

**UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND**

DAVID STARR,
SANDI COOK,
BERNADETTE MAVRIKOS,
EDWARD QUIAMBAO,
JAMES TETTENHORST,
JEREMY HANSEN,
KRISTA KARO,
ARLENE REED-COSSAIRT,
PETER STAVROS,
SCOTT OFFUTT,
HEATHER FARKAS and
STACEY HOLZ,
*on behalf of themselves and all others similarly
situated,*

Plaintiffs,

v.

VSL PHARMACEUTICALS, INC.,
LEADIANT BIOSCIENCES, INC., *f/k/a*
Sigma-Tau Pharmaceuticals, Inc., and
ALFASIGMA USA, INC.,

Defendants.

Civil Action No. TDC-19-2173

MEMORANDUM OPINION

Plaintiffs have filed this class action lawsuit against Defendants VSL Pharmaceuticals, Inc. (“VSL”), Leadiant Biosciences, Inc. (“Leadiant”), and Alfasigma USA, Inc. (“Alfasigma”) alleging violations of the Racketeer Influenced and Corrupt Organizations Act (“RICO”), 18 U.S.C. §§ 1961–68 (2018); breach of express warranty, in violation of the Uniform Commercial Code (“UCC”); unjust enrichment; and violations of various state consumer protection statutes. Defendants have filed a consolidated Motion to Dismiss, seeking dismissal of the entirety of

Plaintiffs' Amended Complaint. Plaintiffs oppose the Motion. Having reviewed the briefs and the submitted materials, the Court finds no hearing necessary. See D. Md. Local R. 105.6. For the reasons set forth below, Defendants' Motion to Dismiss will be GRANTED IN PART and DENIED IN PART.

BACKGROUND

This case is the latest in a long-running intellectual property dispute between former business partners Claudio De Simone and VSL as to who has rightful ownership of a proprietary probiotic formulation ("the De Simone Formulation") used in a product sold for many years under the name "VSL#3," a trademark owned by VSL. In prior litigation, that issue was put to a jury which, in November 2018, returned a verdict in favor of De Simone and his new business venture, ExeGi Pharma, LLC ("ExeGi"). On June 20, 2019, this Court issued a Permanent Injunction against Leadiant and Alfasigma, the companies that have marketed and distributed VSL#3 on behalf of VSL, enjoining them from (1) stating or suggesting in VSL#3 promotional materials directed at United States consumers that the present version of VSL#3 produced in Italy ("Italian VSL#3" or "the new VSL#3") continues to contain the De Simone Formulation, including by stating that VSL#3 contains the "original proprietary blend" or the "same mix in the same proportions" as the earlier version of VSL#3; and (2) "citing to or referring to any clinical studies performed on the De Simone Formulation or earlier versions of VSL#3 as relevant or applicable to Italian VSL#3." Prelim. Inj. Order at 2, ECF No. 930, *De Simone v. VSL Pharm., Inc.*, No. TDC-15-1356 (D. Md. June 20, 2019).

The full history of this dispute is set forth in the multiple opinions issued by this Court in that prior litigation. See *De Simone v. VSL Pharm., Inc.*, 133 F. Supp. 3d 776 (D. Md. 2015); *De Simone v. VSL Pharm., Inc.*, No. TDC-15-1356, 2016 WL 3466033 (D. Md. June 20, 2016); *De*

Simone v. VSL Pharm., Inc., 352 F. Supp. 3d 471 (D. Md. 2018); *De Simone v. VSL Pharm., Inc.*, 395 F. Supp. 3d 617 (D. Md. 2019); and *De Simone v. VSL Pharm., Inc.*, No. TDC-15-1356, 2019 WL 2569574 (D. Md. June 20, 2019). New facts or revisited facts central to Plaintiffs' claims, as stated in the Amended Complaint, are set forth below.

Plaintiffs allege that beginning in about 2013, Paulo Cavazza and members and representatives of the Cavazza family in Italy (collectively, "the Cavazza Family"), De Simone's original business partners in bringing the De Simone Formulation to market as VSL#3, began to push for changes to that formulation, specifically the use of cheaper bacterial strains in place of the original strains in order to increase profit margins. In mid-2014, with pressure mounting to market a fraudulent version of VSL#3, De Simone broke from the Cavazza Family, took the De Simone Formulation with him to a new company, ExeGi, and severed the rights of VSL and Leadiant, the company which marketed and distributed VSL#3, to buy or market the De Simone Formulation. At some point in 2016, Defendants ran out of their existing supply of VSL#3 containing the De Simone Formulation and thus began selling the new VSL#3, a probiotic produced in Italy with a different formulation, under the name "VSL#3," while claiming in their packaging materials and marketing activities that it still contained the De Simone Formulation. Plaintiffs allege that Defendants made such claims despite scientific evidence establishing that the new VSL#3 was neither the same, nor as clinically effective, as the De Simone Formulation.

As to packaging, Plaintiffs assert that Defendants improperly continued to use the VSL#3 trademark to identify the new probiotic, even though that mark had become associated with the De Simone Formulation. At some point, however, the packaging was changed to remove labeling information detailing the specific bacterial strains in the probiotic. Plaintiffs assert that this change was made to enable Defendants to avoid making any admission that their formulation was no

longer the De Simone Formulation. Yet on the product information sheet inside the package, Defendants continued to state that the new VSL#3 had been the subject of extensive clinical research and cited to clinical studies establishing the efficacy of the De Simone Formulation, not the new formulation.

As to advertising, in May 2016, after Defendants lost access to the De Simone Formulation, Leadiant sent a letter to all health care providers who had previously recommended VSL#3 to their patients stating that production of VSL#3 would be moving to Italy but assuring customers that they would be receiving “the same quality product, containing the same genus and species of bacteria, in the same proportions you have come to expect.” Am. Compl. ¶ 79, ECF No. 40. Other Leadiant marketing materials made similar representations. For example, a script to be used in responding to inquiries from health care providers stated that the new VSL#3 remained “the same multi-strain probiotic” as the De Simone Formulation. *Id.* ¶ 80. A May 24, 2016 Leadiant press release stated that the new VSL#3 was “supported by more than 170 studies” and thus falsely claimed a continuity between the studies, which were conducted on the De Simone Formulation, and the new version of VSL#3. *Id.* ¶¶ 79-81.

When Alfasigma took over the distribution of VSL#3 from Leadiant in mid-2016, its advertising advanced the same message, including in an August 2016 press release asserting that the new VSL#3 “maintain[ed] the original proprietary mix of eight strains of live bacteria” and was “supported by more than 170 published studies over the past 15 years.” *Id.* ¶ 86. Similar statements appeared on Alfasigma’s website. In Facebook postings responding to customer inquiries, Alfasigma stated that the new VSL#3 contained the “same 8 diverse strains and high potency” that had proven effective for the past 15 years. *Id.* ¶ 92. Such advertising and marketing

statements appear to have continued through 2018, when the Alfasigma website contained the statement that VSL#3 had “demonstrated over 15 years of success.” *Id.* ¶ 97.

Between June 2016 and the present, each of the named Plaintiffs routinely purchased the new VSL#3 and assert that, in doing so, they relied on the packaging and marketing materials, which convey the message that the new version of VSL#3 is the same as the version produced with the De Simone Formulation. Many also relied on the recommendation of their doctors. Each Plaintiff thus believed that the new VSL#3 continued to contain the De Simone Formulation.

On July 23, 2019, Plaintiffs filed this class action lawsuit. Defendants filed a Motion to Dismiss, to which the Plaintiffs responded by filing an Amended Complaint. In their Amended Complaint, Plaintiffs assert 19 causes of action, numbered as follows: (1) violations of RICO, 18 U.S.C. §§ 1962(c)-(d); (2) breach of express warranty, in violation of the UCC; (3) unjust enrichment; (4) a violation of the Massachusetts Consumer Protection Act, Mass. Gen. Laws Ann. ch. 93A § 2 (West 2006); (5) a violation of the California Consumer Legal Remedies Act, Cal. Civ. Code §§ 1750–85 (West 2019); (6) a violation of the California False Advertising Law, Cal. Bus. & Prof. Code §§ 17500–09 (West 2017); (7) a violation of the California Unfair Competition Law, Cal. Bus. & Prof. Code §§ 17200–10; (8) a violation of the Texas Deceptive Trade Practices Act, Tex. Bus. & Com. Code Ann. §§ 17.01–17.955 (West 2020); (9) a violation of the New Jersey Consumer Fraud Act, N.J. Stat. Ann. § 56:8-1–8-226 (West 2012); (10) a violation of the Michigan Consumer Protection Act, Mich. Comp. Laws Ann. §§ 445.901–922 (West 2011); (11) a violation of the Illinois Consumer Fraud and Deceptive Business Practices Act, Ch. 815 Ill. Comp. Stat. Ann. Act 505 §§ 1–12 (West 2008); (12) a violation of the Illinois Uniform Deceptive Trade Practices Act, Ch. 815 Ill. Comp. Stat. Ann. Act 510 §§ 1–7; (13) a violation of the Washington Consumer Protection Act, Wash. Rev. Code Ann. §§ 19.86.010–920 (West 2013); (14) a violation

of the Florida Deceptive and Unfair Trade Practices Act, Fl. Stat. Ann. §§ 501.201–213 (West 2016); (15) violations of Florida false advertising laws, Fl. Stat. Ann. §§ 817.06, 817.40–47 (West 2016); (16) a violation of the Idaho Consumer Protection Act, Idaho Code Ann. §§ 48-601–619 (West 2006); (17) a violation of the Kentucky Consumer Protection Act, Ky. Rev. Stat. Ann. §§ 367.110–360 (West 2015); (18) a violation of the Tennessee Consumer Protection Act, Tenn. Code Ann. §§ 47-18-101–132 (West 2002); and (19) a violation of the Wisconsin Deceptive Trade Practices Act, Wis. Stat. Ann. §§ 100.18–187 (West 2010).

DISCUSSION

In their Motion to Dismiss, Defendants generally assert that Plaintiffs’ allegations fail to satisfy the heightened pleading standards of Federal Rule of Civil Procedure 9(b). They also argue that the allegations in the Amended Complaint fail to state plausible claims of violations of RICO, breach of an express warranty, unjust enrichment, or violations of any of the identified state consumer protection laws.

I. Legal Standard

To defeat a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), the complaint must allege enough facts to state a plausible claim for relief. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). A claim is plausible when the facts pleaded allow “the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* Legal conclusions or conclusory statements do not suffice. *Id.* The Court must examine the complaint as a whole, consider the factual allegations in the complaint as true, and construe the factual allegations in the light most favorable to the plaintiff. *Albright v. Oliver*, 510 U.S. 266, 268 (1994); *Lambeth v. Bd. of Comm’rs of Davidson Cty.*, 407 F.3d 266, 268 (4th Cir. 2005).

Because some of Plaintiffs' allegations sound in fraud, they are subject to the heightened pleading standards of Rule 9(b) for those counts. *See* Fed. R. Civ. P. 9(b) ("In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake."). Under this heightened pleading standard, Plaintiffs must allege "the time, place, and contents" of the fraudulent representation, the identity of the person who made the misrepresentation, and "what he obtained thereby." *See Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 784 (4th Cir. 1999).

II. Rule 9(b)

Defendants first assert that the Amended Complaint fails to fulfill the Rule 9(b) heightened pleading standard for fraud-based claims because, for example, the allegations do not adequately distinguish between Defendants; they do not provide enough specificity on the language in the VSL#3 marketing materials alleged to be fraudulent; and they fail to plead with sufficient particularity the specific acts of mail or wire fraud by each Defendant.

