UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES – GENERAL

Case No.	LA CV15-00200 JAK (Ex)	Date	June 18, 2015
Title	Oula Zakaria v. Gerber Products Co.		

Present: The Honorable	JOHN A. KRONSTADT, UNITED STATES DISTRICT JUDGE
Andrea Keifer	Not Reported
Deputy Clerk	Court Reporter / Recorder
Attorneys Present for Plaintiffs:	Attorneys Present for Defendants:
Not Present	Not Present

Proceedings: **(IN CHAMBERS) ORDER RE DEFENDANT'S MOTION TO DISMISS FIRST AMENDED COMPLAINT (DKT. 27)**

I. Introduction

Oula Zakaria ("Plaintiff") is the mother of Layla, who was born on September 4, 2013. First Amended Complaint ("FAC"), Dkt. 26, ¶ 59. In October 2013, Plaintiff took Layla to an appointment with a pediatrician. *Id.* ¶ 60. The pediatrician introduced Plaintiff to Gerber Good Start Gentle ("Good Start Gentle") and Gerber Good Start Soothe. Each is an infant formula produced by Gerber Products Co. ("Defendant"). *Id.*

Plaintiff alleges that in October 2013 and November 2013, she "researched Good Start formula and reviewed statements made by Defendant on its website highlighting Good Start Gentle's endorsement by the [Food and Drug Administration ('FDA')] and its ability to protect infants from developing allergies." *Id.* ¶ 61. Plaintiff contends that Defendant misrepresented that Good Start Gentle, which contains partially hydrolyzed whey protein, reduces the risk of infants developing atopic dermatitis, a form of eczema. *Id.* ¶¶ 20, 36, 64. Based on this alleged misrepresentation and the related one that the FDA endorsed Defendant's health claims, Plaintiff discontinued the use of other formula products, and exclusively purchased Good Start Gentle. *Id.* ¶¶ 62, 68.

Plaintiff estimates that she purchased one container of Good Start Gentle per week from October 2013 to November 2014, from stores in Porter Ranch, California. *Id.* ¶¶ 65, 66. Some of the containers of Good Start Gentle purchased by Plaintiff had a label that read, "1st & Only Routine Formula to Reduce Risk of Developing Allergies, see label inside." *Id.* ¶¶ 62-63; Dkt. 26-3. But for Defendant's allegedly false and misleading representations, Plaintiff alleges that she would not have made these purchases. FAC, Dkt. 26, ¶¶ 67-69.

On January 9, 2015, Plaintiff filed this putative class action against Defendant. Dkt. 1. The Complaint was amended pursuant to the stipulation of the parties. Dkts. 23-26. On February 27, 2015, Plaintiff filed the FAC. Dkt. 26. Plaintiff seeks certification of a class of "[a]ll persons who have purchased Gerber Good

Start Gentle infant formula in California during the applicable statute of limitations." *Id.* ¶ 70. Plaintiff asserts federal jurisdiction under the Class Action Fairness Act ("CAFA"), 28 U.S.C. § 1332(d)(2). *Id.* ¶ 15.

The FAC advances eight causes of action: (i) unlawful business acts and practices in violation of California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code §§ 17200 *et seq.*; (ii) unfair and fraudulent business acts and practices in violation of the UCL; (iii) violation of the California False Advertising Law ("FAL"), Cal. Bus. & Prof. Code §§ 17500 *et seq.*; (iv) violation of the Consumer Legal Remedies Act ("CLRA"), Cal. Civ. Code §§ 1750 *et seq.*; (v) breach of express warranty in violation of Cal. Commercial Code § 2313; (vi) breach of the implied warranty of merchantability in violation of Cal. Commercial Code § 2314; (vii) negligent misrepresentation; and (viii) intentional misrepresentation. *Id.* ¶¶ 82-155. Plaintiff contends that her allegations are supported by certain administrative actions by the FDA as well as the decision by the Federal Trade Commission ("FTC") to bring a civil action against Defendant in the District of New Jersey. That action arises from allegations about Defendant's marketing and sale of Good Start Gentle. *Id.* ¶¶ 21-58.

On March 23, 2015, Defendant filed a motion to dismiss the FAC ("Motion"). Dkt. 27. Defendant contends that, under the doctrine of primary jurisdiction, and in deference to the FDA, the Court should abstain from proceeding in this matter. Defendant also contends that, if the claims are analyzed on their merits, they are inadequately or improperly pleaded. *Id.* at 31.

After a hearing on the Motion on June 15, 2015, it was taken under submission. Dkt. 50. For the reasons stated in this Order, the Motion is **DENIED**.

