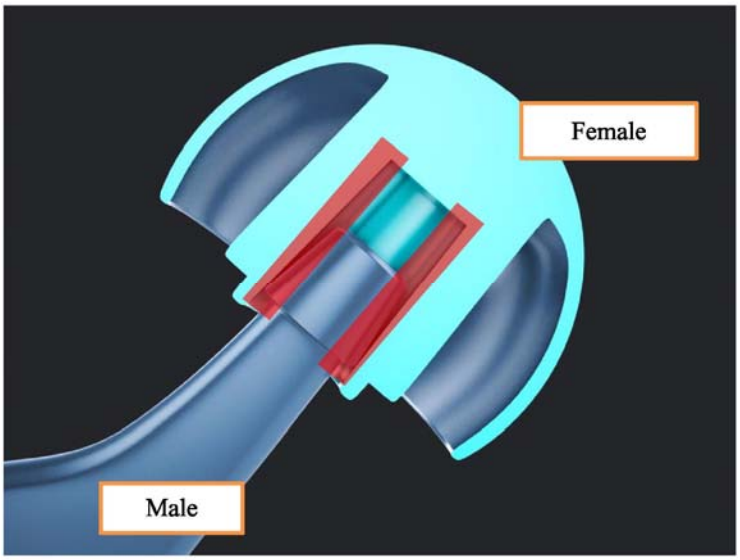
194. DePuy would later learn, however, that the larger head sizes in DePuy hip systems were incompatible with that tolerance band. Relators themselves informed DePuy of this defectively designed taper angle mismatch in as early as 2010. Relators' own research has also shown that, over time, this design defect may increase the chance that the Pinnacle's manufacturing defects will cause failure in a given device.

E. The Pinnacle's Surface Roughness Dimensions

195. The Pinnacle's taper junction consists of two parts, a "male" and a "female" component. The trunnion is designed to be rough in texture, but the head taper is designed to be as smooth as possible on the surface at which they interface. However, if either or both surfaces are rough, high contact stresses are

created. The resulting frictional forces lead to release of metal debris that then disperses into the surrounding tissue and the body. The result is ARMD, a soft-tissue reaction similar to a tumor and the release of metal ions into the bloodstream.

196. The diagram below depicts a cross-section of the so-called "male" and "female" parts of the taper. The areas highlighted in red indicate the areas of surface roughness referred to above. If a nonconforming head taper is present in the implant, when the patient moves, these red areas grind against each other, causing the release of metal debris.



197. In 2014, Relators observed that, in the Pinnacle implants derived from their Retrieval Database, the surfaces of the female head taper were unacceptably rough. This roughness caused the release of substantial metal debris and a correspondingly high level of wear on the taper junction. Relators' research

indicates that this wear indicates that the female taper was manufactured improperly.

198. The Pinnacle's taper junction mechanism was approved by the FDA through means of 510(k) substantial equivalence to the predicate Ultima product's taper device. Therefore the angle and surface finish of the male and female components should be identical as between the two devices.

199. The Ultima taper drawing appearing in the ASR XL 510(k) application for approval sets forth a required surface roughness dimension of 0.6 microns.

200. In 2014, Relators confirmed that the Pinnacle's surface roughness dimensions consistently failed to conform to its FDA-required 0.6 micron specification, and that this nonconformity contributed substantially to the Pinnacle's abnormally high failure rates.

VIII. DEPUY'S FRAUDULENT CONDUCT IN RELATION TO THE PINNACLE

A. DePuy Knowingly Made Material False Statements and Omissions to the FDA and to Medical Providers

201. DePuy made various misrepresentations about the specifications, manufacturing process, safety, and failure rates of its MoM hip implants. These false statements deprived the Government of the benefit of its bargain to purchase medical devices fit for use in patients who needed hip replacements.

202. Specifically, DePuy: (1) knowingly misrepresented that its Pinnacle implants were safe, medically effective, and compliant with specifications; (2) provided false and/or or incomplete statistics about the device's failure rates; and (3) willfully omitted information establishing that these affirmative represen-

tations were untrue. As a result, the Government purchased DePuy products that were unfit for their intended use. Without DePuy's misrepresentations and with knowledge of the true facts, no reasonable healthcare consumer would have purchased the Pinnacle implant.

203. DePuy's false statements also caused doctors to falsely certify that DePuy's products were medically reasonable and necessary to treat hip-implant patients. In particular, DePuy's advertising and promotional materials consistently stated or indicated that the company's devices were manufactured within specification and were safe and effective. These statements were false. DePuy's false statements armed and induced surgeons to make similar certifications when seeking reimbursement from the Government. Therefore, the surgeons' false certifications had a natural tendency to influence the Government's payment for the Pinnacle devices.

* * *

of February 29, 2012, DePuy's internal DOTS files showed the metal Pinnacle hips had a 15% cumulative revision rate after five years of use.

230. Even before the dissemination of internal DOTS data, DePuy knew or recklessly disregarded the fact that its failure rate was substantially higher than it advertised.

231. DePuy possessed this knowledge, in part, because relators themselves informed DePuy of the Pinnacle's alarmingly high failure rates. On April 20, 2012, during a meeting that included, among possible others, representatives from DePuy; a committee from the MHRA; NJR executives; and the British Orthopaedic Association President, Dr. Nargol gave a

presentation that shared his calculated failure rate for Pinnacle as approximately nine percent at five years (the "April 2012 Disclosure"). This high revision rate was almost double the internationally accepted National Institute for Health and Care Excellence ("NICE") guidelines, which mandated a maximum of 5% failure rate at five years.

232. At this same meeting in April 2012, before U.K. regulatory authorities and prominent members of the medical community, DePuy presented that Pinnacle experienced device failures of approximately four percent at five years after implantation. DePuy thus improperly downplayed the evidence it possessed of even higher failure rates. But even a 4% failure rate was approximately 400 times higher than the .1% rate DePuy continued to tout in its marketing materials.

3. DePuy Made False Statements to Surgeons Regarding the Accuracy and Benefit of the Pinnacle's Diametrical Clearance Dimensions

233. Beyond Pinnacle's overall survival rate, DePuy actively—and falsely—claimed that the Pinnacle devices' low diametrical clearances created a benefit to patients that distinguished the devices from competing products.

