UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF CALIFORNIA

J.J., C.D., C.B., and D.F. v. Ashlynn Marketing Group, Inc.

Case No. 3:24-cv-00311-GPC-MSB (S.D. Cal. Oct. 16, 2025) · No. 3:24-cv-00311-GPC-MSB · Decided October 16, 2025

OPINION

1 2 3 4 5 6 7 8 UNITED STATES DISTRICT COURT 9 SOUTHERN DISTRICT OF CALIFORNIA 10 11 J.J., C.D., C.B., and D.F., individually and Case No.: 3:24-cv-00311-GPC-MSB on behalf of all others similarly situated, 12 ORDER DENYING DEFENDANT'S Plaintiffs, 13 MOTION FOR v. RECONSIDERATION 14 ASHLYNN MARKETING GROUP, 15 [ECF No. 84] INC., 16 Defendant. 17 18 This case concerns Defendant's alleged failure to warn consumers of the purportedly 19 addictive nature of kratom when marketing and labeling its kratom-based products.

On 20 July 1, 2025, this Court issued an order granting in part and denying in part Defendant 21 Ashlynn Marketing Group, Inc.'s second motion to dismiss. ECF No. 77. Currently before 22 the Court is Defendant's motion for reconsideration. ECF No. 84.

The motion has been 23 fully briefed. ECF Nos. 90, 94. The matter was scheduled for a hearing on October 17, 24 2025. The Court vacates the hearing and, for the reasons discussed below, DENIES 25 Defendant's motion for reconsideration. 26 / / / 27 1 BACKGROUND 2 The factual and procedural background of this case is outlined in this Court's July 3 1, 2025, order granting in part and denying in part Defendant's motion to dismiss.

ECF No. 4 77. Accordingly, the Court will address only those facts relevant to the motion currently 5 before the Court. 6 On March 7, 2025, Plaintiffs J.J., C.D., C.B., and D.F. filed their Consolidated Class 7 Action Complaint (CCAC), individually and on behalf of three putative classes, alleging 8 that Defendant failed to warn consumers of the potentially addictive nature of its products, 9 which contain dried leaves from a plant called kratom.

ECF No. 50. Specifically, Plaintiffs 10 allege that Defendant misled consumers by espousing the purported health benefits of 11 kratom without disclosing kratom's addictive properties on its product labels or in its 12 advertising. Id. at 8, 16. Plaintiffs' CCAC alleges violations of (1) California's Unfair 13 Competition Law; (2) California's Consumers Legal Remedies Act; (3) New York's 14 Consumer Protection from Deceptive Acts and Practices Act; and (4) New York's False 15 Advertising Act.

ECF No. 50, at 25-33. The CCAC also includes a count of common law 16 fraudulent omission. Id at 33-34. 17 Defendant moved to dismiss Plaintiffs' CCAC on April 7, 2025. ECF No. 57. In its 18 motion to dismiss, Defendant argued, among other things, that Plaintiffs' claims must be 19 dismissed on the grounds that they are preempted by federal law. ECF No. 57-1, at 19.1 20 Specifically, Defendant noted that Plaintiffs' state law claims were premised on 21 Defendant's failure to disclose kratom's alleged addictiveness.

However, Defendant 22 claimed that labeling its products with any such warning would run afoul of the Federal 23 Food, Drugs, and Cosmetic Act (FDCA). See ECF No. 57-1, at 21; ECF No. 68, at 7. 24 25 26 1 Throughout the order, the pagination for docketed documents is derived from the numbering generated by the ECF system. 27 1 According to Defendant, the relevant state law, which allegedly compels Defendants to 2 warn consumers of potential addictive properties, conflicts with federal law, which 3 purportedly prohibits Defendant from providing such a warning absent FDA approval.

4 Given the conflict, Defendant claims that Plaintiffs' state law claims are preempted and 5 must be dismissed. ECF No. 57-1, at 22; ECF No. 68, at 7. 6 The Court concluded that attaching a warning that kratom is addictive would not 7 violate the FDCA's labeling regulations for dietary supplements. ECF No. 77, at 13-14. 8 Further, the Court found that Defendant could comply with both state and federal law, and 9 Plaintiffs' claims were not preempted.

