IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO
Judge Raymond P. Moore

Civil Action No. 14-cv-01684-RM-MJW

GREGORY REICH and
LYNN REICH, his wife;
individually, and on behalf of all others similarly situated,

Plaintiffs,

v.

GENZYME CORPORATION,
ACCREDO HEALTH GROUP, and
CURASCRIPT, INC.,

Defendants.

ORDER

This matter is before the Court on United States Magistrate Judge Michael J. Watanabe's Recommendation ("Recommendation") (ECF No. 73) that the Court grant Defendant Genzyme Corporation's ("Genzyme") motion to dismiss (ECF No. 44) and grant Defendants Accredo Health Group and Curascript, Inc.'s ("Accredo/Curascript") motion to dismiss (ECF No. 43). Both motions to dismiss address Plaintiffs Gregory Reich ("Reich") and Lynn Reich's ("L. Reich") amended complaint ("Amended Complaint") (ECF No. 31). Plaintiffs timely objected to parts of the Recommendation ("Objection") (ECF No. 74) to which Defendants responded (ECF Nos. 76; 77).

For the reasons stated below, the Court (1) OVERRULES, in part, and SUSTAINS, in part, the Objection; (2) MODIFIES, in part, and ACCEPTS, in part, the Recommendation; (3)

GRANTS, in part, and DENIES, in part, Genzyme's motion to dismiss; and (4) GRANTS, in part, and DENIES, in part, Accredo/Curascript's motion to dismiss.

I. LEGAL STANDARDS

A. Review of the Magistrate Judge's Recommendation

When a magistrate judge issues a recommendation on a dispositive matter, Federal Rule of Civil Procedure 72(b)(3) requires that the district court judge "determine *de novo* any part of the magistrate judge's [recommendation] that has been properly objected to." In conducting its review, "[t]he district judge may accept, reject, or modify the recommended disposition; receive further evidence; or return the matter to the magistrate judge with instructions." Fed. R. Civ. P. 72(b)(3). An objection to a recommendation is proper if it is filed timely in accordance with the Federal Rules of Civil Procedure and specific enough to enable the "district judge to focus attention on those issues – factual and legal – that are at the heart of the parties' dispute." *United States v. 2121 E. 30th St.*, 73 F.3d 1057, 1059 (10th Cir. 1996) (quoting *Thomas v. Arn*, 474 U.S. 140, 147 (1985)). In the absence of a timely and specific objection, "the district court may review a magistrate's report under any standard it deems appropriate." *Summers v. Utah*, 927 F.2d 1165, 1167 (10th Cir. 1991) (citations omitted); *see also* Fed. R. Civ. P. 72 Advisory Committee's Note ("When no timely objection is filed, the court need only satisfy itself that there is no clear error on the face of the record in order to accept the recommendation.").

B. Rule 12(b)(6) Motion

Under Rule 8(a)(2) of the Federal Rules of Civil Procedure, a pleading must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, a complaint must be dismissed if it does not plead "enough facts to state a claim to relief that is plausible on its

face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A pleading that offers labels and conclusions or a formulaic recitation of the elements of a cause of action will not do. Nor does a complaint suffice if it tenders naked assertions devoid of further factual enhancement." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal quotation marks and citation omitted).

"While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, . . . a plaintiff's obligation to provide the 'grounds' of his 'entitlement to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do. . . ." *Id*. at 555 (citations omitted). "Factual allegations must be enough to raise a right to relief above the speculative level." *Id*. A "plaintiff must 'nudge [] [his] claims across the line from conceivable to plausible' in order to survive a motion to dismiss. . . . Thus, the mere metaphysical possibility that *some* plaintiff could prove *some* set of facts in support of the pleaded claims is insufficient; the complaint must give the court reason to believe that *this* plaintiff has a reasonable likelihood of mustering factual support for *these* claims." *Ridge at Red Hawk, L.L.C. v. Schneider*, 493 F.3d 1174, 1177 (10th Cir. 2007) (emphasis in original, internal citation and quotation omitted).

The Tenth Circuit Court of Appeals has held "that plausibility refers to the scope of the allegations in a complaint: if they are so general that they encompass a wide swath of conduct, much of it innocent, then the plaintiffs have not nudged their claims across the line from conceivable to plausible." *Khalik v. United Air Lines*, 671 F.3d 1188, 1191 (10th Cir. 2012) (internal quotation and citation omitted). The Tenth Circuit has further noted "that the nature and specificity of the allegations required to state a plausible claim will vary based on context." *Id*. (Internal quotation and citation omitted.) Thus, the Tenth Circuit "concluded the *Twombly/Iqbal* standard is 'a middle ground between heightened fact

pleading, which is expressly rejected, and allowing complaints that are no more than labels and conclusions or a formulaic recitation of the elements of a cause of action, which the [Supreme C]ourt stated will not do.'" *Id*. (Citation omitted.)

For purposes of a motion to dismiss pursuant to Rule 12(b)(6), the Court must accept all well-pled factual allegations in the complaint as true and resolve all reasonable inferences in a plaintiff's favor. *Morse v. Regents of the Univ. of Colo.*, 154 F.3d 1124, 1126-27 (10th Cir. 1998) (citation omitted); *Seamons v. Snow*, 84 F.3d 1226, 1231-32 (10th Cir. 1996) (citations omitted). However, "when legal conclusions are involved in the complaint 'the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to [those] conclusions. . . .'" *Khalik*, 671 F.3d at 1190 (quoting *Iqbal*, 556 U.S. at 678). "Accordingly, in examining a complaint under Rule 12(b)(6), [the Court] will disregard conclusory statements and look only to whether the remaining, factual allegations plausibly suggest the defendant is liable." *Id*.

II. BACKGROUND

No party objects to Magistrate Judge Watanabe's recitation of the case's procedural history. Accordingly, the Court adopts and incorporates the procedural history included within the Recommendation (ECF No. 73 at 1-2, 7-9) as if set forth herein. No party objects to Magistrate Judge Watanabe's recitation of Plaintiffs' factual allegations[1] against Defendants. Accordingly, the Court adopts and incorporates the factual allegations included within the Recommendation (ECF No. 73 at 2-7) as if set forth herein.