234. DePuy sought to convince surgeons that its devices' purportedly low diametrical clearances would reduce wear and help the devices last longer.

235. But DePuy lacked empirical support for such claims. And, in fact, DePuy knew that its devices' actual diametrical clearances were causing dangerously elevated metal ion concentrations in patients' blood and hip fluids.

236. DePuy was further aware that, even if it were possible that low clearances could increase survivorship or reduce wear, the Pinnacle devices' dimensions consistently deviated from the diametrical clearance dimensions mandated by FDA and marketed by the Company. Therefore, DePuy did not have any basis to represent that certain clearances—which its products did not actually bear—could benefit patients.

237. DePuy possessed this knowledge in part because Relators warned them of the relationship between the Pinnacle devices' diametrical clearance dimensions and their failure in as early as 2010.

238. In 2009, Dr. Langton, funded in part by a DePuy research grant, measured and identified the nonconformance of a large volume of failed Pinnacle and ASR implants. As part of this study, Dr. Langton determined that the diametrical clearance of the ASR device was considerably lower than the specification required by the FDA. In 2010, Dr. Langton's research confirmed that the Pinnacle suffered from this very same diametrical clearance defect.

239. Dr. Langton found that a significant percentage of the measured components were below the clearance specifications reported to and/or mandated by the FDA. The average diametrical clearance for the Pinnacle was well below the standard value of 100 microns. Dr. Langton provided his measurements, along with the explanted devices themselves, directly to Depuy. This enabled Depuy to readily trace the explants back to the manufacturing process by lot number.

240. Relators' analysis of these data revealed that, when Pinnacle explants were measured, the clearance values (at the mean, median, and mode) were well

below the 100 micron nominal size reported to and approved by the FDA. Instead, clearance values appeared to cluster near to the lower tolerance band, meaning that they typically had a lesser clearance than the target approved by the FDA. Further, many Pinnacle devices measured fully below the lower tolerance band.

241. Relators' internal measurements and professional experience, developed over many years, establish that neither implantation nor explantation alters the devices in a manner that would affect accurate dimensional measurement of the explants using Dr. Langton's methodology.

242. Relators would later determine, based upon analysis of Pinnacle explant data derived from their Retrieval Database, that the degree of nonconformance of the devices' diametrical clearance was so great that it failed to meet minimum FDA and industry standards of manufacturing quality. Further, Relators discovered that DePuy knowingly or recklessly failed to detect or correct this manufacturing deficiency.

243. Relator Langton's unique and as-yet-unpublished findings mirrored the failure rates that had occurred in the field. Moreover, nonconformance and device failures with the Pinnacle Hip dramatically increased after 2005.

244. By early 2010, Dr. Langton and Dr. Nargol had confirmed with a high degree of certainty that the diametrical clearance defect had been a substantial factor in the failures of the Pinnacle, as had been true of the ASR. Relators repeatedly advised DePuy of this problem from early 2010 to the present.

245. In or about March 2010, Dr. Nargol traveled to DePuy's headquarters in Leeds to discuss the concerns

he had about diametrical clearance. He spoke with executives including Mary Stewart, a top executive in DePuy's Research & Development unit, Magnus Flett, the DePuy Group Product Manager for Hips, and DePuy engineers Graham Isaac and James Anderson. Dr. Nargol was told his concerns were unwarranted.

246. On May 5, 2010, Relators met with DePuy at North Tees hospital. They showed DePuy a slide about out-of-specification implants and told DePuy that they had manufactured the implants with improper clearances. Relator Langton provided DePuy with several examples of nonconforming ASR and Pinnacle implants that he had removed from patients whose implants had failed. Shortly thereafter, Relator Nargol traveled to DePuy's Leeds Headquarters, where DePuy asserted, without support, that the implants were within specification.

247. After DePuy denied that there were any clearance defects in Relators' explants, Relator Nargol spoke with Mike Tuke, a DePuy executive and engineer. In private, Mr. Tuke admitted to Relator Nargol that Relators' concerns regarding clearance were warranted, that the clearances on the implants that the Relators had provided to DePuy were too small, and that DePuy had failed to manufacture them within their intended specifications.

248. In the summer of 2010, Relators further warned DePuy about the high rates of nonconformance they were finding in Pinnacle heads and liners at a meeting attended by Professor Michael Morlock, an expert on MoM hip technology located in Germany, with DePuy engineers and executives, including Mr. Isaac, in the audience.

249. DePuy's statements to surgeons regarding the Pinnacle's diametrical clearance dimensions constitute both affirmative false statements and false statements by omission.

250. Specifically, DePuy claimed in one representative marketing pamphlet distributed to surgeons in the UK that Pinnacle's "cup-to-head bearing clearance, enhances the potential for fluid lubrication and minimises [sic] wear to maximize survivorship." A true and accurate copy of the relevant portion of this pamphlet appears below:

> ULTAMET
>
> ***Optimised motion and wear performance.*** *Ultamet™ 36 mm metal-on-metal bearings provide excellent range of motion. The hard, forged, high carbon cobalt chrome is given a smooth finish for low surface roughness, and in combination with its cup-to-head bearing clearance, enhances the potential for fluid lubrication and minimises wear[12] to maximise survivorship.*

251. In the same pamphlet, DePuy represented to surgeons that the diametrical clearance of its large-head components "leads to a significant reduction in wear." A true and accurate copy of the relevant portion of this pamphlet appears below:

> ***Optimised bearing clearance and measured deflection assures fluid film lubrication and lower wear.*** *Large component diameter and optimized radical clearance accounts for cup deflection and assures fluid film lubrication. This leads to a significant reduction in wear compared to third generation resurfacing systems.[18,19,20]*

252. These marketing materials appear to be representative of other marketing materials disseminated by DePuy globally. Therefore, on information and belief, similar materials were distributed to surgeons in the United States.

253. DePuy also represented to surgeons that Pinnacle Metal-on-Metal Implants experienced reduced wear because of the purported benefit of their low diametrical clearances.

