UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

FOR ONLINE PUBLICATION ONLY

AMY JOVEL, individually, and on behalf of other members of the general public similarly situated,

Plaintiff,

- versus -

i-HEALTH, INC., a Delaware Corporation,

Defendant.

MEMORANDUM
AND ORDER
12-CV-5614 (JG)

A P P E A R A N C E S

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JOHN GLEESON, United States District Judge:

In May 2012, plaintiff Amy Jovel filed a Second Amended Complaint ("SAC") in a putative class action against i-Health, Inc. ("i-Health") in the Superior Court of California, Los Angeles county, alleging violations of (1) California's unfair competition law, § 17200 *et seq.* ("UCL"); (2) California's Consumers Legal Remedies Act, Cal. Civ. Code § 1750 *et seq.* ("CLRA"); and (3) various state consumer protection laws; and further alleging (4) a breach of express warranty. The claims are brought on behalf of two putative classes consisting of: "[a]ll consumers who purchased BrainStrong Toddler, BrainStrong Kids and/or BrainStrong Adults,"

or, in the alternative: "[a]ll California consumers who purchased BrainStrong Toddler, BrainStrong Kids and/or BrainStrong Adults." [1] SAC ¶¶ 29-30.

In June 2012, i-Health removed the case from Superior Court of the State of California for the County of Los Angeles to the United States District Court for the Central District of California. ECF No. 1. In August 2012, i-Health moved to transfer the case to this district pursuant to 28 U.S.C. §1404(a). ECF No. 16. Over Jovel's objection (ECF No. 19), the court granted i-Health's motion to transfer the case. ECF No. 25.

Defendant now moves to dismiss Jovel's claims on grounds of: (1) federal preemption; (2) primary jurisdiction; (3) failure to state a cognizable claim as a matter of law; (4) failure to satisfy the pleading standards of Federal Rules of Civil Procedure 8 and 9(b); and (5) lack of standing. For the reasons set for below, defendant's motion is denied.

BACKGROUND

The following facts are drawn from Jovel's Second Amended Complaint and are accepted as true for the purposes of this motion. *See Harris v. Mills*, 572 F.3d 66, 71 (2d Cir. 2009).

Since April 2011 i-Health has manufactured, marketed, sold and distributed BrainStrong products, a line of four dietary supplements fortified with highly processed fermented algae, throughout the United States. SAC ¶ 1. The BrainStrong products are (1) BrainStrong Prenatal, (2) BrainStrong Toddler, (3) BrainStrong Kids, and (4) BrainStrong Adults. SAC fn. 1. Jovel alleges claims against three of the four products: BrainStrong Toddlers, BrainStrong Kids, and BrainStrong Adults (the "products"). SAC ¶ 12.

[1] Each class excludes "Defendant and its officers, directors and employees and those who purchased BrainStrong for the purpose of resale." SAC ¶¶ 29-30.

In December 2011, Jovel, who resides in Los Angeles County, California, purchased one box of BrainStrong Kids from a Wal-Mart in Los Angeles. SAC ¶ 10. Prior to purchasing BrainStrong Kids, Jovel saw i-Health's advertisements claiming that the products support brain health in adults and children. *Id.* She also read BrainStrong Kids' label reaffirming the advertised claims. *Id*. Relying on these claims, Jovel purchased BrainStrong Kids for her daughter, paying approximately $15. *Id*. Jovel gave the product to her daughter as directed, but found that the BrainStrong Kids product did not support brain health as represented. *Id.*

i-Health conveys to consumers in a nationwide marketing campaign that its products provide the essential docosahexaenoic acid or DHA[2] algal oil daily supplement that "supports brain health and function in children and adults." SAC ¶ 14. The BrainStrong products have labels stating that the products contain "life's DHA." SAC ¶ 15. The front and back panels of every product package emphasize the DHA algal oil and its ability to support brain health. SAC ¶¶ 20-21. The BrainStrong Toddlers and Kids packaging states that the product "[s]upports brain development and function," while the Adult packaging states that the product is "clinically shown to improve memory," "naturally supports mental clarity" and "helps protect against normal cognitive decline." SAC ¶ 1. i-Health has employed numerous methods to convey its brain health representations to consumers via the "BrainStrong" name, including i-Health's website, online and print materials, and the prominent statements on the products' packaging. SAC ¶ 3.

BrainStrong products do not support brain health in children or adults. SAC ¶ 2. Clinical cause and effect studies have found no causative link between DHA algal oil supplementation and brain health. *Id.* i-Health's representations are false, misleading and

[2] DHA is a long-chain omega-3 fatty acid typically found in cold water fish. SAC ¶ 15.

reasonably likely to deceive the public. *Id.* Because of i-Health's deceptive brain health representations, Jovel and members of the proposed class purchased products that do not perform as advertised, giving rise to Jovel's claims. SAC ¶ 5.