Genzyme produces Cerezyme—the only treatment for Gaucher disease approved by the Food and Drug Administration ("FDA") available in the United States. (*See* ECF No. 31 ¶¶ 1, 8,

[1] Plaintiffs object to Magistrate Judge Watanabe's analysis as to whether the alleged facts, as pled, are sufficient to state a claim. (ECF No. 74 at 4-5, 7-9.)

12.) Around July 2009, due to various problems at its manufacturing facility, Genzyme was unable to manufacture sufficient Cerezyme to meet the demand for the drug. (*See* ECF No. 31 ¶¶ 17, 20-21.) During this shortage, Genzyme adopted a rationing plan under which United States Gaucher sufferers would be allocated less than the recommended dose. (*See* ECF No. 31 ¶¶ 21, 38, 48, 71.) Plaintiffs have sued Genzyme and Accredo/Curascript asserting various state and federal claims alleging that they have been harmed by Defendants' conduct. (ECF No. 31 ¶¶ 124-202.)

Reich (who is an individual with Gaucher disease) and his spouse (who makes a derivative consortium claim) reside in Colorado. (ECF No. 31 ¶¶ 1-2.) Gaucher disease is a genetic metabolic disorder characterized by the lack of the lysosomal enzyme acid beta-glucosidase which breaks down glucosylceramide. (ECF No. 31 ¶ 9.) If left untreated, Gaucher disease causes hepatosplenomegaly, thrombocytopenia, anemia, and skeletal pathology issues. (ECF No. 31 ¶ 10.) Further, untreated Gaucher patients have an enhanced risk of developing myeloma. (ECF No. 31 ¶ 11.) Cerezyme reduces the risk and severity of secondary pathologies from Gaucher disease. (ECF No. 31 ¶ 12.)

Cerezyme is the only enzyme replacement therapy with FDA approval. (ECF No. 31 ¶ 12.) In 1991[2], Reich was placed on Cerezyme treatment at 60 units/kg injected every two weeks. (ECF No. 31 ¶ 15.) Further, this treatment was "billed at a rate of over $500,000 per year." (ECF No. 31 ¶ 15.) Defendant Accredo Health Group distributed Cerezyme and Defendant CuraScript was the billing entity for the drug. (ECF No. 31 ¶ 48.)

Sometime prior to July 2009, Genzyme's bioreactors—in which Cerezyme was produced—was discovered to be contaminated with vesivirus. (ECF No. 31 ¶ 20.) As a result, Genzyme could not meet customer demand for Cerezyme as it was forced to shut down

[2] The Court notes that Plaintiffs pled that Cerezyme was not approved by the FDA until 1994. (ECF No. 31 ¶ 12.)

manufacturing of the drug as it sanitized the facility. (ECF No. 31 ¶ 21; ECF No. 31-2 at 2.) Vesivirus causes infectious diseases in humans with observations of viremia, vesicular skin lesions, antigenicity, antibody seroconversion, and hepatitis. (ECF No. 31 ¶ 27.) The vesivirus was in the Cerezyme that Genzyme and Accredo shipped. (ECF No. 31 ¶ 38.) In addition to the vesivirus, vials of Cerezyme were contaminated with "glass, rubber and steel particles known to be toxic to humans leading to complications including pulmonary thrombi and micro-emboli, infusion phlebitis, and end-organ granuloma formation and inflammation." (ECF No. 31 ¶ 29.)

Because of the "viral contamination, [Genzyme] could not meet customer demand" for Cerezyme and Genzyme thus implemented a plan to ration the remaining Cerezyme inventory. (ECF No. 31 ¶ 21.) Genzyme created an ad hoc committee titled "Cerezyme Stakeholders Working Group" ("CSWG"), allegedly comprised of Genzyme employees and affiliates to conserve the supply of Cerezyme. (ECF No. 31 ¶¶ 30, 39; ECF No. 31-2 at 1-2.) The CSWG solely functioned as an instrumentality of Genzyme. (ECF No. 31 ¶ 62.) The CSWG issued guidance, subsequently revised, to the U.S. Gaucher community concerning conservation of the remaining Cerezyme inventory. (ECF No. 31-2.) The revised guidance advised that those patients who were considered to be the most vulnerable and critically ill should continue to receive Cerezyme without any interruption, provided information about an emergency access program, noted that all individuals receiving Cerezyme during the temporary shortage should be considered for individualized dose reductions, indicated that patients receiving dose reductions or treatment interruptions should be monitored and have clinical data collected and registered into a registry, and noted that individuals undergoing treatment interruptions may be candidates for clinical trials or treatment protocols using alternative investigational therapies. (ECF No. 31-2 at 2.)

From July 2009 until September 2011, Defendants *substituted* "Dr. Reich's injections of Cerezyme for experimental doses of an untested drug that was intentionally mislabeled, diluted below FDA approved levels, adulterated with glass rubber and steel particles, and contaminated with a viral pathogen known to be dangerous to humans." (ECF No. 31 ¶ 17.) Genzyme advised that this treatment is for patients who were classified as "Group 2." (*See* ECF No. 31 ¶ 55.) Genzyme controverted the judgment of treating physicians in undertaking this action. (ECF No. 31 ¶¶ 17, 55, 58.)

Respectively, Accredo and Curascript distributed and billed for Cerezyme. (ECF No. 31 ¶ 73.) Accredo/Curascript "participated in the national sales and marketing of diluted, untested, and ineffective medication substitute by acting as a middle-man identifying which Gaucher patients to target for the substitute medication." (ECF No. 31 ¶ 73.) Accredo/Curascript referred to these Gaucher patients as Group 2. (ECF No. 31 ¶ 73.) In contrast, "Group 1" patients received full doses although these patients were also injected with the vesivirus. (ECF No. 31 ¶ 73.) To facilitate sales of Cerezyme, Accredo/Curascript contacted Gaucher patients' physicians to obtain medical information to target "Group 2" patients. (ECF No. 31 ¶ 74.)

