UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 10-11822-RGS

UNITED STATES OF AMERICA *ex rel.* JEFFREY D'AGOSTINO; STATES OF CALIFORNIA, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MARYLAND, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS and WISCONSIN; COMMONWEALTHS OF MASSACHUSETTS and VIRGINIA; and the DISTRICT OF COLUMBIA

v.

EV3, INC.; MICRO THERAPEUTICS, INC.; JOHN HARDIN; and BRETT WALL

MEMORANDUM OF DECISION AND ORDER
ON RELATOR'S MOTION TO AMEND THE COMPLAINT

December 30, 2015

STEARNS, D.J.

This case was remanded by the Court of Appeals for reconsideration of the court's refusal to grant leave to plaintiff/relator Jeffrey D'Agostino to file a fifth iteration of his *qui tam* Complaint. In its opinion, the Circuit Court did not delve into this court's substantive discussion of the merits of the collective defendants' motion to dismiss. *See United States ex rel. D'Agostino v. EV3, Inc.*, 802 F.3d 188, 191 (1st Cir. 2015) ("First, [plaintiff/relator] contends that the district court improperly thwarted his

efforts to amend his complaint. Second, he challenges the court's dismissal of his complaint and the subsidiary legal determinations undergirding that dismissal. We start – and end – with the first claim."). For that reason, the court believes that the most efficacious way to proceed is by adopting and adapting its previous discussion of the merits of the case, and analyzing any new allegations for their effect on the court's thinking.

D'Agostino, a former employee of defendant EV3, Inc., filed the prototype of this action under seal on October 26, 2010. At the time, EV3 was the sole defendant. On February 3, 2011, D'Agostino amended the original Complaint to add three defendants, among them John Hardin, the Vice President of Sales and Global Marketing at EV3 for the Onyx device. D'Agostino sought and received permission to amend the Complaint two additional times, the first on August 28, 2012, and the second on May 17, 2013, while the case remained under seal. On October 1, 2013, the United States filed a notice of non-intervention, followed on December 19, 2013, by twenty-five named states and the District of Columbia.[1] On December 26,

[1] The State of Maryland did not appear on the Notice of Non-Intervention filed by the Commonwealth of Massachusetts on behalf of the other States and the District of Columbia. Maryland has not intervened in the action since the case was unsealed.

2013, the court unsealed the case.[2] D'Agostino received permission to amend the Complaint yet again on April 28, 2014, adding Microtherapeutics, Inc. (the company that developed the Onyx and Axium devices before merging with EV3), and Brett Wall (a former marketing executive at EV3) as defendants.

On August 1, 2014, on completion of the briefing of the motion to dismiss, D'Agostino sought to amend his Complaint for a fifth time.[3] The court denied leave to amend pursuant to Fed. R. Civ. P. 16(b)(4), which requires a showing of "good cause," and on September 30, 2014, dismissed the Third Amended Complaint (TAC) with prejudice.

On September 30, 2015, the Court of Appeals remanded with the instruction that the court consider D'Agostino's request to amend under the more lenient standard of Fed. R. Civ. P. 15(a)(2), which permits an amendment only with leave of the court, but also stipulates that leave is to be granted freely "when justice so requires." Nonetheless, as the Court of

[2] Under 31 U.S.C § 3730(b)(1), while the United States, the twenty-six named states and the District of Columbia decline to be actively involved, they retain the right to approve dismissal by the relator.

[3] D'Agostino did not, at the time, file a motion for leave to amend his Complaint. Rather, he "conditionally" requested leave to amend in his Opposition to EV3's Motion to Dismiss, in the event the court were to decide to grant defendants' motion to dismiss.

Appeals noted, while leave is to be freely granted, a court may deny leave to amend under Rule 15(a)(2) for essentially the same reasons as under Rule 16(b)(4), including "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, [or] futility of amendment." *Foman v. Davis*, 371 U.S. 178, 182 (1962). *See D'Agostino*, 802 F.3d at 195 ("Let us be perfectly clear. We do not suggest that the district court will be compelled to grant the motion to amend on remand.").

On November 9, 2015, D'Agostino filed a new motion to amend, attaching a superseding Proposed Complaint (Dkt. # 128-1). Defendants now oppose this motion, arguing *inter alia* that it would cause undue delay, undue prejudice, that D'Agostino has repeatedly tried and failed to cure deficiencies in the Complaint, and that any further attempt to amend would be futile.

The defendants focus the bulk of their briefs on the "futility" exception. "[A] judge may deny leave if amending the pleading would be futile – that is, if the pined-for amendment does not plead enough to make out a plausible claim for relief." *HSBC Realty Credit Corp. (USA) v. O'Neill*, 745 F.3d 564, 578 (1st Cir. 2014). "Futility of the amendment constitutes an adequate

reason to deny the motion to amend." *Todisco v. Verizon Commc'ns, Inc.*, 497 F.3d 95, 98 (1st Cir. 2007). While "plaintiff typically will not be precluded from amending a defective complaint in order to state a claim on which relief can be granted . . . several courts have held that if a complaint as amended could not withstand a motion to dismiss or summary judgment, then the amendment should be denied as futile." 6 Charles Alan Wright & Arthur R. Miller, Fed. Prac. & Proc. Civ. § 1487 (3d ed.); *cf. Hatch v. Dep't for Children, Youth & Their Families*, 274 F.3d 12, 19 (1st Cir. 2001) ("If leave to amend is sought before discovery is complete and neither party has moved for summary judgment, the accuracy of the 'futility' label is gauged by reference to the liberal criteria of Federal Rule of Civil Procedure 12(b)(6).").

THE AMENDED DECISION[4]

In this now five-year-old *qui tam* action, plaintiff/relator Jeffrey D'Agostino, a former medical device salesman for defendant EV3, Inc., alleges that EV3, Micro Therapeutics, Inc. (MTI), John Hardin, and Brett Wall violated the federal False Claims Act (FCA), 31 U.S.C. § 3729 *et seq.*, as well as the False Claims Acts of twenty-six states and the District of Columbia. According to the Proposed Complaint, defendants knowingly

[4] The court will signal any potentially material amendments to the Proposed Complaint by the use of italics.

caused the submission of false claims for reimbursement in violation of FCA § 3729(a)(1)(A) (Count I), and knowingly made, or caused to be made, false records or statements that were material to the false reimbursement claims in violation of FCA § 3729(a)(1)(B) (Count II), *and made, used or caused to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the government, or knowingly concealed, avoided or decreased such obligation, in violation of 31 U.S.C. § 3729(a)(1)(G) (Count III),*[5] all the while conspiring to commit these acts in violation of FCA § 3729(a)(1)(C) (Count IV). The Proposed Complaint makes parallel allegations under the various state and District of Columbia analogs

[5] In the TAC, D'Agostino initially alleged the same claim: violation of 31 U.S.C. § 3729(a)(1)(G) (Count III of the TAC). D'Agostino voluntarily dismissed this Count on August 1, 2014, without prejudice, in the body of his "Consolidated Opposition to the Defendants' Motions to Dismiss" (Consolidated Opposition). However, D'Agostino resuscitated the claim, also styled as Count III, in the Proposed Complaint. As was the case in the TAC, he does not indicate what, if any, "obligation to pay the government" was avoided. D'Agostino also pleads violations of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b). Prop. Compl. ¶¶ 199-201. However, no distinct Count within the Proposed Complaint alleges a violation of the Anti-Kickback Statute, or seeks damages for such a violation; it appears that any alleged violation of the Anti-Kickback Statute may be intertwined with the alleged false claims. At the hearing before this court on D'Agostino's Motion to Amend, counsel equivocated on whether the Proposed Complaint does or does not state a claim under the Anti-Kickback statute, and declined to state one way or the other whether D'Agostino seeks relief under such a theory.

to the FCA (Counts V-XXXI).[6] For reasons to be explained, D'Agostino's motion under Rule 15(a)(2) to amend his complaint once more will be denied.

