

**FOR PUBLICATION**

**UNITED STATES COURT OF APPEALS  
FOR THE NINTH CIRCUIT**

TUCKER DURNFORD,  
individually and on behalf of  
all others similarly situated,  
*Plaintiff-Appellant,*

v.

MUSCLEPHARM CORP.,  
*Defendant-Appellee.*

No. 16-15374

D.C. No.  
3:15-cv-00413-HSG

OPINION

Appeal from the United States District Court  
for the Northern District of California  
Haywood S. Gilliam, Jr., District Judge, Presiding

Argued and Submitted November 15, 2017  
San Francisco, California

Filed October 12, 2018

Before: Marsha S. Berzon and Michelle T. Friedland,  
Circuit Judges, and William K. Sessions III,\* District  
Judge.

Opinion by Judge Berzon

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\* The Honorable William K. Sessions III, United States District  
Judge for the District of Vermont, sitting by designation.

**SUMMARY\*\***

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**Preemption / Food, Drug, and Cosmetic Act**

The panel reversed the district court's dismissal of an action alleging California consumer claims against MusclePharm Corporation, a manufacturer of nutritional supplements, for making false or misleading statements about the protein in one of its products; and remanded for further proceedings.

The district court dismissed the action as preempted by the Food, Drug, and Cosmetic Act ("FDCA"), reasoning that any declarations of protein content anywhere on a product label could not be false or misleading if the listed amount of protein reflected measurements made in accordance with federal regulations concerning the federally mandated nutrition panel.

The panel held that, as relevant here, the FDCA and its implementing regulations concerned only the calculation and disclosure of protein *amounts*. Specifically, the panel held that the FDCA preempted a state-law misbranding theory premised on the supplement's use of nitrogen-spiking agents to inflate the measurement of protein for the nutrition panel. The panel further held that the FDCA did not, however, preempt a state-law misbranding theory premised on the label's allegedly false or misleading implication that the supplement's protein came entirely from two specifically named, genuine protein sources. The panel concluded that

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\*\* This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

plaintiff's claims were not preempted to the extent they arose under this theory.

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### COUNSEL

Matt J. Malone (argued), Susan F. Brown, and Michael F. Ram, Ram Olson Cereghino & Kopczynski, San Francisco, California, for Plaintiff-Appellant.

Michael J. Suffern (argued) and Linda E. Maichl, Ulmer & Berne LLP, Cincinnati, Ohio, for Defendant-Appellee.

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### OPINION

BERZON, Circuit Judge:

Tucker Durnford brought California consumer claims against MusclePharm Corporation, a manufacturer of nutritional supplements, for making false or misleading statements about the protein in one of its products. The district court dismissed Durnford's action as preempted by the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301–399i, reasoning that any declarations of protein content anywhere on a product label could not be false or misleading if the listed amount of protein reflected measurements made in accordance with federal regulations concerning the federally mandated nutrition panel. We disagree. As here relevant, the FDCA and its implementing regulations concern only the calculation and disclosure of protein *amounts*. They say nothing about the source or composition of protein, factors which underlie one of Durnford's several theories of consumer deception.

Durnford's claims are therefore not preempted to the extent they arise under that theory.

## I

MusclePharm is a Nevada corporation that produces a line of nutritional supplements, including the "Arnold Schwarzenegger Series Iron Mass" supplement ("the Supplement") here at issue. Durnford is a California citizen who purchased the Supplement from a sports nutrition retailer in 2014.

The Supplement is marketed as a muscle-building or weight-gain product, with a focus on its "revolutionary 5-stage mass delivery system." According to the Supplement's label,<sup>1</sup> this "system" consists of "advanced protein technology, elite complex carbs, healthy fats, cutting-edge performance ingredients and a balanced digestive blend."

The label describes the "stages" of the Supplement's "system" in some detail. In particular, the second stage is described as "Muscle plasma protein technology: 40g of a potent blend of hydrolyzed beef protein and lactoferrin protein." The fourth stage is described as "Performance growth & muscle volumizer: Creatine and BCAA nitrates help promote muscular strength, size and endurance."

