UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

Conformis, Inc., and John M. Schaub,	*	
	*	
Plaintiffs,	*	
	*	
v.	*	Civil Action No. 1:20-cv-10890-IT
	*	
Aetna, Inc., and Aetna Life Insurance Company,	*	
	*	
	*	
Defendants.	*	
	*	

MEMORANDUM & ORDER

March 31, 2021

TALWANI, D.J.

Plaintiffs Conformis, Inc. ("Conformis") and John M. Schaub brought this action against Defendants Aetna, Inc., and Aetna Life Insurance Company (collectively "Aetna") after Aetna categorized customized knee replacements as "experimental" and "investigational" and denied Schaub insurance coverage for the use of Conformis' customized knee replacement.

Presently before the court is Defendants' Motion to Dismiss Plaintiffs' Amended Complaint [#26] pursuant to Fed. R. Civ. P. 12(b)(6). For the reasons explained below, Defendants' motion is GRANTED as to all claims brought by Conformis and DENIED as to all claims brought by Schaub.

I. Facts As Alleged

The following facts are drawn from the First Amended Complaint ("Am. Compl.") [#17], the well-pleaded allegations of which are taken as true for the purposes of evaluating the motion to dismiss. See Ruivo v. Wells Fargo Bank, N.A., 766 F.3d 87, 90 (1st Cir. 2014).

Conformis is a medical device company that manufactures a customized knee

replacement called the Conformis iTotal Knee Replacement System ("Conformis System" or "Conformis knee replacement"). Am. Compl. ¶ 1 [#17]. The Conformis System "uses computed tomographic imagery generated by a CT scan to create an 'individualized solution' for patients in four key areas: (1) individualized fit; (2) individualized shape; (3) simplified surgical technique; and (4) improved operating room efficiencies." Id. at ¶ 22. Because Conformis knee replacements are shaped to a patient's body, recipients may avoid pain and feelings of a foreign object in their body that may be caused by off-the-shelf knee replacements that do not fit as well. Id. at ¶¶ 22-26. The upfront cost of the Conformis System is higher than off-the-shelf knee replacements, but the Conformis System may lead to fewer complications and attendant costs later. Id. at ¶¶ 30, 64-73.

The Conformis System received Food and Drug Administration ("FDA") clearance in February 2011, and since then, over 100,000 patients have received Conformis knee replacements. Id. at ¶¶ 5, 16, 33. The Conformis System is covered by over 90% of commercial payors, including United HealthCare, Cigna, and Anthem Blue Cross and Blue Shield; it is also covered by the Centers for Medicare and Medicaid Services. Id. at ¶¶ 16, 34-34, 38.

Aetna provides healthcare insurance, administration, and/or benefits to policy holders or plan participants pursuant to a variety of healthcare benefit plans and insurance policies. Id. at ¶ 3. Aetna has guidelines in place precluding coverage for experimental and investigative medical treatments. Id. at ¶¶ 39, 46, 50-51. Aetna defines experimental services and procedures as "often newer drugs, treatments or tests [that] are not yet accepted by doctors or by insurance plans as standard treatment. They may not be proven as effective or safe for most people." Id. at ¶ 48. Aetna uses the same definition for investigational services. Id. at ¶ 49.

Between February 2011 and September 21, 2018, Aetna covered Conformis knee

replacements under its policy on Uni-compartmental, Bi-compartmental, and Bi-unicompartmental Knee Arthroplasties, numbered 0660 ("Policy No. 0660"). Id. at ¶ 38. During this time, Aetna did not label the Conformis System as experimental or investigative, id. at ¶ 40, and approximately 5,000 Aetna patients received Conformis knee replacements. Id. at ¶ 98.

On September 21, 2018, Aetna amended Policy No. 0660, in relevant part, to say: "Aetna considers customized total knee implant experimental and investigational because its effectiveness has not been established." Policy No. 0660, Ex. 1 to Mem. of Law in Support of Defendants' Motion to Dismiss Plaintiffs' Amended Complaint ("Mem. Mot. Dismiss") 6 [#27-1].[1] Studies cited by Aetna to support the amendment show instead that the Conformis knee replacement is a safe, proven, and effective medical device. Am. Compl. ¶¶ 43-44 [#17]. Aetna published amended Policy No. 0660 to its website. Id. at ¶ 59.