BACKGROUND

EV3 manufactures the two medical devices implicated in the Proposed Complaint, the Onyx Liquid Embolic System (Onyx) and the Axium Detachable Coil System (Axium). Both Onyx and Axium were developed by MTI (which later merged with EV3).[7] Defendant Brett Wall held executive sales and marketing positions at EV3, MTI, Boston Scientific, and Covidien (the current parent company of EV3). Wall was actively involved in the marketing of Onyx and Axium. Defendant John Hardin was the Vice President of Sales and Global Marketing for Onyx at EV3.[8] D'Agostino

[6] In the case of Louisiana only the making or causing the making of false claims is alleged in the Proposed Complaint; in the case of Texas, the Proposed Complaint makes the additional allegation that defendants caused the submission of claims for "adulterated, debased, [or] mislabeled" products. Prop. Compl. ¶¶ 364-367.

[7] MTI developed Onyx and shepherded the device through Food and Drug Administration (FDA) approval. MTI was also the prime developer of Axium. After the merger, EV3 assumed the responsibility for obtaining FDA approval to market Axium.

[8] The Proposed Complaint alleges (with scant factual elaboration) that Hardin and Wall bore responsibility for the off-label promotion of Onyx and the failure to initiate recalls of several generations of allegedly defective Axium devices.

served as the Territory Sales Manager for EV3 in the eastern United States between 2005 and 2010.

A. Onyx

Onyx is a synthetic liquid that, when introduced by a catheter, forms a solid mass (embolus) inside a patient blocking the flow of blood. The FDA approved Onyx in July of 2005 for use in the presurgical treatment of a vascular defect in the brain known as brain arteriovenous malformation (BAVM). The market for the on-label use of Onyx is very small; there are only an estimated 3,000 cases of BAVM treated annually in the United States.

1. Misleading the FDA in the Onyx Approval Process

In broad terms, D'Agostino alleges that MTI misled the FDA during the Onyx approval process by proposing an overly narrow indication for its use, while concealing the true scope of its marketing strategy, and failing to report relevant safety information. D'Agostino alleges that, but for MTI's fraud, Onyx would not have been approved for *any* use by the FDA.[9]

[9] D'Agostino also attempts to set out specific subsets of false claims, in an effort to provide the requisite specificity to his Proposed Complaint.

The factual allegations, distilled from the legal conclusions in which they are embedded, are as follows.[10] According to the Proposed Complaint, the FDA advisory panel appointed to review the safety and efficacy of Onyx expressed concern that the device (despite MTI's assurances) might be marketed for the off-label treatment of other types of vascular disease, or might be left permanently embedded in a BAVM patient if follow-up surgery was not performed.[11] In response to the panel's reservations, the Proposed Complaint alleges that MTI gave false assurances that it would institute a program to train surgeons in the proper use of Onyx.[12] The FDA

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[10] Factual allegations will be attributed to the Proposed Complaint; legal conclusions and arguments directly to D'Agostino.

[11] An FDA medical device advisory panel gathers information and opinions from medical experts, the applicant, and other interested parties. It makes its recommendations regarding the device to the Center for Devices and Radiological Health, which is the ultimate FDA approving authority. The panel's recommendations are not binding on the FDA (or the applicant), unless they are incorporated as conditions in the FDA approval to market the device.

[12] D'Agostino alleges that MTI undertook to train *all* physicians who used Onyx; however, the relevant transcript passage reproduced in the Proposed Complaint is more nuanced and states only that "the objective of the physician education program is to ensure that all **participating** physicians thoroughly understand the Onyx system." Prop. Compl. ¶ 52 (emphasis added). This is consistent with the labeling approved by the FDA, which states that the device "should be used only by physicians with neurointerventional training," and while calling attention to the EV3 training program, does not require a surgeon implanting the device to have received Onyx-specific training from EV3. *Id.* ¶¶ 57, 95.

subsequently approved Onyx for sale and use, subject to the conditions listed on its label.[13] The Proposed Complaint alleges that when EV3 later sought to expand the scope of the FDA's approval to include the use of Onyx in the treatment of vascular defects in the "the periphery" (that is, in the vasculature outside the brain or below the neck), the FDA denied the request because of insufficient supporting medical evidence. Prop. Compl. ¶ 59. Notwithstanding the FDA's refusal, MTI (and EV3) continued to promote the use of Onyx for peripheral indications and neurointerventional indications other than the presurgical treatment of BAVM.[14]

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[13] The FDA-approved label stated that "[p]erforming embolization to occlude blood vessels is a high-risk procedure. This device should be used only by physicians with neurointerventional training and a thorough knowledge of the pathology to be treated, angiographic techniques, and super-selective embolization." Prop. Compl. ¶¶ 57, 95. It stated further that "[s]erious, including fatal, consequences could result with the use of the Onyx LES without adequate training. Contact your [MTI] sales representative for information on training courses." *Id.* ¶¶ 58, 96. D'Agostino presents several additional recommendations of the FDA advisory panel as "conditions" for Onyx's approval and usage, *id.* ¶ 94, although these were not mandated by the FDA-approved label.

[14] The TAC noted that EV3's sales quotas for Onyx were seven times the estimated total market, even if it were assumed that sales of Onyx captured 100% of the procedures for which the device was indicated (in other words, $1.2M of the $1.4M sales quota could only be attributable to off-label uses of Onyx). TAC ¶ 110. Defendants do not dispute the fact that off-label uses of Onyx made up a significant portion of its sales. The Proposed Complaint replaces the calculations in the TAC with the following example: *"In 2009, EV3's own assessment of the on-label sales potential for Relator's sales territory was $506,250, i.e., if he was successful in capturing* ***100%*** *of the*

At some point, MTI licensed the right to fabricate the liquid material from which Onyx is manufactured to Enteric Medical Technologies, Inc., another medical devices company. After acquiring Enteric, Boston Scientific used the material to manufacture Enteryx, which was approved by the FDA in April of 2003 for the treatment of gastroesophageal reflux disease. Enteryx is injected into the musculature below the esophagus where it solidifies to create a partial barrier preventing the reflux of stomach acid. According to the Proposed Complaint, in some cases physicians injecting Enteryx missed the esophageal musculature, risking potentially fatal complications.[15] D'Agostino argues that because of the intimate corporate collaboration among EV3, Enteric, Boston Scientific, MTI, and Covidien (fostered by the hiring of senior executives by one company from another), EV3 bears responsibility for failing to alert the FDA during the Onyx approval process to problems being encountered by physicians using Enteryx: EV3 "was representing to the FDA that Onyx was safe, [while] the

BAVM business in his territory, his maximum revenue was just over $500,000. Notwithstanding that limited market, the Onyx revenue quota placed on Relator for 2009 was $1,509,533." Prop. Compl. ¶ 107 (emphasis in original).