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<sup>1</sup> We refer to the product's packaging as a whole as the "label." We refer to the federally mandated declaration of nutritional content within the label as the "nutrition panel." As will be explained, the latter is subject to a unique set of stringent federal regulations.

# REVOLUTIONARY 5-STAGE MASS DELIVERY SYSTEM

Attacks Every Angle of Muscle Building!

**1. ELITE COMPLEX CARBOHYDRATES MATRIX:**

Quicker recovery & muscle building, giving muscles a skin-splitting look

**2. MUSCLE PLASMA PROTEIN TECHNOLOGY:**

40g of a potent blend of hydrolyzed beef protein and lactoferrin protein

**3. HIGH PERFORMANCE HEALTHY FATS:**

Blend of healthy fats (EFA's), MCT's and saturated fats which are essential for hormone production

**4. PERFORMANCE GROWTH  
& MUSCLE VOLUMIZER:**

Creatine and BCAA nitrates help promote muscular strength, size and endurance

**5. PRO-DIGEST BLEND:**

Special dietary fiber blend, aids with digestion of added protein, carbs and fat you need to

**GET BIG—AND STAY BIG**

The nutrition panel at the back of the label also reflects the “five-stage system.” For example, in listing the Supplement’s ingredients, the front of the label divides ingredients according to the “five stages.” The nutrition panel then repeats the five stages in the same order they appear on the front of the label, and repeats the same jargon in describing them.

<b>Supplement Facts</b>		
Serving Size: 95g (2 scoops)		
Servings Per Container: 24 (2.27kg/5lbs)		
	Amount Per Serving	% DV*
<b>Calories</b>	485	
Calories From Fat	190	
<b>Total Fat</b>	21 g	41%
Saturated Fat	1 g	6%
Trans Fat	1 g	
<b>Cholesterol</b>	2 mg	1%
Sodium	240 mg	10%
Potassium	550 mg	27%
<b>Total Carbohydrate</b>	34 g	25%
Dietary Fiber	1 g	4%
Sugars	4 g	
<b>Protein</b>	40 g	72%
<b>Iron Mass Proprietary Blend</b>	71500 mg	**
<b>Elite Complex Carbohydrates Matrix</b> Sweet Potato Powder, Barley Starch.		
<b>Muscle Plasma Protein Matrix</b> Hydrolyzed Beef Protein, Lactoferrin.		
<b>High Performance Healthy Fats Matrix</b> Sunflower Oil Powder, Whipped Cream Powder, MCT Powder (Medium-Chain Triglycerides from Coconut).		
<b>Performance Growth &amp; Muscle Volumizer</b> Creatine Monohydrate, L-Glycine, BCAA Nitrates (Leucine, Iso-Leucine, Valine) (3.1.2 Patent Pending Ratio), D-Ribose.		
<b>Pro-Digest Blend</b> Protease, Lactase, Amylase, Lipase, Inulin, Fructooligosaccharides (FOS).		
*Percent Daily Value (%DV) Based on a 2,000 Calorie Diet **Daily Value (DV) Not Established		
<b>Other Ingredients:</b> Glucose Polymers, Cocoa Powder, Natural and Artificial Flavors, Sea Salt, Acesulfame Potassium, Sucralose.		

As should be apparent, the second group of ingredients listed on the nutrition panel corresponds to the second stage of the Supplement's "system." This group of ingredients is described as the "Muscle Plasma Protein Matrix," consisting of "Hydrolyzed Beef Protein, Lactoferrin." The fourth group of ingredients listed on the nutrition panel corresponds to the fourth stage of the Supplement's system. This group of ingredients is described as the "Performance Growth & Muscle Volumizer," consisting of "Creatine Monohydrate, L-Glycine, BCAA Nitrates (Leucine, Iso-Leucine, Valine) . . . , D-Ribose." The nutrition panel states that a single

serving of 95 grams of the Supplement contains 40 grams of protein, or 72% of the recommended daily value.

