United States Court of Appeals
For the First Circuit

No. 16-1126

JEFFREY D'AGOSTINO,

Plaintiff, Appellant,

STATE OF CALIFORNIA; STATE OF CONNECTICUT; DISTRICT OF COLUMBIA; STATE OF FLORIDA; STATE OF GEORGIA; STATE OF HAWAII; STATE OF ILLINOIS; STATE OF INDIANA; STATE OF LOUISIANA; STATE OF MARYLAND; COMMONWEALTH OF MASSACHUSETTS; STATE OF MICHIGAN; STATE OF MONTANA; STATE OF NEVADA; STATE OF NEW HAMPSHIRE; 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; JOHN DOE; UNITED STATES; STATE OF DELAWARE; STATE OF MINNESOTA,

Plaintiffs,

v.

EV3, INC.; MICROTHERAPEUTICS, INC.,

Defendants, Appellees,

JOHN CUBELIC; VITAS J. SIPELIS; JOHN HARDIN; BRETT WALL,

Defendants.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

[Hon. Richard G. Stearns, U.S. District Judge]

Before

Howard, Chief Judge,
Selya and Kayatta, Circuit Judges.

Daniel Robert Miller, with whom Susan Schneider Thomas, Berger & Montague PC, Lynn G. Weissberg, Jonathan Shapiro, and Shapiro, Weissberg & Garin LLP were on brief, for appellant.

Joshua S. Levy, with whom Mitchell Stromberg, Rebecca C. Ellis, Bryan Alexander Pennington, Jeremy E. Kanarek, and Ropes & Gray LLP were on brief, for appellees.

Tara S. Morrissey, Attorney, Department of Justice, Civil Division, with whom Michael S. Raab, Attorney, Civil Division, Benjamin C. Mizer, Principal Deputy Assistant Attorney General, Civil Division, and Carmen M. Ortiz, United States Attorney, were on brief, for amicus curiae the United States of America.

December 23, 2016

KAYATTA, **Circuit Judge**. This qui tam action makes its second appearance before us. Last year, we held that the district court should have evaluated Jeffrey D'Agostino's request for leave to file his fourth amended complaint under the standard set forth in Federal Rule of Civil Procedure 15(a). United States ex rel. D'Agostino v. ev3, Inc. (D'Agostino I), 802 F.3d 188, 193–96 (1st Cir. 2015). On remand, the district court found that D'Agostino's desired amendment failed under that standard because, even as proposed to be amended, the complaint did not allege claims upon which the court could grant relief. United States ex rel. D'Agostino v. ev3, Inc., 153 F. Supp. 3d 519, 538 (D. Mass. 2015). For the following reasons, we agree.

I. Background

A. Factual Allegations

Defendant ev3, Inc. ("ev3") discovers, develops, manufactures, and markets medical devices. Defendant Micro Therapeutics, Inc. ("MTI"), ev3's subsidiary since 2006, likewise manufactures and markets medical devices. D'Agostino's original and proposed complaints against these companies focus on two devices, the Onyx Liquid Embolic System ("Onyx") and the Axium Detachable Coil System ("Axium"). We recite the relevant facts concerning each device as they are alleged by D'Agostino in his proposed complaint, assuming them to be true unless they are merely conclusory. See Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009).

1. Onyx

Onyx is an artificial liquid material developed by MTI to treat malformed blood vessels in the brain. In plain terms, it is injected into blood vessels near the brain, and then forms a mass blocking the flow of blood to facilitate subsequent surgery. In the early 2000s, MTI licensed the Onyx molecule to a company named Enteric. Enteric used the molecule to develop another medical device, Enteryx, which went to market first, after gaining Food and Drug Administration ("FDA") approval in April 2003 for the treatment of gastroesophageal reflux disease. A series of adverse events involving Enteryx followed, prompting a patient safety alert in October 2004, and culminating in a complete recall of the device in September 2005.