II. Factual and Procedural Background

A. 2005-2011: The FDA Rejects Two Qualified Health Claims Proposed by Defendant and Provides Guidance

The FDA is the federal administrative agency that reviews and authorizes health claims related to food products sold in the United States. FAC, Dkt. 26, ¶¶ 21, 24. The FDA permits a "qualified health claim" to be made about a food product where it is "supported by scientific evidence, but does not meet the significant scientific agreement standard," i.e., most qualified experts agree the claim is "supported by the totality of publicly available scientific evidence for a substance/disease relationship." *Id.* ¶¶ 22, 23. The FDA requires qualified health claims to be "accompanied by a disclaimer or other qualifying language to accurately communicate the level of scientific evidence supporting the claim." *Id.* ¶ 23.

In June 2005, Defendant filed a petition with the FDA seeking its approval of the following qualified health claim:

> Breastfeeding is the best way to nourish infants. For infants who are not exclusively breastfed, emerging clinical research in healthy infants with family history of allergy shows that feeding a 100% Whey-Protein Partially Hydrolyzed formula may reduce the risk of common food allergy symptoms, particularly allergic skin rash, when used instead of

> whole-protein cow's milk formula from the initiation of formula feeding.

Id. ¶ 25.

On May 11, 2006, the FDA denied Defendant's petition. *Id.* ¶ 26. Based on a review of 36 studies, the FDA determined that there was "no credible evidence for a relationship between the consumption of 100 percent partially hydrolyzed whey protein in infant formula and a reduced risk of food allergy," and determined that "neither a disclaimer nor qualifying language would suffice to prevent consumer deception in this circumstance." *Id.* ¶¶ 26-27.

In May 2009, Defendant filed a second petition. It sought FDA approval of the following qualified health claim:

> Breastfeeding is the best way to nourish infants. For infants who are not exclusively breastfed, emerging clinical research shows that, in healthy infants with family history of allergy, feeding a 100% Whey-Protein Partially Hydrolyzed infant formula instead of a formula containing intact cow's milk proteins may reduce the risk of developing the most common allergic disease of infancy – atopic dermatitis – throughout the 1st year of life and up to 3 years of age.

Id. ¶ 30.

On May 24, 2011, after reviewing publicly available scientific evidence, the FDA made two determinations.[1] First, there was "very little credible evidence for a qualified health claim about the relationship between feeding a 100 percent whey-protein partially hydrolyzed infant formula for the first 4 months of life and a reduced risk of atopic dermatitis throughout the first year of life and up to 3 years of age." *Id.* ¶ 31. Second, there was "little credible evidence for a qualified health claim about the relationship between feeding 100 percent whey-protein partially hydrolyzed infant formula for the first four months of life and a reduced risk of atopic dermatitis throughout the first year of life." *Id.* The FDA determined that "the current scientific evidence is appropriate for consideration of a qualified health claim regarding the relationship between the consumption of 100 percent whey-protein partially hydrolyzed infant formula and a reduced risk of atopic dermatitis, provided that the qualified health claims are appropriately worded so as not to mislead consumers." Dkt. 28, Ex. B at 10. However, it rejected Defendant's proposed language as "mischaracteriz[ing] the strength of the evidence and . . . misleading." *Id.* The FDA suggested certain qualified health claims for which it would "consider the exercise of its enforcement discretion." *Id.*

[1] The FDA reviewed 20 intervention studies "designed to evaluate the relationship between the consumption of 100 percent whey-protein partially hydrolyzed infant formula and a reduced risk of atopic dermatitis." Dkt. 28, Ex. B at 5. It determined that scientific conclusions could not be drawn from 16 of these studies, and limited its review to four intervention studies published in six reports. *Id.* at 5-8.

B. June 2011: The Lowe Study Finds No Evidence that Partially Hydrolyzed Whey Formula Reduces the Risk of Infant Allergic Disease

In June 2011, a study by Adrian J. Lowe and others ("Lowe Study") was published in the Journal of Allergy & Clinical Immunology. Dkt. 26-2. The Lowe Study concluded that there was

> no evidence that introducing [partially hydrolyzed whey formula ('pHWF')] at the cessation of breast-feeding reduced the risk of allergic manifestations, including eczema, asthma, and allergic rhinitis, in this study of high-risk infants. Our findings do not support the recommendation that pHWF should be used after breast-feeding as a preventive strategy for infants at high risk of allergic diseases.

Id. at 6.[2]

The FDA did not consider the Lowe Study in connection with its Letter of Enforcement Discretion to Defendant in May 2011. Opp'n, Dkt. 35 at 10 n.2. Plaintiff alleges Defendant was on notice of the existence and results of this study because Nestec Ltd., a subsidiary of Nestle Australia, Ltd. that is affiliated with Defendant, "provided the Lowe Study with study formula and staff funding for the first 6 years of the study." FAC, Dkt. 26, ¶ 41.