In January 2015, Durnford brought an action alleging that MusclePharm had engaged in “protein spiking” or “nitrogen spiking” — the practice of inflating measurements of a supplement’s protein content using non-protein substances — thereby rendering the Supplement falsely or misleadingly labeled.<sup>2</sup> Specifically, Durnford alleged that MusclePharm used creatine monohydrate and free-form amino acids (l-glycine, leucine, iso-leucine, and valine) to inflate protein figures. These are the substances that appear at stage four of the Supplement’s “system.” Durnford also alleged that an independent study of the Supplement demonstrated that its true protein value was not 40 grams per serving, but 19.4 grams per serving.

Durnford brought claims under California’s Unfair Competition Law (“UCL”), Cal. Bus. & Prof. Code §§ 17200–17210; False Advertising Law (“FAL”), Cal. Bus. & Prof. Code §§ 17500–17509; and Consumer Legal Remedies Act (“CLRA”), Cal. Civ. Code §§ 1750–1784; and for breach of express warranty. The express warranty claim was premised on the theory that the Supplement’s “labeling, marketing and advertising constitute express warranties and became part of the basis of [the] bargain” — a bargain struck, according to the complaint, “at the time [consumers] purchased the Product.”

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<sup>2</sup> According to the complaint, because nitrogen is used as marker for protein, manufacturers seeking a low-cost way of inflating their protein figures are known to “spike” their formulations with nitrogen-rich additives that provide little or none of the benefit of actual protein. Free-form amino acids — amino acids that are not bound together in complex chains, as proteins are — are sometimes used as nitrogen-spiking agents.

Durnford also alleged that, at some point, an individual “tweeted at” MusclePharm’s official Twitter account to ask about the truth behind product reviews accusing MusclePharm of nitrogen spiking. MusclePharm responded via Twitter: “Those [reviews] are fake then. We don’t do anything like that. All products legit and scientifically backed[.]” The individual who tweeted at MusclePharm identified himself on Twitter as “Jacob Henderson.” The complaint did not explain who Jacob Henderson was, what relationship he had to Durnford or to this case, when the Twitter interaction took place, or whether Durnford was aware of it.

Durnford did not explain his reasons for purchasing the Supplement. For example, he did not allege that he purchased the product intending to gain weight or add muscle, the likely reason for most purchases of the product. He did state, however, that he “would not have purchased the Supplement had [he] known the true nature of the protein content.” And he alleged that he “purchased the [Supplement] in reliance on [MusclePharm’s] labeling and marketing claims.”

MusclePharm moved to dismiss the complaint on preemption grounds, for failure to plead reliance adequately, and for failure to plead fraud with particularity. In granting the motion to dismiss, the district court divided Durnford’s four legal claims into three theories of misrepresentation, each tied to one of MusclePharm’s “claims” about its product. The “Protein Content Claim” referred to the theory that Durnford was misled by the 40-gram figure on the Supplement’s nutrition panel, as independent testing allegedly revealed that figure to be heavily influenced by nitrogen-rich *non*-protein substances such as free-form amino acids. The “Protein Composition Claim” referred to



the theory that Durnford was misled by the label's suggestion that the product contained 40 grams of protein derived entirely from hydrolyzed beef protein and lactoferrin rather than nitrogen-spiking agents. The "Nitrogen Spiking Claim" referred to the theory that Durnford was misled by the statement MusclePharm made on its Twitter account in response to a direct question about nitrogen spiking.

The district court ruled for MusclePharm on preemption grounds with respect to the "Protein Content Claim." Specifically, the court noted that Food and Drug Administration ("FDA") regulations allow a manufacturer to use nitrogen content as a proxy for protein content, thus permitting the practice of nitrogen spiking.<sup>3</sup> As the FDCA expressly preempts state-law requirements that are "not identical to" those in the FDCA itself, 21 U.S.C. § 343-1(a)(5), the district court concluded that even if the label might be considered misleading, California consumer law could not be used to create liability for an FDA-compliant measurement.