Id. Accordingly, on July 1, 2025, the Court granted 10 in part and denied in part Defendant's motion. Id. at 35. The Court granted Defendant's 11 motion to dismiss only as to Plaintiffs' nationwide class claims. Id. at 17-21.

The Court 12 denied Defendant's motion on all other grounds. Id. at 35. 13 Defendant now moves for reconsideration on the grounds that the Court made a clear 14 legal error by finding that federal law does not preempt Plaintiffs' state law claims. ECF 15 No. 84-1, at 2. Plaintiffs filed a response in opposition to Defendant's motion on August 16 29, 2025, ECF No. 90, to which Defendant replied on September 19, 2025, ECF No. 94.

17 LEGAL STANDARD 18 Defendant raises its motion for reconsideration under Federal Rule of Civil 19 Procedure 60(b) and this district's Local Civil Rule 7.1(i)(1). ECF No. 84-1, at 4. Because 20 the Court's order on Defendant's motion to dismiss did not terminate the case, Defendant's 21 current motion is better suited to proceed under Rule 54(b)—which provides that any order 22 that does not terminate a case may be revised at any time prior to final judgment—than 23 Rule 60(b)—which refers to final judgments.

See, e.g., Fay Ave. Props., LLC v. Travelers 24 Prop. Cas. Co. of Am., No. 11-CV-2389-GPC-WVG, 2014 WL 6980248, at *1 (S.D. Cal. 25 Dec. 9, 2014) ("A motion for reconsideration may be brought under Rule 54(b) which 26 27 1 provides that any order which does not terminate the

case is subject to revision at any time 2 before the entry of judgment."). 3 However, under either Rule 54(b) or Rule 60(b), "[r]econsideration is appropriate if 4 the district court (1) is presented with newly discovered evidence, (2) committed clear error 5 or the initial decision was manifestly unjust, or (3) if there is an intervening change in 6 controlling law." Sch.

Dist. No. 1J, Multnomah Cnty., Or. v. ACandS, Inc., 5 F.3d 1255, 7 1263 (9th Cir. 1993) (addressing a motion for reconsideration under Rule 60(b) and Rule 8 59(e)). See also Fay Ave. Props., LLC, 2014 WL 6980248, at *1 (applying the same 9 standard to a motion for reconsideration under Rule 54(b)); Sherman v. Yahoo! Inc., 997 10 F. Supp. 2d 1129, 1139 (S.D.

Cal. 2014) (same). Of relevance here, clear error occurs when 11 "the reviewing court on the entire record is left with the definite and firm conviction that a 12 mistake has been committed." Smith v. Clark County School Dist., 727 F.3d 950, 955 (9th 13 Cir. 2013) (quoting United States v. U.S. Gypsum Co., 333 U.S. 364, 395 (1948)). 14 In the Southern District of California, motions for reconsideration are also governed 15 by Local Rule 7.1(i), under which a party may apply for reconsideration "[w]henever any 16 motion... has been made to any judge and has been refused in whole or in part[.]" S.D.

17 Cal. Civ. L.R. 7.1(i)(1). Local Rule 7.1(i) requires that a party seeking reconsideration 18 include an affidavit or certified statement of a party or attorney identifying, among other 19 things, "what new or different facts and circumstances are claimed to exist which did not 20 exist, or were not shown, upon such prior application." Id. 21 "Reconsideration is an 'extraordinary remedy, to be used sparingly in the interests 22 of finality and conservation of judicial resources.'" Sherman, 997 F. Supp. 2d at 1139 23 (quoting Kona Enters., Inc. v. Estate of Bishop, 229 F.3d 877, 890 (9th Cir.2000)). "A 24 motion for reconsideration is not an opportunity to renew arguments considered and 25 rejected by the court, nor is it an opportunity for a party to re-argue a motion because it is 26 dissatisfied with the original outcome." Id. (quoting FTC v. Neovi, Inc., 2009 WL 56130, 27 1 at *2 (S.D.

