APPENDIX

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Appendix A

UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

No. 16-1442

UNITED STATES, ex rel., ANTONI NARGOL AND DAVID LANGTON; STATE OF ARKANSAS, STATE OF CALIFORNIA, CITY OF CHICAGO, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF FLORIDA, STATE OF GEORGIA, STATE OF HAWAII, STATE OF ILLINOIS, STATE OF INDIANA, STATE OF IOWA, STATE OF LOUISIANA, STATE OF MARYLAND, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF MONTANA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF NEW YORK, STATE OF NORTH CAROLINA, STATE OF OKLAHOMA, STATE OF RHODE ISLAND, STATE OF TENNESSEE, STATE OF TEXAS, COMMONWEALTH OF VIRGINIA, STATE OF WISCONSIN, COMMONWEALTH OF MASSACHUSETTS, CITY OF NEW YORK, STATE OF NEW HAMPSHIRE, STATE OF MISSOURI, STATE OF WASHINGTON, ex rel., ANTONI NARGOL AND DAVID LANGTON,

Plaintiffs-Appellants,

v.

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

Defendants-Appellees.

Appeal from the United States District Court for the District of Massachusetts

Hon. F. Dennis Saylor IV, U.S. District Judge

July 26, 2017

Before Torruella, Thompson, and Kayatta, Circuit Judges.

KAYATTA, Circuit Judge. In this action brought by two private individuals under the False Claims Act ("FCA"), 31 U.S.C. § 3729, and various state analogues, we review de novo the dismissal of a complaint under Federal Rules of Civil Procedure 9(b) and 12(b)(6). Applying and extending our holding in *United States ex rel. D'Agostino v. ev3, Inc.*, 845 F.3d 1 (1st Cir. 2016), we affirm the dismissal of the complaint to the extent it relies on the alleged falsity of statements made by the product manufacturer in securing approval from the U.S. Food and Drug Administration ("FDA") to market a hip-replacement device. At the same time, we reverse the district court's dismissal of the complaint to the extent it rests on allegations that the manufacturer palmed off latently defective versions of its FDA-approved product on unsuspecting doctors who sought government reimbursement for the defective products.

I. Background

Doctors Antoni Nargol and Robert Langton (together, "Relators") claim to be experts in hip-replacement techniques and devices. They brought this qui tam suit in May 2012 against DePuy

Orthopaedics, Inc., DePuy, Inc., and Johnson & Johnson Services, Inc. (collectively, "DePuy") and filed an amended complaint under seal in November 2013. As in all other qui tam actions under the FCA, *see Vt. Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 769 (2000), the U.S. Department of Justice was given time to conduct an investigation to determine whether the United States would intervene. In July 2014, it declined to do so. Relators then filed a second amended complaint (for our purposes, the "complaint") in May 2015. This is the complaint we now review, because it was the one the district court found lacking and dismissed with prejudice. Quite unhelpfully, it is 168 pages long and contains over 800 paragraphs of allegations, from which we distill the following:

Total hip replacement surgery involves replacing the bone components of the joint—the ball-like femoral head and the cup-like acetabulum—with artificial substitutes. In addition, a standard prosthetic hip replaces the bit of femur directly below the femoral head with an artificial "femoral stem," the top of which is connected to a "trunnion" that inserts into a "taper" in the artificial head (this union is known as the "taper trunnion" or the "taper junction"). Hip replacements also typically include liners that form a buffer between the artificial cup and the artificial head. The particular hip-replacement device at issue on this appeal is a so-called metal-on-metal ("MoM") device employing a metal artificial acetabular cup and a metal artificial femoral head. DePuy marketed the device under its "Pinnacle" product line. We will use the name "Pinnacle MoM

device" to refer to this device, as distinguished from other DePuy hip-replacement devices.

To ensure that hip-replacement devices work properly and do not unexpectedly degrade over time, all of the components must be carefully designed and manufactured to be consistently and correctly sized, shaped, and smoothed. This is especially true for MoM devices because any time two metal components of an MoM device put pressure on or rub against one another, tiny metal shavings can make their way into the recipient's bloodstream, causing pain and Adverse Response to Metal Debris (ARMD), a soft-tissue reaction similar to a tumor, and requiring medical treatment or "revision" surgery (a surgery in which a hip-replacement device must itself be replaced). Friction between components of an MoM device can also cause the artificial cup to prematurely loosen, and can cause the device to corrode, leading to the same type of pain and difficulty walking that gave rise to the need for hip arthroplasty in the first place.

In December 2000, DePuy received FDA approval under section 510(k) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360e(b)(1)(B)(ii), to market and sell the Pinnacle MoM device. Ordinarily, a medical device like the Pinnacle MoM device would be required to undergo an extensive premarket approval process. The Pinnacle MoM device, however, was approved by way of a different, less arduous process because DePuy represented to the FDA that the Pinnacle MoM device was "substantially equivalent" to the "ASR," an earlier MoM hip-replacement device for which DePuy had previously received premarket approval. Although Relators describe both the ASR

and the Pinnacle MoM device throughout their complaint, only the Pinnacle MoM device is at issue in this case.

Relators allege two types of fraud in DePuy's marketing of the Pinnacle MoM device. First, Relators allege that DePuy made a series of false statements to the FDA and doctors, but for which the FDA would not have approved the Pinnacle MoM device for hip replacements or would have withdrawn that approval, and doctors would not have certified the devices for government reimbursement. Second, Relators allege that DePuy falsely palmed off devices that, due to latent manufacturing defects, materially deviated from the design specification of the FDA-approved Pinnacle MoM device.

The alleged manufacturing defects at issue are of two types. One defect occurred when the sizes as manufactured of the artificial femoral head and its acetabular cup caused them to fit too snugly, impeding the cushioning intervention of bodily fluid that precluded the head and cup from rubbing directly against each other. According to the complaint, "DePuy's manufacturing process fail[ed] to produce implant heads within specification 14.93% of the time and implant liners 50.41% of the time." The second defect occurred when the surface of the taper trunnion that interacted with the taper emerged from the manufacturing process with too much roughness. This roughness increased friction and the shedding of small metal debris when the trunnion moved against the taper. Over fifty percent of the Pinnacle MoM devices as sold allegedly suffered from this defect and were "well outside of their required manufacturing

specifications." Combined with the first defect, it caused the devices sold as Pinnacle MoM devices to have a five-year failure rate of nearly fifteen percent, as compared to a five-year failure rate of 4.5% or lower as claimed by DePuy (and characteristic of or superior to the failure rates of other competing devices).

Relators allege that DePuy made direct claims to the federal government and various state governments seeking payment for some of the defectively manufactured Pinnacle MoM devices. They also allege that DePuy was indirectly responsible for the claims for payment that healthcare providers submitted to the federal and state governments for reimbursement for defectively manufactured Pinnacle MoM devices that the healthcare providers had purchased from DePuy.

The district court found that Relators failed to plead false claims under either the FCA or the cited state-law versions of the FCA with the particularity required by Federal Rule of Civil Procedure 9(b). *See United States ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 159 F. Supp. 3d 226, 248-55, 259-60 (D. Mass. 2016).[1] In so finding, the district court bifurcated its analysis by focusing first on all direct claims submitted by DePuy to the government, and then on indirect claims made through health care providers. The court found that the complaint's allegations

[1] The district court also dismissed Relators' claim that DePuy and its officers and employees conspired to defraud the government in violation of 31 U.S.C. § 3729(a)(1)(C), a claim the court determined was not cognizable. *See Nargol*, 159 F. Supp. 3d at 258-59. Relators have not challenged on appeal the district court's ruling on this issue.

concerning "direct" claims for payment that DePuy allegedly submitted to the Department of Veterans Affairs, the Naval Medical Center, and the Department of the Army failed to plead that the claims for government payment were for the Pinnacle MoM device at issue in this suit (as opposed to other hip-replacement devices) and failed to identify any specific false claims. *See id*. at 247-52. As for the "indirect" false claims for payment that DePuy caused others to submit, the district court found that Relators failed to identify even a single representative false claim for payment for a defective Pinnacle MoM device, and that the complaint did not cite sufficient "other factual and statistical evidence to strengthen the inference of fraud beyond a mere possibility." *Id*. at 252. Noting that the case had been pending for nearly four years and that Relators, even after their third try at drafting a compliant complaint, had yet to particularly plead a cognizable claim for relief under the FCA, the district court dismissed the complaint with prejudice, entered judgment in favor of DePuy, and rejected Relators' motion to reconsider its judgment by allowing the filing of a third amended complaint. *Id*. at 262.

Relators now appeal. They argue that the district court should have found that they plausibly and particularly alleged that every claim submitted to the government for payment, directly or indirectly, was false because the Pinnacle MoM device was dangerously designed. They also contend that the district court erred in dismissing their claims arising out of indirect sales because the Rule 9(b) requirements for pleading fraud in connection with government reimbursements of intermediary parties

is "more flexible," *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 30 (1st Cir. 2009) (quoting *United States ex rel. Gagne v. City of Worcester*, 565 F.3d 40, 46 (1st Cir. 2009)), than the district court realized. Relators further argue that the district court erred in denying them leave to amend their complaint a third time, and in rejecting their motion to reconsider that denial.

II. Discussion

A.

Rather than initially separating Relators' allegations into those involving "direct" false claims for government payment and those involving "indirect" false claims, we focus first on all of Relators' claims, whether direct or indirect, that rest on the allegation that DePuy misrepresented the safety and effectiveness of the product's design in order to secure or maintain FDA approval for the Pinnacle MoM device. We recently dealt with an analogous claim in *D'Agostino*, in which we held that "the FDA's failure actually to withdraw its approval of [the device at issue] in the face of [the relator's] allegations precludes [the relator] from resting his claims on a contention that the FDA's approval was fraudulently obtained." 845 F.3d at 8. The claim in this case is not quite on all fours with the claim we confronted in *D'Agostino* because the FDA does not independently assess the safety and effectiveness of a medical device that qualifies for approval under section 510(k). *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493 (1996). Rather, the process under section 510(k) allows a device manufacturer to piggyback on the full-scale review and approval of another device by

demonstrating that the new device is "'substantially equivalent' to a predicate device" which itself may be marketed pending the completion of a full premarket approval process. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 345 (2001) (quoting 21 U.S.C. § 360e(b)(1)(B)).

Nevertheless, the process constitutes the government's method of determining whether a device is safe and effective as claimed. That determination is what makes the product marketable, and Relators offer no suggestion that government reimbursement rules require government health insurance programs to rely less on section 510(k) approval than they do other forms of FDA approval. The FDA, in turn, possesses a full array of tools for "detecting, deterring, and punishing false statements made during … approval processes." *Id.* at 349. Its decision not to employ these tools in the wake of Relators' allegations so as to withdraw or even suspend its approval of the Pinnacle MoM device leaves Relators with a break in the causal chain between the alleged misstatements and the payment of any false claim. *D'Agostino*, 845 F.3d at 8. It also renders a claim of materiality implausible. *See id.* at 7. The FCA's "materiality standard is demanding." *Universal Health Servs., Inc. v. United States*, 136 S. Ct. 1989, 2003 (2016). Even in an ordinary situation not involving a misrepresentation of regulatory compliance made directly to the agency paying a claim, when "the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material." *Id.* Such very strong evidence becomes compelling when an agency armed

with robust investigatory powers to protect public health and safety is told what Relators have to say, yet sees no reason to change its position. In such a case, it is not plausible that the conduct of the manufacturer in securing FDA approval constituted a material falsehood capable of proximately causing the payment of a claim by the government. Ruling otherwise would "turn the FCA into a tool with which a jury of six people could retroactively eliminate the value of FDA approval and effectively require that a product largely be withdrawn from the market even when the FDA itself sees no reason to do so." *D'Agostino*, 845 F.3d at 8.

Here, as in *D'Agostino*, there is no allegation that the FDA withdrew or even suspended product approval upon learning of the alleged misrepresentations. To the contrary, the complaint alleges that Relators told the FDA about every aspect of the design of the Pinnacle MoM device that they felt was substandard, yet then FDA allowed the device to remain on the market until DePuy, on its own volition, discontinued the device in 2013. There are allegations that an FDA official sent a letter in 2005 that "imposed an affirmative obligation on DePuy to provide the FDA with updated information if … data indicated that DePuy's 'change or modification to the device or its labeling could significantly affect the device's safety or effectiveness and thus require submission of a new 510(k),' " and that a 2011 FDA Establishment Inspection Report concerning a DePuy plant in Indiana determined that DePuy was not adequately reporting adverse events or investigating complaints of device failure. Such evidence does show that the FDA was paying attention. But the lack of any further

action also shows that the FDA viewed the information, including that furnished by Relators, differently than Relators do.

Admittedly, the complaint does seem to posit a second twist that we did not encounter in *D'Agostino*: In theory, a product may be sufficiently "safe" and "effective" to secure FDA approval for a given use, 21 U.S.C. § 360e(d)(2), yet its use might nonetheless not be sufficiently "reasonable and necessary" for patient care to warrant Medicare reimbursement for its use, 42 U.S.C. § 1395y(a)(1)(A). *See United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 487-88 (3d Cir. 2017); *Int'l Rehab. Sci. Inc. v. Sebelius*, 688 F.3d 994, 1002 (9th Cir. 2012) ("FDA clearance … is *necessary*, but not *sufficient*, for Medicare coverage. FDA review and Medicare coverage review have different purposes." (citations omitted)); *Almy v. Sebelius*, 679 F.3d 297, 308 (4th Cir. 2012) (approving Secretary's decision not to reimburse because device was not "reasonable and necessary," despite device's approval under section 510(k)). Assuming that to be so, then it is possible that a particular attribute of a product would not be required to secure FDA approval, yet it would be necessary to secure reimbursement. In such circumstances, a manufacturer's false statement that its product possesses such an attribute might in theory both cause the presentment of a claim and be material to the government's decision to pay the claim in a way that involves no second guessing of the government's still-extant FDA approval of the product.

In Relators' complaint, this theory takes the form of allegations that DePuy told doctors that the

Pinnacle MoM device had a failure rate of 0.1% at five years, as opposed to the more modest 4%-4.5% claimed in DePuy's FDA filings. The complaint is devoid of particularized allegations, though, that any doctor submitted a claim he or she would not have submitted if DePuy's 0.1%-failure-rate boast had not been made. More importantly, Relators level no allegation that the difference between 0.1% and 4%-4.5% was the difference between being reimbursable by the government (as "reasonable and necessary") and not being reimbursable. Rather, on that crucial point the complaint admits that a 4%-4.5% failure rate would suffice because it is less than the five-percent maximum failure rate provided under industry guidelines, and alleges only that the true five-year failure rate (purportedly much greater than five percent) rendered the product not reasonable and necessary. And *that* allegation (as far as the design-defect-based claims are concerned) simply runs Relators back into their claim that DePuy misled the FDA to obtain or maintain approval for the Pinnacle MoM device.

Relators additionally argue that their causal theory posits a chain running not just through the FDA, but also directly from DePuy to doctors precisely because DePuy repeated to doctors the statements it made to the FDA. We see no reason, though, why such a likely and customary repetition of the statements made to the FDA renders it more plausible that a materially false statement caused the payment of a claim that would not have been made otherwise. The government, having heard what Relators had to say, was still paying claims not because of what was said to or by the doctors, but because the government

through the FDA affirmatively deemed the product safe and effective. And, absent some action by the FDA, we can see no plausible way to prove to a jury that FDA approval was fraudulently procured. *See D'Agostino*, 845 F.3d at 8.

Finally, Relators seem to suggest that we should revisit our holding in *D'Agostino* because a panel in the Ninth Circuit recently reversed the dismissal of an FCA claim predicated in part on allegations that the defendant misled the FDA. *See United States ex rel. Campie v. Gilead Scis., Inc.*, No. 15-16380, 2017 WL 2884047, at *13 (9th Cir. July 7, 2017). Of course, one panel of this court may not revisit the holding of a prior panel merely because another circuit disagrees. In any event, we find nothing in *Campie* to warrant revisiting *D'Agostino*. The example of a valid claim given in *Campie*[2], see *id.* at *10 n.8, would be a valid claim under *D'Agostino* too, since it rests not on lying to the FDA but rather on palming off one product as another. Additionally, the record in *Campie* lacked what we have here: a situation in which the FDA was not alleged to have ever withdrawn its approval, even long after it acquired full knowledge of Relators' claims. *Id.* at *11. Otherwise, *Campie* offers no rebuttal at all to *D'Agostino*'s observation that six jurors should not be able to overrule the FDA. *See D'Agostino*, 845 F.3d at 8. And it offers no solution to the problems of proving that the FDA would have made a different approval decision in a situation where a fully informed FDA has not itself even hinted at doing anything. Instead, it decides not to deem these problems to be fatal on a Rule 12(b)(6) motion,

[2] Supplying FDA-approved Tylenol rather than Atripla.

even if, apparently, no plausible solutions can be envisioned, even in theory.