This argument warrants little comment. A review of the 94-page Amended Complaint reveals numerous allegations of specific false statements in packaging and marketing materials by Leadiant and Alfasigma, assertions that VSL provided content for some of these false statements posted on the VSL#3 website controlled by Alfasigma, and allegations that Defendants were working in concert to advance the fraudulent scheme based on such statements. Moreover, the United States Court of Appeals for the Fourth Circuit has stated that a court should "hesitate to dismiss a complaint under Rule 9(b) if [it] is satisfied (1) that the defendant has been made aware of the particular circumstances for which it will have to prepare a defense at trial, and (2) that plaintiff has substantial prediscovery evidence of those facts." *McCauley v. Home Loan Inv. Bank, F.S.B.*, 710 F.3d 551, 559 (4th Cir. 2013). Here, the extensive history of litigation between these

parties—consisting of at least four different lawsuits filed in this Court alone—makes clear that these parties are not strangers to one another, and that the disputes at the core of this lawsuit are no surprise to Defendants. Indeed, in another case about this same probiotic, VSL has a pending counterclaim against De Simone and ExeGi in which it asserts that it is they—not VSL—who are selling a misleading product. *See ExeGi v. VSL*, No. TDC-19-2479 (D. Md. July 23, 2020). Further, each Defendant was also a party to the original case in this Court, in which the parties litigated the question whether Leadiant and Alfasigma had engaged in false advertising involving some of the same alleged false statements recounted in the Amended Complaint. Defendants thus know well what this case is about, and, where there is an extensive record relating to alleged false statements in marketing materials from that earlier litigation, Plaintiffs plainly have “substantial prediscovery evidence” of the relevant facts. *McCauley*, 710 F.3d at 559. Defendants’ Rule 9(b) arguments therefore fail.

III. RICO

In Count 1, Plaintiffs allege that Defendants engaged in a civil violation of RICO and a RICO conspiracy, in violation of 18 U.S.C. § 1962(c) and (d). As relevant here, RICO makes it “unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise’s affairs through a pattern of racketeering activity.” 18 U.S.C. § 1962(c). The same statute makes it “unlawful for any person to conspire to violate” RICO provisions, including § 1962(c). 18 U.S.C. § 1962(d). Under RICO, a “person” is “any individual or entity capable of holding a legal or beneficial interest in property.” 18 U.S.C. § 1961(3). An “enterprise” includes “any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity.”

18 U.S.C. § 1961(4). The term “racketeering activity” includes acts that are “indictable” under various federal criminal laws, including mail fraud, 18 U.S.C. § 1341, and wire fraud, 18 U.S.C. § 1343. 18 U.S.C. § 1961(1).

In Count 1, Plaintiffs allege that there was a RICO “enterprise,” which they label as the “VSL#3 Enterprise,” consisting of Defendants, representatives of the Cavazza Family, and the Italian manufacturers of VSL#3, whose aim was to manufacture, market, and sell the new VSL#3 while deceiving consumers with false representations that the current formulation is the same as the De Simone Formulation, in order to cause them to purchase the new VSL#3 and thereby maximize revenues and profits. Am. Compl. ¶¶ 154-55. Plaintiffs assert that each member of the enterprise played a different and important role in the enterprise’s purpose, with VSL licensing the right to sell VSL#3 and with Leadiant and Alfasigma marketing and selling VSL#3 pursuant to that license. The scheme was allegedly spearheaded by the Cavazza Family, which had ownership interests in the various Defendant companies. Plaintiffs allege, in particular, that Defendants engaged in acts of mail fraud and wire fraud in order to effectuate the scheme.

Defendants assert that the allegations are insufficient to support a plausible RICO claim on several grounds. First, Defendants argue that the Amended Complaint does not plausibly allege (1) acts of racketeering activity, specifically, either acts of mail fraud or wire fraud, or (2) that Defendants acted with fraudulent intent. Second, they assert that the allegations do not show that they were part of a RICO “enterprise” under 18 U.S.C. § 1962(c), because Plaintiffs have inadequately distinguished between “person” and “enterprise” and have inadequately alleged that Defendants engaged in the work of the enterprise itself rather than merely working to advance their own individual interests. Mot. Dismiss at 18-21, ECF No. 49. Third, Defendants assert that Plaintiffs have failed adequately to allege that Defendants conducted the affairs of the enterprise

by participating in the operation or management of the enterprise. Fourth, Defendants argue that the allegations do not establish a “pattern” of racketeering activity actionable under RICO. Fifth, Defendants assert that the allegations are insufficient to establish that the acts of racketeering activity actually caused them injury because Plaintiffs have not adequately pleaded detrimental reliance on the alleged false statements. Lastly, Defendants assert that because the substantive RICO claim fails, the RICO conspiracy claim necessarily also fails.

A. Racketeering Activity

Defendants’ first argument for dismissal of the RICO claim is that the requisite racketeering activity, specifically, acts of mail and wire fraud, are not pleaded with sufficient particularity. Mail fraud consists of (1) devising or intending to devise “any scheme or artifice to defraud, or for obtaining money or property by means of false or fraudulent pretenses, representations, or promises”; and (2) “for the purpose of executing such scheme or artifice or attempting so to do,” placing “any matter or thing whatever to be sent or delivered by the Postal Service” into “any post office or authorized depository for mail matter” or knowingly causing such matter to be delivered by mail. 18 U.S.C. § 1341. Wire fraud, similarly, consists of (1) devising or intending to devise “any scheme or artifice to defraud, or for obtaining money or property by means of false or fraudulent pretenses, representations, or promises”; and (2) transmitting or causing to be transmitted “by means of wire, radio, or television communication in interstate or foreign commerce, any writings, signs, signals, pictures, or sounds for the purpose of executing such scheme or artifice.” 18 U.S.C. § 1343.

As discussed above, Plaintiffs have adequately and specifically alleged that Defendants engaged in a scheme to deceive consumers by selling the new VSL#3 through the use false representations that it was the same as the prior version that used the De Simone Formulation, and

they sought to obtain money in the form of increased profits from sales. *See supra* part II. These allegations are sufficient on the element of a scheme to defraud. As for the use of the mails and interstate wires, Plaintiffs assert that the scheme was furthered by the shipping of VSL#3 packages and the sending of marketing materials and other correspondence to prescribing physicians by U.S. mail, and by the distribution by wire, specifically the internet, of marketing and advertising materials with false or fraudulent misrepresentations, such as the false or misleading statements on the VSL#3 website.

Although Defendants argue that Plaintiffs have not alleged that VSL specifically transmitted advertising materials relating to VSL#3, and that Plaintiffs have not alleged that the advertising materials sent by Alfasigma or Leadiant actually made their way directly to consumers, Defendants misunderstand the mail and wire elements of these offenses. A defendant need not personally mail or transmit by a wire; it is sufficient to have acted in way that caused such a mailing or transmission. *See* 18 U.S.C. §§ 1341, 1343. Moreover, there is no requirement that the mailed VSL#3 packages or electronically transmitted materials actually contained false statements relied upon by consumers. These elements can be satisfied by, for example, “‘innocent’ mailings—ones that contain no false information,” or mail or wire communications that are “routine,” as long as they are in furtherance of the overall unlawful scheme. *Schmuck v. United States*, 489 U.S. 705, 714–15 (1989). Here, Plaintiffs have alleged that VSL participated in the scheme to defraud and worked with Alfasigma on misleading content for the VSL#3 website, and they have alleged facts supporting the conclusion that Defendants used both the U.S. mail and interstate wires in furtherance of a scheme to defraud, including that VSL#3 packages with inserts containing false claims were mailed and false statements about the current formulation of VSL#3 were posted on the VSL#3 website. The Court therefore finds the allegations sufficient on these points.

Defendants also assert that Plaintiffs fail to plead Defendants' criminal intent to defraud with requisite specificity. This argument ignores the plain text of Rule 9(b), which states that "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). Where Plaintiffs have alleged, among other facts, that the Cavazza Family specifically proposed to change the formulation of VSL#3 to use cheaper bacterial strains without telling consumers, and that Defendants were acting in concert with the Cavazzas, this argument provides no basis for dismissal.

B. Enterprise

Defendants also seek dismissal on the ground that Plaintiffs have failed to allege that there was an "enterprise" within the meaning of RICO. Plaintiffs have alleged the existence of "the VSL#3 Enterprise" consisting of Defendants, members of the Cavazza Family, and CSA and Nutrilinea, two Italian manufacturers of VSL#3. Am. Compl. ¶ 154. Where, as here, Plaintiffs are not alleging that the RICO enterprise at issue is an "individual, partnership, corporation, association, or other legal entity," but rather is a "union or group of individuals associated in fact although not a legal entity," 18 U.S.C. § 1961(4), it is considered an "associated-in-fact enterprise." *United States v. Tillett*, 763 F.2d 628, 631 n.2 (4th Cir. 1985). An associated-in-fact enterprise consists of "a group of persons associated together for a common purpose of engaging in a course of conduct" and thus requires the existence of "an ongoing organization, formal or informal" and various members functioning "as a continuing unit." *Boyle v. United States*, 556 U.S. 938, 944-45 (2009). It must have certain structural features consisting of: (1) "a purpose," (2) "relationships among those associated with the enterprise," and (3) "longevity sufficient to permit these associates to pursue the enterprise's purpose." *Id.* at 946.

Defendants first argue that Plaintiffs have not properly alleged an enterprise because they have not identified an enterprise separate from the “persons” alleged to be at the center of the racketeering activity, the Cavazza Family. To support a RICO violation under § 1962(c), which applies to the conduct of a “person employed by or associated with [an] enterprise,” 18 U.S.C. § 1962(c), there must be both a “person” and an “enterprise” that is not the same as the “person” but just “referred to by a different name.” *Cedric Kushner Promotions, Ltd. v. King*, 533 U.S. 158, 161 (2001). Although Defendants point to the allegations that the Cavazza Family, directly or indirectly, has a controlling interest in each of their companies, the Amended Complaint specifically states that each named Defendant is, on its own, a “person” within the meaning of RICO because each is “capable of holding a legal or beneficial interest in property,” Am Compl. ¶ 153, and that each, as a separate entity, took its own specific acts separate from other acts taken by the Cavazza Family. *See Chambers v. King Buick*, 43 F. Supp. 3d 575, 590 (D. Md. 2014) (rejecting an argument that the complaint failed adequately to distinguish between “person” and “enterprise” where it stated that each Defendant was “a separately incorporated entity” and “had its own business location and employees”). Plaintiffs have adequately alleged both that Defendants were “persons” and that there was a separate “enterprise.”

Next, Defendants argue that the Amended Complaint does not adequately allege that Defendants conducted the enterprise’s affairs, rather than merely running their own businesses. For a RICO violation under § 1962(c), there must be a showing that “the defendants conducted or participated in the conduct of the ‘enterprise’s affairs,’ not just their own affairs.” *Cedric Kushner Promotions, Ltd.*, 533 U.S. at 163 (quoting *Reves v. Ernst & Young*, 507 U.S. 170, 185 (1993)). A RICO enterprise cannot merely be a “run-of-the-mill commercial relationship where each entity acts in its individual capacity to pursue its individual self-interest.” *Bible v. United Student Aid*

Funds, Inc., 799 F.3d 633, 655–56 (7th Cir. 2015). Instead, it must be a “truly joint enterprise where each individual entity acts in concert with the others to pursue a common interest.” *Id.* at 656.

Accepting the allegations in the Amended Complaint as true, as required at this stage of the proceedings, *Albright*, 510 U.S. at 268, the Court finds that Plaintiffs have adequately alleged such a joint enterprise. In particular, Plaintiffs have alleged an overarching plan developed by the Cavazza Family to change the formulation of VSL#3 without informing consumers that was executed through coordinated efforts of all three Defendant entities, over which the Cavazza Family had significant influence and control. Where the Cavazza Family and its plan provide the thread that ties these Defendants together, Plaintiffs have plausibly alleged that Defendants were not just separate, stranger businesses engaged in independent commercial activity. The allegations here thus differ from those in *United Food and Commercial Workers Union and Employers Midwest Health Benefits Fund v. Walgreen, Co.*, 719 F.3d 849 (7th Cir. 2013), relied on by Defendants, in which a complaint asserting that the defendants jointly participated in a drug substitution and overcharging scheme contained no allegations that either defendant was “involved ... in the affairs of the other,” but instead described conduct “entirely consistent” with each company “going about its own business” to “advance their individual self-interests.” *Id.* at 854–55.

In particular, contrary to Defendants’ claim, the Amended Complaint alleges facts showing that Defendants engaged in coordinated efforts and were not simply engaged in “parallel conduct” which may be insufficient to establish an enterprise under RICO. *Almanza v. United Airlines, Inc.*, 851 F.3d 1060, 1068 (7th Cir. 2017). Not only did Leadiant and Alfasigma use strikingly similar language in their marketing materials, but the Amended Complaint also asserts that VSL and

Alfasigma collaborated on the content of the VSL#3 website, which contained many of the false statements about VSL#3, even while the Chief Executive Officer of VSL, Luca Guarna, as well as Paulo Cavazza, were aware that Defendants' scientists were not able to reverse engineer the De Simone Formulation. The Amended Complaint therefore sufficiently alleges coordinated efforts among the members of the enterprise.