[15] These include the accidental introduction of the rapidly solidifying liquid Onyx into the aorta, the body's largest artery, which lies close to the esophagus.

same molecule, in the form of Enteryx, was killing people." Prop. Compl. ¶ 81. D'Agostino alleges that EV3, during the Onyx approval process, failed to adequately warn the FDA about the dangers of Enteryx, and that "[h]ad the FDA known what MTI was planning, it probably would not have granted the approval." Prop. Compl. ¶ 176.[16]

2. Training Program Used to Drive Off-Label Sales

The Proposed Complaint describes a surgical training program in which, after a physician was trained in the use of Onyx, EV3 would supply Onyx to any hospital facility at which the physician had admitting privileges. These included facilities that had no surgeons on staff with practices requiring the on-label use of Onyx. The Proposed Complaint further alleges that EV3 paid physicians to conduct Onyx training for other physicians, which sometimes included training in off-label uses. Prop. Compl. ¶ 132. Because vascular "holes" in areas below the neck (the periphery) are typically much larger than those in the brain, more Onyx is required to plug them,

[16] D'Agostino's Enteryx theory is inconsistent with the "new evidence" he proffers to bolster the Proposed Complaint, specifically the declaration of Dr. Johnny Pryor. D'Agostino contends on the one hand that Onyx was patently unsafe, and that adverse events associated with Enteryx belied MTI's "represent[ations] to the FDA that Onyx was safe." Prop. Compl. ¶ 81. Dr. Pryor's statement on the other hand praises Onyx as *"an excellent product"* which *"can and has saved many lives"* in the hands of trained surgeons. *Id.* ¶ 93.

thus making off-label uses more lucrative for EV3. This recognition, according to the Proposed Complaint, led EV3 to ramp up the dissemination to physicians of information promoting Onyx's off-label use. An example given by the Proposed Complaint is a 2008 EV3 national sales meeting at which National Marketing Manager (and former defendant) Vitas Sipelis discussed case reports involving the use of Onyx in peripheral vasculature surgical interventions, while at the same time urging sales staff to "[g]et users to think about additional [off-label] applications (i.e., [dural arteriovenous fistulas] DAVFs)." Prop. Compl. ¶ 117.[17]

3. Filing of False Claims

Inpatient and outpatient hospital treatment procedures for eligible patients are paid by Medicare subject to the condition that the treatment is certified to be medically reasonable and necessary.[18] Reimbursement is at the rates established by the Diagnosis Related Group (DRG) or the

[17] While D'Agostino calls particular attention to the fact that Onyx was not "approved to treat dural arteriovenous fistulas," Prop. Compl. ¶ 3, and that MTI and EV3 promoted its use for this purpose, the statement of D'Agostino's expert, Dr. Pryor, suggests that such treatment was medically reasonable. Dr. Pryor acknowledges that he has himself presented talks extolling the safety and effectiveness of Onyx for this very purpose. *Id.* ¶ 93.

[18] In cases in which a physician bills separately for his or her services in performing an eligible procedure, he or she must also certify that the care provided was medically indicated and necessary.

Ambulatory Payment Classification, as appropriate. Although the cost of a medical device is not billed directly to Medicare, the hospital ultimately recovers the cost of the device indirectly by way of the fixed aggregate reimbursement rates. Where the actual cost of a particular procedure exceeds the fixed limit, the hospital is permitted to bill Medicare for the additional cost (a so-called "outlier payment").

D'Agostino originally maintained that all off-label uses of Onyx were "affirmatively unsafe, ineffective, and hazardous to patient health,"[19] and that consequently, all "claims which fall into this category were false under the FCA." TAC ¶ 181. In the Proposed Complaint, D'Agostino repeats this allegation in slightly altered language: "*All claims submitted by hospitals and doctor to government healthcare programs for procedures involving Onyx were fraudulent under the FCA.*" Prop. Compl. ¶ 186 n.19. While Medicare is prohibited from reimbursing hospitals or physicians for unapproved devices (unless they are part of an FDA-authorized clinical trial),

[19] The TAC described two incidents in which embolization of a dural fistulae failed leading, in one of the instances, to the patient's permanent impairment. The TAC alleged that the surgeon in the latter case had attended an EV3 training session promoting the off-label use of Onyx to treat dural fistula some two weeks prior to the failed operation. TAC ¶¶ 203-205. *The Proposed Complaint replaces the references to these two incidents with language from an FDA advisory notice identifying some 100 adverse events that may have been related to Onyx use.*

see 42 C.F.R § 411.15(o), D'Agostino acknowledges that Onyx was FDA-approved (and therefore eligible for Medicare reimbursement). Nonetheless, D'Agostino argues that because defendants fraudulently induced the FDA to grant the initial approval for Onyx, all off-label reimbursement claims were tainted as a result.[20]

B. Axium

Axium is an embolization coil attached to a delivery pusher equipped with a manual detacher. A surgeon threads the coil into the position at which he or she wishes to promote the formation of an embolus, and then detaches the coil and removes the pusher. First marketed in 2007, Axium was developed with the intent of embolizing intracranial aneurysms and other neurovascular anomalies.

1. Axium Defects

The Proposed Complaint alleges that EV3 unnecessarily hurried the development of Axium, resulting in the launching of a product that "was not adequately designed, was not properly manufactured, and was not safe for

[20] The TAC also alleged that because off-label procedures using Onyx as an agent of embolization are more expensive to perform than conventional embolization in the peripheral vasculature, "there is a **substantial likelihood** that government payers incurred significant additional reimbursement requests." TAC ¶¶ 207-208 (emphasis added). *D'Agostino omits this allegation from the Proposed Complaint.*

use." Prop. Compl. ¶ 208. During the first year following the launch, the device was modified "more than a half dozen times" to correct problems encountered during surgeries. *Id.* According to the Proposed Complaint, EV3 actively explored ways of minimizing losses on the recall of earlier iterations of Axium. As an example, the Proposed Complaint cites an internal EV3 email from National Manager Fred Gunderman to EV3 executives, written after generation 1E of Axium was marketed.[21] *See* Prop. Compl. ¶ 224. The email, in discussing the need to withdraw the earlier generations 1 through 1B from the market, suggested trading out generations 1C and 1D<7mm for the more expensive version 1E to recoup losses on the recalled units. *Id.* The email also discussed the possibility of selling the superannuated prior generations into the peripheral market.[22] *Id.*

The Proposed Complaint notes that Dr. Stephen Ohki at Hartford Hospital in Connecticut reported an Axium coil detachment failure in late

[21] Axium 1E continued to have detachment problems leading successively to the 1F and Axium Prime models.

[22] Like Onyx, Axium was intended for vasculature treatments in the brain. While the Proposed Complaint is agnostic on the issue of whether anything ever came of the email discussion, D'Agostino alleges that some older generation Axium devices were shipped back to EV3 where they were rebranded and remarketed under the name Concerto. D'Agostino conceded, when this court considered the TAC, that the FDA had approved Concerto for use in treatments of vasculature diseases in the peripheral region.