DISCUSSION

A. Rule 12(b)(6) Standard

Pursuant to Federal Rule of Civil Procedure 12(b)(6), a defendant may move to dismiss an action for failure to allege "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has 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. 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." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal citation omitted). For purposes of ruling on a Rule 12(b)(6) motion, "the court must accept the factual allegations set forth in the complaint as true and draw all reasonable inferences in favor of the plaintiff." *Volpe v. Nassau Cnty.*, 12-CV-2416 (JFB), 2013 WL 28561, at *5 (E.D.N.Y Jan. 3, 2013); *see also Erickson v. Pardus*, 551 U.S. 89, 93-94 (2007) (per curiam). However, "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." *Ashcroft*, 556 U.S. at 678.

When considering a motion to dismiss, a court may examine the following: "(1) facts alleged in the complaint and documents attached to it or incorporated in it by reference, (2) documents 'integral' to the complaint and relied upon in it, even if not attached or incorporated by reference, (3) documents or information contained in defendant's motion papers if plaintiff has knowledge or possession of the material and relied on it in framing the complaint, (4) public

disclosure documents required by law to be, and that have been, filed with the Securities and Exchange Commission, and (5) facts of which judicial notice may properly be taken under Rule 201 of the Federal Rules of Evidence." *Nasso v. Bio Reference Labs, Inc.*, 11-cv-3480 (JFB), 2012 WL 4336429, at *3 (E.D.N.Y. Sept. 24, 2012) (quoting *In re Merrill Lynch & Co., Inc.*, 273 F.Supp.2d 351, 356–57) (S.D.N.Y. June 30, 2003) (internal citations omitted).

B. The Federal Regulatory Scheme

The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 343 *et seq*. ("FDCA"), was enacted in 1938 as a successor to the 1906 Pure Food and Drugs Act, 34 Stat. 768, *repealed by* Act of June 25, 1938, ch. 675, § 902(a), 52 Stat. 1059, which had been the first comprehensive federal legislation designed to protect consumers from fraud or misrepresentation in the sale of food and drugs. *See generally* James T. O'Reilly, *Food and Drug Administration* § 3:1–13 (3d ed. 2009). The FDCA empowers the Food and Drug Administration ("FDA") to (a) protect the public health by ensuring that "foods are safe, wholesome, sanitary, and properly labeled," 21 U.S.C. § 393(b)(2)(A); (b) promulgate regulations pursuant to this authority; and (c) enforce its regulations through administrative proceedings. *See* 21 C.F.R. § 7.1 *et seq.* There is no private right of action under the statute. *Merrell Dow Pharms., Inc. v. Thompson*, 478 U.S. 804, 810 (1986).

In 1990 Congress amended the FDCA by enacting the Nutrition Labeling and Education Act (the "NLEA"), codified as amended at 21 U.S.C. §§ 301, 321, 337, 343, 371. "The NLEA was passed to 'clarify and to strengthen the Food and Drug Administration's legal authority to require nutrition labeling on foods, and to establish the circumstances under which claims may be made about the nutrients in foods.'" *Nutritional Health Alliance v. Shalala*, 144

F.3d 220 (2d Cir. 1998) (citing H.R.Rep. No. 101–538, at 7 (1990)). The NLEA also added a preemption provision to Section 403A of the FDCA. It states, in relevant part:

> Except as provided in subsection (b), no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce
> . . .
>
> (5) any requirement respecting any claim of the type described in section 343(r)(1) of this title [i.e., nutrition levels and health-related claims], made in the label or labeling of food that is not identical to the requirement of section 343(r) of this title . . . .

21 U.S.C. § 343–1(a)(5) ("Section 403A").

This statutory provision has been repeatedly interpreted not to preempt requirements imposed by state law that effectively parallel or mirror the relevant sections of the NLEA. *See, e.g., New York State Rest. Ass'n*, 556 F.3d 114, 123 (2nd Cir. 2009); *Chavez v. Blue Sky Natural Beverage Co.*, 268 F.R.D. 365, 370 (N.D.Cal. 2010). Thus, the NLEA contemplates state enactment and enforcement of labeling requirements as long as they are identical to or parallel NLEA requirements. The purpose of the NLEA is to prevent State and local governments from adopting inconsistent requirements with respect to the labeling of nutrients. *Astiana v. Ben & Jerry's Homemade, Inc.*, 2011 WL 2111796, at *9 (N.D.Cal. May 26, 2011).

Section 343(r)(1) of the NLEA describes " nutrition levels and health-related claims" in the labeling of food as those that "expressly or by implication," "characterize[ ] the level of any nutrient" or "characterize[ ] the relationship of any nutrient . . . to a disease or health related condition . . ." 21 U.S.C. § 343(r)(1). Section 343(r)(6) includes labels of dietary supplements as one of those claims. *See* § 343(r)(1)(B).

