UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

COLLEEN GALLAGHER, et al.,

Plaintiffs,

v.

BAYER AG, et al.,

Defendants.

Case No. 14-cv-04601-WHO

ORDER GRANTING IN PART AND DENYING IN PART MOTION TO DISMISS

Re: Dkt. No. 39

INTRODUCTION

Plaintiffs sue Bayer AG and related entities (Bayer) for violation of various consumer protection statutes under California, Florida, and New York law because Bayer falsely and deceptively misrepresents the health benefits of 20 varieties of its One A Day multivitamin/multimineral supplements (Supplements). *See* Amended Class Action Complaint (ACAC) [Docket No. 36] ¶ 1. Plaintiffs challenge three statements made by Bayer on each of the Supplements at issue: that the Supplements promote or support (i) "heart health"; (ii) "immunity"; and (iii) "physical energy." *Id.* ¶ 6 (Statements). As the ACAC is currently pleaded, claims regarding "heart health" and "immunity" are preempted as "structure/function claims" expressly approved by the FDA. Bayer's motion to dismiss regarding those issues is GRANTED with leave to amend, and the remainder of its motion is DENIED.

BACKGROUND

I assume the truth of the allegations in the ACAC. Plaintiffs contend that the three Statements are made in the same manner on each of the twenty varieties of the Supplements and that all of the Statements are based on the same 11 vitamins and minerals found in every One A Day product. *Id.* ¶¶ 7, 29. Plaintiffs assert that despite the different varieties of One a Day products, the Supplements are "essentially the same product." *Id.* ¶ 5.

Plaintiffs challenge Bayer's representation that its Supplements "support heart health" by asserting that:

- by making that Statement, Bayer is representing that its Supplements can prevent,

mitigate, or treat "cardio vascular disease";

- those claims are false and deceptive;
- the Statement is based on Bayer's products containing vitamins B6, B12, C, E and folic acid (vitamin B9);
- studies have shown that supplements with these vitamins do not prevent heart disease;
- Bayer makes these deceptive blood pressure and heart health Statements for at least 10 of its Supplements, on its product packaging, Bayer's website, and in print and television advertisements;
- plaintiffs and reasonable consumers interpret Bayer's heart health Statements to mean that the Supplements will prevent or ameliorate heart disease, which they do not do;

Id. ¶¶ 31-43.

With respect to "immunity" plaintiffs contend that:

- Bayer states that many of its Supplements "support immunity";
- plaintiffs and reasonable consumers interpret that claim to mean that taking Supplements will help them get sick less often and that these products will help prevent disease;
- the immunity Statement is false and deceptive;
- Bayer makes its immunity Statement based in its Supplements containing vitamins A, C, and E, selenium, iron, beta-carotene, and zinc;
- the Statement is false and deceptive because studies confirm that supplementation with these vitamins and minerals has no effect on the immunity of adults in developed countries like the United States;
- the Statement is made for at least 15 of its Supplements on product packaging, Bayer's website, and in print and television advertisements.

Id. ¶¶ 44-55.

With respect to "physical energy" plaintiffs allege that:

- Bayer states many of its Supplements help "support physical energy";

- plaintiffs and reasonable consumers interpret this Statement to mean they will feel more energetic simply due to taking the Supplements;
- Bayer makes this energy Statement based on it Supplements containing vitamins B6, B12, pantothenic acid (B5), chromium, thiamin (B1), riboflavin (B2), niacin (B3), and folic acid (B9);
- studies confirm that no amount of supplementation with these vitamins or minerals has any effect on energy levels of typical Americans (individuals who are not vitamin deficient);
- Bayer makes these deceptive Statements for at least 15 of its Supplements on product packaging, Bayer's website, and in print and television advertisements.

Id. ¶¶ 56-64.

Plaintiffs state that federal dietary guidelines and nutrition science experts agree that: (i) nutrient needs should be met primarily by consumption of foods, (ii) most Americans are not vitamin deficient and consume adequate amounts of vitamins and minerals; (iii) only those Americans suffering from vitamin or mineral deficiencies benefit from vitamin or mineral supplements; and (iv) multivitamin/multimineral supplements are not effective for preventing or treating diseases. *Id*. ¶¶ 3-4. According to plaintiffs, each of the Statements "has been proven false by numerous scientific studies." *Id*. ¶ 28. Bayer does not disclose that only consumers suffering from a vitamin or mineral deficiency will benefit from the Supplements. *Id*. ¶ 9. Plaintiffs contend that the Statements deceive consumers and that consumers could not discover the truth about the Supplements – their lack of benefit – without a nutrition science degree and that simple review of the labels of the Supplements would not allow consumers to determine whether they will benefit from taking the Supplements. *Id*. ¶¶ 13-14.

