FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

JAMES KROESSLER, individually, and on behalf of all others similarly situated, *Plaintiff-Appellant*, v. CVS HEALTH CORPORATION, *Defendant-Appellee.*	No. 19-55671 D.C. No. 3:19-cv-00277-CAB-JLB OPINION

Appeal from the United States District Court
for the Southern District of California
Cathy Ann Bencivengo, District Judge, Presiding

Argued and Submitted July 8, 2020
Pasadena, California

Filed October 9, 2020

Before: Richard A. Paez and Bridget S. Bade, Circuit Judges, and Eric F. Melgren,[*] District Judge.

Opinion by Judge Melgren

[*] The Honorable Eric F. Melgren, United States District Judge for the District of Kansas, sitting by designation.

SUMMARY[**]

Federal Food, Drug, and Cosmetic Act / Preemption

The panel reversed the district court's dismissal of a putative class action brought against CVS Corporation, and remanded for further proceedings. The district court dismissed based on Federal Food, Drug, and Cosmetic Act ("FDCA") preemption of California state law claims

Plaintiff, a California consumer representing a putative class, sued CVS Corporation under California law, alleging that CVS glucosamine-based supplements did not provide the advertised benefits. Plaintiff alleged that CVS violated California Unfair Competition Law and Consumer Legal Remedies Act, and breach of express warranty through the use of false and misleading labels on the supplements. So long as California laws impose requirements identical to the FDCA, the FDCA will not preempt plaintiff's state law causes of action.

The FDCA requires manufacturers of dietary supplements to ensure that the labels on their products are not "false or misleading in any particular." 21 U.S.C. § 343(a). The FDCA distinguishes between "disease claims" and "structure/function claims" that manufacturers make about their products. Plaintiff alleged that CVS lacked substantiation for its structure/function claims.

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

The panel held that the district court erred in holding that CVS's glucosamine labels presented proper structure/function claims under the FDCA, and in concluding that plaintiff's state law causes of action were preempted. Specifically, first, the panel held that the district court erred in applying *Dachauer v. NBTY, Inc.*, 913 F.3d 844 (9th Cir. 2019), to the present case. Because plaintiff "matched" his evidence with CVS's structure/function claims, and he did not otherwise allege effects on the risk of all-cause mortality, his case presented a scenario that *Dachauer* did not explicitly address. Second, this case was distinguished from *Dachauer* by its procedural posture. Third, the district court erred by greatly expanding the present state of federal preemption jurisprudence under the FDCA, contrary to public policy.

The panel held that the district court erred in holding that any amendment by plaintiff attempting to state an "implied disease" claim would be futile. The panel held that the FDCA allows courts examining implied disease claims to consider extra-label evidence. The district court should have given plaintiff the chance to present such evidence and allegations. The panel further held that the district court correctly concluded that CVS's glucosamine-based supplements did not present implied disease claims on the face of the label alone.

COUNSEL

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Jean-Claude André (argued) and Adriane Peralta, Sidley Austin LLP, Los Angeles, California; Amy P. Lally, Sidley Austin LLP, Los Angeles, California; for Defendant-Appellee.

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OPINION

MELGREN, District Judge:

Appellant James Kroessler purchased one of CVS's glucosamine-based supplements in 2017, believing it would provide the advertised joint health benefits. He sued CVS under California law, alleging that the supplement he purchased, and five additional CVS glucosamine-based supplements, did not provide the advertised benefits. He sought to certify a class of similarly situated consumers who purchased CVS's glucosamine-based supplements during the relevant limitations period. The district court dismissed the case without leave to amend, holding that federal law preempted Kroessler's California claims. For the following reasons, we reverse and remand for further proceedings.

BACKGROUND

Kroessler is a California consumer who represents a putative class that asserts claims against CVS Health Corporation ("CVS"), alleging violations of the California Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code §§ 17200–17210, and the California Consumer Legal Remedies Act ("CLRA"), Cal. Civ. Code §§ 1750–1759, as well as a common-law breach of express warranty claim.