Enacted in 1994, the Dietary Supplement Health and Education Act ("DSHEA") added a "dietary supplement" definition to the FDCA[3] and created a new regime for the FDA's regulation of dietary supplements. Pub.L. 103–417, 108 Stat. 4325. The DSHEA allows dietary supplement labeling to include, among other types of statements, a statement that "describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans" or that "characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function." § 343(r)(1)(A). These structure/function claims are not required to be pre-approved by the FDA. Instead, companies that make them must provide notice to the FDA within 30 days of first use of the claim, and must include a disclaimer on the label stating that the FDA has not evaluated the claim and that the product is not intended to "diagnose, treat, cure or prevent any disease." § 343(r)(6)(C); 21 C.F.R. § 101.93. Section 343(r)(6) expressly prohibits claims that dietary supplements can "diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases."

The DSHEA also provides that "dietary supplements," which include vitamins, minerals, amino acids and herbs, are a "food" and are not to be classified as a "drug" under section 321(g)(1). *See* § 321(ff).

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[3] Section 321(ff) provides in pertinent part:

> The term "dietary supplement"-
> (1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:
> (A) a vitamin;
> (B) a mineral;
> . . . [and]
> (2) means a product that-
> (A)(i) is intended for ingestion in a form described in section 350(c)(1)(B)(i) of this title; or
> (ii) complies with section 350(c)(1)(B)(ii);
> (B) is not represented for use as a conventional food or as a sole item of a meal or the diet; and
> (C) is labeled as a dietary supplement....
> Except for purposes of [section 321](g), a dietary supplement shall be deemed to be a food within the meaning of [the FDCA].

Among the ways a nutritional supplement is considered "misbranded" under the DSHEA are (a) it "fails to have the identity and strength that the supplement is represented to have" and (b) it "fails to meet the quality (including tablet and capsule disintegration), purity, or compositional specifications, based on a validated assay or other appropriate methods, that the supplement is represented to meet." *Id.* at § 343(s)(E)(ii).

C. Federal Preemption of State Law Claims

i-Health argues that Jovel's claims are preempted because "Plaintiff's challenges to [i-Health's structure/function claims] under state law as enforced by the judiciary necessarily would impose non-identical requirements on i-Health." Def.'s Mem. of Law at 12. Specifically, it argues that Jovel's claims seek to impose an additional layer of review – through the court – which would disregard the FDA's authority and discretion over dietary supplement structure/function claims.

Federal preemption of state law derives from the Supremacy Clause of the United States Constitution. The Supremacy Clause, U.S. Const., art. VI, cl. 2, "invalidates state laws that 'interfere with, or are contrary to,' federal law." *Hillsborough Cnty., Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 712 (1985) (quoting *Gibbons v. Ogden*, 22 U.S. (9 Wheat) 1, 211 (1824)). Preemption inquiries are "guided by the rule that [t]he purpose of Congress is the ultimate touchstone in every pre-emption case." *Altria Grp., Inc. v. Good*, 555 U.S. 70, 76 (2008) (alteration in original and internal quotation marks omitted). In addressing questions of preemption, courts are to begin their analysis "with the assumption that the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Id.* at 77 (alteration in original). This assumption "applies with particular force when Congress has legislated in a field traditionally occupied by the States." *Id.*

In fields traditionally occupied by the states, such as health and safety regulation, there is a strong presumption against federal preemption. *See Medtronic, Inc. v. Lohr,* 518 U.S. 470, 485 (1996); *N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 654–55 (1995). Where Congress exacts an express preemption clause, that presumption requires courts to read the clause narrowly. *Lohr*, 518 U.S. at 485 (citing *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 518 (1992)).

To overcome the presumption, the party urging preemption must show that either (1) Congress or an agency with delegated authority has expressly stated that preemption is intended ("express preemption"), *see Medtronic*, 518 U.S. at 484–85; *Cipollone*, 505 U.S. at 516; or (2) Congress intended to occupy the field ("field preemption"), *see Travelers*, 514 U.S. at 654; or (3) state causes of action conflict with federal objectives to such a degree that harmony between the two becomes impossible ("conflict preemption"); *see Hillsborough County*, 471 U.S. at 71.

The NLEA added an express preemption provision to the FDCA. That provision preempts any state requirement that is different than the FDCA's regulation in Section 343(r)(1). There are two ways plaintiffs may escape preemption under that provision: (1) if their claims seek to impose requirements that are identical to those imposed by the FDCA; or (2) if the requirements plaintiffs seek to impose are not with respect to claims of the sort described in Section 343(r)(1).

i-Health relies heavily on the well-established principle that enforcement of the FDCA is the sole province of the FDA. 21 U.S.C. § 337(a) ("[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States."); *see Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). i-Health argues

that Jovel's claims are not identical to the FDCA because they would "impose an additional burden and requirement on i-Health to demonstrate, in private litigation to a judge and/or jury (in addition to the FDA), the scientific support for its claims." Def.'s Mem. of Law at 13. It has not identified any other additional requirements or burdens it believes Jovel is seeking to impose.

