UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

ELENA NACARINO, et al., Plaintiffs, v. KASHI COMPANY, Defendant.	Case No. 21-cv-07036-VC **ORDER GRANTING MOTION TO DISMISS** Re: Dkt. No. 21

The plaintiffs challenge the statements Kashi makes on its packaging about the amount of protein in its food products. Although the underlying regulatory scheme is convoluted, the ultimate issue is simple: Is it "false or misleading" within the meaning of the Food, Drug, and Cosmetic Act (FDCA) for a manufacturer to state on the front of the package that a product contains eleven grams of protein, when that figure has been calculated using a technique authorized by FDA regulations? The answer is no. Because the technique is FDA-approved, the statement cannot be considered misleading within the meaning of the statute. The motion to dismiss is therefore granted. And because the defect with the plaintiffs' case lies in the legal theory, not the factual allegations, the dismissal is with prejudice.

I

A

Everyone knows that protein is essential for a healthy diet. It's therefore common for consumers to pick the foods they eat based on protein content. Manufacturers are well aware of this, as a quick trip to the grocery store demonstrates—walk down any aisle and you'll see products boasting their protein content left and right ("Good source of Protein!" "High Protein!"

"11g Protein!"). When one cereal claims eight grams, and another eleven, it's no mystery which one a protein-conscious consumer is going to choose, all other things being relatively equal. But as it turns out, these figures may not be as comparable as they seem.

Protein is not a monolithic substance, but rather consists of chains of amino acids. Different combinations of amino acids make different types of protein. And the ability of the human body to use protein depends on its composition; certain combinations of amino acids are more digestible than others. As a result, from the perspective of a human consumer, protein quality varies. Whey protein, for example, is particularly high quality, as it is fully digestible by humans. But the protein in oats is lower quality, as roughly half of oat protein is not digestible by (and therefore, not beneficial to) the human body. Due to the difference in protein quality, two cereals that both contain eleven grams of protein may vary significantly in the amount of protein that is usable by the human consumer.

Additionally, the way protein is measured makes a difference. According to the complaint, the amount of protein in food can be measured directly by calculating its amino acid content (a technique the plaintiffs call "amino acid content testing"). But protein can be measured indirectly too. The more protein that a product has, the more nitrogen there will be. Thus, the amount of protein in a product can be estimated by multiplying its nitrogen content by some factor (6.25, as it turns out). As the complaint describes the procedures, direct measurement will always be the more reliable technique.

An assertion that a product contains eleven grams of protein, then, raises two questions. First, quality: How much of this protein is digestible by the human body? Second, accuracy: Is this an estimate based on the product's nitrogen, or is it a direct measurement?

B

Given the complexities of protein and its measurement, the Food and Drug Administration (FDA) extensively regulates what manufacturers may say about the protein in their products. The most relevant regulatory provision is 21 C.F.R. § 101.9(c)(7), which is specific to protein. Section 101.9 governs what a manufacturer can (and sometimes, must) say in

the Nutrition Facts label—the box on the back or side of the packaging that lists the amounts of relevant nutrients. Under subsection 101.9(c)(7), manufacturers must include "the number of grams of protein in a serving, expressed to the nearest gram." *Id.* § 101.9(c)(7). This figure may be calculated using the nitrogen-content method—the estimate, discussed above, calculated by multiplying the amount of nitrogen in a product by 6.25. *Id.*

If the packaging contains any additional statements about protein outside the Nutrition Facts label (for example, "Great source of protein!"), manufacturers must add the "corrected amount of protein per serving" to the nutrition label, expressed as a "Percent of Daily Value." *Id.* § 101.9(c)(7)(i). This figure takes the "actual amount of protein" from the nutrition label and adjusts it for digestibility based on the product's "protein digestibility-corrected amino acid score." *Id.* § 101.9(c)(7)(ii).[1]

In addition to section 101.9(c)(7), which governs statements about protein within the Nutrition Facts label, there is a more general provision—section 101.13—that governs statements about nutrients outside the Nutrition Facts label. 21 C.F.R. § 101.13. The default rule is that manufacturers may not make any statements about the nutrients in their products beyond what is required in the Nutrition Facts label. But there are exceptions. The exception relevant here is that a product's packaging "may contain a statement about the amount or percentage of a

[1] A source of confusion in the briefing is the difference between "amino acid content testing" and the "amino acid score." As described in the complaint, amino acid content testing is the direct way of measuring the amount of protein in a product. While the nitrogen method estimates the protein quantity based on the amount of nitrogen present, amino acid content testing directly measures the amount of protein in a product. Amino acid content testing is more accurate than the nitrogen method, but it too does not consider the quality of the protein—just the quantity.

