UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

SHANNON MAHONEY, individually and on behalf of herself and all others similarly situated, Plaintiff, -v- ENDO HEALTH SOLUTIONS, INC., a Delaware corporation; ENDO PHARMACEUTICALS, INC., a Delaware corporation; GENERICS INTERNATIONAL (US PARENT), INC., a Delaware corporation, d/b/a QUALITIEST PHARMACEUTICALS; GENERICS INTERNATIONAL (US), INC., a Delaware corporation; GENERICS BIDCO I, LLC, a Delaware limited liability company; GENERICS INTERNATIONAL (US HOLDCO), INC., a Delaware corporation; GENERICS INTERNATIONAL (US MIDCO), INC., a Delaware corporation; and VINTAGE PHARMACEUTICALS, LLC, a Delaware limited liability company, Defendants.	:	15cv9841(DLC) OPINION AND ORDER

APPEARANCES:

For the plaintiff:
Ryon M. McCabe
Robert C. Glass
McCabe Rabin, P.A.
1601 Forum Place, Suite 505
West Palm Beach, FL 33401

David M. Buckner
Brett E. von Borke
Buckner & Miles
3350 Mary Street
Miami, FL 33129

For the defendants:
Ingo W. Sprie, Jr.
Benjamin C. Wolverton
Arnold & Porter, LLP
399 Park Avenue
New York, NY 10022

Jonathan L. Stern
David D. Fauvre
Katharine C. Hinkle
Arnold & Porter, LLP
601 Massachusetts Ave, N.W.
Washington, DC 20001

DENISE COTE, District Judge:

Plaintiff Shannon Mahoney ("Mahoney") has brought a putative class action on behalf of a national class and a New York class against Endo Health Solutions, Inc. ("Endo Health") and several related corporations. Mahoney alleges that she and other class members suffered an economic loss when they purchased Qualitest Multi-Vitamin with Fluoride Chewable Tablets ("Tablets"), which are available by prescription for children who do not have access to fluoridated drinking water. Mahoney claims that the defendants marketed the Tablets as having a certain concentration of fluoride, when in fact the concentration of fluoride was much lower than the label indicated and lower than the medically-recommended dosage.

The defendants have settled a related qui tam action and paid substantial sums of money to the federal government and to certain States. The defendants filed a motion to dismiss the

amended complaint in Mahoney's action in its entirety. For the reasons that follow, the motion is granted in part. The plaintiff's claims for a violation of N.Y. Gen. Bus. Law § 349, breach of express warranty, fraud and fraudulent concealment may proceed. Her claims for violations of the Magnuson-Moss Warranty Act, breach of the implied warranty of merchantability, unjust enrichment and negligent misrepresentation are dismissed.

Background

These facts are taken from the amended complaint or documents integral to it. Fluoride helps prevent dental caries, which is more commonly known as tooth decay. The American Dental Association ("ADA") and the American Academy of Pediatrics ("AAP") advocate that all geographic areas fluoridate their community drinking water. Approximately 95.5 million Americans do not receive fluoride through their community's water source, however. In communities that do not have fluoridated water, the ADA and the AAP recommend that children under 16 years of age receive daily dietary fluoride supplements. These supplements can take many forms, including chewable multivitamins with fluoride. The ADA and the AAP publish a table recommending the appropriate dosage of fluoride for children. The three recommended dosage levels are 0.25 milligrams, 0.5 milligrams, and 1 milligram of "fluoride ion"

depending on the age of the child.[1] Dentists and other doctors rely on this table of recommended dosages in prescribing fluoride supplements to children.

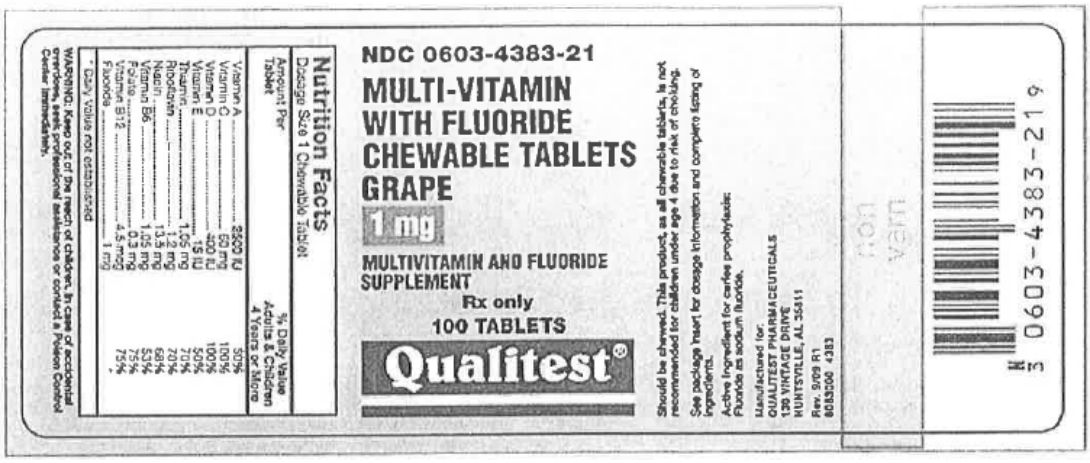
Fluoride for use in chewable tablets can be obtained from different sources, which include "sodium fluoride." Sodium fluoride is a salt form of fluoride and contains 54.5% sodium and 45.5% fluoride ion. The ADA's recommended dosage chart notes that it takes 2.2 milligrams of sodium fluoride to yield 1 milligram of fluoride ion. These pills must be prescribed by a dentist or physician.