For these reasons, the district court did not err in dismissing any claim based on Relators' design-defect theory of fraud.[3]

B.

We now arrive at Relators' principal theory of fraud raised on this appeal: that DePuy often sold to health care providers a defectively manufactured product that materially differed from the device the FDA approved. Specifically, Relators point to the allegations in their complaint that, based 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." This theory—that DePuy got FDA approval for a device and then palmed off a defective version of that device both directly on the government itself and on unsuspecting doctors and patients, who then submitted claims for payment to unsuspecting government payors—is a

[3] The district court dismissed these claims for failure to plead them with the particularity required under Rule 9(b). *See Nargol*, 159 F. Supp. 3d at 255. Relators urge us to vacate and remand so that the district court can consider whether the complaint complies with Rule 12(b)(6). We are not bound, however, by the reasoning of the district court, and we "may affirm an order of dismissal on any ground evident from the record." *MacDonald v. Town of Eastham*, 745 F.3d 8, 11 (1st Cir. 2014).

theory of actionable misconduct under the FCA, to which *D'Agostino* poses no impediment. *See, e.g.*, *Universal Health Servs.*, 136 S. Ct. at 2001-02. The key question is whether this theory has been pled with the requisite particularity.

The complaint in this case contains a description of just one actual sale of a defectively manufactured product to a provider that sought government reimbursement. Specifically, the complaint alleges that a surgeon at Stony Brook University Medical Center in New York implanted a Pinnacle MoM device in a patient in November 2007. The device failed "as a result of manufacturing defects in the device, including nonconforming diametrical clearance dimensions." Not knowing that the device was defectively manufactured, "Stony Brook University Medical Center submitted a claim to Medicaid for [the patient's] Pinnacle hip device and implant surgery."

The district court observed that the complaint alleges no "specific representations or materials that the doctor received and relied upon, nor does it allege the specific DePuy device for which the doctor filed a claim." *Nargol*, 159 F. Supp. 3d at 254. 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.

The question remains, however, whether identifying this single exemplar false claim is sufficient to clear the hurdle imposed by Federal Rule of Civil Procedure 9(b). Rule 9(b) applies because FCA actions sound in fraud. *See United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 228 (1st Cir. 2004), *abrogated on other grounds by Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662 (2008); *see generally* John T. Boese, *Civil False Claims and Qui Tam Actions* § 5.04[C] (4th ed. 2016) (collecting cases). FCA complaints must therefore "state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b).

The drafters of Rule 9(b) left us only a few hints of the purposes sought to be furthered by the rule. The 1937 advisory committee notes state only: "See *English Rules Under the Judicature Act* (The Annual Practice, 1937) O. 19, r. 22." Fed. R. Civ. P. 9(b) advisory committee's note (1937) . That source, while voicing a roughly similar rule,[4] offers no express insight into the rule's purpose. Nor does further excavation provide any firm evidence of what the drafters of our Federal Rules of Civil Procedure meant to accomplish with the words they used. *See generally* Christopher M. Fairman, *An Invitation to the Rulemakers-Strike Rule* 9(b), 38 U.C. Davis L. Rev. 281, 287 (2004). The only other tidbit gleaned by academic review of the rule's provenance is that Judge

[4] "Fraud must be distinctly alleged and proved. The acts alleged to be fraudulent must be stated, otherwise no evidence in support of them will be received." Jeff Sovern, *Reconsidering Federal Rule 9(b): Do We Need Particularized Pleading Requirements in Fraud Cases?*, 104 F.R.D. 143, 146 n.19 (1985).

Charles E. Clark, the advisory committee's first reporter, once opined that "[w]hile useful, this rule probably states only what courts would do anyhow and may not be considered absolutely essential." *Id.* (quoting Charles E. Clark, *Simplified Pleading*, 2 F.R.D. 456, 463-64 (1943)).

Like nature upon encountering a vacuum, courts have since filled this gap with a list of purposes inferred to be the objects of the rule's aim. In our own circuit, we have ascribed to Rule 9(b) the purposes of "[giving] notice to defendants of the plaintiffs' claim, [protecting] defendants whose reputation may be harmed by meritless claims of fraud, [discouraging] 'strike suits,' and [preventing] the filing of suits that simply hope to uncover relevant information during discovery." *Karvelas*, 360 F.3d at 226 (quoting *Doyle v. Hasbro, Inc.*, 103 F.3d 186, 194 (1st Cir. 1996)). To this list the Fifth Circuit has added the purpose of ensuring that qui tam complaints include only as-yet nonpublic information that the government may need in order to decide whether to take the case over. *United States ex rel. Russell v. Epic Healthcare Mgmt. Grp.*, 193 F.3d 304, 308-09 (5th Cir. 1999).[5]

The circuits have varied, though, in their statements of exactly what Rule 9(b) requires in a qui tam action. Of most relevance here, a consensus has yet to develop on whether, when, and to what extent a relator must state the particulars of specific examples of the type of false claims alleged. *See Foglia v. Renal*

[5] To be precise, this purpose would seem to be less a purpose for Rule 9(b) and more a policy reason for applying it to qui tam complaints. Whether the FCA supports such a policy we need not decide.

Ventures Mgmt., LLC, 754 F.3d 153, 155-56 (3d Cir. 2014) (surveying circuits).

Following the lead of the Eleventh Circuit, our circuit staked out its general position in *Karvelas*, which concerned allegations that a hospital subverted government standards but claimed it was in full compliance when it billed Medicare and Medicaid for services rendered. 360 F.3d at 223. As we explained:

> In a case such as this, details concerning the dates of the claims, the content of the forms or bills submitted, their identification numbers, the amount of money charged to the government, the particular goods or services for which the government was billed, the individuals involved in the billing, and the length of time between the alleged fraudulent practices and the submission of claims based on those practices are the types of information that may help a relator to state his or her claims with particularity. These details do not constitute a checklist of mandatory requirements that must be satisfied by each allegation included in a complaint. However, like the Eleventh Circuit, we believe that "some of this information for at least some of the claims must be pleaded in order to satisfy Rule 9(b)."

Id. at 233 (quoting *United States ex rel. Clausen v. Lab. Corp. of Am.*, 290 F.3d 1301, 1312 n.21 (11th Cir. 2002)); *see United States ex rel. Ge v. Takeda Pharm. Co.*, 737 F.3d 116, 123-25 (1st Cir. 2013).

In applying this general rule over time, we have nevertheless recognized at least one exception to the

expectation that a relator should be able to allege the essential particulars of at least some actual false claims that were in fact submitted to the government for payment. "[W]e have … recognized a difference between *qui tam* actions alleging that the defendant made false claims to the government and those alleging that the defendant induced third-parties to file false claims with the government." *Lawton ex rel. United States v. Takeda Pharm. Co.*, 842 F.3d 125, 130 (1st Cir. 2016) (citing *Duxbury*, 579 F.3d at 29). We apply a "more flexible" standard in actions of the latter, indirect type: where the defendant allegedly "induced *third parties* to file false claims with the government … a relator could 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." *Duxbury*, 579 F.3d at 29 (quoting *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 733 (1st Cir. 2007)); *see Ge*, 737 F.3d at 123-24. Such evidence must pair the details of the scheme with "reliable indicia that lead to a strong inference that claims were actually submitted." *Id.* (quoting *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009)).

Seeking to take advantage of this increased flexibility for indirect claims, relators in actions alleging unlawful, off-label marketing of prescription drugs have often sought to rely on the following reasoning: Drug was approved for Use X; Company successfully marketed it also for Use Y; lots of Drug has been prescribed in the United States; a significant number of U.S. patients are covered by government insurance; therefore it is rational to assume that some

payments for off-label use of Drug have been made or reimbursed by the government.

Rost was the first case in which we considered this line of reasoning. We agreed that the claimed inference generated by such reasoning was "not irrational." *Rost*, 507 F.3d at 732. The strength of the inference, though, depended on an unstated assumption that physicians or patients would improperly seek government reimbursement for the off-label prescription, rather than paying out-of-pocket. And the record in *Rost* showed that, in fact, "[i]n most, if not all, instances," patients paid out-of-pocket for off-label prescriptions. *Id.* (alteration in original). Accordingly, the inference that false claims were filed rose to the level of a "possibility" only. *Id.* at 733. This holding has controlled our subsequent disposition of qui tam pleadings in at least four other cases alleging unlawful marketing for off-label uses or off-label dosages. *See, e.g.*, *United States ex rel. Booker v. Pfizer, Inc.*, 847 F.3d 52, 57-58 (1st Cir. 2017); *D'Agostino*, 845 F.3d at 11; *Lawton*, 842 F.3d at 132; *United States ex rel. Kelly v. Novartis Pharm. Corp.*, 827 F.3d 5, 15 (1st Cir. 2016).[6]

In one instance, on de novo review we did reverse a Rule 9(b) dismissal of a qui tam action. *See Duxbury*, 579 F.3d at 32. The fraudulent scheme alleged in

[6] Of course, our case selection is quite skewed because we generally only see the weaker complaints. This is because almost all of the qui tam cases that reach our court are ones in which a capable district court, after briefing, has found the complaint lacking. Conversely, rulings sustaining the sufficiency of the stronger complaints are generally not appealable until after final judgment, and few complex civil cases go the whole nine yards.

Duxbury involved the payment of kickbacks to health care providers in a manner designed to artificially inflate the reported price of a pharmaceutical product. *Id*. at 17. The kickbacks took the form, in large part, of free product given to providers "so that" they could submit the free product for reimbursement at the reported price, pocketing the payment. *Id*. at 31. The relator did "not identify specific claims." *Id.* at 30. He did, however, identify "as to each of … eight medical providers (the who), the illegal kickbacks (the what), the rough time periods and locations (the where and when), and the filing of the false claims themselves." *Id.* These allegations were sufficient to show "that false claims were in fact filed by the medical providers [the relator] identified, which further support[ed] a strong inference that such claims were also filed nationwide." *Id*. at 31.

What most distinguishes *Duxbury* from our off-label marketing cases is the nature of the conspiracy. In *Rost*, we found no strong reason to believe that patients provided drugs for off-label use would seek reimbursement where the use was not eligible for reimbursement. *Rost*, 507 F.3d at 732. In *Duxbury*, though, the entire purpose of giving doctors free product was so that they would seek reimbursement to realize the kickback. *Duxbury*, 579 F.3d at 31. The alleged scheme would have made little sense had reimbursement not been sought. And the added detail about transactions involving eight providers, while not claim-specific within the sense described in *Karvelas*, made the filing of some claims "beyond possib[le]." *Id.* (quoting *Rost*, 507 F.3d at 733).

Here, Relators press yet a third type of alleged fraud, which involves neither off-label marketing nor kickbacks. The fraudulent scheme alleged here—after our rejection of claims based on the FDA-approved product design—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. *Cf. D'Agostino*, 845 F.3d at 12 (finding insufficient a pleading that false claims were likely submitted for government payment for defectively manufactured devices because the complaint alleged not "a latent manufacturing defect that manifested itself only after the surgery was completed and the claim for reimbursement submitted," but rather a "defect [that] caused the device to fail as the surgeons tried to use it, and thus before any claim for reimbursement might have been submitted"). 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.[7]

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. In short, we have in this case a complaint that alleges the details of a fraudulent scheme with "reliable indicia that lead to a strong inference that claims were actually submitted," *Duxbury*, 579 F.3d at 29 (quoting *Grubbs*, 565 F.3d at

[7] For example, the complaint alleges that approximately 18,750 Pinnacle MoM devices were sold to Medicare patients alone between 2005 and 2009, and that those patients made up roughly half of the total number of people who received Pinnacle MoM devices during that timeframe.

190), for government reimbursement from the United States and from the state of New York.[8]

C.

While the foregoing suffices to sustain Relators' claims under the FCA[9] and New York's state-law analogue for indirect false claims for government payment, it does not sustain Relators' claims alleging that DePuy directly submitted false claims for

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[8] Whether the one pleaded example offered here is necessary we need not and do not decide.

[9] This includes both count 1 (alleging that DePuy violated 31 U.S.C. § 3729(a)(1)(A)) and count 2 (alleging that DePuy violated 31 U.S.C. § 3729(a)(1)(B)). As Relators observe, the district court stated: "The First Circuit has distinguished pleading standards for direct claims, or sales to the government, which are governed by 31 U.S.C. § 3729(a)(1)(A), from indirect claims to the government where a defendant causes third-parties to submit false claims, which are governed by 31 U.S.C. § 3729(a)(1)(B)." *Nargol*, 159 F. Supp. 3d at 252. This is incorrect: neither § 3729(a)(1)(A) nor § 3729(a)(1)(B) applies only to direct or indirect claims for government payment. Section 3729(a)(1)(A) imposes liability on defendants who directly "present[] … a false or fraudulent claim for payment or approval," and defendants who indirectly "cause[] to be presented[] a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). Likewise, section 3729(a)(1)(B) similarly prohibits both directly "mak[ing or] us[ing] … a false record or statement material to a false or fraudulent claim" and "caus[ing] to be made or used[] a false record or statement material to a false or fraudulent claim." *Id.* § 3729(a)(1)(B). Relators allege that doctors certified to Medicare that the device they implanted was reasonable and necessary for patient care because it was the Pinnacle MoM device that the FDA had approved, and that such certifications were frequently false because manufacturing defects made the implanted device materially different from the one the FDA approved. This is sufficient to particularly plead a cause of action under both § 3729(a)(1)(A) and § 3729(a)(1)(B).

payment to the government, or any of Relators' claims at all under the other state laws cited in the complaint. With regard to direct claims, Relators make no argument that the "more flexible" standard articulated in *Duxbury* and *Gagne* applies, or that their allegations satisfactorily plead the transactional particulars required under *Karvelas*. They argue only that they need offer no transactional particulars because all sales were fraudulent. Yet, Relators themselves concede that not all of the Pinnacle MoM devices were manufactured defectively, and we have in turn rejected their argument that their design-defect theory works. In short, this is not a case in which every claim for payment was by definition fraudulent, so we need not decide how we might rule in such a case.

With respect to payments by states other than New York, Relators for the most part have made conclusory allegations that state and municipal analogues to the FCA were violated when claims for reimbursement were submitted for covered patients in a handful of states and municipalities, but the complaint does nothing to allege that Pinnacle MoM devices were advertised to and implanted by physicians in Arkansas, California, Colorado, Chicago, or any other state or municipality except for the state of New York. Relators do not allege that DePuy made the Pinnacle MoM device available to surgeons and their patients in those places, much less how many of such devices (if any) were ordered and implanted in patients, how many total-hip-replacement surgeries (if any) were performed in these places, or how many people in these places were covered by government healthcare programs during the relevant timeframe.

The exception, again, is New York. Relators do allege that between 2005 and 2010, "New York State Medicaid paid for an average of approximately 1280 claims each year for total hip replacement devices," fifty percent of each of which the United States paid; that MoM hip-replacement devices made up a large percentage of devices being prescribed and installed during that time; and that given both DePuy's general market share and the specific market share of the Pinnacle MoM device, "nearly 425 Pinnacle devices bearing the diametrical-clearance manufacturing defect would have been paid for by New York State Medicaid," and the United States, "between 2005 and 2010." This is enough for Relators' manufacturing-defect-based indirect claims under New York's analogue to the FCA to satisfy Rule 9(b)'s particularity requirement.

D.

Finally, Relators argue that the district court should have permitted them leave to amend so that they could file yet another (i.e., a fourth) version of their complaint that would comply with the strictures of Rules 9(b) and 12(b)(6). *But see In re Biogen Inc. Sec. Litig.*, 857 F.3d 34, 45 (1st Cir. 2017) (explaining that we review denials of motions to amend and for reconsideration for abuse of discretion, discouraging "any expectation that there will be leisurely repeated bites at the apple" (internal citation omitted)). Relators contend that they made this request both before and after the district court entered judgment against them, first by seeking leave to amend under Rule 15(a) and then by seeking reconsideration and leave under Rules 59 and 60.