2008 that "led to a negative outcome for the patient." Prop. Compl. ¶ 245. In October 2009, Dr. Ohki reported a similar problem with another Axium coil. When D'Agostino was asked by Hartford Hospital's legal department for an internal report on the failures, he contacted EV3's engineering department. D'Agostino was told that coils were failing to detach properly because of a manufacturing error (over welding), caused by a laser welder being set "too hot." *Id.* ¶ 247. The Proposed Complaint lists eleven additional instances of alleged Axium failures supplementing the two failures (reported by Dr. Ohki) that were also listed in the TAC.

The Proposed Complaint recites the previously alleged manufacturing defects in other versions of Axium, including instances of a malformed retainer ring caused by worn manufacturing equipment, and a welding error that resulted in an improper coupling of the detachment wire to the inner wall of the coil. *Id.* ¶¶ 245-249. While detachment failures can be remedied by secondary detachment methods (such as tugging on the device with a forceps), these also entail risks to patients.[23] D'Agostino, however, omits

[23] According to the Proposed Complaint, instead of recalling the defective devices, EV3's management decided to instruct sales staff to emphasize the use of the secondary/manual detachment method of overcoming a detachment failure, while avoiding mention of the use of forceps or "torque devices," as it was thought that the disclosure might draw negative attention from the FDA. *Id.* ¶ 252.

from the Proposed Complaint the misbranding and adulteration claims related to Axium alleged in the TAC.

2. Axium Adverse Event Reporting

The Proposed Complaint alleges that EV3's investigations into adverse events involving Axium were "often bogus, blaming the problem on everything but the defective product." Prop. Compl. ¶ 268.[24] By minimizing Axium's role in causing "hundreds" of adverse events, D'Agostino argues that EV3 avoided its obligation to file Medical Device Reports with the FDA, and had the FDA been aware of EV3's misfeasance, "it could have recalled the devices, or greatly restricted the instructions for [their] use." *Id.* ¶ 277. As with Onyx, D'Agostino maintains that, in the case of Axium, defendants induced "hospitals and physicians to certify . . . that the medical products . . . provided to patients were in compliance with applicable statutes [and] regulations," and that such certifications "were false [] because EV3 was not in statutory or regulatory compliance." *Id.* ¶ 278. In other words, EV3 was marketing medical devices that were eligible for Medicare reimbursement

[24] D'Agostino claims that he personally "wrote very detailed adverse event reports, including such details as physicians being forced to use pliers and other torque devices . . . ." *Id.* ¶ 275 (which were presumably ignored by EV3).

only because the government did not know "the truth about these products." *Id.* ¶ 277.

DISCUSSION

"FCA liability attaches to any individual who 'knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval,' 31 U.S.C. § 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,' § 3729(a)(1)(B)." *United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 380 n.3 (1st Cir. 2011).

> For purposes of both subsections, "[a] person acts 'knowingly' if he or she '(1) had actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information.'"

United States ex rel. Dyer v. Raytheon Co., 2011 WL 3294489, at *6 (D. Mass. July 29, 2011), quoting *Hutcheson*, 647 F.3d at 380; *see also Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 672-673 (2008) (the elements of an FCA claim require proof that a defendant knew, as a "natural, ordinary and reasonable consequence[]" of its acts, that false claims would be submitted to the government for payment). The statute further prohibits "conspir[acies] to defraud the Government by getting a false or fraudulent claim allowed or paid." *United States ex. rel. Gagne v. City of*

Worcester, 565 F.3d 40, 42 (1st Cir. 2009); *Allison Engine*, 533 U.S. at 672. Persons who violate the FCA are liable for civil penalties and double or treble damages, plus the costs (including attorney's fees) incurred in bringing the *qui tam* action. 31 U.S.C. § 3729(a)(2)-(3).

1. Public Disclosure Bar

"The threshold question in a False Claims Act case is whether the statute bars jurisdiction." *United States ex rel. Rost v. Pfizer, Inc.,* 507 F.3d 720, 727 (1st Cir. 2007), *overruled in part on other grounds by Allison Engine*, 553 U.S. 662. The Public Disclosure Bar, as set out in 31 U.S.C. § 3730(e)(4), provides:

> (A) The court shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed–
>
> > (i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party;
> >
> > (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or
> >
> > (iii) from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.
>
> (B) For purposes of this paragraph, "original source" means an individual who either (i) prior to a public disclosure under subsection (e)(4)(a), has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (2) who has knowledge that

> is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section.

A multi-part test is used to decide whether the Public Disclosure Bar applies. *See United States ex rel. Ondis v. City of Woonsocket*, 587 F.3d 49, 53 (1st Cir. 2009); *United States ex rel. Poteet v. Bahler Med. Inc.*, 619 F.3d 104, 109 (1st Cir. 2010). The court must determine:

> (1) whether there has been public disclosure of the allegations or transactions in the relator's complaint;
>
> (2) if so, whether the public disclosure occurred in the manner specified in the statute;
>
> (3) if so, whether the relator's suit is "based upon" those publicly disclosed allegations or transactions; and
>
> (4) if the answers to these questions are in the affirmative, whether the relator falls within the "original source" exception as defined in § 3730(e)(4)(B).

Rost, 507 F.3d at 728. "For the purpose of the FCA, public disclosure occurs when the essential elements exposing the particular transaction as fraudulent find their way into the public domain." *Ondis*, 587 F.3d at 54. "[T]he disclosure must reveal both the misrepresented state of facts and the true state of facts so that the inference of fraud may be drawn." *Id.*, quoting *United States ex rel. Mistick PBT v. Hous. Auth. of Pittsburgh,* 186 F.3d 376, 385 (3d Cir. 1999). "The two states of facts may come from different sources,

as long as the disclosures together lead to a plausible inference of fraud." *Ondis*, 587 F.3d at 54.[25]

With respect to the fraud-on-the-FDA allegations regarding the approval of Onyx, defendants raise the Public Disclosure Bar, arguing that D'Agostino's allegations are based on materials that had been disclosed to the FDA well before the filing of D'Agostino's original Complaint. While defendants do not argue that a direct allegation of fraud was a matter of public record, they rely on the fact that "both [the allegedly] misrepresented state of facts and a true state of facts [were in the public realm] so that the . . . reader [had the means to] infer fraud." *Poteet*, 619 F.3d at 110.[26]

The essential allegations of the Proposed Complaint with regard to Onyx and the alleged fraud-on-the-FDA are: (1) that MTI fraudulently omitted safety information pertaining to Enteryx; (2) that MTI fraudulently misrepresented the substance of the training program that it proposed to

[25] In *Poteet*, the First Circuit noted that the Public Disclosure Bar was "designed to preclude qui tam suits based on information that would have been equally available to strangers to the fraud transaction had they chosen to look for it." *Poteet*, 619 F.3d at 110.

[26] D'Agostino concedes in his Reply that he has provided no supplementary reasoning, evidence, or developments in the law addressing the Public Disclosure Bar since the TAC was filed. Instead, D'Agostino urges the court to reconsider its previous rulings.

provide for Onyx users; and (3) that MTI concealed its intention to market Onyx for uses other than the treatment of BAVM.