First, Jovel's claims that i-Health misrepresented the effectiveness of its products is a traditional claim of consumer misrepresentation, not an attempt to enforce the FDCA's labeling requirements. *Jackson v. Balanced Health Prods.,* No. 08-cv-05584, 2009 WL 1625944, at *4 (N.D.Cal. June, 10, 2009) (rejecting defendants' argument that plaintiffs' claims that dietary supplement was misleadingly advertised were only attempts to enforce the FDCA "to the extent that Plaintiffs have alleged that Defendants made statements that were fraudulent"); *In re Bextra & Celebrex Marketing Sales Prac. & Prod. Liab. Litig.,* 05-MDL-1699 (CRB), 2006 WL 2374742, at *11 (N.D. Cal. Aug. 16, 2006). Jovel's claims do not rely on the notification requirement of the FDCA or claim that defendant violated it. Jovel alleges the products were labeled as supporting brain development and function, improving memory, supporting mental clarity and protecting against normal cognitive decline even though they do not do any of those things. Although these statements are part of the products' labeling and may touch on an area regulated by the FDA, consumer protection claims founded on their falsity are not preempted. *See Jackson,* 2009 WL 1625944; *In re Epogen,* 590 F.Supp.2d at 1291; *see also Mut. Pharm.,* 459 F.Supp.2d at 935; *see also Summit II,* 933 F.Supp. at 935 ("If the allegedly false or misleading nature of a statement can be easily verified, then the fact that the determination of the truth of that statement was made by the FDA is immaterial so long as the party can also show the other requirements for establishing a [false advertising] claim."). Jovel's claims do not require

reference to FDA definitions and the misleading nature of the statement can be verified without relying on any special expertise of the FDA. *In re Epogen*, 590 F.Supp.2d at 1291–92.

Next, i-Health argues that the FDA "applies its own standards to determine whether competent and reliable evidence substantiates the label claims at issue." Mot. in Opp. at 11. Therefore, the argument continues, state-law challenges to the labeling of dietary supplements as misleading are preempted. I disagree.

Section 343(r)(6)(B) provides that a statement regarding a dietary supplement may be made if the manufacturer has "substantiation that such statement is truthful and not misleading." The crux of i-Health's argument is that review of Jovel's claims would afford her a remedy that she would not have under the FDCA. However, providing a damage remedy for conduct that violates federal law, even if the federal statute provides no private right of action, does not impose an additional requirement warranting preemption. *See Bates*, 544 U.S. at 432. The allegedly misleading nature of the representations can be evaluated without relying on any special expertise of the FDA, and a claim that i-Health's representations are false or misleading does not impose a requirement other than those imposed by federal law.

Further, though the FDCA preempts all conflicting state-law requirements, federal law constitutes only a floor upon which states can build additional protections. "The FDCA and the state law consumer protection statutes serve complementary, though somewhat overlapping, roles. 'The FDCA . . . 'is not focused on the truth or falsity of advertising claims,' but is [ ] directed to protecting the public by ensuring that drugs sold in the marketplace are 'safe, effective and not misbranded,' a task vested in the FDA to implement and enforce." *Mut. Pharm. v. Ivax Pharm., Inc.*, 459 F.Supp.2d 925, 933 (C.D. Cal. 2006) (quoting *Sandoz Pharm. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 230 (3d Cir. 1990)). "The main purpose of the advertising

restrictions set forth in the FDCA [ ] is not to protect consumers from deceptive advertising, but rather to further the FDCA's underlying goal of ensuring the safety of prescription drugs." *In re Epogen & Aranesp Off–Label Mktg. and Sales Practices Litig.*, MDL 08–1934, 2009 WL 1703285, at *7 n. 4 (C.D.Cal. June 17, 2009) ("*In re Epogen II* ").[4]

For these reasons, I conclude that plaintiff's claims are not preempted.

D. Primary Jurisdiction

i-Health argues that even if Jovel's claims are not preempted I should dismiss the case under the doctrine of primary jurisdiction. That doctrine "allows a federal court to refer a matter extending beyond the conventional experiences of judges or falling within the realm of administrative discretion to an administrative agency with more specialized experience, expertise, and insight." *Nat'l Commc'ns Ass'n v. AT&T Co.*, 46 F.3d 220, 222-223 (2d Cir. 1995) (quotations omitted).

As the Supreme Court explained in *United States v. Western Pacific Railroad Company*:

> The doctrine of primary jurisdiction, like the rule requiring exhaustion of administrative remedies, is concerned with promoting proper relationships between the courts and administrative agencies charged with particular regulatory duties. . . . "Primary jurisdiction[]" . . . applies where a claim is originally cognizable in the courts, and comes into play whenever enforcement of the claim requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body; in such a case the judicial process is suspended pending referral of such issues to the administrative body for its views.

[4] i-Health points to the FDA's letter to White Wave Company regarding a label claim that DHA Omega-3 "[s]upports brain, heart, & eye health;" the FDA stated that this statement would not be objectionable based on the information provided. i-Health contends that the FDA has "voiced disagreement with the fundamental factual proposition and result now urged by this Plaintiff." Def. Mem. of Law at 10. That fact may bear on the merits of plaintiff's claims, but it passes in the night with whether those claims are preempted. I need not decide whether even if the statements met the FDA's threshold requirements, they could still be misleading under state law consumer protection statutes. *See In re Bextra*, 2006 WL 237472, at *11.