The relevant gist of the proposed fourth complaint is the addition of transactional particulars for some indirect claims for government payment for Pinnacle MoM devices. Those details do nothing to overcome the defect in Relators' fraud-on-the-FDA, design-defect claims, or the absence of transactional particulars for the alleged direct claims that Relators do not argue are within *Duxbury*'s "more flexible" exception to the requirements of *Karvelas*. The proposed amendments are also unnecessary to rescue the manufacturing-defect claims under federal and New York state law that we have already found were properly pleaded. And they do nothing to cure the defects we have identified in Relators' claims under the laws of other states. In short, the proposed amended complaint is either futile or redundant.

III. Conclusion

We *vacate* the dismissal of Relators' claims that DePuy caused physicians to submit claims to the United States and New York for payment for Pinnacle MoM devices that did not materially comport with the specifications of the FDA approval for those devices in violation of the FCA, 31 U.S.C. § 3729(a)(1)(A)-(B) (counts 1 and 2), and its New York state analogue, N.Y. State Fin. Law § 189(1)(a)-(b) (count 27). We *affirm* the dismissal of all other claims, and of the denial of further requests to amend the complaint. We *remand* the case solely for resolution of the surviving claims. All parties shall bear their own costs on this appeal.

Appendix B

UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

No. 16-1442

UNITED STATES, ex rel., ANTONI NARGOL AND DAVID LANGTON; STATE OF ARKANSAS, STATE OF CALIFORNIA, CITY OF CHICAGO, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF FLORIDA, STATE OF GEORGIA, STATE OF HAWAII, STATE OF ILLINOIS, STATE OF INDIANA, STATE OF IOWA, STATE OF LOUISIANA, STATE OF MARYLAND, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF MONTANA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF NEW YORK, STATE OF NORTH CAROLINA, STATE OF OKLAHOMA, STATE OF RHODE ISLAND, STATE OF TENNESSEE, STATE OF TEXAS, COMMONWEALTH OF VIRGINIA, STATE OF WISCONSIN, COMMONWEALTH OF MASSACHUSETTS, CITY OF NEW YORK, STATE OF NEW HAMPSHIRE, STATE OF MISSOURI, STATE OF WASHINGTON, ex rel., ANTONI NARGOL AND DAVID LANGTON,

Plaintiffs-Appellants,

v.

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

Defendants-Appellees.

Before
Howard,* *Chief Judge*,
Torruella, Lynch,** Thompson,
Kayatta and Barron, *Circuit Judges*

Entered: September 27, 2017

ORDER OF COURT

The petition for rehearing having been denied by the panel of judges who decided the case, and the petition for rehearing en banc having been submitted to the active judges of this court and a majority of the judges not having voted that the case be heard en banc, it is ordered that the petition for rehearing and the petition for rehearing en banc be denied.

By the Court:

/s/ Margaret Carter, Clerk

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* Chief Judge Howard is recused and did not participate in the consideration of this matter.

** Judge Lynch is recused and did not participate in the consideration of this matter.

Appendix C

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

Civil Action No. 12-10896-FDS

UNITED STATES OF AMERICA *et al. ex rel.*
ANTONI NARGOL and DAVID LANGTON,

Plaintiffs,

v.

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

Defendants.

Filed: February 2, 2016

MEMORANDUM AND ORDER
ON MOTION TO DISMISS

SAYLOR, J.

This is a *qui tam* action alleging the submission of false claims to government health-care programs for a defective hip-replacement device. Relators Dr. Antoni Nargol and Dr. David Langton, who are expert witnesses in a related products-liability case involving the same device, have brought suit against defendants DePuy Orthopaedics, Inc., DePuy, Inc., and Johnson

& Johnson Services, Inc.1 DePuy manufactured and sold, among other hip-replacement devices, the Pinnacle metal-on-metal total hip-replacement device ("Pinnacle MoM"). The second amended complaint alleges that DePuy directly submitted and indirectly caused third parties to submit false claims for payments to government health-care programs for the Pinnacle MoM. According to the second amended complaint, the claims were false because DePuy made numerous misrepresentations to the FDA and surgeons concerning, among other things, the Pinnacle MoM's failure rates.

The relators filed the original complaint in this action under seal on May 18, 2012. On December 2, 2013, the relators filed a first amended complaint. The government declined to intervene on July 29, 2014. On June 5, 2015, the Court granted the relators' request to file a second amended complaint ("SAC"). Although the 168-page SAC alleges that DePuy made numerous misrepresentations about two of their devices—the ASR device and the Pinnacle MoM device—the specific counts in the SAC seek damages only as to the latter device. The SAC alleges claims of (1) causing false or fraudulent claims for payment to be presented to the United States in violation of 31 U.S.C. § 3729(a)(1)(A) (Count One); (2) knowingly making, using, or causing to be made or used false records or statements material to a false or fraudulent claim paid by the United States in violation of 31 U.S.C. § 3729(a)(1)(B) (Count Two); (3) conspiracy to violate the FCA in violation of 31 U.S.C. § 3729(a)(1)(C)

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[1] For clarity, the defendants will be referred to collectively as "DePuy."

(Count Three); and (4) violations of various state and municipal analogues to the Federal FCA (Counts Four through Thirty-Seven).

DePuy has moved to dismiss the SAC under Fed. R. Civ. P. 12(b)(6) for failure to state a claim upon which relief can be granted and under Fed. R. Civ. P. 9(b) for failure to satisfy the heightened pleading requirements for fraud. The relators have since moved to unseal the SAC, and DePuy has assented to that motion while requesting that documents concerning the motion to dismiss also be unsealed. Finally, while they have not formally filed a motion to amend the SAC, the relators contend in the conclusion of their opposition memorandum, sur-reply, and a post-hearing supplemental filing that they should be granted leave to amend and file a third amended complaint.

The essence of a False Claims Act violation is making, or causing the making, of one or more false claims—that is, claims for payment—against the United States. The statute provides large awards to *qui tam* relators as an incentive to bring such cases. The prospect of such an award may also, however, provide an incentive for individuals to try to convert virtually any set of allegations arising out of a defective product or faulty service into an FCA case. That is particularly true in the medical field, where the government purchases medical supplies and services on a large scale through Medicare, Medicaid, the VA, and other health-care programs. Normally, it requires no great leap of logic to conclude that if a medical device or a pharmaceutical is defective, the government must have purchased that product in

great quantities, and therefore the manufacturer must have caused, directly or indirectly, the submission of false claims.

In order to avoid so-called "parasitic" claims, and to try to guard against misuse of the FCA, the First Circuit has construed the statute fairly strictly. In doing so, the court has emphasized that the statute "attaches liability, not to the underlying fraudulent activity or to the government's wrongful payment, but to the claim for payment." *United States v. Rivera*, 55 F.3d 703, 709 (1st Cir. 1995). Among other things, FCA complaints must satisfy the particularity requirements of Fed. R. Civ. P. 9(b). The law requires relatively specific allegations of false claims, rather than generalized allegations based on supposition and logic; the relator must set forth with particularity the "who, what, when, where, and how" of actual claims that are alleged to be false. *United States ex rel. Ge v. Takeda Pharm. Co.*, 737 F.3d 116, 123 (1st Cir. 2013).

Here, the SAC includes hundreds of paragraphs of allegations, covering dozens of pages, of claimed fraudulent activity by DePuy. That satisfies one of the components of an FCA claim, but it does not satisfy them all. As set forth below, the allegations as to specific claims for payment for the specific device actually at issue in this case are sparse indeed. For that reason, and the other reasons set forth below, DePuy's motion to dismiss will be granted.

The relators' request for leave to amend the SAC and file a third amended complaint will be denied. The present case is nearly four years old, has had three iterations of the complaint, and has seen the desks of three judges in this district. The relators have had

ample opportunity to file a complaint that complies with the requirements of Rule 9(b), and have failed to do so. Finally, the parties' motions to unseal the SAC and other filings related to the motion to dismiss will be granted.

I. Background

The facts summarized below are set forth in the SAC unless otherwise noted.

A. Factual Background

1. The Parties

Relator Dr. Antoni Nargol is an orthopedic surgeon residing in the United Kingdom. (SAC ¶ 63). In 2003 he became one of the earliest British adopters of the Pinnacle MoM device, and DePuy invited him to be on its "Pinnacle user group team." (SAC ¶ 66). Dr. Nargol served as a testifying expert for the plaintiffs in *Strum v. DePuy Orthopaedics, Inc. and Premier Orthopaedic Sales, Inc.*, No. 2011 L 009352 2404 (Cook Cty., Ill., Cir. Ct.) ("*Strum* litigation"). (SAC ¶ 68). Dr. Nargol also provided expert assistance to the plaintiffs' executive committee in *Kransky v. DePuy, Inc.*, No. BC 456086 (Cal. Sup. Ct.), in which the plaintiffs' allegations focused on perceived design defects in the "ASR," a device that is similar to the one at issue in this case, the Pinnacle MoM. (SAC ¶ 68). Dr. Nargol also served as a fact witness in *Herlihy-Paoli v. DePuy Orthopaedics, Inc.*, No. 3:11-CV-04975-K (N.D. Tex.) ("*Herlihy-Paoli* litigation"). (SAC ¶ 68).

Relator Dr. David Langton is an orthopedic surgeon residing in the United Kingdom. (SAC ¶ 69). Dr. Langton has performed research on failed hip-replacement surgeries and devices, including the

Pinnacle MoM device. (SAC ¶ 70). The United States Food and Drug Administration ("FDA") has retained Dr. Langton as a consultant regarding "failure rates and dimensions of MoM products sold in the United States, including the Pinnacle." (SAC ¶ 72). Dr. Langton served as an expert witness in the *Strum* litigation and as a fact witness in the *Herlihy-Paoli* litigation. (SAC ¶ 72). According to the SAC, both the relators had personal experience in implanting the Pinnacle MoM device in their patients and began to alert defendants of the device's defects in 2009. (SAC ¶ 24).

Defendant DePuy Orthopaedics, Inc. is a designer, manufacturer, and distributor of orthopedic products that is based in Warsaw, Indiana. (SAC ¶ 73). DePuy Orthopaedics manufactured the Pinnacle MoM device. (SAC ¶ 73). DePuy Orthopaedics is a wholly-owned subsidiary of Delaware-based DePuy, Inc., which in turn is a subsidiary of New Jersey-based Johnson & Johnson Services, Inc. (SAC ¶¶ 75-77).

2. Government Health-Care Programs

Medicare is a health-insurance program administered by the United States Department of Health and Human Services ("HHS"). (SAC ¶ 85). Medicare provides payment for, among other things, medical services and equipment to persons over 65 years of age and those who are 18 years of age or older and are eligible for disability benefits. (SAC ¶ 82). For inpatient treatment, Medicare reimburses hospitals and other treating facilities through Medicare Part A. (SAC ¶ 83). For outpatient treatment, Medicare

reimburses physicians and health-care providers through Medicare Part B. (SAC ¶ 83).

Under the Medicare program, "no payment may be made under Part A or Part B for any expenses incurred for items or services which … are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of the malformed body member." (SAC ¶ 84) (citing 42 U.S.C. § 1395y(a)(l)(A)). To satisfy that standard, providers must provide, among other things, economical medical services, along with evidence that the service will be of a quality that meets professionally recognized standards of healthcare and will be supported by evidence of medical necessity and quality. (SAC ¶ 84) (citing 42 U.S.C. § 1320c-5(a)(1-3)). The SAC alleges that Medicare reimbursed qualified individuals for the purchase of the Pinnacle MoM device and the surgical procedures necessary to implant the device. (SAC ¶ 99).

Medicaid is a health-insurance program administered by HHS jointly with agencies in each state. (SAC ¶ 100). It is designed to assist states in providing medical services, medical equipment, and prescription drugs for low-income persons who qualify for the program. (SAC ¶ 100). The SAC alleges that Medicaid, like Medicare, reimbursed qualified individuals for the purchases of the Pinnacle MoM device and the surgical procedures necessary to implant the device. (SAC ¶ 104).

The United States Department of Veterans Affairs ("VA") provides medical assistance, including comprehensive coverage for hip replacement, to

military veterans. (SAC ¶ 105). The SAC alleges that DePuy "sold its Pinnacle hip implants directly to the VA." (SAC ¶ 106). The National Contract Service ("NCS)" provides the VA with acquisition support for medical equipment and pharmaceuticals. (SAC ¶ 112). According to the SAC, "NCS is also responsible for national committed-use contracts and standardized blanket purchase agreements established against the Federal Supply Schedule Program." (SAC ¶ 112). Medical equipment and supplies contracts are governed by the Federal Supply Schedule Group 65 Part II Section A. (SAC ¶ 115). That contract states that a "[c]ontractor warrants and implies that the items delivered hereunder are merchantable and fit for use of the particular purpose described in this contract," and that "[a]ll offerors must be in compliance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act for those medical device products intended to be delivered to the Government." (SAC ¶¶ 116-17).[2] The 65 II A contract also requires the contractor to notify the Assistant Director of the National Acquisition Center and various other officials if it sells a VA facility a product that "(1) requires modification, (2) is removed or recalled by the contractor or manufacturer due to defects in the product or potential dangers to patients, or (3) is subject to a suggested or mandatory modification,

[2] The 65 II A contract further states that the general controls of the FD&C Act controlling medical devices "are the baseline requirements that apply to all medical devices necessary for marketing, proper labeling and monitoring [ ] performance once the device is on the market." (SAC ¶ 119).

removal, or recall by a regulatory or official agency." (SAC ¶ 120).

The Civilian Health and Medical Program of the United States, now known as TRICARE, provides benefits for health-care services furnished to members of the U.S. military and their family members. (SAC ¶ 124). TRICARE pays for medical devices and surgeries for its beneficiaries, including total hip-replacement devices like the Pinnacle MoM. (SAC ¶ 125).

3. FDA Regulations Governing Medical Devices

The SAC contains significant detail concerning the FDA regulations governing medical devices that need not be fully detailed here. (*See generally* SAC ¶¶ 127-66). The FDA, which protects and promotes the public health through regulation of medical devices and pharmaceuticals, has three risk-based regulatory classifications for medical devices. (SAC ¶¶ 127-28). The Pinnacle MoM device was a Class III device and subject to the most stringent level of regulation imposed by the FDA. (SAC ¶¶ 129-30). There are only two ways by which a manufacturer can seek FDA approval for a new Class III medical device: the premarket approval ("PMA") process and the "510(k)" clearance process. (SAC ¶ 131). The "more onerous" PMA process requires, among other things, a full report of all information known to the manufacturer concerning investigations into the device's safety. (SAC ¶ 131). In contrast, under the 510(k) process, the manufacturer is required to demonstrate only that the device is "substantially equivalent in terms of safety and effectiveness to an

existing FDA-approved device." (SAC ¶ 131) (citing 21 C.F.R. § 807.92(a)(3)). 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. (SAC ¶ 133). A device with different technological characteristics can be considered substantially equivalent only if the information submitted to the FDA does not raise new questions of safety and demonstrates that the device is at least as safe and effective as the predicate device. (SAC ¶ 133).

4. The Pinnacle MoM Device

Before the alleged defects in DePuy's Pinnacle MoM device came to light, another DePuy hip-replacement device, the ASR, suffered from alleged defects and was the subject of many products-liability lawsuits. (SAC ¶¶ 56-57). Those actions were ultimately the subject of an MDL proceeding in the Northern District of Ohio. (SAC ¶¶ 56-57). The SAC includes numerous references to ASR defects and allegedly fraudulent behavior by DePuy in connection with that device. (*See, e.g.*, SAC ¶¶ 15, 24, 31-33, 35, 37-39, 42, 45, 47, 54-58, 64-66, 68, 71-72, 130, 184, 189, 190-91, 199, 238, 246, 262, 327). Those allegations, however, are not particularly relevant to the relators' claims in this case, which is solely focused on the Pinnacle device—and more specifically, the Pinnacle MoM device comprised of a metal head and metal liner, as explained below.