Each plaintiff states that she purchased Bayer One A Day for Women's Supplement, read and relied on the Statements made that the Supplement was "formulated to support heart health, immunity, and physical energy," and had seen similar representations made by Bayer regarding the Supplement "in online, print and television advertising." *Id*. ¶¶ 18-22. Plaintiffs seek to represent a class of all persons who purchased Bayer One A Day Supplements in the United States, as well as three subclasses for persons who purchased the Supplements in California,

Florida and New York. *Id*. ¶ 66.

LEGAL STANDARD

Under Federal Rule of Civil Procedure 12(b)(6), a district court must dismiss a complaint if it fails to state a claim upon which relief can be granted. To survive a Rule 12(b)(6) motion to dismiss, the plaintiff must allege "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007). A claim is facially plausible when the plaintiff pleads facts that "allow the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation omitted). There must be "more than a sheer possibility that a defendant has acted unlawfully." *Id*. While courts do not require "heightened fact pleading of specifics," a plaintiff must allege facts sufficient to "raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555, 570.

In deciding whether the plaintiff has stated a claim upon which relief can be granted, the Court accepts the plaintiff's allegations as true and draws all reasonable inferences in favor of the plaintiff. *Usher v. City of Los Angeles*, 828 F.2d 556, 561 (9th Cir. 1987). However, the court is not required to accept as true "allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences." *In re Gilead Scis. Sec. Litig*., 536 F.3d 1049, 1055 (9th Cir. 2008).

DISCUSSION

Bayer moves to dismiss for three reasons. First, it contends that plaintiffs' claims are preempted by the Food, Drug and Cosmetic Act (FDCA) because Bayer's statements are – as defined by Food and Drug Administration (FDA) guidance – structure/function claims and not disease claims. Second, it argues that the claims are without basis under the state laws plaintiffs invoke because those state laws require allegations that the claims are false, not just that the claims may not be substantiated. Finally, it asserts that plaintiffs lack standing because they do not allege they were not benefitted by the products they purchased and they cannot sue over claims made as to any One A Day Supplement except for the one each plaintiff purchased; One A Day

Women's.[1] I address each argument below.

I. PREEMPTION

Bayer asserts that each of the Statements – supports heart health, immunity, and physical energy – is a structure/function claim explicitly approved by the FDA and, therefore, that plaintiffs' causes of action are preempted under the FDCA.

A. Relevant Statutes and Regulations

The Federal Food, Drug, and Cosmetic Act ("FDCA") was enacted in 1938 and prohibits the misbranding of food. Congress amended the FDCA in 1990 through the passage of the Nutritional Labeling and Education Act ("NLEA"). The purpose of the NLEA was to "'clarify and to strengthen [FDA's] authority to require nutrition labeling on foods, and to establish the circumstances under which claims may be made about the nutrients in foods.'" *Nat'l Council for Improved Health v. Shalala*, 122 F.3d 878, 880 (11th Cir.1997) (quoting H.R.Rep. No. 101–538, at 7 (1990), reprinted in 1990 U.S.C.C.A.N. 3336, 3337).

In 1994, Congress passed the Dietary Supplement Health and Education Act (DSHEA), providing the FDA with regulatory authority over dietary supplements. The DSHEA explained what statements supplement manufacturers would be allowed to make in conjunction with their products, and which statements had to be approved by the FDA prior to their use. *See* 21 U.S.C. § 343(r)(6). In particular, the DSHEA and regulations promulgated by the FDA distinguish between "structure/function" claims and "disease claims" with respect to dietary supplements. A structure/function claim is one that:

> claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such

[1] Both sides ask me to take judicial notice of screenshots from defendants' website http://www.oneaday.com. *See* Defendants' Request for Judicial Notice [Docket No. 39-2]; Plaintiffs' Partial Opposition to Defendants' Request and Plaintiffs' Request for Judicial Notice [Docket No. 41]. I GRANT the unopposed request for judicial notice of the screenshots. Plaintiffs object to defendants' request for judicial notice of "online supplement labels" for a few of the One A Day products. Docket No. 41 at 2. Because the contents of the online supplement labels – even if I were to take judicial notice of them – are irrelevant to the determination of this motion, the request for judicial notice of the labels is DENIED as moot.

> structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient.

21 U.S.C. § 343(r)(6)(A); 21 C.F.R. § 101.93(f).[2] Disease claims are express or implied claims that claim "to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases." 21 U.S.C. § 343(r)(6); 21 C.F.R. § 101.93(g).[3] In guidance issued by the FDA along with its final regulation, the FDA attempted to explain the differences between structure/function and disease claims and provided various examples of statements the FDA considered fell within each category. *See* 65 F.R. 1000 (January 6, 2000).

B. Preemption Under the FDCA Generally

The FDCA, as amended by the NLEA, contains an express preemption provision making clear that state laws imposing labeling requirements not identical to FDA mandates are preempted. 21 U.S.C. § 343–1(a)(5).[4] Therefore, preemption only occurs where application of state laws would impose more or inconsistent burdens on manufacturers than the burdens imposed by the FDCA. If a lawsuit asserts that a manufacturer has violated the FDCA (as amended by NLEA) and does not seek to impose additional or contrary burdens to those imposed under the FDCA, the claims raised under state law are not preempted. *See, e.g.*, *Salazar v. Honest Tea, Inc*., No. 2:13-CV-02318-KJM, 2014 WL 2593601, at *4 (E.D. Cal. June 10, 2014) ("The NLEA is clear, however, that if state law seeks to impose liability consistent with the FDCA, the law is not preempted."); *Victor v. R.C. Bigelow, Inc*., No. 13-CV-02976-WHO, 2014 WL 1028881, at *11 (N.D. Cal. Mar. 14, 2014) (rejecting preemption where the requirements of the Sherman Law are "identical to the requirements imposed under the FDCA"); *Hesano v. Iovate Health Sciences, Inc*., No. 13CV1960-WQH-JMA, 2014 WL 197719, at *6 (S.D. Cal. Jan. 15, 2014) (rejecting

---

[2] A manufacturer can use a structure/function claim on a supplement without prior FDA approval as long as the manufacturer has substantiation that the statements are truthful and not misleading, provides a disclaimer that the statement has not been approved by the FDA, and notifies the FDA of its use of the statement no later than 30 days after its first use. 21 U.S.C. § 343(r)(6).

[3] A manufacturer can only use a disease claim on a supplement after receiving prior approval from the FDA based on proof of substantiation. 21 U.S.C. § 343(r)(3).

[4] The provision provides that "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 . . . any requirement respecting any claim of the type described in section 343(r)(1) of this title, made in the label or labeling of food that is not identical to the requirement of section 343(r) of this title, except a requirement respecting a claim made in the label or labeling of food which is exempt under section 343(r)(5)(B) of this title." 21 U.S.C. § 343-1(a)(5).

preemption argument where complaint's "first cause of action for violations of the UCL adequately alleges that Defendants' conduct violates specific provisions of the FDCA and its implementing regulations, as well as the Sherman Law."); *Trazo v. Nestle USA, Inc*., No. 12–2272, 2013 WL 4083218, at *5 (N.D. Cal. Aug.9, 2013) ("To avoid express preemption under Section 343–1(a), the plaintiff must be suing for conduct that *violates* the FDCA." (emphasis in original)).

However, where a plaintiff seeks to challenge a statement that has been approved by the FDA under the FDCA, the claim may be preempted. *See Pratt v. Whole Foods Mkt. California, Inc*., No. 5:12-CV-05652-EJD, 2014 WL 1324288, at *5 (N.D. Cal. Mar. 31, 2014) ("courts in this district have generally found express preemption under the FDCA only when: (1) the FDA requirements with respect to a particular food label or package are clear; and (2) the product label or package at issue is in compliance with that policy, such that plaintiff necessarily seeks to enforce requirements in excess of what the FDCA, NLEA, and the implementing regulations require.").

C. Preemption With Respect to Statements About Supplements

Plaintiffs argue that there is no preemption of any claims about Supplements under the FDCA because the FDCA preemption provision – 21 U.S.C. § 343-1(a)(5) – only preempts "claims of the type described" in 21 U.S.C. § 343(r)(1). 21 U.S.C. section 343(r)(1), in turn, governs claims about nutrients in foods. More specifically, section 343(r)(1)(B) governs statements that characterize the relationship of nutrients to a "disease or health-related condition."

