UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

CONFORMIS, INC. and JOHN MICHAEL SCHAUB, Plaintiffs, v. AETNA, INC. and AETNA LIFE INSURANCE COMPANY, Defendants.	Civil Action No. 1:20-CV-10890-IT Leave granted on July 22, 2020 to file memorandum that exceeds page limitations (Dkt. No. 12)

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS

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Plaintiffs Conformis, Inc. ("Conformis") and John Michael Schaub filed a Complaint for Injunctive Relief and Damages (Dkt. No. 1) (the "Complaint" or "Compl.") against Defendants Aetna Life Insurance Company ("ALIC") and Aetna, Inc.[1] (together with ALIC, "Aetna"), in which Conformis alleges various state law causes of action, and Plaintiffs together allege violations of the Employee Retirement Income Security Act of 1974, as amended ("ERISA"). Pursuant to Federal Rule of Civil Procedure 12(b)(6), Aetna moves to dismiss the entire Complaint for failure to state a claim with the sole exception of Mr. Schaub's ERISA denial of benefits claim.

I. INTRODUCTION

In reviewing Plaintiffs' Complaint, one might ask: Why would Mr. Schaub, who lives in Colorado, file an ERISA denial of benefits claim in the District of Massachusetts? The reason, as evident from Plaintiffs' pleading, is that this action is really an attempt by Conformis, a Massachusetts-based medical device manufacturer, to coopt Mr. Schaub's ERISA denial of benefits claim and turn it into a quasi-class action to force Aetna to cover the Conformis custom total knee replacement device on a nationwide basis. In an attempt to disguise its motivation and to bring credibility to this ploy, Conformis brings companion (and baseless) state law claims.

Conformis' strategy turns ERISA on its head. ERISA is a federal statute with the express purpose of creating uniform rules for employee benefit plans; it is not a vehicle by which well-heeled medical device manufacturers can force insurers and ERISA-covered plans to pay for their products. And Conformis' attempt to do so as an assignee brazenly flouts settled First Circuit precedent, and indeed highlights the very policy purpose of limiting assignments.

[1] Plaintiffs have named Aetna, Inc. as a defendant, but it is an improper party to this action, as no allegations are averred against it. The only proper party defendant named is Aetna Life Insurance Company.

Conformis' business dispute with Aetna began nearly two years ago when, in September 2018, Aetna updated and re-published Clinical Policy Bulletin ("CPB") No. 0660, to state that custom knee replacements (a category that includes, but is not limited to, the Conformis System[2]) were "experimental and investigational." Since then, Conformis has doggedly sent Aetna increasingly threatening correspondence and cease-and-desist letters, aimed at changing Aetna's decision.

After these avenues failed, Conformis turned to litigation. But without a contract with Aetna, or standing to sue under ERISA, the only claims Conformis can muster against Aetna are tenuous state law claims, such as product libel, tortious interference, or unfair trade practices. And Conformis' chances of prevailing on these claims are slim—indeed, other courts have dismissed similar state law claims in the same circumstances in Mr. Schaub's home state of Colorado.[3]

Consequently, Conformis opted for a novel tactic: get an assignment of benefits from Mr. Schaub—a participant in an Aetna-administered plan with a coverage dispute—and piggyback on his right to sue for benefits under ERISA with a broad and bogus claim for breach of fiduciary duty and equitable relief. Conformis then tosses in its state law claims for good measure, claims to which Mr. Schaub is not even a party.

At bottom, the Complaint presents the Court with ***two unrelated, standalone lawsuits***—one a state tort law case by Conformis, based on Aetna's decision that custom knee replacement systems (not just Conformis') are "experimental and investigational"; and the other an ERISA case

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[2] Capitalized terms not otherwise defined herein retain the definitions assigned to them in the Complaint.

[3] *See, e.g.*, *TMJ Implants, Inc. v. Aetna, Inc.*, 498 F.3d 1175, 1196, 1200-01 (10th Cir. 2007) (concluding that statements regarding a medical device being "experimental and investigational" were expressions of opinion, and affirming dismissal of state law defamation, product disparagement, and intentional interference claims).

by Mr. Schaub, for benefits that he claims Aetna denied improperly. Not only have Plaintiffs failed to state plausible claims in both cases, but the cases are incompatible to attempt to combine in one pleading.

- ***First***, Conformis' case against Aetna for its clinical determination regarding custom knees should be dismissed under Rule 12(b)(6):
    - Conformis' product disparagement claim (Count I) fails as a matter of law, given that Conformis insufficiently alleges falsity or bad intent with respect to the challenged stated opinion of Aetna that the effectiveness of custom knee implants is not established by the clinical literature;
    - Conformis' tortious interference claim (Count II) fails because the Complaint does not allege Aetna's improper or intentional interference in any actual or identifiable contract or business relationship; and
    - Conformis' Chapter 93A claim (Count III) fails because the Complaint alleges no unfair conduct by Aetna that could form the basis for a plausible claim, since Aetna's stated opinion that custom knees are experimental and investigational followed a thorough review of available medical literature, and it is a reasoned conclusion in furtherance of Aetna's and its members' legitimate interests.
- ***Second***, the Court should reject Conformis' attempt to inject itself into Mr. Schaub's ERISA claims via an assignment of benefits. As Plaintiffs admit, Mr. Schaub's health plan contains an anti-assignment provision. But the First Circuit has ***enforced*** these provisions, contrary to Plaintiffs' conclusory allegations. Enforcing the anti-assignment provision will ensure that manufacturers are not able to weaponize ERISA to shore up whatever state law claims they might have. With no actionable assignment, Conformis lacks any means of suing under ERISA, and Counts IV, V, and VI should be dismissed as to Conformis.
- ***Third***, if the Court accepts Conformis' conclusory allegation that the anti-assignment provision in Mr. Schaub's plan is unenforceable, Conformis has standing to sue under ERISA. But if Conformis can sue in Mr. Schaub's name under ERISA, it follows that ERISA preempts Conformis' state law claims, given that those claims—and the relief

Conformis seeks—are duplicative of the ERISA claims. The box Conformis finds itself in shows the effect of Plaintiffs' having squished two distinct lawsuits together in this action. Moreover, if Conformis has standing to sue under ERISA, its breach of fiduciary duty claims under Count V should be dismissed with respect to allegations beyond Mr. Schaub's dispute over benefits. Conformis itself has no plausible basis on which to allege that Aetna owed it a fiduciary duty under ERISA.

- ***Fourth***, Mr. Schaub's ERISA claims should be dismissed, beyond his claim for wrongful denial of benefits under 29 U.S.C. § 1132(a)(1)(B) in Count IV. Specifically, (1) his claim for equitable relief under § 1132(a)(3) (Count V) should be dismissed as a repackaged denial of benefits claim[4]; (2) his claim for denial of a full and fair review under § 1133 (Count VI) should be dismissed because that section does not provide a private right of action; and (3) his request for prospective injunctive relief should be dismissed for lack of standing because he alleges no immediate risk of harm from Aetna in the future.[5]

Accordingly, Aetna asks that the Court dismiss Plaintiffs' Complaint.

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[4] This very court recognized as much in a recent opinion. *See Weissman v. United Healthcare Ins. Co.*, No. 1:19-CV-10580-ADB, 2020 WL 1446734, at *7 (D. Mass. Mar. 25, 2020).