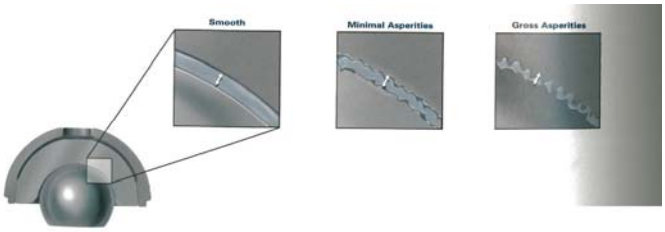
254. For example, the Technical Monograph on the Pinnacle Ultamet system stated that "low clearance values can result in larger head-cup contact areas and the corresponding generation of thicker lubricant film layers at the articulating surface." A true and accurate copy of the relevant portion of this monograph appears below:

> PERFORMANCE CHARACTERISTICS
>
> FLUID FILM LUBRICATION
>
> In modern metal-on-metal hip implants, a type of lubrication known as fluid film lubrication may occur where a thin microscopic layer of lubricant completely separates the head and cup surfaces during relative motion. Theoretical studies employing advanced lubrication theory have indicated that strict control over design and manufacturing parameters can produce conditions favorable for fluid lubrication.[34,45,48] Specifically, low clearance values can result in larger head/cup contact areas and the corresponding generation of thicker lubricant film layers at the articulating interface.[34,45]

Furthermore, lower surface roughness values have also been shown theoretically to result in a more effective lubricant layer.[34,45] This is because rough counterface surfaces require a thicker lubricant layer for complete separation, compared with smooth surfaces that can be separated by thinner lubricant layers.[34,45]

One study, in which a lubrication model was developed, suggested that sufficiently low-clearance and low-surface roughness can result in good fluid film lubrication of metal-on-metal implants even under the varying loads experienced in service due to normal gait.[34,45]

A recent study has provided direct experimental evidence of lubrication for metal-on-metal hip implants tested on a hip simulator.[30] This hip simulator study corroborated the previous theoretical studies indication that the protection of metal-on-metal articulating surfaces is possible through an interposed fluid layer and that fluid film lubrication can play a major role in further reducing the wear of metal-on-metal implants.



Lower surface roughness values have been shown to result in a more effective lubricant

> layer as surface asperity contact is minimized.
>
> Fluid film lubrication can play a major role in further reducing the wear of metal-on-metal implants.[31,34]

* * *

281. On November 13, 2000, DePuy submitted an application for 510(k) approval of the Pinnacle 36mm Metal-on-Metal Acetabular Cup Liners.

282. As part of that application, Lynette Whitaker, then DePuy's Manager for Regulatory Affairs, certified that she had "conducted a reasonable search of all information known or otherwise available about the types and causes of safety and effectiveness problems that have been reported for metal-on-metal hip systems." She further certified that "the following summary of the types and causes of safety or effectiveness problems is complete and accurate."

283. DePuy included a description of verification tests purportedly showing that it had measured Pinnacle 36mm Metal-on-Metal Acetabular Cup Liners, and certified the application as "complete and accurate."

284. DePuy's application also included a certification from Natalie Heck, Design Quality Engineer for DePuy Orthopaedics, Inc., that "the verification activities, as required by the risk analysis, for this modification were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met." Applicable regulations require that "[e]ach manufacturer shall ensure that all inspection, measuring, and test equipment, including mechanical, automated, or electronic inspection and

test equipment, is suitable for its intended purposes and is capable of producing valid results." 21 CFR 820.72(a).

285. On the basis of DePuy's certifications of compliance, the FDA cleared DePuy's Pinnacle 36mm Metal-on-Metal Acetabular Cup Liners through the 510(k) process on December 13, 2000.

286. On July 26, 2005, Rhonda A. Myer, a Regulatory Affairs Associate for DePuy wrote to the FDA. Specifically, she wrote that an attached chart "replaces the chart originally

* * *

and Pinnacle MoM components was flawed. Based on these discrepancies, DePuy knew or should have known that, through use of a flawed measurement system, nonconforming components could be misidentified as having been manufactured within their proper diametrical clearance specifications.

335. These discrepancies further corroborate Relators' allegation that DePuy's validation testing procedures were inadequate, at least prior to the acquisition of Finsbury and its state-of-the-art measuring equipment in 2009. DePuy's acquisition of Finsbury and its Redlux machine placed DePuy on notice of the inadequacy of its own testing methods. Still, Relators' findings as well as FDA's suspicions raised in 2011 indicate that DePuy continued to manufacture and sell nonconforming Pinnacle implants in 2010 and thereafter.

336. Indeed, Mr. Tuke himself, upon learning of the discrepancies in clearance measurements illuminated by the Redlux machine, stated to Relator Nargol that

the components that had been measured were "too small and not made correctly."

337. Soon thereafter, in 2010, Dr. Nargol travelled to DePuy's headquarters in Leeds to discuss his concerns about diametrical clearance. After meeting with DePuy executives including Messrs. Flett, Isaac and Anderson, and Ms. Stewart, Relator Nargol was told that his concerns were unwarranted.

338. But DePuy knew internally that such manufacturing inconsistencies severely compromised the integrity of its products, carrying grave consequences to patients. In June 2010, just two months prior to the to Finsbury visit, Ms. Stewart wrote an email directly to Dr. Langton admitting that, were DePuy to conclude from Relators' research that its MoM parts "were out of specification," the Company would "need to notify patients if we have made a serious manufacturing error."

* * *

DePuy: In no later than 2010, Relators' compelling evidence demonstrated that the manufacture of materially non-conforming parts was causing not only the acceleration of ASR failures, but the failure of Pinnacle devices as well. Nonetheless, DePuy continued to manufacture Pinnacle components with full knowledge that the manufacturing process was producing yet more parts with the same conformance issues.

344. These concerns and others prompted FDA to instruct DePuy to provide it with any and all statistical analyses DePuy Orthopaedics had conducted on the Pinnacle MoM since 2008. Such statistical analyses to assess trending is one of FDA's several codified methods in which medical device manufacturers may

validate their manufacturing operations. 21 C.F.R. 820.250.