However, 21 U.S.C. § 343(r)(6), a DSHEA-added provision, explains the different treatment of supplement structure/function claims (which can be made without prior FDA approval) versus supplement disease claims (which are subject to prior approval by the FDA). Section 343(r)(6) explains that "[f]or purposes of paragraph (r)(1)(B)" non-disease statements for dietary supplements may be made if they meet specific criteria. Because plaintiffs characterize at least two of the three Bayer Statements ("supports heart health" and "supports immunity") as inferring that the Supplements prevent or treat diseases – whereas Bayer contends those statements are instead are structure/function claims – I find that the express preemption provision of 21

U.S.C. § 343-1(a)(5) applies to statements the FDA regulates under 21 U.S.C. § 343(r)(6).

The only case plaintiffs rely on to argue against express preemption is *Consumer Justice Ctr. v. Olympian Labs, Inc.*, 99 Cal. App. 4th 1056 (2002). In that case, the California Court of Appeal concluded there was no express preemption of cases involving the false advertising of dietary supplements, relying exclusively on the fact that the plaintiff had failed to identify any federal statute or regulation which supports preemption of the "field" of false advertising under state law and a law review commentator who suggested the DSHEA should be amended to explicitly preempt state regulation of dietary supplements. *Id*. at 1058-59. That decision is wrong because it addressed the wrong issue – the question is not field preemption but express preemption. Given the interplay between Section 343(r)(6) and Section 343(r)(1), limited express preemption applies to statements considered by the FDA to be structure/function claims. Any state law claim that would impose a labeling requirement that is in addition to or in conflict with the FDA's requirements for structure/function claims is preempted. *See Bronson v. Johnson & Johnson, Inc*., No. C 12-04184 CRB, 2013 WL 1629191, at *6 (N.D. Cal. Apr. 16, 2013) (Section 343(r)(6) preempts "any state law that is not identical to the federal structure/function guidelines for dietary supplements through § 343–1(a)(5)."); *see also Hoffman v. Nordic Naturals, Inc*., No. 12-CV-05870 SDW MCA, 2014 WL 1515602, at *3 (D.N.J. Apr. 17, 2014) ("NLEA's preemption provision applies to the labeling of dietary supplements.")[5]; *Trujillo v. Walgreen Co*., No. 13 C V1852, 2013 WL 4047717, at *1 (N.D. Ill. Aug. 9, 2013), appeal dismissed (Nov. 18, 2013) (NLEA contains "an express preemption provision which prohibits states from imposing, directly or indirectly, requirements as to [supplement] labels like the Statement that is not identical to the federal requirements.").[6]

---

[5] The *Hoffman* Court concluded that Section 343-1(a)'s preemption provision applied to labeling of dietary supplements by noting that under 21 U.S.C. § 343-1(a)(4) a state may not impose "any requirement for nutritional labeling of food that is not identical to the requirement[s]" imposed by the Act and that under the "Dietary Supplement Health and Education Act of 1994, 21 U.S.C. § 321(ff), 'a dietary supplement shall be deemed to be a food within the meaning of the [FDCA].'" *Id*. at *3.

[6] Bayer's argument that the state laws are preempted because they fail to track the language of the FDCA/DSHEA is without support. Motion at 6-7. The applicable question is not whether the language of the state laws track the federal statutes but whether those state laws would impose obligations on supplement manufacturers that are in addition to or conflict with the requirements

Preemption only applies where the requirements that would be imposed as a matter of state law exceed or contradict the labeling requirements under the FDCA. Further, as the FDA itself has recognized in issuing the regulation on Supplements:

> The rule is neither intended to establish whether any particular structure/function claim is appropriate for any specific product, nor whether the claim would be permitted under other provisions of the act. Like the labeling of any other FDA-regulated product, the labeling of dietary supplements must comply with all applicable requirements of the act and regulations. For example, an otherwise acceptable structure/function claim might nevertheless be false or misleading for other reasons, causing the product to be misbranded under section 403(a)(1) of the act.

Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 65 FR 1000 at 1001. The FDA similarly recognized that under the DSHEA, all "food claims, including structure/function claims on dietary supplements, [are subject] to the 'truthful and non-misleading' standard." *Id*. at 1003.[7]

D. Whether Plaintiffs' Challenges to the Three Specific Statements at Issue are Preempted

Bayer argues that the three challenged Statements in this case – supports heart health, immunity and physical energy – are structure/function claims that have been expressly approved by the FDA and, therefore, plaintiffs' challenges to those Statements are necessarily preempted.