[5] Plaintiffs demand "a trial by jury on all issues so triable," *see* Compl. at 30, but they do not specify to which counts they intend their demand to apply. If Plaintiffs' ERISA claims in Counts IV, V, and/or VI survive the instant Motion, Aetna would move to strike Plaintiffs' jury demand with respect to those claims, given that this Court does not recognize a right to a jury trial under ERISA. *See, e.g.*, *Gammon v. Reliance Standard Life Ins. Co.*, No. 1:18-CV-11665-DPW, 2020 WL 1190926, at *3 (D. Mass. Mar. 12, 2020) (noting that "'ERISA does not provide for a trial by jury and the majority of courts, within and without the First Circuit, have found no congressional intent to provide such a right'") (quoting *Turner v. Fallon Cmty. Health Plan Inc.*, 953 F. Supp. 419, 423 (D. Mass 1997)); *Tracey v. Mass. Inst. of Tech.*, No. CV 16-11620-NMG, 2019 WL 1005488, at *4 (D. Mass. Feb. 28, 2019), *aff'd*, 395 F. Supp. 3d 150 (D. Mass. 2019) ("In accord with the great weight of authority in the federal courts holding actions under ERISA to remedy alleged violations of fiduciary duties are equitable in nature, there is no right to a jury trial under the Seventh Amendment in this action.").

II. RELEVANT FACTUAL AND PROCEDURAL BACKGROUND[6]

A. Aetna's Clinical Policy Bulletin No. 0660

At issue in this case is Aetna's CPB No. 0660, which provides clinical guidance regarding knee replacement surgeries. The CPB, which is currently titled "Unicompartmental, Bicompartmental, and Bi-unicompartmental Knee Arthroplasties," was first issued in 2003.[7] Aetna has revised and updated the CPB 21 times, most recently on June 17, 2020.[8] As Plaintiffs admit, the CPB and each update is not unique to Mr. Schaub's health plan. *See* Compl. ¶ 4 (alleging that "Aetna implemented and has, upon information and belief, universally followed Policy No. 0660 . . . .").

On September 21, 2018, Aetna issued a revised version of CPB No. 0660, reflecting Aetna's determination that all customized total knee implants were "'experimental and investigational because [their] effectiveness has not been established.'" *See* Compl. ¶¶ 41-42. Plaintiffs ***do not*** allege that, prior to that change, CPB No. 0660 provided that customized total knee implants were not experimental or investigational. *See id.* ¶ 46.

B. Conformis' Crusade to Convince Aetna to Change Its Clinical Policy

The Complaint represents Conformis' latest attempt to compel Aetna to change its clinical determination that custom total knee implants in general, and by extension the Conformis custom knee in particular, are experimental and investigational. Conformis first sent Aetna a letter about CPB No. 0660 on April 29, 2019. *See id.* ¶ 63. As Plaintiffs allege, Aetna considered Conformis' letter and its attached bibliography, but it did not convince Aetna to alter its CPB except to add

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[6] In reciting and referring to Plaintiffs' allegations here for purposes of the instant Motion, Aetna does not admit those allegations, and Aetna reserves the right to contest them if necessary.

[7] *See* http://www.aetna.com/cpb/medical/data/disclaimer/history/600_699/0660.html (last visited July 23, 2020).

[8] *Ibid.*

cites to studies that, in Aetna's opinion, supported its conclusion that the Conformis custom knee was experimental and investigational. *See id.* ¶¶ 65-66.

On January 13, 2020, Conformis sent Aetna a "cease and desist" letter with respect to CPB No. 0660. *See id.* ¶ 70. Aetna acknowledged receipt of the letter but did not otherwise respond before Plaintiffs filed their Complaint. *See id.* ¶¶ 70-72, 75.

C. Mr. Schaub's Claims

Mr. Schaub receives healthcare coverage through his employer, Genesis HCC ("Genesis"), under the "Aetna Choice POS II – Advantage Plan – APCN PLUS health plan" (the "Genesis Plan"). *See* Compl. ¶¶ 76-77. ALIC is the third-party administrator for the Genesis Plan, and ALIC "contracts with eviCore Healthcare ("eviCore") to handle claims under the Genesis Plan, including Mr. Schaub's."[9] *See id.* ¶ 78.

Mr. Schaub describes his claim for benefits in paragraphs 88-120 of the Complaint. On March 20, 2020, Mr. Schaub signed a purported assignment of benefits to Conformis. *See* Compl. Ex. A. Plaintiffs do not allege that Mr. Schaub will need any additional services with respect to his claim. S*ee* Compl. ¶ 121.

III. STANDARD OF REVIEW

The Court should dismiss a complaint that fails to allege sufficient facts to state a claim for relief that is plausible on its face. Fed. R. Civ. P. 12(b)(6); *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). To be facially plausible, a complaint must contain "factual content" that "allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.*

[9] Plaintiffs allege that ALIC was the Genesis Plan third party administrator, yet throughout Plaintiffs' causes of action, they lodge allegations against "Aetna," a term that Plaintiffs define to include Aetna, Inc. as well as ALIC. But Plaintiffs do not allege any actions or wrongdoing by Aetna, Inc.—nor could they, given that it is a holding company that is separate from ALIC. Aetna, Inc. had no duties or dealings with the Genesis Plan whatsoever.

Although the Court must accept well-pleaded facts as true on a motion to dismiss, mere "labels and conclusions," a "formulaic recitation of the elements of a cause of action," and "naked assertions devoid of further factual enhancement" do not state a claim. *Id.* In addition, there must be "more than a sheer possibility that a defendant has acted unlawfully." *Id.*; *see Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). "If the factual allegations in the complaint are too meager, vague, or conclusory to remove the possibility of relief from the realm of mere conjuncture, the complaint is open to dismissal." *S.E.C. v. Tambone*, 597 F.3d 436, 442 (1st Cir. 2010).

IV. ARGUMENT

A. Conformis Fails to State Claims Under Its Massachusetts Common Law and Statutory Causes of Action (Counts I-III)[10]

1. Count I Fails to State a Claim for Product Disparagement/Trade Libel

A product disparagement or trade libel claim "seek[s] to impose liability on a defendant for harm sustained by a plaintiff as a result of the publication of a false statement about the plaintiff to others[,]" and "affords a remedy for harm to the economic interests of the injured party that results in pecuniary loss." *Hipsaver, Inc. v. Kiel*, 464 Mass. 517, 522 (2013) (citations omitted). To prevail, 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." *Id.* at 523. "[A] failure of proof as to even one element would be sufficient to defeat a claim for commercial disparagement." *Id.* at 524.

[10] As noted in Section IV.C *infra*, if this Court permits Conformis to proceed in Mr. Schaub's stead to bring ERISA denial of benefit claims pursuant to the purported assignment, then all three of Conformis' state law claims are fully preempted and should be dismissed on that basis alone.