Accredo/Curascript classified Reich as a Group 2 patient and submitted this information to Genzyme. (ECF No. 31 ¶ 87.) Subsequently, "Reich was sold the impure and ineffective drug substitute for which he and his insurance company paid [Accredo/Curascript] on at least the following dates: 1/4/2010, 1/11/2010, 1/18/2010, 2/12/2010, 3/23/2010, 4/15/2010, and 3/7/2011." (ECF No. 31 ¶ 88.) This drug was "mislabeled, impure, filth-contaminated, ineffective, diluted, and [] substituted but marketed as if it were a beneficial treatment for Gaucher disease. . . ." (ECF No. 31 ¶ 21.) Genzyme, Accredo (as the distribution entity), and Curascript (as the billing entity) substituted the "inferior, ineffective[,] and dangerous dose in

lieu of that of the drug prescribed." (ECF No. 31 ¶ 48.) Genzyme and Accredo/Curascript[3] "did not revise the product labels to indicate that the substitution medication was impure or contaminated or that it was administrated at less than the recommended dosage, or warn of any risk of injury from the dilution, adulteration, or contamination." (ECF No. 31 ¶ 81.)

Dr. Reich's physician "*reportedly* opposed Genzyme's rations on his patient's behalf three times after submitting the Group 2 paper work." (ECF No. 31 ¶ 33 (emphasis added).) Genzyme, Accredo, and Curascript "refused to honor physician's requests to let 'Group 2' patients . . . opt out of being injected with the impure, untested, and ineffective substitute medication. . . ."[4] (ECF No. 31 ¶ 79.)

On June 19, 2012, Reich was diagnosed with multiple myeloma. (ECF No. 31 ¶ 95.) "Due to the conduct of . . . Defendants, [Reich] has been subjected to involuntary and illegal human medical experimentation without informed consent, and as a result of the injections and exposure to the impure, unsafe drug substitute." (ECF No. 31 ¶ 96.) "Due to the conduct of . . . Defendants, [Reich] has been physically injured having suffered from glucocerebroside deposition, from having developed multiple myeloma, from having had bone deterioration, from having had excisional bone surgery, from having undergone chemotherapy, from having lost the ability to walk without assistance, from having developed skin lesions[,] and from having suffered (and continuing to suffer) chronic pain." (ECF No. 31 ¶ 102.)

Plaintiffs raise class allegations as well as the following eleven claims against all Defendants: (1) negligence (ECF No. 31 ¶¶ 124-27, Claim I); (2) negligence per se (ECF No. 31 ¶¶ 128-31, Claim II); (3) strict liability (ECF No. 31 ¶¶ 132-34, Claim III); (4) breach of warranty (ECF No. 31 ¶¶ 135-38, Claim IV); (5) tortious interference with a physician/patient

[3] Plaintiffs do not allege how Accredo/Curascript had the capacity to revise the product label. (*See generally* Dkt.)
[4] Plaintiffs do not allege that Reich's physician requested that Reich be allowed to opt out of the injections. (*See generally* Dkt.)

relationship (ECF No. 31 ¶¶ 139-44, Claim V); (6) a Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1962(c), violation with respect to the "CSWG Enterprise" (ECF No. 31 ¶¶ 145-64, Claim VI); (7) a RICO violation with respect to the "Group 2 Enterprise" (ECF No. 31 ¶¶ 165-85, Claim VII); (8) intentional/negligent misrepresentation (ECF No. 31 ¶¶ 186-91, Claim VIII); (9) a Colorado Consumer Protection Act ("CCPA"), Colo. Rev. Stat. § 6-1-101 *et seq.*, violation (ECF No. 31 ¶¶ 192-94, Claim IX); (10) unjust enrichment (ECF No. 31 ¶¶ 195-99, Claim X); and (11) loss of consortium (ECF No. 31 ¶¶ 200-02, Claim XI).

Subsequent to Defendants' filing their respective motions to dismiss, Magistrate Judge Watanabe ordered the matter set for an oral hearing on the motions to dismiss. (ECF No. 69.) Specifically, Magistrate Judge Watanabe ordered Plaintiffs to clarify "whether the terms such as 'medication substitute,' 'substitute medication,' 'drug substitutions,' 'drug substitute,' 'diluted,' 'adulterated,' and 'off-label use' used throughout the Amended Complaint ([ECF No. 31]) merely mean that [Reich] received a reduced or interrupted dosage of Cerezyme." (ECF No. 69.) At the oral hearing, Plaintiffs' counsel confirmed that the terms referred to in the Amended Complaint as identified by Magistrate Judge Watanabe merely refer to "underdosing," *i.e.*, that no therapeutic dose was ever given to the patient. (ECF No. 75 at 16-17, Mtn. Hearing 16:20-25, 17:1-22.)

III. ANALYSIS[5,6]

The Court agrees with Magistrate Judge Watanabe's characterization of the Amended Complaint as "prolix, obfuscatory, and convoluted." (ECF No. 73 at 12.) Nevertheless, the matter is not before the Court on a motion for a more definite statement. (*See generally* Dkt.) Rather, the matter is before the Court on the Recommendation to grant Defendants' respective motions to dismiss.

A. Claims to Which No Objection Was Filed[7]

Magistrate Judge Watanabe recommended dismissing the following of Plaintiffs' claims to which Plaintiffs do not object: (1) tortious interference with a physician/patient relationship (ECF No. 31 ¶¶ 139-44, Claim V); (2) RICO (ECF No. 31 ¶¶ 145-85, Claims VI and VII); and (3) unjust enrichment (ECF No. 31 ¶¶ 195-99, Claim X).

The Recommendation advised the parties that specific written objections were due within fourteen days after being served with a copy of the Recommendation. (ECF No. 73 at 26.) Despite this advisement, no objection to the Recommendation with respect to those claims identified above, *supra* III.A, have to date been filed by any party and the time to do so has expired. (*See generally* Dkt.)