C. 2011-14: Defendant Markets Good Start Gentle

Plaintiff alleges that "[s]ince at least 2011, Defendant knowingly disseminated or has caused to be disseminated advertisements, packaging, and promotional materials for Good Start Gentle in California containing false and misleading statements . . . ." *Id.* ¶ 43. These include the following, all of which are attached as exhibits to the FAC (Dkts. 26-3 to 26-9):

- The "1st and Only Routine Formula to Reduce the Risk of Developing Allergies" label, on which Plaintiff personally relied. *Id.* ¶ 44;
- A product label that stated that "Good Start Gentle 'is the first and only formula brand . . . that meets the criteria for a FDA Qualified Health Claim for atopic dermatitis.'" *Id.* ¶ 45;
- A television commercial in which an announcer states, "[y]ou want your Gerber baby to have your imagination . . . your smile . . . your eyes . . . not your allergies. . . . [I]f you introduce formula, choose the Gerber Good Start Comfort Proteins Advantage." *Id.* ¶ 46;
- A print advertisement depicting a baby's face on a canister of Good Start Gentle, with the caption, "I love Mommy's eyes, not her allergies. If you have allergies in your family, breastfeeding your baby can help reduce their risk. And if you decide to introduce formula research shows the formula you first provide to your baby may make a difference." *Id.* ¶ 47;

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[2] The Lowe Study cited six other studies in support of the proposition that "[p]artially hydrolyzed whey formulas . . . have been widely recommended to prevent the development of allergic diseases in early childhood." Dkt. 26-2 at 2.

- A magazine advertisement that promoted Good Start Gentle as "the first and only infant formula that meets the criteria for a FDA Qualified Health Claim." *Id.* ¶ 48;
- A gold badge that appeared on a supermarket display of a canister of Good Start Gentle, on which "the words 'Meets FDA' are printed at the top, '1st and Only' is printed in the center, and 'Qualified Health Claim' is printed at the bottom." *Id.* ¶ 49; and
- A magazine advertisement that showed a mother feeding an infant, on which a badge appeared stating that Good Start Gentle is the "1st Formula with FDA Qualified Health Claim." *Id.* ¶ 50.

Plaintiff alleges that she personally saw the "1st and Only Routine Formula" label, but does not contend that she saw any of the others.

D. October 29, 2014: The FTC Sues Defendant in Connection with Its Advertising, Marketing and Sale of Good Start Gentle

On October 29, 2014, the FTC filed an action against Defendant in the District of New Jersey ("FTC Action"). *Federal Trade Comm'n v. Gerber Products Co*., 2:14-cv-06771-SRC-CLW; FTC Compl., Dkt. 28-1. It remains pending. The FTC contends Defendant has falsely, misleadingly, or without substantiation represented that "feeding Gerber Good Start Gentle formula to infants with a family history of allergies prevents or reduces the risk that they will develop allergies." *Id.* ¶¶ 19-20. It also contends that Defendant falsely or misleadingly represented that "Gerber Good Start Gentle formula qualified for or received approval for a health claim from the Food and Drug Administration." *Id.* ¶ 22.

The FTC seeks "preliminary and permanent injunctive relief, rescission or reformation of contracts, restitution, the refund of monies paid, disgorgement of ill-gotten monies, and other equitable relief for Defendant's acts or practices, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52, in connection with the labeling, advertising, marketing, distribution, and sale of Gerber Good Start Gentle, an infant formula that purports to prevent or reduce the risk of the development of allergies." *Id.* ¶ 1.

E. October 31, 2014: The FDA Sends a Warning Letter to Defendant Regarding the Marketing and Branding of Good Start Gentle

On October 31, 2014, the FDA sent a "Warning Letter" to Gary Tickle, the President and CEO of Defendant. Dkt. 39-2. It states that Good Start Gentle was misbranded within the meaning the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 343(a)(1), (r)(1)(B), because its labeling "bears health claims that were not authorized by FDA," and is "misleading." *Id.* at 2. The Warning Letter also states that the claims on Defendant's product label and website "asserting the limited evidence linking the benefit between consumption of '100% whey partially hydrolyzed' and atopic dermatitis are generally consistent with the claims suggested in the 2011 letter announcing the claims for which FDA would consider the exercise of enforcement discretion." *Id.* at 4. However, the FDA determined that Defendant did not make sufficiently clear the risk Good Start Gentle posed to infants with milk allergies, or the need to consult with a doctor regarding the care and feeding choices for an infant that is allergic or suspected to be allergic to milk. *Id.* at 4-6.

The Warning Letter also stated that Defendant made an unapproved health claim because in the FDA's 2011 correspondence with Defendant, it considered only health claims about "an infant formula made with 100% whey-protein partially hydrolyzed." *Id.* at 4. However, the Good Start Gentle packaging claimed that "100% whey partially hydrolyzed . . . may reduce the risk of atopic dermatitis." *Id.* at 2, 4. Whey contains lactose, minerals, vitamins and fat as well as protein, and the FDA's 2011 analysis did not evaluate whey as distinct from whey protein. *Id.* at 4-5. The Warning Letter stated, "[t]he above violations are not intended to be an all-inclusive list of deficiencies associated with your products or their labeling." *Id.* at 6.