CVS sells a line of glucosamine-based supplements. Kroessler alleges that CVS markets these supplements to consumers using express and implied messages. The express marketing message—which CVS concedes—states that CVS's glucosamine-based supplements maintain or support joint health. Kroessler alleges that the implied marketing message—which CVS contests—states that the supplements ameliorate the cardinal symptoms of arthritis, namely joint pain, discomfort, stiffness, and lack of mobility or flexibility. Kroessler alleges that the supplements do not provide the advertised benefits.

The complaint identifies six CVS glucosamine-based supplements: glucosamine maximum strength tablets, glucosamine MSM caplets, glucosamine chondroitin with MSM tablets, glucosamine chondroitin with vitamin D caplets, and glucosamine chondroitin, available in both tablets and capsules. In marketing these supplements, CVS makes various claims on the products' labels. One label states that the supplement "[s]upports flexibility & range of motion," "help[s] support and maintain the structure of joints," and "work[s] to support joint comfort while helping to promote joint mobility." The message includes the disclaimer that it is a "DIETARY SUPPLEMENT" that "is not intended to diagnose, treat, cure, or prevent any disease" and that "[i]ndividual results may vary." Another states that the supplement "[n]ourishes cartilage and promotes comfortable joint movement" and "[s]upports cartilage health & joint comfort."

Kroessler alleges that glucosamine neither supports healthy joint function nor ameliorates joint pain, discomfort, stiffness, or other symptoms of joint disease. He claims that CVS's glucosamine-based supplements "[have] been extensively studied in large, well-conducted and published

studies involving persons with and without diagnosed arthritis and [have] been proven to be ineffective at supporting or benefiting joint health, including by positively impacting the signs and symptoms of arthritis."[1] His complaint summarizes four clinical trials conducted on persons without diagnosed arthritis, or on a mix of subjects with and without osteoarthritis, that allegedly support those contentions. He also cites numerous articles and other clinical trials concluding that glucosamine is no more effective than a placebo in preventing osteoarthritis. Kroessler alleges these studies also show that glucosamine is no more effective than a placebo at reducing joint pain, relieving joint stiffness, improving joint function, impacting joint swelling or space width loss, rebuilding joint cartilage, or relieving the symptoms of osteoarthritis or slowing their progression.

CVS moved to dismiss the complaint under Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6), arguing in pertinent part that federal law preempted Kroessler's state-law causes of action. The district court granted CVS's motion to dismiss and denied Kroessler leave to amend.

JURISDICTION AND STANDARDS OF REVIEW

The district court entered final judgment on May 16, 2019, after granting CVS's motion to dismiss Kroessler's claims. Kroessler timely filed a notice of appeal on June 12, 2019, under the Class Action Fairness Act.[2] 28 U.S.C.

[1] These studies are not part of the record. Kroessler merely referenced them in his complaint. Accordingly, the district court did not consider the contents of the studies.

[2] Kroessler appeals only the dismissal of his claims pertaining to the label of the product he purchased. The district court resolved the motion

§ 1332(d)(2). Accordingly, this Court has jurisdiction to review the final judgment. 28 U.S.C. § 1291.

We review de novo a district court's dismissal of a case under Rule 12(b)(6) for failure to state a claim. *Marder v. Lopez*, 450 F.3d 445, 448 (9th Cir. 2006). Likewise, we review de novo a district court's determination that a federal statute preempts state law claims. *Niehaus v. Greyhound Lines, Inc.*, 173 F.3d 1207, 1211 (9th Cir. 1999). On review, we accept the plaintiff's allegations as true and construe them in the light most favorable to the plaintiff. *Gompper v. VISX, Inc.*, 298 F.3d 893, 895 (9th Cir. 2002). A district court properly dismisses a complaint if the complaint fails to "plead 'enough facts to state a claim to relief that is plausible on its face.'" *Weber v. Dep't of Veterans Affairs*, 521 F.3d 1061, 1065 (9th Cir. 2008) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

Ordinarily, we review a district court's decision to deny a party leave to amend its complaint for an abuse of discretion. *Cervantes v. Countrywide Home Loans, Inc.*, 656 F.3d 1034, 1041 (9th Cir. 2011). However, if a district court denies leave to amend based on the futility of the amendment or inability to allege a valid cause of action, we review the decision de novo. *See Leadsinger, Inc. v. BMG Music Publ'g*, 512 F.3d 522, 532 (9th Cir. 2008).