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[5] In Plaintiffs' Objection to the Recommendation, Plaintiffs request leave to amend their Amended Complaint. (ECF No. 74 at 6-7.) Such a request is not properly before the Court in such a procedural posture. D.C. Colo. L. Civ. R. 7.1(d) ("A motion shall not be included in a response or reply to the original motion. A motion shall be made in a separate document."); *see*, *e.g.*, *Calderon v. Kan. Dep't of Social & Rehab. Servs.*, 181 F.3d 1180, 1185-87 (10th Cir. 1999) (a response to a motion to dismiss is insufficient to be construed as request to amend a complaint).

[6] The Recommendation recommended dismissal of Plaintiffs' class allegations. (ECF No. 73 at 25.) Plaintiffs object to this part of the Recommendation. (ECF No. 74 at 7.) The Court is dismissing the Amended Complaint in its entirety. If Plaintiffs file an amended complaint as permitted by this Order, the Court reserves ruling on whether a class action, pursuant to Rule 23 of the Federal Rules of Civil Procedure, is appropriate.

[7] Plaintiffs did not file an objection to the Recommendation with respect to their loss of consortium claim (ECF No. 31 ¶¶ 200-02, Claim XI). (*See generally* ECF No. 74.) Because the loss of consortium claim is derivative of Reich's claims and the Court is permitting certain of Reich's claim to be amended (*see infra* III.B), the loss of consortium claim similarly can be amended in that respect.

As to Plaintiffs' (1) tortious interference with a physician/patient relationship; (2) RICO; and (3) unjust enrichment claims, the Court concludes that Magistrate Judge Watanabe's analysis was thorough and sound, and that there is no clear error on the face of the record. *See* Fed. R. Civ. P. 72(b) advisory committee's note ("When no timely objection is filed, the court need only satisfy itself that there is no clear error on the face of the record in order to accept the recommendation."); *see also Summers*, 927 F.2d at 1167 ("In the absence of timely objection, the district court may review a magistrate's report under any standard it deems appropriate."). The Recommendation with respect to Plaintiffs' (1) tortious interference with a physician/patient relationship (ECF No. 31 ¶¶ 139-44, Claim V); (2) RICO (ECF No. 31 ¶¶ 145-85, Claims VI and VII); and (3) unjust enrichment (ECF No. 31 ¶¶ 195-99, Claim X) claims is accepted as an order of the Court.

B. Claims to Which an Objection Was Filed

Magistrate Judge Watanabe recommended dismissing the following claims to which Plaintiffs did file an objection: (1) negligence (ECF No. 31 ¶¶ 124-27, Claim I); (2) negligence per se (ECF No. 31 ¶¶ 128-31, Claim II); (3) strict liability (ECF No. 31 ¶¶ 132-34, Claim III); (4) breach of warranty (ECF No. 31 ¶¶ 135-38, Claim IV); (5) misrepresentation (ECF No. 31 ¶¶ 186-91, Claim VIII); and (6) CCPA (ECF No. 31 ¶¶ 192-94, Claim IX). (ECF No. 74 at 4-5, 7-9.)

1. Misrepresentation and CCPA Claims

Plaintiffs' Objection fails to identify with specificity the basis on which they object to the Magistrate Judge's Recommendation to dismiss Plaintiffs' (1) misrepresentation (ECF No. 31 ¶¶ 186-91, Claim VIII) and (2) CCPA claims (ECF No. 31 ¶¶ 192-94, Claim IX). (*See generally* ECF No. 74.) Plaintiffs simply argue that "Plaintiffs have properly and thoroughly pled factual

content to allow this Court to draw the reasonable and positive inference that Defendants are liable for the misconduct alleged." (ECF No. 74 at 5.) Plaintiffs point to no error in Magistrate Judge Watanabe's finding that Plaintiffs fail to allege facts that "create a plausible claim that [D]efendants made any express or implied warranty or any misrepresentation regarding the efficacy of Cerezyme at any particular dosage." (ECF No. 73 at 23.) Further, Magistrate Judge Watanabe found that "Plaintiffs have not pled any specific misrepresentations made by [D]efendants." (ECF No. 73 at 23.)

"[O]nly an objection that is sufficiently specific to focus the district court's attention on the factual and legal issues that are truly in dispute will advance the policies behind the Magistrate's Act." *2121 E. 30th St.*, 73 F.3d at 1060. Further, "objections should not be construed as a second opportunity to present the arguments already considered by the Magistrate Judge." *Haden v. Green*, Case No. 10-cv-0515-RBJ-KMT, 2013 WL 328992, *1 (D. Colo. Jan. 29, 2013) (citation omitted).

Because Plaintiffs do not specifically object to Magistrate Judge Watanabe's Recommendation with respect to the misrepresentation and CCPA claims, the Court has great discretion in determining what level of scrutiny to use in reviewing the Recommendation. *Summers*, 927 F.2d at 1167. De novo review is not triggered where a party's objections to a recommendation are not specific but rather are "conclusory or general objections," or a reiteration of a party's original arguments. *Rocha v. CCCF Admin.*, Case No. 09-cv-01432-CMA-MEH, 2010 WL 1333185, *3 (D. Colo. Apr. 2, 2010) (citation omitted). The Court does not believe that Plaintiffs' objection with respect to their misrepresentation and CCPA claims are specific enough to trigger de novo review.

Rule 9(b) of the Federal Rules of Civil Procedure requires that "[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." Fed. R. Civ. P. 9(b). That is Plaintiffs must set forth the time, place, and contents of the false misrepresentation, the identity of the party making the false statements and the consequences thereof. *See Tal v. Hogan*, 453 F.3d 1244, 1263 (10th Cir. 2006) (citation omitted); *see Tatten v. Bank. of Am. Corp.*, 912 F. Supp. 2d 1032, 1041 (D. Colo. 2013) (dismissing fraudulent misrepresentation claim because it "failed to set forth the who, what, when, where and how of the alleged fraud . . . and [of] the mandate of Rule 9(b)."); *see Duran v. Clover Club Foods Co.*, 616 F. Supp. 790, 793 (D. Colo. 1985) (applying Rule 9(b) to a CCPA claim).