1. Supports Heart Health

Plaintiffs contend that by using "supports heart health" on its packaging and advertising, Bayer is representing that its Supplements can prevent, mitigate, or treat "cardio vascular disease." ACAC ¶ 32; *see also id*. ¶¶ 33-43.

If plaintiffs' claim is that Bayer is violating the FDA (and therefore the underlying California, Florida and New York state laws alleged) because Bayer is making a *disease* claim,

---

imposed under the FDCA and DSHEA amendments. *See, e.g., Chacanaca v. Quaker Oats Co*., 752 F. Supp. 2d 1111, 1118 (N.D. Cal. 2010) ("Where a requirement imposed by state law effectively parallels or mirrors the relevant sections of the NLEA, courts have repeatedly refused to find preemption.").

[7] I agree with plaintiffs that there is no support for defendants' arguments that Congress occupied the field of regulating supplement labeling and marketing and that the existence of state laws, like California's Sherman Law, necessarily create conflict preemption. As the cases discussed above hold, the only claims that are preempted are state law requirements that seek to impose burdens on supplement manufacturers that are greater than or conflicting with those imposed by the FDCA and DSHEA amendments.

that legal claim is preempted. The FDA guidance explicitly characterizes the following as permissible structure/function statements: "helps maintain cardiovascular function and a healthy circulatory system" 65 FR 1000 at 1012, and that "[a specific nutrient] supports the cardio vascular by inhibiting leukotriene and thromboxane synthesis, substances associated with platelet aggregation." *Id*. at 1030. Plaintiffs' argument that Bayer's "supports heart health" Statement is instead, as interpreted by a reasonable consumer, an impermissible disease claim, is preempted. Oppo. at 8 ("Bayer's heart and immunity claims are illegal disease prevention claims, not structure/function claims").[8]

While the FDA recognizes that a structure/function claim could nevertheless become a disease claim if the statement's location or use linked it to treatment or prevention of a disease,[9] plaintiffs have pointed to no *specific* language on the packaging, websites, or advertisements of the Supplements that would take the "supports heart health" language and move it towards a disease claim. *See* ACAC ¶¶ 38-40. Based on the record before me, plaintiffs' claims based on the argument that "supports heart health" is an impermissible disease claim are preempted by the FDA guidance suggesting use of "supports heart health" without more is a structure/function claim.

Not preempted would be a claim that "supports heart health" as a structure/function claim is a false and misleading statement contrary to scientific studies. *See* 65 FR 1000 at 1003 ("Section 403(a)(1) of the act already subjects all food claims, including structure/function claims on dietary supplements, to the 'truthful and non-misleading' standard."). Whether plaintiffs have alleged that claim sufficiently in the ACAC will be addressed below.[10]

---

[8] Plaintiffs apparently argue that the heart and immunity claims also violate 21 C.F.R. § 101.14(a)(1). Oppo. at 8 & fn. 43. But that regulation explains that "use Health claim means any claim made on the label or in labeling of a food, including a dietary supplement, that expressly or by implication, including 'third party' references, written statements (e.g., a brand name including a term such as 'heart'), symbols (e.g., a heart symbol), or vignettes, characterizes the relationship of any substance to a disease or health-related condition." Plaintiffs do not allege that Bayer uses the term heart in its brand names or otherwise uses symbols or vignettes in conjunction with the Statements.

[9] *See* 65 FR 1000 at 1002 (an "otherwise acceptable structure/function claim might nevertheless be false or misleading for other reasons, causing the product to be misbranded under section 403(a)(1) of the act.").

[10] I note that alleged alongside the "support heart health" allegations, plaintiffs also attempt to challenge Bayer's statements regarding "blood pressure." *See* ACAC ¶ 35. However, the only evidence of any Bayer products' packaging or advertising that contain a blood pressure statement

Plaintiffs' state law claims based on the argument that "supports heart health" is an illegal disease Statement are preempted. These claims are DISMISSED WITH LEAVE TO AMEND to allow plaintiffs the chance to plead facts showing that this Statement has been linked – by virtue of specifically identified packaging or marketing – to treatment or prevention of cardiovascular disease.