It was during this timeframe--between Enteryx's approval and recall--that MTI sought approval for Onyx. The FDA's regulations require a premarket approval ("PMA") process for medical devices like Onyx. See 21 C.F.R. § 814.1(c). During that process, the device manufacturer supplies the FDA with extensive information regarding the device--including its design, manufacturing, packing, labeling, and testing--to satisfy the agency that the device is safe and effective. Id. § 814.20. A "sufficiently complete" application proceeds to substantive review. Id. § 814.42(a). That review is performed by FDA personnel and, at the FDA's election as in this instance, by an

advisory panel of outside experts. Id. § 814.44(a). The panel holds a public meeting to review the PMA before making a recommendation to the FDA. Id. § 814.44(b). The FDA then considers the PMA application, together with any advisory panel report and recommendation, before issuing a decision on approval. Id. § 814.44(c).

MTI's PMA application identified a narrow indication for Onyx: "use in the treatment of brain arteriovenous malformations ('BAVM's'), when embolization is indicated to minimize blood loss to reduce the BAVM size prior to surgery." While seeking approval, MTI emphasized the narrow scope of the indication as well as the rigorous nature of the training program required for physicians using Onyx. According to the testimony of MTI's Vice President before the FDA advisory panel, that training program would include an instructional session, a hands-on workshop, a case review, and observations. According to another MTI witness, any physician who completed this training would receive the assistance of an experienced proctor the first time he or she used Onyx. The advisory panel members placed great weight on these training requirements, describing them as "critically important" and "a very big component of getting [Onyx] into safe use."

The panel ultimately recommended approval of Onyx. However, several of its members explained that it was a "cautious approval," and others warned that they would advise the FDA to

rescind approval if MTI disregarded their suggestions for carefully monitoring Onyx cases.

The FDA adopted the panel's recommendation, granting approval to Onyx in July 2005. The Onyx label authorized by the FDA restricted the device's use to "physicians with neurointerventional training and a thorough knowledge of the pathology to be treated, angiographic techniques, and super-selective embolization." It stated, "Contact your Micro Therapeutics Inc. sales representative for information on training courses."

Enter D'Agostino, a sales representative who worked at ev3 from January 2005 until his termination in January 2010. After ev3 acquired MTI in 2006, D'Agostino became familiar with the manner in which the defendants promoted and sold Onyx. He says that he observed physician trainings that lasted as little as four hours and proctored surgeries that involved off-label procedures. He also alleges that the defendants instituted a "Site Certification Process" whereby they certified and sold Onyx to any site where a single neurosurgeon who had completed their training enjoyed privileges. As a result, he says that Onyx fell into the hands of physicians at those sites with inadequate training or no training at all. Additionally, the defendants encouraged off-label marketing by setting sales quotas for their representatives that anticipated such sales, educating their sales force on

"peripheral applications," and providing off-label training to physicians during all-expenses-paid retreats. All in all, it became clear, alleges D'Agostino, that the defendants never intended to honor the commitments that MTI had made to the FDA.

2. Axium

Because clinical trials involving Onyx in the treatment of aneurysms evinced numerous complications, the defendants in 2007 launched a new medical device, Axium.[1] Put simply, Axium provides another means of generating an embolism to facilitate the surgical treatment of anomalies in blood vessels in the brain. Surgeons use the device to place a small, detachable coil at a desired spot to generate a blockage of blood flow to an abnormality such as an aneurysm. Following the initial launch in 2007, the defendants redesigned the device several times in response to reports that it malfunctioned during procedures. They did not, however, recall earlier generations or relabel any devices. Problems persisted, notwithstanding frequent modifications. On top of these design challenges, irregularities during manufacturing resulted in defective lots of the devices that the defendants nonetheless sold. D'Agostino, who also promoted Axium, attended a February 2009 meeting where top brass admonished the

[1] The proposed complaint does not allege that Axium was not FDA-approved.

sales force to keep quiet about defects in hopes of dodging FDA scrutiny.

3. Qui Tam Action

Approximately one year later, the defendants terminated D'Agostino's employment. In October 2010, he brought this qui tam action as a "relator" on behalf of the United States under the False Claims Act ("FCA"), 31 U.S.C. §§ 3729–3733, and on behalf of numerous states under similar state statutes. The relevant provisions of the FCA are those imposing liability on anyone who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," id. § 3729(a)(1)(A), or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," id. § 3729(a)(1)(B). D'Agostino's proposed complaint accuses ev3 and MTI of violating those provisions in selling Onyx and Axium to hospitals that seek reimbursement from the federal government through, for example, the Center for Medicare and Medicaid Services ("CMS").