With respect to Enteryx, the Proposed Complaint contrasts MTI's submissions to the FDA and the FDA advisory panel during the Onyx approval process with the FDA's internal records concerning safety issues associated with Enteryx. By citing extensively from the publicly available FDA documents, the Proposed Complaint itself establishes the first element of the Public Disclosure Bar under *Rost*.[27] As the FDA was the source of both sets of public records, the second prong of the *Rost* test is also met. Finally, D'Agostino does not (by definition) qualify as an "original source" of the Enteryx disclosure, as he did not provide the FDA with the safety information concerning Enteryx.[28] Consequently, the Enteryx allegations are precluded by the Public Disclosure Bar.

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[27] For example, D'Agostino quotes from the Onyx FDA Preclinical Review, showing the link between Onyx and Enteryx, and reproduces a passage from FDA Patient Safety Alert # 32, October 2004, detailing the death of a patient who had undergone treatment with Enteryx. Prop. Compl. ¶¶ 60-62. In addition, D'Agostino references reports from the FDA adverse event reporting system (*id.* ¶ 60 n.4) and the FDA recall notification for Enteryx dated October 14, 2005. *Id.* ¶ 64. Based on his analysis of FDA published records, D'Agostino concludes that none of the dangers of Enteryx were effectively communicated to the FDA regulators considering the Onyx application.

[28] D'Agostino now claims that he qualifies as an "original source" based upon "insider' knowledge" that Onyx, once in the marketplace, ultimately

The same is true with respect to the Onyx training program that was ultimately instituted by EV3. The court is constrained to accept the Proposed Complaint's version of the program as the one actually implemented (providing training per site rather than per physician). *But see* footnote 12, *supra*. Nonetheless, as defendants note, a record of MTI's promise to the advisory panel to implement an "all physician" training program was placed in the public domain (first prong) by the FDA (second prong). And because the disclosures were made public before D'Agostino began his employment at EV3, he could not have been their original source (third prong).[29]

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created the same safety hazards as Enteryx. Reply at 5-6. This claim is irrelevant to whether MTI withheld information from the FDA regarding Enteryx at the time of approval, and whether that information was in fact then publicly available.

[29] D'Agostino now counters that, while the alleged promise of an "all physician" training program was indeed a matter of public record, "[p]rior to the unsealing of this case, there was no public evidence that [EV3] would 'turn on the Onyx faucet'" by providing training per site rather than per physician. Reply at 5. D'Agostino's counsel repeated this argument at the hearing. However, as EV3 pointed out in its Motion to Dismiss the TAC, the FDA's published Summary of Safety and Effectiveness Data (SSED) references the training program "that all **sites** will participate in prior to independently using [Onyx]." Dkt. # 75 at 8 n.14 (emphasis added). An SSED is made publicly available upon notice of approval of a drug or device (in this case, in July of 2005). D'Agostino makes no claim as to having been the original source of the information disclosed by the SSED.

Moreover, whether or not MTI ultimately failed to institute the training program promised to the FDA, D'Agostino has failed to plausibly allege scienter: that MTI's representations to the FDA regarding the training

Consequently, the court lacks jurisdiction over the training program allegations by operation of the Public Disclosure Bar.

With respect to the final allegation, that MTI misrepresented the breadth of its off-label marketing plans with respect to Onyx, the court agrees with D'Agostino that the Public Disclosure Bar does not divest jurisdiction. While the purported misrepresentation was clearly in the public domain, the facts from which the existence of a fraud might be inferred were drawn from D'Agostino's experience as a senior sales manager for EV3. Consequently, the court will consider the off-label marketing allegations, along with D'Agostino's argument that Onyx was not Medicare reimbursable because of a lack of medical reasonableness and necessity on their merits.[30]

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program were false *when made*, and that MTI knew that they were false. A relator "does not satisfy the requirements of Rule 9(b) merely by pleading 'fraud by hindsight.'" *Gross v. Summa Four, Inc.*, 93 F.3d 987, 991 (1st Cir. 1996). "[A] general averment that defendants knew earlier what later turned out badly does not convey the necessary particularity that Rule 9(b) requires." *Id.* D'Agostino proffers only the conclusory allegation that "the company planned" at the time to market Onyx off-label, as a permanent implant, or to physicians without neurointerventional training, Prop. Compl. ¶ 174, without providing any basis for this allegation. D'Agostino acknowledges that company policy was for MTI sales representatives to provide additional (presumably individualized) training to physicians who did not attend neurovascular training. Prop. Compl. ¶ 103.

[30] Defendants do not attempt to raise the Public Disclosure Bar with respect to this latter allegation.

2. Failure to Plead with the Specificity and Particularity Required Under Rule 9(b)

The strict pleading requirements of Fed. R. Civ. P. 9(b) apply to an FCA *qui tam* action. *See United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 228 (1st Cir. 2004). *Qui tam* relators bringing an action under the False Claims Act are required to set forth with particularly the "'who, what, when, where, and how' of the alleged fraud." *United States ex rel. Ge v. Takeda Pharm. Co. Ltd.*, 737 F.3d 116, 123 (1st Cir. 2013), quoting *United States ex rel. Walsh v. Eastman Kodak Co.*, 98 F. Supp. 2d 141, 147 (D. Mass. 2000).

> [D]etails 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 . . . we believe that some of this information for at least some of the claims must be pleaded in order to satisfy Rule 9(b).

Karvelas, 360 F.3d at 233 (internal citations and quotations omitted). 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 the rule

requiring fraud to be pled with particularity 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 123-124, quoting *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 29 (1st Cir. 2009). There is, however, an important caveat: "[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 . . . [would] violate[] the specificity requirements of Rule 9(b)." *Ge*, 737 F.3d at 124.[31]

[31] D'Agostino's theory of "total falsity" essentially maintains that, if the FDA had been aware of the company's off-label marketing plans for Onyx, it would not (or at least may not) have approved the device. Because all claims submitted to government agencies for Onyx were based on an FDA approval acquired through fraud, the theory goes, all such claims were *ipso facto* false claims. The court's research has uncovered no case in this Circuit that endorses D'Agostino's theory. Indeed, the Court of Appeals for the First Circuit has indicated its disapproval of similar claims in the context of securities class actions and state tort claims, particularly in the absence of FDA findings of fraud. *See, e.g., New Jersey Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35, 49 (1st Cir. 2008) (finding in a securities class action that "[p]laintiffs' claim that the FDA gave its approval only because defendants hid data from it . . . is a very serious charge and is not substantiated by the allegations in the complaint or the documents in the record."); *id.* at 49-50 (observing that "[t]he plaintiffs' claim that Biogen hid data from the FDA is not based on any FDA finding that this was true. Rather, it is based primarily on plaintiffs' reading of after-the-fact statements about earlier events."). Moreover, as set forth below, the court finds that even were it to adopt D'Agostino's litigation theory of "total falsity," D'Agostino has failed to allege sufficient facts to support a plausible inference of fraudulent inducement of FDA approval.