The defendants constituted, collectively, a dominant manufacturer of fluoride tablets in the United States. They manufactured and distributed the Tablets under the Qualitest Pharmaceuticals brand in fluoride concentrations that corresponded to all three of the ADA-recommended dosages. The label on the outside of the Tablet bottles states the purported dosage of fluoride in milligrams in bold letters. In small print that appears perpendicular to the main, bolded print indicating the fluoride concentration, the labels indicate that the "[a]ctive ingredient for caries prophylaxis [is] [f]luoride

[1] Fluoride ion refers to fluoride in its purer form, and is contrasted with the diluted sodium fluoride, as explained below. The ADA-AAP recommended dosages are measured in terms of fluoride ion levels.

as sodium fluoride." An image of the label is below.

PRINCIPAL DISPLAY PANEL



The package insert describes in some detail the different dosage recommendations for fluoride tablets, and states, for example, that a 1 milligram Tablet is recommended for children ages 6-16 years. The package insert tracks the ADA and AAP recommended dosages for the Tablets based on the child's age. Mahoney contends that the bottle label and insert were deliberately misleading because they were intended to convey falsely that the Tablets provided the dosage of fluoride ion recommended by the ADA and the AAP.

On December 16, 2015, the Court signed a Stipulation and Order of Settlement and Dismissal ("Settlement") in a related qui tam action, United States of America ex rel. Porter v. Endo Health Solutions, Inc. et al., 13cv1506. All of the defendants in this litigation were signatories to the Settlement. In the

Settlement, the defendants admitted that "the product labeling for [the Tablets] included dosage information, which stated the supplements contained 1.0 mg, 0.5 mg, or 0.25 mg of fluoride, respectively"; the "Defendants used sodium fluoride . . . as an ingredient to manufacture [the Tablets]"; and that the Tablets contained approximately "44% of the fluoride ion recommended by the ADA-AAP Guidelines." This sub-potency pervaded all of the Tablets manufactured from 2007 through the middle of 2013.

Mahoney, a resident of New York, is the mother of two children who were prescribed fluoride supplements. Mahoney's pediatrician prescribed a generic chewable multivitamin with fluoride, specifying the fluoride dosage but not a particular manufacturer. Mahoney filled the prescription, typically at three month intervals, at her local pharmacy. The pharmacist filled the prescription with pills that purportedly contained the appropriate fluoride amount, relying on the labels for the Tablets in order to fill the prescription correctly. Mahoney's prescriptions were filled with the defendants' Tablets. According to Mahoney, she would never have purchased the Tablets had she known that their labels were incorrect.

Based on these events, Mahoney brings several causes of action: (1) violation of the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301 et seq.; (2) breach of express warranty; (3)

negligent misrepresentation; (4) unjust enrichment; (5) violation of N.Y. Gen. Bus. Law § 349; (6) breach of the implied warranty of merchantability; (7) fraud; and (8) fraudulent concealment.[2] The complaint was filed on December 17, 2015, the day after the Settlement was signed by the Court. The defendants moved to dismiss on February 24, 2016. The plaintiff filed an amended complaint on March 18, and the defendants filed a renewed motion to dismiss on April 19, which became fully submitted on June 2.

Discussion

When deciding a motion to dismiss under Rule 12(b), Fed. R. Civ. P., a court must "accept all allegations in the complaint as true and draw all inferences in the non-moving party's favor." LaFaro v. New York Cardiothoracic Group, PLLC, 570 F.3d 471, 475 (2d Cir. 2009). "To survive a motion to dismiss under Rule 12(b)(6), a complaint must allege sufficient facts which, taken as true, state a plausible claim for relief." Keiler v. Harlequin Enters. Ltd., 751 F.3d 64, 68 (2d Cir. 2014); Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) ("[A] complaint must contain sufficient factual matter, accepted as true, to state a claim for relief that is plausible on its face."). "A claim has

[2] Subject matter jurisdiction over this action exists under 28 U.S.C. § 1332(d)(2)(A) even if no federal cause of action provides jurisdiction.

facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Parkcentral Global Hub Ltd. v. Porsche Auto. Holdings SE, 763 F.3d 198, 208 (2d Cir. 2014) (citation omitted).

I. Group Pleading

The defendants argue that the amended complaint should be dismissed because the plaintiff engages in impermissible "group pleading." Complaints that "lump[]" several defendants together and make allegations against those defendants "collectively" may violate Rule 8, Fed. R. Civ. P. Zurich Am. Ins. Co. v. Dah Sing Bank, Ltd., No. 03cv7778 (DLC), 2004 WL 1328215, at *6 (S.D.N.Y. June 15, 2004). One of the core purposes of Rule 8 is to "give the defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests." E.E.O.C. v. Port Auth. of New York & New Jersey, 768 F.3d 247, 253 (2d Cir. 2014) (citation omitted). In the context of the heightened pleading requirements of Rule 9(b), however, the Second Circuit has held that, in certain instances, "group pleading may satisfy the source identification" required by Rule 9. Loreley Fin. (Jersey) No. 3 Ltd. v. Wells Fargo Sec., LLC, 797 F.3d 160, 173 (2d Cir. 2015). As such, "there is no fixed requirement . . . to identify a single entity within a group on pain of

dismissal." Id.