Since September 21, 2018, Aetna has uniformly followed Policy No. 0660 and has denied coverage for the Conformis System. Id. at ¶ 4. Conformis sent multiple letters, including a cease-and-desist letter, to Aetna asking it to recategorize the Conformis System to no avail. Id. at ¶¶ 76-79, 85-90. Since September 21, 2018, "Conformis has seen a significant drop-off in Aetna patients who have received the Conformis System." Id. at ¶ 99. Many orthopedic surgeons have moved away from prescribing Conformis knee replacements to Aetna and non-Aetna patients because it is unclear whether they will be covered by insurance. Id. at ¶ 92.

Plaintiff Schaub, a Colorado resident, developed osteoarthritis in his knee and his

[1] Both parties have attached documents referred to in Plaintiffs' Amended Complaint [#17]; the Plaintiffs attached the Assignment Agreement [#17-1] and the Defendants attached the Medical Clinical Policy Bulletins [#27-1] and the Genesis Plan [#27-2]. Neither side argues that this Motion to Dismiss [#26] should be converted to a motion for summary judgment and the court finds that the attached documents are "central to the [P]laintiffs' claim[s]" and are "sufficiently referred to in the [amended] complaint" to be considered in reviewing a motion to dismiss under Rule 12(b)(6). Miss. Public Emps.' Ret. Sys. v. Bos. Sci. Corp., 523 F.3d 75, 86 (1st Cir. 2008).

orthopedic surgeon recommended a total knee replacement. Id. at ¶¶ 103-05. Schaub began preparations for a knee replacement surgery in February 2020. Id. at ¶¶ 110-12. At the time, he was covered by the "Genesis Plan," a health plan provided by his employer, Genesis HCC, and administered by Aetna. Id. at ¶¶ 100-01.

The Genesis Plan covers reconstructive surgery and related supplies where a surgery is "to implant or attach a covered prosthetic device," that a physician orders and administers, where the prosthetic device is defined as "[a] device that temporarily or permanently replaces all or part of an external body part lost or impaired as a result of illness or injury or congenital defects." Genesis Plan 28, 41 [#27-2]. The Genesis Plan does not cover "[e]xperimental or investigational drugs, treatments or procedures unless otherwise covered under clinical trial therapies (experimental or investigational) or covered under clinical trials (routine patient costs)." Id. at 45. The Genesis Plan also contains the following provision regarding "Assignment of Benefits":

> When you see a **network provider** they will usually bill us directly. When you see an **out-of-network provider**, we may choose to pay you or to pay the **provider** directly. Unless we have agreed to do so in writing and to the extent allowed by law, we will not accept any assignment to an **out-of-network provider** or facility under this plan. This may include:
>
> - The benefits due
> - The right to receive payments or
> - Any claim that you make for damages resulting from a breach, or alleged breach, of the terms of this plan.

Id. at 76 (emphasis in original). Schaub's pre-surgery CT scan was authorized by the Genesis Plan claim administrator; a CT scan was required for the Conformis knee replacement, but would not have been required for an off-the-shelf knee replacement. Am. Compl. ¶¶ 101-02, 113-14 [#17]. Schaub's surgeon, the hospital staff, and an Aetna benefits advisor told Schaub that his insurance authorizations were complete, and his surgery would proceed. Id. at ¶ 118. However, a few days prior to the scheduled surgery, the surgeon told Schaub that the authorization had been

reversed based on his choice of knee replacement, and that Aetna was denying coverage. Id. at ¶¶ 124-25.

In March 2020, Schaub contacted Aetna multiple times over the phone and by mail, id. at ¶¶ 125-27, 133; eventually he confirmed that coverage was denied because he chose the Conformis knee replacement. Id. at ¶ 129. After completing the formal appeal process, Schaub received his first written denial on March 16, 2020. Id. at ¶¶ 136-27, 141.

On March 19, 2020, having reached the point where he could not work or live without significant pain, Schaub had knee replacement surgery, using the Conformis System. Id. at ¶ 144.

On April 20, 2020, Schaub signed an "Assignment of Insurance Benefits" stating that he assigned his rights and benefits under the Genesis Plan to Conformis. Id. at ¶ 204; Assignment Agreement [#17-1].