III. Analysis

A. Legal Standard

Fed. R. Civ. P. 8(a) provides that a "pleading that states a claim for relief must contain . . . a short and plain statement of the claim showing that the pleader is entitled to relief . . . ." The complaint must state facts sufficient to show that a claim for relief is plausible on its face. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). The complaint need not include detailed factual allegations, but must provide more than a "formulaic recitation of the elements of a cause of action." *Twombly*, 550 U.S. at 555. "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully. Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal citations and quotations omitted).

A party may move to dismiss for failure to state a claim pursuant to Fed. R. Civ. P. 12(b)(6). Dismissal is appropriate only where the complaint lacks a cognizable legal theory or sufficient facts to support one. *Mendiondo v. Centinela Hosp. Med. Ctr.*, 521 F.3d 1097, 1104 (9th Cir. 2008). In considering a motion to dismiss, the allegations in the challenged complaint are deemed true and must be construed in the light most favorable to the non-moving party. *Cahill v. Liberty Mut. Ins. Co.,* 80 F.3d 336, 337-338 (9th Cir. 1996). However, a court need not "accept as true allegations that contradict matters properly subject to judicial notice or by exhibit. Nor is the court required to accept as true allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences." *In re Gilead Sciences Sec. Litig.* 536 F.3d 1049, 1055 (9th Cir. 2008) (citing *Sprewell v. Golden State Warriors*, 266 F.3d 979, 988 (9th Cir. 2001)).

B. Application

1. Whether a Stay or Dismissal Is Required Under the Primary Jurisdiction Doctrine

Under the doctrine of primary jurisdiction, a court may refer an issue "within the special competence of an administrative agency" to the agency, and stay or dismiss without prejudice the underlying action pending agency review. *Reiter v. Cooper*, 507 U.S. 258, 268-69 (1993). "Primary jurisdiction is not a doctrine that implicates the subject matter jurisdiction of the federal courts. Rather, it is a prudential doctrine under which courts may, under appropriate circumstances, determine that the initial decision-making responsibility should be performed by the relevant agency rather than the courts." *Syntek Semiconductor*

Co. v. Microchip Tech. Inc., 307 F.3d 775, 780 (9th Cir. 2002).

This doctrine "applies in a limited set of circumstances," and is "not designed to secure expert advice from agencies every time a court is presented with an issue conceivably within the agency's ambit." *Clark v. Time Warner Cable*, 523 F.3d 1110, 1114 (9th Cir. 2008) (internal quotation marks omitted). "Instead, it is to be used only if a claim requires resolution of an issue of first impression, or of a particularly complicated issue that Congress has committed to a regulatory agency." *Id.* (citation and internal quotation marks omitted). "The 'deciding factor' in determining whether the primary jurisdiction doctrine should apply is 'efficiency.'" *Reid v. Johnson & Johnson*, 780 F.3d 952, 967 (9th Cir. 2015) (citation omitted).

Defendant contends there is a need for FDA expertise in the evaluation of health claims made in product labeling, and contends that Plaintiff seeks to "enforce her own idiosyncratic, subjective requirements regarding what can and cannot appear on Gerber's labels." Mot., Dkt. 27 at 21.[3] Plaintiff cites several opinions that have rejected the application of the primary jurisdiction doctrine to putative consumer class actions based on deceptive and misleading marketing. Opp'n, Dkt. 35 at 13-16; *see also Reid*, 780 F.3d at 967 ("The issue that this case ultimately turns on is whether a reasonable consumer would be misled by [defendant's] marketing, which the district courts have reasonably concluded they are competent to address in similar cases.").

The primary jurisdiction doctrine does not warrant the stay or dismissal of Plaintiff's claims. Plaintiff raises neither an issue of first impression nor a complex one. Instead, her claims turn on whether Defendant's representations concerning the health benefits of Good Start Gentle and the FDA's approval of the formula were false or misleading. To be sure, in analyzing Defendant's health claims, a factfinder may be required to consider evidence about clinical studies including the Lowe Study and those evaluated by the FDA. This is not a sufficient basis to apply the primary jurisdiction doctrine. *Clark v. Time Warner Cable*, 523 F.3d 1110, 1114 (9th Cir. 2008). Further, the FDA's 2009 and 2011 determinations, on which Plaintiff relies, were based on medical evidence available at the time each was made, and do not present a