Cal. Jan. 7, 2009)). Ultimately, whether to grant or deny a motion for 2 reconsideration lies within the Court's sound discretion. Navajo Nation v. Confederated 3 Tribes and Bands of the Yakama Indian Nation, 331 F.3d 1041, 1046 (9th Cir. 2003). 4 DISCUSSION 5 Defendant's motion for reconsideration contends that the Court committed a clear 6 error in declining to find that Plaintiffs' claims are preempted by the Federal Food, Drug, 7 and Cosmetic Act (FDCA).

Defendant does not assert any intervening change in law, new 8 evidence, or changed circumstances. Instead, Defendant largely reiterates the same 9 "impossibility" arguments it made previously regarding an alleged conflict between state 10 and federal law. ECF No. 57-1, at 19-22; ECF No. 84-1, 9-10. Distilled to its essence, 11 Defendant contends that "a disclosure stating that kratom is 'addictive' constitutes an 12 impermissible disease claim" under the FDCA.

ECF No. 84-1, at 5. The Court notes that 13 arguments that have already been considered and rejected by the Court are not an 14 appropriate basis for a motion for reconsideration. See Sherman, 997 F. Supp. 2d at 1139. 15 However, the Court will consider Defendant's arguments, as they invite a more nuanced 16 assessment of the statutory language than the Court provided in its prior opinion.

17 In previously denying Defendant's motion to dismiss on the issue of preemption, the 18 Court concluded that an addiction disclosure is not a disease claim as defined by federal 19 statute, ECF No. 77, at 13—a determination Defendant now challenges as clear error, ECF 20 No. 84-1, at 2. Specifically, Defendant argues that, in finding that an addiction disclosure 21 is not a disease claim, the Court failed to consider the relevant statutory and regulatory 22 authority.2 Id. at 5.

Having revisited the relevant authority, the Court finds that there was 23 24 25 2 To "aid the Court's reconsideration," Defendant has made an unopposed request for judicial notice of documents in the public domain, all issued by government entities or 26 well-known and respected health organizations. ECF No. 84-1, at 4.

The documents 27 discuss the differentiation of structure/function and disease claims, and the classification 1 no error in determining that an addiction disclosure is not a disease claim as contemplated 2 by the FDCA. 3 I. Federal Preemption 4 A presumption against preemption exists because the "historic police powers of the 5 States were not to be superseded by [a] Federal Act unless that was the clear and manifest 6 purpose of Congress." United States v. Locke, 529 U.S. 89, 108 (2000) (quoting Rice v. 7 Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947)).

In the area of proper marketing and 8 labeling of food products, the presumption against preemption is strong. Gustavson v. 9 Wrigley Sales Co., 961 F. Supp. 2d 1100, 1117 (N.D. Cal. 2013); see also Dachauer v. 10 NBTY, Inc., 913 F.3d 844, 847 (9th Cir. 2019) ("[T]he FDCA classifies dietary supplements 11 as food[.]"). 12 The U.S. Supreme Court has also recognized that "[i]mpossibility pre-emption is a 13 demanding defense," Wyeth v. Levine, 555 U.S. 555, 573 (2009), and has identified two 14 cornerstones of pre-emption jurisprudence: 15 First, "the purpose of Congress is the ultimate touchstone in every pre-emption case." Medtronic, Inc. v. Lohr, 518 U.S. 470, 16 485 (1996) (internal quotation marks omitted); see Retail Clerks 17 v. Schermerhorn, 375 U.S. 96, 103 (1963).

Second, "[i]n all pre- 18 19 of addiction is a disease. Id. Federal Rule of Evidence 201(b) allows courts to take judicial 20 notice of matters that are either "generally within the trial court's territorial jurisdiction" or 21 "can be accurately and readily determined from sources whose accuracy cannot be questioned." Fed. R. Evid. 201(b). 22 "Courts may take judicial notice of publications introduced to 'indicate what was in the 23 public realm at the time, not whether the content of those articles were in fact true.'" Von 24 Saher v. Norton Simon Museum of Art at Pasadena, 592 F.3d 954, 960 (9th Cir.