The defendants' argument regarding group pleading may be swiftly dismissed. Each defendant signed the Settlement, accepting responsibility for manufacturing the Tablets with less than the stated amount of fluoride ion.

II. Negligent Misrepresentation

> To prevail on a claim of negligent misrepresentation under New York law, a plaintiff must show (1) the existence of a special or privity-like relationship imposing a duty on the defendant to impart correct information to the plaintiff; (2) that the information was incorrect; and (3) reasonable reliance on the information.

Crawford v. Franklin Credit Mgmt. Corp., 758 F.3d 473, 490 (2d Cir. 2014) (citation omitted).[3] "New York law strictly limits negligent-misrepresentation claims to situations involving actual privity of contract between the parties or a relationship so close as to approach that of privity." Fin. Guar. Ins. Co. v. Putnam Advisory Co., LLC, 783 F.3d 395, 405 (2d Cir. 2015) (citation omitted). Absent actual privity of contract,

> there must be (1) an awareness by the maker of the statement that the statement is to be used for a

[3] The Court must determine what substantive law governs the dispute. Neither party explicitly addresses the choice of law question. The defendants rely on New York law in their briefs, and the plaintiff impliedly consents to the application of New York law by failing to argue that another law should apply. Moreover, the first amended complaint identifies New York law as the basis for the plaintiff's statutory claims. Thus, New York law applies to the plaintiff's state law claims. See Chau v. Lewis, 771 F.3d 118, 126 (2d Cir. 2014).

> particular purpose; (2) reliance by a known party on the statement in furtherance of that purpose; and (3) some conduct by the maker of the statement linking it to the relying party and evincing its understanding of that reliance.

N. Star Contracting Corp. v. MTA Capital Const. Co., 993 N.Y.S.2d 11, 14 (1st Dep't 2014); Sykes v. RFD Third Ave. 1 Associates, LLC, 15 N.Y.3d 370, 373 (2010) (relying on the same three-part test in discerning whether there was a privity-like relationship). See also Fin. Guar. Ins. Co., 783 F.3d at 405 (the relationship must be such that the defendant "owed [the plaintiff] a duty to speak with care" (citation omitted)).[4]

The plaintiff's negligent misrepresentation claim is dismissed. Mahoney has not plausibly pled that she was in privity with the defendants or that her relationship with them was so close that it resembled privity of contract under New York law. A "privity-like" relationship does not exist when a plaintiff is one of a large class of possible consumers. See Sykes v. RFD Third Ave. 1 Associates, LLC, 884 N.Y.S.2d 745, 749 (1st Dep't 2009), aff'd, 15 N.Y.3d 370 (2010).

The plaintiff's arguments to the contrary are unavailing.

[4] The Second Circuit has not definitively ruled that claims for negligent misrepresentation must be pled with the particularity that Rule 9(b) requires, but courts in this District frequently hold that Rule 9 applies. See Eternity Glob. Master Fund Ltd. v. Morgan Guar. Trust Co. of N.Y., 375 F.3d 168, 188 (2d Cir. 2004).

The plaintiff relies on a three-part test articulated in Kimmell v. Schaefer, 89 N.Y.2d 257, 264 (1996), and repeated in Suez Equity Inv'rs, L.P. v. Toronto-Dominion Bank, 250 F.3d 87 (2d Cir. 2001), designed to determine whether the duty to speak with care exists in a commercial context. Kimmel, 89 N.Y.2d at 263. Kimmel determined that liability for a negligent misrepresentation may exist in that context when the defendant is in a "special position of confidence and trust with the injured party" that justifies reliance on the defendant's speech. Id. at 263-64.

> In determining whether justifiable reliance exists in a particular case, a fact finder should consider whether the person making the representation held or appeared to hold unique or special expertise; whether a special relationship of trust or confidence existed between the parties; and whether the speaker was aware of the use to which the information would be put and supplied it for that purpose.

Suez, 250 F.3d at 103 (quoting Kimmel, 89 N.Y.2d at 264) (analyzing a negligent misrepresentation claim in connection with securities fraud). See also Mandarin Trading Ltd. v. Wildenstein, 16 N.Y.3d 173, 180 (2011) (listing the same three factors in upholding the dismissal of a negligent misrepresentation claim in connection with a fraudulent art transaction). In Suez, the court found that a special relationship between the plaintiff and defendant existed because

the relationship "extended beyond the typical arm's length business transaction." Suez Equity Inv'rs, 250 F.3d at 103. The "defendants [had] initiated contact with the plaintiffs, induced them to forbear from performing their own due diligence, and repeatedly vouched for the veracity of the allegedly deceptive information." Id.

The Suez test for pleading justifiable reliance does not assist the plaintiff in her effort to plead the existence of a privity-like relationship here.[5] No privity-like relationship exists in the absence of "even [] bare, minimal contact" between the parties. Mandarin Trading Ltd., 16 N.Y.3d at 181. Expertise alone cannot create a special relationship when "the relationship between the parties is too attenuated." Id. The plaintiff has not pled that her relationship with the defendants extended beyond that which exists between an ordinary consumer and a prescription drug manufacturer. Thus, the negligent misrepresentation claim is dismissed.