B. Procedural History

Our opinion in D'Agostino I provides a full recitation of the suit's early procedural history, 802 F.3d at 190–91, which we repeat only briefly here. D'Agostino filed his original complaint under seal in October 2010 and amended the complaint as a matter of course in February 2011. Through two subsequent

amendments, both with permission of the court, D'Agostino added several defendants[2] and retooled his claims. In October 2013, the United States declined to intervene, and the court lifted the seal and authorized service. The parties then submitted a joint briefing schedule to the court for the defendants' motion to dismiss. The court endorsed the schedule and the defendants timely filed their motion.

A few days before his opposition was due, D'Agostino filed a fourth amended complaint (i.e., his fifth version of the complaint). The defendants immediately moved to strike, insisting that D'Agostino had used up his right to amend as a matter of course back in February 2011. The court agreed but construed D'Agostino's filing as a request for leave to amend. It applied to that request the "good cause" standard from Rule 16(b) of the Federal Rules of Civil Procedure and struck the amended complaint for want of good cause. His fourth amended complaint rejected, D'Agostino opposed the motion to dismiss his third amended complaint. The district court sided with the defendants, ruling that certain claims were subject to the FCA's public disclosure

[2] The defendants named in the fourth amended complaint are ev3, MTI, and two individuals: John H. Hardin II, a Vice President of Sales at ev3 who oversaw Onyx and Axium, and Brett Wall, a Director at MTI who joined ev3 to serve as a Vice President of Marketing. During the pendency of this appeal, D'Agostino voluntarily dismissed with prejudice his appeal as to those individual defendants.

bar, 31 U.S.C. § 3730(e)(4), and that the remaining claims failed to satisfy the pleading requirements of Rules 9(b) and 12(b)(6). See United States ex rel. D'Agostino v. ev3, Inc., No. 10-CV-11822, 2014 WL 4926369, at *5–9 (D. Mass. Sept. 30, 2014).

In the appeal that followed, we held that the district court erred by applying Rule 16(b)'s standard rather than Rule 15(a)'s more lenient standard. D'Agostino I, 802 F.3d at 194. We therefore remanded the case to the district court to evaluate under Rule 15(a) D'Agostino's request to file a fourth amended complaint. Id. at 195–96. After briefing and argument on the proposed amendment, the district court once again denied D'Agostino's request to file a fourth amended complaint. See D'Agostino, 153 F. Supp. 3d at 525. As before, the district court determined that certain claims were subject to the FCA's public disclosure bar. Id. at 530–32. Others, it found, lacked particularity per Rule 9(b), id. at 533–38, or otherwise failed to state a claim upon which relief can be granted per Rule 12(b)(6), id. at 538–39. It therefore deemed the motion to amend futile.

In addition to finding the proposed amendment futile, the district court expressed the "tentative view that permitting a further amendment would substantially prejudice the individual defendants," id. at 539, but decided it was "not necessary for the court to definitively resolve the issue," id. at 540. The court finally noted that it was "inclined to agree" with undue delay

arguments advanced by the defendants, which faulted D'Agostino for labeling as "new evidence" information that he could have obtained through reasonable diligence before filing the third amended complaint. Id.

This appeal followed.

II. Discussion

A district court's ruling under Rule 15(a) that amendment would be futile "means that the complaint, as amended, would fail to state a claim upon which relief could be granted." Glassman v. Computervision Corp., 90 F.3d 617, 623 (1st Cir. 1996) (citing 3 Moore's Federal Practice ¶ 15.08[4], at 15–80 (2d ed. 1993)).[3] While we review Rule 15(a) rulings for abuse of discretion, see, e.g., Nikitine v. Wilmington Trust Co., 715 F.3d 388, 389 (1st Cir. 2013), a material error of law constitutes such an abuse, and the question whether a motion to amend is futile because the amended complaint fails to state a claim upon which relief can be granted is a question of law, see Ouch v. Fed. Nat'l Mortg. Ass'n, 799 F.3d 62, 65 (1st Cir. 2015). Hence, our review in this case is actually de novo.