[3] Defendant cites two district court cases, *Mutual Pharmaceutical Co. v. Watson Pharmaceuticals, Inc*., 2009 WL 3401117 (C.D. Cal. Oct. 19, 2009), and *Gordon v. Church & Dwight Co*., 2010 WL 1341184 (N.D. Cal. Apr. 2, 2010), for the proposition that the primary jurisdiction doctrine may apply to claims that "challenge[] the adequacy of the labeling of an FDA-regulated product." Mot., Dkt. 27 at 21-22. These cases are not controlling. Moreover, each is distinguishable. In *Mutual Pharmaceutical*, in denying a plaintiff's motion for a preliminary injunction, the court stated in dicta that disputes concerning the content of pharmaceutical labels and inserts falls "squarely within the primary jurisdiction of the FDA," but denied the motion on other grounds. 2009 WL 2401117, at *4. After the case was transferred to the District of New Jersey, the district court there denied the defendants' motion to dismiss and rejected their primary jurisdiction argument. *Mut. Pharm. Co. v. Watson Pharm., Inc*., 09-cv-5421, Dkt. 209 at 3 (D.N.J. Feb. 8, 2010). *Gordon* concerned latex condoms containing the spermicidal lubricant nonoxynol-9, which were labeled as helping to reduce the transmission of sexual diseases, including AIDS. 2010 WL 1341184, at *1. The plaintiffs argued that this lubricant increased the risk of AIDS transmission. At the time the action was dismissed, the FDA, which had actively regulated nonoxynol-9 condoms for 30 years under the FDCA, was considering substantial changes to its labeling requirements "in connection with warnings similar to those that plaintiffs seek to have the court impose." *Id.* at *3. Therefore, *Gordon* is distinguishable because in that case, unlike the instant one, a "particularly complicated issue" was presented.

"substantial danger of inconsistent rulings" that warrants application of the primary jurisdiction doctrine. *Brown v. MCI WorldCom Network Servs., Inc*., 277 F.3d 1166, 1173 (9th Cir. 2002). Defendant argues that dismissal or abstention is warranted because "the FDA is currently considering certain of Gerber's claims regarding Good Start." Reply, Dkt. 39 at 11. However, the October 31, 2014 Warning Letter reiterates the factual findings of the 2011 determination. The claims currently under consideration relate to milk allergies and the distinction between whey and whey protein. Neither of these issues is material to Plaintiff's claims.

For all of these reasons, the adjudication of Plaintiff's claims in this forum is appropriate. The primary jurisdiction doctrine does not apply.

2. Whether the FAC Complies with Fed. R. Civ. P. 8(a)

Defendant argues that the FAC must be dismissed because it does not provide a short and plain statement of the claim showing that the Plaintiff is entitled to relief, as required by Fed. R. Civ. P. 8(a). Mot., Dkt. 35 at 13-18. Defendant contends that, because the FAC improperly references advertisements that Plaintiff did not personally see, she does not have standing to challenge them. *Id.* at 16-17. Defendant also argues the FAC fails to link the limited factual allegations about Plaintiff's personal experience with Good Start Gentle with the description of the FDA and FTC proceedings, or the "conclusory allegations contained in the 73 paragraphs that make up the eight causes of action." *Id.* at 17. For these reasons, Defendant argues that Plaintiff "fails to allege any of the required facts that could allow this Court to reasonably infer that Gerber could be liable under any of the claims that she asserts with respect to her actual experience." Reply, Dkt. 39 at 10.

Even if the references to the FDA and FTC proceedings and the advertisements not personally seen by Plaintiff were removed from the FAC, it would still be sufficient. Thus, it would adequately allege a sequence of events in which Defendant made misrepresentations about the health benefits of, and FDA support for, Good Start Gentle, as well as Plaintiff's reliance on them when she decided to purchase Defendant's product instead of alternatives.[4] For purposes of this Motion, the FAC sets forth "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2).

Further, the references to the FDA and FTC proceedings and the other advertisements are not improper. Plaintiff may reasonably have determined these additional allegations were necessary because certain of her claims are evaluated under the standards of Fed. R. Civ. P. 9(b), discussed *infra*, which requires the circumstances of fraud to be pleaded "with particularity." It is also significant that this is a putative class action, in which other putative class members may have encountered these advertisements. *Cf. In re First Alliance Mortgage Co*., 471 F.3d 977, 992 (9th Cir. 2006) ("The class action mechanism would be impotent if a defendant could escape much of his potential liability for fraud by simply altering the wording

[4] Although the labels seen by Plaintiff did not contain the pertinent language about FDA support for Good Start Gentle, it is also alleged that Plaintiff "reviewed statements made by Defendant on its website highlighting Good Start Gentle's endorsement by the FDA . . . ." FAC, Dkt. 26, ¶ 61.

or format of his misrepresentations across the class of victims.").

For these reasons, the FAC complies with Fed. R. Civ. P. 8(a).