DISCUSSION

We address two issues in this appeal. First, whether the district court erred in holding that the Federal Food, Drug,

to dismiss solely on preemption grounds without addressing CVS's other arguments, including that Kroessler lacked standing to challenge the claims made on the labels on the five products that he did not purchase. We limit our review accordingly.

and Cosmetic Act ("FDCA") preempts Kroessler's California state-law causes of action. Second, whether the district court erred in dismissing Kroessler's complaint without granting him leave to amend.

I. FDCA Preemption

Congress enacted the FDCA to "promote the public health" by ensuring that "foods are safe, wholesome, sanitary, and properly labeled." 21 U.S.C. § 393(b)(2)(A). In 1990, Congress amended the FDCA with the Nutrition Labeling and Education Act ("NLEA"), 21 U.S.C. § 343 *et seq*., and established new requirements governing the labeling of food, including dietary supplements. In 1994, Congress further amended the FDCA with the Dietary Supplement Health and Education Act ("DSHEA"), Pub. L. No. 103-417, 108 Stat. 4325.[3] The NLEA and DSHEA together established a new category of food products—specifically, dietary supplements—that have unique safety, labeling, manufacturing, and other related standards.

All proceedings "for the enforcement, or to restrain violations, of" the FDCA must "be by and in the name of the United States." 21 U.S.C. § 337(a). Private plaintiffs may not bring actions to enforce violations of the FDCA. *See POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 109 (2014) (citing 21 U.S.C. § 337(a)). Instead, private plaintiffs may bring analogous state law claims as long as the FDCA does not preempt those claims. *See Farm Raised Salmon Cases*, 175 P.3d 1170, 1177 (Cal. 2008).

[3] We refer to the FDCA, NLEA, and DSHEA collectively as "the FDCA."

Federal preemption can be either express or implied. *See Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 152–53 (1982). Express preemption exists when a statute explicitly addresses preemption. *Chicanos Por La Causa, Inc. v. Napolitano*, 558 F.3d 856, 863 (9th Cir. 2009). "When a federal statute contains an explicit preemption provision, we are to identify the domain expressly pre-empted by that language." *Id.* (internal quotations omitted). The FDCA expressly preempts any state law that establishes "any requirement respecting any claim of the type described in section 343(r)(1) of this title made in the label or labeling of food that is not identical to the requirement of section 343(r) of this title." 21 U.S.C. § 343-1(a)(5). 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]." 21 C.F.R. § 100.1(c)(4). Furthermore, "§ 343-1(a)(5) preempts state-law requirements for claims about dietary supplements that differ from the FDCA's requirements." *Dachauer v. NBTY, Inc.*, 913 F.3d 844, 848 (9th Cir. 2019). Therefore, private plaintiffs may bring only actions to enforce violations of "*state laws* imposing requirements identical to those contained in the FDCA." *Farm Raised Salmon Cases*, 175 P.3d at 1177 (citing 21 U.S.C. §§ 337, 343-1).

A.

In the present case, Kroessler brings claims for violations of the California UCL and CLRA, as well as breach of express warranty. The UCL prohibits unfair competition, defined as any "unlawful, unfair or fraudulent business act

or practice," as well as any "unfair, deceptive, untrue or misleading advertising." Cal. Bus. & Prof. Code § 17200. Similarly, the CLRA declares unlawful various anti-competitive, unfair, or deceptive acts, including misrepresenting that goods have characteristics, uses, or benefits that they do not possess. Cal. Civ. Code § 1770(a). Kroessler alleges that CVS violated California law by selling glucosamine-based supplements with false and misleading labels. So long as California laws impose requirements identical to the FDCA, the FDCA will not preempt Kroessler's state law causes of action. Accordingly, it is necessary to consider the FDCA's requirements.

B.

The FDCA requires manufacturers of dietary supplements to ensure that the labels on their products are not "false or misleading in any particular." 21 U.S.C. § 343(a). The Food and Drug Administration ("FDA")—the primary enforcer of the FDCA—specifies that a supplement's label is misleading if, among other things, it

> fails to reveal facts that are: (1) Material in light of other representations made or suggested by statement, word, design, device or any combination thereof; or (2) Material with respect to consequences which may result from use of the article under: (i) The conditions prescribed in such labeling or (ii) such conditions of use as are customary or usual.