In performing this review, we, like the district court, confront a proposed complaint that covers 123 pages and features

[3] To be more precise, a futility finding could also mean that the proposed complaint would require dismissal for other reasons, such as lack of subject-matter jurisdiction under Rule 12(b)(1).

extensive single-spaced excerpts. D'Agostino devotes most of his pleading to establishing in excessive detail that the defendants said and did things that they knew were false or improper, and to critiquing the Onyx and Axium devices. At the same time, the pleading offers hints of numerous theories for tying the alleged improprieties and defects to false claims. D'Agostino's briefs on appeal call for us to consider two of those theories for his claims concerning Onyx, and two for his claims concerning Axium.

A. Onyx Fraudulent Inducement Claims

D'Agostino's principal claim relating to the government's payment for the use of MTI's Onyx device rests on an allegation that MTI made three fraudulent representations to the FDA in seeking approval to market Onyx. Specifically, the defendants disclaimed uses for the device they later pursued, overstated the training they later provided, and omitted critical safety information about the molecule, including its failure in the Enteryx device. The FDA, however, made none of the payments at issue in this lawsuit. Rather, CMS made the payments by reimbursing physicians who performed procedures using Onyx and hospitals where such procedures took place. "FCA liability attaches to a 'false or fraudulent claim for payment or approval' or to a 'false record or statement material to a false or fraudulent claim.'" United States ex rel. Kelly v. Novartis Pharm. Corp., 827 F.3d 5, 14 (1st Cir. 2016) (quoting 31 U.S.C.

§ 3729(a)(1)(A)–(B)). To link those CMS payments to the fraudulent representations allegedly made to the FDA, D'Agostino notes that FDA approval is a precondition to CMS reimbursement for use of a medical device, and argues that the fraudulent representations allegedly made by MTI to the FDA "could have" influenced the FDA to grant that approval.

We reject this argument because alleging that the fraudulent representations "could have" influenced the FDA to approve Onyx falls short of pleading a causal link between the representations made to the FDA and the payments made by CMS. If the representations did not actually cause the FDA to grant approval it otherwise would not have granted, CMS would still have paid the claims. In this respect, D'Agostino's fraudulent inducement theory is like a kick shot in billiards where the cue ball "could have" but did not in fact bounce off the rail, much less hit the targeted ball.

D'Agostino tries to rebut this conclusion by relying on the FCA's materiality standard. Under that standard, a representation made to secure a payment is material if it has "a natural tendency to influence, or [is] capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). He reasons that as long as MTI's representations at issue "could have" influenced the FDA to grant approval, the representations were material.

This argument may well misconstrue the FCA's materiality standard. It is a "demanding" standard. Universal Health Servs., Inc. v. United States, 136 S. Ct. 1989, 2003 (2016). Moreover, the FCA requires that the fraudulent representation be material to the government's payment decision itself. Id. at 2002–04. The fact that CMS has not denied reimbursement for Onyx in the wake of D'Agostino's allegations casts serious doubt on the materiality of the fraudulent representations that D'Agostino alleges. Id. at 2003–04 ("[I]f the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material.").

In any event, even if the alleged fraudulent representations were material as defined by the FCA, the elements of D'Agostino's fraudulent inducement claims include not just materiality but also causation; the defendant's conduct must cause the government to make a payment or to forfeit money owed. See United States ex rel. Westrick v. Second Chance Body Armor Inc., 128 F. Supp. 3d 1, 18 (D.D.C. 2015) (holding that a plaintiff asserting fraudulent inducement claims must demonstrate "not only that the omitted information was material but also that the government was induced by, or relied on, the fraudulent statement or omission" (quoting United States ex rel. Thomas v. Siemens AG, 991 F. Supp. 2d 540, 569 (E.D. Pa. 2014))), reconsideration granted

in part on other grounds sub nom. United States v. Second Chance Body Armor Inc., No. 04-CV-280, 2016 WL 3033937 (D.D.C. Feb. 11, 2016); see also, e.g., United States ex rel. Main v. Oakland City Univ., 426 F.3d 914, 916 (7th Cir. 2005) ("The [FCA] requires a causal rather than a temporal connection between fraud and payment."). See generally 1 John T. Boese, Civil False Claims and Qui Tam Actions §§ 2.01[A][3], 2.05 (4th ed. 2016). If the FDA would have approved Onyx notwithstanding the alleged fraudulent representations, then the connection between those representations to the FDA and a payment by CMS relying on FDA approval disappears.