345. In response, DePuy produced selected materials derived from an executive management review. Relators, on information and belief, allege that the critical analyses Relators provided to DePuy were not included among these materials.

346. DePuy knew that Relators possessed a data set of hundreds of Pinnacle patients found with blood metal ions, likely the largest such data set in existence at the time. DePuy had also clearly endorsed Dr. Nargol's credibility in the past: DePuy had previously selected Dr. Nargol as a Key Opinion Leader ("KOL") for the Pinnacle product, and had even invited him to tour the country of India on behalf of the Company to demonstrate surgical methods during live Pinnacle surgeries.

347. Relators further allege on information and belief that the materials DePuy provided to the FDA will instead show that many of the same senior executives to whom Relators had personally reported evidence of Pinnacle failures failed to meaningfully acknowledge or address Relator's findings or to convey any corresponding information or concerns to the FDA.

348. Following receipt of these materials from DePuy, the FDA inspector clarified that the FDA sought "all statistical analysis conducted now back to January 2007 for Pinnacle MoM no matter where the source." DePuy then responded by producing "very little data," and stated that "MoM was a very stable product, based upon the registry survivorship data and has been around longer than ASR."

349. In response, the FDA inspector stated, "I did not understand why in light of the recent ASR recall there was not any additional statistical analysis conducted for Pinnacle MoM and that I figured those involved in the inspection would be providing more than I would want to review in order to show me the extent the firm went through to show there was no problem with Pinnacle MoM."

350. DePuy's failure to conduct and report such statistical analyses violated 21 C.F.R. 820.250, which requires statistical analysis to assess trending. These analyses would have demonstrated that DePuy was manufacturing a high volume of non-conforming parts, which should, in turn, have prompted DePuy to address deficiencies in its manufacturing operations. But because DePuy never performed and/or reported the requisite statistical analyses, it also never validated its manufacturing operations. This led to an environment where the quality and conformity of the product was neither stable nor predictable.

351. Among the data analyses DePuy should have disclosed to FDA was a presentation made by Dr. Langton at DePuy's Leeds Headquarters on July 7, 2010, entitled "Early Failure of Metal on Metal Bearings in Hip Resurfacing and Large Diameter THR: A Consequence of Excess Wear" (the "July 2010 Leeds Presentation." A primary focus of Relator Langton's presentation and the discussion that ensued thereafter was "Clearance Issues" (the title of the first two slides of the presentation), referring to the diametrical clearance nonconformity in DePuy's MoM hip products.

352. Slide three of the presentation displays a scatterplot graph prepared by Relators based on data drawn from their Retrieval Database. The data, incor-

porated into the slide, raises concerns about diametrical clearance nonconformity in DePuy's MoM hip implant devices.

353. Along with the presentation, Relators also provided DePuy with an Excel file containing data that was prepared on the same date as the 2010 Leeds Presentation. The spreadsheet identifies components of failed ASR and Pinnacle devices by lot number. Among the attendees at the meeting were Ms. Stewart, Mr. Isaac, and Mr. Flett.

354. On information and belief, DePuy also knowingly or recklessly disregarded evidence within its possession that the surface roughness manufacturing defect later to be discovered by Relators in 2014 had been contributing significantly to failures in the Pinnacle device.

355. And statistical analysis was not the only data that DePuy failed to adequately investigate and report to the FDA. The 2011 Inspection Report also determined that DePuy employed a single employee to investigate all complaints originating out of the Warsaw facility for all DePuy hip products, including the Pinnacle. DePuy represented that the Complaint Analyst's duties were to: receive the complaints (from any and all product lines); make the determination of how to conduct the investigation; and determine if additional departments were needed in order to complete an investigation. DePuy maintained that one person was able to adequately review and analyze the approximate 450 complaints received per month.

356. Unsurprisingly, DePuy willfully ignored and mischaracterized the causes of these complaints in order to avoid its obligation to adequately verify and validate its manufacturing processes.

357. DePuy's failure to respond to Relators' complaints regarding the clearance deformities also caused the deformed devices to be adulterated under cGMP. This resulted in various legal violations, including violations of 21 C.F.R. § 820.198(a) (failure to establish and maintain adequate procedures for receiving, reviewing, and evaluating complaints).

2. DePuy Knowingly Failed to Adopt Process Validation Methods Necessary to Consistently Manufacture Its Pinnacle Devices Within Specification

358. DePuy knowingly or recklessly failed to adopt adequate process validation methods for the manufacture of Pinnacle components. Relators allege on information and belief that this failure extends back at least to 2005.

359. DePuy was obligated to assure the devices' quality and conformity to the FDA's required diametrical clearance and surface roughness specifications, through implementation of adequate verification and validation procedures.

360. Relators, with additional expert assistance, have determined that DePuy's inspection and testing procedures were unable to verify whether DePuy's Pinnacle devices are manufactured within their required specifications. Under the FDA's cGMP and relevant industry standards, all relevant operations performed during DePuy's manufacture of its Pinnacle devices must be not only verified, but also validated with a high degree of assurance.

361. Manufacture of MoM hip replacement devices does not lend itself to verification alone, because, among other reasons, the consequences of a given degree of non-conformity cannot be known until the

results in patients have been observed over a longer timeframe.

362. Accordingly, DePuy should have implemented, among other things, process validation procedures to ensure that its manufacturing process was capable of producing devices within their required specifications.

363. In failing to do so, DePuy produced, marketed, and sold what was "a device that is different than the subject of the 510(k)."

364. In failing to do so, DePuy produced a "device that is different than the subject of the 510(k)" in regard to the Pinnacle's diametrical clearance and surface roughness dimensions.

365. And, without 510(k) approval, the Government would not have purchased Pinnacle devices for any purpose.

a. DePuy's Plants Generated Nonconforming Devices at Rates Well Beyond Minimum Industry and FDA Standards.