III. Breach of Implied Warranty of Merchantability

Under the Uniform Commercial Code ("UCC"), which New York

[5] The plaintiff also relies on a district court case denying a motion to dismiss a negligent misrepresentation claim when a patient sued the manufacturer of a defective medical device, Williamson v. Stryker Corp., No. 12cv7083 (CM), 2013 WL 3833081 (S.D.N.Y. July 23, 2013). In Williamson, however, the plaintiff alleged reliance on conversations with corporate representatives of the defendant.

has adopted, "a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind." N.Y. U.C.C. § 2-314(1). Goods are merchantable if they meet certain requirements, including "fit[ness] for the ordinary purposes for which such goods are used." Id. § 2-314(2)(c). Additionally, goods must "conform to the promises or affirmations of fact made on the container or label if any." Id. § 2-314(2)(f). To succeed on an implied warranty claim, the plaintiff "must show both the existence and breach of the warranty and that the breach was the proximate cause of plaintiff's damages." Bellevue S. Associates v. HRH Const. Corp., 78 N.Y.2d 282, 298 (1991).

There is no requirement of privity for such a warranty claim so long as the plaintiff's claim is one for personal injury. "A seller's warranty whether express or implied extends to any natural person if it is reasonable to expect that such person may use, consume or be affected by the goods and who is injured in person by breach of the warranty." N.Y. U.C.C. § 2-318 (emphasis added); Ross v. Alexander Mitchell & Son, Inc., 31 N.Y.S.3d 703, 703 (4th Dep't 2016) ("Privity is not required in a personal injury action for breach of express or implied warranty." (citation omitted)). But, "no implied warranty will extend from a manufacturer to a remote purchaser not in privity

with the manufacturer where only economic loss and not personal injury is alleged." Lexow & Jenkins, P.C. v. Hertz Commercial Leasing Corp., 504 N.Y.S.2d 192, 193-94 (2d Dep't 1986); see Adirondack Combustion Techs., Inc. v. Unicontrol, Inc., 793 N.Y.S.2d 576, 579 (3d Dep't 2005) ("A claim based upon a breach of an implied warranty requires a showing of privity . . . when there is no claim for personal injuries"); Gordon v. Ford Motor Co., 657 N.Y.S.2d 43, 43 (1st Dep't 1997) (holding that "there can be no implied warranty absent privity between [the defendants] and the plaintiffs"). See also Bellevue S. Associates, 78 N.Y.2d at 298 ("Defenses available to claims of breach of the implied warranty of merchantability include . . . lack of privity.").

The plaintiff's implied warranty claim is dismissed. She has not pled that she is in privity with the defendants and the plaintiff has not alleged that her children were personally injured as a result of ingesting the sub-potent fluoride Tablets. Thus, the injury she claims is limited to the economic loss she experienced when she paid for Tablets that were not fit for their ordinary purpose of preventing tooth decay. Privity is required for a successful implied warranty claim where only economic damages are alleged, and there is no privity here.

The plaintiff principally argues that privity is not

required under New York law, citing Goldberg v. Kollsman Instrument Corp., 12 N.Y.2d 432 (1963). Goldberg, however, was a wrongful death case.

The plaintiff next contends that, even if privity were required, there is an exception to that requirement for "things of danger" such as the Tablets. She relies on Hubbard v. Gen. Motors Corp., No. 95cv4362, 1996 WL 274018 (S.D.N.Y. May 22, 1996), in which the plaintiff alleged that the defendant had manufactured a defective braking system in cars. Hubbard found that "New York recognizes an exception to [the privity requirement] where the product in question is a 'thing of danger.'" Id. at *5. The decision cites only Goldberg and All-Tronics, Inc. v. Ampelectric Co., 354 N.Y.S.2d 154 (2d Dep't 1974), which recognized "the principle that a defect in a potentially hazardous product subjects the distributor-vendor and the manufacturer to liability to a purchaser for breach of implied warranties" where the plaintiff claimed property damage from a fire allegedly caused by the defendant's defective products. All-Tronics, 354 N.Y.S.2d at 156. This purported "thing of danger" exception does not appear in recent New York cases, however, which have overwhelmingly upheld the privity requirement where only economic loss is alleged in cases that involve indisputably dangerous products. Adirondack Combustion

Techs., Inc., 793 N.Y.S.2d at 579 (privity required for economic damages involving an exploding boiler). Accordingly, even if the plaintiff had adequately pled that the Tablets are things of danger, which she has not, her claim for a breach of the implied warranty of merchantability must be dismissed because she only seeks economic losses associated with paying for the Tablets themselves.

Finally, recognizing this hurdle to her implied warranty claim, the plaintiff suggests in her brief that she may bring an implied warranty claim for the increased health risk her children experienced from consumption of the defendants' Tablets. In her amended complaint, the plaintiff asserts that her children experienced "increased risk for developing tooth cavities." She does not claim any damages for that injury, however, instead alleging throughout her complaint that she "suffered damages and ascertainable losses of money and property by paying for" the Tablets when she would not have done so absent the alleged misrepresentation.[6] Thus, although she does describe an increased risk of tooth decay in the complaint, she does not plead that she suffered any compensable damages other than economic damages as a result of that increased risk. Thus,

[6] A lawsuit claiming personal injury would, of course, present certain challenges when pursued on behalf of a class.

her attempt to recast this increased risk as a personal injury that would satisfy § 2-318 is unavailing.