2010). Moreover, courts “may take judicial notice of public documents, records, and reports of 25 government bodies.” Bargetto v. Walgreen Co., No. 22-cv-02639-TLT, 2022 WL 26 18539360, at *2 (N.D. Cal. Dec. 19, 2022) (citing Barron v. Reich, 13 F.3d 1370, 1377 (9th Cir. 1994)).

Accordingly, the Court takes judicial notice of Defendant’s Exhibits 1-4. 27 1 emption cases, and particularly in those in which Congress has ‘legislated... in a field which the States have traditionally 2 occupied,’... we ‘start with the assumption that the historic 3 police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of 4 Congress.’” Lohr, 518 U.S., at 485 (quoting Rice v. Santa Fe 5 Elevator Corp., 331 U.S. 218, 230 (1947)).

6 Id. at 565 (alterations in original). 7 In Wyeth, the plaintiff contended that a drug manufacturer had breached a state tort- 8 law duty to provide an adequate warning label. 555 U.S., at 559–560. The Court held that 9 the lawsuit was not preempted because it was possible for Wyeth, a brand-name drug 10 manufacturer, to comply with both state and federal law.

Id., at 572–573. Here, the question 11 posed is whether it is possible for Defendant to comply with a state law duty to warn and 12 federal law. Focusing on the purpose of the FDCA, the answer is yes. 13 A. The Purpose of the FDCA. 14 The FDCA governs what claims manufacturers of dietary supplements may make 15 about their products. 21 U.S.C. § 343(r)(6).

As the Ninth Circuit has explained: 16 The FDA has limited authority under the Federal Food, Drug, and Cosmetic Act (FDCA) to regulate dietary supplements, 17 which include vitamin, botanical, enzyme, and amino acid 18 products. Unlike with drugs, the FDA does not pre-approve product labels for dietary supplements. It, however, requires that 19 the labels be truthful and not misleading, 21 U.S.C. § 20 343(r)(6)(B), and authorizes several categories of statements that can be made on the product if certain requirements are met.

21 Greenberg v. Target Corp., 985 F.3d 650, 654 (9th Cir. 2021). 22 Meanwhile, “States have always possessed a legitimate interest in ‘the protection of 23 (their) people against fraud and deception in the sale of food products’ at retail markets 24 within their borders.” Florida Lime & Avocado Growers v. Paul, 373 U.S. 132, 144 (1963) 25 (alterations in original) (quoting Plumley v. Com. of Mass., 155 U.S. 461, 472 (1894)).

As 26 a result, the “presumption against preemption is heightened” in the areas of state regulation 27 1 concerning issues of health and safety. Chacanaca v. Quaker Oats Co., 14, 752 F. Supp. 2 2d 1111, 1118 (N.D. Cal. 2010) (citing N.Y. State Conference of Blue Cross & Blue Shield 3 Plans v. Travelers Ins. Co., 514 U.S. 645, 655 (1995)); see also Hillsborough County v. 4 Automated Med.

Labs., Inc., 471 U.S. 707, 718 (1985) (“Given the presumption that state 5 and local regulation related to matters of health and safety can normally coexist with federal 6 regulations, we will seldom infer, solely from the comprehensiveness of federal 7 regulations, an intent to pre-empt in

its entirety a field related to health and safety."). 8 These cases stand for the proposition that "supplement makers can be sued for false 9 claims, and no federal preemption exists under the FDCA either by statute or by 10 implication, since the FDA does not occupy the field and its controls are unaffected by 11 private false advertising suits against supplement makers." Kroessler v. CVS Health Corp., 12 977 F.3d 803, 814 (9th Cir.

2020) (quoting 1 James T. O'Reilly, Food and Drug 13 Administration § 10:112 (Katharine A. Van Tassel, 4th ed. 2020)). 14 Here, the Court concludes that Congress' purpose in regulating the labeling of 15 supplements was not to shield manufacturers from liability for failing to warn of the 16 addictive nature of a supplement, and there is no indication that the FDA sought to preempt 17 state laws that require such warning labels.3 Thus, Defendant can comply with both state 18 and federal law.