2. Supports Immunity

Plaintiffs argue that by using "supports immunity" on its packaging and advertising Bayer is representing that its Supplements can help consumers "get sick less often, i.e., that these products will help them prevent disease." ACAC ¶ 45; *see also id*. ¶¶ 46-55. However, the FDA has approved as examples of structure/function claims the following statements: "supports the immune system," 65 FR 1000 at 1029; and "vitamin A is necessary to maintaining a healthy immune response." *Id*. Like plaintiffs' challenge to "supports heart health," Bayer's use of "supports immunity" is a structure/function claim and any argument that it is an actionable, illegal disease claim is preempted. As with the heart health Statement, plaintiffs have pointed to no specific language on the packaging, websites, or in advertisements of the Supplements that would take the "supports immunity" language and move it towards a disease claim. *See* ACAC ¶¶ 44-55. Based on the record before me, plaintiffs' claims based on the argument that "supports immunity" an impermissible disease claim, are preempted by the FDA guidance providing that use of "supports immunity" without more is a structure/function claim.

These claims are likewise DISMISSED WITH LEAVE TO AMEND, to allow plaintiffs the chance to plead facts showing this Statement has been linked – by virtue of specifically identified packaging or marketing – to treatment or prevention of disease. Whether plaintiff has sufficiently alleged that the "supports immunity" Statement, as a structure/function claim, is

---

are the One A Day Men's Health Formula and the One A Day Men's 50+. *Id*. ¶ 40; *see also* Plaintiff's RJN, Ex. D (website advertisement for One A Day Men's 50+). The plaintiffs in this suit only purchased the One A Day Women's Supplement, and there is no evidence that the Women's Supplement's advertising contained any representation about blood pressure. As such, plaintiffs lack standing to pursue any claim regarding statements about blood pressure. *Brazil v. Dole Food Co., Inc*., No. 12-CV-01831-LHK, 2013 WL 5312418, at *9 (N.D. Cal. Sept. 23, 2013) (rejecting standing for statements plaintiff did not view). The blood pressure claims are DISMISSED WITH LEAVE TO AMEND.

nonetheless false and misleading will be addressed below.[11]

3. Supports Physical Energy

In their opposition, plaintiffs admit that Bayer's use of "supports physical energy" is a structure/function Statement and that the basis for plaintiffs' state law claims is that the Statement is false and misleading. Oppo. at 8, fn.45. As such the claims are not preempted and I will address the sufficiency of the pleading of these claims below.

II. LACK OF SUBSTANTIATION OR FALSITY

Bayer argues that plaintiffs' claims must also be dismissed because they are essentially claims that Bayer lacks scientific substantiation for its Statements and lack of substantiation claims have been rejected under the state consumer protection laws at issue in this case. *See, e.g., Bronson v. Johnson & Johnson, Inc*., No. C 12-04184 CRB, 2013 WL 1629191, at *8 (N.D. Cal. Apr. 16, 2013) ("Claims that rest on a lack of substantiation, instead of provable falsehood, are not cognizable under the California consumer protection laws."); *Hughes v. Ester C Co*., 930 F. Supp. 2d 439, 459 (E.D.N.Y. 2013) (under New York law "where a party asserts fraudulent misrepresentation based on a lack of substantiation, that party must allege sufficient facts from which a court may infer deception. In other words, the simple allegation that a given statement is unsubstantiated or unsupported by scientific evidence, standing alone, will not be enough for purposes of showing a deceptive or fraudulent representation."). Bayer argues that while the issue has not been decided by under Florida law, it is unlikely that Florida courts would disagree with California, New York and the decisions of the Seventh and Third Circuits; all of whom reject lack of substantiation claims. Motion at 8-9 (citing *Bober v. Glaxo Wellcome Plc*, 246 F.3d 934, 936 (7th Cir. 2001) and *Franulovic v. Coca Cola Co*., 390 F. App'x 125, 126 (3d Cir. 2010)).

[11] Plaintiffs appear to argue that the heart health and immunity claims cannot be considered structure/function claims because structure/function claims must claim "a benefit related to a classical nutritional deficiency and disclose the prevalence of such disease in the United States" and because manufacturers must disclose their use of structure/function statements to the Secretary of the FDA. Oppo. at 9-10; 21 U.S.C. § 343(r)(6). Plaintiffs ignore that the statute uses "or" when describing the four different types of structure/function claims that are allowed (*one* of which is the nutritional deficiency statement). Also, plaintiffs' argument that defendants have failed to demonstrate compliance with the statute's notice requirement is wholly misplaced. It is *plaintiffs' burden* to plead in their complaint that defendants' have not complied with the notice requirement, which they fail to do.