Hip-replacement devices replace the bone components of a hip joint, including the ball (femoral head) and socket (acetabulum). (SAC ¶¶ 167-69). A hip-replacement device generally includes four

components: (1) a femoral stem; (2) a femoral head; (3) an acetabular cup; and (4) a liner that fits inside the cup and interacts with the head. (SAC ¶ 170). In metal-on-metal hip-replacement devices, the head, cup, and liner are all metal; MoM devices are expected to last longer than devices comprised of ceramic or polyethylene. (SAC ¶ 169). The space between the head and cup is referred to as "diametrical clearance." (SAC ¶ 179). Bodily fluid fills in the diametrical clearance between the head and cup to prevent friction and wear caused by the two pieces rubbing together. (SAC ¶ 180).

Under the brand of "DePuy Orthopaedics Pinnacle Hip Solutions," DePuy marketed three head-on-liner categories of Pinnacle devices: "metal-on-metal, ceramic-on-polyethylene, and metal-on-polyethylene." (SAC ¶ 176; Def. Mem. Ex. C at 5).[3]

[3] The Court will consider two sets of DePuy marketing materials along with the facts as alleged in the SAC. First, it will consider Exhibit C attached to DePuy's motion to dismiss: the 2011 "Pinnacle Hip Solutions Compatibility Guide," a marketing document that DePuy provided to health-care providers. Second, the Court will consider Exhibit D attached to DePuy's motion to dismiss: the 2008 "Design Rationale" for Pinnacle products. On motions to dismiss, courts can properly take into account (1) documents the authenticity of which are not disputed by the parties; (2) documents that are official public records; (3) documents central to plaintiffs' claim; or (4) documents sufficiently referred to in the complaint. *Watterson v. Page*, 987 F.2d 1, 3 (1st Cir. 1993); *see also Romani v. Shearson Lehman Hutton*, 929 F.2d 875, 879 n.3 (1st Cir. 1991) (considering securities-offering documents submitted by defendants with motion to dismiss for claim of securities fraud); *Fudge v. Penthouse Int'l, Ltd.*, 840 F.2d 1012, 1014-15 (1st Cir. 1988) (considering allegedly libelous article submitted by defendants with motion to dismiss).

DePuy offered three types of Pinnacle heads: (1) aSphere M-Spec and M-Spec (both metal); (2) Standard Metal (metal); and (3) BIOLOX delta (ceramic). (Def. Mem. Ex. C at 3). DePuy offered three types of Pinnacle liners: (1) Ultamet and Ultamet XL (both metal); (2) Marathon (polyethylene); and (3) AltrX (polyethylene). (Def. Mem. Ex. C at 3). The Standard Metal head was not compatible with Pinnacle metal liners; it could be used only with polyethylene liners. (*Compare* Def. Mem. Ex. C at 8, *with* Def. Mem. Ex. C at 10, 16). Thus, there was one combination of Pinnacle components that combined to create a Pinnacle MoM device: an aSphere M-Spec or M-Spec metal head with an Ultamet or Ultamet XL metal liner. (SAC ¶ 176; Def. Mem. Ex. C at 3). The Pinnacle device—consisting of a head, cup, and liner—could be used with a variety of separate DePuy femoral stems, including the CORAIL stem, the SUMMIT stem, the AML stem, the TRI-LOCK stem, and the S-ROM stem. (*See* Def. Mem. Ex. D at 29). But those stems were not part of the Pinnacle MoM device, as they could be used with other DePuy hip-replacement devices, such as the ASR. (*Id.*).

As alleged in Counts One through Thirty-Seven of the SAC, the relators seek recovery under 31 U.S.C. § 3729(a)(1)(A)-(C) for claims involving only DePuy's

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Here, the SAC refers to DePuy's "marketing materials" and other documents that it provided to health-care providers numerous times. (*See, e.g.*, SAC ¶¶ 9, 165, 183, 232, 252, 419). Moreover, the documents were publicly-distributed marketing materials. Accordingly, Exhibits C and D are documents whose authenticity is not disputed, are central to the relators' claims, and are sufficiently referred to in the SAC.

Pinnacle MoM device (which must use an M-Spec head and an Ultamet liner).

On December 13, 2000, the FDA approved the Pinnacle Ultamet 36mm metal liner as part of the 510(k) approval process, based on "substantial equivalence with the DePuy Ultima Unipolar Adapter Sleeves ("Ultima"), cited as the Ultamet's predicate device." (SAC ¶ 177). The diametrical clearance set forth in the Ultamet's 510(k) application was in the "40-80 micron tolerance band." (SAC ¶ 181).[4] According to the SAC, DePuy purposely manufactured the Pinnacle MoM device with a lower diametrical clearance than other devices. (SAC ¶ 183). It marketed the Pinnacle MoM's lower diametrical clearance under the theory that as diametrical clearance decreases, the volume of fluid lubricating the joint increases. (SAC ¶ 183). The SAC alleges that when diametrical clearance is small, "the consequences of any deformation of the cup, even if slight, are dire for the patient." (SAC ¶ 183). When DePuy added the 36mm Ultamet liner to its Pinnacle product line in 2005, DePuy advised the FDA that the diametrical clearance dimension was not 40-80 microns, but was in fact 80-120 microns. (SAC ¶ 186).

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[4] DePuy manufactured liners and heads at a specified "nominal" size. (SAC ¶ 182). Along with a nominal size, each component was assigned an upper and lower tolerance, representing the "permissible diametrical clearance measurements of the manufactured component." (SAC ¶ 182). The acceptable range of diameter measurements for each component is plus or minus 10 microns (0.010 millimeters) from the nominal size; accordingly, "the complete range of acceptable deviation [for a device] is 20 microns for each component." (SAC ¶ 182).

The SAC alleges that the FDA, upon learning of the inaccuracy, "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." (SAC ¶ 187).

5. DePuy's Allegedly Fraudulent Acts Involving the Pinnacle Device

The relators allegedly learned of the defects in the ASR and Pinnacle MoM devices through their own work with the hip implants. (SAC ¶¶ 24, 47). They began reporting those defects to DePuy in 2007, and continued to do so through 2011. (SAC ¶¶ 24, 47). Those defects included (1) surface wear resulting in metal ion exposure causing patient necrosis (tissue death), metallosis (metallic staining of tissues), and osteolysis (degradation of the bone) (SAC ¶ 29); (2) "diametrical clearance" and "taper trunnion" defects causing high device-failure rates (SAC ¶ 42); and (3) femoral neck fractures at high rates. (SAC ¶ 45).

The SAC includes nearly fifty pages detailing DePuy's allegedly fraudulent actions in concealing those defects while pursuing FDA approval for the Pinnacle MoM device, marketing the device to surgeons, and selling the device to government health-care programs. (*See generally* SAC ¶¶ 201-412). The Court will not detail every allegation of DePuy's claimed improper conduct, many of which are irrelevant to the Pinnacle MoM device and the present FCA claims. The Court will, however, attempt to summarize the allegations, which fall into two broad categories.

First, the SAC alleges that DePuy knowingly made material false statements and omissions to the FDA and to medical providers about the "specifications, manufacturing process, safety, and failure rates" of its Pinnacle MoM device. (SAC ¶ 201). Those false statements, according to the SAC, "armed and induced surgeons to make similar certifications when seeking reimbursement from the [g]overnment" and "had a natural tendency to influence the [g]overnment's payment for the Pinnacle devices." (SAC ¶ 203). The SAC identifies nine sub-categories of materially false statements that DePuy made to the FDA and surgeons. The SAC alleges that but for those false statements, the FDA would not have approved the device and "surgeons would not have utilized Pinnacle hip replacements or certified them to government health programs as reasonable and medically necessary." (SAC ¶ 256).

1. The SAC alleges that "in official communications with the FDA, DePuy falsely represented that Pinnacle implants had a 96 percent to 96.5 percent success rate." (SAC ¶ 204). Specifically, it alleges that on June 27, 2012, a DePuy director gave a presentation to the FDA's Orthopedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee. (SAC ¶ 205). The purpose of that meeting was to "seek expert scientific and clinical opinion on the risks and benefits of these types of devices based on available scientific data." (SAC ¶ 205). At the meeting, the DePuy director told the panel that "Ultamet metal-on-metal articulation is performing consistent with or better than

other metal-on-metal products: 4 to 4.5 percent cumulative revision rate at five years, regardless of head size." (SAC ¶ 206). According to the SAC, as of February 29, 2012, DePuy's own internal database showed that "metal Pinnacle hips" had a cumulative revision rate of 15 percent after five years of use. (SAC ¶ 207). The SAC alleges that "had DePuy truthfully stated its internal results indicating a 15 percent revision rate at five years, the FDA would likely not have continued to clear the product for the market … [and] the government would likely have discontinued use of the Pinnacle device for government health-care recipients." (SAC ¶ 210). When the FDA approved the Pinnacle for implantation in patients, the FDA stated "[i]t is, however, [DePuy's] responsibility to determine if the change [or] modification to the device or its labeling could significantly affect the device's safety or effectiveness and thus require submission of a new 510(k)." (SAC ¶ 211).

2. The SAC alleges that "DePuy made false statements to surgeons claiming that Pinnacle boasted a 99.9 percent success rate" and that those statements caused surgeons to submit false claims to the government. (SAC ¶ 212). Specifically, it alleges that DePuy began circulating marketing materials in 2007 that touted a 99.9 percent success rate for "Pinnacle products" based on data and research that was "conducted and written up by DePuy itself and funneled to a third-party author to create the

appearance of impartiality." (SAC ¶¶ 212-13). It alleges that DePuy continued to advertise this false figure until 2013, even though its internal data showed a 15 percent cumulative revision rate as early as February 29, 2012. (SAC ¶¶ 228-29).

3. The SAC alleges that DePuy made false statements to surgeons "claim[ing] that the Pinnacle device's low diametrical clearances created a benefit to patients that distinguished the devices from competing products." (SAC ¶ 233). Beginning in early 2010, the relators conducted research on a "large volume of failed Pinnacle … implants" and concluded that the device suffered from a "diametrical clearance defect" such that "the diametrical clearance of the [ ] device was considerably lower than the specification required by the FDA." (SAC ¶ 238). After the research, the relators repeatedly alerted DePuy executives about the improper clearances. (SAC ¶¶ 245-48). DePuy, in apparently undated marketing materials to surgeons, touted that the Pinnacle's "cup-to-head bearing clearance, enhances the potential for fluid lubrication and minimizes wear to maximize survivorship." (SAC ¶ 250). According to the SAC, "DePuy knew that patients were not obtaining the purported benefits of Pinnacle's low diametrical clearances" and "was fully aware that many patients and surgeons—most notably Dr. Nargol—were complaining of high ion rates and high failure rates." (SAC ¶ 255).

4. The SAC alleges that even though "DePuy knew that its devices were responsible for dangerous concentrations of metal ions in the bloodstreams of patients," it told the FDA that "metal ions were not a source of concern for metal-on-metal patients." (SAC ¶ 257). In the June 2012 presentation to the FDA, the DePuy director said that the Pinnacle generated "metal wear debris" in patients' bloodstreams in "low amounts." (SAC ¶ 258). The SAC alleges that surgeons began notifying DePuy "as early as 2001 that metal ions generated by metal-on-metal implants were a cause for concern." (SAC ¶ 260).
5. The SAC alleges that DePuy made false statements to surgeons about the causes of the Pinnacle MoM's high failure rates. Specifically, "[b]eginning in 2009, Dr. Nargol repeatedly contacted DePuy to warn it of explosive growth in the number of Pinnacle hip revision surgeries he was performing." (SAC ¶ 269). According to the SAC, DePuy told Dr. Nargol that the "problems resulted from his implantation technique." (SAC ¶ 270). At the time, "DePuy knew … that the problems in Dr. Nargol's patients stemmed from device defects, not from [his] surgical methods" because, in part, other surgeons were "experiencing and notifying DePuy of widespread failures with the Pinnacle implant." (SAC ¶¶ 271-72).
6. The SAC alleges that DePuy made false statements to surgeons about the Pinnacle

MoM's angle of inclination in its use instructions. (SAC ¶ 276). It cites an internal DePuy e-mail written by an engineer expressing confusion about the proper angle of inclination for the Pinnacle's cup positioning. (SAC ¶ 277). Accordingly, the SAC alleges, "DePuy did not know the proper angle of implantation for Pinnacle hips, and [ ] any recommendation it made in its manuals disseminated to hospitals and surgeons was therefore false." (SAC ¶ 278).

7. The SAC alleges that DePuy "intentionally withheld disclosure of the Pinnacle's diametrical clearance manufacturing defects to [the] FDA, contrary to its FDA-mandated obligation to report them in an updated 510(k) application." (SAC ¶ 280). In 2000, DePuy submitted its 510(k) application along with various certifications that it "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." (SAC ¶ 282). On July 26, 2005, a DePuy regulatory-affairs associate wrote to the FDA attaching a chart "replac[ing] the chart originally included as Exhibit 4 of the submission, which contained a miscalculation." (SAC ¶ 286). The SAC alleges "[o]n information and belief, the 'corrected' 2005 table contained measurements or analysis of measurements of DePuy's devices that DePuy learned were not accurate." (SAC

¶ 287).[5] On August 5, 2005, a member of the FDA cautioned DePuy that it would be the company's "responsibility to determine if the change or modification to the device or its labeling could significantly affect the device's safety or effectiveness and thus require submission of a new 510(k)." (SAC ¶ 291). According to the SAC, that notification "imposed an affirmative obligation on DePuy to provide the FDA with updated information," and even when the relators notified DePuy of the Pinnacle diametrical clearance issues beginning in 2008, "[o]n information and belief, DePuy never corrected its July 26, 2005 submissions to reflect Relator Langton's measurements." (SAC ¶¶ 292-96).

8. The SAC alleges that DePuy "intentionally withheld disclosures of the Pinnacle device's taper trunnion and surface roughness defects in presentations to the FDA." (SAC ¶ 300). The alleged "taper trunnion" defect concerns the area where the end of the femoral stem (the trunnion) is inserted into the area of the head (the taper); that taper trunnion "is not meant to move and thus should not generate any wear." (SAC ¶¶ 188-89). However, the SAC

[5] Also in 2005, DePuy's director of regulatory affairs wrote an e-mail to DePuy's global vice president of clinical research, indicating that the regulatory submission "stretch[ed] the 510(k) idea to its limits" and further elaborated, "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)." (SAC ¶ 288).

alleges that the relators discovered a defect in the Pinnacle device where, due in part to the large head size of the Pinnacle, the "taper toggles against the trunnion, causing the release of metal debris." (SAC ¶ 190). The alleged "surface roughness" defect also concerns the taper trunnion area of the device, but involves friction between the trunnion, which is designed to be rough, and the taper, which is designed to be smooth. (SAC ¶ 195). The SAC alleges that the relators discovered a defect in many Pinnacle devices where the surface of the taper was rough and created friction with the trunnion, which in turn caused friction and release of metal debris. (SAC ¶ 197). The relators allege that they notified DePuy of the two defects beginning in 2011 and continued to do so into 2012. (SAC ¶¶ 305-06). The SAC alleges that DePuy willfully omitted any discussion of the reported taper trunnion and surface roughness defects during the June 2012 meeting with the FDA. (SAC ¶¶ 307-10).

9. The SAC alleges that "DePuy intentionally failed to disclose adverse events to the FDA." (SAC ¶ 312). On June 7, 2011, following an Establishment Inspection of DePuy's Indiana facility, the FDA issued a report concluding that DePuy had "delayed reporting adverse [Pinnacle] MoM events by five months to three-and-a-half years, well beyond the acceptable timeframe under FDA regulations." (SAC ¶ 314). The report also noted that DePuy failed to investigate complaints involving the

possible failure of its device to meet production specifications; a DePuy employee stated that the company received approximately 450 complaints per month about hip-replacement devices but that DePuy assigned only one employee to investigate them. (SAC ¶ 315).

Second, the SAC alleges that DePuy knowingly caused the submission of direct claims for "medical devices with dimensions materially different than those the government bargained for." (SAC ¶ 201). The SAC identifies three sub-categories of DePuy's allegedly materially false statements or omissions that caused the government to pay for "nonconforming, nonfunctioning, and unsafe devices that would not have been purchased but for DePuy's fraudulent conduct." (SAC ¶ 325).