The district court ruled for MusclePharm on the "Protein Composition Claim" on preemption grounds as well, but on narrower reasoning. The court accepted the theory that MusclePharm's label falsely or misleadingly suggested that the Supplement contained 40 grams of protein derived entirely from hydrolyzed beef protein and lactoferrin and therefore not from nitrogen spiking. The court also accepted that a misbranding theory of that kind went beyond a claim

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<sup>3</sup> The Secretary of Health and Human Services ("HHS") has "authority to promulgate regulations for the efficient enforcement of" the FDCA. 21 U.S.C. § 371(a). The agency within HHS responsible for FDCA regulations is the FDA. We therefore refer to the relevant regulations in this case as "FDA regulations."

based purely on the FDA’s approved methods of calculating protein content. Nonetheless, the district court concluded that Durnford’s claims, “as currently pled, are preempted,” as Durnford did not allege that his independent study demonstrating a lack of true protein “conformed to the [FDA] requirements” for measuring protein content.

Finally, the district court ruled for MusclePharm on its “Nitrogen Spiking Claim” for failure to plead reliance adequately, a problem the court described as a lack of statutory standing under California’s consumer protection laws. The court noted that it could be “reasonable to presume that consumers read and rely on product labels when purchasing a supplement.” But the court was unable to draw such an inference regarding the comment made on Twitter.

The district court dismissed the complaint without prejudice to repleading to cure the preemption and reliance problems. Durnford allowed the period for amendment to lapse, and the court entered judgment. This appeal followed.

## II

We begin with a review of federal preemption under the relevant provision of the FDCA. The FDCA provides, in relevant part, that

no State . . . may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce . . . (4) any requirement for nutrition labeling of food that is *not identical to the requirement of section 343(q)* of this title . . . or, (5) any requirement respecting any claim . . . made in the label or labeling of food that is *not*

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*identical to the requirement of section 343(r) of this title.*<sup>4</sup>

21 U.S.C. § 343-1(a) (emphases added).<sup>5</sup> Section 343(q) addresses the information that must be disclosed in a nutrition panel under the FDCA. *See* 21 U.S.C. § 343(q)(1), (q)(5)(F); Revision of the Nutrition and Supplement Facts Labels, 81 Fed. Reg. 33,742, 33,744 (May 27, 2016). As here relevant, the section provides that food is deemed “misbranded” unless its nutrition panel includes a statement of the product’s “total protein.” 21 U.S.C. § 343(q)(1)(D).

FDA regulations provide guidance as to the acceptable means of calculating “total protein” for purposes of the mandatory nutrition panel. Specifically, “[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 . . . .” 21 C.F.R. § 101.9(c)(7). This regulation applies equally to ordinary food and to dietary supplements, “except that [for dietary supplements] the sample for analysis shall consist of a composite of 12 subsamples (consumer packages) or 10 percent of the number of packages in the same inspection lot, whichever is smaller, randomly selected to be representative of the lot.” 21 C.F.R. § 101.36(f)(1).

Section 343(r) addresses statements concerning nutritional content other than those required to be included

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<sup>4</sup> Both section references are to title 21 of the United States Code.

<sup>5</sup> This section and the sections cited within it were added to the FDCA in 1990 in the Nutrition Labeling and Education Act (“NLEA”), Pub. L. No. 101-535, 104 Stat. 2353 (Nov. 8, 1990). For simplicity, we refer to the NLEA provisions as part of the FDCA except as necessary to distinguish them.

in the nutrition panel. As relevant here, the section provides that products whose labels “characterize[] the level of any nutrient” listed in section 343(q) are deemed misbranded unless they comply with specific requirements, established by regulation, for nutrient disclosures of that kind. 21 U.S.C. § 343(r)(1)–(2). A separate provision of the FDCA provides another, broader description of misbranding. According to section 343(a), “food shall be deemed to be misbranded . . . [if] its labeling is false or misleading in any particular.” 21 U.S.C. § 343(a).