After reviewing Magistrate Judge Watanabe's Recommendation with respect to Plaintiffs' misrepresentation and CCPA claims, the Court agrees with the Recommendation's legal analysis and findings. Defendants are entitled to dismissal of the (1) misrepresentation (ECF No. 31 ¶¶ 186-91, Claim VIII) and (2) CCPA (ECF No. 31 ¶¶ 192-94, Claim IX) claims against them.

2. Negligence; Negligence Per Se; Strict Liability; and Breach of Warranty Claims

Due to Plaintiffs' obfuscatory pleading, it was difficult for the Court (as it was for Magistrate Judge Watanabe) to discern the bases upon which Plaintiffs allege "the conduct of Defendants" has caused Plaintiffs' injuries. (*See* ECF No. 31 ¶¶ 99, 102.) The Court has discerned two bases: underdosage[8] and vesivirus.

a. *Underdosage Theory*

[8] Plaintiffs, in their Objection, attempt to revive their "impure" theory. (ECF No. 74 at 5.) The Court is not persuaded.

As stated previously, Magistrate Judge Watanabe ordered Plaintiffs to clarify "whether the terms such as 'medication substitute,' 'substitute medication,' 'drug substitutions,' 'drug substitute,' 'diluted,' 'adulterated,' and 'off-label use' used throughout the Amended Complaint ([ECF No. 31]) merely mean that [Reich] received a reduced or interrupted dosage of Cerezyme." (ECF No. 69.) At the oral hearing, Plaintiffs' counsel confirmed that the terms referred to in the Amended Complaint as identified by Magistrate Judge Watanabe[9] merely refer to "underdosing," *i.e.*, that no therapeutic dose was ever given to the patient. (ECF No. 75 at 16-17, Mtn. Hearing 16:20-25, 17:1-22.) Oral arguments materially assisted the Magistrate Judge in making his Recommendation because he was able to discern a basis for Plaintiffs' claim. D.C. Colo. L. Civ. R. 7.1(h). Because Plaintiffs' counsel conceded certain facts in the Amended Complaint at oral argument, *i.e.*, that the "medication substitute," "substitute medication," "drug substitution," "drug substitute," "diluted" drug, "adulterated" drug, and "off-label use" drug were merely Plaintiffs' attempt to explain that Reich was simply receiving less Cerezyme than he received prior to the Cerezyme shortage, the Court analyzes the Amended Complaint as to whether "underdosage" of Cerezyme states a claim. *See Al-Owhali v. Holder*, Case No. 07-cv-02214-LTB-BNB, 2011 WL 288523, *3 (D. Colo. Jan. 27, 2011) (where at oral argument, the plaintiff's counsel conceded certain facts in the complaint which were detrimental to plaintiff's claim), *aff'd* 687 F.3d 1236 (10th Cir. 2012).

Plaintiffs object to Magistrate Judge Watanabe's Recommendation to dismiss Plaintiffs' claims as to negligence (ECF No. 31 ¶¶ 124-27, Claim I); negligence per se (ECF No. 31 ¶¶ 128-31, Claim II); strict liability (ECF No. 31 ¶¶ 132-34, Claim III); and breach of warranty (ECF No. 31 ¶¶ 135-38, Claim IV). (ECF No. 74 at 4-5, 7-9.) Plaintiffs object on the basis that the

[9] Magistrate Judge Watanabe specifically excluded the word "contaminated" from his list of terms to which Plaintiffs were to provide clarification. (*See generally* ECF No. 69.)

Magistrate Judge "confuses the background of a market shortage (no-sales theory) with the actual sale of a defective drug during this shortage (product sales theory)." (ECF No. 74 at 8.) But Plaintiffs "defective drug" theory is just a reframing of the failure to supply Cerezyme at its previous non-rationed amount. (ECF No. 75 at 16-17, Mtn. Hearing 16:20-25, 17:1-22.) Plaintiffs are unable to present the Court with any authority that Defendants had a duty to sell to Reich all the Cerezyme he desired during the shortage. The Court agrees with Magistrate Judge Watanabe's analysis that Defendants lacked such a duty (ECF No. 73 at 20-22). *See Hochendonder v. Genzyme Corp.*, Case No. 11-10739-DPW, 2015 WL 1333271, *11 (D. Mass. Mar. 25, 2015); s*ee Schubert v. Genzyme Corp.*, Case No. 2:12CV587DAK, 2013 WL 4776286, *3-4 (D. Utah Sept. 4, 2013); *see Lacognata v. Hospira, Inc.*, Case No. 12-CV-822-T-30TGW, 2012 WL 6962884, *2 (M.D.Fl. July 2, 2012), *aff'd*, 521 F. App'x 866 (11th Cir. 2013) (unpublished), *cert. denied*, 134 S. Ct. 458 (2013).

(1) Accredo/Curascript's Innocent-Seller Status with Respect to Plaintiffs' Underdosage Theory

Magistrate Judge Watanabe additionally recommended that the Court dismiss Plaintiffs' claims against Accredo/Curascript on the basis of negligence (ECF No. 31 ¶¶ 124-27, Claim I); negligence per se (ECF No. 31 ¶¶ 128-31, Claim II); strict liability (ECF No. 31 ¶¶ 132-34, Claim III); and breach of warranty (ECF No. 31 ¶¶ 135-38, Claim IV), on the basis that they are protected under Colorado's "Innocent Seller" statute, Colo. Rev. Stat. § 13-21-402. (ECF No. 73 at 18-20.) Plaintiffs object on the basis that they adequately pled that Accredo/Curascript had "actual knowledge of a defect" in Cerezyme and are therefore not protected under the Innocent Seller statute. (ECF No. 74 at 9.) The Court finds no merit to Plaintiffs' argument with respect to the underdosage theory.