Conformis has the burden to prove that Aetna published a false statement about it to a third party. *See Flotech, Inc. v. E.I. Du Pont de Nemours Co.*, 627 F. Supp. 358, 365 (D. Mass. 1985), *aff'd*, 814 F.2d 775 (1st Cir. 1987) (in commercial disparagement action, plaintiff must prove falsity of offending statements). Conformis fails to sufficiently allege that any statement in the CPB is false. The CPB simply states that "Aetna considers customized total knee implant experimental and investigational because its effectiveness has not been established." *See* CPB, attached hereto as Exhibit 1 (¶ VI at 6).[11] As is clear from the face of the document, the CPB summarizes scientific studies and articles, citing the clinical authors' own conclusions and noting the studies' limitations and drawbacks. *See generally* Exhibit 1. The CPB discusses custom knee replacements *in general*, and while concluding that the effectiveness of such devices has not been established, it does not specifically call out Conformis. Indeed, Aetna only mentions Conformis in a subheading related to clinical studies that specifically reference its device. Conformis fails to identify any falsity in Aetna's CPB—nor could it, because the CPB only sets forth dispassionate, fact-laden summaries of scholarly publications, and concludes on the data that ***all*** custom knees are experimental and investigational.

Conformis, however, asserts that the challenged CPB statements must be false because: (i) the Centers for Medicare and Medicaid Services, along with certain commercial insurance carriers, cover the Conformis System; (ii) the CPB cites to four of the same studies that Conformis cites in support of its product; and (iii) Conformis believes that Aetna's definitions of "experimental services" and "investigational services" improperly exclude the Conformis System from coverage.

[11] In ruling on Aetna's Motion, the Court may consider documents sufficiently referred to in Plaintiffs' Complaint without converting the motion to dismiss into a motion for summary judgment—including the CBP at issue here, to which Plaintiffs refer in detail throughout their Complaint. *See, e.g.*, *Giragosian v. Bettencourt*, 614 F.3d 25, 27-28 (1st Cir. 2010); *Hahren v. Brown*, 431 Mass. 838, 839-40 (2000) (citations omitted).

See Compl. ¶¶ 5, 44, 45, 53, 56-59. None of these grounds alleges that Aetna's statements in the CPB are false. Indeed, the challenged statements and conclusions, which apply in the same way to ***all*** custom knees, rely upon no fewer than 110 scholarly articles and studies, presenting comprehensive data and demonstrating well-supported expert analysis. *See* Exhibit 1 at 25-50. While Conformis may disagree with the opinions and conclusions reached by some of those scholars, doctors and experts, or may disagree with Aetna's interpretation, Conformis did not, and cannot, show that Aetna's stated opinions are false. This deficiency highlights Conformis' motive in bringing this flawed, hybrid-theory lawsuit—to attempt to strong-arm Aetna into covering the Conformis System under benefit plans that Aetna administers.

Conformis alleges further that several commercial insurers cover the Conformis System. However, even assuming *arguendo* the truth of that allegation, the fact that other carriers cover the product does not allege plausibly that Aetna's CPB conclusions are false. This factor simply shows that another insurer may have had a different opinion. *See TMJ Implants, Inc.*, 498 F.3d at 1200-01 (Tenth Circuit concluded that Aetna's statements denoting a medical device as "experimental and investigational" were expressions of opinion, and affirmed dismissal of defamation, product disparagement, and intentional interference claims under Colorado law); *see also Jones ex rel. U.S. v. Mass. Gen. Hosp.*, 780 F.3d 479, 486 (1st Cir. 2015) (in context of *qui tam* action under federal False Claims Act, recognizing that expressions of opinion and matters of scientific judgment cannot constitute a false statement). Conformis does not (and cannot) allege that the other insurers reviewed the same medical information, studied the same clinical issues, underwent the same vigorous review, or came to a reasoned conclusion. *See id.* ¶¶ 47-49. Nonetheless, Conformis' point concerning other carriers' views is a red herring, as it does not support a claim that Aetna's opinions about the clinical science are false.

Next, Conformis must allege plausibly, by an exacting standard mirroring the "actual malice" standard for defamation claims, that Aetna published the challenged statements with knowledge of or reckless disregard to their falsity. *See Hipsaver, Inc.*, 464 Mass. at 529-31. To meet this standard, "[t]here must be sufficient evidence to permit the conclusion that the defendant in fact entertained serious doubts as to the truth of his publication." *Id.* at 530 (quoting *St. Amant v. Thompson*, 390 U.S. 727, 731 (1968)). Here, Conformis asserts that Aetna did not pay enough credence to "the wealth of positive indications set forth in" the several clinical studies cited in its Complaint, and Aetna failed to consider other "literature and [] registry data." Compl. ¶¶ 59-61.

Even assuming the truth of these alleged oversights—which are belied by the CPB's lengthy bibliography, *see* Exhibit 1 at 65-75—***nowhere*** does Conformis show that Aetna acted with reckless disregard for truth or falsity. It is clear from the CPB's text that Aetna undertook a thorough review of available data and literature discussing the relative strengths and weaknesses of ***all*** customized knee implants, and Aetna reached a conclusion with which Conformis disagrees. Different parties' review of significant clinical data and literature likely will often lead to different opinions and conclusions, but those opinions and conclusions cannot fathomably constitute recklessness. Put simply, Conformis has failed to satisfy its significant burden to allege adequately that Aetna harbored serious doubts about the truth of the CPB's statements such that Aetna could be deemed to have acted with reckless disregard. *Hipsaver, Inc.*, 464 Mass. at 529-31.

Third, Conformis must allege plausibly that Aetna intended or recognized that the challenged statements would, and did, result in pecuniary harm to Conformis. *Id.* at 534 (quoting *Dulgarian v. Stone*, 420 Mass. 843, 852 (1995)). Here, Conformis does not allege that Aetna intended its general statements about custom knees to cause harm to Conformis, nor does Conformis specifically allege pecuniary harm that could be remedied by, for example, a monetary

damages award. *See* Compl. ¶ 140 (alleging harm to Conformis' goodwill and brand, affording "no adequate remedy at law."). Accordingly, this fourth element of Conformis' disparagement claim fails for lack of pleading Aetna's intent to cause harm.

Lastly, Conformis must prove that it actually sustained "special damages" in the form of pecuniary loss. *Hipsaver, Inc.*, 464 Mass. at 535. Conformis does not identify specific instances whereby patients would have received its implant but for Aetna's policy; nor does it allege any amount of actual or estimated lost revenue brought about as a direct and immediate result of Aetna's CPB. Indeed, Mr. Schaub went forward with his procedure using the Conformis System despite Aetna's coverage determination, thereby proving that Conformis cannot allege any damages from that instance. Conformis' failure to allege this essential fifth element of special damages from pecuniary loss alone necessitates dismissal of Count I.

2. Count II Fails to State a Claim for Tortious Interference with a Contractual or Business Relationship

Count II, a claim for tortious interference, also fails, given that the Complaint does not allege any facts establishing improper interference, or identifying any actual or prospective contract with which Aetna knowingly interfered by improper motive or means. To state a plausible claim for tortious interference with contractual relations, "the plaintiff must allege facts to support the inferences that: (1) he had a contract with a third party; (2) the defendant knowingly induced the third party to breach that contract; (3) the interference was not only intentional, but 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.*, C.A. No. 16-11522-MLW, 2018 WL 1586340, at *7 (D. Mass. Mar. 26, 2018) (citing *JNM Hospitality, Inc. v. McDaid*, 90 Mass. App. Ct. 352, 354 (2016)). Similarly, the elements of tortious interference with advantageous business relations are (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, 394-95 (2005)).