C. Conduct of the Enterprise

Defendants also argue that the Amended Complaint does not allege sufficient facts to show that they acted "to conduct or participate, directly or indirectly, in the conduct of [the] enterprise's affairs" in order to be liable under RICO. 18 U.S.C. § 1962(c). This provision requires that the defendant have "participated in the operation or management of the enterprise itself." *Reves v. Ernst & Young*, 507 U.S. 170, 183 (1993). Defendants assert that Plaintiffs' allegations are lacking because they do not show that Defendants themselves directed the enterprise, but instead assert that it was the Cavazza Family that directed the operation and management of the purported enterprise while VSL, Leadiant, and Alfasigma were merely "surrogates" used "to implement the purported scheme." Mot. Dismiss at 22. Defendants misread this provision because under *Reves*, participating in the conduct of the enterprise's affairs includes not only the actions of "upper management" of the enterprise, but also the actions of "lower rung participants in the enterprise who are under the direction of upper management." *Reves*, 507 U.S. at 184. Where the Amended Complaint contains ample allegations that Defendants, even if under the direction of the Cavazza Family, participated extensively in the operation of the enterprise, this purported flaw in the Amended Complaint provides no basis for dismissal.

D. Pattern of Racketeering Activity

Defendants also contest whether the Amended Complaint adequately alleges a “pattern of racketeering activity” within the meaning of § 1962(c), which requires “at least two acts of racketeering activity” within a 10 year period. 18 U.S.C. §§ 1961(5), 1962(c). The “pattern” element requires the existence of predicate acts that (1) are “related” and (2) “amount to or pose a threat of continued criminal activity.” *H.J. Inc. v. Nw. Bell Tel. Co.*, 492 U.S. 229, 239 (1989). Predicate acts are “related” if they have “the same or similar purposes, results, participants, victims, or methods of commission, or otherwise are interrelated by distinguishing characteristics and are not isolated events.” *Id.* at 240 (quoting 18 U.S.C. § 3575(e)). Acts constitute “continued criminal activity” if there is a “closed period of repeated conduct . . . extending over a substantial period of time.” *Id.* at 241-42. The period of time to establish this “closed-ended” form of continuity typically must last over a year. *See Jackson v. BellSouth Telecomm’n*, 372 F.3d 1250, 1266–67 (11th Cir. 2004) (collecting cases); *see also Menasco v. Wasserman*, 886 F.2d 681, 684 (4th Cir. 1989) (finding no continuity where the predicate acts occurred over a one-year period). Alternatively, there is “continued criminal activity” if there has been repeated conduct “that by its nature projects into the future with a threat of repetition.” *H.J. Inc.*, 492 U.S. at 241–42. This form of continuity, focusing on the possibility of future conduct, is “open-ended” and can be established by, for example, evidence that “the predicate acts or offenses are part of an ongoing entity’s regular way of doing business.” *Id.* at 241-42.

Here, where Plaintiffs have alleged that the scheme lasted for three years—from June 2016 until the issuance of the June 2019 permanent injunction in *DeSimone v. VSL*, No. TDC-15-1356—they have plausibly alleged closed-end continuity. Moreover, Plaintiffs also properly allege open-ended continuity by asserting that Defendants and the other enterprise members effected this

scheme through a series of related acts that posed and continue to pose a threat of criminal activity, and that Defendants have shown that they would do so indefinitely. Although Defendants argue that there is no open-ended continuity because the June 20, 2019 permanent injunction prohibited Defendants from making false statements about VSL#3 going forward, Plaintiffs allege that VSL and Alfasigma are continuing such conduct even today. Even without that allegation, while the Fourth Circuit has rejected open-ended continuity when a defendant has voluntarily ceased his criminal activity “independently of discovery,” *Parcoil Corp. v. NOWSCO Well Serv., Ltd.*, 887 F.2d 502, 504 (4th Cir. 1989), it has nowhere endorsed the idea that forced cessation brings with it the boon of foreclosing liability under an open-ended continuity theory. Indeed, at least one United States Court of Appeals has suggested the contrary. See *Blue Cross & Blue Shield of Mich. v. Kamin*, 876 F.2d 543, 545–46 (6th Cir. 1989) (noting, in finding an open-ended scheme, that “if he had not been caught, there is no reason to believe [the defendant] would not still be submitting false claims”). Cf. *Lyons P’ship, L.P. v. Morris Costumes, Inc.*, 243 F.3d 789, 800 (4th Cir. 2001) (stating that “it is well established that the voluntary discontinuance of challenged activities by a defendant does not necessarily moot a lawsuit” (citation omitted)). Plaintiffs’ allegations, when credited, permit the inference that selling VSL#3 as “the same” as the De Simone Formulation was part of Defendants’ “regular way of doing business,” and that, in the absence of the permanent injunction, “by its nature” such conduct would “project[] into the future with a threat of repetition.” *H.J., Inc.*, 492 U.S. at 241-42. The Court thus concludes that Plaintiffs have adequately alleged continuity.

On the broader question of whether they have plausibly alleged a “pattern” of racketeering activity, in the Fourth Circuit, the existence of a pattern is to be determined not based on “mechanical rules,” but on a “case-by-case” basis upon consideration of “all the facts and

circumstances of the particular case,” including “criminal dimension and degree.” *Brandenburg v. Seidel*, 859 F.2d 1179, 1185 (4th Cir. 1988). “Factors relevant to this inquiry include the number and variety of predicate acts and the length of time over which they were committed, the number of putative victims, the presence of separate schemes, and the potential for multiple distinct injuries.” *Id.* Although the existence of only a single illegal scheme is relevant and weighs against a finding of continuity, “[p]redicate acts which arise under a single scheme ... may be a pattern for RICO purposes if they are continuous and related.” *Menasco*, 886 F.2d at 684. In weighing the factors, courts are to give “special attention to the context in which the predicate acts occur” and whether they reflect “ongoing criminal activity of sufficient scope and persistence to pose a special threat to social well-being.” *Brandenburg*, 859 F.2d at 1185 (citations omitted). Courts generally do not permit “ordinary business contract or fraud disputes to be transformed into federal RICO claims” and instead limit such claims to “schemes whose scope and persistence set them above the routine.” *Flip Mortg. Corp. v. McElhone*, 841 F.2d 531, 538 (4th Cir. 1988).

Defendants first argue that the pattern alleged by Plaintiffs is insufficient where it consists “a single scheme with a discrete goal.” Mot. Dismiss at 27 (quoting *Jackson*, 372 F.3d at 1267). The presence of only one scheme, however, does not alone preclude a finding of a pattern. See *Menasco*, 886 F.2d at 684; *Int’l Data Bank, Ltd. v. Zepkin*, 812 F.2d 149, 155 (4th Cir. 1987) (emphasizing that “no mechanical test can determine the existence of a RICO pattern” and rejecting a test that would foreclose RICO liability in all cases where there was only “one continuous scheme”). Defendants therefore also argue that the scheme that Plaintiffs have described amounts to ordinary commercial fraud and is not one for which the “scope and persistence pose a special threat to social well-being.” Mot. Dismiss at 25 (quoting *Menasco*, 886 F.2d at 684).

Here, Plaintiffs' allegations involve a single product—VSL#3—and largely focus on a single scheme to pass off a new formulation of VSL#3 as containing the De Simone Formulation when it does not. Defendants, together with members of the Cavazza Family and the Italian manufacturers of VSL#3, continued to market and sell VSL#3 as containing the De Simone Formulation despite knowing that they no longer had access to that formulation, and as having the same clinical effectiveness as the De Simone Formulation despite research findings to the contrary. The scheme consisted of unsuccessfully attempting to reverse engineer the De Simone Formulation and then developing a different formulation and establishing a manufacturing process in Italy; affirmatively marketing VSL#3 as the same product as the De Simone Formulation; falsely citing clinical studies on the De Simone Formulation as studies of their new formulation; and affirmatively concealing information about the differences between the products. The predicate acts included a wide variety of different forms of marketing and advertising by mail and wire, including the mailing of product packaging with false statements on the product information sheets, the posting of false or misleading statements on the VSL#3 website, the sending of letters with such statements directly to physicians who had previously prescribed VSL#3, and the posting of false or misleading information on Facebook and other social media. The victims of this scheme included a substantial number of consumers who previously used VSL#3, located all across the United States, and who used doctors similarly located nationwide. Plaintiffs assert that this conduct continued even after Defendants lost at trial and up until this Court issued a permanent injunction.

Upon consideration of these facts, the Court finds that while Plaintiffs allege a single scheme, its duration, the number and variety of forms of predicate acts, and the number of victims place it beyond the single schemes referenced by Defendants that were of limited duration or

involved only one or a limited number of victims. For example, in *Flip Mortgage v. McElhone*, 841 F.2d 531 (4th Cir. 1988), cited by Defendants, the court found that the scheme in question was not actionable where it was a “single scheme” against a “single victim” and was effectively a dispute between two companies over the equitable division of profits and a failure by one of the companies to properly account for—and remit the appropriate share of—some of those profits. *Id.* at 533, 538. Likewise, in *Jackson v. BellSouth Telecommunications*, 372 F.3d 1250 (11th Cir. 2004), the court upheld the dismissal of a RICO claim based on the lack of allegations of a pattern of racketeering activity where the alleged racketeering occurred over a period of only nine months and stemmed entirely from allegedly “unlawful and unethical” practices by defendant BellSouth and plaintiffs’ counsel in the negotiation of a global settlement of two multi-plaintiff employment discrimination suits. *Id.* at 1255-60, 1267 (noting that the case involved a “single lawsuit” rather than a “series of cases” in which the alleged misconduct occurred).

Moreover, the alleged scheme is not comparable to the “ordinary or garden-variety fraud claims better prosecuted under state law” that are insufficient to support a RICO claim. *Al-Abood ex rel. Al-Abood v. El-Shamari*, 217 F.3d 225, 238 (4th Cir. 2000). In *Al-Abood*, the Fourth Circuit upheld a grant of judgment as a matter of law in favor of defendants because although there were three different fraud schemes over several years, the focus of the pattern of activity was “narrow” in that it was “essentially a dispute between formerly close family friends” in which a single victim, a widow, lost her personal savings in fraudulent investment arrangements proposed by her friend and the friend’s son. 217 F.3d at 230-31, 238 (finding the scheme “not sufficiently outside the heartland of fraud cases to warrant RICO treatment”). Likewise, in *International Data Bank, Ltd. v. Zepkin*, 812 F.2d 149 (4th Cir. 1987), the court found no viable RICO claim arising from a “single, limited scheme to defraud” predicated only on a statement in an investment prospectus

issued for a financial services company for which the defendants had advanced over \$116,685 in startup costs, which was later found to be untrue. *Id.* at 150-51, 154.

By contrast, though Plaintiffs' allegations involve a commercial dispute between former business partners, they arguably include an additional layer of impact where they describe a multi-year enterprise involving a substantial number of false and misleading marketing and advertising materials disseminated through a nationwide distribution and sales network that victimized numerous individuals across the United States. It can therefore be viewed as the kind of "open-ended scheme contemplating the repeated infliction of independent economic injuries on an indiscriminate number of victims" that "may well pose a special threat to social well-being." *See Walk v. Balt. & Ohio R.R.*, 847 F.2d 1100, 1105 (4th Cir. 1988), *vacated on other grounds*, 492 U.S. 914 (1989). Notably, Plaintiffs have alleged a scheme whose victims generally have health conditions for which they had come to rely on a particular product, such that it had, at a minimum, the potential to adversely impact the health of a significant number of individuals. Under these circumstances, the alleged scheme, when viewed in the light most favorable to Plaintiffs, arguably has the kind of "scope and persistence to pose a special threat to social well-being" that places the alleged pattern of racketeering activity beyond the ordinary fraud claims consisting of private economic disputes that do not qualify as RICO claims. *Brandenburg*, 859 F.2d at 1185.

E. Causation

The RICO statute provides that "[a]ny person injured in his business or property by reason of a violation of section 1962" may pursue a civil action for damages. 18 U.S.C. § 1964(c). Presumably drawing on this statutory language, Defendants assert that Plaintiffs must allege both "injury and causation" in order to have standing to assert a RICO claim. *Mot. Dismiss* at 28.

