UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

DAVID SWARTZ,

Plaintiff,

v.

DAVE'S KILLED BREAD, INC. AND FLOWERS FOODS, INC.

Defendants.

Case No. 4:21-cv-10053-YGR

ORDER GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTION TO DISMISS

Defendants Dave's Killer Bread, Inc. and Flowers Foods, Inc. filed the pending motion to dismiss. In this putative class action, plaintiff alleges state law claims premised on alleged misrepresentations about the quantity and quality of protein in defendants' products made on the products' packaging. (Dkt. No. 1, "Complaint," "Comp.") Plaintiff alleges that defendants' actions caused plaintiff and others to pay a price premium for defendants' products due to the mistaken belief that the products contained a higher amount of digestible protein than they do. (Comp. ¶ 24.) Plaintiff brings claims under the California Consumer Legal Remedies Act ("CLRA," Cal. Civil Code § 1750 *et seq.*); California False Advertising Law ("FAL," Cal. Bus. & Prof. Code § 17500 *et seq.*); and California Unfair Competition Law ("UCL," Cal. Bus. & Prof. Code § 17200 *et seq.*), as well as for fraud, deceit and/or misrepresentation; and unjust enrichment.

Having considered the parties' briefs and for the reasons set forth herein, the Court hereby **GRANTS WITH PREJUDICE** dismissal of plaintiff's claims regarding statements defendants make about protein on the front label of their products and **GRANTS WITH LEAVE TO AMEND** dismissal of plaintiff's claims regarding defendants' omission of percent daily value ("%DV") protein from

nutrition labels.[1]

I. BACKGROUND

The complaint alleges as follows[2]:

Protein consumption is important for human health. (Comp. ¶ 26.) Health-conscious consumers seek out products that will provide them with protein and make food purchases based on nutritional representations made on product packaging. (*Id.* at ¶¶ 2, 25.) Some protein sources are better than others. The human body can only use protein when nine specific amino acids are present in the protein. (*Id.* at ¶ 3.) Proteins known as "complete proteins" contain all nine amino acids. (*Id.* at ¶ 31.) Complete proteins are readily used by the human body. Other proteins do not have all nine amino acids. Those proteins may go undigested and unused. (*Id.*)

Defendants manufacture, distribute, market, advertise, and sell a variety of bread products under the label "Dave's Killer Bread." (*Id.* ¶ 22.) Their products include statements on the front labels advertising the amount of protein in the product. (*See, e.g.*, images of defendants' products at *id.* at ¶ 23.) These statements indicate the total amount of protein per serving, which includes both digestible and non-digestible protein. (*Id.* at ¶ 24.) Defendants use low-quality proteins, such as oats and wheat. (*Id.*) As a result, only about half of the protein in a serving of defendants' products is digestible. (*Id.*) Defendants' packaging therefore misleads reasonable consumers into

[1] The Court has reviewed the papers submitted by the parties in connection with defendants' motion to dismiss and has determined that the motion is appropriate for decision without oral argument, as permitted by Civil Local Rule 7-1(b) and Federal Rule of Civil Procedure 78. *See Lake at Las Vegas Investors Group, Inc. v. Pacific Malibu Dev. Corp.*, 933 F.2d 724, 729 (9th Cir. 1991).

[2] In connection with their motion to dismiss defendants request that the Court take judicial notice of several documents. Dkt. No. 21. The Court denies the request as to Exhibits 1-2, copies of email exchanges allegedly between counsel in other cases and the FDA, and 6-7, declarations submitted in those same cases to substantiate the emails, as inappropriate under Rule 201 (prohibiting judicial notice of facts "subject to reasonable dispute"). The Court grants notice of Exhibits 3-5, the complaints from two cases and a page from the FDA website, and will afford them their proper evidentiary weight. *See Rejoice! Coffee Co., LLC v. Hartford Fin. Servs. Grp.*, No. 20-cv-06789-EMC, 2021 U.S. Dist. LEXIS 235263, at *32-33 (N.D. Cal. Dec. 8, 2021) (stating a court may take judicial notice of a public record, but not the facts therein when the facts are in dispute).

believing that "a serving of the Products will provide the grams of protein as represented on the label, when in fact, correcting for the Products [*sic*] poor protein quality [ ] the amount provided will be approximately half of less because Defendants uses [*sic*] proteins of low biological value to humans." (*Id.* at ¶ 24.)