Massachusetts courts recognize that "[t]ortious interference has become the 'tort du jour' in the world of commercial litigation; that increases the importance of distinguishing truly inappropriate behavior for which there should be a remedy from normal competitive behavior permissible in the marketplace." *Pembroke Country Club, Inc. v. Regency Sav. Banks, F.S.B.*, 62 Mass. App. Ct. 34, 38 (2004). Where a defendant's purpose lay solely in achieving its own legitimate advancement, there is no improper motive or means to sustain a tortious interference claim. *Id*. at 39; *see also Sherman v. Clear Channel Outdoor, Inc.*, 889 F. Supp. 2d 168, 176-77 (D. Mass. 2012) (no actionable improper motive where defendant acted in pursuit of its own business purposes). "That the plaintiff may have suffered a loss as a consequence of the defendant's pursuit of its own interest is a by-product of a competitive marketplace; it does not render the defendant's effort tortious." *Pembroke Country Club, Inc.*, 62 Mass. App. Ct. at 39.

Count II alleges in conclusory form that "Conformis had established contractual relationships and/or advantageous business relationships with physicians and patients,"[12] of which Aetna was supposedly aware. *See* Compl. ¶¶ 132-33. But this claim is defective because the Complaint fails to identify any specific contracts or business relationships with any discernible third party that are the subject of the alleged interference. It is well accepted that a plaintiff "may not speculate about future business relationships when alleging this tort," but must base its claim on "a specific business relationship that was interfered with by [Aetna]." *Singh v. BC/BS of Mass., Inc.*, 308 F.3d 25, 47-48 (1st Cir. 2002). The "mere possibility" that physicians or patients would

[12] Conformis' allegations make no sense in the context of health insurance plans, as no such "contracts" could possibly exist between Conformis and either individual physicians or patients regarding use of the Conformis System.

have potentially formed or continued contractual or business relationships with Conformis is not sufficient to plead plausibly the existence of a relationship that would underpin the first element of Conformis' tortious interference claim. *Sherman*, 889 F. Supp. 2d at 177 (dismissing tortious interference claim for failure to allege improper means or motive or an actual contract).

Further, Count II fails because, although the Complaint includes a conclusory allegation that Aetna was aware of Conformis' unidentified contracts and business relationships, *see* Compl. ¶ 133, Conformis states no facts whatsoever to allege plausibly how Aetna knew, or could have known, of any such alleged relationships. It is axiomatic that Conformis must sufficiently allege Aetna's knowledge of the purported contractual or business relationship as a prerequisite to establishing ***knowing inducement*** of a third party's breach, the second prong of a tortious interference claim. *See, e.g.*, *Grammenos v. Zolotas*, 356 Mass. 594, 597 (1970) (a person must know of a contract to be under a duty to refrain from interfering with it) (citing *Anderson v. Moskovitz*, 260 Mass. 523, 526 (1927)).

In addition, the Complaint pleads no facts to satisfy the legal standard to establish the third element—an improper motive or means. Conformis merely asserts that Aetna misrepresented to physicians and patients that Conformis' products are "experimental and investigational," and therefore would not be covered under Aetna's commercial plans. *Id.* ¶ 134. But the Complaint contains no facts to allege plausibly that Aetna engaged in any improper conduct vis-à-vis Conformis or any third party, or that could lead to an inference that Aetna had any inappropriate motivation. Indeed, to establish improper motive or means, Massachusetts law requires a finding of "actual malice" or "a spiteful, malignant purpose, unrelated to [a] legitimate corporate interest." *Tuli*, 656 F.3d at 43 (quoting *King v. Driscoll*, 418 Mass. 576, 587 (1994)). Aetna's efforts to craft its CPB and administer its plans according to a rational understanding of medical necessity and

clinical judgment is not an improper motive. *Id.*; *see also Hamann v. Carpenter*, 937 F.3d 86, 90 (1st Cir. 2019) (rejecting cursory allegations parroting the element of improper motive or means).

At bottom, Aetna reached its opinion that customized knee implants were experimental and investigational after extensively reviewing expert medical and scientific studies. Conformis may disagree with that conclusion, but a disagreement of opinion on the available scientific and medical data is not grounds to say there has been a "misrepresentation," let alone sufficient to establish improper motive or means. Accordingly, Count II should be dismissed.

3. Count III Fails to State a Claim for Unfair Trade Practices under Chapter 93A

Chapter 93A is intended to protect consumers from "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." M.G.L. c. 93A, § 2(a). In the context of business disputes where both parties are sophisticated commercial entities, 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). In addition, Conformis bears the burden to allege plausibly not only that Aetna's acts were unfair or deceptive, but also that Conformis suffered a "loss of money or property," ***and*** that Aetna's allegedly unfair or deceptive acts caused such loss. M.G.L. c. 93A, § 11; *see Lyle Richards Int'l, Ltd. v. Ashworth, Inc.*, 132 F.3d 111, 115 (1st Cir. 1997) (loss under § 11 must have stemmed from deceptive act).

Conformis fails to identify any loss that would support the extraordinary remedies potentially available under Chapter 93A, alleging instead that it suffered damage for which there is "no adequate remedy at law"—*i.e.*, that money damages cannot redress its alleged injuries. *See, e.g.*, *Ruggieri v. M.I.W. Corp.*, 826 F. Supp. 2d 334 (D. Mass. 2011); Compl. ¶ 147. Conformis

fails to specify any acts or practices by Aetna that would constitute conduct sufficient to support a Chapter 93A violation. Given this deficiency in the claim, the Court should reject Conformis' attempt to use a Chapter 93A claim as leverage to obtain what Conformis was not able to secure before litigation.

As described above, Conformis challenges Aetna's statements in the CPB concerning Aetna's opinions and conclusions that customized knee implants are not shown to be effective by sufficient clinical studies. These factual allegations, even taken as true, lead only to the conclusion that Aetna made a decision based upon its assessment that the available literature does not establish that customized knees provide a better clinical outcome than a standard knee replacement device. There are no allegations of deception, no allegations of stolen information or money, and no allegations of secrecy. The allegations concerning Aetna's statement of its opinion and conclusions on the clinical literature do not come close to crossing the heightened standard of unfairness that courts require for sophisticated commercial entities to avail themselves of Chapter 93A. *Malden Transp., Inc.*, 404 F. Supp. 3d at 419.

Additionally, the Chapter 93A claim is wholly derivative of Conformis' untenable tortious interference and product disparagement claims, and the Court should dismiss Count III on this basis. *See Reed v. Zipcar, Inc.*, 883 F. Supp. 2d 329, 334-35 (D. Mass. 2012), *aff'd*, 527 F. App'x 20 (1st Cir. 2013) (discussing the need for a litigant to offer separate arguments in support of a Chapter 93A claim for it to be "entertained irrespective of whether other colorable bases for relief remain"); *Pimental v. Wachovia Mortg. Corp.*, 411 F. Supp. 2d 32, 40 (D. Mass. 2006) (dismissing Chapter 93A claim where plaintiff failed to sustain contract and negligence claims on which it was based, and plaintiff made "no unique arguments" as to that claim). Just like a party's advancement of its own legitimate interest cannot sustain a tortious interference claim, the same facts fail to

state a plausible claim that the party's conduct was egregious enough to constitute unfair or deceptive acts or practices under Chapter 93A. *See Stemgent, Inc. v. Orion Equity Partners*, No. SUCV20132212BLS2, 2016 WL 8200496, at *5 (Mass. Super. Ct. Dec. 22, 2016) (dismissing complaint where plaintiff failed to prove tortious interference and Chapter 93A claims relying on the same facts that did not show improper motive/means or requisite level of unfair conduct).