II. Legal Standard

To evaluate a motion to dismiss for failure to state a claim under Rule 12(b)(6) of the Federal Rules of Civil Procedure, the court must accept as true all well-pleaded facts, analyze those facts in the light most favorable to the plaintiff's theory, and draw all reasonable inferences from those facts in favor of the plaintiff. U.S. ex rel. Hutcheson v. Blackstone Med., Inc., 647 F.3d 377, 383 (1st Cir. 2011). To avoid dismissal, a complaint must set forth "'factual allegations, either direct or inferential, respecting each material element necessary to sustain recovery under some actionable legal theory.'" Gagliardi v. Sullivan, 513 F.3d 301, 305 (1st Cir. 2008) (citation omitted). The plaintiff's obligation to articulate the basis of his claims "requires more than labels and conclusions." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007). The facts alleged, when taken together, must be sufficient to "state a claim to relief that is plausible on its face." A.G. ex rel. Maddox v. Elsevier, Inc., 732 F.3d 77, 80 (1st Cir. 2013)

(quoting Twombly, 550 U.S. at 570). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (citation omitted).

III. Discussion

A. ERISA Claims, Counts IV-VI

Conformis asserts claims for Schaub's benefits under the Employee Retirement Income Security Act ("ERISA"), 29 U.S.C. § 1001, based on his assignment of such claims to Conformis. To the extent that assignment is prohibited or invalid, Schaub asserts those ERISA claims directly. The court addresses each Plaintiff's ERISA claims in turn.

1. Conformis' ERISA Claims

Defendants contend that Conformis may not bring claims under the ERISA plan. ERISA specifically enumerates the parties with standing to sue to enforce ERISA's provisions: participants, beneficiaries, fiduciaries, and the Secretary of Labor. 29 U.S.C. § 1132. A "participant" under ERISA is "any employee or former employee of an employer . . . who is or may become eligible to receive a benefit of any type from an employee benefit plan." 29 U.S.C. § 1002(7). Plaintiffs have alleged facts to support their claim that Schaub is a plan participant. Plaintiffs have further alleged that Schaub has assigned his rights under ERISA to Conformis. The question posed is whether Schaub's rights under the Genesis Plan may be assigned.

In Mackey v. Lanier Collection Agency & Servs., Inc., 486 U.S. 825 (1988), the Supreme Court addressed the garnishment of benefits under ERISA welfare plans. The Court noted that while Congress prohibited the assignment of benefits under pension plans, 29 U.S.C. § 1056(d)(1), it was silent as to assignment of benefits under welfare plans; the Court reasoned that "Congress' decision to remain silent concerning the attachment or garnishment of ERISA

welfare benefits plans acknowledged and accepted the practice, rather than prohibiting it." Mackey, 486 U.S. at 837-38. The First Circuit found "the logic" of the Mackey decision "allowing the garnishment of benefits under ERISA-regulated welfare plans," persuasive in concluding that the assignment generally of welfare benefits under such plans is allowed. City of Hope Nat. Med. Ctr. v. HealthPlus, Inc., 156 F.3d 223, 226 (1st Cir. 1998).

At the same time, the First Circuit also evaluated the validity of contractual anti-assignment clauses in benefits plans. Id. at 229. The plaintiff in City of Hope asked the First Circuit to "read into ERISA's allowance for the assignability of ERISA-regulated welfare plan benefits a bar to the contractual non-assignability of such benefits." Id. at 229. The First Circuit declined to do so; it held "that ERISA leaves the assignability or non-assignability of health care benefits under ERISA-regulated welfare plans to the negotiations of the contracting parties." Id. Therefore, "for an assignee to prevail on an ERISA claim . . . the assignee must establish the existence of a valid assignment that comports with the terms of the welfare benefits plan." Neuroaxis Neurosurgical Assoc., PC v. Costco Wholesale Co., 919 F. Supp. 2d 345, 351 (S.D.N.Y. 2013). Where the plan language unambiguously prohibits assignment, an attempted assignment will be ineffectual, and the would-be assignor will not be entitled to recover under ERISA. City of Hope, 156 F.3d at 229.

Here, the Genesis Plan specifically provided that "[u]nless we have agreed to do so in writing and to the extent allowed by law, we will not accept any assignment to an out-of-network provider or facility under this plan." Genesis Plan 76 [#27-2] (emphasis omitted). The Genesis Plan specified further that this non-acceptance of assignments included: the benefits due; the right to receive payments; and any claim for damages resulting from a breach, or alleged breach, of the terms of this plan. Id. This language is unambiguous.

