UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 10-11822-RGS

UNITED STATES OF AMERICA, 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 *ex rel.* JEFFREY D'AGOSTINO

v.

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

MEMORANDUM OF DECISION AND ORDER
ON DEFENDANTS' MOTION TO DISMISS

September 30, 2014

STEARNS, J.

In this now three-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.[1] According to the Third Amended Complaint (TAC), defendants knowingly 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), all the while conspiring to commit these acts in violation of FCA § 3729(a)(1)(C) (Count IV). The TAC makes parallel allegations under the various state and District of Columbia analogs to the FCA (Counts V-XXXI).[2] For reasons that will be explained, defendants' motions to dismiss the TAC with prejudice will be allowed.

BACKGROUND

EV3 manufactures the two medical devices implicated in the TAC, the Onyx Liquid Embolic System (Onyx) and the Axium Detachable Coil System (Axium). Both Onyx and Axium were developed by MTI (which

[1] D'Agostino also alleged violations of 31 U.S.C. § 3729(a)(1)(G) (Count III of the Third Amended Complaint). 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 or Opp'n).

[2] Except in the case of Louisiana where only the making or causing the making of false claims is alleged in the TAC.

later merged with EV3).[3] 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.[4] D'Agostino served as the Territory 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

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

[4] The TAC 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 iterations of allegedly defective Axium devices.

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.

The factual allegations, distilled from the legal conclusions in which they are embedded, are as follows.[5] According to the TAC, 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 in the BAVM patient if follow-up surgery was not performed.[6] In response to the panel's reservations, the TAC alleges that MTI gave false assurances that it would institute a program to train

[5] Factual allegations will be attributed to the TAC; legal conclusions and arguments directly to D'Agostino.

[6] 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.

surgeons in the proper use of Onyx.[7] The TAC 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. 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.[8]

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

[7] D'Agostino alleges that MTI undertook to train *all* physicians who used Onyx; however, the relevant transcript passage reproduced in the TAC 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." TAC ¶ 53 (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*. ¶ 98.

[8] The TAC notes that EV3's sales quotas for Onyx were seven times the estimated total market, even if it is 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). *Id*. ¶ 110. Defendants do not dispute the fact that off-label uses of Onyx made up a significant portion of its sales.

Scientific used the material to manufacture Enteryx, which was approved by the FDA in April of 2003 for the treatment of gastroesophageal reflux disease (GERD). 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 TAC, in some cases physicians injecting Enteryx missed the esophageal musculature, risking potentially fatal complications.[9] D'Agostino argues that because of the intimate associations 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 same molecule, in the form of Enteryx, was killing people." TAC ¶ 82.

2. Training Program Used to Drive Off-Label Sales

The TAC 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

[9] 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.

on-label use of Onyx. The TAC further alleges that EV3 paid physicians to conduct Onyx training for other physicians, which sometimes included training in off-label uses. 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, thus making off-label uses more lucrative for EV3. This recognition, according to the TAC, led EV3 to ramp up the dissemination to physicians of information promoting Onyx's off-label use. An example given by the TAC 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 areteriovenous fistulas] DAVFs)." TAC ¶ 120.

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.[10] Reimbursement is at the rates established by the Diagnosis Related Group (DRG) or the

[10] 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 maintains that all off-label uses of Onyx were "affirmatively unsafe, ineffective, and hazardous to patient health,"[11] and that consequently, all "claims which fall into this category were false under the FCA." *Id*. ¶ 181. While Medicare is prohibited from reimbursing hospitals or physicians for unapproved devices (unless they are part of an FDA-authorized clinical trial), *see* 42 C.F.R § 411.15(o), D'Agostino acknowledges that Onyx was FDA-approved (and therefore Medicare eligible). Nonetheless, D'Agostino argues that because defendants fraudulently induced the FDA to grant approval for Onyx, all off-label reimbursement claims were tainted as a result. As suggested in the TAC,

[11] The TAC describes two incidents in which embolization of a dural fistulae failed leading, in one of the instances, to the patient's permanent impairment. The TAC alleges 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.

"[h]ad the FDA known what MTI was planning, it *probably* would not have granted approval." TAC ¶ 189 (emphasis added).[12]

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 TAC 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 use." *Id*. ¶ 216. 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 TAC, EV3 actively explored ways of minimizing losses on the recall of earlier iterations of Axium. As an

[12] The TAC also alleges 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).

example, the TAC cites an internal EV3 email from National Manager Fred Gunderman to EV3 executives, written after generation 1E of Axium was marketed.[13] *See id.* ¶ 232. 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.[14] *Id.*

The TAC notes that Dr. Stephen Ohki at Hartford Hospital in Connecticut reported an Axium coil detachment failure in late 2008 that "led to a negative outcome for the patient." *Id.* ¶ 246. 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.

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

[14] Like Onyx, Axium was intended for vasculature treatments in the brain. While the TAC is coy 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 concedes that the FDA approved Concerto for use in treatments of vasculature diseases in the peripheral region.

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*. ¶ 248.

The TAC recites 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*. ¶¶ 249-250. While detachment failures could be remedied by secondary detachment methods (such as tugging on the device with a forceps), these also entailed risks to patients.[15] The TAC alleges that over time "thousands of Axium coils" were not manufactured in accordance with current Good Manufacturing Practice regulations and therefore qualified as "adulterated" products under the Federal Food, Drug, and Cosmetics Act of 1938 (FDCA). *Id*. ¶ 256. Moreover, because the Axium coils were allegedly hazardous to patients when used as directed, D'Agostino argues that they were misbranded under FDCA § 502(j). *Id*. ¶ 257. Because "[a] device which is

[15] According to the TAC, 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, but to avoid mentioning the use of forceps or "torque devices," as it was thought that the disclosure might draw negative attention from the FDA. *Id*. ¶ 253.

adulterated, misbranded, or dangerous . . . cannot be 'reasonable and necessary'" (and therefore Medicare reimbursable), D'Agostino contends that by knowingly selling defective Axium coils, "EV3 caused hospitals and physicians to submit false claims" in violation of the FCA. *Id*. ¶¶ 258-259.