352 U.S. 59, 63–64 (1956) (citing *Gen. Am. Tank Car Corp. v. El Dorado Terminal Co.,* 308 U.S. 422, 433 (1940)). Dismissal on primary jurisdiction grounds "does not speak to the jurisdictional power of the federal courts," but rather "structures the proceedings as a matter of judicial discretion, so as to engender an orderly and sensible coordination of the work of agencies and courts." *United States v. Bessemer & L.E.R. Co.,* 717 F.2d 593, 599 (D.C.Cir.1983). While "[n]o fixed formula exists for applying the doctrine of primary jurisdiction," the Second Circuit has generally focused on four factors: (1) whether the question at issue is within the conventional experience of judges or involves technical or policy considerations within the agency's particular field of expertise; (2) whether the question at issue is particularly within the agency's discretion; (3) whether there exists a substantial danger of inconsistent rulings; and (4) whether a prior application to the agency has been made. *Ellis v. Tribune Television Co.*, 443 F.3d 71, 82-83 (2d Cir. 2006) (citing *Nat'l Commc'ns Ass'n, Inc*, 46 F.3d at 222)).

Jovel's claim that i-Health has marketed its products in a manner that misleads consumers into believing that the products support brain development and function when the scientific evidence says otherwise is one courts are well-equipped to handle, and thus those claims are not an appropriate basis for invoking the primary jurisdiction doctrine. "[T]his is not a technical area in which the FDA has greater technical expertise than the courts – [as] every day courts decide whether conduct is misleading." *Lockwood v. Conagra Foods, Inc.,* 597 F.Supp.2d 1028, 1035 (N.D.Cal. 2009) (declining to apply primary jurisdiction doctrine in false advertising case concerning definition and deceptive use of the term "natural"); *see also Chacanaca v. The Quaker Oats Co.,* 752 F.Supp.2d 1111, 1124 (N.D.Cal. 2010) (plaintiffs advanced a "relatively straightforward claim: they assert that defendant has violated FDA regulations and marketed a

product that could mislead a reasonable consumer. This is a question courts are well-equipped to handle."). Further, proof of i-Health's deceptive advertisements does not depend on violation of, or compliance with, the FDA, NLEA or DHSEA regulation or threaten the uniform application of FDA labeling guidelines.

Pointing to the scientific studies attached to Jovel's complaint, i-Health asserts that her claims "present questions outside the conventional experience of the judiciary and juries . . ." Mot. in Opp. at 16. However, the primary jurisdiction doctrine "is not designed to secure expert advice from agencies every time a court is presented with an issue conceivably within the agency's ambit," but instead "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." *Clark v. Time Warner Cable*, 523 F.3d 1110, 1114 (9th Cir. 2008).

Finally, deferral to the FDA is unlikely to result in a timely resolution of plaintiff's claims. The FDCA does not provide a private right of action, and there is no reason to believe that plaintiff could obtain a timely determination from the FDA concerning the merits of her claims. *See Golden Hill Paugussett Tribe of Indians v. Weicker*, 39 F.3d 51, 60 (2d Cir. 1994) (noting, in considering the issue of primary jurisdiction, that "[t]here clearly is a public interest in reasonably prompt adjudication.").

E. Failure to State a Claim: Lack of Substantiation Theory

i-Health argues that Jovel's claims do not rely on false or misleading statements on its labels; rather, according to i-Health, Jovel alleges that the labels lack scientific substantiation, and therefore she fails to state a cognizable claim. Mem. of Law pp. 20-22.

Claims that rest on a lack of substantiation, rather than a provable falsehood, are not cognizable under the California consumer protection laws. *In re Clorox Consumer Litig.*, No.

12-cv-00280 (SC), 2012 WL 3642263, at *4 (N.D.Cal. Aug. 24, 2012) (collecting cases); *Scheuerman v. Nestle Healthcare Nutrition, Inc.*, No. 10-cv-3684, 2012 WL 2916827, at *5 (D.N.J. July 17, 2012). Challenges based on a lack of substantiation are left to the Attorney General and other prosecuting authorities; private plaintiffs, by contrast, have the burden of proving that advertising is actually false or misleading. *Nat'l Council Against Health Fraud v. King Bio Pharm., Inc.*, 107 Cal.App.4th 1336, 1344–45 (2003) ("private plaintiffs are not authorized to demand substantiation for advertising claims").

Courts look to a plaintiff's complaint as a whole in determining whether a plaintiff has merely alleged a lack of substantiation claim. *See In re Clorox*, 2012 WL 3642263, at *4. A claim can survive such a challenge by, for example, alleging that studies show defendant's statement to be false. *See, e.g., id.* at *5 (denying defendant's motion to dismiss where plaintiffs alleged that two scientific studies directly contradicted defendant's advertising).

Jovel alleges that i-Health's "representations are false, misleading, and likely to deceive the public." SAC ¶ 2; *see also id.* ¶¶ 5, 14, 26. To support those claims she further alleges that there are "no reasonable competent and reliable scientific studies that DHA algal oil supplementation supports brain health." SAC ¶ 16; *see also id.* ¶¶ 20, 22, 24, 26.