Plaintiffs argue that Aetna "buried" this provision in "the boilerplate of the over 125-page Genesis Plan" and as such, the provision was not calculated to be read or understood. Opp'n 6 [#36]. There may be contract provisions that are unenforceable because they are hidden or illegible or clearly designed to evade the notice of the non-drafting party. See Cullinane v. Uber Techs. Inc., 893 F.3d 53, 61 (1st Cir. 2018) (explaining the need for "reasonably conspicuous notice of the existence of contract terms and unambiguous manifestation of assent to those terms"); see also Am. Orthopedic & Sports Med. v. Indep. Blue Cross Blue Shield, 890 F.3d 445, 452 (3rd Cir. 2018) (describing that an anti-assignment clause *could* be unenforceable if it was illegible, hidden, or not intended to be read, but finding the clause at issue to be enforceable because it was on the first page of the plan). However, the mere fact that the Genesis Plan is a long document does not defeat the enforceability of the anti-assignment clause. Nor is the provision hidden. The Table of Contents includes a section entitled "General provisions – other things you should know," with a subheading for "Financial information." 5 [#27-2]. The first subsection thereunder is entitled, in bold and large font, "Assignment of benefits." Id. at 76. Finally, the paragraph includes language that clearly states that the Plan "will not accept an assignment to an out-of-network provider or facility." Id.

Plaintiffs argue further that the anti-assignment provision is contrary to public policy. The First Circuit declined, however, to hold a similar anti-assignment clause unenforceable for public policy reasons. City of Hope, 156 F.3d at 229 (anti-assignment clause indicated that "[a]ll entitlements of a member to receive covered rights are personal and may not be assigned").

Plaintiffs argue finally that Aetna "waived" enforcement of the anti-assignment provision. But the Amended Complaint [#17] includes no facts to support such a waiver.

In sum, because the Genesis Plan contains an anti-assignment provision, and Plaintiffs

have pled no facts to support their argument that this provision is unenforceable or invalid, Conformis has failed to state claims under ERISA.

2. Schaub's ERISA Claims

Schaub asserts three ERISA claims: in Count IV (Claim for ERISA Benefits), he alleges that he is entitled pursuant to ERISA § 502(a)(1), 29 U.S.C. § 1132(a)(1), to unpaid benefits, declaratory and injunctive relief to clarify the right to future benefits under the plans, as well as attorneys' fees; in Count V (Violation of Fiduciary Duties of Loyalty and Due Care in Violation of ERISA), he alleges that Aetna has breached its fiduciary duty by failing to act prudently and in accordance with the Genesis Plan and that he is entitled pursuant to ERISA § 502(a)(3), 29 U.S.C. § 1132(a)(3), to declaratory and injunctive relief; and in Count VI (Denial of Full and Fair Review in Violation of ERISA § 502), he alleges that Aetna failed to comply with substantive and procedural requirements such that further exhaustion is futile, and he is entitled, pursuant to ERISA § 502(a)(3), 29 U.S.C. § 1132(a)(3), to declaratory and injunctive relief to remedy Aetna's failures. Defendant concedes that Schaub has pled sufficient facts to state a claim under ERISA for benefits under Count IV, but challenges the other two claims. The court addresses these two claims in turn.

a. Violation of Fiduciary Duties of Loyalty and Due Care – Count V

Under ERISA, an actor "is a fiduciary with respect to a plan to the extent . . . he exercises any discretionary control" with respect to "management of such plan" or "in the administration of such plan." 29 U.S.C. § 1002(21)(A). "[A] plan administrator engages in a fiduciary act when making a discretionary determination about whether a claimant is entitled to benefits under the terms of the plan documents." Varity Corp. v. Howe, 516 U.S. 489, 511 (1996). ERISA requires that a fiduciary "shall discharge his duties with respect to a plan solely in the interest of the

participants and beneficiaries." 29 U.S.C. § 1104(a)(1).

Defendants argue that Count V must be dismissed because it is duplicative of Schaub's ERISA benefits claim in Count IV; "seeks relief that is generally available under § 1132(a)(1)(B)"; and is, thus, an "inappropriately repackaged [] request for relief under § 1132(a)(1)(B) as an action under § 1132(a)(3)." Mem. Mot Dismiss 26 [#27] (citing Weissman v. United HealthCare Ins. Co., Civ. Action No. 1:19-CV-10580-ADB, 2020 WL 1446734, at *7 (D. Mass. Mar. 25, 2020)). Plaintiff responds that he seeks equitable relief, not damages, under Count V, that the count is not duplicative, and that he has stated a claim for relief. Opp'n 23-25 [#36].