Plaintiffs respond that they are not alleging a lack of substantiation theory, but instead that the three Statements made by Bayer are false and deceptive. As courts in California, New York, and Florida have held, where plaintiffs allege that manufacturers' food or supplement claims are false and cite to scientific studies in support, those allegations are adequate to plead false and misleading conduct under their consumer protection statutes. *See, e.g., In re Horizon Organic Milk Plus DHA Omega-3 Mktg. & Sales Practice Litig*., 955 F. Supp. 2d 1311, 1344 (S.D. Fla. 2013) ("Plaintiffs' allegations that WhiteWave's brain health representations are false and that the falsity of these representations is shown by scientific studies are sufficient to allege false statements and misrepresentations under the various consumer fraud statutes at issue."); *Hughes v. Ester C Co*., 930 F. Supp. 2d 439, 461 (E.D.N.Y. 2013) ("In light of defendants' alleged representations of scientific backing to its claims . . . plaintiffs' asserted scientific study . . . is sufficient to state a plausible claim of affirmative misrepresentation."); *Bronson v. Johnson & Johnson, Inc*., No. C 12-04184 CRB, 2013 WL 1629191, at *9 (N.D. Cal. Apr. 16, 2013) (claim that labeling is misleading supported by citation to a study in support, adequate to state a claim under California's UCL).

Plaintiffs repeatedly plead that Bayer's three Statements are false, and they cite to numerous scientific studies in support. *See* ACAC ¶¶ 32, 34 n.14, 36, 45, 46, 47 n.20, 56, 58 n.25, 60. As such, plaintiffs have adequately pled the falsity of the heart and immunity Statements. However, plaintiffs assert those Statement are false because the cited studies do not prove that the Supplements treat or prevent heart *disease* or provide immunity from *disease*. *See* ¶¶ACAC 32, 36, 45. These are the disease claims that are preempted by the FDCA. Plaintiffs are only allowed – absent submission of a further amended pleading showing that Bayer's use of these Statements in specific marketing materials move these structure/function claims towards disease claims – to allege that these Statements are false as structure/function claims. In other words, plaintiffs are limited to alleging that Bayer's statements that its Supplements "support" or help heart health and immunity are false. Plaintiffs must then cite to scientific studies to support those specific (and as yet not-alleged) claims. Plaintiffs are given leave to amend to attempt to cure these deficiencies and explicitly plead – with support to scientific evidence – that Bayer's support heart health and

support immunity claims are false as structure/function claims.

With respect to the "supports physical energy" Statement, plaintiffs have adequately pleaded that the Statement is false because scientific evidence confirms that the vitamins Bayer asserts help support immunity do "not affect the energy levels of typical Americans." ACAC ¶¶ 56, 60. As a matter of pleading, that is sufficient to state a false and misleading claim under the consumer protection statutes at issue. Defendants argue that the scientific studies cited by plaintiffs in fact fatally undermine plaintiffs' assertion because those studies show that vitamins and nutrients in Bayer's Supplements actually support physical energy or at most are inconclusive. Motion at 12-13. I have reviewed the citations relied on by Bayer and do not find that they necessarily undermine plaintiffs' allegations of falsity.

The portions of the studies Bayer cites address specific vitamin deficiencies (B6, B12, folic acid) and do not necessarily prove the benefit or admit to inconclusive evidence of the benefit from taking supplements with those vitamins for "supported" or "increased" physical energy. They instead discuss the potential benefit from taking specific vitamins for individuals who are anemic or suffer from a nutritional deficit. Whether the fact that certain vitamins may support certain nutrient-deficient individuals is legally the same as Bayer's broad claim of "supporting physical energy" for all consumers is a matter that cannot be determined on a motion to dismiss on this limited record. *See,e.g., Quinn v. Walgreen Co.,* 958 F. Supp. 2d 533, 544 (S.D.N.Y. 2013) ("Whether or not the studies support plaintiff's proposition . . . is an issue of fact the Court cannot resolve on a motion to dismiss.").

Without further explanation of the context for the particular portions of the studies cited by Bayer, I cannot say as a matter of law that the excerpts actually support, or prove that evidence is inconclusive, regarding Bayer's broad Statement regarding physical energy. At this juncture, I find that plaintiffs' have adequately alleged falsity of the "supports physical energy" claim to be able to proceed.