The Innocent Seller statute, Colo. Rev. Stat. § 13-21-401, defines "manufacturer" as

> a person or entity who designs, assembles fabricates, produces, constructs or otherwise prepares a product or a component part of a product prior to the sale of the product to a user or consumer. The term includes any seller who has actual knowledge of a defect in a product or a seller of a product who creates and furnishes a manufacturer with specifications relevant to the alleged defect for producing the product or who otherwise exercises some significant control over all or a portion of the manufacturing process or who alters or modifies a product in any significant manner after the product comes into his possession and before it is sold to the ultimate user or consumer.

Colo. Rev. Stat. § 13-21-401(1). Plaintiffs argue that at paragraphs 124-127 of the Amended Complaint, they sufficiently pled Accredo/Curascript's actual knowledge of a defect in Cerezyme. (ECF No. 74 at 9.) First, underdosage cannot be a "defect in [the] product" as defined by the statute because the dosage rate is external to the product. Second, Plaintiffs' allegations as Accredo/Curascript's knowledge that underdosage would be defective are conclusory. (*See* ECF No. 31 ¶¶ 124-27 ("Defendants . . . through knowledge . . . sold impure and ineffective drug substitutes. . . .") Such conclusory allegations are properly disregarded by the Court. *Khalik*, 671 F.3d at 1190 (quoting *Iqbal*, 556 U.S. at 678).

b. *Vesivirus Theory*

Plaintiffs object to Magistrate Judge Watanabe's Recommendation to dismiss Plaintiffs' claims as to negligence (ECF No. 31 ¶¶ 124-27, Claim I); negligence per se (ECF No. 31 ¶¶ 128-31, Claim II); strict liability (ECF No. 31 ¶¶ 132-34, Claim III); and breach of warranty (ECF No. 31 ¶¶ 135-38, Claim IV). (ECF No. 74 at 4-5, 7-9.) Magistrate Judge Watanabe recommended to dismiss Plaintiffs' claims on the basis that the Amended Complaint "does not state a claim of injury as a result of [the vesivirus] contaminants."[10] (ECF No. 73 at 13-14.) Specifically, Magistrate Judge Watanabe found that Reich's "purported injuries . . . do not on their face include any of the possible complications of the contaminants that were . . . alleged in

[10] Plaintiffs allege that there were other contaminants in Cerezyme. (ECF No. 31 ¶ 29.) Magistrate Judge Watanabe found that Plaintiffs did not allege an injury due to the presence of other contaminants. (ECF No. 73 at 13-14.) The Court has reviewed the Magistrate Judge's finding in this regard and agrees with his legal analysis and findings.

[the Amended Complaint]." (ECF No. 73 at 14.) Plaintiffs object to the exclusion of the vesivirus from causing Plaintiffs' injuries. (ECF No. 74 at 2 n.1, 4-5, 7-9.) The Court agrees with Plaintiffs.

That is Plaintiffs pled that Cerezyme contained vesivirus. (ECF No. 31 ¶ 17.) Vesivirus causes infectious diseases in humans with observations of viremia, *vesicular skin lesions*, antigenicity, antibody seroconversion, and hepatitis. (ECF No. 31 ¶ 27.) Reich was treated with Cerezyme that contained vesivirus. (ECF No. 31 ¶¶ 17, 55.) Genzyme, Accredo, and Curascript sold Reich Cerezyme that contained vesivirus. (*See* ECF No. 31 ¶¶ 38, 73, 88.) Reich developed *skin lesions* due to Defendants' conduct. (ECF No. 31 ¶ 102.) Thus, the Court finds Plaintiffs pled a causal connection between vesivirus and Reich's injuries.

Plaintiffs' Amended Complaint, however, fails to comply with Rule 8(a)(2) of the Federal Rules of Civil Procedure as it does not contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Further, the Amended Complaint does not comply with Rule 8(d)(1) of the Federal Rules of Civil Procedure which requires that "[e]ach allegation must be simple, concise, and direct." Fed. R. Civ. P. 8(d)(1). Based upon the Amended Complaint, motions to dismiss, oral argument, and Recommendation, the Court is unable to determine, at this time, whether Plaintiffs' negligence (ECF No. 31 ¶¶ 124-27, Claim I); negligence per se (ECF No. 31 ¶¶ 128-31, Claim II); strict liability (ECF No. 31 ¶¶ 132-34, Claim III); and breach of warranty (ECF No. 31 ¶¶ 135-38, Claim IV) claims are sufficient as a matter of law.

Plaintiffs are given leave to file an amended complaint with respect to the negligence (ECF No. 31 ¶¶ 124-27, Claim I); negligence per se (ECF No. 31 ¶¶ 128-31, Claim II); strict

liability (ECF No. 31 ¶¶ 132-34, Claim III); and breach of warranty (ECF No. 31 ¶¶ 135-38, Claim IV) claims under the vesivirus theory.

(1) Accredo/Curascript's Innocent-Seller Status with Respect to Plaintiffs' Vesivirus Theory

Prior to July, 2009, Genzyme learned that vesivirus was present in its bioreactors which caused reduced output of Cerezyme. (ECF No. 31 ¶¶ 19-20.) From July 2009 until September 2011, Reich received Cerezyme that had been contaminated with vesivirus. (ECF No. 31 ¶¶ 17, 55; ECF No. 31-2 at 2.) Genzyme and Accredo shipped Cerezyme that had the vesivirus in it. (ECF No. 31 ¶ 38.) Accredo and Curascript "distributed and billed for Cerezyme and participated in the national sales" of that drug[11]. (ECF No. 31 ¶ 73.) Reich and his insurance company paid Accredo and Curascript, during the time of rationing, for Cerezyme that had vesivirus in it. (ECF No. 31 ¶ 88.)

On June 24, 2009, the CSWG issued guidance, subsequently revised, to the U.S. Gaucher community concerning conservation of the remaining Cerezyme inventory due to the presence of vesivirus. (*See* ECF No. 31-2 at 2.) That is the presence of vesivirus, *i.e.*, contamination, was well-known and all Defendants admit as such in their motions to dismiss. (ECF No. 43 at 2; ECF No. 44 at 6.) Thus, Accredo/Curascript had knowledge of the presence of vesivirus in the Cerezyme sold to Reich. (*See* ECF No. 31 ¶¶ 44, 48, 81, 88.)

