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]

Before

Torruella, Thompson, and Kayatta,
Circuit Judges.

Russell L. Kornblith, with whom David W. Sanford, Ross B. Brooks, Sanford Heisler, LLP, Kevin M. Kinne, and Cohen Kinne

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Valicenti & Cook, LLP, were on brief, for appellants.
Mark D. Seltzer, with whom D. Danielle Pelot, Hannah R. Bornstein, and Nixon Peabody LLP were on brief, for appellees.

July 26, 2017

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

[1] The district court also dismissed Relators' claim that DePuy and its officers and employees conspired to defraud the government

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 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

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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.

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 the 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

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

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, 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

[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).

"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 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 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

[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).

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 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

[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.

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

[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.

32. The fraudulent scheme alleged in 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

[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.

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 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

[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,

claims for government payment, it does not sustain Relators' claims alleging that DePuy directly submitted false claims for 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

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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).

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.