3. Whether the FAC Complies with Fed. R. Civ. P. 9(b)

Fed. R. Civ. P. 9(b) requires that a plaintiff "state with particularity the circumstances constituting fraud or mistake." "Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." *Id.* Rule 9(b) requires a plaintiff to allege specific details about the fraud "including an account of the time, place, and specific content of the false representations as well as the identities of the parties to the misrepresentations." *Swartz v. KPMG LLP*, 476 F.3d 756, 764 (9th Cir. 2007) (internal quotation marks omitted). Allegations must be "specific enough to give defendants notice of the particular misconduct which is alleged to constitute the fraud charged so that they can defend against the charge and not just deny that they have done anything wrong." *Id.* (internal quotation marks omitted); *see also Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1126 (9th Cir. 2009) (a plaintiff must "articulate the who, what, when, where and how of the alleged misconduct").

Defendant argues that all of Plaintiff's claims "are grounded in the same conclusory allegations of fraud, namely that Gerber purportedly misrepresented the allergy claims relating to Good Start." Mot., Dkt. 27 at 19. Defendant advances three reasons why these claims are not pleaded with the particularity required by Rule 9(b). First, Defendant reads the FAC to allege that Plaintiff purchased Good Start based on the recommendation of her pediatrician, and not because of any advertisement she may have seen. *Id.* Second, Plaintiff "never alleges . . . that her daughter presented any manifestation of infant allergies." *Id.* Third, the only advertisement Plaintiff alleges she actually saw references the qualified health claim authorized by the FDA, and directed purchasers to "See Label Inside." *Id.*

The time, place, and content of the false representations as well as the identities of the parties to the misrepresentations are all set forth in the FAC. Defendant's arguments do not show that these allegations are ambiguous. First, although it is alleged that a physician introduced Plaintiff to Good Start Gentle, it is also alleged that Plaintiff ceased buying other infant formulas after reading the allegedly false and misleading statements on Defendant's website and the product label. FAC, Dkt. 26, ¶¶ 60-63. This is sufficient to establish a causal link between the alleged misconduct of Defendant and the claimed deception of Plaintiff.[5] *See, e.g.*, *In re Tobacco II Cases*, 46 Cal. 4th 298, 326 (2009) ("While a plaintiff

[5] Elsewhere in the Motion, Defendant contends Plaintiff has not pleaded reliance and causation, and repeats its arguments as to Civil Rules 8(a) and 9(b). Mot., Dkt. 27 at 26-27. Defendant also substantially repeats this argument in connection with Plaintiff's standing to bring UCL and FAL claims. *Id.* at 27-28 (Plaintiff "receive[d] exactly what she set out to purchase (an infant formula) and no particular representation made by the manufacturer of the product is material"). The FAC adequately pleads reliance and causation for the same reasons it is pleaded with particularity for purposes of Rule 9(b). It is also plausibly alleged that the misrepresentations were material, i.e., that "Plaintiff would not have purchased Gerber Good Start Gentle had she known (1) that partially hydrolyzed whey protein does not reduce the risk of allergies (including atopic dermatitis) in children or (2) that the FDA did not endorse, approve or certify the health claims Defendant made on its labels, in its advertisements, and on its

must show that the misrepresentation was an immediate cause of the injury-producing conduct, the plaintiff need not demonstrate it was the only cause. . . . It is enough that the representation has played a substantial part, and so had been a substantial factor, in influencing his decision.") (internal quotation marks omitted).

Second, it is not necessary for Plaintiff to allege that her daughter suffered from allergies before Plaintiff purchased Good Start Gentle, because Defendant represented that the formula would "Reduce Risk of Developing Allergies." *Id.* ¶ 62. Construing any ambiguities in the light most favorable to Plaintiff, *see Cahill v. Liberty Mut. Ins. Co.,* 80 F.3d 336, 337-338 (9th Cir. 1996), the FAC plausibly and with particularity alleges that Plaintiff switched to the purchase of Good Start Gentle to prevent her daughter from developing allergies rather than to treat existing ones.

Third, even if the inside label "cured" the allegedly misleading representation on the front of the package, whether the packaging as a whole was deceptive is a question of fact that cannot be resolved on a motion to dismiss. *See Williams v. Gerber Products Co*., 552 F.3d 934, 939 (9th Cir. 2008) (dismissal is appropriate only where it would be "impossible for the plaintiff to prove that a reasonable consumer was likely to be deceived" based on what is alleged, and "reasonable consumers should [not] be expected to look beyond misleading representations on the front of the box to discover the truth from the ingredient list in small print on the side of the box").

For these reasons, the FAC satisfies the pleading standard of Fed. R. Civ. P. 9(b).