Finally, no Chapter 93A claim can lie against Aetna on the facts alleged, because the challenged conduct did not occur "primarily and substantially" in Massachusetts. *See* M.G.L. c. 93A, § 11 ("No action shall be brought or maintained under this section unless . . . the unfair or deceptive act or practice occurred primarily and substantially within the commonwealth [of Massachusetts]."). Courts are obliged to determine "the center of gravity of the circumstances that give rise to the claim." *Kenda Corp. v. Pot O'Gold Money Leagues, Inc.*, 329 F.3d 216, 235 (1st Cir. 2003) (quoting *Kuwaiti Danish Computer Co. v. Digital Equip. Corp.*, 438 Mass. 459, 473 (2003)). In many—but ***not all***—cases where the plaintiff resides in Massachusetts and the injury allegedly occurred here, a Chapter 93A claim can survive a "primarily and substantially" dismissal challenge at the pleadings stage. *Jofran Sales, Inc. v. Watkins & Shepard Trucking, Inc.*, 216 F. Supp. 3d 206, 216 (D. Mass. 2016). However, "where the relevant deceptive conduct involves communications between a defendant and third parties, courts have said that the 'center of gravity' lies in the state in which the communications occurred." *Pegasystems, Inc. v. Appian Corp.*, 424 F. Supp. 3d 214, 224-25 (D. Mass. 2019) (quoting *HipSaver Co. v. J.T. Posey, Co.*, 490 F. Supp. 2d 55, 71 (D. Mass. 2007)).

Plaintiffs allege that Conformis is based in Massachusetts, and they will presumably argue that the alleged injury to Conformis occurred within the Commonwealth as well. However, unlike the defendants in *Pegasystems, Inc.*, here, neither named Defendant is based in Massachusetts, and

the CPB is not alleged to have been created or published from here. Further, the so-called "misrepresentation" forming the basis for Chapter 93A liability is not alleged to have been directed at "physicians and patients and/or prospective physicians and patients" within this Commonwealth. *See* Compl. ¶ 129. Accordingly, under these particularly sparse allegations showing no contact with Massachusetts, the relevant conduct did not occur primarily and substantially in the Commonwealth, and the Chapter 93A claim should be dismissed.

4. Conformis Failed to Allege Its Fraud-Based State Law Claims with Sufficient Particularity

Each of Conformis' common law claims, while not styled as fraud counts, are premised on alleged misrepresentations by Aetna concerning customized knee devices. Rule 9(b) provides that, "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). The First Circuit has explained that "[t]he circumstances to be stated with particularity under Rule 9(b) generally consist of 'the who, what, where, and when of the allegedly [misleading] representation." *Kaufman v. CVS Caremark Corp.*, 836 F.3d 88, 91 (1st Cir. 2016) (quoting *Alt. Sys. Concepts, Inc. v. Synopsys, Inc.*, 374 F.3d 23, 29 (1st Cir. 2004)) (alteration in original). Conformis' state law claims actually sound in fraud, and they fail to meet the heightened particularity required for pleading fraud. Fraud-based Chapter 93A claims are subject to Rule 9(b). *See Mulder v. Kohl's Dep't Stores, Inc.*, 865 F.3d 17, 21-22 (1st Cir. 2017) (observing that the Rule 9(b) heightened pleading standard applies to Chapter 93A claims involving fraud); *Zak Law Offices, P.C. v. Reed*, No. 10-10333-LTS, 2010 WL 2802068, *4 (D. Mass. July 13, 2010) (same). Where an alleged misrepresentation underlies a tortious interference claim, Rule 9(b) is triggered. *N. Am. Catholic Educ. Programming Found., Inc. v. Cardinale*, 567 F.3d 8, 14 (1st Cir. 2009) (dismissing tortious interference claim under Rhode Island law for noncompliance with Rule 9(b)). Courts have also applied Rule 9(b) to disparagement claims. *See,*

e.g., *Demandforce, Inc. v. Patterson Dental Supply, Inc.*, No. 19-1116 (PAM/HB), 2019 WL 4721273, at *3-4 (D. Minn. Sept. 26, 2019) (dismissing trade libel claim under Delaware law for lack of particularity under Rule 9(b)).

Conformis does not identify or state with particularity any specific misrepresentation by Aetna. Conformis alleges only that Aetna's CPB designates customized knee implants as "experimental and investigational because [their] effectiveness has not been established[,]" as well as the conclusory assertion that this designation constitutes a "misrepresentation" to unidentified physicians and patients. *See* Compl. ¶¶ 42, 134, 144. Neither allegation provides any specificity, and neither is specific to Conformis. Accordingly, Counts I, II, and III run afoul of Rule 9(b)'s particularity requirements for allegations sounding in fraud and should be dismissed.

B. Conformis' ERISA Claims (Counts IV-VI) Should be Dismissed Because the Genesis Plan Contains an Enforceable Anti-Assignment Provision

ERISA provides that a claim for benefits under 29 U.S.C. § 1132(a)(1)(B) may only be brought "by a participant or beneficiary," and a claim for an injunction or other appropriate equitable relief under § 1132(a)(3) by a "participant, beneficiary, or fiduciary." Nowhere in the Complaint do Plaintiffs allege Conformis is a participant, beneficiary, or fiduciary as to the Genesis Plan, which would grant Conformis standing under ERISA. Rather, Conformis' claim to statutory standing in Counts IV, V, and VI hinges entirely on Mr. Schaub's purported assignment of benefits to Conformis. *See* Compl. ¶¶ 153-54, 168-69, 171, 176; *see also* Compl. Ex. A.

Plaintiffs admit, however, that the Genesis Plan contains an anti-assignment provision. *See* Comp. ¶ 155. Indeed, the Plan provides:

> **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 an 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 you make for damages resulting from a breach, or alleged breach, of the terms of this plan.

Exhibit 2 at 76.[13]

Recognizing that Conformis lacks any basis to sue under ERISA other than its purported assignment, Plaintiffs allege that the Plan's anti-assignment provision is "invalid." *See* Compl. ¶ 155. Plaintiffs allege ***only one fact*** in support of this claim—that the Genesis Plan is over 125 pages long. *See id.* Beyond alleging this one patently insufficient fact, Plaintiffs argue that the provision is invalid for a host of legally conclusory reasons, *see id.* ¶¶ 155-156, which the Court can (and should) disregard, *see Iqbal*, 556 U.S. at 678 ("[T]he tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions").

In addition to being predicated on conclusory legal allegations, Plaintiffs' claim that the Genesis Plan's anti-assignment provision is invalid runs contrary to First Circuit precedent. The First Circuit has held, "[c]onsistent with the other circuits which have addressed this issue, . . . that ERISA leaves the assignability or non-assignability of health care benefits under ERISA-regulated welfare plans to the negotiations of the contracting parties." *City of Hope Nat'l Med. Ctr. v. HealthPlus, Inc.*, 156 F.3d 223, 229 (1st Cir. 1998). Other circuit courts have held, similarly, that plans may include anti-assignment provisions and such provisions are enforceable. *See, e.g.*, *Physicians Multispecialty Grp. v. Health Care Plan of Horton Homes, Inc.*, 371 F.3d 1291, 1295

[13] The Court may consider the Genesis Plan document at this stage because Plaintiffs discuss it throughout their Complaint. *See* note 11 *supra*.