The FDA has promulgated regulations attempting to clarify the scope of express preemption under the “not identical to” standard stated in section 343-1(a). According to the FDA, in preempting state law that would impose requirements “not identical to” those in the FDCA, the statute is not concerned with “the specific words in the [state-law] requirement.” 21 C.F.R. § 100.1(c)(4). Instead, the federal statute displaces “obligations or . . . provisions concerning the composition or labeling of food . . . [that] [a]re not imposed by or . . . [that] [d]iffer from those specifically imposed by” the FDCA.<sup>6</sup> 21 C.F.R. § 100.1(c)(4)(i)–(ii).

FDCA preemption is subject to well-established limiting principles. First, federal preemption arising from the provisions at issue in this case is, by statutory prescription, express preemption only. *See* NLEA § 6(c)(1), 104 Stat. at

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<sup>6</sup> In the absence of a specific congressional delegation of authority to interpret the scope of preemption, agency interpretations regarding the scope of preemption are not entitled to deference under *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1984). *See Wyeth v. Levine*, 555 U.S. 555, 576 (2009). Durnford has not, however, challenged the FDA’s interpretation of the preemptive effect of the FDCA, so we assume its applicability.

2364 (codified at 21 U.S.C. § 343-1 note) (“The [NLEA] shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under [section 343-1].”); *Hawkins v. The Kroger Co.*, No. 16-55532, slip op. at 8 (9th Cir. Oct. 4, 2018) (citing *Reid v. Johnson & Johnson*, 780 F.3d 952, 959 (9th Cir. 2015)). Second, a presumption against preemption applies to the extent the FDCA is used to displace state law in an area of traditional state police power. *See Wyeth v. Levine*, 555 U.S. 555, 565 & n.3 (2009); *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 334–35 (3d Cir. 2009). Consumer protection falls well within that category. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996).

### III

We turn now to review of the order granting MusclePharm’s motion to dismiss. Our review is *de novo*. *Edwards v. Marin Park, Inc.*, 356 F.3d 1058, 1061 (9th Cir. 2004). The district court’s three-part categorization of Durnford’s claims is a useful framework for evaluating Durnford’s theories of misbranding, so we adhere to it.

#### A

The “protein content” theory of misbranding refers to Durnford’s allegations that he was misled by the 40-gram figure on the Supplement’s nutrition panel, because it was a product of nitrogen spiking and so not an accurate measurement of true protein content. This theory is foreclosed by the FDCA.

The FDCA requires the disclosure of the “amount” of “total protein” in the nutrition panel, 21 U.S.C. § 343(q)(1)(D), and FDA regulations approve of the use of nitrogen as a proxy in complying with that requirement,

21 C.F.R. § 101.9(c)(7). These regulations have the same preemptive effect as a statute, *Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153–54 (1982), and so foreclose the possibility of liability under state law for nitrogen spiking.

Durnford argues otherwise, maintaining that the regulation serves internal “regulatory” purposes and is not intended to have preemptive effect. But the regulation is not just an internal guidance; it is an interpretation of the statutory provision requiring that manufacturers disclose a product’s protein content, a concept that requires federal agency clarification if there is to be national uniformity in labeling. *See Reid*, 780 F.3d at 959. Where, as here, “Congress has ‘explicitly left a gap for an agency to fill, there is an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation,’ and any ensuing regulation is binding unless . . . defective.” *United States v. Mead Corp.*, 533 U.S. 218, 227 (2001) (*Chevron U.S.A. Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 843–44 (1984)).

*Astiana v. Hain Celestial Grp., Inc.*, 783 F.3d 753 (9th Cir. 2015), is consistent with this conclusion. *Astiana* held that a state law challenge to a cosmetic labeled “natural” was not preempted because “*Astiana* [was] not asking [the manufacturer] to modify or enhance any aspect of its cosmetics labels that are required by federal law.” *Id.* at 758. No statute or regulation governed “the use of ‘natural’ on cosmetics labels.” *Id.* There was therefore no basis for express preemption in *Astiana*. Not so here, where disclosure of the amount of protein content on the nutrition panel is required by statute, and the proper means of calculating that amount is set out in the regulation.