a. Onyx

With respect to the marketing of Onyx, D'Agostino fails to even approximate the level of particularity required to meet the Rule 9(b) requirements limned by the First Circuit in *Karvelas*, *Ge*, and *Duxbury*. D'Agostino theorizes that because Onyx should not have been approved by the FDA in the first instance, or, alternatively, because it should have been withdrawn from the market or placed under more stringent controls (by EV3 or the FDA), all reimbursement claims for the use of Onyx must be deemed categorically false. While the TAC specified two adverse incidents attributed to Onyx, TAC ¶¶ 203-205, any identification of the surgeons or facility involved was missing, any description of a monetary loss to the government was omitted,[32] and there was no allegation that a claim for payment (false or otherwise) was presented to any government payer as a result of either of the alleged incidents. The conclusory allegation that "hundreds" of similar incidents must have occurred and that some of these must have cost the

[32] While D'Agostino alleges that Onyx claims inflated DRG reimbursement requests, thereby increasing the cost to the government, at no point does the TAC (or the Proposed Complaint) give the factual details of any specific claim, any description of how DRG rates were impacted by Onyx, any specific outlier claims involving Onyx, or any details of claims for off-label use of Onyx that might show how the costs were inflated with respect to alternative or non-conventional treatments.

government money is illustrative of the kind of opportunistic pleading that Rule 9(b) is designed to prevent. *See* TAC ¶¶ 206, 271. In his Proposed Complaint, D'Agostino substitutes the two adverse events allegedly connected to Onyx with new examples. The Proposed Complaint, in an attempt to import the requisite specificity, cites an FDA advisory from 2012, which warns of the possibility of catheter entrapment associated with the use of Onyx. In this advisory notice, the FDA stated that it had received *"more than 100 reported cases, including nine patient deaths, of catheter breakage that may be related to catheter entrapment."* Prop. Compl. ¶ 160. D'Agostino has not, however, identified the hospitals at which these adverse events occurred, which surgeons were involved, whether the surgeons were trained in using Onyx, whether their uses of Onyx were off-label, or whether claims for reimbursement were submitted to government payers for any of these procedures. D'Agostino's theory that "**every** claim paid by the government which involved the use of Onyx violated the FCA," fits precisely in the legal-argument-disguised-as-fact category that the First Circuit flatly rejected in *Ge*. Consolidated Opp'n at 17 (emphasis supplied).

Moreover, even were the court to accept D'Agostino's theory of total falsity as a working premise, he has failed to meet the "materiality" standard of the FCA. 31 U.S.C. § 3729(a); *see Allison Engine*, 553 U.S. at 665 (plaintiff

"must prove that the defendant intended that the false record or statement be material to the Government's decision to pay or approve the false claim."). D'Agostino has not alleged with specificity that any misrepresentations to the FDA about the off-label marketing of Onyx were material to the FDA's decision to approve the device. D'Agostino has alleged no facts which plausibly suggest that the FDA relied upon, or even considered, MTI's marketing strategy when it approved Onyx for use, or that the FDA would not have approved the device were it aware of MTI's plans for off-label marketing.[33] As the Supreme Court has observed, there is nothing improper per se about off-label uses of drugs and medical devices:

> "[O]ff-label" usage of medical devices (use of a device for some other purpose than that for which it has been approved by the FDA) is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine. *See, e.g.*, Beck & Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 Food & Drug L.J. 71, 76-77 (1998) (noting that courts, several States, and the "FDA itself recogniz[e] the value and propriety of off-label use.").

Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 350 (2001). Certainly, the FDA might reasonably expect that a device with a limited label indication

[33] The court notes that in the five years since this litigation began, despite the fact that D'Agostino's alleged misrepresentations have been brought to the FDA's attention, the FDA has not elected to withdraw its approval of Onyx or to recall the device.

would be marketed and used accordingly; but a promise broken after the fact is not, without more, the equivalent of a false claim for purposes of the FCA.[34] Here, D'Agostino again adopts the approach that the First Circuit rejected in *Ge*: From a generalized allegation of misconduct or deception (the alleged off-label marketing scheme), he asks the court to infer the global existence of false claims.

This, however, does not end the discussion. Although D'Agostino has not plausibly alleged facts supporting an inference that all claims for reimbursement of Onyx were false per se, he also alleges that a specific subset of claims for reimbursement were false.[35] First, D'Agostino alleges that certain claims were not "medically reasonable or medically necessary,"

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[34] D'Agostino's extensive quotations from the FDA panel transcript do not compel D'Agostino's conclusion (that the FDA was duped about the safety profile of Onyx), but rather the opposite. They suggest instead that the FDA advisory panel engaged in a difficult cost-benefit analysis with respect to the safety of Onyx, and concluded that the potential benefits of the device outweighed the significant risks. For example, D'Agostino quotes a member of the panel as stating, "[I] do believe that actually if this product is associated with a number of deaths that it will be a small victory here." Prop. Compl. ¶ 55.

[35] Simply alleging a scheme of off-label promotion is, for this purpose, insufficient. "Proof of unlawful off-label promotion alone cannot sustain a successful FCA action; the FCA does not impose liability for all fraudulent acts, only for fraudulent claims." *United States ex rel. Nowak v. Medtronic, Inc.*, 806 F. Supp. 2d 310, 345 (D. Mass. 2011). Providing evidence of an actual false claim is "the *sine qua non* of a False Claims Act violation." *Karvelas*, 360 F.3d at 225.

because they were submitted by surgeons inadequately trained in the use of Onyx. To support this "medical necessity" claim, D'Agostino presents the expert opinion of the new-to-the-case Dr. Pryor.[36] Dr. Pryor opines that use of Onyx, absent sufficient device-specific training, is never medically reasonable or necessary.[37] Dr. Pryor's opinion does not, however, satisfy D'Agostino's task of identifying a specific subset of false claims. While Dr. Pryor reports having witnessed the use of Onyx by several untrained physicians for both approved and off-label purposes, Dr. Pryor's account does not identify those physicians, the dates their allegedly medically unreasonable uses of Onyx occurred, or (most crucially) whether any of these

[36] Dr. Pryor does not contend that Onyx is, like the 1963 Chevrolet Corvair, "unsafe at any speed" (or even that off-label uses of Onyx are per se unsafe, see footnote 17, *supra*). Dr. Pryor merely states that (in his professional opinion) use of Onyx is never medically reasonable in the hands of untrained physicians even if the outcomes are benign.

[37] EV3 emphasizes that it is the professional opinion of treating physicians, rather than Dr. Pryor's purported witnessing, which is relevant to the question of medical necessity. D'Agostino rebuts this characterization in his Reply, noting that "a physician's determination of necessity does not answer the reimbursement inquiry. Rather, coverage decisions are made by Medicare and other government healthcare programs, not the prescribing physician." Reply at 9. D'Agostino does not, however, suggest why, once Medicare has made the decision that a particular treatment is reasonable and necessary in a given case, Dr. Pryor's expert opinion should overrule the agency's finding.

physicians in fact submitted claims for reimbursement to federal or state governmental entities.[38]

[38] Despite repeated attempts to cure this deficiency, D'Agostino's Proposed Complaint fails to identify with particularity the "*sine qua non*" of the FCA: a specific false claim submitted to a government payer for reimbursement. D'Agostino notes that both Axium and Onyx were sold to several government hospitals, including some Veterans Administration hospitals. However, he provides scant evidence of the amounts of Onyx and Axium sold to these hospitals; moreover, he again fails to allege with particularity that these hospitals used Onyx in any improper or medically unreasonable manner.