Jovel also alleges that three scientific studies support her allegations that i-Health's advertisement claims are actually false, not simply that they are not backed up by scientific evidence. The first study is *A Double-Blind, Placebo-Controlled Study Investigating the Effects of Omega-3 Supplementation in Children Aged 8-10 Years from a Mainstream School Population*. Kirby, A., et al., 31(3) Research in Developmental Disabilities 718-30 (2010) (the "Kirby Study"). Jovel alleges that this study found that "DHA supplementation resulted in no significant differences in cognitive results." SAC ¶ 17; *see also* Kirby Study at 729. The study

is the "largest [omega]-3 study to be carried out in the UK with a typically developing population over the age of 4 years." *Id.* at 729. The study found "very few significant differences . . . between the supplemented and placebo group on the learning and performance measured used." *Id.* The study also notes that a "number of other supplementation studies have also employed many outcome measures but have found little or no effect of supplementation, or report results in favour of a placebo group." Kirby Study at 728.

The 2008 article cited by Jovel allegedly found "no statistically significant difference between the DHA and placebo group in cognitive function." SAC ¶ 18; *see* Ryan, A., et al., *Assessing the Effect of Docosahexaenoic Acid on Cognitive Functions in Healthy Preschool Children*, 47(4) Clin. Pediatr. 355-62 (2008) (the "Ryan Study"). The results of the Ryan study "did not demonstrate statistically significant improvements in cognitive measures" on the four cognitive tests used. Ryan Study at 359.

The last study relied on by Jovel allegedly found that the evidence of "benefits of n-3 LCPUFA[5] on cognitive development in healthy children older than 2 years of age is too limited to allow a clear conclusion." SAC ¶ 18 (citing Eilander, A., et al, *Effect of n-3 Long Chain Polyunsaturated Fatty Acid Supplementation on Visual and Cognitive Development Throughout Childhood: a Review of Human Studies*, 76(4) J. Prostaglandins, Leukotrienes and Essential Fatty Acids 189-203 (Apr. 2007) ("Eilander Study").

Looking at Jovel's complaint as a whole and viewing the well-pleaded facts as proven, she has alleged that i-Health's representations of brain health benefits are false, not merely unsubstantiated. *See Pearson v. Target Corp.*, 11-cv-7972 (JBZ), 2012 WL 7761986, at *2 (N.D. Ill. Aug. 7, 2012) ("[W]hether or not the proffered studies are applicable to [the

[5] "The n-3 fatty acid docosahexaenoic acid (DHA) and the n-6 fatty acid arachidonic acid (AA) are the major [long chain polyunsaturated fatty acids] in the brain." Eilander Study at 189.

supplement at issue] is a question of fact that I do not decide at this stage. The fact that these studies looked at products that shared the same active ingredients . . . makes Plaintiff's claim facially plausible.); *Ackerman v. Coca–Cola Co.*, 09-cv-0395 (JG) 2010 WL 2925955, at *17 (E.D.N.Y. July 21, 2010) ("whether a practice is deceptive, fraudulent, or unfair is generally a question of fact which requires consideration and weighing of evidence from both sides and therefore usually cannot be resolved through a motion to dismiss") (internal quotation marks omitted)).

Accepting the allegations as true and drawing all reasonable inferences in plaintiff's favor, I conclude that Jovel's claim has sufficiently alleged misleading and deceptive misrepresentations in i-Health's labels and packaging.

F. Jovel's Standing as to Products Not Purchased

i-Health argues that Jovel does not have standing to bring claims relating to the two BrainStrong products that she did not purchase: BrainStrong Toddler and Adult. Jovel alleges that she purchased only BrainStrong Kids. SAC ¶ 10. Jovel counters that she has established standing because the products are substantially similar in all material respects and – in any event – the issue of whether she can bring claims based on the two products she did not purchase should be addressed at the class action certification stage. Pl.'s Mem. of Law in Opp. at 17, 18.

Dismissal of a claim is appropriate under Rule 12(b)(1) when the court lacks subject matter jurisdiction over the claim. Standing is jurisdictional and cannot be waived. *See United States v. Hays*, 515 U.S. 737, 742 (1995); *Chandler v. State Farm Mut. Auto Ins. Col.*, 598 F.3d 1115, 1122 (9th Cir. 2010). The plaintiff asserting the claim has the burden of establishing standing. When ruling on a motion to dismiss for lack of standing, the court "must

accept as true all material allegations of the complaint, and must construe the complaint in favor of the complaining party." *Graham v. FEMA*, 149 F.3d 997, 1001 (9th Cir. 1998) (quoting *Warth v. Seldin*, 422 U.S.490, 501 (1975)).