4. Whether Plaintiff's Claims Are Based on Non-Actionable Lack of Substantiation

Under California law, a private plaintiff may not bring UCL or FAL claims based on a claim made in advertising that is merely unsubstantiated; actual falsehood in the advertising is required. *See, e.g.*, *Eckler v. Wal-Mart Stores, Inc*., 2012 WL 5382218, at *1-2 (S.D. Cal. Nov. 1, 2012) (citing *Nat'l Council Against Health Fraud, Inc. v. King Bio Pharm., Inc*., 107 Cal. App. 4th 1336, 1345 (2003)). Courts have also dismissed analogous common law claims premised on lack of substantiation. *See, e.g.*, *Fraker v. Bayer Corp*., 2009 WL 5865687, at *9 (E.D. Cal. Oct. 6, 2009) (dismissing breach of express warranty claim because it was "predicated on the unsupported legal proposition that an advertising claim creates both a contractual obligation as to the claim's truthfulness and a contractually enforceable duty of the advertiser to have at hand scientific evidence to substantiate the claim").[6]

Defendant argues that because Plaintiff alleges that, at most, Defendant's health claims lacked substantiation, dismissal is required. Mot., Dkt. 27 at 22-25. Plaintiff cannot "piggy-back[]" on the FTC Action, because the FTC has the sole remedial authority to bring enforcement actions based on unsubstantiated advertisements, and Plaintiff lacks this authority. *Id.* at 10, 23-24. Defendant contends

website." FAC, Dkt. 26, ¶ 68.

[6] Because Plaintiff adequately pleads affirmative false statements, whether the dismissal of the common law claims would be required if only lack of substantiation were pleaded is not addressed.

the FDA's 2011 letter, which the FAC incorporates by reference, determined that it was "uncertain" whether the available scientific evidence supported Defendant's proposed qualified health claim, and this speaks to lack of substantiation rather than affirmative falsity. *Id.* at 24-25 & n.4.

The FAC alleges that the Lowe Study, which purports to be "the second largest trial to randomize individual infants to receive either pHWF or a conventional cow's milk formula," and which was published after the FDA's 2011 letter, conclusively refuted the health claims made by Defendant. Plaintiff also alleges that, although Defendant was on notice of the findings of this study, it continued falsely to advertise Good Start Gentle. *See* Opp'n, Dkt. 35 at 16-18; Lowe Study, Dkt. 26-2 at 6. Factual issues related to the relative merits and conclusions of the various studies cited by the parties cannot be decided on this Motion. Expert testimony and other evidence may be required to do so. *See In re Gerber Probiotic Sales Practices Litig.*, 2013 WL 4517994, at *8 (D.N.J. Aug. 23, 2013); *see also Reid v. Johnson & Johnson*, 780 F.3d 952, 964-65 (9th Cir. 2015) (informal FDA letter setting forth criteria under which product could be marketed did not preempt UCL, FAL, or CLRA claims).

It is also alleged that, on its website and in advertising that Plaintiff viewed, Defendant misrepresented the degree of the FDA support for its claims. This is sufficient to plead an affirmative falsehood.

For these reasons, the FAC sufficiently alleges that Defendant's health claims and representations of FDA support were actually false and not just unsubstantiated.

5. Whether Plaintiff Adequately Alleges Economic Injury

To state a claim under the UCL and FAL, a plaintiff must "demonstrate some form of economic injury." *Kwikset Corp. v. Superior Court*, 51 Cal. 4th 310, 323 (2011). Defendant contends this was not adequately pleaded because Plaintiff "fails to allege how much more she paid for Good Start over the other infant formulas that she purchased," and she was "required to plead at a minimum what she would have paid for a different product." Mot., Dkt. 27 at 28.[7]

Plaintiff alleges that she "purchased Good Start Gentle at an inflated cost" and "would have paid less than what [she] did for Good Start Gentle, or would not have purchased the product at all," but for Defendant's misrepresentations. FAC, Dkt. 26, ¶¶ 8, 91. For purposes of this Motion, these factual allegations are sufficient to state a claim of economic injury resulting from unfair competition and false advertising. *See Kwikset Corp.*, 51 Cal. 4th at 323 (economic injury may be alleged if a plaintiff "surrender[s] in a transaction more, or acquire[s] in a transaction less, than he or she otherwise would have"). Defendant provides no support for the heightened standard it would impose on the pleading of economic injury, and it is not imposed by the UCL, FAL or Rules 8 or 9.

For these reasons, the FAC plausibly alleges economic injury.

[7] Defendant also argues that Plaintiff is not entitled to injunctive relief. However, that is not sought in the FAC, nor does Plaintiff claim in its Opposition that it plans to pursue it. Mot., Dkt. 27 at 33-34; Opp'n, Dkt. 35 at 9.

6. Duty to Disclose

Defendant contends Plaintiff did not adequately allege that Defendant had a duty to disclose anything to her. Mot., Dkt. 27 at 29-30. Plaintiff acknowledges this, but argues that this was not necessary because her claims are based on affirmative misrepresentations rather than concealment or failure to disclose. Opp'n, Dkt. 35 at 20-21. Defendant does not renew this issue in its Reply. As stated elsewhere in this Order, Plaintiff has adequately alleged affirmative misrepresentation.