On these grounds, plaintiff asserts the six claims listed above.

II. LEGAL STANDARD

A defendant may move to dismiss a complaint for failing to state a claim upon which relief can be granted under Federal Rule of Civil Procedure 12(b)(6). "Dismissal under Rule 12(b)(6) is appropriate only where the complaint lacks a cognizable legal theory or sufficient facts to support a cognizable legal theory." *Mendiondo v. Centinela Hosp. Med. Ctr.*, 521 F.3d 1097, 1104 (9th Cir. 2008). To survive a Rule 12(b)(6) motion, a plaintiff must plead "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 is facially plausible when a plaintiff pleads "factual content that allows 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). In reviewing the plausibility of a complaint, courts "accept factual allegations in the complaint as true and construe the pleadings in the light most favorable to the nonmoving party." *Manzarek v. St. Paul Fire & Marine Ins. Co.*, 519 F.3d 1025, 1031 (9th Cir. 2008). Nonetheless, courts do not "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).

Federal Rule of Civil Procedure 9(b) heightens these pleading requirements for all claims that "sound in fraud" or are "grounded in fraud." *Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1125 (9th Cir. 2009) (citation omitted); Fed. R. Civ. P. 9(b) ("In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake."). The Ninth Circuit has interpreted Rule 9(b) to require that allegations of fraud are "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." *Neubronner v. Milken*, 6 F.3d 666, 671 (9th Cir. 1993) (internal quotation omitted).

III. DISCUSSION

Plaintiff's claims are based on two theories of why defendants' packaging is misleading. First defendants violate the federal Food Drug and Cosmetics Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.* and mislead consumers into believing that defendants' products contain more digestible protein than they do by representing total protein (calculated using the nitrogen-content method) in nutrient content claims. Second, defendants fail to include %DV corrected protein per serving in the nutrient label of their products, as required by 21 C.F.R. § 101.9(c)(ii) on any packaging containing a nutrient content claim about protein.

In response, defendants move to dismiss on the grounds that claims under plaintiff's first theory are preempted by the FDCA and that plaintiff lacks standing to bring claims brought under his second theory because he has not properly alleged reliance on defendants' allegedly misleading representation. The Court addresses each.

A. Preemption of Plaintiff's Claims Regarding Defendant's Use of Total Rather Than Corrected Protein in Nutrient Content Claims

Plaintiff claims that defendants' use of total protein in nutrient content claims violates 21 C.F.R. §§ 101.9(c)(7), 101.13(i)(3), and 343(a). Defendants respond that plaintiff's claims are preempted on the grounds that 21 C.F.R. § 101.9(c)(7) allows them to use total protein and the nitrogen-content method for nutrient content claims on their labels.

There is a "strong presumption" against federal preemption, especially regarding laws, such as those at issue in this case, that address health and safety, which are traditionally governed by the states. *Law v. Gen. Motors Corp.*, 114 F.3d 908, 910 (9th Cir. 1997). This presumption may be overcome where a statute includes express language preempting conflicting state law. The FDCA includes this kind of preemption statute. *Hawkins v. Kroger Co.*, 906 F.3d 763, 769 (9th Cir. 2018). Under 21 U.S.C. § 343–1(a)(5) states are prohibited from imposing any requirement for the labeling of food that is "not identical to" the federal requirements. "The phrase 'not identical to' means 'that the State requirement directly or indirectly imposes obligations or contains provisions concerning the composition or labeling of food [that] . . . [a]re not imposed by or contained in the applicable [federal regulation] . . . or [d]iffer from those specifically imposed