19 II. Disease Claims under the Code of Federal Regulations 20 21 22 3 "[T]hrough many amendments to the FDCA and to FDA regulations, it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the 23 content of its label at all times." Wyeth, 555 U.S. at 570-571; see also 21 CFR § 201.80(e) 24 (requiring a manufacturer to revise its label "to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug").

While Wyeth 25 involved a drug as opposed to a supplement, it recognizes that it is the manufacturer, not 26 the FDA, that is responsible for warning the consumer when it learns of serious hazards associated with a product regulated by the FDCA. 27 1 The Code of Federal Regulations offers additional interpretive instruction as to what 2 claims a supplement manufacturer can make.

21 C.F.R. § 101.93(g). Manufacturers of 3 dietary supplements are allowed, subject to certain requirements, to make 4 "structure/function" claims about their supplements without prior FDA approval. See 21 5 C.F.R. § 101.93(f); 21 U.S.C. § 343(r)(6); Dachauer v. NBTY, Inc., 913 F.3d 844, 846 (9th 6 Cir. 2019). These are claims that "describe[] the role of a nutrient or dietary ingredient 7 intended to affect the structure or function in humans" or "characterize[] the documented 8 mechanism by which a nutrient or dietary ingredient acts to maintain such structure or 9 function." See 21 U.S.C. § 343(r)(6)(A); Dachauer, 913 F.3d at 846.

However, a 10 manufacturer may not make a "disease claim," which "claims to diagnose, mitigate, treat, 11 cure, or prevent disease," either explicitly or implicitly. See 21 C.F.R. § 101.93(g); 21 12 U.S.C. § 343(r)(6); Dachauer, 912 F.3d at 846. 13 Per the FDA, these regulations arose from the concern that "unproven disease claims 14... may encourage consumers to self-treat for a serious disease without a medical diagnosis 15 or treatment"; "substitute potentially ineffective products for proven ones"; or "feel 16 sufficiently protected from developing serious disease... that they delay or forego regular 17 screening." Regulations on Statements Made for

Dietary Supplements Concerning the 18 Effect of the Product on the Structure or Function of the Body, 65 Fed.

Reg. 1000, 1001 19 (Jan. 6, 2000). Thus, policymakers developed rules specifically targeted towards 20 “determining when a statement about a dietary supplement is a claim to diagnose, cure, 21 mitigate, treat, or prevent disease (‘disease claim’), and thus requires prior approval.” Id. 22 at 1002.

The rules reflect “an interest both in preventing direct harm from such products— 23 i.e. protecting the public from adverse events that such products might cause—and 24 preventing the indirect harm to health that is caused when an ill person foregoes medical 25 care in favor of ineffective self-treatment.” Id. at 1039. 26 A. An Addiction Disclosure Is Not a Disease Claim.

27 1 Federal law provides that a manufacturer may not make a “disease claim,” which 2 “claims to diagnose, mitigate, treat, cure, or prevent disease,” either explicitly or implicitly, 3 without prior FDA approval. See 21 C.F.R. § 101.93(g); 21 U.S.C. § 343(r)(6). Defendant 4 begins its preferred reading of 21 U.S.C. § 343(r)(6) by making the unremarkable 5 observation that addiction is a disease.4 Defendant then interprets “disease claim” as 6 including “any statement on a label that so much as refers to a disease.” ECF No. 84-1, at 7 8.

Under Defendant’s interpretation, “effect” within the statute “encompasses any effect, 8 whether positive or negative, direct or indirect.” ECF No. 94, at 3. Thus, Defendant asserts 9 that any statements that expressly or impliedly refer to the disease of addiction “are disease 10 claims, regardless of whether they purport to diagnose, mitigate, treat, cure, or prevent the 11 disease,” and chastises Plaintiffs’ effort to “collapse the definition of ‘disease claim’ into 12 only those claims that relate to diagnosis, mitigation, treatment, cure, or prevention.” Id. at 13 4.