With RICO, as with all causes of action in federal court, a “plaintiff only has standing if, and can only recover to the extent that, he has been injured in his business or property by the conduct constituting the [RICO] violation.” *Sedima, S.P.R.L. v. Imrex Co.*, 473 U.S. 479, 496 (1985). However, “[w]here the plaintiff alleges each element of [a RICO] violation,” namely, the “(1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity,” “the compensable injury necessarily is the harm caused by predicate acts sufficiently related to constitute a pattern, for the essence of the violation is the commission of those acts in connection with the conduct of an enterprise.” *Id.* at 496–97. Accordingly, a complaint “is not deficient for failure to allege ... an injury separate from the financial loss stemming from the alleged acts of mail and wire fraud.” *Id.* at 500. Where Plaintiffs have alleged such injury in the form of the costs of VSL#3 that they would not have otherwise incurred, they have provided sufficient allegations on this issue.

As for the issue of causation, Defendants assert that a civil RICO claim, in providing that a plaintiff must be injured “by reason of a violation of § 1962,” 18 U.S.C. § 1964(c), requires that Plaintiffs allege detrimental reliance on a Defendant’s misrepresentation. As Defendants acknowledge, however, the United States Supreme Court has expressly held that on a RICO claim, there is no requirement that the plaintiff establish reliance on the defendant’s misrepresentation, not even to establish proximate causation. *Bridge v. Phoenix Bond & Indem. Co.*, 553 U.S. 639, 655–56 (2008). Rather, reliance “has no place in a remedial scheme keyed to the commission of mail fraud, a statutory offense that is distinct from common-law fraud and that does not require proof of reliance.” *Id.* at 656. As an example relevant here, the Court noted that if an enterprise seeking to “get rid of rival businesses mails misrepresentations about them to their customers and suppliers, but not to the rivals themselves,” the rival business could still be injured by the

misrepresentations “even though they never received, and therefore never relied on, the fraudulent mailings.” *Id.* at 649-50. The Court further concluded that although “it may well be that a RICO plaintiff ... must establish at least third-party reliance in order to prove causation,” that is, that “*someone* relied on the defendant’s misrepresentations,” such reliance would be a means to establish causation, not an element of the plaintiff’s cause of action. *Id.* at 658–59. Plaintiffs are therefore not required to allege that they relied on any of the allegedly false statements about VSL#3 made by Defendants.

Defendants, however, point to case law in which courts, including the United States Court of Appeals for the Seventh Circuit, rejected RICO claims filed by health insurance companies who alleged injury when representatives of prescription drug manufacturers made misrepresentations to physicians who then prescribed the drugs to patients, resulting in insurance charges. *See, e.g., Sidney Hillman Health Ctr. of Rochester v. Abbott Labs.*, 873 F.3d 574, 578 (7th Cir. 2017) (affirming a grant of a motion to dismiss); *Sergeants Benevolent Assoc. Health and Welfare Fund v. Sanofi-Aventis U.S. LLP*, 806 F.3d 71, 98 (2d Cir. 2015) (affirming a grant of summary judgment); *see also Se. Laborers Health & Welfare Fund v. Bayer Corp.*, 444 F. App’x 401, 410 (11th Cir. 2011). In *Sidney Hillman*, for example, the court reasoned that there were “so many layers, and so many independent decisions, between promotion and payment” that the allegations were insufficient to support a finding that a misrepresentation caused the charge to the insurance company. 873 F.3d at 578.

By contrast, however, the United States Court of Appeals for the First Circuit has held, after a trial on a RICO claim, that there was sufficient evidence to support a finding of causation against Pfizer based on alleged misrepresentations by its representatives marketing the drug Neurontin to physicians that then caused a “huge increase” in off-label prescriptions of Neurontin,

resulting in charges to the plaintiff insurance company. See *In re Neurontin Mktg. & Sales Practices Litig.*, 712 F.3d 21, 39 (1st Cir. 2013). The court found that the fact that some physicians prescribed based on reasons other than the fraudulent marketing did not break the causal chain but instead “present[ed] a question of proof regarding the total number of prescriptions that were attributable to Pfizer’s actions.” *Id.*; cf. *In re Avandia Mktg., Sales Practices & Prod. Liab. Litig.*, 804 F.3d 633, 634, 645-46 (3d Cir. 2015) (affirming the district court’s denial of a motion to dismiss a RICO claim in which a third party alleged that it was directly injured because it stocked Avandia in its formulary based on the defendant’s misrepresentations). Thus, while courts differ on the issue, Plaintiffs have alleged, at a minimum, a legally viable theory of causation. Indeed, where they are patients, rather than third-party payors of healthcare costs, the chain of causation between the marketing and the decision to take VSL#3 may be more direct than in *In re Neurontin*.

Lastly, Defendants note that Plaintiffs have not explicitly alleged that any particular physician relied on misrepresentations in marketing materials in prescribing VSL#3 to one or more them. Plaintiffs, however, have alleged that the scheme included “a steady stream of communications to consumers and physicians that were designed to, and did in fact, create the false impression that VSL#3 was the same as it was before,” “written representations to the medical community, which were designed to influence advice by the medical community to consumers,” and statements that were “intended to confuse physicians and patients.” Am. Compl. ¶¶ 77, 93, 96. Some Plaintiffs allege that they took VSL#3 on the recommendation of their physician. Viewed in the light most favorable to Plaintiffs, these allegations collectively could support an inference that the misrepresentations influenced their physicians’ recommendations and thus caused them to purchase VSL#3. See *In re Neurontin*, 712 F.3d at 39. Though it is unclear whether Plaintiffs will identify sufficient evidence to establish causation through such third-party reliance

or some other means, that question will be resolved after discovery. At the pleading stage, however, Plaintiffs have stated a plausible claim for relief. Defendants' Motion will be denied as to the substantive RICO claim.

F. RICO Conspiracy

In seeking dismissal of Plaintiffs' RICO conspiracy claim under 18 U.S.C. § 1962(d), Defendants rely solely on their arguments for dismissal of the substantive RICO claim under § 1962(c). Because the Court will deny the Motion as to § 1962(c) claim, and the Amended Complaint alleges facts supporting an inference of an agreement to engage in concerted action among Defendants, the Court finds no basis for dismissal of the § 1962(d) claim.

IV. Breach of Express Warranty

Defendants seek dismissal of the breach of express warranty claim on the grounds that Plaintiffs have failed adequately to allege that (1) there was an express "affirmation of fact" or "promise"; (2) there was privity between Plaintiffs and Defendants; and (3) there was reliance upon the promise.

In Count 2, Plaintiffs allege a cause of action for breach of express warranty in violation of the UCC. Section 2-313 of the UCC, governing express warranties, states:

- (1) Express warranties by the seller are created as follows:
 - (a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.
 - (b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.
 - (c) Any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model.

- (2) It is not necessary to the creation of an express warranty that the seller use formal words such as “warranty” or “guarantee” or that he have a specific intention to make a warranty, but an affirmation merely of the value of the goods or a statement purporting to be merely the seller’s opinion or commendation of the goods does not create a warranty.

U.C.C. § 2-313 (West 2019). The UCC is a “model code” that “does not itself have the force of law Instead, it has been enacted with modifications in the several states.” *Linear Tech. Corp. v. Micrel, Inc.*, 275 F.3d 1040, 1048 (Fed. Cir. 2001). Plaintiffs’ claim thus must be construed as a breach of express warranty claim under the laws of the states of each of the named Plaintiffs. *See id.* (noting that interpreting a UCC provision requires a court to “draw guidance [from] the state and federal courts interpreting their individual versions of the UCC”). The Court therefore discusses any specific, variant state provisions, and relevant interpretations thereof, as needed below.

A. “Affirmation of Fact” or “Promise”

Defendants first assert that Plaintiffs fail adequately to plead that Defendants made an express affirmation of fact or promise as to the quality or characteristics of VSL#3. Defendants identify no salient distinctions between the various state laws on this point, so the Court addresses the argument using the language of the UCC model provision.

Plaintiffs identify two primary promises. First, they allege that the product information sheet within the packaging of the new VSL#3 contained the statement that “VSL#3 has been the subject of extensive clinical research in the dietary management of IBS, UC, and an ileal pouch” despite the fact that it was the De Simone Formulation, not the new VSL#3, that had been the subject of those clinical studies. Am. Compl. ¶ 74. Defendants offer no argument as to why this statement was not an affirmation of fact or promise about the new VSL#3. Based on this statement alone, Defendants’ claim that Plaintiffs failed to allege a promise necessarily fails. *See, e.g., Small*

v. Amgen, Inc., 2 F. Supp. 3d 1292, 1298–99 (M.D. Fla. 2014) (finding that the plaintiffs had adequately alleged a breach of express warranty claim based on claims in package inserts and marketing literature that a drug was fit for use).

Second, Plaintiffs assert that the continued use of the term “VSL#3” on the packaging of the new VSL#3 itself constituted an affirmation of fact that the product was the same as the prior version of VSL#3 using the De Simone Formulation. On this point, Defendants assert that no breach of express warranty claim can be based on the use of the VSL#3 trademark alone because it “at most, expressly warrants that the product the consumer purchased is the product sold under the VSL#3 trademark,” not that it is a specific product with particular ingredients and of particular quality. Mot. Dismiss at 34. Defendants rely on various cases in which the use of a trademark or brand name was deemed not to constitute an affirmative representation about the quality of a product. For example, in *Rubenstein v. The Gap*, 222 Cal. Rptr. 3d 397, 404 (Cal. Ct. App. 2017), a California court applying state consumer protection laws concluded that The Gap, Inc.’s use of its brand name on clothing produced for its factory stores was not deceptive or a form of false advertising even if that clothing was of a lower quality than the clothes sold in regular Gap stores, because the purchaser was “still getting a Gap . . . item” and in any event a customer could personally assess the quality of the goods in the store. *Id.* at 874, 877. Similarly, in *Hodges v. Apple, Inc.*, No. 13-cv-01128-WHO, 2013 WL 6698762 (N.D. Cal. Dec. 19, 2013), a plaintiff asserted a claim against Apple, Inc. that because MacBook Pro laptop computers manufactured by LG were inferior in quality to those produced by Samsung, the use of the Apple mark on the LG-manufactured MacBook Pros amounted to a false “affirmative representation of equal quality” that violated various California consumer protection statutes. *Id.* at *1-2, *5. In dismissing the claim, the court found no misrepresentation because Apple’s trademark had not functioned as an

“affirmative representation[] that all products named the same are, in fact, alike.” *Id.* at *5 (citation omitted).

Although instructive on the principle that the use of a brand name or trademark, in and of itself, does not necessarily convey a particular representation about the contents or quality of a product, these cases focus on the meaning conveyed by the use of a brand name or trademark for multiple products at the same time and do not address the present issue of whether a brand name or trademark can, over time, become so identified with a particular product that its continued use constitutes an affirmation of fact of continuity. Notably, a trademark “is not only a symbol of origin,” but also “a symbol of a certain type of goods or services and their level of quality,” such that “a sudden or substantial change in the nature or quality of the goods sold under a mark may so change the nature of the thing symbolized that the mark becomes fraudulent.” 3 McCarthy on Trademarks and Unfair Competition § 17:24 (5th ed. 2020). Consistent with this principle, Plaintiffs rely on *Royal Baking Powder Company v. Federal Trade Commission*, 281 F. 744 (2d Cir. 1922), in which the Royal Baking Powder Company (“Royal Baking”) had for 60 years produced a “superior” baking powder under the brand name “Dr. Price’s Cream Baking Powder” which contained cream of tartar, rather than phosphate or alum, and had in its advertising touted the benefits of cream of tartar while warning of the dangers of phosphate and alum. *Id.* at 747, 753. Where Royal Baking substituted phosphate in place of cream of tartar for cost reasons, but kept the same product name and used the reference “Makers for 60 years,” the United States Court of Appeals of the Second Circuit upheld a Federal Trade Commission order directing Royal Baking to cease and desist from selling the new version as “Dr. Price’s Cream Baking Powder,” unless the word “cream” was omitted and the word “phosphate” included, because it was a “deception of the public” to sell an “inferior powder” “under an impression induced by its

advertisements that the product purchased was the same in kind and as superior as that which had been so long manufactured by it.” *Id.* at 747–48, 750, 753. Likewise, in a case under state law addressing the exact same issue of the arguable deceptiveness of “Dr. Price’s Cream Baking Powder,” the United States Court of Appeals for the Eighth Circuit held that “[i]f the manufacturer makes a change in the article and that change be of a character which would, considering all of the attendant circumstances, naturally affect the attitude of the purchasers of that article, fair dealing and the law require that such purchasers be effectively informed of that change.” *Royal Baking Powder Co. v. Emerson*, 270 F. 429, 440 (8th Cir. 1920). The court therefore concluded that where the product’s “label has been long employed and has become familiar to the public” and “the acid ingredient of the baking powder was a material consideration in the mind of the purchasing public,” the continued use of the former brand name and trade dress amounted to a “misbrand, which would probably and naturally deceive the average purchasers of the former powder.” *Id.* at 440–41.