The defect in D'Agostino's claim is not a mere flaw in the complaint's choice of words. In the six years since D'Agostino surfaced the alleged fraud, the FDA has apparently demanded neither recall nor relabeling of Onyx--this notwithstanding the agency's option to impose postapproval requirements, 21 C.F.R. § 814.82(a), its clear prerogative to suspend approval temporarily, id. § 814.47(a), and its broad authority to withdraw approval, id. § 814.46(a). In particular, when the FDA concludes that it has been misled because an "application contained or was accompanied by an untrue statement of a material fact," it can commence an "informal" hearing and withdraw its approval allowing the marketing of a device. See 21 U.S.C. § 360e(e). In such an instance, it acts with the benefit, where appropriate, of "advice

on scientific matters from a panel or panels [of experts] under section 360c." Id.

The FDA's failure actually to withdraw its approval of Onyx in the face of D'Agostino's allegations precludes D'Agostino from resting his claims on a contention that the FDA's approval was fraudulently obtained. To rule otherwise would be to 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. The FCA exists to protect the government from paying fraudulent claims, not to second-guess agencies' judgments about whether to rescind regulatory rulings. See D'Agostino, 153 F. Supp. 3d at 539 ("Surely, where the FDA was authorized to render the expert decision on . . . use and labeling, it, and not some jury or judge, is best suited to determine the factual issues and what their effect would have been on its original conclusions." (quoting King v. Collagen Corp., 983 F.2d 1130, 1140 (1st Cir. 1993) (Aldrich, J., concurring))).

The collateral effects of allowing juries in qui tam actions to find causation by determining the judgment of the FDA when the FDA itself has not spoken are akin to those practical effects that counsel in favor of not allowing state-law fraud-on-the-FDA claims. See Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 349–51 (2001). If jurors in a single qui tam case could

determine precisely what representations were essential to approval, which experts to believe, and how the FDA interpreted submissions made to it, some potential applicants who would otherwise seek approval for new products might be deterred, others might swamp the FDA with more data than it wants, and the "FDA's responsibility to police fraud consistently with the Administration's judgment and objectives" might be undercut. Id. at 350.

Practical problems of proof also inform our conclusion. How would a relator prove that the FDA would not have granted approval but for the fraudulent representations made by the applicant? Would competing experts read someone's mind? Whose? What if former officials no longer in government were of one view, and current officials of another? These and similar questions all support our position that the absence of some official agency action confirming its position and judgment in accordance with the law renders D'Agostino's fraud-on-the-FDA theory futile.

The United States as amicus curiae agrees that D'Agostino's fraudulent inducement theory "necessarily asks whether [the] FDA would have made a different decision absent the fraud." The United States does request that we reject any reading of the district court's opinion as implying that a fraudulent inducement claim would not lie even if fraudulent representations "actually caused [the] FDA to approve or clear the device."

We do not read the district court's carefully crafted opinion that way. Its holding does not, in our view, hinge on rejecting or accepting the position of the United States, and neither does ours. Nor are we saying that the FCA is in this context preempted by the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–399f. We hold only that causation is an element of the fraudulent inducement claims D'Agostino alleges and that the absence of official action by the FDA establishing such causation leaves a fatal gap in this particular proposed complaint. Certainly some official action by the FDA confirming that its approval was actually procured by the alleged fraudulent representations would fill that particular gap in the proposed complaint. Whether it would suffice to sustain the proposed complaint we need not decide.

We do recognize that, should a valid FCA claim exist if the FDA withdrew its approval for a product upon discovering fraud, our ruling today would pose a theoretical risk that the whistleblowing relator might be deprived of his or her bounty by a government intent on doing so. This is because the relator would need to alert the FDA--to secure withdrawal of approval--before the relator could allege causation. In theory, the government in such an instance might first file an FCA action itself, thereby arguably precluding the whistleblower from qualifying for a share of the recovery under 31 U.S.C. § 3730(d). As a practical matter,

though, this risk is small, and it does not warrant eliminating causation as an element of the claim. As the United States notes, instances in which fraudulent representations "masked problems that are so serious that [the] FDA would have (for example) withheld or withdrawn its approval" are "likely rare." Moreover, if such a case actually arises, there is no logical reason why the government itself (in a case involving what the FDA finds to be the fraudulent procural of approval) would want to proceed in a manner that deprives the whistleblower of a bounty, thereby reducing the incentive for future potential whistleblowers aware of fraud on the FDA.[4]

In any event, the FDA approved Onyx, and has never withdrawn that approval. D'Agostino therefore cannot establish a causal link between the alleged fraudulent representations made to the FDA and the payment of claims for reimbursement by the government.