That section 343(a) prohibits false or misleading statements *in general* does not alter our analysis. Durnford has not on appeal challenged as invalid the FDA regulation allowing the use of nitrogen content as a proxy for protein. He does not argue, for example, that the agency has authorized, by regulation, an inherently misleading means of calculating protein, such that it has exceeded its congressionally delegated authority in light of section 343(a). *See Chevron*, 467 U.S. at 843; *see also Mead*, 533 U.S. at 227. Any such argument is thus forfeited.<sup>7</sup> *See Smith v. Marsh*, 194 F.3d 1045, 1052 (9th Cir. 1999).

Durnford's remaining arguments against preemption are without merit. Durnford misreads the FDA's protein regulation as precluding the use of nitrogen as a benchmark when calculating a percentage of recommended daily value. The regulation provides only that, if a percentage of recommended daily value is declared on the nutrition panel, it should be calculated using the "corrected amount of protein per serving." 21 C.F.R. § 101.9(c)(7)(i). The corrected amount of protein per serving "is equal to the actual amount of protein . . . per serving [in grams] multiplied by the amino acid score corrected for protein digestibility." 21 C.F.R. § 101.9(c)(7)(ii). The "correction" is therefore not to remove nitrogen-spiking agents, as Durnford suggests, but to account for digestibility. This *digestibility* correction has no apparent impact on the validity of the MusclePharm label, nor has Durnford suggested any. And although Durnford notes that a separate regulation states that "[p]rotein shall not be declared on labels of products that, other than ingredients added solely for technological reasons, contain *only* individual amino

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<sup>7</sup> As the nitrogen-as-protein regulation has not been challenged, this opinion should not be taken as either approving it or disapproving it.

acids,” the Supplement is not such a product. 21 C.F.R. § 101.36(b)(2)(i) (emphasis added). It contains more than just individual amino acids.

In sum, federal regulations allow nitrogen to be used on the nutrition panel as a proxy for protein content. Accordingly, a state-law misbranding claim premised on nitrogen spiking — that is, a claim that would permit a state to impose requirements for the measurement of protein for purposes of the federal mandated nutrition panel different from those permitted under the FDCA — is preempted.

## B

Durnford’s “protein composition” theory of misbranding is that the Supplement’s label misled him into believing the Supplement’s protein came entirely from genuine protein sources — hydrolyzed beef protein and lactoferrin — rather than nitrogen-spiking agents. The district court accepted the possibility that the label created a false or misleading impression in this respect. The district concluded, however, that Durnford’s claims were nonetheless preempted because he did not allege that he had any independent study contradicting the label that used the FDA’s elaborate 12-sample testing protocol. *See* 21 C.F.R. § 101.36(f)(1).

This reasoning misapprehends Durnford’s protein composition theory. That theory rests not on the misleading nature of nitrogen spiking but on the label’s misleading suggestion that all of the protein in the Supplement, in whatever amount it exists, comes from specific protein sources. In other words, Durnford’s argument goes not to the amount of protein, but to its composition. The FDA’s testing protocol is relevant only to the former.



As an initial matter, the premise behind the protein composition theory is correct. The label — separately from the mandatory nutrition panel — twice identifies hydrolyzed beef protein and lactoferrin as *the* protein sources in the Supplement. The label then apparently distinguishes those protein sources from nitrogen compounds, which are listed and identified separately not as protein, but as “performance growth and muscle volumizer.” The label further states that the Supplement’s proteins are present in the amount of “40g of a . . . blend of . . . beef protein and lactoferrin” — the same amount of protein claimed per serving on the nutrition panel. Finally, in its ingredients list, the label repeats the distinction in nomenclature between true proteins and other substances, referring to hydrolyzed beef protein and lactoferrin part of the Supplement’s “protein technology,” and calling the free-form amino acids “muscle volumizer.”