Although not addressing an issue of trademark or a claim of breach of express warranty, the *Royal Baking* cases are instructive in their conclusion that a brand name can come to function as a representation of a continuity of product contents and quality that could deceive those “familiar with the old brand and ignorant of any change.” *Emerson*, 270 F. at 440. As in these cases, and unlike in *Rubinstein* and *Hodges*, VSL#3 was used for years to signify a particular product formulation—a probiotic with the De Simone Formulation—only to have Defendants change the longstanding formulation while continuing to appear as if they had not and thereby seek to “pass off” a new, inferior product as the original one. *Royal Baking*, 281 F. at 753. Thus, the *Royal Baking* cases suggest that Plaintiffs’ trademark-as-warranty legal theory is at least plausible one. Particularly when the use of the mark “VSL#3” not only could arguably constitute an affirmation of fact, but also was accompanied by a product information sheet containing more

specific false affirmations, dismissal of the breach of express warranty claim at this stage is not warranted.

Lastly, Defendants contend that the warranty claim failed adequately to plead an affirmation of fact or promise because the UCC “requires that a consumer have, at the *least*, pre-sale knowledge of or exposure to a specific advertisement or promotional representation that he or she alleges became part of the contract.” Mot. Dismiss at 36. However, in *In re Myford Touch Consumer Litigation.*, No. C-13-3072 EMC, 2015 WL 5118308 (N.D. Cal. Aug. 31, 2015), cited by Defendants, the court expressly rejected the argument that “a plaintiff must plead awareness of the terms of a clearly labeled express warranty that was provided to the consumer at the time of sale, in order to sue for breach of that warranty.” *Id.* at *5. Although *Center City Periodontists, P.C. v. Dentsply International, Inc.*, 321 F.R.D. 193 (E.D. Pa 2017), also cited by Defendants, noted that New Jersey law “require[s] awareness of extrinsic representations to activate the presumption that they became a part of the sales contract,” that case involved an express warranty class action claim based on information in the “Directions for Use” contained inside the product package, not visible prior to sale, and clarified that in determining if and when a buyer became aware of a seller’s representations, “[t]he focus is not on any particular language at a particular point in time but whether the seller’s actions or language when viewed in light of his relationship with the buyer were fairly regarded as part of the contract to purchase the good.” *Id.* at 198, 210. Regardless of the existence and contours of any such requirement in certain states, where Plaintiffs’ breach of warranty claim is based in part on the continued use of the VSL#3 brand name, and Plaintiffs have alleged that they were aware of its continued use on the packaging, such a requirement does not provide a basis for dismissal at the pleading stage.

B. Privity

Defendants further assert that in order to succeed on an express warranty claim under the respective laws of Washington, Texas, California, Illinois, Kentucky, Wisconsin, Florida, Tennessee, and Michigan, a plaintiff must be in privity with the defendant, and no such privity is pleaded or provable here.

As an initial matter, Plaintiffs correctly note that not all of Defendants' listed states have such a requirement. There is no such requirement in Washington. *See Fortune View Condo. Ass'n v. Fortune Star Dev. Co.*, 90 P.3d 1062, 1065 (Wash. 2004) (“[C]ontractual privity is not required to create express warranties.”). Nor does there appear to be such a requirement in Texas. *See PPG Indus., Inc. v. JMB/Houston Centers Partners Ltd. P’ship*, 146 S.W.3d 79, 88 (Tex. 2004) (stating that no privity of contract is required for an implied warranty claim and noting that “several lower courts have applied the same rule” to express warranties because “express warranties pass with the goods”); *Berge Helene Ltd. v. GE Oil & Gas, Inc.*, 830 F. Supp. 2d 235, 251 (S.D. Tex. 2011) (“As noted by the Texas Supreme Court in 2004, however, the more recent trend among the courts of appeals is not to require privity of contract for express warranty claims generally.” (citing *PPG Indus., Inc.*)).

Other identified states make an exception to the privity requirement when a manufacturer makes an express warranty to the ultimate consumer, such as through product packaging. For example, in California, “[t]he general rule is that privity of contract is required in an action for breach of either express or implied warranty,” but there is an exception to the rule when “the purchaser of a product relied on representations made by the manufacturer in labels or advertising material.” *Burr v. Sherwin Williams Co.*, 268 P.2d 1041, 1048–49 (Cal. 1954); *see Clemens v. DaimlerChrysler Corp.*, 534 F.3d 1017, 1023 (9th Cir. 2008) (noting, in the context of an implied

warranty, that California has an exception to the privity requirement “when the plaintiff relies on written labels or advertisements of a manufacturer”) (citing *Burr*).

Illinois has adopted a similar rule. See *Aquino v. C.R. Bard, Inc.*, 413 F. Supp. 3d 770, 787 (N.D. Ill. 2019) (holding that, under Illinois law, “[a]lthough generally there must also be privity of contract, an exception exists when a manufacturer expressly warranted its goods to the ultimate consumers and this was the basis for the bargain and relied upon by plaintiffs” (citations omitted)). Kentucky courts have not directly decided the issue, but a federal district court, upon consideration of relevant precedent, has “anticipate[d]” that Kentucky would adopt such a rule. *Naiser v. Unilever U.S., Inc.*, 975 F. Supp. 2d 727, 740 (W.D. Ky. 2013) (“The Court anticipates that Kentucky state courts would hold that an express warranty action can be maintained in cases such as this, where Unilever’s alleged written, express warranties were clearly intended for the product’s consumers.”).

Wisconsin has reached the same conclusion by different means, holding that when a manufacturer offers an express warranty, the manufacturer and the ultimate consumer are thereby in privity. See *Sunnyslope Grading, Inc. v. Miller, Bradford & Risberg, Inc.*, 437 N.W.2d 213, 215 (Wis. 1989) (“Because they were parties to an enforceable warranty, Sunnyslope and Hein–Werner were in privity.”); see also *Midwhey Powder Co. v. Clayton Indus.*, 460 N.W.2d 426, 430 (Wis. Ct. App. 1990) (stating that “[t]he *Sunnyslope* court held that because the ultimate purchaser of a backhoe and its manufacturer were parties to an enforceable warranty, they were in privity”).

As to Florida, Plaintiffs correctly note that Florida courts “have recognized a relaxed privity requirement in express warranty claims where a manufacturer makes direct representations to a purchaser.” *Atl. Specialty Ins. Co. v. Mercier Marine Enter., LLC*, No. 2:18-CV-93-FTM-29CM, 2018 WL 2331979, at *4 (M.D. Fla. May 23, 2018) (citing *Cedars of Lebanon Hosp. Corp.*

v. European X-Ray Distrib. of Am., Inc., 444 So. 2d 1068 (Fla. Dist. Ct. App. 1984)). In *Cedars*, however, the court expressly relied on “direct representations” consisting of an actual sales call by the manufacturer’s representative to the purchaser, who later purchased the equipment from a dealer, as the basis to permit a warranty claim absent strict privity. *Cedars of Lebanon Hosp. Corp. v. European X-Ray Distrib. of Am., Inc.*, 444 So. 2d 1068, 1072 & n.4 (Fla. Dist. Ct. App. 1984). Though such direct contact was not present here, Florida law appears to recognize an exception in cases where the product was a food or drug, and it has identified other privity exceptions such that Florida law remains unsettled on the question of whether privity is strictly required. *See id.* at 1071-72 (cataloguing the history of exceptions to the privity requirement in Florida courts). The Court thus cannot conclude that a privity requirement necessarily bars Plaintiffs’ claim for breach of express warranty in Florida.

As for Tennessee and Michigan, neither has articulated a relevant exception to the privity requirement. Instead, “Tennessee has joined those jurisdictions which hold that product liability claims resulting in pure economic loss can be better resolved on theories other than negligence.” *Ritter v. Custom Chemicides, Inc.*, 912 S.W.2d 128, 133 (Tenn. 1995). Thus, “a plaintiff may not maintain a claim for purely economic losses absent contractual privity with the party charged with responsibility for those losses.” *Messer Griesheim Indus., Inc. v. Cryotech of Kingsport, Inc.*, 131 S.W.3d 457, 463 (Tenn. Ct. App. 2003). While Tennessee has carved out an exception to this rule for some actions, including breach of express warranty claims, that exception extends only to causes of action for personal injury and property damage. *Id.* Where Tennessee law generally requires contractual privity for claims of economic loss and Plaintiffs have pointed to no authority establishing that the claims here fall within the permissible exceptions, the Court finds that this requirement applies to the breach of express warranty claim in Tennessee.

Plaintiffs' argument that the issue remains unsettled under Michigan law is unpersuasive. Though they are correct that "the Michigan Supreme Court has yet to rule on the privity issue regarding express-warranty claims," *Montgomery v. Kraft Foods Glob., Inc.*, 822 F.3d 304, 308 (6th Cir. 2016), the Michigan Court of Appeals, the intermediate appellate court, has held that for a breach of express warranty claim, "privity of contract is necessary for a remote purchaser to enforce a manufacturer's express warranty." *Heritage Res., Inc. v. Caterpillar Fin. Servs. Corp.*, 774 N.W.2d 332, 343 n. 12 (Mich. Ct. App. 2009); *Montgomery*, 822 F.3d at 308. In the absence of a decision from the Michigan Supreme Court, a decision from the Michigan Court of Appeals is binding authority. *See Montgomery*, 322 F.3d at 308.

The Court thus concludes that Tennessee and Michigan law each require a plaintiff to plead privity in order to sustain an express warranty claim. Plaintiffs have identified no such factual allegations in the Amended Complaint, nor has the Court found any. The Court will therefore grant the Motion as to Plaintiffs' UCC claims under Tennessee and Michigan law.

C. Reliance

Defendants next assert that under the respective laws of California, Florida, Wisconsin, Massachusetts, Tennessee, Texas, and Kentucky, Plaintiffs' express warranty claim requires that they plead reliance on the affirmation of fact, but Plaintiffs have failed adequately to do so. In response, Plaintiffs argue that California, Florida, Wisconsin, Massachusetts, and Tennessee either impose no reliance requirement or have a less stringent requirement than the one asserted by Defendants, and that in any event, they have adequately pleaded reliance. Because the Court will dismiss the Tennessee breach of express warranty claim based on a lack of privity, it need not address that claim here.

First, on the issue of whether these states impose a reliance requirement, California imposes no such requirement. *See Loomis v. Slendertone Distribution, Inc.*, 420 F. Supp. 3d 1046, 1087 (S.D. Cal. 2019) (stating that for express warranty claims “[u]nder the California Commercial Code, a plaintiff need not show reliance”) (citing *Weinstat v. Dentsply Int’l, Inc.*, 103 Cal. Rptr. 3d 614, 626 (Cal. Ct. App. 2010)). Nor does Florida require a plaintiff to plead reliance. *See CC-Aventura, Inc. v. Weitz Co., LLC*, No. 06-21598-CIV, 2009 WL 2136527, at *4 (S.D. Fla. July 13, 2009) (“Indeed, affirmations of fact made by the seller about the goods during a bargain are regarded as part of the description of those goods; hence no particular reliance on such statements need be shown in order to weave them into the fabric of the agreement.” (citing *Carter Hawley Hale Stores, Inc. v. Conley*, 372 So.2d 965, 968 (Fla. 3d DCA 1979))). Wisconsin law also lacks such a requirement. *See Ewers v. Eisenzopf*, 276 N.W.2d 802, 805 (Wis. 1979) (stating “that the seller’s intent and the buyer’s reliance were irrelevant to a determination of whether an express warranty had been made”); *Haley v. Kolbe & Kolbe Millwork Co.*, No. 14-CV-99-BBC, 2015 WL 3774496, at *16 (W.D. Wis. June 16, 2015) (“Although defendant suggests that plaintiffs must have ‘relied’ on the advertising statements, the statute does not make this an express requirement.”) (citing *Ewers*).