by or contained in the applicable [federal regulation].'" *Hawkins v. Kroger Co.*, 906 F.3d 763, 769 (9th Cir. 2018) (citing *Reid v. Johnson & Johnson*, 780 F.3d 952, 959 (9th Cir. 2015)). In effect, to avoid preemption under section 343–1(a), "the plaintiff must be suing for conduct that violates" the FDCA or its enabling regulations. *Trazo v. Nestle USA, Inc.*, 2013 WL 4083218, at *5 (N.D.Cal. August 9, 2013); *see also Nacarino v. Kashi Company*, 2022 WL 390815 *5 (finding plaintiff's claims preempted where based on conduct permitted by FDCA regulations); *Chong v. Kind LLC*, 2022 WL 464149 *3 (same); *Brown v. Natures Path Foods, Inc.*, No. 21-CV-05132-HSG, 2022 WL 717816, at *7 (N.D. Cal. Mar. 10, 2022) (same).

In assessing the preemptive effect of the FDCA and its regulations, courts consider FDA guidance. Courts defer to such guidance unless "demonstrably irrational," *Ford Motor Credit Co. v. Milhollin*, 444 U.S. 555, 565–66 (1980), such as where an "alternative reading is compelled by the regulation's plain language." *Bassiri v. Xerox Corp.*, 463 F.3d 927, 931 (9th Cir. 2006) (internal quotation omitted).

To analyze whether the FDCA preempts plaintiff's claim that defendants may not make nutrient content claims on products based on total protein, an overview of relevant federal authority governing nutritional information on packaged foods is warranted. The FDCA, "governs the labeling of food." *Lilly v. ConAgra Foods, Inc.*, 743 F.3d 662, 664 (9th Cir. 2014). The FDA has promulgated regulations on how information about nutrient content is provided on packaged foods. Several of these regulations are relevant here.

By way of background, 21 C.F.R. § 101.9(c)(7) allows two different approaches to representing and measuring protein content on food packaging. Protein representations may either indicate "total protein" or "corrected protein." Total protein must be calculated using a method commonly referred to as the "nitrogen-content method."[3] *See, e.g., Nacarino v. Kashi Co.*, No.

[3] Specifically, the regulation states that "[p]rotein content may be calculated on the basis of the factor 6.25 times the nitrogen content of the food as determined by the appropriate method of analysis as given in the 'Official Methods of Analysis of the AOAC International,' except when official AOAC procedures described in this paragraph (c)(7) require a specific factor other than 6.25, that specific factor shall be used." 21 C.F.R. § 101.9(c)(7).

21-CV-07036-VC, 2022 WL 390815, at *2 (N.D. Cal. Feb. 9, 2022) (using this term). Corrected protein is calculated using a method commonly referred to as the Protein Digestibility Corrected Amino Acid Score or "PDCAAS."[4] 21 C.F.R. § 101.9(c)(7)(ii); (Comp. ¶ 33).

All nutrition labels for packaged foods must include the total amount of protein per serving, calculated using the nitrogen-content method. 21 C.F.R. § 101.9(c)(7). In addition to stating protein per serving in the nutrition label, manufacturers may include explicit statements about protein on areas of the packaging other than the nutrition label. These are called "nutrient content claims." 21 C.F.R. § 101.13(c). For example, the statement "5 Grams of Protein" included on the front label of defendants' products constitutes an explicit nutrient content claim. (*See* Comp. ¶ 23 for images of this packaging.) The regulations do not specify whether nutrient content claims must indicate total or corrected protein.

In 2022, the FDA released guidance explaining that use of total or corrected protein, calculated using the nitrogen-content method or PDCAAS respectively, are appropriate for nutrient content claims. *Industry Resources on the Changes to the Nutrition Facts Label*, U.S. Food & Drug Administration (content current as of May 11, 2022), https://www.fda.gov/food/food-labeling-nutrition/industry-resources-changes-nutrition-facts-label ("2022 Nutrient Content Claim Guidance"). If a manufacturer includes a nutrient content claim for protein, it must add the percent daily value [5] protein per serving to the nutrition label. 21 C.F.R. § 101.9(c)(7)(i). The %DV protein must be calculated using corrected protein as calculated by PDCAAS. (*Id.*)

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[4] The exact language of 21 C.F.R. §101.9(c)(7)(ii) states that this test measures: "the actual amount of protein (gram) per serving multiplied by the amino acid score corrected for protein digestibility."