IV. Breach of Express Warranty

Express warranties are governed by N.Y. U.C.C. § 2-313(1)(a), which provides that an express warranty includes "[a]ny 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." Moreover, "[a]ny 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." Id. § 2-313(1)(b). Section 2-318 further provides that "[a] seller's warranty whether express or implied extends" to any foreseeable user "who is injured in person by breach of the warranty."

The defendants moved to dismiss the plaintiff's express warranty claim because the plaintiff is not in privity with the defendants. The New York Court of Appeals has dispensed with the requirement of privity in cases involving breach of an express warranty where only economic damages are alleged. Randy Knitwear, Inc. v. Am. Cyanamid Co., 11 N.Y.2d 5, 16 (1962); Jesmer v. Retail Magic, Inc., 863 N.Y.S.2d 737, 739 (2d Dep't 2008); Murrin v. Ford Motor Co., 756 N.Y.S.2d 596, 597 (2d Dep't 2003). As the New York Court of Appeals observed:

> The policy of protecting the public from injury, physical or pecuniary, resulting from misrepresentations outweighs allegiance to old and out-moded technical rules of law which, if observed, might be productive of great injustice. The manufacturer unquestionably intends and expects that the product will be purchased and used in reliance upon his express assurance of its quality . . . [h]aving invited and solicited the use, the manufacturer should not be permitted to avoid responsibility, when the expected use leads to injury and loss, by claiming that he made no contract directly with the user.

Codling v. Paglia, 32 N.Y.2d 330, 339 (1973) (citing Randy Knitwear)). Thus, privity is not required and the defendants' motion to dismiss the plaintiff's express warranty claim is denied.

The defendants' arguments to the contrary are not persuasive. The defendants primarily contend that, because Randy Knitwear predated the effective date of the UCC (1964) and the subsequent amendment of § 2-318 (1975), it is no longer good law.[7] The commentary on relevant UCC sections, however, indicates that Randy Knitwear remains controlling precedent despite the subsequent enactment of the UCC. It explains that "the warranty sections of this Article are not designed in any

[7] See Jeffrey W. Deaver, Products Liability in New York: Section 2-318 of the UCC -- the Amendment Without A Cause, 50 Fordham L. Rev. 61, 70 (1981) (UCC became effective in New York in 1964); id. at 74 (discussing the 1975 amendment of § 2-318 that increased the number of plaintiffs who could sue manufacturers for breach of warranties if personal injury was alleged).

way to disturb those lines of case law growth which have recognized that warranties need not be confined either to sales contracts or to the direct parties to such a contract." N.Y. U.C.C. § 2-313, cmt.2 (discussing express warranties). For example, express warranties "may arise in other appropriate circumstances such as in the case of bailments for hire." Id.; see also Vermont Plastics, Inc. v. Brine, Inc., 79 F.3d 272, 280 (2d Cir. 1996) (discussing the same comment to the same provision of the Vermont UCC and finding that "[a]ccording to the comment, among the circumstances in which contractual privity is not required are (1) bailments for hire, and (2) situations covered by [§] 2-318. . . . Beyond these two circumstances, however, the matter is left to the case law." (citation omitted)). Thus, the official comment accompanying § 2-313 leaves Randy Knitwear undisturbed.

The comments accompanying § 2-318 further support this view. The New York annotations to § 2-318 explain that:

> [T]he Code enlarges the number of prospective plaintiffs in a warranty action but it does not increase the number of potential defendants. In no way is the Code intended to limit the extension of warranty protection by the courts to a greater number of plaintiffs or the expansion of the manufacturer's liability as in [Randy Knitwear].

N.Y. U.C.C. § 2-318, N.Y. Annotations. See also Barkley Clark and Christopher Smith, 1 Law of Prod. Warranties § 10:11 (2015)

(observing that "§ 2-318 is 'neutral' on vertical privity," and "the great weight of authority follows Randy Knitwear"). The official and state-specific comments on §§ 2-313 and 2-318 thus show that Randy Knitwear's holding remains good law even though it predates the UCC. Moreover, as described above, more recent authority follows Randy Knitwear and does not require privity between a consumer and a manufacturer where the plaintiff alleges breach of an express warranty and seeks only economic damages.

In support of their argument that privity is required, the defendants cite Koenig v. Boulder Brands, Inc., 995 F. Supp. 2d 274, 290 (S.D.N.Y. 2014), and Carcone v. Gordon Heating & Air Conditioning Co., 623 N.Y.S.2d 679, 680 (4th Dep't 1995), among other decisions. These cases are not sufficiently persuasive to overcome the New York Court of Appeals' ruling in Randy Knitwear and the commentary explaining that Randy Knitwear remains good law. The defendants' motion to dismiss the plaintiff's express warranty claim is therefore denied.