D'Agostino claims that he "can state that more than 50% of the patients who underwent procedures involving Onyx were insured by government healthcare programs." Prop. Compl. ¶ 186. The evidence for this statement, however, appears to be that over 50% of the patients in hospitals within the northeastern United States were insured by governmental programs, and that it must logically follow that the patient population treated with Onyx had similar rates of Medicare or Medicaid coverage. Prop. Compl. ¶ 186 n.16. D'Agostino's back-of-the-envelope "statistical analyses" fall well short of the particularity requirement of Rule 9(b), much less the evidentiary standards governing the admissibility of statistical proofs. *Indeed, D'Agostino acknowledges that his 50% figure is merely what he considers a "conservative estimate,"* Prop. Compl. ¶ 197 n.21.

D'Agostino alleges that he has personal knowledge that several physicians (whom D'Agostino names) at Massachusetts General Hospital and at Brigham & Women's Hospital submitted bills to government healthcare programs for uses of Onyx. Prop. Compl. ¶ 187. However, he provides no evidence of dates or amounts of the claims filed, or (most critically) whether those physicians were either untrained in using Onyx or used Onyx for off-label purposes.

Finally, D'Agostino cites two doctors – Christopher Kwolek and Chieh-Min Fan – who allegedly performed procedures involving Onyx, although neither was a neurosurgeon and neither attended EV3's training program. Again, D'Agostino does not identify with particularity any Onyx-related

b. Axium

While the TAC contained little that could be read as the kind of particularized pleading that satisfies the criteria identified in *Karvelas* or *Ge*,[39] in his Consolidated Opposition to the defendants' motion to dismiss the TAC D'Agostino attempted to collate disparate allegations in the Complaint under the headings "Who," "What," "When," and "How." Consolidated

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claims submitted to government programs by either of these surgeons. D'Agostino alleges that "over 50%" of the two surgeons' patients were insured by government programs, but that is the extent of his identification of possible false claims. The court cannot conclude, based on this information, that D'Agostino has identified actual false claims with the specificity demanded by Rule 9(b). To take an example, while 45.3% of Americans do not file tax returns, it does not follow that nearly half the American population are necessarily tax scofflaws (because of withholding, death or dislocation, or failure to meet the minimum income threshold), nor does it mean that any particular subset of Americans, like physicians who use Onyx, are more likely than not to have failed to meet their tax obligations. (The 45.3 percent figure and the explanation are from Roberton Williams, *New Estimates Of How Many Households Pay No Federal Income Tax*, TaxVox (October 6, 2015), *available at* http://taxvox.taxpolicycenter.org/2015/10/06/new-estimates-of-how-many-households-pay-no-federal-income-tax/ (last visited December 23, 2015)).

[39] While D'Agostino makes general allegations linking defective Axium coils with false claims, the only details offered are those concerning Dr. Ohki's patients and the eleven additional events cited in the Proposed Complaint. However, it is not alleged in the Proposed Complaint that a claim for reimbursement for the treatment provided to either of these patients was ever submitted to Medicare.

Opp'n at 9-12. In the summary under "Who" (which also attempts to fulfill the role of "where"), D'Agostino cited six hospitals named in the TAC as sources of false claims. Only one of these, however, is linked to Axium. Although a specific physician was mentioned, there was no allegation that any claim was submitted to a government payer. In the discussion under "What," D'Agostino simply alleged a legal conclusion: that because Axium was knowingly sold as a defective and misbranded device, it was not medically necessary. The category of "When" received even more conclusory treatment. D'Agostino stated in his Consolidated Opposition that the Axium device was defective from the time it was first placed on the market. In other words, the answer to the question "When?" appeared to be "Always." This court has previously ruled that it is impermissible to assume that *any* claim in a date range is, *ipso facto*, false simply because *some* intermittent device failures were identified. *See United States ex rel. Provuncher v. Angioscore, Inc.*, 2012 WL 3144885, at *1-2 (D. Mass. Aug. 3, 2012). The "How" element was equally lacking in specifics. Here again, D'Agostino returned to his overarching theory of total falseness as a substitute for specific and particular examples of false claims. Finally, D'Agostino's arguments that all Axium claims are false because they contributed indirectly to inflated Medicare

costs were cut from the same cloth as the Onyx allegations. In sum, the TAC failed to satisfy the Rule 9(b) criteria mandated by *Karvelas* and *Ge*.

While D'Agostino does not address these deficiencies directly, he now claims that the Proposed Complaint "establishes conclusively that Axium coils were defectively designed." Reply at 17. This, in the court's view, is a gross overstatement. With respect to Axium, D'Agostino's Proposed Complaint does nothing to elaborate in any material fashion the conclusory allegations of the TAC and the Consolidated Opposition to EV3's Motion to Dismiss. D'Agostino alleges that EV3 released several iterations of Axium, each of which made moderate improvements over the previous release. D'Agostino proposes that this fact demonstrates EV3 was aware that Axium was defective and required fixing. The court sees no reason to conclude that the release of a newer and safer version of a device indicates *ipso facto* that the older version was defective or unreasonably dangerous. For a court to so hold would perversely act as a disincentive for manufacturers to make safety improvements in a marketed device after FDA-approval for fear of litigation.

D'Agostino's primary supplement to the TAC is a list of eleven additional examples of supposed Axium failures, offered as evidence of the device's alleged defectiveness (bringing the total number of examples to thirteen). Without an indication of Axium's failure **rate**, however, the

Proposed Complaint – which alleges that Axium was so patently defective that all claims for reimbursement were false claims – again falls short of the particularity required by Rule 9(b). As this court has observed, it is perfectly reasonable for government agencies to allow for a modicum of risk and a certain failure rate for medical devices, or for other products for which the government pays. Were the perfect allowed to become the enemy of the good, the many patients, indeed the overwhelming majority of patients, whose lives are saved or prolonged because of devices like Onyx would be unnecessarily sacrificed in the quest for a defect-free world. [40]

As with his Onyx allegations, D'Agostino depends largely on an overarching theory that all claims for Axium were false because the product was defective per se. D'Agostino alleges in the Proposed Complaint that all Axium claims were false because "a device which is dangerous to patient health is, a priori, not 'reasonable and necessary' for the treatment of illness or injury." Prop. Compl. ¶ 255. This is not only a legal (and not a factual)

[40] D'Agostino also alleges, for both Onyx and Axium, that EV3 failed to comply with adverse-event reporting requirements and improperly "watered down" adverse event reports. D'Agostino does not, however, identify even a single specific instance of a "squelched" or "watered down" report, Prop. Compl. ¶¶ 268-270, nor does he link any such report to a claim for government reimbursement or a prospect for an FDA reconsideration of its approval of the marketing of the devices.

conclusion, but also an incorrect one. As the court has previously said, the FDA and insurers may, in their discretion, determine that a certain degree of danger or risk is acceptable when weighed against the potential benefits of a device. As with Onyx, D'Agostino does not buttress his allegation with any details regarding specific false claims submitted to the government. While D'Agostino observes that more than 50% of patients in the hospitals he identifies are on some form of government insurance, Prop. Compl. ¶ 186 n.16, as with Onyx, he does not establish that any of those patients were in fact treated with Axium.