366. Relators have performed a statistical analysis of Dr. Langton's explant data with the assistance of medical device Quality Systems expert, QA Consulting ("QA"). QA performed a statistical analysis of numerous failed Pinnacle explants. QA's analysis confirmed the inadequacy of DePuy's process for validating the manufacture of Pinnacle heads, cups, and liners. QA found that the components' high rates of diametrical clearance nonconformance indicated that DePuy's manufacturing process had failed to satisfy basic industry and FDA standards of manufacturing integrity.

367. Moreover, DePuy's validation testing methods were so grossly deficient as to be considered, at a minimum, reckless. The adequacy of a manufacturer's validation testing is measured by the process performance index ("Ppk) of a statistically valid sample. Ppk is an estimate of the process capability, which compares the behavior of a process characteristic to engineering specifications.

368. QA performed two statistical analyses of data maintained by Dr. Langton relating to failed Pinnacle implants. Dr. Langton obtained the underlying data by measuring implant components in order to determine whether their dimensions met the diametrical clearance specifications set forth in the relevant 510(k) application.

369. Per typical industry practice, a Ppk of 1.0 would be required for the process to be marginally capable of producing products meeting the specification. A Ppk of greater than 1.33 is typically required during process validation for medical devices.

370. Based upon Dr. Langton's raw data – which was representative of the outcomes of DePuy's manufacturing process – QA concluded that the process was incapable of consistently producing Pinnacle cups, heads, and liners that would meet the required diametrical clearance. The Ppk was .38 for the explant heads and 0.1 for the explant liners—both well below the minimum industry standard of 1.0.

371. Based upon QA's statistical analysis, DePuy's manufacturing process fails to produce implant heads within specification 14.93% of the time and implant liners 50.41% of the time.

372. QA concluded that such pervasive failures in DePuy's quality controls required far greater scrutiny

and monitoring of its manufacturing process. In order to ensure an acceptable rate of nonconformance under such conditions, QA concluded, DePuy's inspectors would have been required to adequately inspect each and every component contained in every production batch in order to ensure that their dimensions met the minimum standard of quality for sale in the marketplace. This is referred to in industry parlance as "100% inspection." On information and belief, DePuy did not ever conduct an adequate 100% inspection. Any such 100% inspection would have conclusively confirmed that unacceptable quantities of non-conforming devices were being produced. Instead, Relators believe that, at most, DePuy would measure a sample from each lot.

373. Indeed, Relator Langton's measurements of failed Pinnacle implants confirms that DePuy's devices were so consistently and radically out of conformance with their 510(k) specifications that DePuy could not possibly have met minimum industry standards of testing to assure the devices came within those specifications.

374. Applicable FDA regulations state that if a manufacturer measures only a sample of its medical device products, then it must ensure adequate validation of its underlying manufacturing operations. This means that DePuy was required to validate its manufacturing operations under one of FDA's codified methods.

375. Based upon their analysis of explant data derived from the Retrieval Database, coupled with the analysis of their expert, QA, Relators allege that DePuy failed to do so.

376. In view of the devices' dramatic rate of nonconformance and associated failures, DePuy knew or should have known that the devices' fitness could not be determined by verification alone. Alternatively, DePuy knew or should have known that the validation methods it had adopted were wholly inadequate to assure its devices' fitness for use.

377. By 2010, Relator Langton fully informed DePuy of his findings that the Pinnacle did not conform to its diametrical clearance specification. Yet, in view of FDA's findings in its May 2011 Inspection Report, DePuy had still not disclosed the results of Langton's analyses to the FDA in 2011. In Relators' numerous discussions with the FDA and MHRA officials from 2011 onwards, Relators came to believe that neither regulatory body was aware of the manufacturing issues with DePuy's Pinnacle devices or even the basic reasons why the devices failed.

378. Also in 2010, Relator Langton determined that the taper trunnion design defect increased the likelihood that the diametrical clearance manufacturing defect would manifest itself in the Pinnacle implant. Therefore, the two device defects discovered by Relators disclosed to DePuy in 2010 were related in a way that resulted in them manifesting themselves simultaneously in the Pinnacle. When existing simultaneously in the Pinnacle, the two device defects are even more likely to result in device failure.

379. Further, on information and belief, DePuy made affirmative misrepresentations and/or material omissions directly to the FDA concerning whether and to what extent the company had adequately performed and acted on available data analyses. DePuy took great pains "to show [the FDA] there was no problem

with Pinnacle MoM." But it made little attempt to ameliorate the Pinnacle's demonstrated flaws.

b. The Pattern of Pinnacle Diametrical Clearance Defects Suggests that DePuy Manipulated its Manufacturing Process in a Manner That Resulted in Increasing Numbers of Non-Conforming Parts

380. In June 2013, Relator Langton prepared a PowerPoint presentation derived from their Retrieval Database and entitled "Pinnacle Clearances By Year" (the "June 2013 Presentation"). This presentation indicates a pattern of increasing levels of nonconformance with the device's specifications over time.

381. As explained above, the 36mm Pinnacle had a designated 80-120 specification from at least 2002. The Relators found that from 2002 to 2005, the failure rates for the device were relatively modest. However, Relator Langton's findings further show that, beginning in 2005, the rate of the Pinnacle's nonconformance with its diametrical clearance specifications began to increase dramatically.

382. Relator Langton's findings support an inference that DePuy consciously altered its manufacturing process, including, on information and belief and without limitation, the manner in which it carried out its verification and process validation methods.

383. Relator Langton's findings further support an inference that manufacturing defects were a substantial cause of Pinnacle devices failures during relevant periods. That is, because the Pinnacle's design did not change between 2002 and 2009, the defect precipitating the elevation in failure rates and non-conformance

in 2005 appears to have been related to the manufacture of the device.

384. Relator Langton's findings of this pattern of nonconformance, when coupled with the Pinnacle failure rates (of which DePuy was already aware), placed DePuy on notice that the manufacturing methods it had adopted in 2005 and thereafter were inadequate.

385. Relator Langton's findings support an inference that the company altered its manufacturing process in order to speed production, at the expense of the integrity and medical viability of its products.