2. Axium Adverse Event Reporting

The TAC alleges that EV3's investigations into adverse events involving Axium were "often bogus, blaming the problem on everything but the defective product." *Id*. ¶ 266.[16] 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 would have recalled the devices, or greatly restricted the instructions for [their] use." *Id*. ¶ 271. 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*. ¶ 272. In other words, EV3 was marketing medical devices that were eligible for Medicare reimbursement

[16] 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*. ¶ 269 (which were presumably ignored by EV3).

only because the government did not know "the truth about these products." *Id*. ¶ 272.

C. Procedural Background

D'Agostino filed this qui tam action under seal on October 26, 2010, with EV3 as the sole named defendant. D'Agostino amended the original complaint as a matter of right on February 3, 2011, adding individual defendants John Cubelic, John Hardin, and Vitas Sipelis. D'Agostino sought and was granted permission to amend the Complaint two additional times while the case remained under seal. On October 1, 2013, the United States filed a notice declining to intervene, but stated that its investigation was ongoing. The twenty-six named plaintiff States and the District of Columbia filed a Notice of Non-intervention on December 19, 2013. The court unsealed the case on December 26, 2013. The TAC was filed on April 28, 2014, with the court's permission, adding defendants MTI and Brett Wall. EV3, MTI, and the individual defendants filed motions to dismiss the TAC on June 30, 2014. D'Agostino voluntarily dismissed defendants John Cubelic and Vitas Sipelis with prejudice on July 29, 2014. The court heard arguments on the remaining defendants' motions to dismiss on September 2, 2014.

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.[17]

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 previously disclosed to the FDA. 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.

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

[17] 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.

With respect to Enteryx, the TAC 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 TAC itself establishes the first element of the Public Disclosure Bar under *Rost*.[18] 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. Consequently, the Enteryx allegations are precluded by the Public Disclosure Bar.

The same is true with respect to the Onyx training program that was ultimately instituted by EV3. The court is constrained to accept the TAC's version of the program as the one actually implemented (providing training per site rather than per physician). *But see* fn. 7, *supra*. Nonetheless, as

[18] 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. TAC ¶¶ 61-63. In addition, D'Agostino references reports from the FDA adverse event reporting system (*id*. ¶ 61 n.4) and the FDA recall notification for Enteryx dated October 14, 2005. *Id*. ¶ 65. 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.

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). 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.[19]

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

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

The strict pleading requirements of Fed. R. Civ. P. 9(b) apply to an FCA qui tam action. *See U.S. 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.

a. Onyx

With respect to the marketing of Onyx, D'Agostino fails to even approximate the level of particularity required to satisfy Rule 9(b) required 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 specifies two adverse incidents attributed to Onyx, TAC ¶¶ 203-205, any identification of the surgeons or facility involved is missing, any description of a monetary loss to the government is omitted,[20]

[20] While D'Agostino alleges that Onyx claims inflated DRG reimbursement requests, thereby increasing the cost to the government, at no point does the TAC give the factual details of any specific claim, any

and there is 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 government money is illustrative of the kind of opportunistic pleading that Rule 9(b) is designed to prevent. *See Id*. ¶¶ 206, 271. Moreover, 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*.[21] Opp'n at 17 (emphasis added).

b. Axium

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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.

[21] In contradiction with this theory, D'Agostino argues elsewhere that he

> does not assert that [the Centers for Medicare and Medicaid Services] would not reimburse for an Onyx-based procedure conducted by a neurosurgeon that has specifically undergone the training mandated through the FDA approval process (except to the extent that the fraud on the FDA would have kept Onyx off the market altogether).

Opp'n at 21.

While the TAC contains little that can be read as the kind of particular pleading that satisfies the criteria identified in *Karvelas* or *Ge*,[22] in his Consolidated Opposition D'Agostino attempts to collate disparate allegations in the TAC under the headings "Who," "What," "When," and "How." *Id*. at 9-12. In the summary under "Who" (which also attempts to fulfill the role of "where"), D'Agostino cites six hospitals named in the TAC as sources of false claims. Only one of these, however, is linked to Axium. Although a specific physician is mentioned, there is no allegation that any claim was submitted to a government payer. In the discussion under "What," D'Agostino simply alleges a legal conclusion: that because Axium was knowingly sold as a defective and misbranded device, it was not medically necessary. The category of "When" receives an even more conclusory treatment. D'Agostino states in his Consolidated Opposition that the Axium device was defective from the time it was first placed on the market. In effect, the answer to the question "When?" appears 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*

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

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 is equally lacking in specifics. Here again, D'Agostino returns 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 are cut from the same cloth as the Onyx allegations. In sum, the TAC fails to satisfy the Rule 9(b) criteria mandated by *Karvelas* and *Ge*.

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

In addition to falling short of Rule 9(b), the TAC 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). *See 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 in effect is asking this court to usurp the FDA 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. 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. 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. 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 venue 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.

ORDER

For the foregoing reasons, defendants EV3, MTI, John Hardin and Brett Wall's Motions to Dismiss are ALLOWED. The Clerk will enter the dismissals with prejudice and close the case.

SO ORDERED.

/s/ Richard G. Stearns
UNITED STATES DISTRICT JUDGE