(11th Cir. 2004) ("[A]n assignment is ineffectual if the plan contains an unambiguous anti-assignment provision."); *St. Francis Reg'l Med. Ctr. v. Blue Cross & Blue Shield of Kan., Inc.*, 49 F.3d 1460, 1464-65 (10th Cir. 1995) ("ERISA's silence on the issue of the assignability of insurance benefits leaves the matter to the agreement of the contracting parties."); *Davidowitz v. Delta Dental Plan of Cal., Inc.*, 946 F.2d 1476, 1478 (9th Cir. 1991) ("As a general rule of law, where the parties' intent is clear, courts will enforce non-assignment provisions.").

Additionally, the First Circuit has held that anti-assignment provisions are "not contrary to public policy," *see City of Hope Nat'l Med. Ctr.*, 156 F.3d at 229, thus rejecting Conformis' exact argument here. *See* Compl. ¶ 156. Moreover, Plaintiffs' attempt to circumvent the Genesis Plan's anti-assignment provision would frustrate important policy goals that such provisions serve. Anti-assignment provisions limit the pool of parties who may bring ERISA claims to those who are directly impacted by the specific claim at issue—which furthers ERISA's goal of "promot[ing] the interests of employees and their beneficiaries in employee benefit plans." *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 90 (1983). Here, Conformis does not allege that it is owed payment for its device used in Mr. Schaub's surgery, or that it was otherwise injured in any way with respect to Mr. Schaub's specific claim. Indeed, Conformis has no relationship with Mr. Schaub whatsoever.

Given that Plaintiffs admit that the Genesis Plan has an applicable anti-assignment provision, and that the First Circuit has enforced such provisions, Mr. Schaub's assignment is invalid. Accordingly, Conformis lacks statutory standing under ERISA, and Counts IV, V, and VI should be dismissed, with prejudice, as to Conformis.[14]

[14] Even if the anti-assignment provision was unenforceable, the Court should conclude that Conformis' assignment is invalid for lack of consideration, based on the four corners of the document (attached to the Complaint at Exhibit A). *See, e.g.*, *Benefit Consulting All., LLC v. AIG Life Ins. Co.*, No. 3:07-1136, 2008 WL 11510630, at *8 (M.D. Tenn. Sept. 26, 2008) (concluding that assignment lacked consideration because "Benefit Consulting suffers no detriment as a result

C. To the Extent Conformis Alleges that Its Assignment is Valid, Conformis' State Law Claims (Counts I-III) Should be Dismissed as Preempted by ERISA

If for some reason the assignment of benefits is valid and Conformis can tag along with Mr. Schaub's ERISA claims, ***all*** of Conformis' state law claims are duplicative and should be dismissed as preempted by ERISA.

Pursuant to 29 U.S.C. § 1144(a), ERISA "shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan" covered by the statute. "A law 'relates to' an employee benefit plan, in the normal sense of the phrase, if it has a connection with or reference to such a plan." *Rogers v. Rogers & Partners, Architects, Inc.*, No. CIV.A. 08-11730-NG, 2009 WL 5124652, at *6 (D. Mass. July 27, 2009).

The Supreme Court has ruled that "if an individual brings suit complaining of a denial of coverage for medical care, where the individual is entitled to such coverage only because of the terms of an ERISA-regulated employee benefit plan, and where no legal duty (state or federal) independent of ERISA or the plan terms is violated, then the suit falls 'within the scope of' ERISA § 502(a)(1)(B)." *Aetna Health Inc. v. Davila*, 542 U.S. 200, 210 (2004). This Court has read *Davila* as imposing a "two-part test to determine whether complete preemption applies"—(1) "the court must determine whether a plaintiff 'could have brought his claim under ERISA § 502(a)(1)(B)'"; and (2) "there must have been 'no other independent legal duty that is implicated by [the] defendant's actions.'" *Halberg v. McLean Hosp.*, No. CV 17-11341-FDS, 2018 WL 2209216, at *4 (D. Mass. May 14, 2018) (alteration in original) (citations omitted). Here, both

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of the Amendment that could constitute consideration to Mrs. Derrington. Benefit Consulting gives nothing of value to Mrs. Derrington or to any other person. It undertakes no legal obligation. It gives up nothing it has a legal right to do").

prongs under *Davila* are satisfied, if one accepts Plaintiffs' allegations that Conformis received a valid and enforceable assignment of benefits from Mr. Schaub.

First, Plaintiffs allege that, pursuant to 29 U.S.C. § 1132(a)(1)(B), Conformis is entitled to "recover benefits due to Mr. Schaub and enforce the rights of Mr. Schaub under the terms of the Genesis Plan," "[a]s assignee of Mr. Schaub to his claims under the Genesis Plan." *See* Compl. ¶ 154. The first prong of the *Davila* test is therefore met, accepting Plaintiffs' allegations.

Second, Plaintiffs' allegations evince that there is "no other independent legal duty" by Aetna that forms the basis of Conformis' state law claims. *See Davila*, 542 U.S. at 210. Aetna has no relationship to/with Conformis, and it owes no duty to Conformis. In *Davila*, the Supreme Court observed with respect to both plaintiffs that the "only action complained of" was their health insurers' refusal to pay medical claims, and the "only connection" between the plaintiffs and their insurers was the insurers' administration of the plaintiffs' health plans. *See id.* at 211-12. The Court concluded, on those facts, that "respondents bring suit only to rectify a wrongful denial of benefits promised under ERISA-regulated plans, and do not attempt to remedy any violation of a legal duty independent of ERISA." *Id.* at 214. So too here. Plaintiffs assert that Aetna's alleged liability derives exclusively from its administration of ERISA-covered health plans (including the Genesis Plan), and Aetna's development of a clinical policy to use in administering ERISA plans. *See, e.g.*, Compl. ¶¶ 3-4. Accordingly, Conformis' state law claims are completely preempted under the *Davila* test and should be dismissed. *See Davila*, 542 U.S. at 210.

Conformis' Complaint alleges a novel legal theory—*i.e.*, that the administrator of a health plan should be liable under state law ***and*** ERISA to a medical device manufacturer. While Aetna has not located a case that is directly analogous to Plaintiffs' theory—for good reason since it is so implausible—a Fifth Circuit opinion illustrates why Conformis' state law claims should be

dismissed as preempted under ERISA. *See Mayeaux v. La. Health Serv. & Indem. Co.*, 376 F.3d 420 (5th Cir. 2004).

In *Mayeaux*, the plaintiffs included a health plan participant and her physician, Dr. Edward Hyman, and they "asserted various causes of action alleged to have arisen from BCBS's denial of insurance coverage for the costs of Dr. Hyman's treatment of Mayeaux's illness with high doses of antibiotics." *Id.* at 423. Notably, defendant BCBS had denied coverage for "High Dose Antibiotic Treatment" ("HDAT") that Dr. Hyman prescribed, on grounds that "it was excluded under the terms of [Ms. Mayeaux's] Plan as experimental or investigational." *Id.* In addition to ERISA claims, Dr. Hyman brought "state law claims, which were grounded in negligence, unfair trade practices, defamation, and intentional interference with contracts." *Id.* at 432.