Article III's case-or-controversy requirement requires the following for each claim: (1) the party invoking federal jurisdiction must have suffered some actual or threatened injury; (2) the injury must be fairly traceable to the challenged conduct; and (3) a favorable decision would likely redress or prevent injury. *See Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC)*, 528 U.S. 167, 180-81 (2000). "In a class action, standing is satisfied if at least one named plaintiff meets the requirements." *Bates v. United Parcel Serv.*, 511 F.3d 974, 985 (9th Cir. 2007).

Some federal courts have held, as a matter of law, that a plaintiff lacks standing to assert claims relating to products they did not purchase. *See, e.g., Granfield v. NVIDIA Corp.*, No. 11-cv-05403 (JW), 2012 WL 2847575, at *6 (N.D.Cal. July 11, 2012) ("when a plaintiff asserts claims based both on products that she purchased and products that she did not purchase, claims relating to products not purchased must be dismissed for lack of standing"); *Carrea v. Dreyer's Grand Ice Cream, Inc.*, No. 10-cv-01044 (JSW), 2011 WL 159380, at *3 (N.D.Cal. Jan. 10, 2011) (dismissing claims based on products other than those purchased by the plaintiff). Other courts have held that the standing inquiry is more appropriately resolved on a motion for class certification. *See, e.g., Cardenas v. NBTY, Inc.*, 870 F.Supp.2d 984, 992–93 (E.D.Cal. 2012) (analyzing "solely under Rule 23" whether plaintiff may assert claims on behalf of purchasers of products she did not purchase); *Forcellati v. Hyland's, Inc.*, 876 F.Supp.2d 1155, 1161 (C.D.Cal. 2012) (denying defendants' motion to dismiss because the "argument is better taken under the lens of typicality or adequacy of representation, rather than standing").

In cases where courts have held that plaintiffs may have standing to assert claims for unnamed class members based on products the plaintiffs themselves did not purchase, the "critical inquiry seems to be whether there is sufficient similarity between the products purchased and not purchased." *See Astiana v. Dreyer's Grand Ice Cream, Inc.*, No. 11-cv-2910 (EMC), 2012 WL 2990766, at *11 (N.D.Cal. July 20, 2012) (different flavors of ice cream carried under different brand names sufficiently similar where same wrongful conduct applied); *see also Anderson v. Jamba Juice,* 888 F.Supp.2d 1000, 1005–06 (N.D.Cal. 2012) (relying on *Astiana* for the same proposition).

I am persuaded that there are sufficient similarities among i-Health's products that any concerns regarding the differences can be addressed at the class certification stage. *Astiana*, 2012 WL 2990766, at *11*; Donohue,* 871 F.Supp.2d at 921–22, 2012 WL 1657119, at *6 (allowing plaintiff to represent a class of persons who purchased different but similar products, reasoning that "questions of whether common issues predominate and whether plaintiff can adequately represent absent class members, [are] issues that are better resolved at the class certification stage."). i-Health's products have similarities in packaging and labeling; each dietary supplement is packaged in a box that states that it is a "natural DHA daily supplement" (SAC ¶ 13, Ex. A) and contains "life's DHA" (*id.* ¶15). Jovel alleges that each product suggests that it supports brain health and function in child and adults. SAC ¶14. BrainStrong Adult represents that it improves memory, supports mental clarity and protects against normal cognitive decline, while the toddler and kids packages do not, SAC ¶ 1, but this difference is immaterial. The crux of the alleged misrepresentation -- that algal DHA provides brain health benefits -- is the same. And Jovel alleges that the three products have the same core active ingredient – algal DHA. SAC ¶¶ 14, 15.

Accordingly, the motion to dismiss for lack is standing is denied.

G. Other Issues Related to Plaintiff's State Law Claims

1. Applicability of Federal Rule of Civil Procedure 9(b)

Claims under California's Unfair Competition Law do not include fraud as an element, and therefore generally do not need to be pled with particularity. *Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1125 (9th Cir. 2009). Nonetheless, such claims may be subject to Rule 9(b) if the claims are premised on allegations of fraud. *Rombach v. Chang*, 335 F.3d 164, 171 (2d Cir. 2004). I-Health argues that Rule 9(b) should apply to all of Jovel's California claims because the complaint sounds in fraud. Because, as discussed below, I conclude that Jovel has pled her California state law claims with sufficient particularity to satisfy Rule 9(b), I do not address whether the complaint sounds in fraud to a degree that would subject them to a heightened pleading standard.[6]

Pursuant to Rule 9(b), a plaintiff claiming fraud "must state with particularity the circumstances constituting fraud." Rule 9(b) generally requires that a plaintiff specify the who, what, where, when and why of the alleged fraud; specifying which statements were fraudulent and why, who made the statements to whom, and when and where the statements were made. *Mills v. Polar Molecular Corp.*, 12 F.3d 1170, 1175 (2d Cir. 1993)).

In brief, i-Health contends that Jovel has failed to allege how the alleged misrepresentations are false. *See* Def.'s Mem. of Law at 23; Def.'s Reply Mem. of Law at 9.