Once the quantity of protein is measured, it can be adjusted for quality (i.e., digestibility) using the "amino acid score." *See* § 101.9(c)(7)(ii). The amino acid score represents the percent of the protein that can be digested by the human body, based on the types of amino acid in the product. (For example, the plaintiffs allege that oat protein typically has a score between 0.45 and 0.51.) Multiplying the quantity of protein (however measured) by the relevant amino acid score adjusts the quantity figure for protein digestibility.

By way of example, consider the plaintiffs' allegations about one of Kashi's cereals. The plaintiffs allege that Kashi represents that its Cinnamon Crisp cereal contains 11 grams of protein, measured via the nitrogen method (and not adjusted for digestibility). When measured via amino acid content testing, however, the cereal is revealed to only contain 9.37 grams of protein. And when this figure is corrected for protein digestibility by multiplying it by the amino acid score, it drops further to 7 grams of protein that are usable by the human body.

nutrient if . . . [t]he statement does not in any way implicitly characterize the level of the nutrient in the food and it is not false or misleading in any respect." *Id.* § 101.13(i)(3). The regulations provide two examples of such permissible statements: "100 calories" or "5 grams of fat." *Id.*

C

Kashi manufactures a range of products, including cereal. According to the allegations in the complaint, Kashi advertises its products as being good sources of protein by stating the amount of protein on the front of the packaging, rather than just in the Nutrition Facts label. One representative cereal box, for example, states "11g Protein" in bold letters on its front. Just like in the Nutrition Facts label, these front-of-the-box figures are calculated using the nitrogen-content method and are not adjusted for protein digestibility. The plaintiffs contend that the statements are misleading and therefore unlawful.

II

A

Before turning to the regulations, a word on preemption. The plaintiffs bring their claims under state consumer protection and tort law. But the FDCA preempts all state causes of action that are "not identical to" the federal requirements. 21 U.S.C. § 343-1(a)(5); *see Hawkins v. Kroger Co.*, 906 F.3d 763, 769–70 (9th Cir. 2018). The question, then, is whether FDA regulations permit the statements that Kashi makes on the face of its products. If they do, any state law claim is preempted. If they do not, the state law claims can go forward.

B

Both parties agree that the plaintiffs' claims turn on section 101.13(i)(3): the regulation authorizing manufacturers to make statements about nutrients outside of the Nutrition Facts label that do not "implicitly characterize the level of the nutrient in the food" and are "not false or misleading in any respect." The plaintiffs do not argue that the challenged statement "implicitly characterize[s]" the amount of protein in the product. Rather, they argue that it is "false or misleading." First, the plaintiffs argue that the methodology Kashi uses to calculate the figure—the nitrogen-content method—overstates the amount of protein per serving. Second, they allege

that Kashi uses low-quality protein that cannot be fully absorbed by the human body, making it misleading to use a figure outside the Nutrition Facts label that has not been adjusted for protein digestibility. The plaintiffs studiously avoid offering any suggestion of how Kashi could correct the allegedly misleading statement, other than to note that it "can simply come off the label."

On one level, the plaintiffs may have a point. The "11g" figure may well be "misleading" in the colloquial sense—a consumer might assume that eating a serving of the cereal will cause their body to digest 11 grams of protein, where in fact it will be less. The problem for the plaintiffs, however, is that what matters is not the colloquial meaning of "misleading" but the regulatory meaning. And the regulations foreclose a conclusion that the "11g" figure is misleading as that term has been used by the FDA. After all, the regulations authorize the nitrogen-content method and do not require manufacturers to adjust statements of protein quantity for digestibility. As discussed, this authorization comes from section 101.9(c)(7), which says that a manufacturer may use the nitrogen-content method without quality adjustment when stating the amount of protein in the Nutrition Facts label. Against the backdrop of this protein-specific provision, the general language of section 101.13 cannot be interpreted as proclaiming that it is "false or misleading" to use the same statement—"11g Protein"—on the front of the box as is authorized in the Nutrition Facts label. The FDA has made a value judgment that the nitrogen-content method, while perhaps not as accurate as direct-measurement techniques, is sufficient. Similarly, the FDA permits manufacturers to list the amount of protein in a product without correcting for digestibility. (Indeed, the regulations refer to this unadjusted figure as the "actual amount of protein" in a product. 21 C.F.R. § 101.9(c)(7)(iii).). Together, this requires a conclusion that Kashi's statements on the front of the package are not "misleading" within the meaning of the FDA's regulations. *Cf. 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.").[2]