[5] "Daily values" are the recommended amounts of nutrients to consume or not to exceed each day. The %DV is how much a nutrient in a single serving of an individual packaged food or dietary supplement contributes to your daily diet. *Daily Value on the New Nutrition and Supplement Facts Labels*, U.S. Food & Drug Administration (content current as of May 10, 2022), https://www.fda.gov/food/new-nutrition-facts-label/daily-value-new-nutrition-and-supplement-factslabels#:~:text=DVs%20are%20the%20recommended%20amounts,contributes%20to%20your%20daily%20diet.

Further, and in general, the FDCA prohibits false or misleading nutritional statements on packaged foods. 21 U.S.C. § 343(a) provides that a food label is unlawfully misbranded if it is "false or misleading in any particular." In addition, any explicit nutrient content claim must not be "false or misleading in any respect." 21 C.F.R. § 101.13(i)(3).

The Court analyzes the parties' arguments in the context of the legal framework described.

First, the Court finds that the FDA's explicit statement that nutrient content claims may be based on total protein, calculated using the nitrogen-content method, is dispositive. The 2022 guidance is reasoned and aligns with the plain language of the regulations. The regulations do not state whether nutrient content claims must indicate total or corrected protein or specify a required method of calculation. The guidance merely confirms that there is no preferred or required method. If, as plaintiff alleges, the FDA required that nutrient content claims show corrected protein, it would have said so, as it does at various other points in the regulation. *See, e.g.*, § 101.9(c)(7) (requiring total protein be used to show protein per serving in nutrition labels and that corrected-protein be used to determine what statements must be included on packaging when a product is intended for certain populations); § 101.9(c)(7)(i) (requiring that when %DV protein is included in a nutrition label that corrected-protein be used). Any claim alleging that defendants' use of total protein in nutrient content statements violates section 101.9(c)(7) is preempted.

Alternatively, plaintiff argues that even if the nitrogen-content method is allowed under section 101.9(c)(7), use of this method violates both section 101.13(i)(3), which prohibits false or misleading statements about the amount of a nutrient in a product, and section 343(a), which prohibits as misbranding any label that is "false or misleading in any material respect." The Court disagrees.[6]

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[6] Plaintiff cites several decisions denying dismissal of the claim that use of total protein in nutrient content claims is misleading. (Dkt. 24 at 2.) (*Porter v. NBTY, Inc.* (*Porter I*), 2016 U.S. Dist. LEXIS 163352, at *17–18 (N.D. Ill. Nov. 28, 2016); *Ulrich v. Probalance, Inc.*, 2017 U.S. Dist. LEXIS 132202, at *11–12 (N.D. Ill. Aug. 18, 2017); *Gubala v. CVS Pharmacy, Inc.*, 2016 U.S. Dist. LEXIS 32759, at *40 (N.D. Ill. Mar. 15, 2016).) These decisions preceded release of the 2022 Nutrient Content Claim Guidance clarifying that it is permissible to use total protein for nutrient content claims. As such, they fail to address the significant issue created by interpreting FDA regulations to conflict and are unpersuasive.

The Court declines to interpret sections 101.13(i)(3) and 343(a) to conflict with section 101.9(c)(7). Regulations may not be interpreted "in isolation" or in ways that would lead to "absurd results," such as rendering a statement that is approved by one regulation misleading under another. *Yumul v. Smart Balance, Inc.*, No. CV 10-00927 MMM, 2011 WL 1045555, at *9 (C.D. Cal. Mar. 14, 2011) ("If Smart Balance complied with the regulatory requirements for labeling a product "Cholesterol Free", then its label is not "false and misleading" under 21 C.F.R. § 101.13(i)(3)); *see also United Savings Association of Texas v. Timbers of Inwood Forest Associates, Ltd.*, 484 U.S. 365, 371 (1988) ("A provision that may seem ambiguous in isolation is often clarified by the remainder of the statutory scheme . . . because only one of the permissible meanings produces a substantive effect that is compatible with the rest of the law.").