Courts applying Massachusetts law, however, have “found that some minimum of reliance is required to state [an express warranty] claim under Massachusetts law.” *Pershouse v. L.L. Bean, Inc.*, 368 F. Supp. 3d 185, 190 (D. Mass. 2019); *Stuto v. Corning Glass Works*, No. 88-1150-WF, 1990 WL 105615, at *5 (D. Mass. July 23, 1990) (finding a requirement of “some minimum of reliance” in part because “three of the leading Massachusetts cases on express warranties all note that the buyer relied on the seller’s representations in discussing the existence of an express warranty”); *Fahey v. R.J. Reynolds Tobacco Co.*, No. CA 927221, 1995 WL 809837, at *3–4

(Mass. Super. Ct. June 12, 1995) (noting that “[a]lthough some courts have found that reliance need not be shown in order to prove breach of an express warranty, the more common view has been that it is, and that either a buyer must prove reliance in order to recover on an express warranty or the seller must be permitted to rebut a presumption of reliance in order to preclude recovery” (internal citation omitted)).

Thus, a failure to plead reliance is not a basis for dismissal as to the breach of express warranty claims under California, Florida, and Wisconsin law, nor is it under the laws of the states for which Defendants have not asserted this issue. As for the remaining states—Massachusetts, Texas, and Kentucky—because those states require some degree of pleading on the issue of reliance, the Court turns to whether Plaintiffs have met the requisite standards.

Defendants assert that Plaintiffs have failed to allege that they personally relied on any misrepresentation made by Defendants in purchasing VSL#3, including those made in marketing materials or advertising, as they have not even specifically alleged that they saw any such materials. Although some Plaintiffs have asserted that they purchased VSL#3 on the recommendation of a doctor, they have not specifically alleged that any recommending doctor was aware of or relied on any misrepresentation. Plaintiffs therefore base their claim of reliance on the Amended Complaint’s allegation that they relied on the VSL#3 packaging that used the VSL#3 name, which “caused consumers to believe the product continued to contain the same formulation as it had previously.” Am. Compl. ¶ 111. In assessing whether this allegation is sufficient, because the parties have provided little guidance on the specific standards in the respective states require to plead reliance adequately, the Court focuses on the centralized resource of the UCC. *See, e.g., Premier Capital, LLC v. KMZ, Inc.*, 984 N.E.2d 286, 290 n.6 (Mass. 2013) (“UCC Official Comments do not have the force of law, but are nonetheless the most useful of several aids to

interpretation and construction of the [UCC].” (citations omitted)); *Legacy Bank v. Fab Tech Drilling Equip., Inc.*, 566 S.W.3d 922, 930 (Tex. App. 2018) (“Although the official comments following the [UCC] provisions are not law, they are persuasive authority concerning interpretation of the statutory language.”) (citation omitted); *Delphi Auto. Sys., LLC v. Capital Cmty. Econ./Indus. Dev. Corp.*, 434 S.W.3d 481, 485 (Ky. 2014) (noting that the Kentucky General Assembly “has indicated” that the Official Comments to the UCC provisions “represent the express legislative intent of the General Assembly and shall be used as a guide for interpretation” (citation omitted)).

The Official Comments to the UCC articulate the general principle that “the whole purpose of the law of warranty is to determine what it is that the seller has in essence agreed to sell.” U.C.C. § 2-313 cmt. 4. Express warranties are accordingly created by, in relevant part, “[a]ny affirmation of fact or promise” or “[a]ny description of the goods” that are “part of the basis of the bargain.” U.C.C. § 2-313(1)(a), (b). “[A]ffirmations of fact and promises made by the seller” are “part of the description of those goods.” *Id.* cmt. 3. Further, “[a] description need not be by words” and may include “[t]echnical specifications” and “[p]ast deliveries,” which “may set the description of quality, either expressly or impliedly by course of dealing.” *Id.* cmt. 5.

The UCC thus contemplates that the course of dealing between parties can create legitimate expectations on the part of the buyer as to the quality of the goods purchased. *See Royal Business Machines, Inc. v. Lorraine Corp.*, 633 F.2d 34, 44 (11th Cir. 1980) (noting that an express warranty claim was “complicated by the fact that it involved a series of sales transactions” over an 18-month period because “[t]he situations of the parties, their knowledge and reliance, may be expected to change in light of their experience during that time”). In the torts context, courts have found justifiable reliance in arguably similar circumstances. *See, e.g., Merrill Lynch, Pierce, Fenner &*

Smith, Inc. v. First Nat. Bank of Little Rock, 774 F.2d 909, 913 (8th Cir. 1985) (noting that justifiable reliance “may arise through the course of dealing between the bank and its customer”). Thus, repeat buyers can, absent any information otherwise, come to rely on the fact that what they are buying now is, in material respects, the same as what they bought before. See *Rock Creek Ginger Ale Co., Inc. v. Thermice Corp.*, 352 F. Supp. 522, 526–27 (D.D.C. 1971) (finding, in relation to an express warranty claim, that a buyer was “entitled to rely upon” a seller’s representations as to the quality of its product based on the parties’ “course of dealings,” which had included the provision of a product sample and numerous past deliveries that “disclosed no deviation from the quality” of the product sample).

The UCC thus appears to provide a basis to support Plaintiffs’ allegation of reliance, based on past purchases under the VSL#3 brand name, that later purchases under the same label continued to be of the same product containing the same De Simone Formulation. Where Plaintiffs’ pleading of reliance is arguably sufficient under the UCC, and where Defendants have pointed the Court to no contrary state law, the Court finds that that Plaintiffs have adequately pleaded reliance under the relevant state statutes.

D. Notice

Lastly, Defendants argue that Plaintiffs’ breach of express warranty claims must be dismissed because the UCC requires a plaintiff to provide pre-suit notice, but they have failed to do so. However, the UCC provision to which Defendants refer states only that “[w]here a tender has been accepted, the buyer must within a reasonable time after he discovers or should have discovered any breach notify the seller of breach or be barred from any remedy.” U.C.C. § 2–607(a). This UCC provision nowhere states that such notice must be pre-suit, nor do Defendants point to particular state deviations from the UCC that might impose such a requirement. Crucially,

the Official Comments to the UCC clarify that any notice deadline for retail purchasers is even more flexible than one for merchant purchasers, with the “reasonable time” requirement to be “extended” to ensure only that the notice rule discourages “commercial bad faith,” rather than to “deprive a good faith consumer of his remedy.” *Id.* cmt. 4. The Court therefore finds Defendants’ pre-suit notice argument unpersuasive.

For the reasons set forth above, the Court will grant the Motion as to the breach of warranty claims under the laws of Tennessee and Michigan based on Plaintiffs’ failure adequately to plead privity of contract. The Motion is otherwise denied as to the breach of express warranty claim.

V. State Consumer Protection Statutes

Defendants assert that Plaintiffs’ various claims under state consumer protection statutes fail for a variety of reasons, including that the Amended Complaint does not adequately allege reliance, causation, intentional deception, and ascertainable loss.

A. Reliance

Defendants return to their reliance argument, asserting that under the consumer protection statutes of Florida, Texas, Michigan, and California, Plaintiffs must, but fail to, plead reliance.

The Florida Deceptive and Unfair Trade Practices Act (“FDUTA”) imposes no such requirement. *See Carriuolo v. Gen. Motors Co.*, 823 F.3d 977, 984 (11th Cir. 2016) (holding that under the FDUTPA “a party asserting a deceptive trade practice claim need not show actual reliance on the representation or omission at issue” (citation omitted)).

Texas’s Deceptive Trade Practices Act (“Texas DTPA”), Tex. Bus. & Com. Code Ann. §§ 17.01–17.955, makes it unlawful to (1) represent “that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another,” *id.* § 17.46(b)(7); (2) advertise “goods or services with intent not to sell them as advertised,” *id.* §

17.46(b)(9); and (3) fail “to disclose information concerning goods or services which was known at the time of the transaction if such failure to disclose such information was intended to induce the consumer into a transaction into which the consumer would not have entered had the information been disclosed,” *id.* § 17.46(b)(24). Reliance is a required element for each of these claims. *Henry Schein, Inc. v. Stromboe*, 102 S.W.3d 675, 693 (Tex. 2002) (noting that reliance was a required element of the plaintiffs’ Texas DTPA “laundry list violations,” which included claims under sections 17.46(b)(7), (9), and (24)). Here, where Plaintiffs have asserted that Defendants did not disclose at the time of the sale of the new VSL#3 that it no longer used the De Simone Formulation, and that they would not have purchased it had they known this fact, they have plausibly alleged reliance on such an alleged material omission under section 17.46(b)(24).

Plaintiffs do not dispute that, in general, the Michigan Consumer Protection Act (“Michigan CPA”) requires a named plaintiff to allege actual reliance. *See In re Sony Gaming Networks & Customer Data Sec. Breach Litig.*, 996 F. Supp. 2d 942, 997 (S.D. Cal. 2014) (“[A] named plaintiff bringing a putative class action under the [Michigan Consumer Protection Act] must still allege actual reliance.”). However, reliance may not be required for an alleged violation of the Michigan CPA based on a material omission, specifically, a failure “to reveal a material fact, the omission of which tends to mislead or deceive the consumer, and which fact could not reasonably be known by the consumer,” Mich. Comp. Laws Ann. § 445.903(1)(s), because Michigan law generally “does not require any proof of actual reliance” for a fraudulent omission but instead “merely requires an intent, on the part of the defendant, to induce reliance on nondisclosure.” *Gasperoni v. Metabolife, Int’l Inc.*, No. 00-71255, 2000 WL 33365948, at *7 (E.D. Mich. Sept. 27, 2000); *see also Papazian v. Lichtman*, No. 180755, 1996 WL 33359823, at *4 (Mich. Ct. App. Sept. 6, 1996) (noting that the language of section 445.903(1)(s) is “practically

identical” to a claim of fraudulent nondisclosure). Any such claim, however, requires that a plaintiff plead that the defendant had a legal duty to disclose the information. *M&D, Inc. v. W.B. McConkey*, 585 N.W.2d 33, 37 (Mich. Ct. App. 1998) (“Michigan courts have recognized that silence cannot constitute actionable fraud *unless* it occurred under circumstances where there was a legal duty of disclosure.”). Here, Plaintiffs have not pleaded such a duty under Michigan law such as when a vendor and purchaser “have generally discussed the condition at issue” or when later acquired information renders untrue or misleading “previous representations” that were true when made. *Id.* at 38 (quoting *U. S. Fid. & Guar. Co. v. Black*, 313 N.W.2d 77, 89 (Mich. 1981)).

As to California, Plaintiffs assert violations of three consumer protection statutes: the California Consumer Legal Remedies Act (“CLRA”), which makes it unlawful, as primarily relevant here, to represent “that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have” or to represent “that goods or services are of a particular standard, quality, or grade . . . if they are of another,” Cal. Civ. Code §§ 1770(5), (7); the California False Advertising Law (“FAL”), which makes it unlawful for a person or entity to “cause to be made or disseminated before the public” through any “advertising device” “any statement” concerning personal property “which is untrue or misleading,” Cal. Bus. & Prof. Code § 17500; and (3) the California Unfair Competition Law (“UCL”), which prohibits unfair competition, defined as “any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising” as well as any act prohibited under the FAL, Cal. Bus. & Prof. Code § 17200. All three of these statutes require a plaintiff to plead actual reliance. *Cohen v. DIRECTV, Inc.*, 101 Cal. Rptr. 3d 37, 47 (Cal. Ct. App. 2009) (“The trial court correctly ruled that actual reliance must be established for an award of damages under the CLRA.”); *In re Tobacco II Cases*, 207 P.3d 20, 40 (Cal. 2009) (stating that for UCL claims, “a

plaintiff must plead and prove actual reliance to satisfy the standing requirement of section 17204”); *Kasky v. Nike, Inc.*, 45 P.3d 243, 250 (Cal. 2002) (“This court has recognized that any violation of the false advertising law necessarily violates the UCL”); *Kwikset Corp. v. Superior Court*, 246 P.3d 877, 884 (Cal. 2011) (noting that the standing provisions of the UCL and the FAL were both were modified in the same way by voter initiative). To do so at the pleading stage, a plaintiff must allege that a defendant’s misrepresentation “was an immediate cause of the injury-producing conduct” and that it “played a substantial part” in influencing the purchase decision, but not that the misrepresentation was “the sole or even the decisive cause” of that conduct. *In re Tobacco II Cases*, 207 P.3d at 39-40. Where a defendant has engaged in an “extensive and long-term advertising campaign,” the requirement is further relaxed in that the plaintiff need not “plead with an unrealistic degree of specificity that the plaintiff relied on particular advertisements or statements.” *Id.* at 40.