V. Magnuson-Moss Warranty Act ("MMWA")

The MMWA, 15 U.S.C. § 2301 et seq., provides consumers with a private cause of action for violations of implied and express warranties in certain circumstances. Wilbur v. Toyota Motor Sales, U.S.A., Inc., 86 F.3d 23, 26 (2d Cir. 1996). The MMWA

provides that "a consumer who is damaged by the failure of a supplier, warrantor, or service contractor to comply with any obligation under this chapter, or under a written warranty, implied warranty, or service contract, may bring suit for damages and other legal and equitable relief" in federal court. 15 U.S.C. § 2310(d)(1). The MMWA limits the subject matter jurisdiction of the federal courts to adjudicate such claims. For example, individual claims must be for $25 or more, and there is a $50,000 amount in controversy requirement for all claims brought in a suit. Id. § 2310(d)(3)(A)-(B). The MMWA further provides that "no claim shall be cognizable . . . if the action is brought as a class action, and the number of named plaintiffs is less than one hundred." Id. § 2310(d)(3)(C). Moreover, in a class action, the "person obligated under the warranty" must be "afforded a reasonable opportunity to cure such failure to comply" with the warranty. Id. § 2310(e).[8] In addition to damages, a successful plaintiff may recover attorney's fees. Id. § 2310(d)(2).

The defendants raise three arguments for dismissing the plaintiff's MMWA claim: (1) the MMWA does not apply because the Tablets are not "consumer products" within the meaning of the

[8] The defendants do not argue that the plaintiff fails to meet these requirements.

statute; (2) the MMWA does not apply because the labels at issue are otherwise governed by federal law; and (3) the MMWA claim fails because the state law warranty claims fail. The plaintiff's MMWA claim is dismissed because the Tablets' labels and package inserts are otherwise governed by the Food, Drug, and Cosmetic Act ("FDCA"). The Court declines to reach the defendants' argument that the Tablets are not consumer products.

The MMWA provides that:

> This chapter . . . shall be inapplicable to any written warranty the making or content of which is otherwise governed by Federal law. If only a portion of a written warranty is so governed by Federal law, the remaining portion shall be subject to this chapter.

15 U.S.C. § 2311(d). Federal Trade Commission ("FTC") regulations also specify that this section "exempts from the Act . . . any written warranty the making or content of which is required by federal law." 16 C.F.R. § 700.3(a).

The FDCA and its accompanying regulations contain labeling requirements for drugs.[9] Under the FDCA, "labeling" is defined as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2)

[9] Under 21 U.S.C. § 321(g)(1)(B), a "drug" is an article "intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in" humans. There is no dispute that the Tablets are drugs within this definition because they are intended to prevent dental caries.

accompanying such article." 21 U.S.C. § 321(m). Labels for drugs must include "the established name and quantity or, if determined to be appropriate by the Secretary, the proportion of each active ingredient." Id. § 352(e)(1)(A)(ii). The regulations accompanying the FDCA contain a complex and lengthy set of requirements that different types of drug labels must satisfy. See generally 21 C.F.R. § 201.56; Id. § 201.80.

The "Indications and Usage" section of the package insert is also addressed in the FDA regulations: "If there is a specific pediatric indication (i.e., an indication different from those approved for adults) . . . it shall be described under the 'Indications and Usage' section of the labeling." Id. § 201.80(f)(9)(ii). Any "appropriate pediatric dosage information shall be given under the 'Dosage and Administration' section of the labeling." Id.

The defendants' motion to dismiss the MMWA claim is granted because the relevant portions of the Tablets' labels and inserts are governed by the FDCA. The alleged false statement at issue in this litigation is narrow. It consists of the defendants' representation that the Tablets contain a certain amount of fluoride ion when they in fact contain less than half that amount. As the plaintiff points out, 21 U.S.C. § 352(e)(1)(A)(ii) requires drug manufacturers to include the

quantity of each active ingredient on the Tablets' labels. Thus, the alleged misrepresentation is governed by the FDCA and is not actionable under the MMWA.

The plaintiff's arguments to the contrary are not persuasive. First, the plaintiff relies on the FTC's regulations concerning the MMWA. Those regulations provide that the § 2311(d) exclusion applies only to warranties "required by federal law." 16 C.F.R. § 700.3(a). The plaintiff contends that this regulation demonstrates that the "governed by" language in § 2311(d) should be applied only where the warranty's contents were required, not simply regulated, by federal law. It is unnecessary to explore whether any tension exists between these two formulations, however, since the disclosure of the Tablets' active ingredient, which is the key misrepresentation at issue here, is both governed by and required by the FDCA.

Next, the plaintiff discusses the second sentence of § 2311(d), which provides that, "[i]f only a portion of a written warranty is so governed by Federal law, the remaining portion shall be subject to this chapter." See Sandoval v. PharmaCare US, Inc., ---F. Supp. 3d---, 2015 WL 7351512, at *8 (S.D. Cal. Sept. 30, 2015) (discussing this provision). The plaintiff contends that certain portions of the "Indications and

Usage" section of the package insert are not required by the FDCA. Specifically, the plaintiff points to a section of the inserts that states, for example: "Multivitamin with 1 mg Fluoride Chewable Tablets provide fluoride in tablet form for children 6-16 years of age in areas where the water fluoride level is less than 0.3 ppm." The plaintiff contends that this language and the rest of the Indications and Usage section are not required by the FDCA, but are actionable warranties under the MMWA.