1. As detailed above, the SAC alleges that DePuy knowingly or recklessly disregarded evidence, allegedly first provided to it by the relators, that the Pinnacle MoM's nonconforming diametrical clearances were causing device failures. (SAC ¶¶ 327-32). It alleges that DePuy was on notice of the Pinnacle MoM's improper measurement testing procedures as early as 2009, when it acquired a competitor and began to use its own "state-of-the-art measuring equipment." (SAC ¶ 335). In June 2010, after the relators notified DePuy of the Pinnacle's improper clearance measurements, a DePuy employee e-mailed Dr. Langton, stating that if DePuy concluded from the relators' research that its MoM parts "were out of specification," the company would "need to

notify patients if [DePuy] had made a serious manufacturing error." (SAC ¶ 338). In its 2011 report, the FDA found that "33 Pinnacle metal liners were out of conformance" because they "fell below the lower specification limit" for diametrical clearance. (SAC ¶ 342). The FDA report notified DePuy that "[t]he production capabilities for the Pinnacle MoM liners and MoM femoral heads at the Leeds facility should be reviewed." (SAC ¶ 343). According to the SAC, "DePuy continued to manufacture Pinnacle components with full knowledge that the manufacturing process was producing yet more parts with the same conformance issues." (SAC ¶ 343). The SAC also alleges "on information and belief" that DePuy provided the FDA with statistical analyses about the failure rates of its Pinnacle device that excluded "critical analyses [that] relators provided to DePuy." (SAC ¶ 345). After the FDA expanded the scope of its request to include data back to January 2007, the SAC alleges that DePuy "responded by producing very little data." (SAC ¶ 348). According to the SAC, "DePuy's failure to conduct and report such statistical analyses violated 21 C.F.R. § 820.250, which requires statistical analysis to assess trending." (SAC ¶ 350). It also alleges that because DePuy employed only one person to "review and analyze the approximately 450 complaints received per month," it "willfully ignored and mischaracterized the causes of the[ ] complaints in order to avoid its obligation to adequately verify and validate its

manufacturing processes." (SAC ¶¶ 355-56). It alleges that DePuy's "failure to respond to relators' complaints regarding the clearance deformities" violated 21 C.F.R. § 820.198(a), which establishes a duty to "maintain adequate procedures for receiving, reviewing, and evaluating complaints." (SAC ¶ 357).

2. The SAC alleges that beginning in 2005, DePuy "knowingly or recklessly failed to adopt adequate process validation methods" that were "necessary to consistently manufacture [ ] Pinnacle devices within specification." (SAC ¶ 358). It alleges that the "relators, with additional expert assistance, have determined that DePuy's inspection and testing procedures were unable to verify whether DePuy's Pinnacle devices [were] manufactured within their required specifications," both for diametrical clearance and surface roughness. (SAC ¶¶ 359-60). It alleges that DePuy, by failing to ensure that its manufacturing process was capable of producing devices within required specifications, "produced, marketed, and sold … a device that [was] different than the subject of the 510(k)" and caused the government to purchase devices that it would not have otherwise purchased without 510(k) approval. (SAC ¶¶ 363-65).

3. The SAC alleges that "DePuy's failure to implement validation procedures necessary to ensure consistent manufacture of products confirming to their specifications was material to the government's purchase of DePuy's

> Pinnacle devices." (SAC ¶ 397). Specifically, it alleges that the "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," and without that approval, the government would not have approved the device for reimbursement. (SAC ¶ 397). When the FDA learned in 2005 that DePuy's 510(k) application in 2000 for the Ultamet 36mm liner contained incorrect diametrical clearance dimensions, it stated that "given this new information, the Pinnacle 36mm system would not have been cleared in 2000." (SAC ¶¶ 399-400). According to the SAC, the FDA "nevertheless did not require DePuy to file a supplemental 510(k), much less obtain PMA, expressly because DePuy represented that the device's failure rates were within industry standards." (SAC ¶ 401). But the SAC alleges that DePuy "was aware [at that time] that the Pinnacle substantially deviated from specifications and had disproportionately high failure rates," and "[i]n 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." (SAC ¶ 403).

In May 2013, DePuy announced that it would stop selling the Pinnacle MoM device as of August 2013. (SAC ¶ 55). More than 5,000 personal injury lawsuits involving the Pinnacle MoM device were eventually

transferred to an MDL proceeding in the Northern District of Texas. (SAC ¶ 58).

The SAC alleges that "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 FDA." (SAC ¶ 412).

Finally, the SAC twice refers to 42 U.S.C. § 1395y(a)(1)(A), which prohibits Medicare payments for treatments that are not "reasonable and necessary." The SAC alleges:

> Hospital certifications involving claims for Pinnacle hip implants were false because claim reimbursements for these products constituted payment for services which were "not reasonable and necessary for the diagnosis and treatment of illness or injury," in violation of 42 U.S.C. § 1395y(a)(l)(A). By marketing these products as safe, effective, and medically appropriate, and concealing overwhelming evidence to the contrary, DePuy willfully caused hospitals to file such false certifications when seeking Medicare reimbursement.
>
> ….
>
> DePuy caused physicians, hospitals and other providers to submit false certifications on all these forms concerning claims for Pinnacle hip surgery procedures. Surgeries to implant these irredeemably faulty devices were not "reasonable and necessary for the diagnosis and treatment of illness or injury," within the meaning of 42 U.S.C. § 1395y(a)(l)(A).

(SAC ¶¶ 88, 99).

6. The Alleged False Claims

The SAC alleges that "the government directly purchased or reimbursed hundreds of thousands of Pinnacle products." (SAC ¶ 7). It alleges that DePuy made false statements that caused health-care providers to submit indirect false claims for the Pinnacle MoM to Medicare and Medicaid, and that DePuy itself also submitted direct false claims to the VA.

a. Alleged Indirect False Claims

The SAC alleges one representative indirect false claim and then supports that claim with statistical evidence of the Pinnacle sales to Medicare and Medicaid patients. (*See* SAC ¶¶ 413-72). As to the indirect claim, the SAC alleges:

> 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, 10 I 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.
>
> 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.

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.

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.

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.

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[.]

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.

....

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 nonconforming diametrical clearance dimensions. The failures resulted in great pain and suffering to F.I. and posed the possibility of additional revision surgery.

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 percent at five years.

....

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)(l)(A). This certification was false as the implantation of a defective device is not a medically reasonable treatment.

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.

New York Medicaid reimbursed approximately $34,000 in costs for the implantation of Mr. F.I.'s Pinnacle device.

....

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.

(SAC ¶¶ 414-20, 423-24, 426-28, 432).

According to the SAC, "over one million MoM hips were sold worldwide" during the times relevant to the complaint. (SAC ¶ 434). "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 market place." (SAC ¶ 434). The SAC alleges that the United States "constitutes almost two-thirds of the world's orthopedic device market." (SAC ¶ 435). Over 300,000 hip-replacement surgeries were performed in the United States in 2010. (SAC ¶ 436). The SAC alleges that, "[a]ccordingly, 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." (SAC ¶ 437).

The SAC alleges that between 2005 and 2010, New York Medicaid paid for an average of approximately 1,280 claims each year for total hip-replacement devices. (SAC ¶ 438). New York State Medicaid paid approximately $52 million to cover its total cost for inpatient visits for those 1,280 claims, or $40,625 per claim. (SAC ¶ 439). In 2010, New York State's Federal Medical Assistance Percentage ("FMAP") was approximately 50 percent. (SAC ¶ 440). The SAC alleges that "[t]herefore, the United States paid an additional $52 million to cover its total cost for each inpatient visit for those 1,280 claims, or $40,625 per claim." (SAC ¶ 441). New York State Medicaid

covers approximately 8 percent of all Medicaid beneficiaries in the United States; therefore, according to the SAC, "thousands more Medicaid patients received total hip-replacement devices in 2010, at a cost of hundreds of millions of dollars to the Plaintiff States and the United States." (SAC ¶ 442).

The SAC alleges that "[a]lthough 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 percent of all total hip-replacement surgeries were MoM device surgeries." (SAC ¶ 443). "During relevant periods, DePuy's two MoM hip implant products (the Pinnacle and the ASR XL) had captured 75 percent of the Metal on Metal hip-replacements market. Prior to 2010, the Pinnacle constituted roughly 50 percent of DePuy's MoM hip-replacement sales." (SAC ¶ 444). The SAC alleges that "[g]iven the August 2010 recall of the ASR, the Pinnacle would have constituted at least 70 percent of DePuy's Metal on Metal hip-replacement sales." (SAC ¶ 445). Therefore, according to the SAC, "between 2005 and 2010, nearly 850 Pinnacle devices were purchased by New York State Medicaid." (SAC ¶ 446). The relators estimate that the diametrical clearance defect affected 14.93 percent of "explant head[s]" and 50.41 percent of "explant liner[s]." (SAC ¶ 447). Thus, "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." (SAC ¶ 448). Based on the alleged 14 percent five-year failure rate in Pinnacle's internal system, the relators allege that between 2005 and 2010, "nearly 130 Pinnacle devices

paid for by New York State Medicaid would have failed in patients at [five] years." (SAC ¶ 451).

b. Alleged Direct False Claims

The SAC alleges that the VA entered into two contracts with DePuy "that include the sale of the Pinnacle hip implants." (SAC ¶ 474). The SAC alleges:

> On February 21, 2006, DePuy was awarded an Orthopaedics Implant contract worth $8,042,500 by the VA National Acquisition Center with the Procurement Instrument Identifier V797P-9 l 88. The VA Point of Contact for the contract was Deborah Koval.
>
> On April 29, 2011 DePuy entered into another Indefinite Delivery contract with the VA National Acquisition Center with the Procurement Instrument Identifier VA-797P-0263. The VA NAC Point of Contact was Timothy Richards and the DePuy Contract Point of Contact was Michelle Roberts. Since 2011, this contract has involved payment for dozens of Pinnacle components.

(SAC ¶¶ 476-77).

The SAC then alleges that the following twelve "purchases" by the VA are "representative claims" for purposes of the False Claims Act. (SAC ¶¶ 479-90).

> 479. [O]n January 18, 2011, VA employee Aryeh Lax from Los Angeles, California ordered a "SUMMIT FEMORAL STEM" and "ARTICUL/EZE METAL ON MET AL FEMORAL HEAD" from DePuy. This order obligated the VA to pay $3,358.38.

480. On January 30, 2011, Lax ordered a "SUMMIT FEMORAL STEM" and "ARTICUL/EZE METAL ON METAL FEMORAL HEAD" from DePuy. This order obligated the VA to pay $3,358.38.

481. On February 27, 2011, Lax ordered a Pinnacle product from DePuy. This order obligated the VA to pay $4,779.50.

482. On June 1, 2012, VA employee Scott Delancey from Grand Junction ordered a Pinnacle product from DePuy. This order obligated the VA to pay $3,967.00.

483. On September 29, 2011, VA employee Loretta Henry McLain from Los Angeles ordered a Pinnacle product from DePuy. This order obligated the VA to pay $8,712.14.

484. On September 27, 2012, VA employee Kami Wiggins from Martinsburg ordered a Pinnacle product from DePuy. This order obligated the VA to pay $15,228.50.

485. On September 28, 2007, Naval Medical Center employee Jojie Urrete from San Diego, California ordered a "Pinnacle metal on metal" device from DePuy. This order obligated the Navy to pay $8,000.00.

486. On February 22, 2008, Urrete ordered a "Summitt (sic) Pinnacle metal on metal" device from DePuy. This order obligated the Navy to pay $13,000.00.

487. On June 18, 2007, Department of the Army employee Ann Slagle from Tacoma, Washington ordered a "SUMMIT METAL ON

METAL" device from DePuy. The Summit stem is one of the parts of the Pinnacle Hip replacement system. This order obligated the Army to pay $9,000.00.

488. On February 7, 2008, Naval Medical Center employee C. Johnson from San

Diego, California ordered a "Srom Metal on Metal" device form DePuy. The S-Rom is a metal head used as a part of the Pinnacle Hip replacement system. This order obligated the Navy to pay $9,000.00.

489. On July 5, 2007, Department of the Army employee Amparo Hall from Tacoma, Washington ordered "SUMMIT METAL ON METAL SYS." The Summit stem is one of the parts of the Pinnacle Hip replacement system. This order obligated the Army to pay $10,000.00.

490. On July 12, 2007, Department of the Army employee Amparo Hall from Tacoma, Washington ordered "SUMMIT METAL ON METAL SYSTEM." The Summit stem is one of the parts of the Pinnacle Hip replacement system. This order obligated the Army to pay $10,000.00.

B. Procedural Background

On May 18, 2012, the relators filed the original complaint in this case under seal.[6] The complaint

[6] The case was initially assigned to Judge O'Toole, then was reassigned to this judge on August 10, 2012, then was reassigned to Judge Talwani on June 26, 2014, and finally reassigned back to this judge on October 8, 2014.

alleged, among other things, violations of the False Claims Act. The FCA claims were pursued by the relators on behalf of the United States as a *qui tam* action. The Court granted the relators' motion to file an amended complaint on December 2, 2013. On July 29, 2014, the government filed a notice declining to intervene in this case. On August 13, 2014, the case was partially unsealed. On May 4, 2015, the relators filed under seal a motion to file a second amended complaint. DePuy opposed that motion on May 26, 2015. On June 5, 2015, the Court granted the relators' motion to amend the complaint and deemed the SAC, effectively the relators' third complaint, as the operative complaint.

The SAC, which remains sealed, alleges claims of (1) causing false or fraudulent claims for payment to be presented to the United States in violation of 31 U.S.C. § 3729(a)(1)(A) (Count One); (2) knowingly making, using, or causing to be made or used false records or statements material to a false of fraudulent claim paid by the United States in violation of 31 U.S.C. § 3729(a)(1)(B) (Count Two); (3) conspiracy to violate the FCA in violation of 31 U.S.C. § 3729(a)(1)(C) (Count Three); and (4) violations of various state analogues to the FCA (Counts Four through Thirty-Seven).

On June 29, 2015, DePuy filed a motion to dismiss. DePuy contends that the relators' FCA claims fail to state a claim for which relief can be granted under Fed. R. Civ. P. 12(b)(6), and that they also fail to satisfy the pleading requirements of Fed. R. Civ. P. 9(b). DePuy also contends that the conspiracy and

state-law FCA claims should be dismissed for the same reasons.

On August 24, 2015, the relators moved to unseal the SAC. DePuy assented to that motion on September 2, 2015, but requested that other documents also be unsealed, including (1) the relators' motion to unseal the SAC, their accompanying memorandum of law and exhibits, and DePuy's response and accompanying exhibits; and (2) all documents and filings related to DePuy's motion to dismiss.

II. Legal Standard

On a motion to dismiss, the Court "must assume the truth of all well-plead[ed] facts and give … plaintiff the benefit of all reasonable inferences therefrom." *Ruiz v. Bally Total Fitness Holding Corp.*, 496 F.3d 1, 5 (1st Cir. 2007) (citing *Rogan v. Menino*, 175 F.3d 75, 77 (1st Cir. 1999)). To survive a motion to dismiss, the complaint must state a claim that is plausible on its face. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). That is, "[f]actual allegations must be enough to raise a right to relief above the speculative level, … on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Id.* at 555 (citations omitted). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 556). Dismissal is appropriate if the facts as alleged do not "possess enough heft to show that plaintiff is entitled to relief." *Ruiz Rivera v. Pfizer Pharm., LLC*, 521 F.3d 76, 84 (1st Cir. 2008)

(alterations omitted) (internal quotation marks omitted).

III. Analysis

A. Counts One and Two: Federal FCA Claims

Counts One and Two of the SAC allege violations of the FCA. Under the FCA, it is unlawful for a person or entity to (1) knowingly present, or cause to be presented, a false or fraudulent claim for payment or approval to the United States, (2) knowingly make, use, or cause to be made or used, a false record or statement material to a false or fraudulent claim; or (3) conspire to commit a violation of the statute. 31 U.S.C. §§ 3729(a)(1)(A)-(C). To be actionable under the FCA, a false statement must be material to a false claim—that is, the false statement must "hav[e] a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." *United States ex rel. Loughren v. Unum Grp.*, 613 F.3d 300, 307 (1st Cir. 2010) (quoting 31 U.S.C. § 3729(b)(4)).

Private persons, known as relators, can file civil *qui tam* actions on behalf of the United States against persons or entities who violate the act. 31 U.S.C. § 3730(b). The government can intervene in a *qui tam* action and assume primary responsibility over it. *Id.* §§ 3730(b)(2), (b)(4), (c)(1). The relator is eligible to collect a portion of any damages awarded in a *qui tam* action, whether or not the government intervenes. *Id.* § 3730(d).