The Court acknowledges that total protein may be misleading in the colloquial sense, but the FDA has explicitly addressed how to communicate with consumers about the nutrient content of packaged foods. The difference between total and corrected protein is not an issue that the agency has overlooked. As the FDA states in the 2022 guidance, use of both total and corrected protein in the regulations is "by design." 2022 Nutrient Content Claim Guidance. The Court sees no reason to second-guess the FDA's chosen approach.

In sum, sections 101.13(i)(3) and 343(a) do not save plaintiff's claims from preemption. *Nacarino*, 2022 WL 390815 at *5 ("Given the FDA's express approval of the nitrogen-content method and failure to require manufacturers to adjust for protein quality when stating the amount of protein in the nutrition label, it does not make sense to read the regulations as barring manufacturers from making identical statements elsewhere on their packaging."); *Chong*, 2022 WL 464149 at *3 ("[A] correct reading of the regulations establishes that producers may state grams of protein even outside the Nutrition Facts panel calculated by the nitrogen-content method, and without adjustment for digestibility."); *Brown*, 2022 WL 717816 at *7 ("the FDA has now made clear that its regulations do not require protein content claims to adjust for digestibility or to be calculated using amino acid contest testing").

Given the inability to avoid the FDA's guidance, the court **DISMISSES** plaintiff's claims regarding defendants' use of total protein in nutrient content claims **WITH PREJUDICE.**

B. Plaintiff's Standing to Bring Claims Regarding Defendants' Omission of %DV Protein

The remainder of plaintiff's claims are based on the contention that defendants' nutrient content claims indicating total protein are misleading because defendants fail to include %DV corrected protein per serving in the nutrient label, as required by section 101.9(c)(7)(ii). Defendants respond that plaintiff lacks standing to bring these claims because he has not alleged that he read or relied upon the nutrition label when he decided to purchase defendants' products. The Court agrees. *Brown*, 2022 WL 717816 at *4 (finding same).

To have standing, a plaintiff must show that his injury-in-fact is concrete, particularized, and actual or imminent; fairly traceable to the challenged action; and redressable by a favorable ruling. *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 149 (2010). To plead standing under the FAL, CLRA, or UCL, a plaintiff must also allege that he relied on the defendants' purported misrepresentations and suffered economic injury as a result. *Brown*, 2022 WL 717816 at *4 (citing *Kwikset Corp. v. Superior Court*, 51 Cal. 4th 310, 326 (2011)).

Plaintiff does not allege that he read or relied upon the nutrition labels prior to purchasing defendants' products. As such, he has failed to show that his injury is fairly traceable to the alleged misrepresentation (defendants' omission of %DV from the nutrition label) or that requiring defendants to include %DV on the nutrition label would redress his alleged confusion over the protein content of the products he purchased. *See, e.g., Pardini v. Unilever United States, Inc.*, 961 F. Supp. 2d 1048, 1060 (N.D. Cal. 2013) ("Plaintiff has not pled that she ever looked at the nutrition panel. As such, it is implausible that she was deceived by its lack of disclosures."); *Delacruz v. Cytosport, Inc.*, No. C 11-3532 CW, 2012 WL 1215243, at *9 (N.D. Cal. Apr. 11, 2012) (dismissing claims based on misrepresentations made on the defendant's website because the plaintiff did "not plead that she read or relied on any statements on the website"). Thus, plaintiff has not met his burden to show standing. *Brown*, 2022 WL 717816 at *4 (dismissing claims based on defendants' omission of %DV protein on a nutrition label where plaintiff only alleged reliance on front label).

That said, it is possible that plaintiff may be able to amend the complaint. Thus, the Court **DISMISSES WITH LEAVE TO AMEND** plaintiff's claims based on defendants' omission of %DV protein on nutrition labels.[7]

IT IS SO ORDERED.

Dated: May 20, 2022

YVONNE GONZALEZ ROGERS
UNITED STATES DISTRICT JUDGE

[7] In light of these findings, the parties' remaining arguments regarding these claims are premature and the court declines to address them at this time.