Defendant’s cramped reading of “disease claim” finds no support in law. 14 Indeed, Defendant’s interpretation ignores well-established canons of statutory 15 construction and is inconsistent with the plain language and purpose of the statute. Words 16 within statutes are not to be read “in a vacuum.” Gundy v. United States, 588 U.S. 128, 141 17 (2019) (quoting Davis v. Michigan Dept. of Treasury, 489 U.S. 803, 809 (1989)).

Rather, 18 “[i]t is a fundamental canon of statutory construction that the words of a statute must be 19 read in their context and with a view to their place in the overall statutory scheme.” Id. 20 (quoting National Assn. of Home Builders v. Defenders of Wildlife, 551 U.S. 644, 666 21 22 23 24 4 In its motion, Defendant argues at length that addiction is a disease as defined by the FDA.

ECF No. 84-1, at 6-7. Indeed, three of the four documents for which Defendant 25 requests judicial notice refer to the matter of addiction as a disease. ECF No. 84-1, at 4. 26 Neither Plaintiffs nor the Court disagree with the proposition that addiction is a disease, nor does it affect the Court’s interpretation of the applicable statute. 27 1 (2007)).

In doing so, courts seek to interpret statutes in a manner that avoids “absurd 2 results.” Tovar v. Sessions, 882 F.3d 895, 904 (9th Cir. 2018). 3 Succinctly stated, a warning of kratom’s addictiveness is not a “claim[] to diagnose, 4 mitigate, treat, cure, or prevent disease.” 21 C.F.R. § 101.93(g)(2). These five associated 5 words all involve protecting one’s health and are further given this related meaning by the 6 fact that they are grouped together.

Third Nat. Bank in Nashville v. Impac Ltd., Inc., 432 7 U.S. 312, 322 (1977) (“It is a familiar principle of statutory construction that words 8 grouped in a list should be given related meaning.”). Each of these terms relates to products 9 that are purchased to safeguard one’s health by preventing disease or diagnosing it so that 10 a disease can be mitigated, treated, or cured.

Conversely, a statement that a supplement is 11 addictive does not describe a product that improves one’s health. Instead, it informs the 12 consumer that kratom may be destructive to one’s health. It does not claim to “diagnose, 13 mitigate, treat, cure or prevent disease.” 21 C.F.R. § 101.93(g)(2). 14 Defendant further argues that the definition of disease claim includes any statement 15 that a supplement “has an effect on a specific disease or class of diseases.” ECF No. 94, at 16 3 (quoting 21 C.F.R. § 101.93(g)(2)(i)).

However, Defendant fails to take into account that 17 the clause, “has an effect on a specific disease,” operates exclusively to provide insight into 18 when “a statement claims to diagnose, mitigate, treat, cure, or prevent disease.” 21 C.F.R. 19 § 101.93(g).

Thus, while the Defendant interprets “effect” in § 101.93(g) as encompassing 20 any effect on health, whether positive or negative, Defendant ignores the full operative 21 term used, i.e. “effect on” a disease. The term is coupled to an effect on the disease, and, 22 more specifically, a health improving effect, not a destructive one. A statement which 23 consists of a warning of addictiveness does not purport to have an “effect on” a specific 24 disease as contemplated by the statute.

Rather, it warns that kratom can lead to the disease 25 of addiction. Thus, Defendant’s insistence on construing “effect” to include all potential 26 negative effects considers the word in a vacuum and leads to absurd results. 27 1 Further, despite Defendant’s criticism of Plaintiffs’ efforts to “limit” the word 2 “effect” to only beneficial effects, it is the statute itself that places the word within the 3 confines of such effects that might imply disease diagnosis, mitigation, treatment, cure, or 4 prevention.

The plain language of the statute repeatedly indicates that disease claims are 5 those which imply that a product might “diagnose, mitigate, treat, cure, or prevent disease.” 6 21 C.F.R. § 101.93(g)(2). 7 The Court’s reading of the statutory language is strengthened when considering the 8 statute’s stated purpose.