1. Rule 9(b)

DePuy contends that the FCA claims should be dismissed because the SAC does not satisfy the

pleading requirements of Fed. R. Civ. P. 9(b). That rule requires that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). The heightened pleading requirements of Rule 9(b) apply to claims brought under all three subsections of the FCA. *United States ex rel. Ge v. Takeda Pharm. Co.*, 737 F.3d 116, 123-24 (1st Cir. 2013).[7] The First Circuit explained the reasoning for applying those requirements to FCA claims in *United States ex rel. Duxbury v. Ortho Biotech Products, L.P.* ("*Duxbury II*"): "Although [the FCA's] financial incentive encourages would-be relators to expose fraud, it also attracts parasitic relators who bring FCA damages claims based on information within the public domain or that the relator did not otherwise discover." 719 F.3d 31, 33 (1st Cir. 2013) (citations and internal quotation marks omitted). "For those reasons, there are a number of limitations on *qui tam* actions, including the particularity requirements of Rule 9(b)." *Ge*, 737 F.3d at 123 (citing *Duxbury II*, 719 F.3d at 33).

a. Direct Claims

For allegations of direct false claims under 31 U.S.C. § 3729(a)(1)(A), "[r]elators are required to set forth with particularity the 'who, what, when, where, and how' of the alleged fraud." *Ge*, 737 F.3d at 123 (quoting *United States ex rel. Walsh v. Eastman Kodak Co.*, 98 F. Supp. 2d 141, 147 (D. Mass. 2000)). "Because

[7] "We recognize that … the 'presentment' requirement applies only to … subsection (a)(1)(A) claims and not … subsection (a)(1)(B) or subsection (a)(1)(C) claims. However, Rule 9(b)'s particularity requirement applies with full force to all three subsections [of the FCA]." *Ge*, 737 F.3d at 124-25 n.5.

FCA liability attaches only to false *claims*, merely alleging facts related to a defendant's alleged *misconduct* is not enough. Rather, a complaint based on § 3729(a)(1)(A) must 'sufficiently establish that false claims were submitted for government payment' as a result of the defendant's alleged misconduct." *Id.* at 124 (emphasis in original) (quoting *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 733 (1st Cir. 2007)). Indeed, "[e]vidence of an actual false claim is the *sine qua non* of a False Claims Act violation." *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 225 (1st Cir. 2004) (internal citations omitted), *abrogated on other grounds by Claudio-De Leon v. Sistema Universitario Ana G. Mendez*, 775 F.3d 41 (1st Cir. 2014); *see also United States v. Rivera*, 55 F.3d 703, 709 (1st Cir. 1995) ("[T]he [FCA] statute attaches liability, not to the underlying fraudulent activity or to the government's wrongful payment, but to the claim for payment.").

As the First Circuit explained in *Ge* concerning the particularity requirement for pleading false claims:

> A relator must provide details that identify particular false claims for payment that were submitted to the government. In a case such as this, details concerning the dates of the claims, the content of the forms or bills submitted, their identification numbers, the amount of money charged to the government, the particular goods or services for which the government was billed, the individuals involved in the billing, and the length of time between the alleged fraudulent practices and

> the submission of claims based on those practices are the types of information that may help a relator to state his or her claims with particularity. These details do not constitute a checklist of mandatory requirements that must be satisfied by each allegations included in a complaint. However, we believe that some of this information for at least some of the claims must be pleaded in order to satisfy Rule 9(b).

737 F.3d at 124 (internal quotation marks and alterations omitted) (quoting *Karvelas*, 360 F.3d at 232-33); *see also United States ex rel. Escobar v. Universal Health Servs.*, 780 F.3d 504, 515 (1st Cir. 2015) (noting that while there was no "mandatory checklist" to satisfy the particularity requirement, relators "succeeded in linking their allegations of fraud to specific claims for payment" because the complaint "allege[d] twenty-seven separate dates on which claims were submitted in connection with Yarushka's care, each time including the relevant billing codes, amount invoiced, and the name of the [ ] staff member who provided the treatment for which reimbursement was sought"), *cert. granted*, 136 S. Ct. 582 (2015).

Here, the SAC alleges that the VA purchased twelve hip devices directly from DePuy pursuant to two procurement contracts. (SAC ¶¶ 473-90). Those alleged false claims, however, do not satisfy Rule 9(b)'s heightened pleading requirements.

First, ten of the twelve alleged claims do not allege with sufficient particularity that the VA purchased the specific DePuy product that is the sole focus of this

action: the Pinnacle MoM hip-implant device. (*See* SAC ¶¶ 494, 500). As described above, DePuy manufactured Pinnacle devices that had various combinations of head, liner, and cup materials, including "metal-on-metal, ceramic-on-polyethylene, or metal-on-polyethylene." (SAC ¶¶ 176-77; Def. Mem. Ex. C at 5). The alleged defects concern the interaction of a metal head with a metal liner in a Pinnacle device. There was only one head and liner combination of Pinnacle parts that produced a Pinnacle metal-on-metal, or MoM, device: a M-Spec or aSphere M-Spec head with an Ultamet or Ultamet XL liner. (SAC ¶¶ 176-77; Def. Mem. Ex. C at 3).

Before turning to the specific alleged false claims, the Court notes that the SAC uses the terms "Pinnacle" and "MoM" inconsistently. In paragraph 6, the SAC states that "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')." (SAC ¶ 6). It is unclear whether the relators intended to define "Pinnacle" to mean "the Pinnacle Acetabular Hip System" (which comprises metal, ceramic, and polyethylene products) or to mean the metal-on-metal subset of Pinnacle devices. Seven paragraphs later, relators use the specific term "MoM." (*See* SAC ¶ 13) ("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.'"). And in the 200-paragraph section detailing the alleged DePuy misrepresentations, relators use

the term "MoM" consistently. (*See, e.g.*, SAC ¶¶ 201, 248, 259, 273, 277, 279, 307, 310-11, 314, 316, 319-20, 334, 338, 340, 343-44, 348-49, 351-52, 361, 379, 395-96). The complaint thus seems to make clear that the only relevant fraudulent activity involved Pinnacle metal-on-metal devices. But in the section that alleges the proposed false claims, the relators use vague terms such as "Pinnacle products" or refer to products that are not a part of the Pinnacle system at all.

i. Paragraphs 479-480

> *479. [O]n January 18, 2011, VA employee Aryeh Lax from Los Angeles, California ordered a "SUMMIT FEMORAL STEM" and "ARTICUL/EZE METAL ON METAL FEMORAL HEAD" from DePuy. This order obligated the VA to pay $3,358.38.*
>
> *480. On January 30, 2011, Lax ordered a "SUMMIT FEMORAL STEM" and "ARTICUL/EZE METAL ON METAL FEMORAL HEAD" from DePuy. This order obligated the VA to pay $3,358.38.*

Depuy's marketing materials demonstrate that the "Summit femoral stem" is not a Pinnacle product, and even the relators appear to concede that it is not part of the Pinnacle MoM device. (*See* SAC ¶ 396) ("[T]he surface roughness manufacturing defect also affects devices *other than the Pinnacle MoM* .... These affected devices include DePuy's S-ROM, SUMMIT, CORAIL, and AML hip replacement products." (emphasis added)). The "Articul/eze metal-on-metal femoral head" does not appear to be a Pinnacle component because the only Pinnacle metal heads were the "aSphere M-Spec," the "M-Spec," and the

"Standard Metal." (*Compare* SAC ¶¶ 176-77, *and* Def. Mem. Ex. C at 3, *with* SAC ¶¶ 479-80). Furthermore, neither paragraph mentions a DePuy Pinnacle liner, much less an Ultamet metal liner. Thus, even assuming the Articul/eze head is metal and part of the Pinnacle device—which it is not—those paragraphs allege only part of a MoM device and ignore the liner. Finally, paragraphs 479 and 480 allege only "orders." They do not allege that those orders formed the basis of any actual claims that were presented to the VA.

ii. Paragraphs 481-484

> *481. On February 27, 2011, Lax ordered a Pinnacle product from DePuy. This order obligated the VA to pay $4,779.50.*
>
> *482. On June 1, 2012, VA employee Scott Delancey from Grand Junction ordered a Pinnacle product from DePuy. This order obligated the VA to pay $3,967.00.*
>
> *483. On September 29, 2011, VA employee Loretta Henry McLain from Los Angeles ordered a Pinnacle product from DePuy. This order obligated the VA to pay $8,712.14.*
>
> *484. On September 27, 2012, VA employee Kami Wiggins from Martinsburg ordered a Pinnacle product from DePuy. This order obligated the VA to pay $15,228.50.*

A "Pinnacle product" could refer to any combination of DePuy's three Pinnacle heads and three Pinnacle liners. (Def. Mem. Ex. C at 3). Only a "M-Spec" head and "Ultamet" liner combined to create the Pinnacle MoM device. It is therefore unclear whether any of the products in question are even

metal-on-metal devices. Also, the prices alleged in paragraphs 481 through 484 vary significantly. If those four "Pinnacle products" were all Pinnacle MoM devices, one would expect the prices to be at least somewhat similar. And as noted above, paragraphs 481 through 484 allege only "orders," not claims.

iii. Paragraphs 487-490

> *487. On June 18, 2007, Department of the Army employee Ann Slagle from Tacoma, Washington ordered a "SUMMIT METAL ON METAL" device from DePuy. The Summit stem is one of the parts of the Pinnacle Hip replacement system. This order obligated the Army to pay $9,000.00.*
>
> *488. On February 7, 2008, Naval Medical Center employee C. Johnson from San Diego, California ordered a "Srom Metal on Metal" device form DePuy. The S-Rom is a metal head used as a part of the Pinnacle Hip replacement system. This order obligated the Navy to pay $9,000.00.*
>
> *489. On July 5, 2007, Department of the Army employee Amparo Hall from Tacoma, Washington ordered "SUMMIT METAL ON METAL SYS." The Summit stem is one of the parts of the Pinnacle Hip replacement system. This order obligated the Army to pay $10,000.00.*
>
> *490. On July 12, 2007, Department of the Army employee Amparo Hall from Tacoma, Washington ordered "SUMMIT METAL ON METAL SYSTEM." The Summit stem is one of the parts of the Pinnacle Hip replacement*

system. This order obligated the Army to pay $10,000.00.

Confusingly, paragraphs 487, 489, and 490 allege that the Summit femoral stem is part of the "Pinnacle Hip replacement system." But as noted above, even the relators allege elsewhere in the SAC that the Summit stem is a different product from the Pinnacle MoM device. (*See* SAC ¶ 396). In fact, Summit stems could be used with entirely different hip-replacement systems, such as the ASR. (Def. Mem. Ex. D at 29). Paragraph 488 alleges an order of a S-Rom metal femoral head and alleges that the S-Rom was part of the "Pinnacle Hip replacement system." But DePuy's marketing materials, which the SAC incorporates, show that S-Rom heads were not part of the Pinnacle system. (Def. Mem. Ex. C at 3).

Thus, paragraphs 479 through 484 and 487 through 490 do not even allege that DePuy presented false claims to the VA for the only device relevant to this action, nor do they plead those "orders" with sufficient particularity to satisfy Rule 9(b). Only two of the twelve direct orders alleged in the SAC actually refer to a Pinnacle MoM device—the two alleged in paragraphs 485 and 486. (SAC ¶¶ 485-86).

iv. Paragraphs 485-486

485. On September 28, 2007, Naval Medical Center employee Jojie Urrete from San Diego, California ordered a "Pinnacle metal on metal" device from DePuy. This order obligated the Navy to pay $8,000.00.

486. On February 22, 2008, Urrete ordered a "Summitt (sic) Pinnacle metal on metal"

> *device from DePuy. This order obligated the Navy to pay $13,000.00.*

To plead direct false claims pursuant to 31 U.S.C. § 3729(a)(1)(A), a complaint must allege at least some hallmarks of particularity. The First Circuit has provided a non-exhaustive list, including

> details concerning the dates of the claims, the content of the forms or bills submitted, their identification numbers, the amount of money charged to the government, the particular goods or services for which the government was billed, the individuals involved in the billing, and the length of time between the alleged fraudulent practices and the submission of claims based on those practices ....

Karvelas, 360 F.3d at 228; *see also Ge*, 737 F.3d at 124. Following the decisions in *Karvelas* and *Ge*, several judges in this district have held that "[i]n cases where the defendant directly presents the claim to the government, the plaintiff must provide details identifying particular false claims submitted, including who filed the claims, the content of the claims, when such claims were submitted, where such claims were submitted, and how much it sought in payment." *United States ex rel. Westmoreland v. Amgen, Inc.*, 738 F. Supp. 2d 267, 275 (D. Mass. 2010) (citing *Karvelas*, 360 F.3d at 225); *see also United States ex rel. Nowak v. Medtronic, Inc.*, 806 F. Supp. 2d 310, 352 (D. Mass. 2011) (noting that relators must plead "which [of defendant's] personnel engaged in [the] conduct, where such conduct took place, which VA personnel were involved, [and] any specific

fraudulent statements made to personnel at the Veterans Administration"). The two descriptions of "orders" set forth in paragraphs 485 and 486 fail to allege with sufficient particularity that DePuy presented false claims to the VA.

First, the allegations focus entirely on the actions of a Naval Medical Center employee and do not specifically allege any actions by DePuy concerning the orders. The SAC lists *orders* by the employee requesting a Pinnacle MoM product, but it does not include any details about alleged *claims* or any actions by DePuy employees in relation to the orders. Paragraphs 485 and 486 do not even allege that DePuy in fact filled the orders and delivered the devices to the Naval Medical Center. Nor are there any allegations that DePuy invoiced the VA for the ordered products or requested payment, other than the broad allegation that the orders "obligated the Navy to pay" certain amounts. The paragraphs do not allege an order number or any other source-identifying information about any particular claim. There is no indication that any DePuy employee solicited, processed, or even knew about those alleged orders.

Second, the allegations fail to allege any details about the products themselves and how they caused the claim in question (if there was a claim) to be *false*. There is no allegation, for example, that those two specific products actually failed, had to be replaced, or were otherwise defective. Indeed, paragraphs 485 and 486 do not even allege that the ordered products were in fact implanted in a patient, or when, where, and by which doctor. In short, the SAC pleads no specific

details that would suggest that the two orders resulted in false claims.

The relators rely on *United States ex rel. Rodwell v. Excelitas Technologies, Corp.*, 2015 WL 3766866 (D. Mass. June 16, 2015), in support of their contention that the complaint is sufficient. In *Rodwell*, the court denied the defendant's motion to dismiss on Rule 9(b) grounds even though the relator "d[id] not identify any particular claim or invoice submitted to the government." *Id.* at *6. But in *Rodwell*, the relator identified specific contracts that the defendant had with the government, the specific terms of those contracts, and three batches of product orders that the government placed pursuant to those contracts, including the specific models of products ordered, specific quantities of each model ordered (more than one thousand in total), and the specific costs to the government. *Id.*

Here, however, the relators' allegations about DePuy's two alleged contracts are vague as to what products they covered, what their terms were, and whether DePuy presented the VA with any false claims for Pinnacle MoM devices pursuant to those contracts. Notably, the SAC does not connect the two contracts to any of the twelve alleged orders in paragraphs 479 through 490. The SAC generally describes the Federal Supply Schedule Service ("FSS") and Federal Supply Schedule Group 65 Part II Section A ("65 II A contract"). (SAC ¶¶ 114-15). But although the SAC describes the two VA contracts, it never actually alleges that DePuy had an FSS contract with the VA. (SAC ¶ 474). The SAC does not allege that either the 2006 "Orthopaedics Implant contract" (SAC

¶ 476) or the 2011 "Indefinite Delivery contract" (SAC ¶ 477) were FSS 65 II A contracts that would be governed by FDA regulations. Nor does the SAC include the contracts as attachments or quote relevant content from their terms. In fact, the SAC does not cite any terms of those specific alleged contracts at all. And finally, unlike in *Rodwell*, the SAC here contains no allegations about the specific products purchased pursuant to the contracts. In *Rodwell*, the relators included specific product models and quantities. Here, the SAC vaguely alleges that DePuy sold an unknown number of "Pinnacle Hip Implant products" under the contracts, without alleging that the contracts covered the sale of the Pinnacle MoM device. (SAC ¶ 478).