The Fifth Circuit concluded that all of Dr. Hyman's state law claims were preempted. *First*, the Fifth Circuit concluded that Dr. Hyman's unfair trade practices claim was preempted, agreeing with the district court's observation that "[t]he purpose of these proceedings is to collaterally attack [BCBS's] determination of the actual obligations under the terms of the insurance policy." *Id.* at 432-33 (second brackets in original). The Fifth Circuit noted that "[i]f a medical practitioner could collaterally challenge a plan's decision not to provide benefits, he would directly affect the relationship between the plan and its beneficiary, two traditional ERISA entities," and "[t]hat clearly cannot be allowed, so Dr. Hyman's . . . unfair trade practice claims cannot survive ERISA conflict preemption." *Id.* at 433.

Second, the Fifth Circuit observed that "[t]o allow a medical practitioner to sue for defamation and intentional interference when an ERISA plan administrator decides that the plan does not cover a particular medical treatment for a particular participant or beneficiary would undoubtedly jeopardize the relationships among the traditional ERISA entities, of which the

treating physician is not one." *Id.* The court therefore concluded that the claims were preempted as "the sort of claims that go to the very heart of the ERISA administration process." *Id.*

The Fifth Circuit's reasoning in *Mayeaux* is directly applicable to Conformis' state law claims. Conformis is attempting to wedge itself into the relationship between a plan participant and his plan's administrator, to force Aetna to cover Conformis' medical device. At bottom, the relationship that Conformis seeks to piggyback onto is governed by the terms of the Genesis Plan, which is covered by ERISA, and for that reason Conformis' state law claims should be dismissed as preempted.[15]

D. Plaintiffs' Breach of Fiduciary Duty Claim Under 29 U.S.C. § 1132(a)(3) (Count V) Should be Dismissed as Duplicative of Plaintiffs' Denial of Benefits Claim

Plaintiffs style Count V as a claim for "Violation of Fiduciary Duties of Loyalty and Due Care in Violation of ERISA," which purportedly arises under 29 U.S.C. § 1132(a)(3). *See* Compl. ¶¶ 164, 174. However, Count V is impermissible, as it is well-settled that an ERISA plaintiff with an adequate remedy under § 1132(a)(1)(B) cannot alternatively plead and proceed under § 1132(a)(3). For this reason, Count V should be dismissed as to Mr. Schaub, and as to Conformis to the extent it brings a breach of fiduciary duty claim in its capacity as Mr. Schaub's assignee.[16]

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[15] Accepting the allegation that Conformis holds a valid assignment, Mr. Schaub has no standing to bring suit in his own name. *See, e.g.*, *CardioNet, Inc. v. Cigna Health Corp.*, 751 F.3d 165, 178 (3d Cir. 2014) ("[A]ssuming the validity of the Participants' assignments to the Providers, CardioNet and LifeWatch now stand in the shoes of the Participants, and have 'standing *to assert whatever rights the assignor[s] possessed*.'") (alteration in original) (underline added, italics in original). Indeed, as the First Circuit has observed, "[i]f an assignee seeking relief in court stands in the place of an assignor, there has been a substitution rather than an expansion of the parties." *City of Hope Nat'l Med. Ctr.*, 156 F.3d at 228 (emphasis added). In other words, Plaintiffs' Complaint as presented would set up the bizarre procedural posture where a product manufacturer remained as the sole claimant in an ERISA denial of benefits action seeking to have its device covered by Aetna on a nationwide basis.

[16] As discussed in Section IV.E *infra*, to the extent Conformis alleges that Aetna breached fiduciary duties outside Conformis' assignment from Mr. Schaub, Conformis' claims should be dismissed for failing to allege plausibly that Aetna owed a fiduciary duty to Conformis.

The Supreme Court has described 29 U.S.C. § 1132(a)(3) as 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 Corp. v. Howe*, 516 U.S. 489, 512 (1996) (emphases added). Following *Varity Corp.*, the First Circuit holds that "if a plaintiff can pursue benefits under the plan pursuant to [29 U.S.C. § 1132(a)(1)], there is an adequate remedy under the plan which bars a further remedy under [§ 1132(a)(3)]." *LaRocca v. Borden, Inc.*, 276 F.3d 22, 28 (1st Cir. 2002); *see also Turner v. Fallon Cmty. Health Plan, Inc.*, 127 F.3d 196, 200 (1st Cir. 1997) (holding that a beneficiary could not sue under section 1132(a)(3) because he sought "damages, not equitable relief, and his grievance . . . is specifically addressed by 29 U.S.C. § 1132(a)(1)(B)").

Plaintiffs' fiduciary breach claims sound under 29 U.S.C. § 1132(a)(1)(B), which entitles a participant to file a civil action "to recover benefits due to him under the terms of his plan, to enforce his rights under the terms of the plan, or to clarify his rights to future benefits under the terms of the plan." Specifically, Plaintiffs allege that Aetna breached fiduciary duties "[i]n failing to act prudently, and in failing to act in accordance with the documents governing the Genesis Plan," and that "[a]s assignee of Mr. Schaub, Conformis is entitled **to recover benefits due to him** and to enforce his rights under the terms of the Genesis Plan." *See* Compl. ¶¶ 166, 171 (emphases added). Accordingly, Plaintiffs' allegations in Count V amount to a claim for benefits, remedied by § 1132(a)(1)(B), and their claim under § 1132(a)(3) should be dismissed. *See, e.g.*, *Weissman*, 2020 WL 1446734, at *7 ("Because the complaint seeks relief that is generally available under § 1132(a)(1)(B), it must be dismissed because it has inappropriately repackaged a request for relief under § 1132(a)(1)(B) as an action under § 1132(a)(3)."); *Kourinos v. Interstate Brands Corp.*, 324 F. Supp. 2d 105, 107 (D. Me. 2004) (dismissing § 1132(a)(3) claim and observing that "[t]o

the extent that Count II(a) alleges that IBC violated its fiduciary duty by wrongfully withholding benefits to which Kourinos was entitled under the plan, Kourinos' remedy is a claim under section 1132(a)(1)(B)"); *see also Johns v. Blue Cross Blue Shield of Mich.*, No. 2:08-CV-12272, 2009 WL 646636, at *4 (E.D. Mich. Mar. 10, 2009) (rejecting claim under 29 U.S.C. § 1132(a)(3) for the use of a clinical policy as part of the decision to deny a claim for benefits, reasoning that it was simply a "repackaged denial-of-benefits claim").[17]

E. Conformis Fails to Allege that Aetna Owed It a Fiduciary Duty

In Count V, Conformis asserts not only that Aetna breached fiduciary duties allegedly owed under the purported assignment from Mr. Schaub, but Conformis slips in allegations of fiduciary breaches that have ***nothing at all to do with Mr. Schaub's assigned claims***. For instance, Plaintiffs allege that Aetna has somehow breached fiduciary duties in "refusing to cover Conformis' products including the Conformis System," and "refusing to allow Conformis any opportunity to negotiate coverage." *See* Compl. ¶ 172. These claims fail as a matter of law for failure to allege plausibly that Aetna had a fiduciary duty to Conformis in these respects.