Schaub has pleaded sufficient facts to state a claim for breach of fiduciary duty. He has asserted that Aetna misrepresented requirements for reimbursement under the Genesis Plan and stopped covering the Conformis System to save money, not because it was best for its members, Am. Compl. ¶¶ 61, 123-26, 129, 132 [#17], and that it refused to reimburse him for his Conformis knee replacement. Id. at ¶¶ 144-48.

Schaub's claim for equitable relief for his own injuries is also sufficiently alleged at this juncture. Section 1132(a)(3) is a "catchall provision[ ]" that acts "as a safety net, offering appropriate equitable relief for injuries caused by violations that § 502 does not elsewhere adequately remedy." Varity, 516 U.S. at 512.

Aetna is correct that Schaub may not obtain duplicative relief. "[W]here Congress elsewhere provided adequate relief for a beneficiary's injury, there will likely be no need for further equitable relief." Id. at 515; Turner v. Fallon Cmty. Health Plan, Inc., 127 F.3d 196, 200 (1st Cir. 1997). "Following this guidance, federal courts have uniformly concluded that, if a plaintiff can pursue benefits under the plan pursuant to [Section 1132(a)(1)], there is an adequate

remedy under the plan which bars a further remedy under Section [1132(a)(3)]." LaRocca v. Borden, Inc., 276 F.3d 22, 28 (1st Cir. 2002) (collecting cases).

Aetna's claim of redundancy should be addressed, however, with a full record such that the court may determine if Schaub is able to obtain adequate relief under Count IV before dismissing Count V. See Steve C. v. Blue Cross & Blue Shield of Mass., Inc., No. 18-cv-12278-ADB, 2020 WL 1514545, at *8 (D. Mass. Mar. 30, 2020) (denying motion to dismiss plaintiffs' claims as duplicative at 12(b)(6)); see also Trovato v. Prudential Ins. Co. of Am., No. 17-cv-11428, 2018 WL 813368, at *3 (D. Mass. Feb. 9, 2018) ("a plaintiff may plead claims under both § 1132(a)(1)(B) and § 1132(a)(3) at the motion to dismiss stage, so long as the plaintiff does not actually recover under both theories") (internal citation omitted).

b. Denial of Full and Fair Review in Violation of ERISA § 503 – Count VI

ERISA § 503, 29 U.S.C. § 1133, requires that:

> every employee benefit plan shall (1) provide adequate notice in writing to any participant or beneficiary whose claim for benefits under the plan has been denied, setting forth the specific reasons for such denial, written in a manner calculated to be understood by the participant, and (2) afford a reasonable opportunity to any participant whose claim for benefits has been denied for a full and fair review by the appropriate fiduciary of the decision denying the claim.

Defendants argue first that this section does not provide for a private cause of action for the recovery of denied benefits. Mem. Mot. Dismiss 29 [#27] (citing Swanson v. Aetna Life Ins. Co., No. 15-cv-0785, 2016 WL 54118, at *3 (D. Colo. Jan. 5, 2016)). But Plaintiffs explain that the claim is brought as a claim for breach of fiduciary duty pursuant to 29 U.S.C. § 1132(a)(3), and that § 1133 details the notice and opportunity for review that the plan fiduciary must provide. Opp'n 26 [#36]. As such, the count may fall within the claim set forth in Count V, but that distinction need not be addressed at this juncture.

Defendants argue further that § 1133 only applies to "employee benefit plan[s,]" id. at 29

(citing 29 U.S.C. § 1133) (emphasis and alteration added by Defendants), and not to the administrators of those plans. The First Circuit has explained, however, that:

> [t]he notice requirements of ERISA are designed to insure that when a claimant appeals a denial to the plan administrator, [he] will be able to address the determinative issues and have a fair chance to present [his] case. This purpose is the lodestar in determining whether there has been substantial compliance with the notice provisions; strict compliance is not required. In assessing a notice-based challenge, we ask whether the beneficiary [was] supplied with a statement of reasons that, under the circumstances of the case, permitted a sufficiently clear understanding of the administrator's position to permit effective review. A claimant typically must demonstrate that he or she has been prejudiced as a result of the notice's inadequacy.