In sum, the SAC spends more than two hundred paragraphs detailing misrepresentations and false statements that DePuy allegedly made to the FDA and surgeons, including the relators themselves. (*See* SAC ¶¶ 201-412). It alleges in general terms that "the government directly purchased … hundreds of thousands of Pinnacle products." (SAC ¶ 7). But ten of the twelve allegedly false claims do not even refer to the only product relevant to this suit: the Pinnacle metal-on-metal device. For the two remaining "orders," the SAC fails to plead with sufficient particularity the who, what, when, where, and how of a single false claim that DePuy presented to the VA. Accordingly, the relators' claims pursuant to 31 U.S.C. § 3729(a)(1)(A) will be dismissed for failure to meet the heightened pleading requirements of Rule 9(b).

b. Indirect Claims

The SAC alleges that DePuy is liable under 31 U.S.C. § 3729(a)(1)(B) because it made false

statements and omissions that were material to the claims of third-party surgeons to government health-care programs such as Medicare and Medicaid. DePuy contends that the claim should be dismissed under Rule 9(b) because the SAC fails to allege any specific false claims and because it fails to suggest an inference of fraud beyond a mere possibility.

The First Circuit has distinguished pleading standards for direct claims, or sales to the government, which are governed by 31 U.S.C. § 3729(a)(1)(A), from indirect claims to the government where a defendant causes third-parties to submit false claims, which are governed by 31 U.S.C. § 3729(a)(1)(B). *See United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 29 (1st Cir. 2009) ("*Duxbury I*"). "In a *qui tam* action in which the defendant is alleged to have induced third parties to file false claims with the government, a relator can satisfy this requirement by 'providing factual or statistical evidence to strengthen the inference of fraud beyond possibility without necessarily providing details as to each false claim.'" *Ge*, 737 F.3d at 123-24 (quoting *Duxbury I*, 579 F.3d at 29). Thus, a *qui tam* complaint alleging that a defendant induced a third party to submit false claims to the government for reimbursement must allege two things to satisfy Rule 9(b): (1) particular details of a scheme to cause the submission of false claims to the government; and (2) factual or statistical evidence that strengthens the inference of fraud on the government beyond a mere possibility. *Duxbury I*, 579 F.3d at 29.

The SAC pleads a single representative indirect claim in paragraph 414. The relators contend that,

even standing alone without further support, the allegation is sufficient to defeat DePuy's motion to dismiss. Specifically, the SAC alleges that on November 12, 2007, patient "'F.I.' was implanted with a DePuy Pinnacle hip implant" by a surgeon in New York. (SAC ¶ 414). For the reasons explained above, such a claim does not meet the requirements of Rule 9(b); it does not identify the specific Pinnacle MoM device that is the subject of the present controversy. Put another way, the SAC 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.

Accordingly, without alleging any details as to a specific false claim for the relevant DePuy Pinnacle device, the relators must rely on the SAC's other factual and statistical evidence to strengthen the inference of fraud beyond a mere possibility. That evidence, however, fails to satisfy the requirements of Rule 9(b) as described by the First Circuit in *Ge* and *Duxbury I*.

In *Ge*, the relator's complaint alleged that the defendant pharmaceutical company had failed to file accurate and timely adverse event reports with the FDA, and that if it had done so, numerous claims for those pharmaceuticals would not have been submitted to the federal government. 737 F.3d at 119-21. The FCA claim was dismissed because the relator "made no attempt in her complaints to allege facts that would show that some *subset* of claims for government payment for the four subject drugs was rendered false as a result of [defendant's] alleged misconduct." *Id.* at 124 (emphasis in original). "What is missing are any

supporting allegations upon which her conclusion rests and any particulars." *Id.*

In contrast, the court in *Duxbury I* found that the complaint sufficiently alleged factual evidence to sustain an inference of fraud. 579 F.3d at 30. The relator alleged that kickbacks provided by the defendant resulted in the submission of false claims by eight named health-care providers in the state of Washington. *Id.* The court concluded that those eight specific allegations were sufficient factual support to satisfy the requirements of Rule 9(b), although it described the matter as "a close call." *Id.*; *see also Ge*, 737 F.3d at 124 (referring to the allegations in *Duxbury I* as "barely adequate").

In *Duxbury I*, the First Circuit quoted one of the specific allegations the plaintiff made in that case:

> In 1997-98 Western Washington Treatment Center in Olympia, Washington, received more than $5,000 of free commercially packaged ProCrit from [defendant] under the direction of Robert Ashe so that Western Washington could submit the free product for reimbursement to Medicare under the false and fraudulent certification that the provider had paid for the product. [Defendant] intended the free commercially packaged ProCrit to be a "cash equivalent" "kickback" to Western Washington in order to induce the provider to purchase ProCrit and to administer ProCrit at the "off-label" once a week dosing regiment. Western Washington was reimbursed by Medicare for the free commercially packaged ProCrit. As a result,

> [defendant] knowingly caused the presentation by Western Washington of these false claims to the United States Government.

579 F.3d at 30. The court concluded that the complaint's collection of eight specific examples of similar specificity, along with other allegations of the defendant's fraudulent scheme, were adequate (if "barely" so) to satisfy the requirements of Rule 9(b). *Id.* As the court noted, the plaintiff "identified, as to each of the eight medical providers (the who), the illegal kickbacks (the what), the rough time periods and locations (the where and when), and the filing of the false claims themselves." *Id.*

This Court has recently addressed another FCA case that presented a close call and found that the complaint satisfied the standards set forth in *Duxbury I* because the relator identified "one of defendants' sales representatives, the doctor, and the patient (the who), the specific misrepresentations made by the defendants (the what), time periods and locations (the where and when), and the filing of the false claims themselves." *See United States ex rel. Leysock v. Forest Labs., Inc.*, 55 F. Supp. 3d 210, 219 (D. Mass. 2014).

Here—setting aside for the moment the SAC's statistical allegations—the factual allegations in the SAC more closely resemble those rejected in *Ge* than those that were acceptable *Duxbury I* and *Leysock*. In *Duxbury I*, the relator alleged that specific employees of the defendant received kickbacks from specific health-care providers *and* that the kickbacks resulted in a false claim. In *Leysock*, the relator alleged that specific physicians were the targets of defendants' off-

label marketing and relied on that marketing, and alleged the specific dates that the physicians filled the prescriptions. The SAC here fails to connect the multiple allegations of DePuy's misrepresentations and omissions to any specific claims for payment. Nor does the SAC appear 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. The closest that the SAC comes to such specificity is "Dr. J.N." and "patient F.I.", but the SAC does not identify the specific representations or materials that the doctor received and relied upon, nor does it allege the specific DePuy device for which the doctor filed a claim. (*See* SAC ¶¶ 414-24).[8]

Furthermore, the SAC's unfocused and imprecise statistical evidence adds little to establish DePuy's fraud beyond a mere possibility. The SAC alleges that more than one million metal-on-metal devices were sold worldwide "[d]uring the times relevant to this complaint," and that in 2010, more than 300,000 "hip-replacement surgeries were performed in the United States." (SAC ¶¶ 434, 436). Therefore, according to the SAC, because "the Pinnacle MoM hip was one of the most widely used hip-replacement systems that remained in the international marketplace," as a matter of logic "it follows that hundreds of thousands of Pinnacle products were implanted in government healthcare recipients and reimbursed by the

[8] It is also noteworthy that the allegations with regard to that order are based on mere "information and belief." (SAC ¶¶ 414-24).

government during the lifespan of the product." (SAC ¶¶ 434, 437). Those statistical allegations are not sufficiently precise or consistent as to the geographical scope, time period, or product type to maintain an inference of fraud. The broad statistical claims made here could be made about virtually any successful medical device or product.[9]

Finally, to the extent that the relators contend that every indirect claim for reimbursement of the Pinnacle MoM device was false because the device's defects made it "not reasonable and necessary" under 42 U.S.C. § 1395y(a)(1)(A), such an argument must fail. Surely to survive a motion to dismiss pursuant to Rule 9(b) and Rule 12(b)(6), the relators must do more than allege that a product's alleged defects automatically make it unreasonable and unnecessary. Such a theory of liability, if allowed to proceed, would convert almost any product-liability suit into one that also states a claim under the False Claims Act.

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[9] If the rule were otherwise, virtually any claim of misrepresentation or a product defect involving medical devices, pharmaceuticals, or other medical products could be brought as a *qui tam* action. Government health-care programs such as Medicare and Medicaid represent a huge portion of health-care expenditures in the United States. As 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. Rule 9(b), however, requires something more than conclusory allegations that false claims must have resulted from the misconduct. *See Ge*, 737 F.3d at 124 (stating that the court "reject[s] [the] approach" sought by the relator, which was "a *per se* rule that if sufficient allegations of misconduct are made, it necessarily follows that false claims and/or material false information were filed").

In short, the SAC is slightly more detailed than the complaint in *Ge*, which the First Circuit found to be inadequate under Rule 9(b). It contains, however, almost no specific allegations as to actual false claims in comparison to the detailed eight claims in *Duxbury I*, which the First Circuit said was "barely adequate" and where dismissal was considered a "close call." Accordingly, DePuy's motion to dismiss will be granted as to the federal FCA claims (Counts One and Two) for failure to comply with the requirements of Rule 9(b).

2. Rule 12(b)(6)

DePuy also contends that the relators' federal FCA claims pursuant to § 3729(a)(1)(A)-(B) should be dismissed for failure to state a claim under Fed. R. Civ. P. 12(b)(6). Specifically, DePuy contends that the SAC fails to state a claim because even if it made misstatements about the Pinnacle MoM device, the relators fail to allege that those misstatements resulted in any claims that were actually "false" as the First Circuit interpreted the meaning of the term in *United States ex rel. Escobar v. Universal Health Services*, 780 F.3d 504, 512 (1st Cir. 2015).[10]

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[10] DePuy also contends that the SAC fails to allege that DePuy made any false statements in submitting or causing third-parties to submit false claims that were "material" to the government's decision to reimburse the claim. In most cases, materiality issues are not appropriate for resolution on the pleadings because the element, as defined by the First Circuit, is highly dependent on the facts. *See, e.g.*, *Loughren*, 613 F.3d at 308 (noting that "materiality in the FCA context involves a factual determination of the weight that the decisionmaker would have given particular information"). Because the Court has resolved the present motion on the narrower issue of Rule 9(b)'s pleading requirements—

After the Court held a hearing on DePuy's motion to dismiss, the Supreme Court, on December 3, 2015, granted a petition for review of the First Circuit's decision in *Escobar*. *See Universal Health Servs., Inc. v. United States*, No. 15-7, 136 S. Ct. 582. As explained more fully below, a complicated circuit split on the issues of (1) implied certification and (2) conditions of participation versus conditions of payment will continue to affect FCA cases until the Supreme Court issues its ruling in *Universal Health Services*. It does not appear that the Supreme Court has set a briefing schedule or argument date, and the Court very well could resolve some issues while reserving others for remand to the First Circuit. Thus, it appears unlikely that the FCA issues presented by *Escobar* and related cases in other circuits—namely, what suffices as a "false" claim—will be resolved within the next year. In any event, the Court has already reached a resolution of the relators' federal FCA claims on the independent grounds of Rule 9(b). Accordingly, the Court will defer ruling on the Rule 12(b)(6) issues.

As noted, the False Claims Act proscribes "knowingly present[ing], or caus[ing] to be presented, a false or fraudulent claim for payment or approval" and "knowingly mak[ing], us[ing], or caus[ing] to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A)-(B). To be actionable, a false or fraudulent claim or statement must also be material to the government's decision to pay a claim. *See Loughren*, 613 F.3d at 307

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along with the fact that *Escobar* would need to be resolved by the Supreme Court—the Court will not address DePuy's second argument.

("We have long held that the FCA is subject to a judicially-imposed requirement that the allegedly false claim or statement be material.").

As one judge in this district has recently noted since the First Circuit's decision in *Escobar*, "[f]alse statements come in the full spectrum of shades of gray, and the False Claims Act provides little help to courts attempting to separate actionable ones from permissible ones." *United States ex rel. Bierman v. Orthofix Int'l, N.V.*, 2015 WL 4197551, at *3 (D. Mass. July 1, 2015) (Zobel, J.). Some circuits have announced fixed rules to determine whether a claim is actionable by separating various types of false claims into categories. One such categorization divides claims and statements that are factually false (such as when a contractor does not provide the product for which reimbursement is sought) from those that are legally false (such as false certifications of compliance with statutes or regulations). *See, e.g.*, *United States ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1217 (10th Cir. 2008); *Mikes v. Straus*, 274 F.3d 687, 696-97 (2d Cir. 2001).

But the disagreement among the circuits about the meaning of a false claim exists at two further levels of categorization. First, one categorization divides legally false statements into groups based on theories of "express" certification and "implied" certification. *See United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 305-06 (3d Cir. 2011) (collecting cases). Under the theory of express certification, a company faces liability under the FCA by fraudulently and expressly certifying compliance with a statute, regulation, or contractual provision

when submitting a claim for payment. *Id.* Under the theory of implied certification, a company may face liability even if it did not certify compliance with a statute or regulation when submitting the claim, but instead made an earlier, more general certification. *Id.* The Seventh Circuit has recently adopted only express certification and rejected all theories of implied certification. *See United States v. Sanford-Brown, Ltd.*, 2015 WL 3541422, at *12 (7th Cir. June 8, 2015) ("Although a number of other circuits have adopted the so-called doctrine of implied false certification … we decline to join them .... "). Other circuits however, including the First Circuit, have accepted, to varying degrees, the theory of implied certification.[11]

Second, the circuits that have accepted the implied certification theory are further divided. Every circuit to accept implied certification requires that compliance with a statute, regulation, or contractual provision that is allegedly violated must be a condition of payment by the government payor. There is disagreement among the circuits, however, as to whether a condition of payment must be expressly identified as such, or whether a statute, regulation, or contractual provision can be a condition of payment if it does not state that payment is conditioned on compliance. The Second and Sixth Circuits fall into the former category, concluding that a company impliedly certifies compliance with a statute, regulation, or contractual provision for purposes of

[11] Although the First Circuit has "eschewed distinctions" used by other circuits in describing types of FCA claims, as discussed below, it appears that the court in *Escobar* applied a theory of implied certification. 780 F.3d at 512.

FCA liability only if the government expressly conditions payment on compliance. *See Chesbrough v. VPA, P.C.*, 655 F.3d 461, 468 (6th Cir. 2011); *Strauss*, 274 F.3d at 700-02. In other words, according to those circuits, the legal obligation in question must be explicitly designated as a condition of *payment*. Conversely, the First, Fourth, and D.C. Circuits do not require a legal obligation to be expressly identified as a condition of payment; instead, those circuits have found "implied conditions of payment"—sometimes referred to as conditions of participation—without explicit language in the relevant statute, regulation, or contract. *See Escobar*, 780 F.3d at 513-14; *United States v. Triple Canopy, Inc.*, 775 F.3d 628, 636 (4th Cir. 2015); *United States v. Science Apps. Int'l Corp.*, 626 F.3d 1257, 1269 (D.C. Cir. 2010) ("*SAIC*").

In *Escobar*, the First Circuit declared that it had "eschewed distinctions between factually and legally false claims, and those between implied and express certification theories, reasoning that they 'create artificial barriers that obscure and distort [the statute's] requirements.'" *Escobar*, 780 F.3d at 512 (quoting *United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 385 (1st Cir. 2011)). Instead, the court wrote that it takes "a broad view of what may constitute a false or fraudulent statement to avoid 'foreclos[ing] [False Claims Act] liability in situations that Congress intended to fall within the Act's scope,'" *United States ex rel. Jones v. Brigham & Women's Hosp.*, 678 F.3d 72, 85 (1st Cir. 2012) (quoting *Hutcheson*, 647 F.3d at 387), "ask[ing] simply whether the defendant, in submitting a claim for reimbursement, knowingly misrepresented compliance with a material precondition of payment."

Escobar, 780 F.3d at 512. As interpreted by the First Circuit, "preconditions of payment, which may be found in sources such as statutes, regulations, and contracts, need not be 'expressly designated.'" *Id.* (quoting *Hutcheson*, 647 F.3d at 387-88). "Rather, the question whether a given requirement constitutes a precondition to payment is a 'fact-intensive and context-specific inquiry,' involving a close reading of the foundational documents, or statutes and regulations, at issue." *Id.* at 512-13 (quoting *New York v. Amgen Inc.*, 652 F.3d 103, 110 (1st Cir. 2011)).