At this time, Plaintiffs' sufficiently pled Accredo/Curascript's actual knowledge of the presence of vesivirus in Cerezyme. Therefore, Accredo/Curascript, at this time, are unable to rely upon the Innocent Seller statute to preclude Plaintiffs' negligence (ECF No. 31 ¶¶ 124-27,

[11] The Court has concern, once again, with Plaintiffs' allegations and whether they support the theory that Curascript "sold" Cerezyme. Specifically, Plaintiffs allege that Curascript was merely the "billing entity." (ECF No. 31 ¶ 48.) The Court doubts that an entity that serves merely as the "billing entity" is a "seller" as defined by the applicable Colorado statute, Colo. Rev. Stat. § 13-21-401(3). But Curascript does not dispute that it is a "seller" of the Cerezyme; rather, Curascript defends itself by asserting it is an "innocent seller." (ECF No. 43 at 3, 10-12.)

Claim I); negligence per se (ECF No. 31 ¶¶ 128-31, Claim II); strict liability (ECF No. 31 ¶¶ 132-34, Claim III); and breach of warranty (ECF No. 31 ¶¶ 135-38, Claim IV) claims predicated upon the vesivirus theory.

IV. CONCLUSION

Based on the foregoing, the Court:

(1) OVERRULES, in part, and SUSTAINS, in part, Plaintiffs' Objection (ECF No. 74), to wit, the Court:

(i) OVERRULES Plaintiffs' objection to the recommended dismissal, with prejudice, of Plaintiffs' (1) negligence (ECF No. 31 ¶¶ 124-27, Claim I); (2) negligence per se (ECF No. 31 ¶¶ 128-31, Claim II); (3) strict liability (ECF No. 31 ¶¶ 132-34, Claim III); (4) breach of warranty (ECF No. 31 ¶¶ 135-38, Claim IV); (5) misrepresentation (ECF No. 31 ¶¶ 186-91, Claim VIII); (6) CCPA (ECF No. 31 ¶¶ 192-94, Claim IX); and (7) loss consortium (ECF No. 31 ¶¶ 200-02, Claim XI) claims under the underdosage theory as well as dismissal of Plaintiffs' class allegations upon the same;

(ii) OVERRULES Plaintiffs' objection to the recommended dismissal, with prejudice, of Plaintiffs' (1) misrepresentation (ECF No. 31 ¶¶ 186-91, Claim VIII) and (2) CCPA (ECF No. 31 ¶¶ 192-94, Claim IX) claims under the vesivirus theory as well as dismissal of Plaintiffs' class allegations upon the same;

(iii) SUSTAINS Plaintiffs' objection to the recommended dismissal, with prejudice, of Plaintiffs' (1) negligence (ECF No. 31 ¶¶ 124-27, Claim I); (2) negligence per se (ECF No. 31 ¶¶ 128-31, Claim II); (3) strict liability (ECF No. 31 ¶¶ 132-34, Claim III); (4) breach of warranty (ECF No. 31 ¶¶ 135-38, Claim IV); (5) and loss consortium (ECF No. 31 ¶¶

200-02, Claim XI) claims under the vesivirus theory as well as dismissal of Plaintiffs' class allegations upon the same;

(2) MODIFIES, in part, and ACCEPTS, in part, the Magistrate Judge's Recommendation (ECF No. 73), to wit, the Court:

(i) ACCEPTS the Recommendation (ECF No. 73 at 15-18) with respect to Plaintiffs' (1) tortious interference with a physician/patient relationship (ECF No. 31 ¶¶ 139-44, Claim V); (2) RICO (ECF No. 31 ¶¶ 145-85, Claims VI and VII); (3) misrepresentation (ECF No. 31 ¶¶ 186-91, Claim VIII); (4) CCPA (ECF No. 31 ¶¶ 192-94, Claim IX); and (5) unjust enrichment (ECF No. 31 ¶¶ 195-99, Claim X) claims as well as dismissal of Plaintiffs' class allegations upon the same;

(ii) ACCEPTS the Recommendation (ECF No. 73 at 20-25) with respect to Plaintiffs' (1) negligence (ECF No. 31 ¶¶ 124-27, Claim I); (2) negligence per se (ECF No. 31 ¶¶ 128-31, Claim II); (3) strict liability (ECF No. 31 ¶¶ 132-34, Claim III); (4) breach of warranty (ECF No. 31 ¶¶ 135-38, Claim IV); and (5) loss consortium (ECF No. 31 ¶¶ 200-02, Claim XI) claims under the underdosage theory as well as dismissal of Plaintiffs' class allegations upon the same;

(iii) MODIFIES the Recommendation (ECF No. 73 at 20-25) to permit Plaintiffs to amend their (1) negligence (ECF No. 31 ¶¶ 124-27, Claim I); (2) negligence per se (ECF No. 31 ¶¶ 128-31, Claim II); (3) strict liability (ECF No. 31 ¶¶ 132-34, Claim III); (4) breach of warranty (ECF No. 31 ¶¶ 135-38, Claim IV); and (5) loss of consortium (ECF No. 31 ¶¶ 200-02, Claim XI) claims under the vesivirus theory as well as Plaintiffs' class allegations upon the same;

(3) GRANTS, in part, and DENIES[12], in part, Defendant Genzyme's motion to dismiss (ECF No. 44), to wit, the Court:

(i) GRANTS Defendant Genzyme's motion to dismiss, with prejudice, Plaintiffs' (1) tortious interference with a physician/patient relationship (ECF No. 31 ¶¶ 139-44, Claim V); (2) RICO (ECF No. 31 ¶¶ 145-85, Claims VI and VII); (3) misrepresentation (ECF No. 31 ¶¶ 186-91, Claim VIII); (4) CCPA (ECF No. 31 ¶¶ 192-94, Claim IX); and (5) unjust enrichment (ECF No. 31 ¶¶ 195-99, Claim X) claims against it;