386. Relator Langton's findings further support Relators' allegation that Dr. Langton's measurements of both the earlier implants and the later implants are accurate and consistent. In 2011, DePuy itself acknowledged that it is important to examine failed devices in order to determine whether a device was manufactured within specification.

c. The Pattern of Pinnacle Surface Roughness Defects Suggests DePuy Knowingly or Recklessly Failed to Adopt Adequate Process Controls to Ensure Consistent Manufacture of Pinnacle Head Tapers Within Their Required FDA Specifications.

387. In addition to the diametrical clearance manufacturing defect, the Pinnacle's taper junction also suffered from the surface roughness manufacturing defect.

388. DePuy knew or acted in reckless disregard of the fact that its Pinnacle devices contained the surface roughness manufacturing defect by as early as 2010.

In July of 2010 DePuy possessed evidence of surface wear in the taper junctions of both Pinnacle and ASR implants.

389. As described above, that July, DePuy measured several implant samples provided by the Relators at both its Finsbury and Leeds manufacturing facilities. DePuy executives, including Mary Stewart, then showed Relators the measurement results. These measurements indicated that DePuy had knowingly or recklessly failed to confirm that the measurements of the Pinnacle's surface roughness dimensions taken at the Leeds plant corresponded with those taken at the Finsbury plant using its more precise Redlux machine.

390. DePuy therefore knew or acted in reckless disregard of the fact that surface roughness was contributing to the release of metal debris in Pinnacle patients from as early as 2010.

391. Using data derived from Relators' Retrieval Database, in 2014, Relator Langton prepared a statistical analysis confirming that the Pinnacle's head tapers are consistently manufactured well outside of their required manufacturing specifications shared with the "substantially equivalent" Ultima device. Among other things, the analysis found that 87 of the 157 36mm Pinnacle heads that were the subject of the study contained the surface roughness manufacturing defect, or over 50%.

392. In 2014, Relator Langton also confirmed a statistical correlation between the Pinnacle's nonconforming head taper surface roughness dimensions and device failure. In particular, Relator Langton found that Pinnacle devices bearing the surface roughness defect have an 80% failure rate at 8 years.

393. Relators discovered that the greater stress on the taper junction caused by the surface roughness manufacturing defect is further exacerbated by the Pinnacle's ultra-low clearances. As noted above, Relators understood this relationship by as early as 2010, when they presented evidence in their June 2010 Ghent Meeting Presentation that nonconforming diametrical clearance dimensions may be "detrimental to taper junction."

394. Therefore, all *three* device defects discovered by Relators were related in a way that resulted in them manifesting themselves simultaneously in the Pinnacle. When two or more defects manifest simultaneously in the Pinnacle, there exists a very strong nexus between the defects in the Pinnacle device and their failure.

395. Because the surface roughness manufacturing defect is unique to the Pinnacle and not found in the ASR, the relationship between this particularly lethal combination of device defects and device failure is unique to all metal heads used with the Pinnacle liner, including the Pinnacle MoM.

396. However, the surface roughness manufacturing defect also affects devices other than the Pinnacle MoM that DePuy continues to sell to the Government as of the date of this complaint. These affected devices include DePuy's S-ROM, SUMMIT, CORAIL, and AML hip replacement products.

3. DePuy's Failure to Implement Controls Necessary to Ensure Consistent Manufacture of Conforming Products Was Material

397. DePuy's failure to implement validation procedures necessary to ensure consistent manufacture

of products conforming to their specifications was material to the Government's purchases of DePuy's Pinnacle devices. In particular, FDA premised its post-market approval of the Pinnacle's diametrical clearance dimensions upon DePuy's representation that the Pinnacle's failure rates were comparable to those of its competitors.

398. In 2000, DePuy submitted an application to the FDA requesting approval of the 36mm Pinnacle for sale in the U.S. In its application, DePuy reported that the 36mm Pinnacle liner's diametrical clearance was identical to that of DePuy's 28mm Pinnacle liner. DePuy at that time claimed the diametrical clearances for both hip implants were 40 to 80 microns.

* * *

> Change to an Existing Device" a. The information you have supplied will be added to the file.

403. But DePuy knew otherwise. It was aware that the Pinnacle substantially deviated from specifications and had disproportionally high failure rates. In order to maintain FDA approval and continue to sell the Pinnacle, DePuy obscured this information from the FDA, medical providers, and the public for several years.

404. In 2005, Cheryl Hastings, then DePuy's Director of Regulatory Affairs wrote an email to Pam Plouhar, then DePuy's Worldwide Vice President of Clinical Research, saying that this regulatory submission "stretch[ed] the 510(k) idea to its limits." Ms. Hastings further said, "*I can see how the FDA looked at it. They want clinical data for metal-on-metal, and we changed the material, the size and 'diametrical*

clearance,' then tested a device that is different than the subject of the 510(k)." (emphasis supplied).

405. Further, as described above, the Pinnacle's head taper component did not conform to its FDA required dimensional specifications shared by the Ultima predicate device. DePuy therefore manufactured "a different device" that what was set forth in the 510(k) with respect to *both* its diametrical clearance *and* its surface roughness dimensions.

406. DePuy became aware by February 2012 and, on information and belief, far earlier, however, that Pinnacle's failure rates were far above the industry standard. In particular, DePuy's internal Pinnacle DOTS showed a nearly 15% failure rate for the device at five years.

407. As a result, DePuy removed the Pinnacle from the market in August 2013.

408. Had the FDA been privy to information concealed by DePuy regarding the Pinnacle's failure rates and/or surface roughness manufacturing defect, DePuy would have been required to submit a supplemental 510(k) for the Pinnacle 36mm. This would have delayed sales of the Pinnacle until DePuy came into compliance. Instead, the device remained on the market, where it was frequently purchased by the Government on behalf of taxpayers.

409. At the time DePuy became aware that the Pinnacle's failure rate materially exceeded the levels deemed acceptable by the Government, it was required to submit a supplemental approval application to the FDA detailing the changed circumstances.

410. Likewise, at the time DePuy became aware that the Pinnacle's surface roughness manufacturing

defect was contributing to the Pinnacle's abnormally high failure rates—particularly when combined with one or both of the Pinnacle's other defects known to DePuy by 2010—it was required to submit a supplemental approval application to the FDA detailing the changed circumstances.