Niebauer v. Crane & Co., 783 F.3d 914, 927 (1st Cir. 2015) (internal citations and quotations omitted). The court is unpersuaded that these requirements do not apply because Aetna is an administrator of the plan and not the plan itself. Cf. id. at 926 (explaining that the notice provisions under § 1133 "require[] plan administrators to 'provide adequate notice in writing to any participant or beneficiary whose claim for benefits under the plan has been denied") (citing 29 U.S.C. § 1133(1)); see also 29 C.F.R. § 2560.503-1 (setting forth certain requirements pursuant to 29 U.S.C. §§ 1133, 1135, and directing administrators to provide required notices).[2]

B. State Law Claims

Conformis also asserts state law tort claims for product disparagement and tortious interference with a contractual/business relationship, and a claim under Mass. Gen. Laws ch. 93A. The court addresses each cause of action in turn.[3]

[2] Swanson, 2016 WL 54118 at *3, on which Defendants rely, is distinguishable. The plaintiff in that case had alleged a violation of § 1133 only, and had not alleged that the § 1133 violation was a breach of fiduciary duty as Plaintiff has alleged here.

[3] Aetna argues that all three state law claims would be preempted if Conformis' ERISA claims proceed. See Mem. Mot Dismiss 22-25 [#27]. The court need not address this argument as Conformis' ERISA claims are subject to dismissal.

1. Product Disparagement/Trade Libel[4] - Count I

Conformis alleges product disparagement based on Aetna's publication on its website of Policy No. 0660, and specifically, the statement therein that "Aetna considers customized total knee implant experimental and investigational because its effectiveness has not been established," Policy No. 0660 6 [#27-1], and Aetna's further statement that the Conformis System is "experimental and investigational" in its denials of insurance claims for the Conformis System. Am. Compl. ¶ 154 [#17]. To prevail on a claim for product disparagement under Massachusetts law, a plaintiff must prove that a defendant "(1) published a false statement to a person other than the plaintiff; (2) of and concerning the plaintiff's products or services; (3) with knowledge of the statement's falsity or with reckless disregard of its truth or falsity; (4) where pecuniary harm to the plaintiff's interests was intended or foreseeable; and (5) such publication resulted in special damages in the form of pecuniary loss." HipSaver Inc. v. Kiel, 464 Mass. 517, 523, 984 N.E.2d 755 (2013). "[A] failure of proof as to even one element would be sufficient to defeat a claim for commercial disparagement." Id. at 524. Defendants do not dispute that the statements were published, but otherwise challenges Conformis' claim as to all elements.

The court finds that Conformis has sufficiently alleged that Aetna's statements were "of and concerning" Conformis' products, that pecuniary harm to Conformis was foreseeable, and that the publications resulted in pecuniary loss. The allegedly disparaging statement published on the website – that "Aetna considers customized total knee implant experimental and investigational because its effectiveness has not been established," Policy No. 0660 6 [#27-1] --

[4] Plaintiffs label the first court as a claim for "product disparagement/trade libel." Am. Compl. 24 [#17]. The terms "disparagement," "product disparagement," "commercial disparagement," and "trade libel" are interchangeable. HipSaver, 464 Mass. at 518 n.1 ("The tort of 'commercial disparagement' also is known as . . . 'trade libel.'"); see also Hi-Tech Pharm., Inc. v. Cohen, 277 F. Supp. 3d 236, 249 n.12 (D. Mass. 2016).

does not mention the Conformis System.[5] "This fact is not dispositive, however, as the law does not require a direct reference to the plaintiff." Advanced Tech. Corp., Inc. v. Instron, Inc., 66 F. Supp. 3d 263, 271 (D. Mass. 2014). Instead, Conformis can show the statement is "of or concerning" the Conformis System by alleging facts showing "that [Aetna] intended the words to refer to the [Conformis System] and that they were so understood[.]" HipSaver, 464 Mass. at 528 (internal quotation and citation omitted).

Here, Conformis has alleged that Aetna denied claims on the basis that the Conformis System is "experimental and investigational" and that doctors treating Aetna and non-Aetna patients stopped prescribing the Conformis System knee replacement after Policy No. 0660 was published which shows they understood that the Conformis System, and not simply customized knee replacements generally, was labeled as experimental and investigative by Aetna. Am. Compl. ¶¶ 92, 96-96, 160 [#17].

Conformis has also sufficiently alleged that it was foreseeable that if Aetna stated that customized knee replacements were experimental (and therefore would not be covered by Aetna plans), Conformis would suffer losses, and that Conformis' sales have suffered "significant drop-off" since Aetna published Policy No. 0660. Id. at ¶ 99.