It is true, of course, that the FDA requires manufacturers to include extra information in the Nutrition Facts label (the digestibility-adjusted figure, expressed as a percent of daily value) when they make statements about protein elsewhere on the packaging. But this does not mean that statements of protein quantity would be misleading without this additional context. To hold otherwise would be to find that an FDA-approved protein measurement technique is inherently misleading. This is not a plausible interpretation of the regulations. A better reading is that the FDA recognizes that in situations where consumers are drawn to a product for its protein content—those situations in which a manufacturer is touting its product's protein on its packaging—consumers deserve additional information in the Nutrition Facts label. This is not to remedy an otherwise misleading figure, but to supply protein-conscious consumers with information that gives them further assistance in deciding what to buy.

The FDA has recently reinforced this interpretation. In agency guidance from early 2022, the FDA clarified that statements about protein made outside of the Nutrition Facts label may be based on "either of the methods mentioned" in section 101.9(c)(7)—that is, the nitrogen-content method or the "protein digestibility-corrected" figure. *Industry Resources on the Changes to the Nutrition Facts Label*, U.S. Food & Drug Administration (content current as of Jan. 11, 2022), https://www.fda.gov/food/food-labeling-nutrition/industry-resources-changes-nutrition-facts-label. In other words, the FDA has now clearly stated that its regulations do not require protein content statements to adjust for digestibility, demonstrating that "uncorrected" claims are not inherently misleading within the meaning of the regulation. Even assuming these statements do not warrant *Auer* deference, they offer persuasive—if ultimately redundant—support for Kashi's position. *See Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944).[3]

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[2] The FDCA provides that food labels shall not be "false or misleading." 21 U.S.C. § 343(a). The plaintiffs have not argued that the FDA's regulations are inconsistent with this statutory command.

[3] Kashi's motion for leave to file notice of a supplemental authority is granted. Dkt. No. 41. The Court takes judicial notice of this guidance document because it is part of the public record. *See MGIC Indemnity Corp. v. Weisman*, 803 F.2d 500, 504 (9th Cir. 1986); Fed. R. Evid. 201(b)(2).

C

The plaintiffs argue that Ninth Circuit case law dictates the contrary result. It is true that the Ninth Circuit has recognized that "a requirement to state certain facts in the nutrition label is not a license to make that statement elsewhere on the product." *Reid v. Johnson & Johnson*, 780 F.3d 952, 960 (9th Cir. 2015). This flows directly from section 101.13(i)(3), which recognizes that statements mirroring claims in the Nutrition Facts label could still be "false or misleading in [some] respect." 21 C.F.R. § 101.13(i)(3). But this is the exception, not the rule. It is no coincidence that the two Ninth Circuit cases that stand for this proposition both involved the unique situation in which a manufacturer claimed that a product had no trans fats when it in fact contained some trans fats. *See Reid*, 780 F.3d at 955; *Hawkins*, 906 F.3d at 767. The claims in *Reid* and *Hawkins* were uncontrovertibly false in a way that the claim in this case is not: It is not true to say that a product does not contain fat when it does. And *Reid* and *Hawkins* further rely on the fact that the "FDA has expressly allowed 'No Fat' and 'No Saturated Fat' claims for products that contain less than 0.5 grams of fat or saturated fat per serving," but has "explicitly decided *not* to authorize a 'No Trans Fat' claim" in analogous situations. *Reid*, 780 F.3d at 962.

The plaintiffs also point out that district courts addressing this issue have come out the other way. *See, e.g.*, *Minor v. Baker Mills, Inc.*, 2020 WL 11564643, *2–3 (N.D. Cal. Nov. 12, 2020); *Ulrich v. Probalance, Inc.*, 2017 WL 3581183, *5 (N.D. Ill. Aug. 18, 2017); *Porter v. NBTY, Inc.*, 2016 WL 6948379, *5–6 (N.D. Ill. Nov. 28, 2016). Fair enough. But for the reasons discussed above, this Court sees the issue differently and declines to follow their lead.[4]

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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

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Kashi's additional requests for judicial notice are denied because they are not required for the resolution of this motion.

[4] It is also worth noting that these rulings came down before the FDA issued its most recent guidance on the topic (although this Court would not have ruled differently absent the new guidance).

label, it does not make sense to read the regulations as barring manufacturers from making identical statements elsewhere on their packaging. Because Kashi's statements are expressly permitted by the FDCA, the plaintiffs' state law claims are preempted and the motion to dismiss is granted.

IT IS SO ORDERED.

Dated: February 9, 2022

VINCE CHHABRIA
United States District Judge