B. Onyx "Training Program" Claims

That leaves, with respect to Onyx, D'Agostino's theory that the defendants caused the submission of false claims by encouraging medically unnecessary and dangerous uses of Onyx by physicians who did not attend the training program offered by the

[4] The whistleblower in such a scenario, as an original source of the information, would trump any copycats who tried to first file suit after the FDA publicly disclosed its actions. See 31 U.S.C. § 3730(e)(4)(A)(i)–(ii).

defendants. Undergirding this theory is the fact that Medicare excludes from coverage claims involving procedures that "are not reasonable and necessary for the diagnosis or treatment of illness or injury." 42 U.S.C. § 1395y(a)(1)(A). D'Agostino's proposed complaint incorporates the statement of a neurosurgeon and leading Onyx user, who opines that it is never "medically reasonable or medically necessary for an untrained physician to use Onyx in procedure [sic] involving a live human being," as such use "creates an exceedingly dangerous situation for the patient." According to D'Agostino, the defendants therefore caused the submission of false claims by "fail[ing] to provide the physician training that the FDA required as a condition of approval usage, and subsequently induc[ing] those untrained doctors to use Onyx anyway." This theory, rather than targeting every Onyx claim, attacks the subset of claims seeking reimbursement for procedures performed by physicians whom the defendants did not train.

We evaluate the sufficiency of these allegations under Federal Rule of Civil Procedure 9(b), which provides 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). More precisely, Rule 9(b) requires a relator to allege with particularity the who, what, when, where, and how of the fraud. United States ex rel. Ge v. Takeda Pharm. Co., 737 F.3d 116, 123 (1st Cir. 2013). Furthermore, allegations limited to

describing the defendant's scheme and intent are insufficient, "[b]ecause FCA liability attaches only to false claims." Id. at 124 (citing United States ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 225 (1st Cir. 2004), abrogated on other grounds by United States ex rel. Gagne v. City of Worcester, 565 F.3d 40 (1st Cir. 2009)). Thus, the allegations must also establish that the fraudulent conduct actually caused the submission of false claims to the government for payment. Id. (citing United States ex rel. Rost v. Pfizer, Inc., 507 F.3d 720, 732–33 (1st Cir. 2007), overruled in part by Allison Engine Co. v. United States ex rel. Sanders, 553 U.S. 662 (2008)). As a general matter, a relator does this by alleging with particularity examples of actual false claims submitted to the government. Karvelas, 360 F.3d at 232–33. By doing so, the relator conveys that if the facts alleged are true, the filing of a false claim is not merely a possibility, but rather, necessarily occurred. Alternatively, in appropriate circumstances, a relator may instead allege "factual or statistical evidence to strengthen the inference of fraud beyond possibility." United States ex rel. Duxbury v. Ortho Biotech Prod., L.P., 579 F.3d 13, 29 (1st Cir. 2009) (quoting Rost, 507 F.3d at 733). See, e.g., United States ex rel. Escobar v. Universal Health Servs., Inc., 780 F.3d 504, 515 (1st Cir. 2015), overruled on other grounds by 136 S. Ct. 1989 (2016) (holding that particular allegations concerning one patient were sufficient

because they arose from a "systematic failure" that necessarily "infected" other claims with fraud).

Applying these rules, the district court found the proposed complaint's allegations insufficient, citing their failure to identify any specific false claim submitted to the government for reimbursement. D'Agostino, 153 F. Supp. 3d at 536 n.38. In response, D'Agostino repeats the argument he made to the district court, pointing to allegations in his proposed complaint that two physicians who did not attend the defendants' training program performed a total of approximately seventy procedures using Onyx, and that "well over 50%" of these physicians' patients were insured under government health plans. So, reasons D'Agostino, the odds are very high that at least some bills were submitted to and paid by the government for use of Onyx by untrained physicians. And since the device label calls for use only by trained physicians, the use by untrained physicians was both off-label and, in the opinion of an expert retained by D'Agostino, not medically necessary.