[17] If the Court were inclined to provide Plaintiffs an opportunity to amend their Complaint, the Court should direct them to plead only a claim for benefits under 29 U.S.C. § 1132(a)(1)(B). Courts in the First Circuit have observed that a plaintiff may not plead duplicative breach of fiduciary duty claims under 29 U.S.C. § 1132(a)(3) in the alternative to benefit claims under 29 U.S.C. § 1132(a)(1)(B). *See, e.g.*, *Cotten v. Blue Cross & Blue Shield of Mass. HMO Blue, Inc.*, No. CV 16-12176-RGS, 2018 WL 6416813, at *3 (D. Mass. Dec. 6, 2018) ("Plaintiffs contend that their section 1132(a)(3) claim can similarly be pled in the alternative. I disagree."). Because Plaintiffs fail to articulate a factual basis for a § 1132(a)(3) claim that is separate from their denial of benefits claim under § 1132(a)(1)(B)—nor could they, given that all of their fact allegations derive from Aetna's administration of benefits under the Genesis Plan—it would be futile for Plaintiffs to attempt to replead Count V. *See, e.g.*, *Jones v. Experian Info. Solutions, Inc.*, 141 F. Supp. 3d 159, 161 (D. Mass. 2015) (observing that "courts have discretion to deny leave [to amend] under 'appropriate circumstances,'" including "futility," and "[i]n determining futility, the court applies the same standard as a motion to dismiss under Fed. R. Civ. P. 12(b)(6)").

Under ERISA's statutory framework, 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); *see also Stein v. Smith*, 270 F. Supp. 2d 157, 166 (D. Mass. 2003) (a plaintiff must plead that the defendant was a fiduciary to a plan and also that the defendant breached a duty within his or her discretion and control).

Fiduciary liability arises only in "specific increments correlated to the . . . performance of particular fiduciary functions in service of the plan, not in broad general terms." *Id.* (citing *Beddall v. State Street Bank & Tr. Co.*, 137 F.3d 12, 18 (1st Cir. 1998) (emphasis added)). As relevant here, "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.*, 516 U.S. at 511 (emphasis added). To that end, a court must evaluate whether the defendant was "performing a fiduciary function [under the terms of the relevant plan] when taking the action subject to complaint." *Pegram v. Herdich*, 530 U.S. 211, 226 (2000). And, importantly, 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).

Plaintiffs' Complaint fails to allege plausibly that Aetna had any fiduciary duty to Conformis whatsoever. Plaintiffs do not allege—nor could they—that Aetna assumed under the terms of the Genesis Plan a duty to cover Conformis' custom knee replacement devices as a general matter, nor that Aetna had a duty under the Plan to allow Conformis to "negotiate for coverage" of its devices. Moreover, Conformis cannot allege plausibly that Aetna owed it any duty, given that ERISA provides that Aetna's fiduciary duties are owed only to "participants and beneficiaries," and Conformis is neither under the Genesis Plan (or under ERISA). *See* 29 U.S.C.

§ 1104(a)(1). Accordingly, any breach of fiduciary duty claim alleged as to Conformis itself is beyond the scope of Mr. Schaub's assignment and should be dismissed.

F. Count VI Should be Dismissed Because ERISA Does Not Provide a Private Right of Action Under 29 U.S.C. § 1133

Plaintiffs allege in Count VI that "Aetna failed to provide a reasonable claims procedure," *see* Compl. ¶ 177, for which Plaintiffs purportedly seek relief, *see id.* ¶ 180. In other words, Plaintiffs seek to enforce the terms of 29 U.S.C. § 1133 and its implementing regulations, which set forth the manner in which ERISA plans must adjudicate participant claims and appeals.

Count VI fails, however, given that courts have ruled that 29 U.S.C. § 1133 "does not provide for a private cause of action for the recovery of denied benefits." *Swanson v. Aetna Life Ins. Co.*, No. 15-cv-0785, 2016 WL 54118, at *3 (D. Colo. Jan. 5, 2016); *see also Bryson v. United Healthcare Ins. Co.*, No. 3:15-cv-00142, 2015 WL 4026009, at *4 (W.D.N.C. July 1, 2015) (dismissing claim to enforce ERISA claims and appeals rules because § 1132(a) "'provides the exclusive statement of civil actions available under ERISA'") (citations omitted). Even if § 1133 provided a private cause of action, Count VI would still fail to state a claim against Aetna because the section applies only to "employee benefit plan[s]." 29 U.S.C. § 1133 (emphasis added); *see Swanson*, 2016 WL 54118, at *3 (noting that § 1133 "establishes requirements of the *benefit plan itself*, not of the administrators of the plan"). As Plaintiffs allege, Aetna "administers the employee-sponsored benefit plans covering Plaintiff Schaub," *see* Compl. ¶ 3—Plaintiffs do not allege that Aetna is a benefit plan. Accordingly, Count VI should be dismissed.

G. Plaintiffs' Request for Prospective Injunctive Relief Should be Dismissed

Among other remedies, Plaintiffs seek "injunctive and declaratory relief to prevent Aetna's continuing actions detailed herein that are unauthorized by the Genesis Plan," and an order "[t]emporarily and permanently enjoining Aetna from continuing to pursue its actions detailed

herein." *See* Compl. at pp. 28-29. But Plaintiffs have not alleged facts showing that they have Article III and/or statutory standing to seek prospective injunctive relief under ERISA.

The First Circuit has held that "when the incident now lies in the past," prospective injunctive relief is available only if there is "a real and immediate threat of future legal violations rather than an abstract or conjectural one." *Asociacion De Periodistas De Puerto Rico v. Mueller*, 680 F.3d 70, 84-85 (1st Cir. 2012). "Any past harm that [a plaintiff] allegedly suffered does not by itself entitle them to obtain equitable relief absent a sufficient likelihood that they will again be wronged in a similar way." *Id.* at 85.

Plaintiffs state no facts to allege plausibly that Mr. Schaub faces a real and immediate threat of Aetna's denying a future request to cover a custom knee replacement surgery. They do not, for example, allege that Mr. Schaub is likely to need another knee replacement in the future, or that Mr. Schaub has plans to seek another knee replacement, and/or that he will seek coverage for such a procedure under the Genesis Plan. *See* Compl. ¶ 121.

Given that none of Plaintiffs' allegations show a probability that they will suffer the same purported injury in the future, the Court should dismiss Plaintiffs' request for prospective injunctive relief for lack of Article III standing. Further, to the extent Conformis may argue that it faces an immediate risk that Aetna will deny claims for custom knee replacement surgeries with Conformis devices in the future, Conformis has alleged no facts establishing that ***it***—as the product manufacturer—would have standing under ERISA to seek injunctive relief for such claims. Conformis' sole basis for bringing ERISA claims against Aetna is its purported assignment from Mr. Schaub, which does not extend to any other participant's claims (past or future).

V. CONCLUSION

Conformis sued Aetna because it could not achieve its business ends through persuasion, and it is dragging Mr. Schaub's ERISA claim along with it. These claims are legally deficient and

turn the entire ERISA statutory framework on its head. For the foregoing reasons, Aetna respectfully requests that the Court dismiss Plaintiffs' Complaint, with the sole exception of Mr. Schaub's claim in Count V for denial of benefits under ERISA, 29 U.S.C. § 1132(a)(1)(B).

Respectfully submitted,

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Dated: July 23, 2020

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing Memorandum of Law in Support of Defendants' Motion to Dismiss and that document was served in its entirety on all counsel of record by the Court's CM/ECF system.

Dated: July 23, 2020

/s/ Stephen M. LaRose
Stephen M. LaRose