411. The FDA's authorization for DePuy to continue to sell the Pinnacle was premised upon its finding that the failure rates of the Pinnacle were commensurate with those of competing products. DePuy knew or came to know that this premise was inaccurate. DePuy's conduct in concealing this information from the Government exerted a strong influence over the Government's decisions to expend public monies on DePuy's devices.

412. Therefore, all claims made to the Government for costs associated with the Pinnacle device at any time from DePuy's 510(k) application to the date the Pinnacle was withdrawn from the market constitute false claims under the FCA.

IX. DePuy's Fraudulent Conduct Resulted in False Claims Paid by the Government

A. The Medicare and Medicaid Programs Paid False Claims as a Result of Defendants' Fraud

413. DePuy's failure to implement requisite controls to ensure that its products were manufactured in conformance with their approved specifications resulted in sales of nonconforming implants to the Government.

414. One such device was implanted into patient "F.I.". On or about November 12, 2007, patient F.I. was implanted with a DePuy Pinnacle hip implant by

a surgeon at Stony Brook University Medical Center, 101 Nicolls Road, Stony Brook, New York 11794. The surgeon was, upon information and belief, Dr. "J.N.". In November 2007, Mr. F.I. received Medicaid insurance through HealthFirst, a managed care organization that provides government-sponsored health insurance plans in New York.

415. On information and belief, DePuy's surgical instructions and materials provided to Dr. J.N. regarding implantation of F.I. with the Pinnacle device represented that the device was a safe and effective hip implant device when implanted in accordance with such instructions.

416. DePuy's product label accompanying the Pinnacle device stated that the product was indicated for use as the acetabular component in total hip replacement procedures. On information and belief, under the heading "Information for Use," the product label stated that an "instrumentation system, as well as a system of trial components, is available to assure proper fit and alignment of the prosthesis" and that physicians should refer to the surgical technique manual on their use.

417. Within the Pinnacle's packaging, DePuy provided surgeons with Instructions for Use ("IFU") of the product. The IFU contained numerous false statements regarding the safety and efficacy of the Pinnacle MoM. The IFU stated, "An instrument system, as well as system of trial components, is available to assure proper fit and alignment of the prosthesis." The IFU also instructed the surgeon to "refer to the appropriate surgical technique manual on the use of the instrument system." In reality, surgeons could not achieve a proper fit and alignment of the prosthesis by using DePuy's tools and instructions.

418. Around the time of Mr. F.I.'s surgery, DePuy widely distributed the Ultamet Technical Monograph, a Pinnacle marketing material, throughout the United States. This pamphlet falsely stated that the Pinnacle MoM implants experienced reduced wear as compared to competing devices because of the purported benefit of their low diametrical clearances.

419. At the time of Mr. F.I.'s surgery, other safe and effective alternatives were widely available on the market. As alleged above, DePuy's marketing materials and device operating instructions claimed that the ASR and Pinnacle's lower failure rates and diametrical clearance specifications were superior to those competing products

420. On information and belief, but for DePuy's false statements, Dr. J.N. would have chosen a different available device for the hip replacement surgery he performed on Mr. F.I.

421. DePuy made these fraudulent false statements with knowledge or in reckless disregard of the fact that the Pinnacle's failure rates were far greater than represented and that the product consistently failed to conform to its diametrical clearance specifications.

422. DePuy further impliedly warranted that the hip implants were merchantable—fit to be used as hip implants—when it sold them to doctors. In order to qualify as merchantable under UCC § 2-314, products must:

> (1) pass without objection in the trade under the contract description; (2) in the case of fungible goods, be of fair average quality with the description; (3) be fit for the ordinary purposes for which such goods are used; (4) run, within the variations permitted by

> the agreement, of even kind, quality and quantity within each unit and among all units involved; (5) be adequately contained, packaged and labeled as the agreement may require; and (6) conform to the promises or affirmations of fact made on the container or label, if any.

423. As with Mr. F.I.'s ASR XL hip prosthesis, Mr. F.I's Pinnacle device quickly failed, as a result of manufacturing defects in the device, including non-conforming diametrical clearance dimensions. The failures resulted in great pain and suffering to F.I. and posed the possibility of additional revision surgery.

424. Mr. F.I's implantation with a Pinnacle device was neither medically reasonable nor medically necessary, because of the unreasonably high possibility that the device would fail and release metal ions into Mr. F.I.'s blood stream. No reasonable physician would implant a hip replacement device with a failure rate of 15% at five years.

425. DePuy knew that its manufacturing practices were resulting in these alarmingly high failure rates that rendered the Pinnacle device non-merchantable. Nevertheless, DePuy warranted that the devices were merchantable and fit for use.

426. In order to obtain Government reimbursement in connection with the procedure, Stony Brook University Medical Center and Dr. J.N. certified that Mr. F.I.'s Pinnacle device was reasonable and medically necessary for his treatment under 42 U.S.C. § 1395y(a)(1)(A). This certification was false as the implantation of a defective device is not a medically reasonable treatment.

427. Upon information and belief, on or about November 2007, Stony Brook University Medical Center submitted a claim to Medicaid for Mr. F.I.'s Pinnacle hip device and implant surgery. Medicaid paid for Stony Brook's hip device and implant surgery.

428.

429. In 2010, New York State's Federal Medical Assistance Percentage ("FMAP") was approximately 50%.

430. The United States paid approximately 50% of the costs associated with the implantation of Mr. F.I.'s Pinnacle device.

431. As a result of Pinnacle's defects—known but not disclosed by DePuy—and DePuy's false promises that the device was safe, effective, and medically appropriate, neither Mr. F.I. nor the Government received the benefit of their bargain with DePuy.

432. Without DePuy's false representations and warranties, Mr. F.I. would not have received a DePuy implant and the Government would not have expended funds on the device. If Dr. J.N. had been provided appropriate information showing the truth about the Pinnacle, Dr. J.N. would not have selected the Pinnacle implant for F.I.'s procedure. Similarly, had DePuy divulged what it knew about the Pinnacle, the Government would not have approved any claim for reimbursement for the costs of the system.