3. Failure to State a Claim Under Rule 12(b)(6)

In addition to falling short of Rule 9(b), the Proposed Complaint does not survive a Rule 12(b)(6) analysis. "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal citations and quotations omitted). "While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (internal citations omitted); s*ee*

also Rodriguez-Ortiz v. Margo Caribe, Inc., 490 F.3d 92, 95-96 (1st Cir. 2007).

In broad generalizations, D'Agostino alleges that all Axium devices on the market were defective and therefore, any claim for Medicare reimbursement involving Axium was false. With regard to Onyx, D'Agostino returns repeatedly to the theme that, but for defendants' misrepresentations, the FDA would not have approved Onyx in the first instance. In another iteration of this argument, D'Agostino speculates that, had the FDA known of all of the alleged hidden defects, it would have withdrawn its approval of Onyx or ordered its recall.

The FDA is charged with the difficult task of balancing the risk and benefits of placing drugs and medical devices on the market, and D'Agostino is, in effect, asking this court to usurp the FDA's prerogative and assume that function. D'Agostino proposes, in the guise of an FCA action, that this court reevaluate years of FDA decisions concerning the approval or recall of EV3's medical devices. As the Court of Appeals has observed, "[s]urely, 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." *King v. Collagen Corp.*, 983 F.2d 1130, 1140 (1st Cir. 1993) (Aldrich and Campbell,

JJ., concurring). The FCA is a vehicle for rooting out undetected financial fraud against the federal government by giving generous financial incentives to insider whistleblowers; it is not a substitute for the certiorari review of discretionary decisions taken by the FDA in the area of competence delegated to it by Congress.

In this latter regard, there is a well-established regulatory path for bringing medical devices (as well as new drugs) to clinical trials on an investigational basis, and if the benefits of the device are determined to outweigh its potential risks, to place it in the stream of commerce. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 325 (2008) (observing that FDA conducts cost-benefit analysis to determine "[h]ow many more lives will be saved by a device which, along with its greater effectiveness, brings a greater risk of harm"). There are also well-established legal, regulatory, and administrative mechanisms for managing the risks and benefits of the device as it is further tested in the marketplace.

While the FDA expects and requires good faith and responsible behavior from participants in the clinical review and marketing processes, it also has significant administrative sanction and enforcement powers, as well as an Office of Criminal Investigations empowered to refer cases to the Department of Justice for prosecution. *See generally Fire & Police Pension*

Ass'n of Colorado v. Abiomed, Inc., 778 F.3d 228, 233-238 (1st Cir. 2015); *see also Biogen*, 537 F.3d at 47-48 ("Fraud on the FDA is, to be sure, prohibited, *see* 21 U.S.C. § 331, and the FDA has statutory power to catch, punish, and deter such fraud, *see id.* § 372 (FDA empowered to conduct investigations); *id.* § 332 (FDA can seek injunctive relief); *id.* § 333 (FDA can pursue criminal prosecutions and civil penalties.)"). Perfecting the science of threading tiny tubes inside the human skull to treat vascular defects requires an acute level of medical judgment that is well beyond that possessed by most courts, lawyers, and medical device salespersons. In short, an FCA action is not the appropriate vehicle for this court to exercise its judgment in second-guessing decisions taken by the FDA in approving the use of medical devices simply because the government happens to pay for some of them.

4. Undue Prejudice

Leaving aside the futility of D'Agostino's proposed amendments, the court is also of the tentative view that permitting a further amendment would substantially prejudice the individual defendants, Hardin and Wall. D'Agostino makes no claim that either Wall or Hardin acted *ultra vires*, or outside the scope of their employment. Nor does D'Agostino provide any indication of what Wall and Hardin bring to this litigation, in their capacity

as defendants, which EV3 and MTI (under the doctrine of respondeat superior) do not provide.[41] Given, however, the court's decision to deny the motion to amend, it is not necessary for the court to definitively resolve the issue of whether the costs and uncertainties of the litigation cause undue hardship to the individual defendants.

5. Undue Delay

The defendants argue that D'Agostino's "new evidence" – the statement of Dr. Pryor, the 2012 FDA advisory cataloguing adverse events

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[41] The theory behind Wall and Hardin's specific culpability appears to be that the two men as corporate executives are personally liable for any wrongdoing by their company. With respect to Hardin, D'Agostino alleges only that Hardin "regularly attended" sales meetings at which off-label marketing plans were discussed (Prop. Compl. ¶ 114); that Hardin introduced, at a national sales meeting, a guest speaker and radiologist who demonstrated "peripheral" uses of Onyx to the sales force (*id.* ¶ 118); that Hardin managed a list of invitees to EV3 physician training sessions, which included training in off-label uses (*id.* ¶¶ 131-146); that Hardin disseminated information about successful off-label uses of Onyx throughout the company (*id.* ¶¶ 147, 149); and that Hardin requested that sales representatives conduct an inventory of older generations of Axium (*id.* ¶ 227).

With respect to Wall, D'Agostino's allegations are even thinner. He proffers only the conclusion that "Wall was responsible for virtually every aspect of the marketing and sales of Onyx and Axium," and "had supervisory authority over many individuals who were illegally marketing and selling both products, was aware of these illegal activities, and supported the efforts of these individuals," (Prop. Compl. ¶ 75 n.9), that Wall, like Hardin, "regularly attended" sales meetings, (*id.* ¶ 114) and that that Wall received, by email, a medical journal extolling the virtues of off-label uses of Onyx (*id.* ¶ 158).

related to Onyx, and eleven additional instances of adverse events correlated with Axium use – was available to D'Agostino throughout much of the litigation, and particularly at the time of the TAC, and therefore should have been included in previous iterations of the Complaint. The court is inclined to agree. D'Agostino could have obtained, with reasonable diligence, the expert opinion of Dr. Pryor and the thirteen listed cases of Axium failure before filing the TAC. The FDA's advisory notice was made public well before the unsealing of the case and nearly two years before D'Agostino submitted the TAC. D'Agostino's argument that the instant motion represents his first opportunity to cure the deficiencies in his Complaint is unavailing. D'Agostino "was put on notice of the deficiencies in the complaint by the motion to dismiss [the TAC]. If [he] had something relevant to add, [he] should have moved to add it then." *Abiomed*, 778 F.3d at 247. D'Agostino was not, at that time, "entitled to wait and see if [his] amended complaint was rejected by the district court before being put to the costs of filing [an additional] amended complaint." *ACA Financial Guaranty Corp. v. Advest, Inc.*, 512 F.3d 46, 57 (1st Cir. 2008). As the First Circuit observed in that case,

> [relator] ha[s] it exactly backwards – [his] methodology would lead to delays, inefficiencies, and wasted work. [Plaintiffs] do not get leisurely repeated bites at the apple, forcing a district judge to decide whether each successive complaint was adequate. . . .

> Plaintiffs may not, having the needed information, deliberately wait in the wings for a year and a half with another amendment to a complaint should the court hold the first amended complaint was insufficient. Such an approach would impose unnecessary costs and inefficiencies on both the courts and party opponents.

Id.

ORDER

For the foregoing reasons, relator Jeffrey D'Agostino's motion to amend his complaint pursuant to Federal Rule of Civil Procedure 15(a)(2) is DENIED. The Clerk will enter dismissals with prejudice as to all defendants, and close the case.

SO ORDERED.

/s/ Richard G. Stearns

UNITED STATES DISTRICT JUDGE