There are several problems with this line of reasoning. First, and most simply, while the FDA-approved label for Onyx does indeed restrict use to "physicians with neurointerventional training," and refers users to MTI "for information on training courses," it contains no requirement that the physician must obtain the training from MTI or ev3. Therefore, D'Agostino's allegation

that the defendants did not train these two physicians falls materially short of alleging facts showing that they were not trained at all. And if they were indeed otherwise trained,[5] the use of Onyx would not have been off-label. For this reason alone, D'Agostino's "training program" claims fail.

Additionally, even if we were to overlook this gap in the allegations, the assumption that physicians submitted claims for reimbursement merely because many of their patients in general were insured under government programs is faulty. The district court noted as much, explaining the distinction between alleging that a certain percentage of patients carried government insurance and alleging that any patient carrying government insurance underwent a procedure involving the device that resulted in a claim for government reimbursement. D'Agostino, 153 F. Supp. 3d at 536 n.38. D'Agostino's assumption is particularly faulty because seeking reimbursement here would have required the physicians knowingly to submit off-label claims if they did indeed lack the training the label plainly required. See Rost, 507 F.3d at 732–34.

For each of these reasons, we agree with the district court that D'Agostino's "training program" version of his Onyx

[5] The proposed complaint alleges that the defendants trained at least one physician at each medical facility, including presumably the facilities at which each of these two physicians worked.

claim fails because it does not sufficiently allege the submission of a false claim nor does it advance a theory and facts that together create a "strong inference" that false claims were actually filed. Id. at 732.

C. Axium Manufacturing Defect Claims

D'Agostino describes various alleged defects in the manufacture of Axium. Instead of identifying specific false claims to CMS involving Axium, the proposed complaint seeks to rely on what D'Agostino calls a "complete falsity" theory. This theory applies, he argues, when every device is defective, rendering each claim for reimbursement involving the product false, and thereby "logically obviat[ing] the need for identification of specific false claims, because their submission is a virtual certainty."

This case presents no need to decide whether such a theory is tenable. The proposed complaint simply does not allege facts making it plausible that all Axium devices--or even most--were defective. It alleges only that "certain lots of Axium" contained manufacturing defects that caused the device to malfunction when the surgeon tried to use it. The proposed complaint does not give the number or percentage of Axium devices that suffered these manufacturing defects. It does identify by hospital, surgeon, date, and (sometimes) Axium generation and lot number a dozen or so surgeries during which the surgeon encountered difficulty or failure in trying to deploy the Axium coil. Only

certain of those instances are said to involve defectively manufactured devices, and none are alleged to have resulted in any particular false claims paid by the government. See, e.g., Hagerty ex rel. United States v. Cyberonics, Inc., No. 16-1304, 2016 WL 7321224, at *4–5 (1st Cir. Dec. 16, 2016) (holding that identifying doctors and hospitals whose patients had device replacement surgeries does not establish that any medical provider actually submitted claims for government reimbursement). Importantly, there is no claim here of a latent manufacturing defect that manifested itself only after the surgery was completed and the claim for reimbursement submitted. To the contrary, the allegation is that the defect caused the device to fail as the surgeons tried to use it, and thus before any claim for reimbursement might have been submitted. We are therefore left with a proposed complaint that neither alleges any specific false claims involving Axium devices with manufacturing defects nor demonstrates beyond possibility that claims of the type said to be false were actually submitted.

D. Axium Design Defect Claims

The proposed complaint also seeks to advance a design defect claim. To do so, it first asserts that Axium was modified and improved over time. It then calls "defective" all earlier versions of the device that predated such improvements. Even by their own conclusory terms, these allegations do not make all

devices defective; for example, any device featuring the most recent modifications when sold would not be "defective." More importantly, we agree with the district court that a product (much less an FDA-approved medical device) cannot be called defective for purposes of establishing falsity in a qui tam case merely because new versions of the product contain design improvements. See D'Agostino, 153 F. Supp. 3d at 537. Indeed, by that standard, most every car sold to the government would be per se defective.

III. Conclusion

None of the claims in D'Agostino's fourth amended complaint is adequately pled, so his request for leave to file that complaint was properly denied as futile. A fortiori, the lesser included factual recitation set forth in the third amended complaint fails as well. We therefore have no need to consider the district court's alternative reasons for rejecting D'Agostino's claims. The district court's order denying D'Agostino's motion to amend the complaint is **affirmed**.