Because Plaintiffs do not allege that they actually saw or relied on the product information sheet or any particular advertisements for the new VSL#3 that asserted its continuity with the original VSL#3, any theory of reliance on such advertising would have to be based on the existence of an “extensive and long-term advertising campaign” that would relieve Plaintiffs from having to “plead and prove individualized reliance on specific misrepresentations or false statements.” *Id.* at 40. Here, however, while Plaintiffs assert that Defendants sent multiple marketing materials, their allegations fall short of describing extensive and long-term campaign that, because of its breadth, would have certainly found its way to the eyes and ears of the average citizen. *See id.* at 26 (alleging that the defendant tobacco companies had engaged in a deceptive advertising campaign for “decades”).

Plaintiffs further allege reliance on a material omission in that Defendants were obligated but failed to inform consumers of the change to the formulation of VSL#3, and they would not have purchased the new VSL#3 had that fact not been omitted. The CLRA, UCL, and FAL each contemplate actions based on alleged fraudulent omissions. *See Daniel v. Ford Motor Co.*, 806 F.3d 1217, 1225 (9th Cir. 2015) (stating that “[f]raudulent omissions are actionable under both” the CLRA and the UCL and that they require pleading and proof of “actual reliance”). However, “to be actionable under all three California consumer protections statutes, an omission must be contrary to a representation actually made by the defendant, or an omission of a fact the defendant was obliged to disclose.” *In re Sony Gaming*, 996 F. Supp. 2d at 991. While Plaintiffs state that the VSL#3 packaging contained material omissions—namely that VSL#3 no longer contained the De Simone Formulation—they have not alleged that they were aware of any contrary statements made by Defendants and upon which they relied in making their purchases. Though they allege that California imposes a duty to disclose when, as relevant here, a “defendant had exclusive knowledge of material facts not known to the plaintiff,” or when a “defendant actively conceals a material fact from the plaintiff,” Opp’n at 41, ECF No. 55 (quoting *In re MyFord Touch Consumer Litigation*, 46 F. Supp. 3d 936, 958 (N.D. Cal. 2014)), the United States Court of Appeals for the Ninth Circuit has stated that the weight of authority in both the California state and federal courts suggests that the duty to disclose material facts is limited, in relevant part, to disclosure of a “safety issue.” *Wilson v. Hewlett-Packard Co.*, 668 F.3d 1136, 1141 (9th Cir. 2012). While Plaintiffs have asserted that the new VSL#3 is not the same and not as clinically effective as the De Simone Formulation, they have not alleged that it poses a safety risk. The Court will therefore grant the Motion as to the California statutory consumer protection claims based on the failure to properly allege reliance.

Plaintiffs' claims under the Michigan and California consumer protection statutes, Counts 5, 6, 7, and 10, will thus be dismissed.

B. Causation

On a related issue, Defendants assert that Plaintiffs' claims under the consumer protection statutes of Washington, Wisconsin, Illinois, Tennessee, Massachusetts, and New Jersey fail because there are insufficient allegations of causation. Mot. Dismiss at 40. Under these laws, a plaintiff must make "some demonstration of a causal link between the misrepresentation and the plaintiff's injury," but that is typically a "factual question to be decided by the trier of fact." *Indoor Billboard/Washington, Inc. v. Integra Telecom of Washington, Inc.*, 170 P.3d 10, 22 (Wash. 2007) (en banc) (Washington Consumer Protection Act); see *Novell v. Migliaccio*, 749 N.W.2d 544, 553 (Wis. 2008) (Wisconsin Deceptive Trade Practices Act); *Connick v. Suzuki Motor Co.*, 675 N.E.2d 584, 595 (Ill. 1996) (Illinois Consumer Fraud Act); *Harvey v. Ford Motor Credit Co.*, No. 03A01-9807-CV-00235, 1999 WL 486894, at *2 (Tenn. Ct. App. July 13, 1999) (Tennessee Consumer Protection Act); *Casavant v. Norwegian Cruise Line Ltd.*, 952 N.E.2d 908, 912 (Mass. 2011) (Massachusetts Consumer Protection Act); *Varacallo v. Mass. Mut. Life Ins. Co.*, 752 A.2d 807, 814 (N.J. App. Div. 2000) (New Jersey Consumer Fraud Act). In Illinois, for example, "the required allegation of proximate cause is minimal since that determination is best left to the trier of fact," and proximate cause had been sufficiently alleged where the plaintiffs asserted that the defendant made allegedly fraudulent statements to a trade publication and that their "purchases occurred after the allegedly fraudulent statements." *Connick*, 675 N.E.2d at 595; see also *McClenahan v. Cooley*, 806 S.W.2d 767, 775 (Tenn. 1991) (stating that "proximate causation is a jury question unless the uncontroverted facts and inferences to be drawn from them make it so clear that all reasonable persons must agree on the proper outcome").

Here, a causal nexus is adequately alleged. Plaintiffs assert that, where the VSL#3 packaging identified no material change to the product, they bought VSL#3 believing it to continue to contain the De Simone Formulation, resulting in the foreseeable loss of monies spent on a product that was no longer of the quality and content that it appeared to be. Defendants' argument relating to causation provides no basis for dismissal.

C. Intentional Deception

Defendants also assert that the consumer protection statutes of California, Texas, Florida, Idaho, and Michigan each require that a plaintiff establish intentional deception, and that Plaintiffs' allegations are deficient in this respect. This argument overlooks the assertions in the Amended Complaint that Defendants created and distributed marketing materials that were specifically "designed to mislead physicians and consumers into believing" that the new VSL#3 continued to contain the De Simone Formulation. Am. Compl. ¶ 87. The Amended Complaint also alleges that Defendants' removal of certain information from the VSL#3 packaging was "deliberately designed to prevent detection of the change in formulation." *Id.* ¶ 76. This basis for dismissal has no merit.

D. Ascertainable Loss

Defendants also assert that the consumer protection laws of Idaho, Kentucky, Tennessee, New Jersey, and Massachusetts require that a plaintiff plead an ascertainable loss, and that Plaintiffs' Amended Complaint falls short on this score. Specifically, Defendants assert that Plaintiffs were required to plead an "identifiable injury distinct from the deceptive conduct that is objectively measurable" and that to do so, they were required to assert more than that the new VSL#3 was "less effective" than the De Simone Formulation and were instead required to "quantify the difference in value" between the two products. Mot. Dismiss at 42.

As noted by Defendants, at least Idaho, Kentucky, Tennessee, and New Jersey require an ascertainable loss as an element of a violation of their consumer protection statutes. *See* Idaho Code Ann. § 48-608 (West 2006) (creating a private right of action for “[a]ny person who purchases or leases goods or services and thereby suffers any ascertainable loss of money or property, real or personal, as a result of the use or employment by another person of a method, act or practice declared unlawful by this chapter”); Ky. Rev. Stat. Ann. § 367.220 (West 2015) (same); *Waggin’ Train, LLC v. Normerica, Inc.*, No. 1:09-CV-01093, 2010 WL 145776, at *4 (W.D. Tenn. Jan. 8, 2010) (finding that the plaintiff had failed adequately to plead “ascertainable loss” under the Tennessee Consumer Protection Act); *Smajlaj v. Campbell Soup Co.*, 782 F. Supp. 2d 84, 97 (D.N.J. 2011) (stating that for a claim under the New Jersey Consumer Fraud Act, a plaintiff must plead “an ascertainable loss”). The concern underlying this requirement is ensuring that the loss be “substantial” and “more than trivial or speculative.” *Waggin’ Train, LLC*, 2010 WL 145776, at *4 (finding allegations of injury insufficient when they described only the “dire straits in which Plaintiff *potentially* could find itself as a result of Defendants’ conduct”). This distinction is evident upon consideration of *Shaulis v. Nordstrom, Inc.*, 865 F.3d 1 (1st Cir. 2017), cited by Defendants, in which the consumer-plaintiff argued that she was deceptively induced into purchasing a sweater by the retailer’s practice of including on an item’s price tag a “compare at” price, which the plaintiff alleged caused her to make a purchase she would not otherwise have made because it led her to falsely believe that she was purchasing a high-value product for a low price, when, in actuality, the retailer had never previously sold the product at the “compare at” price. *Id.* at 5. In finding no actionable injury under the Massachusetts Consumer Protection Act because the plaintiff had failed to “show ‘real’ economic damages,” the court concluded that the plaintiff had ultimately received “exactly what she paid for, no more and no less” because there

was no claim that the product was not worth the price paid and expressly distinguished the claim from one in which “the product itself was deficient in some objectively identifiable way.” *Id.* at 12.

Here, Plaintiffs have asserted that the product that they bought was “inferior” to the “substantially more valuable” product that Defendants had promised. Am. Compl. ¶ 112. Because Plaintiffs’ claims relate to the quality and economic value of the product, and describe an actual monetary loss that could be quantified, they have alleged an ascertainable loss.

Although Defendants further argue that the Amended Complaint is deficient because it does not specifically “quantify the difference in value” between the new VSL#3 and the original VSL#3, Mot. Dismiss at 42, as to most states, they have identified no authority imposing such a requirement at the pleading stage. *See, e.g., Waggin’ Train, LLC*, 2010 WL 145776, at *4 (noting that the allegation of ascertainable loss could be of one that is “tangible or intangible”); *Schlenk v. Ford Motor Credit Co.*, 308 F.3d 619, 622 (6th Cir. 2002) (finding on summary judgment in a rent dispute case that the plaintiff had failed under Kentucky’s Consumer Protection Act to adduce sufficient evidence of an “ascertainable loss”). Where the requirement is an “ascertainable” loss rather than an “ascertained” loss, the Court finds no pleading requirement of a specific quantity inherent in this term and declines to read in such a requirement absent authority specific to a particular state.

As to New Jersey, however, the Supreme Court of New Jersey, outside the context of the pleading standard, has emphasized the importance of the ascertainable loss requirement “as an integral check upon the balance struck” under the New Jersey Consumer Fraud Act “between the consuming public and sellers of goods.” *See Thiedemann v. Mercedes-Benz USA, LLC*, 872 A.2d 783, 794 (N.J. 2005) (requiring evidence of a measurable loss at the summary judgment stage).

Accordingly, courts applying New Jersey law have construed the ascertainable loss requirement to impose a pleading requirement of an actual quantification of the loss, even if not entirely specific. *See Smaljaj*, 782 F. Supp. 2d at 101 (“Failure to quantify this difference in value results in dismissal of the claim.”); *In re Caterpillar, Inc., C13 & C15 Engine Prod. Liab. Litig.*, No. 1:14-CV-3722 JBS-JS, 2015 WL 4591236, at *4 (D.N.J. July 29, 2015) (“[C]ourts in this District have required plaintiffs to specify the price paid for the product and the price of comparable products to adequately state a claim under the NJCFA”). *But see Maniscalco v. Brother Int’l Corp. (USA)*, 627 F. Supp. 2d 494, 503 (D.N.J. 2009) (stating that under the New Jersey Consumer Fraud Act, “the loss must be ascertainable” but “no special specificity with regard to pleading ascertainable loss is required,” yet finding that quantification was in fact provided). Where the weight of authority calls for a quantification at the pleading stage, the Court will grant the Motion as to the New Jersey Consumer Fraud Act claim only.

E. Miscellaneous Arguments

Defendants argue that the claims under the Illinois and Wisconsin consumer protection statutes based on a material omission fail because Plaintiffs have not alleged a duty to disclose. As to Illinois, this argument fails because in that state, “it is unnecessary to plead a common law duty to disclose in order to state a valid claim of consumer fraud based on an omission or concealment.” *Connick v. Suzuki Motor Co.*, 675 N.E.2d 584, 595 (Ill. 1996). The Wisconsin Deceptive Trade Practices Act (“Wisconsin DTPA”), however, “prohibits only affirmative assertions, representations, or statements of fact that are false, deceptive, or misleading.” *See Tietsworth v. Harley-Davidson, Inc.*, 677 N.W.2d 233, 245 (Wis. 2004) (“Silence—an omission to speak—is insufficient to support a claim under [the Wisconsin DTPA].”). Nevertheless, Plaintiffs have pleaded deceptive and misleading affirmative statements in the form of

advertisements for new VSL#3, and Defendants make no argument that the Wisconsin DTPA requires reliance, so the unavailability of a theory of liability based on material omissions is not a basis to dismiss the Wisconsin DTPA claim.