The plaintiff is wrong. As the plaintiff recognizes, the language in the "Indications and Usage" section is consistent with the ADA-AAP dosage recommendations.[10] The statements are not themselves misrepresentations, nor do they specifically identify the amount of fluoride ion in the Tablets. While these statements may be evidence of the defendants' fraudulent intent with respect to the label's representation about the actual fluoride concentrations in the Tablets, they are not the alleged false warranty at issue in this litigation.

[10] The insert makes reference to the AAP when it states that: The AAP "recommends that children up to age 16, in areas where drinking water contains less than optimal levels of fluoride, receive daily fluoride supplementation." This statement is not alleged to be false and does not contain a specific warranty about the concentration of fluoride in the Tablets.

VI. New York General Business Law § 349

N.Y. Gen. Bus. Law § 349 prohibits "deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state." Orlander v. Staples, Inc., 802 F.3d 289, 300 (2d Cir. 2015) (citation omitted). To succeed on a § 349 claim, "a plaintiff must allege that a defendant has engaged in (1) consumer-oriented conduct that is (2) materially misleading and that (3) plaintiff suffered injury as a result of the allegedly deceptive act or practice." Id. (citation omitted). "The New York Court of Appeals has adopted an objective definition of 'misleading,' under which the alleged act must be likely to mislead a reasonable consumer acting reasonably under the circumstances." Cohen v. JP Morgan Chase & Co., 498 F.3d 111, 126 (2d Cir. 2007) (citation omitted). In addition, there must be a causal "connection between the misrepresentation and some harm from, or failure of, the product." Orlander, 802 F.3d at 302 (citation omitted).

Under New York law, conduct is "consumer-oriented" when it "had a broader impact on consumers at large." Crawford, 758 F.3d at 490 (citation omitted). "Private contract disputes, unique to the parties, for example, would not fall within the ambit of the statute." Id. (citation omitted). This element

thus "may be satisfied by showing that the conduct at issue potentially affects similarly situated consumers." Sykes v. Mel S. Harris & Associates LLC, 780 F.3d 70, 84 (2d Cir. 2015) (citation omitted). In sum, "the injury must be to the public generally as distinguished from the plaintiff alone." Wilson v. Nw. Mut. Ins. Co., 625 F.3d 54, 64-65 (2d Cir. 2010) (citation omitted); see Euchner-USA, Inc. v. Hartford Cas. Ins. Co., 754 F.3d 136, 143 (2d Cir. 2014) ("deceptive conduct aimed at the public at large" is consumer-oriented (citation omitted)).

The plaintiff has plausibly pled that the defendants violated N.Y. Gen. Bus. Law § 349. The labels and inserts were directed towards pharmacists and consumers, and the plaintiff alleges that these labels were materially misleading. The defendants' only ground for moving to dismiss the § 349 claim is that the conduct alleged is not consumer-oriented. The defendants contend that the statements at issue were directed to doctors or pharmacists, not patients, and therefore the statements were not meant to mislead consumers. The cases the defendants cite in support of their argument involve large private transactions between sophisticated businesses and therefore do not address the facts at hand. E.g., Weiss v. Polymer Plastics Corp., 802 N.Y.S.2d 174, 176 (2d Dep't 2005) ("The transaction in this case was between two companies in the

building and supply industry."); St. Patrick's Home for Aged & Infirm v. Laticrete Int'l, Inc., 696 N.Y.S.2d 117, 122 (1st Dep't 1999) ("The transaction in this case was a sizable one between two companies . . . this was not the type of 'modest' transaction that the statute was intended to reach." (citation omitted)). The defendants' reading of the phrase "consumer-oriented" under New York law is therefore unduly narrow.[11] The plaintiff has plausibly pled that the defendants' conduct was consumer-oriented and the defendants' motion to dismiss the § 349 claim is denied.

VII. Fraud and Fraudulent Concealment

"Under New York law, fraud requires proof of (1) a material misrepresentation or omission of a fact, (2) knowledge of that fact's falsity, (3) an intent to induce reliance, (4) justifiable reliance by the plaintiff, and (5) damages." Loreley Fin. (Jersey) No. 3 Ltd., 797 F.3d at 170 (citation omitted). Fraudulent concealment requires that the plaintiff plead "(1) failure to discharge a duty to disclose; (2) an intention to defraud, or scienter; (3) reliance; and (4)

[11] The defendants' attempt to apply the learned intermediary doctrine to this suit also fails. The learned intermediary doctrine applies to failure to warn claims and provides that a "drug manufacturer's duty to warn of the dangers of using the drug in question" is "fulfilled by giving adequate warning to the prescribing physician." Spensieri v. Lasky, 94 N.Y.2d 231, 239 (1999).

damages." TVT Records v. Island Def Jam Music Grp., 412 F.3d 82, 90-91 (2d Cir. 2005).

> In the context of a business transaction, the duty to disclose arises where a party, with a duty to be complete, has made only a partial or ambiguous statement, or where one party possesses superior knowledge, not readily available to the other, and knows that the other is acting on the basis of mistaken knowledge.

Id. at 91 (citation omitted).