In *Escobar*, the relators' daughter died while receiving treatment from unlicensed providers at a Massachusetts counseling center owned by Universal Health Services. *Id.* at 509. The relators alleged that the treatment facility violated the FCA because it, in submitting claims for payment, impliedly falsely represented that it had complied with various state regulations, including regulations concerning the licensing and supervision of providers. *Id.* at 510-11. The district court dismissed the complaint in its entirety for failure to plead the requisite element of falsity. *United States ex rel. Escobar v. Universal Health Servs., Inc.*, 2014 WL 1271757, at *7 (D. Mass. Mar. 26, 2014). The district court drew a distinction between requirements that MassHealth imposed on providers as conditions of payment, and those imposed as conditions to participation in the program in the first instance. *Id.* at *6 ("Violations of only a condition of participation will not suffice."). The district court concluded that only one of the regulations cited by the relators was a condition of payment, and for that regulation, it concluded that the relators had not plausibly alleged that the defendant had violated the

provision. *Id.* at *11-12. The First Circuit reversed, finding that a regulation that the district court did not address was a condition of payment, and held that "[b]ecause [First Circuit] case law makes clear that a healthcare provider's noncompliance with conditions of payment is sufficient to establish the falsity of a claim for reimbursement, we need not address here whether the False Claims Act embraces a distinction between conditions of payment and conditions of participation." *Escobar*, 780 F.3d at 517. Nonetheless, the court further stated that "express certification" of compliance with a condition of payment is not required under the FCA. *Id.* at 514 n.14.

Thus, even though the First Circuit indicated that it would not entertain distinctions between express and implied certification, the defendant filed a petition for a writ of certiorari asking the Supreme Court to address issues of implied certification and conditions of payment. The Supreme Court granted review on two questions:

> (1) Whether the "implied certification" theory of legal falsity under the FCA—applied by the First Circuit below but recently rejected by the Seventh Circuit—is viable; and
>
> (2) Whether, if the "implied certification" theory is viable, a government contractor's reimbursement claim can be legally "false" under that theory if the provider failed to comply with a statute, regulation, or contractual provision that does not state that it is a condition of payment, as held by the First, Fourth, and D.C. Circuits; or whether liability for a legally "false" reimbursement

> claim requires that the statute, regulation, or contractual provision expressly state that it is a condition of payment, as held by the Second and Sixth Circuits.

Universal Health Services, Inc. v. United States, 136 S. Ct. 582 (2015).

Here, taking all of the SAC's allegations as true, it appears that DePuy's motion to dismiss on Rule 12(b)(6) grounds depends on the resolution of those two issues by the Supreme Court. Liberally construed, the SAC alleges that DePuy had two contracts to sell DePuy Pinnacle devices to the VA; that the contracts at least implicitly certified that the devices were sold pursuant to Federal Supply Schedule Group 65 Part II Section A, which requires that items are "merchantable and fit for use of the particular purpose described in th[e] contract" and "in compliance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act"; and that the MoM device did not comply with those implied certifications. (SAC ¶¶ 117, 281-99, 474-78).

Thus, it appears that in order to address DePuy's motion to dismiss on Rule 12(b)(6) grounds, the Court would need to await a decision from the Supreme Court about the viability of the implied-certification theory—and in particular, the theory of implied certification adopted by the First Circuit in *Escobar*. Accordingly, the Court will reserve judgment as to those issues.

B. Count Three: FCA Conspiracy Claim

Count Three alleges that DePuy violated the FCA by conspiring with its own employees to defraud government health-care programs. The SAC alleges

that "[a]s set forth above, all named defendants have conspired with its officers, agents, and employees to defraud the United States government by presenting false or fraudulent claims for payment in violation of 31 U.S.C. § 3729(a)(1)(C)." (SAC ¶ 506). The SAC further alleges that "defendants conspired with its officers, agents, and employees authorizing them to take and conceal the actions set forth above." (SAC ¶ 507). DePuy contends that the conspiracy claim should be dismissed because a corporation cannot conspire with its officers and employees to violate the FCA.

Pursuant to 31 U.S.C. § 3729, "any person who—(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; [or] (C) conspires to commit a violation of subparagraph (A) [or] (B) … is liable" for a violation of the FCA.

Of course, a corporation can only violate the FCA through the actions of its agents and employees. If DePuy is violating the FCA, there is no meaningful distinction between the relators' claims in Counts One and Two for false or fraudulent claims, statements, and records and Count Three for conspiracy to defraud the government health-care programs.

It therefore does not make sense to permit a conspiracy claim under the FCA to proceed on the theory that DePuy has conspired with its officers and employees. This concept has been endorsed by the Supreme Court in antitrust law. *See Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 769 (1984)

(explaining that "officers of a single firm are not separate economic actors pursuing separate economic interests, so agreements among them … do not provide the plurality of actors imperative for a" conspiracy under section 1 of the Sherman Act). Multiple courts have found that companies cannot conspire with their employees or agents in the FCA context. *See, e.g.*, *United States ex rel. Ruhe v. Masimo Corp.*, 929 F. Supp. 2d 1033, 1037-38 (C.D. Cal. 2012) (holding that conspiracy claim failed to state a claim because a corporation cannot conspire with its own employees or agents); *United States ex rel. Head v. Kane & Co.*, 798 F. Supp. 2d 186, 201 (D.D.C. 2011) (finding that a company could not have conspired with its employees to violate the FCA); *United States ex rel. Loughren v. Unumprovident Corp.*, 2008 WL 4280133, at *3 (D. Mass. Sept. 15, 2008) (dismissing FCA conspiracy claims during periods when defendants were corporate affiliates because parent and subsidiary corporation cannot conspire as a matter of law); *United States ex rel. Brooks v. Lockheed Martin Corp.*, 423 F. Supp. 2d 522, 528 (D. Md. 2006) (finding that parent company and its two wholly-owned subsidiaries could not conspire among themselves to violate the FCA); *United States ex rel. Reagan v. East Tex. Med. Ctr. Reg'l Health-care Sys.*, 274 F. Supp. 2d 824, 856 (S.D. Tex. 2003) (finding that a parent corporation cannot conspire with various components and subsidiaries to commit a conspiracy in violation of the FCA).

In short, although corporate employees could conspire with outside individuals, such as physicians, the conspiracy cannot be between the corporations and their officers and employees. Accordingly, DePuy's

motion to dismiss the conspiracy claim (Count Three) will be granted.

C. Counts Four through Thirty-Seven: State FCA Claims

Counts Four through Thirty-Seven of the SAC allege violations of various state and municipal analogues to the federal FCA.[12] DePuy contends that those claims should be dismissed for the same reasons the federal FCA claims should be dismissed.

The First Circuit has noted that "[g]iven the substantive similarity of the state FCAs … and the federal FCA with respect to the provisions at issue in this litigation, the state statutes may be construed consistently with the federal act." *Amgen*, 652 F.3d at 109. Thus, Rule 9(b)'s heightened pleading requirements apply equally to allegations made pursuant to violations of a state FCA. *See, e.g.*, *Nowak*, 806 F. Supp. 2d at 357 ("In order to satisfy Rule 9(b), [relator] must allege some specificity with respect to each asserted state and cannot rely upon generalized pleadings.").

Here, with two exceptions, the SAC's state FCA allegations do not even come close to satisfying the pleading requirements of Rule 9(b). For 33 of the state-law FCA counts, the SAC contains identical language that "repeat[s] and reallage[s] each and every allegation contained in the paragraphs above as though fully set forth herein." (*See, e.g.*, SAC ¶ 509).

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[12] For these purposes, the District of Columbia will be considered a "state."

With the exceptions of California[13] and New York, the SAC contains no allegations of fraudulent conduct or false claims for the Pinnacle MoM device beyond the repeated conclusory allegations found in the specific counts.

Moreover, the SAC's allegations concerning California are limited to a San Diego patient who allegedly ordered a Pinnacle MoM device and a "Summitt Pinnacle metal on metal" device through the VA on September 28, 2007. (SAC ¶¶ 485-86). For the reasons discussed above, those allegations are insufficient to meet the requirements of Rule 9(b). Finally, the SAC's allegations about the one New York Medicaid patient who received a "Pinnacle hip implant"—along with the related New York statistics—are insufficient to survive Rule 9(b) because they 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. (SAC ¶¶ 414-28, 438-55).

Accordingly, DePuy's motion to dismiss will be granted as to the state and municipal FCA claims (Counts Four through Thirty-Seven) for failure to comply with the requirements of Rule 9(b).

D. Motion to Unseal

On August 24, 2015, the relators moved under seal to unseal the SAC. DePuy assented to that motion on September 2, 2015, but requested that certain other documents also be unsealed: (1) the relators' motion to

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[13] California is the only state among the alleged false claims in paragraphs 479 through 490 where the SAC alleges an order of a Pinnacle MoM device. (*See* SAC ¶¶ 479-90).

unseal the SAC, the accompanying memorandum of law and exhibits, and DePuy's response and accompanying exhibits; and (2) all documents and filings relating to DePuy's motion to dismiss.

Under the FCA, a *qui tam* relator must comply with the following pre-suit requirements:

> A copy of the complaint and written disclosure of substantially all material evidence and information the person possesses shall be served on the Government .... The complaint shall be filed in camera, shall remain under seal for at least 60 days, and shall not be served on the defendant until the court so orders. The Government may elect to intervene and proceed with the action within 60 days after it receives both the complaint and the material evidence and information.

31 U.S.C. § 3730(b)(2).

The relators filed the initial complaint under seal on May 18, 2012. Judge Talwani partially unsealed the case on August 12, 2014, but the complaint remained under seal. This Court denied a renewed motion to unseal the case on March 18, 2015, without prejudice. The SAC and documents relating to DePuy's motion to dismiss have remained under seal since.

The case has reached a point where unsealing the complaint and related documents is appropriate. Accordingly, both parties' motions to unseal certain documents will be granted and the Court directs the clerk to unseal the following docket number entries,

including exhibits: Docket Nos. 145, 146, 152, 153, 159, 166, 172, and 177.

E. Leave to Amend

The relators filed the initial complaint in this case on May 18, 2012. The relators filed an amended complaint on December 2, 2013. On June 5, 2015, the Court granted, over the objection of DePuy, the relators' motion to amend the first amended complaint and file a second amended complaint. On June 29, 2015, DePuy filed its motion to dismiss. The relators have not filed a formal motion for leave to amend the SAC. However, in the conclusion section of their opposition to DePuy's motion to dismiss, filed on July 13, 2015, the relators conclude: "For all the foregoing reasons, defendants' motion to dismiss the SAC should be denied. In the alternative, relators should be granted leave to amend insofar as it may be necessary to plead additional facts to meet the standards of Rule 12(b)(6) and/or 9(b)." (Relators' Mem. Opp. 30).[14]

The SAC will be dismissed with prejudice and the relators' request to file a fourth complaint will be denied. Relators filed their original complaint in 2012, three years after *Duxbury I* firmly established the FCA pleading requirements in the First Circuit. After

[14] The relators made similar requests in their sur-reply brief and post-hearing supplemental filing. (Docket Nos. 166, 179). The relators also contend that leave to amend should be granted because DePuy did not move to dismiss the SAC with prejudice. But DePuy explicitly did so, as noted on the first page of its motion to dismiss, filed on June 29, 2015. (Docket No. 145) ("Pursuant to Federal Rules of Civil Procedure 9(b) and 12(b)(6), Defendants … respectfully move to dismiss the relators' second amended complaint with prejudice.").

amending their complaint twice, relators opposed DePuy's motion to dismiss instead of filing a request to amend the complaint a third time. Hedging their bets, at the very end of their opposition, relators requested leave to amend using boilerplate language. *See Ge*, 737 F.3d at 128 ("[W]here, as here, a request to file an amended complaint consists of nothing more than 'boilerplate sentences stating the well-settled 'freely given' standard under which a request for leave to amend is generally analyzed,' a district court 'acts well within its discretion when completely disregarding the request.'" (quoting *Silverstrand Invs. v. AMAG Pharm., Inc.*, 707 F.3d 95, 107-08 (1st Cir. 2013))). Moreover, as the First Circuit has held in the context of post-judgment requests to amend a complaint, allowing relators to file a fourth complaint here after fully litigating the issues "would allow plaintiffs to pursue a case to judgment and then, if they lose, to reopen the case by amending their complaint to take account of the court's decision. Such a practice would dramatically undermine the ordinary rules governing the finality of judicial decisions, and should not be sanctioned in the absence of compelling circumstances." *James v. Watt*, 716 F.2d 71, 78 (1st Cir. 1983) (Breyer, J.).

Despite full awareness of Rule 9(b)'s pleading standards, the relators—who are expert witnesses in related products-liability lawsuits against DePuy—have failed to plead with requisite particularity even a single false claim for the Pinnacle MoM device in their 168-page second amended complaint. The Federal Rules call for courts to "freely give leave [to amend] when justice so requires." Fed. R. Civ. P. 15(a)(2). Justice would not be served by granting

relators' request to file a third amended complaint; rather, such a grant would prejudice the defendants and incentivize future unfair amendment tactics.

Accordingly, relators' request to file a third amended complaint is denied on the grounds of undue delay. *See Foman v. Davis*, 371 U.S. 178, 182 (1962) (noting that amendments may be denied on the basis of "undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, [and] futility of amendment"); *United States ex rel. D'Agostino v. EV3, Inc.*, 802 F.3d 188, 195 (1st Cir. 2015) (noting that, even though the Rule 15 standard applied—instead of the Rule 16 good cause standard—to a relator's request to amend a *qui tam* complaint, "[l]et us be perfectly clear. We do not suggest that the district court will be compelled to grant the motion to amend on remand. After all, there are myriad reasons that might justify the denial of a motion for leave to amend, including undue delay, repeated failure to cure deficiencies, or futility." (citing *Foman*, 371 U.S. at 182)). "When 'considerable time has elapsed between the filing of the complaint and the motion to amend, the movant has [at the very least] the burden of showing some valid reason for his neglect and delay.'" *In re Lombardo*, 755 F.3d 1, 3 (1st Cir. 2014) (internal quotation marks omitted) (quoting *Stephanischen v. Merchants Despatch Transp. Corp.*, 722 F.2d 922, 933 (1st Cir. 1983)). The First Circuit has "previously labeled as 'considerable time' warranting explanation, periods of fourteen months, fifteen months, and seventeen months." *Id.* (citations omitted) (citing

Grant v. News Grp. Bos., Inc., 55 F.3d 1, 6 (1st Cir. 1995) (fourteen months); *Acosta-Mestre v. Hilton Int'l of P.R., Inc.*, 156 F.3d 49, 51-52 (1st Cir. 1998) (fifteen months); *Stepanischen*, 722 F.2d at 933 (sixteen months)). The First Circuit has "also held that in assessing whether delay is undue, a court will take account of what the movant 'knew or should have known and what he did or should have done.'" *Id.* at 3-4 (quoting *Invest Almza v. Temple-Inland Forest Prods. Corp.*, 243 F.3d 57, 72 (1st Cir. 2001)). Delays for periods as short as eleven months, four months, and less than three months have been found to constitute undue delay. *See Calderón-Serra v. Wilmington Trust Co.*, 715 F.3d 14, 19-20 (1st Cir. 2013) (eleven-month delay); *Villanueva v. United States*, 662 F.3d 124, 127 (1st Cir. 2011) (four-month delay); *Kay v. N.H. Dem. Party*, 821 F.2d 31, 34 (1st Cir. 1987) (less than three-month delay).

Here, the relators filed their original complaint in 2012, when they should have already been aware of the First Circuit's Rule 9(b) pleading standard in FCA cases. Since that time, they have amended the complaint twice. At the very latest, they should have been aware of the SAC's deficiencies when DePuy filed its motion to dismiss in June 2015. Instead, the relators vigorously litigated the motion, including the filing of a sur-reply and multiple post-argument supplemental briefs. Now, they wish to amend the complaint a third time. Considerable time has passed since the filing of the original complaint and since the relators were put on notice of the defects in the complaint, and the relators have not demonstrated a legitimate reason for their neglect and delay. Accordingly, the relators' request for leave to amend

the SAC and file a third amended complaint will be denied.

IV. Conclusion

For the foregoing reasons, DePuy's motion to dismiss the second amended complaint with prejudice is GRANTED, and the clerk is hereby directed to unseal the docket entries indicated above. Relators' request for leave to amend its second amended complaint is DENIED.

So Ordered.

/s/ F. Dennis Saylor

Dated:
February 2, 2016

F. Dennis Saylor IV
United States District Judge