Defendants also assert that the claims under the Kentucky and Idaho consumer protection laws fail because Plaintiffs have not alleged contractual privity with Defendants. Although the Kentucky Consumer Protection Act has such a requirement, Plaintiffs correctly state that this privity requirement does not apply to express representations, which are alleged here. *See Estate of DeMoss by & through DeMoss v. Eli Lilly & Co.*, 234 F. Supp. 3d 873, 884 (W.D. Ky. 2017) (noting that “[c]ourts have recognized that an exception to the privity requirement when express representations are alleged”) (citations omitted). As for Idaho, the Supreme Court of Idaho has expressly stated that “[i]n order to have standing under the Idaho Consumer Protection Act (ICPA) ... the aggrieved party must have been in a contractual relationship with the party alleged to have acted unfairly or deceptively.” *Taylor v. McNichols*, 243 P.3d 642, 662 (Idaho 2010). Though Plaintiffs argue that a federal district court in California has questioned the scope of this pronouncement, Opp’n at 44-45 (citing *In re Chrysler-Dodge-Jeep Ecodiesel Mktg., Sales Practices, & Prod. Liab. Litig.*, 295 F. Supp. 3d 927, 1021 (N.D. Cal. 2018)), this Court finds no reason to second-guess the plain language of the Supreme Court of Idaho on this issue of Idaho law. *See Taylor*, 243 P.3d at 662. Because Plaintiffs have not alleged such privity as to their Idaho Consumer Protection Act claim in Count 16, the Court will grant the Motion on that count.

Defendants further argue that the claim under the Tennessee Consumer Protection Act fails because a class action is not available for such a claim. The issue of class certification is not presently before the Court, so that argument is premature.

Lastly, Defendants assert that there is a requirement imposed by the Fourth Circuit in *In re GNC Corp.*, 789 F.3d 505, 516 (4th Cir. 2015), that for a false advertising claim to proceed on a theory of literal falsity, it must allege that all reasonable scientific experts in a field agree. Beyond the fact that not all of Plaintiffs' claims necessarily rely on a theory of literal falsity, the Court finds that Plaintiffs' allegations of the evidence presented in the prior litigation adequately supports the inference, consistent with the jury verdict in that case, that all reasonable experts agree on the issue at hand. *See De Simone v. VSL Pharm., Inc.*, 395 F. Supp. 3d 617, 626 (D. Md. 2019).

VI. Unjust Enrichment

On the unjust enrichment claim in Count 3, Defendants first assert that unjust enrichment is not an independent cause of action under the state laws of Illinois, California, Texas, and New Jersey. In response, Plaintiffs argue that it need not, at the pleading stage, identify the applicable state law underlying its claims. Even if correct, where Defendants argue that unjust enrichment is not a valid claim under the applicable law, the Court must address the issue of choice of law in order assess the viability of the claim.

For a common law cause of action, because this Court sits in Maryland, it looks to Maryland law to determine what law governs those claims. *See Branhaven, LLC v. BeefTek, Inc.*, 965 F. Supp. 2d 650, 664 (D. Md. 2013) ("When a claim is based on state law, the choice of law rules are those of the state in which the district court sits."). For state common law torts, Maryland applies the law of the state in which the injury occurred. *See Lab. Corp. of Am. v. Hood*, 911 A.2d 841, 845 (Md. 2006). Here, the alleged injuries are economic, rather than personal, so courts traditionally deem them to have accrued where the injured party resides. *See 21 M.L.E. Torts* § 2 (West 2018) ("The place of injury means the place where the injury was suffered rather than the place where the wrongful act took place[.]"). Because the named Plaintiffs each

reside in different states, what Plaintiffs have pleaded as a single unjust enrichment claim appears, in fact, to be multiple unjust enrichment claims proceeding under the laws of the various states in which the named Plaintiffs reside. The Court thus considers whether unjust enrichment is a cause of action in the identified states.

As to Illinois, contrary to the lower court precedent cited, *see C. Szabo Contracting, Inc. v. Lorig Construction Company*, 19 N.E.3d 638, 644 (Ill. App. 2014), the Illinois Supreme Court has not only recognized unjust enrichment as a cause of action, but also has defined its elements. *See HPI Health Care Servs., Inc. v. Mt. Vernon Hosp., Inc.*, 545 N.E.2d 672, 679 (Ill. 1989) (“To state a cause of action based on a theory of unjust enrichment, a plaintiff must allege that the defendant has unjustly retained a benefit to the plaintiff’s detriment, and that defendant’s retention of the benefit violates the fundamental principles of justice, equity, and good conscience”).

California and Texas, while not labeling unjust enrichment as an independent cause of action, recognize it as viable theory of recovery grounded in equity. *Cheremie v. HBB, LLC*, 545 F. App’x 626, 628 (9th Cir. 2013) (“The law concerning unjust enrichment in California is unclear. . . . The weight of authority indicates that ‘[u]njust enrichment is not a cause of action, just a restitution claim.’” (quoting *Hill v. Roll Int’l Corp.*, 128 Cal. Rptr. 3d 109, 118 (Cal. Ct. App. 2011))); *Argyle Indep. Sch. Dist. ex rel. Bd. of Trustees v. Wolf*, 234 S.W.3d 229, 246–47 (Tex. App. 2007) (stating that unjust enrichment is a “doctrine [that] applies the principles of restitution to disputes where there is no actual contract,” such that “[t]o recover under an unjust enrichment theory, the benefits to the other party must be actually unjust under the principles of equity” (citations omitted)). New Jersey likewise does not recognize unjust enrichment as an independent tort cause of action but accepts it as a claim that “may be sustained independently as an alternative theory of recovery” based on a “quasi-contractual or implied contractual relationship.” *Torres-*

Hernandez v. CVT Prepaid Sols., Inc., No. 3:08-CV-1057-FLW, 2008 WL 5381227, at *9 (D.N.J. Dec. 17, 2008). Where Plaintiffs have pleaded unjust enrichment in the alternative to an express warranty claim, it is arguably grounded in such a relationship. Because, even without necessarily labeling it as an independent cause of action, all of these states recognize unjust enrichment as a theory under which Plaintiffs could recover in this action, the Court will not dismiss the claim as to Illinois, California, Texas, or New Jersey.

Alternatively, Defendants assert that the unjust enrichment claim cannot proceed in a variety of states because, as an equitable remedy, it is available only where no legal remedy exists. Here, however, Plaintiffs have plainly pleaded unjust enrichment in the alternative should their breach of warranty claim fail. Since there is no express written contract signed by both parties that would clearly foreclose an equitable remedy asserted in the alternative, the Court finds no basis to foreclose a claim of unjust enrichment at the pleading stage. *See, e.g., Metro. Life Ins. Co. v. Cotter*, 984 N.E.2d 835, 849 (Mass. 2013) (noting that “ordinarily, a claim of unjust enrichment will not lie where there is a valid contract that defines the obligations of the parties” (citation omitted)); *Chang v. Winklevoss*, 123 N.E.3d 204, 212 (Mass. App. Ct. 2019) (noting that “[a]lthough damages for breach of contract and unjust enrichment are mutually exclusive, it is accepted practice to pursue both theories at the pleading stage”).

Lastly, Defendants assert that Plaintiffs’ unjust enrichment claims fail under the laws of various states because Plaintiffs have not alleged that they conferred a direct benefit on Defendants. However, Plaintiffs allege that they paid Defendants for VSL#3, and the Court discerns no reason, nor do Defendants explain, why the benefit of Plaintiffs’ payment for an allegedly inferior product is insufficient to satisfy this requirement. The Motion will be denied as to the unjust enrichment claim in Count 3.

VII. Lediand

Lediand asserts additional bases for dismissal of the claims against it, particularly arguments based on the statute of limitations. For state law claims asserted under diversity jurisdiction, federal courts apply the choice of law rules of the forum state. *See Klaxon v. Stentor Elec. Mfg. Co.*, 313 U.S. 487, 496 (1941); *Branhaven, LLC v. BeefTek, Inc.*, 965 F. Supp. 2d 650, 664 (D. Md. 2013) (“When a claim is based on state law, the choice of law rules are those of the state in which the district court sits.”). Maryland choice of law principles dictate that “procedural matters are governed by Maryland law.” *Doughty v. Prettyman*, 148 A.2d 438, 440 (1959). In Maryland, statutes of limitations are procedural for choice of law purposes. *Lewis v. Waletzky*, 31 A.3d 123, 133 (2011) (“We have also held that statutes of limitations are procedural for choice-of-law purposes.”). Maryland law thus determines the statute of limitations, and in Maryland, the general statute of limitations for civil actions is three years. Md. Code Ann., Cts. & Jud. Proc. § 5-101 (West 2011).

According to Lediand, because Plaintiffs have alleged in the Amended Complaint that Lediand sold the rights to market and sell VSL#3 to Alfasigma in June 2016, a date more than three years before this lawsuit was filed, Plaintiffs’ claims under the state consumer protection statutes of Florida, Idaho, Kentucky, and Wisconsin, as well as the unjust enrichment claims relating to California, Massachusetts, Michigan, Tennessee, Texas, and Washington, are time-barred. Plaintiffs concede that the state law claims against Lediand in Florida and Kentucky are time-barred, so those claims will be dismissed.

Defendants, however, cite no authority for the proposition—crucial to their argument—that the statute of limitations on the claims against Lediand necessarily began to run on the date Lediand’s rights to market and sell VSL#3 were transferred to Alfasigma. Plaintiffs have

identified one example, from Idaho law, that a cause of action accrues not necessarily when the defendant takes the last act relevant to the claim, but when the plaintiff “knew or, with the exercise of reasonable diligence, should have been able to know” of the claim. *Performance Chevrolet, Inc. v. Mkt. Scan Info. Sys.*, 402 F. Supp. 2d 1166, 1172 (D. Idaho 2005). Such a “discovery rule” standard is applied in Maryland. *See, e.g., Poffenberger v. Risser*, 431 A.2d 677, 680 (Md. 1981) (stating that under Maryland’s “discovery rule,” a claim in a civil action does not accrue until the plaintiff “in fact knew or reasonably should have known of the wrong”). Moreover, where Plaintiffs have alleged concerted action and overlapping ownership among Leadiant and Alfasigma, the Amended Complaint is not entirely clear that Leadiant had no role in claims arising after June 2016. Where the statute of limitations is not a pleading requirement but is instead an affirmative defense, *see* Fed. R. Civ. P. 8(c)(1), and Defendants have not provided sufficient information to allow for a definitive conclusion on this issue, the Court will not grant the Motion on this basis at this stage. Likewise, it is premature to grant dismissal based on Leadiant’s other arguments relating to fact-based issues of timing.

As for Leadiant’s arguments relating to injunctive relief and the public interest requirement of the Washington Consumer Protection Act, the Court rejects them for the reasons set forth in one of its prior opinions in the previous litigation. *See De Simone v. VSL Pharm., Inc.*, No. TDC-15-1356, 2019 WL 2569574, at *3 (D. Md. June 20, 2019) (rejecting Leadiant’s argument that, having transferred its marketing and distribution rights to Alfasigma, it should not be enjoined from falsely advertising VSL#3 because, where these companies had common ownership, the Court “cannot conclude that Leadiant has met its burden of establishing that there is no reasonable expectation that the wrong will be repeated”).

CONCLUSION

For the foregoing reasons, Defendants' Motion to Dismiss will be GRANTED IN PART and DENIED IN PART. The Motion will be granted as to the claims in Count 2 (breach of express warranty) asserted under Tennessee and Michigan law. The Motion will be granted as to Counts 5, 6, 7, 9, 10, and 16, consisting of the California, New Jersey, Michigan, and Idaho statutory consumer protection claims. The Motion will also granted as to the Florida and Kentucky statutory consumer protection claims in Counts 14, 15, and 17 against Leadant only. The Motion will be otherwise denied. A separate Order shall issue.

Date: December 28, 2020

/s/ Theodore D. Chuang
THEODORE D. CHUANG
United States District Judge