III. STANDING

A. Injury-in-Fact

Bayer first argues that plaintiffs lack standing to attack Bayer's "support physical energy"

Statement because plaintiffs fail to allege that they were not benefitted from the Supplements they actually purchased. Bayer notes that plaintiffs allege that the Statement is false because scientific studies show that the Supplements will not have any effect on the energy level of typical Americans who are not vitamin or mineral deficient. ACAC ¶ 58. Therefore, Bayer contends that to have standing to pursue this claim, plaintiffs must allege they were not nutritionally deficient and were not benefitted by their Supplements. Motion at 14-15.

However, as plaintiffs point out, they allege that Bayer's own Statement is that all who take the Supplement will benefit, not just nutritionally deficient individuals. Oppo. at 19-2. In that light, plaintiffs have sufficiently alleged that they reasonably interpreted Bayer's Statement to mean that "they will experience increased energy" when in fact Bayer's products "will not in fact increase consumers' energy." ACAC ¶ 64. That is sufficient to establish standing for pleading purposes.

B. Products Not Purchased

Bayer more broadly challenges plaintiffs' standing to sue over Statements made on One A Day varieties that they did not purchase. While plaintiffs only purchased one of the 20 different One A Day products included in their suit – One A Day Women's – this does not prevent them from suing on behalf of individuals who purchased the other Supplements. The three Statements plaintiffs challenge are identical across all of the Supplements.[12] *See, e.g., Bohac v. Gen. Mills, Inc.*, No. 12-CV-05280-WHO, 2014 WL 1266848, at *12 (N.D. Cal. Mar. 26, 2014) (although defendant argued "that the products are not 'substantially similar' because ingredients and labeling vary across the 29 products, these differences do not change the fact that, as alleged, the challenged representations are the same and cause the same harm."); *Ang v. Bimbo Bakeries USA, Inc.*, No. 13-CV-01196-WHO, 2014 WL 1024182, at *8 (N.D. Cal. Mar. 13, 2014) (where "the

[12] Plaintiffs admit that not every Supplement's packaging or marketing materials refers to each of the three Statements, but contend that each of the Statements is used in an identical fashion on specifically identified Supplements. Oppo. at 17. Defendants do not dispute this assertion or attempt to put evidence before me that would undermine it. However, as noted above, plaintiffs' claims based on "blood pressure" statements have been dismissed with leave to amend, because there is no evidence that any of the plaintiffs purchased a product whose packaging or marketing materials contained any reference to blood pressure.

type of claim and consumer injury is substantially similar as between the purchased and unpurchased products," plaintiffs will have standing to pursue claims for unpurchased products).

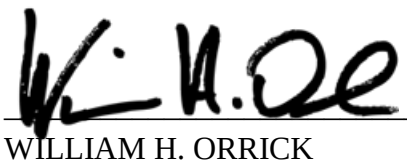
Defendants contend that many of the Supplements at issue have different vitamins and minerals in them, often in different amounts. This fact – even if I take it as true – does not undermine plaintiffs' standing because plaintiffs plead that Bayer makes each of the Statements at issue based on the presence of *specifically* identified vitamins or nutrients that are included in *each* of the Supplements that are marketed with each of the challenged Statements. *See* ACAC ¶¶ 33, 46, 57. Plaintiffs also plead that each of the Supplements "provides an essentially identical combination of *relevant* vitamins and minerals." *Id*., ¶ 29 (emphasis added). That is adequate. Defendants have not shown that because some of the Supplements have additional vitamins/minerals or have different amounts of vitamins/minerals, the consumers' claims are different or that consumers will suffer different injuries as a result of the materially identical Statements.

CONCLUSION

For the foregoing reasons, plaintiffs' claims that Bayer is making illegal disease claims by using the Statements "supports heart health" and "supports immunity" are preempted and DISMISSED. Because plaintiffs may be able to state additional facts showing that those two Statements are used in a manner that makes them impermissible disease claims, plaintiffs are GRANTED LEAVE TO AMEND. Plaintiffs are also given LEAVE TO AMEND to plead that the supports heart health and immunity Statements are false as structure/function claims. The motion to dismiss is DENIED as to plaintiffs' claims regarding "supports physical energy." Plaintiffs' amended complaint shall be filed within 20 days of the date of this Order.

IT IS SO ORDERED.

Dated: March 10, 2015



WILLIAM H. ORRICK
United States District Judge