The falsity elements are a more difficult hurdle. The first element requires Conformis to allege facts showing that the published statements were false. The further element requires Conformis to allege facts showing that Aetna knew the statements were false or was recklessly indifferent to their potential falsity, that is, that "[t]here must be sufficient evidence to permit the

[5] The only specific references to Conformis knee replacements in Policy No. 0660 do not include the allegedly disparaging language, but instead discuss a number of clinical trials where outcomes of the Conformis knee replacement are compared to off-the-shelf knees. Policy No. 0660 33-50 [#27-1]

conclusion that the defendant in fact entertained serious doubts as to the truth of his publication." HipSaver, 464 Mass. at 530. "This element mirrors the 'actual malice' requirement in a defamation case." Instron, Inc., 66 F. Supp. 3d at 274 (citing HipSaver, 464 Mass. at 530).

Aetna argues the statements are opinions, and are not provably false. Mem. Mot. Dismiss 7-10 [#27]. In defamation actions, the court looks to how the "reasonable reader" would understand the "statements at issue." Scholz v. Delp, 473 Mass. 242, 251, 41 N.E.3d 38 (2015). Arguably, a reasonable patient, and perhaps even a health care provider, may understand Aetna's statements to be statements of fact, that the Conformis System does not "produc[e] a decided, decisive, or desired effect," Merriam-Webster Dictionary, https://www.merriam-webster.com/dictionary/effective (last visited, Mar. 26, 2021), and is not clinically-effective, where Aetna itself has defined those terms as "not . . . proven as effective and safe for most people," "not yet accepted by doctors or by insurance plans and standard treatment," and "effectiveness has not yet been established." Am. Compl. ¶ 152 [#17].

At the same time, a reasonable insurer or even a health care provider may well understand Aetna's statement of effectiveness as an opinion that the product is not cost effective, or not a sufficient improvement over existing off-the-shelf knee replacements to warrant coverage. See TMJ Implants, Inc. v. Aetna, Inc., 498 F.3d 1175, 1195 (10th Cir. 2007). And given that possible reasonable understanding of the statements, Conformis has failed to plead facts to plausibly allege that Aetna knew the statements were false or was recklessly indifferent to their potential falsity.

As Conformis argues, the underlying scientific studies may well have suggested positive results concerning the efficacy of customized knee replacements. See Clinical Policy Bulletin 34-43 (studies indicating positive outcomes for Conformis System and also indicating that more

research, bigger samples, longer term follow up was needed to draw further conclusions) [#27-1]. Nonetheless, where reasonable insurers could understand the term "effective" to include cost-effective or more effective than existing treatments, Aetna's classification of customized knee replacements as experimental and investigative does not suggest, without more, that Aetna acted with actual malice when it published Policy No. 06660.

In sum, the Amended Complaint [#17] fails to allege sufficient facts to support the claim that Aetna "entertained serious doubts as to the truth of [its] publication"; accordingly, Conformis' claim for product disparagement fails. HipSaver, 464 Mass. at 530 (citing St. Amant v. Thompson, 390 U.S. 727, 731 (1968)).

2. Tortious Interference with Contractual / Business Relationship – Count II

Under Massachusetts law, the elements of tortious interference with contractual relations and tortious interference with advantageous business relations are similar. Under the former, "the plaintiff must allege facts to support the inferences that: (1) he had a contract with a third party; (2) the defendant knowingly induced a third party to breach that contract; (3) the interference was not only intentional, but was also 'improper' in motive or means of accomplishment; and (4) the plaintiff was harmed by the defendant's actions." Ligotti v. Daly XXL Commc'ns, Inc., Civ. Action No. 16-cv-11522-MLW, 2018 WL 1586340, at *7 (D. Mass. Mar. 26, 2018). Under the latter, the plaintiff must allege facts showing: "(1) a known advantageous relationship; (2) deliberate interference; (3) improper in motive or means; and (4) resulting economic harm." Tuli v. Brigham & Women's Hosp., 656 F.3d 33, 43 (1st Cir. 2011) (citing Ayash v. Dana-Farber Cancer Inst., 443 Mass. 367, 822 N.E.2d 667, 690 (2005). Conformis fails to allege facts to support either claim.

On the tortious interference with contractual relations, Conformis has not identified any

actual contracts where patients or providers had agreed to buy the Conformis knee replacement, but failed to do because of Aetna's interference, and accordingly, the claim fails at the first element.