(ii) GRANTS Defendant Genzyme's motion to dismiss, with prejudice, Plaintiffs' (1) negligence (ECF No. 31 ¶¶ 124-27, Claim I); (2) negligence per se (ECF No. 31 ¶¶ 128-31, Claim II); (3) strict liability (ECF No. 31 ¶¶ 132-34, Claim III); (4) breach of warranty (ECF No. 31 ¶¶ 135-38, Claim IV); and (5) loss of consortium (ECF No. 31 ¶¶ 200-02, Claim XI) claims against it which are predicated upon an "underdosage" theory;

(iii) GRANTS Defendant Genzyme's motion to dismiss, without prejudice, Plaintiffs' (1) negligence (ECF No. 31 ¶¶ 124-27, Claim I); (2) negligence per se (ECF No. 31 ¶¶ 128-31, Claim II); (3) strict liability (ECF No. 31 ¶¶ 132-34, Claim III); (4) breach of warranty (ECF No. 31 ¶¶ 135-38, Claim IV); and (5) loss of consortium (ECF No. 31 ¶¶ 200-02, Claim XI) claims against it which are predicated upon the "vesivirus" theory;

(4) GRANTS, in part, and DENIES[13], in part, Defendants Accredo/Curascript's motion to dismiss (ECF No. 43),

(i) GRANTS Defendants Accredo/Curascript's motion to dismiss, with prejudice, Plaintiffs' (1) tortious interference with a physician/patient relationship (ECF No. 31 ¶¶ 139-44, Claim V); (2) RICO (ECF No. 31 ¶¶ 145-85, Claims VI and VII); (3)

[12] Denial is as to Defendant Genzyme's request to dismiss the Amended Complaint, in its entirety, with prejudice.
[13] Denial is as to Defendants Accredo/Curascript's request to dismiss the Amended Complaint, in its entirety, with prejudice.

misrepresentation (ECF No. 31 ¶¶ 186-91, Claim VIII); (4) CCPA (ECF No. 31 ¶¶ 192-94, Claim IX); and (5) unjust enrichment (ECF No. 31 ¶¶ 195-99, Claim X) claims against it;

(ii) GRANTS Defendants Accredo/Curascript's motion to dismiss, with prejudice, Plaintiffs' (1) negligence (ECF No. 31 ¶¶ 124-27, Claim I); (2) negligence per se (ECF No. 31 ¶¶ 128-31, Claim II); (3) strict liability (ECF No. 31 ¶¶ 132-34, Claim III); (4) breach of warranty (ECF No. 31 ¶¶ 135-38, Claim IV); and (5) loss of consortium (ECF No. 31 ¶¶ 200-02, Claim XI) claims against it which are predicated upon an "underdosage" theory;

(iii) GRANTS Defendants Accredo/Curascript's motion to dismiss, without prejudice, Plaintiffs' (1) negligence (ECF No. 31 ¶¶ 124-27, Claim I); (2) negligence per se (ECF No. 31 ¶¶ 128-31, Claim II); (3) strict liability (ECF No. 31 ¶¶ 132-34, Claim III); (4) breach of warranty (ECF No. 31 ¶¶ 135-38, Claim IV); and (5) loss of consortium (ECF No. 31 ¶¶ 200-02, Claim XI) claims against it which are predicated upon the "vesivirus" theory;

(5) DISMISSES the Amended Complaint (ECF No. 31) as follows:

(i) DISMISSES Plaintiffs' negligence claim (ECF No. 31 ¶¶ 124-27, Claim I) with prejudice as to the underdosage theory and without prejudice as to the vesivirus theory;

(ii) DISMISSES Plaintiffs' negligence per se claim (ECF No. 31 ¶¶ 128-31, Claim II) with prejudice as to the underdosage theory and without prejudice as to the vesivirus theory;

(iii) DISMISSES Plaintiffs' strict liability claim (ECF No. 31 ¶¶ 132-34, Claim III) with prejudice as to the underdosage theory and without prejudice as to the vesivirus theory;

(iv) DISMISSES Plaintiffs' breach of warranty claim (ECF No. 31 ¶¶ 135-38, Claim IV) with prejudice as to the underdosage theory and without prejudice as to the vesivirus theory;

(v) DISMISSES Plaintiffs' tortious interference with a physician/patient relationship claim (ECF No. 31 ¶¶ 139-44, Claim V) with prejudice;

(vi) DISMISSES Plaintiffs' RICO claim predicated upon the CSWG enterprise (ECF No. 31 ¶¶ 145-64, Claim VI) with prejudice;

(vii) DISMISSES Plaintiffs' RICO claim predicated upon the Group 2 enterprise (ECF No. 31 ¶¶ 165-85, Claim VII) with prejudice;

(viii) DISMISSES Plaintiffs' misrepresentation claim (ECF No. 31 ¶¶ 186-91, Claim VIII) with prejudice;

(ix) DISMISSES Plaintiffs' CCPA claim (ECF No. 31 ¶¶ 192-94, Claim IX) with prejudice;

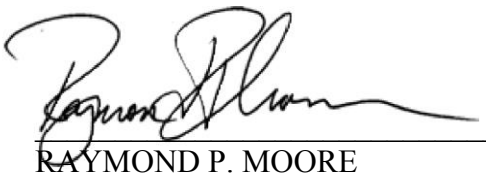
(x) DISMISSES Plaintiffs' unjust enrichment claim (ECF No. 31 ¶¶ 195-99, Claim X) with prejudice;

(xi) DISMISSES Plaintiffs' loss of consortium claim (ECF No. 31 ¶¶ 200-02, Claim XI) with prejudice as to the underdosage theory and without prejudice as to the vesivirus theory; and

(6) GRANTS Plaintiffs leave to file a second amended complaint, on or before October 23, 2015, with respect to the Amended Complaint's Claims I-IV (negligence, negligence per se, strict liability, and breach of warranty) and XI (loss of consortium) (ECF No. 31 ¶¶ 124-38, 200-02) under the vesivirus theory and Defendants' alleged liability.

DATED this 7th day of October, 2015.

BY THE COURT:



RAYMOND P. MOORE
United States District Judge