Rule 9(b) has heightened pleading requirements for fraud claims in federal court. Under these requirements, the complaint must "(1) detail the statements (or omissions) that the plaintiff contends are fraudulent, (2) identify the speaker, (3) state where and when the statements (or omissions) were made, and (4) explain why the statements (or omissions) are fraudulent." Loreley Fin. (Jersey) No. 3 Ltd., 797 F.3d at 171 (citation omitted). "[T]hough mental states may be pleaded generally, Plaintiffs must nonetheless allege facts that give rise to a strong inference of fraudulent intent." Id. (citation omitted). "An inference is strong if it is cogent and at least as compelling as any opposing inference one could draw from the facts alleged." Id. at 176-77. "At the pleading stage, . . . a fraud plaintiff may establish a strong inference of scienter . . . by alleging facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness." Id. at 177

(citation omitted). The facts alleged in the pleadings are considered "in their totality, not in isolation." Id. at 171. The key purpose of these requirements is to "inform each defendant of the nature of its alleged participation in the fraud." Id. at 172 (citation omitted).

The plaintiff has pled sufficient facts to raise a strong inference of fraudulent intent and the remaining elements of a fraudulent concealment claim. The defendants manufactured and sold the Tablets, which included labels and package inserts implying that the fluoride dosage was sufficient to prevent tooth decay and that the Tablets complied with the ADA-AAP recommendations. The defendants admitted that the Tablets were sub-potent and did not deliver the dosage of fluoride ion indicated on the labels. The defendants allegedly knew that the master formula for the Tablets differed from the fluoride concentration listed on the labels and package inserts. These facts constitute strong circumstantial evidence of scienter and therefore satisfy Rule 9(b)'s pleading requirements. See Loreley Fin. (Jersey) No. 3 Ltd., 797 F.3d at 174 ("At the pleadings stage, the alleged fraud need only be plausible based on the complaint; it need not be more likely than other possibilities.").

The defendants' arguments to the contrary are not

persuasive. The defendants primarily contend that the labels are inconsistent with an intent to deceive because they listed the active ingredient of "fluoride as sodium fluoride." According to the defendants, this small-print, sideways disclosure undermines any inference of fraudulent intent. A disclosure on the label and package insert that the active ingredient is fluoride as sodium fluoride does not render the plaintiff's fraud claim implausible. Nothing in the label or the insert explained that the Tablets do not contain the recommended dosages of fluoride ion that are discussed on the insert itself or that sodium fluoride contains only 45% of the recommended amount of fluoride ion.[12] Thus, although the labels indicate that the active ingredient was sodium fluoride, the complaint contains strong circumstantial evidence of the defendants' fraudulent intent.

VIII. Unjust Enrichment

The elements of an unjust enrichment claim are "(1) the other party was enriched, (2) at the other party's expense, and

[12] Read together, the label and the insert add to the confusion. The active ingredient in a 1 milligram Tablet is listed as "fluoride as sodium fluoride." But the "Nutrition Facts" section lists "Fluoride" and then indicates that there is "1 mg" of that ingredient. Thus, even a careful reader could conclude that there was sufficient sodium fluoride in the Tablet to yield an overall fluoride concentration of 1 milligram (meaning that there were 2.2 milligrams of sodium fluoride in the Tablet).

(3) that it is against equity and good conscience to permit the other party to retain what is sought to be recovered." Georgia Malone & Co. v. Rieder, 19 N.Y.3d 511, 516 (2012) (citation omitted). Unjust enrichment "is available only in unusual situations when, though the defendant has not breached a contract nor committed a recognized tort, circumstances create an equitable obligation running from the defendant to the plaintiff." Corsello v. Verizon New York, Inc., 18 N.Y.3d 777, 790 (2012). "Typical cases are those in which the defendant, though guilty of no wrongdoing, has received money to which he or she is not entitled." Id. "[U]njust enrichment is not a catchall cause of action" and it "is not available where it simply duplicates, or replaces, a conventional contract or tort claim." Id.; see Scarola Ellis LLP v. Padeh, 984 N.Y.S.2d 56, 59 (1st Dep't 2014).

The defendants' motion to dismiss the unjust enrichment claim is granted. As discussed above, the typical unjust enrichment case involves a party who retains money to which he is not entitled despite the fact that he has not committed a recognized tort or breached a contract. Here, the accusations surrounding the plaintiff's unjust enrichment claim overlap with her fraud, fraudulent concealment, express warranty, and § 349 claims, all of which may proceed. She therefore may not bring

an unjust enrichment claim as a catch-all cause of action where she adequately pleads that the defendants committed the recognized tort of fraud and breached an express warranty.

The plaintiff's brief arguments to the contrary are not persuasive. She primarily contends that other courts in this district have allowed unjust enrichment claims to proceed alongside § 349 claims, for example. E.g., Quinn v. Walgreen Co., 958 F. Supp. 2d 533, 545 (S.D.N.Y. 2013) (allowing a § 349 claim and an unjust enrichment to proceed, but not addressing whether the unjust enrichment claim was duplicative). These cases do not overcome the New York Court of Appeals' decision in Corsello, however, which held that "[a]n unjust enrichment claim is not available where it simply duplicates, or replaces, a conventional contract or tort claim." 18 N.Y.3d at 790.

Conclusion

The defendants' April 19, 2016 motion to dismiss is granted in part. The following claims remain: (1) the § 349 claim; (2) breach of express warranty; and (3) the fraud and fraudulent concealment claims.

Dated: New York, New York
July 20, 2016

DENISE COTE
United States District Judge