7. Breach of Express Warranty

"In order to plead a cause of action for breach of express warranty, one must allege the exact terms of the warranty, plaintiff's reasonable reliance thereon, and a breach of that warranty which proximately causes plaintiff injury." *Williams v. Beechnut Nutrition Corp*., 185 Cal. App. 3d 135, 142 (Cal. Ct. App. 1986). Defendant argues that Plaintiff's express warranty claim fails because Plaintiff "fails to plead what warranty she relied on and clearly fails to allege that Good Start did not work for her as she claims was warranted," and "the label at issue cites a product description, not a warranty against defects or guarantees of future performance." Mot., Dkt. 27 at 30-31.

The FAC alleges that the terms of the express warranty are set forth in Defendant's "representations to the public, including Plaintiff and the Class, by its advertising, packaging, labeling, and other means, that Good Start Gentle was FDA approved to reduce the risk of allergies in infants and that Good Start Gentle did in fact reduce the risk of allergies in infants." FAC, Dkt. 26, ¶ 127. Although factual allegations related to reasonable reliance are not recited under the heading of this cause of action, "allegations elsewhere in the Complaint" are incorporated, and these include those related to Plaintiff's reliance. *Id.* ¶¶ 67, 125. Finally, it is alleged that the warranty was breached. *Id.* ¶ 129. Plaintiff sufficiently alleges damages. "[S]tatements made by a manufacturer or retailer in an advertising brochure which is disseminated to the consuming public in order to induce sales can create express warranties." *Keith v. Buchanan*, 173 Cal. App. 3d 13, 22 (Cal. Ct. App. 1985).

For these reasons, Plaintiff's breach of express warranty claim is adequately pleaded.

8. Breach of Implied Warranty

"Unless excluded or modified . . . 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." Cal. Commercial Code § 2314. To be merchantable, it is required, *inter alia*, that they "[c]onform to the promises or affirmations of fact made on the container or label if any." *Id.* § 2314(2)(f). "Unlike express warranties, which are contractual in nature, the implied warranty of merchantability arises by operation of law." *Viggiano v. Hansen Natural Corp*., 944 F. Supp. 2d 877, 895-96 (C.D. Cal. 2013).

Defendant argues that this claim fails because "there are no allegations that Good Start was defective or unfit for its intended purpose as an infant formula." Mot., Dkt. 27 at 32. It also contends that "privity of contract is required when asserting a breach of an implied warranty." *Id.* at 33 (citing *Blanco v. Baxter Healthcare Corp.*, 158 Cal. App. 4th 1039, 1058 (2009)).

Plaintiff's breach of implied warranty claim is based on alleged affirmative representations made by Defendant on the labeling of the formula. Thus, the claim is not based on an alleged failure by Defendant to conform to the intended purpose of infant formula in general. Therefore, the claim is one that is appropriate under Cal. Commercial Code § 2314(2)(f), which modifies the common law definition of merchantability. *See Augustine v. Natrol Products, Inc*., 2014 WL 2506284, at *5 (S.D. Cal. May 15, 2014) (citing *Hauter v. Zogarts*, 14 Cal. 3d 104, 118 (1975) (in bank)). Nor is privity of contract required in implied warranty claims related to substances intended for human consumption. *See Mexicali Rose v. Superior Court*, 1 Cal. 4th 617, 621 (1992) ("foodstuffs do not fall within the general rule of privity between the manufacturer and the consumer, even though the purchase is made through a retailer") (citing *Klein v. Duchess Sandwich Co*., 14 Cal. 2d 272 (1939)). Although Plaintiff's implied warranty claim overlaps substantially with her express warranty claim, under California law, such overlap does not preclude either claim.

For these reasons, the Motion is denied as to this claim.

9. Negligent Misrepresentation

Defendant contends Plaintiff cannot state a claim for negligent misrepresentation because she cannot seek remedies for negligence as to "pure economic losses." Mot., Dkt. 27 at 33 (citing *Williamson v. Reinalt-Thomas Corp*., 2012 WL 1438812, at *14 (N.D. Cal. Apr. 25, 2012)). This rule does not apply to Plaintiff's negligent misrepresentation claim. "California law classifies negligent misrepresentation as a species of fraud, *see Bily v. Arthur Young & Co*., 3 Cal.4th 370, 11 Cal.Rptr.2d 51, 834 P.2d 745, 768 (1992), for which economic loss is recoverable. *See Robinson Helicopter Co., Inc. v. Dana Corp*., 34 Cal.4th 979, 22 Cal.Rptr.3d 352, 102 P.3d 268, 275 & n. 7 (2004))." *Kalitta Air, L.L.C. v. Cent. Texas Airborne Sys., Inc*., 315 F. App'x 603, 607 (9th Cir. 2008) (unpublished opinion).

For these reasons, the Motion is denied as to this claim.

IV. Conclusion

For the reasons stated in this Order, the Motion is **DENIED**.

IT IS SO ORDERED.

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