The regulation of disease claims sought to limit unapproved 9 statements that might encourage consumers to “self-treat,” “substitute potentially 10 ineffective products for effective ones,” or “feel sufficiently protected from developing 11 serious disease” that they forego medical care. Regulations on Statements Made for Dietary 12 Supplements Concerning the Effect of the Product on the Structure or Function of the 13 Body, 65 Fed.

Reg. 1000, 1001 (Jan. 6, 2000). A warning that a dietary supplement might 14 cause a particular harm—such as addiction—is not the type of claim that might encourage 15 an individual to self-treat or forego care. Thus, an addiction disclosure is not the type of 16 claim the statute sought to limit. 17 B. Caselaw Within the Ninth Circuit 18 Defendant’s argument that Ninth Circuit precedent compels the Court to find that an 19 addiction disclosure is a disease claim is unpersuasive and contradicted by prior holdings.

20 The Ninth Circuit has expressly rejected Defendant’s interpretation, observing that “a 21 disease claim refers to a statement that the product itself can cure or treat a disease.” 22 Greenberg v. Target Corp., 985 F.3d 650, 654 (9th Cir. 2021).

Here, an addiction 23 disclosure is not a statement that a product (i.e. kratom) can cure or treat disease. 24 Defendant relies on Dachauer v. NBTY, 913 F.3d 844 (9th Cir. 2019), and Kroessler 25 v. CVS Health Corp, 977 F.3d 803 (9th Cir. 2020), for the proposition that “a statement 26 that avoids reference to disease... may be a permissible structure/function claim, but a 27 1 statement that invokes a disease... is a disease claim.” ECF No. 94, at 5.

Neither case 2 supports this misguided proposition. In both Kroessler and Dachauer, the Ninth Circuit 3 considered claims espousing the positive effects of a supplement—the types of claims 4 contemplated by policymakers in drafting the legislation at issue.

In Kroessler, the court 5 considered CVS’s claims that certain supplements “maintain[ed] or support[ed] joint 6 health.” 977 F.3d at 806. Similarly, in Dachauer, the court considered claims that vitamin 7 E supplements “support cardiovascular health,” and promote “immune function, immune 8 health, heart health, and circulatory health.” 913 F.3d at 846 (internal quotation marks 9 omitted).

Both cases defined a disease claim as one that “claims to diagnose, mitigate, treat, 10 cure, or prevent disease.” Kroessler, 977 F.3d, at 809; Dachauer, 913 F.3d at 846. Indeed, 11 the Kroessler court emphasized that disease claims included those which “implie[d] disease 12 prevention or treatment.” 977 F.3d at 815. Neither case considered whether the definition 13 of a disease claim might encompass a warning, such as an addiction disclosure.

Thus, 14 Dachauer and Kroessler do not stand for the conclusion presented by Defendants: that a 15 statement that warns of a potential disease is a disease claim. Rather, they support the 16

finding that a disclosure of kratom's addictiveness is not a disease claim under the FDCA 17 because it does not explicitly or impliedly claim that kratom prevents or treats disease.

18 III. Structure/Function Claims. 19 Lastly, Defendant takes particular issue with the fact that the Court, after 20 determining that an addiction disclosure is not a disease claim, chose to analyze such a 21 disclosure as a structure/function claim. ECF No. 84-1, at 2 ("[T]he Court improperly and 22 without any cited legal support found that an addiction disclosure is a structure/function 23 claim rather than a disease claim.").

As seen above, a warning of addictiveness is not a 24 disease claim, and the FDCA, on this basis, does not make it impossible for Defendant to 25 comply with both federal and state law. 26 27 1 Nor is it impossible for Defendant to comply with both the FDCA and state law 2 when analyzing an addiction disclosure as a structure/function claim. "The FDCA's 3 preemption provision covers structure/function claims because its requirements appear in 4 [§] 343(r)(6), which falls under the preemption provision's umbrella." Greenberg, 985 F.3d 5 at 655.

Thus, the FDCA preempts claims to the extent that a plaintiff alleges that 6 structure/function claims are false or misleading because a supplement does not prevent a 7 particular disease. Dachauer, 913 F.3d at 848 (citing 21 U.S.C. § 343-1(a)(5)); see also id. 8 at 848 ("[W]e hold that § 343-1(a)(5) [of the FDCA] preempts state-law requirements for 9 claims about dietary supplements that differ from the FDCA's requirements.").