[6] Plaintiff relies heavily on Ninth Circuit and California cases regarding the applicability of Rule 9(b)'s heightened pleading standard to her California state law claims. Ninth Circuit law does not bind this court with respect to the applicability of Rule 9(b) in this case. There is no dispute that, as a matter of California state law, plaintiff's California claims do not contain fraud as an element. Whether plaintiff's claims must comply with the pleading burdens imposed by Rule 9(b) by virtue of the complaint "sounding in fraud" or being "grounded in fraud" is an issue of federal law, not state law. *See Northwestern Mut. Life Ins. Co. v. Banc of Am. Sec. LLC*, 254 F.Supp.2d 390, 396 (S.D.N.Y. 2003) (concluding that "[t]his Court is required to follow the precedent of the Court of Appeals for the Second Circuit with respect to the interpretation and application of Rule 9(b)," regardless of which state's law governs the underlying claim.). In any event, my conclusion that plaintiff's California claims satisfy Rule 9(b) disposes of this issue.

But Jovel clearly identifies the specific representations in the products' packaging, labeling, and marketing that are allegedly misleading (*id.* ¶¶ 1-3, 14-15); and she identifies where the allegedly fraudulent statements were made, namely, at a particular Wal-Mart in Los Angeles (*id.* ¶ 10). She alleges the specific time when she purchased BrainStrong Kids (*id.* ¶¶ 10, 12). She alleges that i-Health representations were deceptive in that they conveyed that Brainstrong "Supports brain development and function," has been "clinically shown to improve memory," "naturally supports mental clarity," and "helps protect against normal cognitive decline." *Id.* ¶ 1. Lastly, Jovel alleges why defendant's statements are fraudulent, namely, because their representations are not supported by the scientific evidence (*see id.* ¶¶2, 17-19). In short, there is ample particularization of Jovel's allegations.

2. The Sufficiency of the Alleged Violations of CLRA

California's CLRA, Cal. Civ.Code § 1750 *et seq.*, prohibits specified "unfair methods of competition and unfair or deceptive acts or practices" in connection with the sale or lease of goods or services to a consumer. *See* Civ. Code, § 1770(a). Among the practices prohibited by the CLRA is "[r]epresenting that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities which they do not have;" "[r]epresenting 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;" "[a]dvertising goods or services with intent not to sell them as advertised;" and "[r]epresenting that the subject of a transaction has been supplied in accordance with a previous representation when it has not." Cal. Civ. Code, §§ 1770(a)(5), (a)(7), (a)(9) & (a)(16).[7] Civil Code section 1760 states that the CLRA "shall be liberally construed and applied to promote its underlying purposes, which are to protect consumers against unfair

[7] Jovel's complaint cites violations of Cal. Civ. Code §§ 1770(a)(5), (7), (9), (16).

and deceptive business practices and to provide efficient and economical procedures to secure such protection."

I conclude that Jovel has adequately pled a violation of the CLRA. The complaint provides a detailed list of the representations that she challenges. SAC ¶ 1. In addition, it sets forth the specific sections of the CLRA that i-Health allegedly violated (*id.*¶ 60), along with a statement of how it violated such sections (*id*. ¶¶ 1-2, 61). Jovel also alleges that she is a "consumer" under Section 1761(d), as she purchased BrainStrong Kids for personal, family, or household purposes (*id.* ¶ 10). *See* Cal. Civ. Code § 1761(d) (defining "consumer" as "an individual who seeks or acquires, by purchase or lease, any goods or services for personal, family, or household purposes"). These allegations are sufficient to survive dismissal at this stage.

3. The Sufficiency of the Alleged Unlawful Business Practices Claim

Jovel alleges that i-Health is liable for violating California's UCL through unlawful business practices and unfair business practices. The UCL prohibits "unfair competition," which is broadly defined as including "any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising." Cal. Bus. & Prof. Code § 17200. The statute "is violated where a defendant's act or practice is (1) unlawful, (2) unfair, (3) fraudulent, or (4) in violation of section 17500 (false or misleading advertisements)." *Lozano v. AT & T Wireless Servs., Inc.*, 504 F.3d 718, 731 (9th Cir. 2007).

An "unlawful" practice is one "forbidden by law, be [it] civil or criminal, federal, state, or municipal, statutory, regulation, or court-made." *VP Racing Fuels, Inc. v. Gen. Petroleum Corp.*, 2010 WL 1611398, at *4 (E.D.Cal. Apr. 20, 2010) (quoting *Saunders v. Superior Court*, 27 Cal.App.4th 832, 838–39, 33 Cal.Rptr.2d 438 (1994)). A plaintiff stating a

cause of action based on an "unlawful" business act or practice under the UCL "must allege facts sufficient to show a violation of some underlying law." *Id.* Jovel pleads sufficient facts to show violations of the CLRA, Cal. Civ. Code § 1770(a)(5), (a)(7), (a)(9), and (a)(16) as set forth above. Thus, her allegations are sufficiently detailed to satisfy the UCL's "unlawful" prong and survive dismissal.

CONCLUSION

For the reasons stated above, the defendant's motion to dismiss is denied.

So ordered.

John Gleeson, U.S.D.J.

Dated: September 27, 2013
Brooklyn, New York