On the tortious interference with advantageous business relations, Conformis alleges that healthcare providers have "routinely" prescribed or otherwise provided the Conformis System since it received FDA clearance in 2011. Am. Compl. ¶ 94 [#17]. The court finds this allegation of "routine use" sufficient to show a "'probable future business relationship anticipating a reasonable expectancy of financial benefits.'" Singh v. BC/BS of Mass., Inc., 308 F.3d 25, 47-48 (1st Cir. 2002) (quoting Singh v. BC/BS of Mass., Inc., 182 F.Supp.2d 164, 178 (D. Mass. 2001)).

Turning to the second element, Conformis must show that Aetna knowingly interfered with those business relationships. Here, the alleged interference was the publication of Policy No. 0660.[6] The court finds that Conformis has adequately pleaded facts showing that, by changing Policy No. 0660, Aetna plan patients and their health care providers would likely forego customized knee replacements, and, thus, would not be able to enter into or maintain business relationship with Conformis.

However, Conformis' tortious interference with advantageous business relationships stumbles at the third element. This element requires Conformis to show that Aetna had an improper motive, as opposed to pursuing its own business purpose, when it published Policy No. 0660. Importantly, "the improper motive or malevolence required is actual malice, a spiteful malignant purpose, unrelated to the legitimate corporate interest." King v. Driscoll, 418 Mass.

[6] The court does not understand this claim to allege that Aetna interfered by denying claims in violation of the terms of the applicable insurance plans.

576, 587, 638 N.E.2d 488 (1994) (internal quotations and citations omitted); Tuli, 656 F.3d at 43 (same); see also Am. Private Line Servs., Inc. v. E. Microwave, Inc., 980 F.2d 33, 37 (1st Cir. 1992) (where party's motivation was its own financial benefit, it was not acting with an improper motive).

Conformis alleges that Aetna's decision to change Policy No. 0660 was "financially-motivated." See Am. Compl. ¶¶ 61, 177 (alleging on information and belief that Aetna acted with a pure financial motive) [#17]. But there is no actionable improper motive when the defendant is simply acting in pursuit of his own business purpose. Sherman v. Clear Channel Outdoor, Inc., 889 F. Supp. 168, 177-78 (D. Mass. 2012). Having failed to plead any facts showing that Aetna acted with actual malice or an improper motive in reaching the decision to categorize customized knee implants as experimental and investigational and not to cover them, Conformis' tortious interference claim is dismissed.[7]

3. Chapter 93A

Chapter 93A protects against "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." Mass. Gen. Laws ch. 93A, § 2(a). In business disputes between sophisticated parties, courts must determine whether the alleged misconduct rises to an unacceptable level of unfairness, considering the "nature of the challenged conduct and the purpose and effect of that conduct"; "the standard of the commercial marketplace"; and "the equities between the parties, including what both parties knew or should have known." Malden Transp., Inc. v. Uber Techs., Inc., 404 F. Supp. 3d 404, 419 (D. Mass. 2019) (citing Auto Flat Car Crushers, Inc. v. Hanover Ins. Co., 469 Mass. 813, 820, 17 N.E.3d

[7] As to the fourth element, whether Conformis has alleged it suffered economic harm, Aetna does not argue otherwise. Mem. Mot. Dismiss 11-15 [#27].

1066 (2014)).

Conformis' Chapter 93A claim hinges upon its disparagement and tortious interference claims. Since Conformis has failed to allege enough for either claim, there is no basis for finding Aetna liable under Chapter 93A. Pimental v. Wachovia Mortg. Corp., 411 F. Supp. 2d 32, 40 (D. Mass. 2006). Moreover, the court finds that the facts pleaded, which do not plausibly allege actual malice, do not rise to the level of egregious misconduct that would "raise an eyebrow of someone inured to the rough and tumble of the world of commerce." Baker v. Goldman, Sachs & Co., 771 F.3d 37, 51 (1st Cir. 2014) (citing Levings v. Forbes & Wallace, Inc., 8 Mass. App. Ct. 498, 502 396 N.E.2d 149 (1979)).

IV. Conclusion

For the aforementioned reasons, Defendants' Motion to Dismiss [#26] is GRANTED as to all claims brought by Plaintiff Conformis and DENIED as to all claims brought by Plaintiff Schaub.

IT IS SO ORDERED.

Date: March 31, 2021

/s/ Indira Talwani
United States District Judge