However, 10 the FDCA also requires that structure/function claims on supplement labels "be truthful 11 and not misleading[.]" Id. (citing 21 U.S.C. § 343(r)(6)(B)). 12 Here, the operative complaint alleges that advertisements and commentary about 13 kratom are misleading by failing to warn the consumer of its addictive qualities or include 14 an addiction disclosure on product labels.

ECF No. 50, ¶ 41. A supplement label is 15 misleading "'if it fails to reveal facts' that are '[m]aterial with respect to consequences 16 which may result from use of the article' under normal conditions of use or the conditions 17 of use that the label prescribes." Dachauer, 913 F.3d at 849 (alterations in original) 18 (quoting 21 C.F.R. § 1.21(a)(2)).

Thus, if use of a supplement causes an increased risk of 19 disease—a material fact "with respect to consequences which may result from use of the 20 article"—the FDCA would deem it misleading not to reveal that fact on the label. Id.; see 21 also Kaufman v. CVS Caremark Corp., 836 F.3d 88, 96 (1st Cir. 2016) (noting that a 22 structure/function claim would be misleading if it "fail[ed] to disclose the harmful aspects 23 of the nutrient's structure/function").

24 Likewise, a label that omitted such a fact would be misleading under California and 25 New York law. See, e.g., Cal. Bus. & Prof. Code § 17200 (prohibiting "unfair, deceptive, 26 untrue or misleading advertising"); N.Y. Gen. Bus. Law § 349 (prohibiting "[d]eceptive 27 1 acts or

practices in the conduct of any business"). Indeed, Defendant's failure to include 2 an addiction disclosure in its labeling has "a capacity, likelihood or tendency to deceive or 3 confuse the public," because a reasonable consumer would not expect to suffer an increased 4 risk of disease from taking the product.

Williams v. Gerber Prods. Co., 552 F.3d 934, 938 5 (9th Cir. 2008) (quoting Kasky v. Nike, Inc. 27 Cal.4th 939, 950 (2002)). Because the 6 FDCA and state laws have the same labeling requirement with respect to failing to disclose 7 an increased risk of disease or death, the FDCA does not preempt this particular aspect of 8 Plaintiff's case. See Dachauer, 913 F.3d at 849 ("[T]he FDCA does not preempt Plaintiff's 9 claim that Defendants' structure/function claim about immune health is misleading because 10 their supplements increase the risk of all-cause mortality.").

11 Defendant's argument that it cannot comply with both state and federal law is 12 without merit. Accordingly, federal law does not preempt Plaintiffs' state law claims. After 13 considering the relevant statutory and regulatory authority alongside the applicable 14 caselaw, the Court is not "left with the definite and firm conviction that a mistake has been 15 committed." Smith v. Clark County School Dist., 727 F.3d 950, 955 (9th 16 Cir.2013) (quoting United States v. U.S. Gypsum Co., 333 U.S. 364, 395 (1948)).

Thus, the 17 Court cannot conclude that it committed clear error in determining that an addiction 18 disclosure is not a disease claim as contemplated by the FDCA and defined by federal 19 statute. 20 Defendant has not shown that it is entitled to the "extraordinary remedy" of 21 reconsideration. Sherman v. Yahoo! Inc., 997 F. Supp. 2d 1129, 1139 (S.D. Cal. 2014).

The 22 Court therefore exercises its discretion to DENY Defendant's motion. See Navajo Nation 23 v. Confederated Tribes and Bands of the Yakama Indian Nation, 331 F.3d 1041, 1046 (9th 24 Cir. 2003). 25 CONCLUSION 26 27 1 For the reasons set forth above, the Defendant's motion for reconsideration is 2 || DENIED. 3 IT IS SO ORDERED. 4 5 Dated: October 16, 2025 Casto 0h 6 Hon. Gonzalo P. Curiel 7 United States District Judge 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 16 28 3:24-cv-0031 1-GPC-MSB

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