433. Mr. F.I.'s experience with DePuy is representative of thousands of similar patients across the United States.

434. During the times relevant to this complaint, over one million MoM hips were sold worldwide. Amongst the models manufactured at DePuy plants,

the Pinnacle MoM Hip was one of the most widely used hip replacement systems that remained in the international marketplace.

435. The United States constitutes almost two thirds of the world's orthopedic device market.

436. In 2010, over 300,000 hip replacement surgeries were performed in the United States.

437. Accordingly, it follows that hundreds of thousands of Pinnacle products were implanted in Government health care recipients and reimbursed by the Government during the lifespan of the product.

438. Between 2005 and 2010, New York State Medicaid paid for an average of approximately 1280 claims each year for total hip replacement devices.

439.

440. In 2010, New York State's Federal Medical Assistance Percentage ("FMAP") was approximately 50%.

441. Therefore, the United States paid an amount equivalent to New York State Medicaid to cover the total cost for each inpatient visit.

442. New York State Medicaid covers approximately 8% of all Medicaid beneficiaries in the United States. Therefore, thousands more Medicaid patients received total hip replacement devices in 2010, at an enormous cost to the Plaintiff States and the United States.

443. Although the proportion of MoM hip replacement devices on the United States market had begun to decline by 2010, according to the FDA, in 2010, a full 27% of all total hip replacement surgeries were MoM device surgeries.

444. During relevant periods, DePuy's two MoM hip implant products (the Pinnacle and the ASR XL) had captured 75% of the Metal on Metal hip replacements market. Prior to 2010, the Pinnacle constituted roughly 50% of DePuy's MoM hip replacement sales.

445. Given the August 2010 recall of the ASR, the Pinnacle would have constituted at least 70% of DePuy's Metal on Metal hip replacement sales.

446. Therefore, between 2005 and 2010, nearly 850 Pinnacle devices were purchased by New York State Medicaid.

447. As described herein, QA determined that DePuy's manufacturing process was incapable of consistently producing Pinnacle cups, heads, and liners that would meet the required diametrical clearance. QA's statistical analysis showed that the manufacturing process fails to produce explant heads within specification 14.93% of the time and 50.41% of the time for the explant liner.

448. Between 2005 and 2010, Relators estimate that nearly 425 Pinnacle devices bearing the diametrical clearance manufacturing defect would have been paid for by New York State Medicaid between 2005 and 2010.

449. As alleged herein, defects in the Pinnacle device, including the diametrical clearance manufacturing defect, were the cause of the Pinnacle's abnormally high failure rates.

450. The Pinnacle DOTS Study showed a greater than 14% failure rate for the Pinnacle Device at five years.

451. Therefore, between 2005 and 2010, nearly 130 Pinnacle devices paid for by New York State Medicaid would have failed in patients at 5 years.

452. The failure rate of the Pinnacle has been calculated to reach 21% at 9 years.

453. Many more Pinnacle devices purchased by New York Medicaid would fail in subsequent years. These failures would include many more of the 425 devices bearing the diametrical clearance manufacturing defect, as well as a many more devices bearing the surface roughness manufacturing defect.

454. DePuy's fraud caused the Government to pay for a grossly disproportionate number of MoM total hip replacement devices that were unfit for their intended use and worthless in patients.

455. In comparison to DePuy's approximately 1,280 implants paid for by New York Medicaid between 2005 and 2010, the remaining 25% MoM total hip replacement market share held by all of DePuy's competitors combined yielded approximately 425 implants paid for by New York Medicaid between 2005 and 2010.

456. Between 2005 and 2010, the standard failure rate for MoM THR in the industry was approximately 4%.

457. Therefore, between 2005 and 2010, a disproportionately large proportion of failed MoM hip implant devices were paid for by New York Medicaid were Pinnacle devices. Were it not for DePuy's false statements and fraudulent conduct, New York's Medicaid patients, including Mr. F.I., would have received hip implant devices substantially less prone to failure.

458. Medicare is the primary payor for hip implants, reimbursing between 55% and 60% of all hip implants in the United States.

459. In 2010 alone, the number of Medicare eligible people implanted with total hip replacement devices was 168,000.

460. Between 2005 and 2009, approximately 50,000 MoM total hip replacement devices were paid for by Medicare.

461. Based upon the Pinnacle's market share for MoM devices, approximately 18,750 of those patients' THR devices were Pinnacle devices, and approximately 31,250 were devices manufactured by all of DePuy's competitors combined.

462. Pinnacle's approximately 14% failure rate yielded 2,625 failed Pinnacle devices paid for by Medicare.

463. The 4% failure rate of all of DePuy's competitors combined yielded approximately 1,250 failed devices paid for by Medicare.

464. Therefore, Medicare paid for over twice as many failed DePuy MoM devices, including the Pinnacle device, than it paid for all failed MoM devices manufactured by all of DePuy's competitors combined.

465. Each and every failed Pinnacle device bearing a nonconforming diametrical clearance specification was unfit for sale and therefore worthless to the Government.

466. Pinnacle devices bearing a nonconforming surface roughness specification have an approximately 80% failure rate at 8 years.

467. Each and every failed Pinnacle device bearing a nonconforming surface roughness specification was unfit for sale and therefore worthless to the Government.

468. Each and every Pinnacle device that was manufactured using DePuy's flawed manufacturing process was unfit for sale and therefore worthless to the government.

469. Therefore, the Government paid for as many as hundreds of thousands of false claims submitted or caused to be submitted by DePuy, costing taxpayers hundreds of millions of dollars.

470. Each and every revision surgery paid for by the Government that was performed on a Pinnacle patient whose device failed would not have been paid for by the Government but for DePuy's fraudulent conduct.

471. Each and every replacement hip implant paid for by the Government following a revision surgery on a Pinnacle patient whose device failed would not have been paid for by the Government but for DePuy's fraudulent conduct.

472. Therefore, the Government paid for thousands of revision surgeries and replacement implants that it would not have paid for but for the acts of DePuy alleged herein, costing taxpayers still many more millions of dollars.

B. The Department of Veterans' Affairs Paid False Claims As a Result of DePuy's Fraud

* * *