Under Durnford’s theory of misbranding, whether or not there was compliance with the FDA’s 12-sample testing protocol does not matter.<sup>8</sup> The disputed testing protocol is a

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<sup>8</sup> We need not address whether plaintiffs are *ever* required to allege, at the pleading stage, that there are tests contradicting the nutrition panel that comply with the FDA’s testing protocols. We note, however, that plaintiffs are generally not expected to provide evidence in support of their claims at the pleading stage, *see Cafasso, U.S. ex rel. v. Gen. Dynamics C4 Sys., Inc.*, 637 F.3d 1047, 1055 (9th Cir. 2011), nor are they required to plead the “probability” of their entitlement to relief, *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). In addition, FDCA preemption, like all federal preemption, is an affirmative defense. *Lusnak v. Bank of Am., N.A.*, 883 F.3d 1185, 1194 n.6 (9th Cir. 2018). “Only when the plaintiff pleads itself out of court — that is, admits all the ingredients of an impenetrable defense — may a complaint that otherwise states a claim be dismissed under Rule 12(b)(6).” *Xechem, Inc. v. Bristol-Myers Squibb Co.*, 372 F.3d 899, 901 (7th Cir. 2004); *see also Scott v. Kuhlmann*, 746 F.2d 1377, 1378 (9th Cir. 1984) (per curiam).

requirement for “[c]ompliance with this section,” 21 C.F.R. § 101.36(f)(1) — that is, for compliance with the section of FDA regulations determining the proper means of calculating protein *content* in dietary supplements. *See also* 21 C.F.R. § 101.9(g). But Durnford’s protein *composition* theory is not concerned with the total amount of protein in the Supplement; it is concerned with the source of that protein. Durnford argues that, whatever the true protein amount in grams per serving, the label falsely or misleadingly suggested that that protein is entirely composed of two kinds of actual, genuine protein. In other words, according to Durnford, the label falsely disclaims nitrogen spiking.

In sum, Durnford’s complaint adequately alleges facts necessary to support a consumer claim premised on his protein composition theory of misbranding.<sup>9</sup> As noted, Durnford brought three California statutory claims, as well

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<sup>9</sup> MusclePharm argues that lack of reliance offers an alternative ground for affirmance, at least as to the three statutory claims. *See Kwikset Corp. v. Superior Court*, 51 Cal. 4th 310, 326 (2011). MusclePharm notes, correctly, that the complaint makes sparse, generic allegations regarding Durnford’s reliance on the Supplement’s label, and fails to explain Durnford’s reasons for purchasing the product. But the district court declined to address this issue, and speculated that an inference of reliance might be reasonable under the circumstances. We decline to reach the question of reliance in the first instance, particularly as the district court retains the discretion, on remand, to grant the plaintiffs leave to amend the complaint so as better to allege reliance on the misbranding.

MusclePharm also argues that failure to plead fraud with particularity is an alternative ground for affirmance. But apart from a possible reliance problem, the “who, what, when, where, and how” required by Federal Rule of Civil Procedure 9(b) are evident in the allegations supporting Durnford’s protein composition theory. *See Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1124 (9th Cir. 2009).

as a claim for breach of express warranty. MusclePharm has made no attempt on appeal to distinguish between the elements of these nominally distinct legal claims for purposes of the protein composition theory, and there is no evident difference. Durnford's protein composition theory is therefore ground for reversal as to all claims.

### C

Finally, the so-called "Nitrogen Spiking Claim" refers to the theory that Durnford was misled by a tweet from MusclePharm stating that it did not use nitrogen-spiking agents to inflate its protein figures. But nothing in the complaint connects this tweet to Durnford's purchase of the Supplement. To the extent Durnford intended the tweet as an independent basis for his claims — rather than simply as illustrative evidence of the way MusclePharm intended its consumers to understand the composition of the Supplement — the complaint is inadequate.

### IV

The FDCA, in light of its implementing regulations, preempts a misbranding theory premised on the Supplement's use of nitrogen-spiking agents to inflate the measurement of protein for the nutrition panel. It does not, however, preempt a misbranding theory premised on the label's allegedly false or misleading implication that the Supplement's protein came entirely from two specifically named, genuine protein sources. The district court's order of dismissal is **REVERSED**, and this case is **REMANDED** for further proceedings consistent with this opinion.