21 C.F.R. § 1.21(a). To these ends, the FDCA distinguishes between "disease claims" and "structure/function claims" that manufacturers make about their products, applying different regulatory standards to each. A structure/function

claim, among other things, "describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans" or "characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function," but "may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases." 21 U.S.C. § 343(r)(6)(A), (C). A disease claim, conversely, "claims to diagnose, mitigate, treat, cure, or prevent disease," either explicitly or implicitly (such as by claiming that a product treats a disease's "characteristic signs or symptoms"). 21 C.F.R. § 101.93(g)(2)(ii); *see also* 21 U.S.C. § 343(r)(6).

Structure/function claims must meet three requirements: (1) the manufacturer has substantiation that the statement is truthful and not misleading; (2) the statement contains a prominent disclaimer that the FDA has not evaluated the statement and that the product "is not intended to diagnose, treat, cure, or prevent any disease"; and (3) the statement itself does not "claim to diagnose, mitigate, treat, cure, or prevent" disease. 21 U.S.C. § 343(r)(6)(C). A dietary supplement manufacturer making only structure/function claims regarding its supplement must notify the Office of Nutritional Products, Labeling, and Dietary Supplements in the FDA. 21 C.F.R. § 101.93(a). Notably, as long as a dietary supplement manufacturer meets these requirements, it may assert structure/function claims without pre-approval from a federal agency. *See id.*

The FDA has published regulations defining acceptable structure/function claims. *See* Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 65 Fed. Reg. 1000 (Jan. 6, 2000) (codified at 21 C.F.R. pt. 101). The guidance recognizes that structure/function claims may use

general terms such as "strengthen," "improve," and "protect," as long as the claims "do not suggest disease prevention or treatment." *Id.* at 1028. For example, the FDA states that " 'joint pain' is characteristic of arthritis . . . [but] [t]he claim 'helps support cartilage and joint function,' on the other hand, would be a permissible structure/function claim, because it relates to maintaining normal function rather than treating joint pain." *Id.* at 1016–17. The guidance further explains that manufacturers of supplements can substantiate structure/function claims with evidence of an effect on a small aspect of the related structure/function, rather than with evidence of an effect on the main disease that consumers might associate with a given bodily structure or function. *See id.* at 1012 ("For example, to substantiate the claim 'supports mood,' it is not necessary to study the effects of a substance on clinical depression. Instead, it is quite possible to assess the effects of a substance on mood changes that do not constitute clinical depression."). As the main enforcer of the FDCA, the FDA would look to these guidelines and requirements when pursuing actions against supplement manufacturers.[4] Because private plaintiffs cannot enforce these provisions, plaintiffs may only seek to enforce those standards through state law causes of action when those state laws hold supplement manufacturers to identical standards.

To briefly refocus on this appeal: Kroessler sues CVS for making false and misleading representations on its glucosamine-based supplement labels, alleging that CVS lacks substantiation for its structure/function claims. He can do so as long as his California causes of action seek to hold

[4] *See* 21 U.S.C. § 393.

CVS to standards identical to the FDCA's and the FDA's implementing regulations and guidelines.

C.

Although the FDCA requires manufacturers to have substantiation for their structure/function claims, California law prohibits private plaintiffs from demanding that advertisers substantiate their claims. *Nat'l Council Against Health Fraud, Inc. v. King Bio Pharm., Inc.*, 133 Cal. Rptr. 2d 207, 213 (Cal. Ct. App. 2003). Rather, the onus is on plaintiffs to prove that advertisers' claims are false. *Id.* In *Dachauer*, we addressed issues similar to those Kroessler raises in the present case. There, a consumer brought a putative class action against manufacturers of vitamin E supplements, alleging that labels on the supplements "violate[d] two California laws against false advertising, because the supplements d[id] not prevent cardiovascular disease and might increase the risk of all-cause mortality." *Dachauer*, 913 F.3d at 846. The district court granted summary judgment to the manufacturers because the plaintiff's claims were preempted by federal law. *Id.*

The consumer appealed, and we affirmed. First, we held that the FDCA preempted the consumer's claims. The consumer alleged that the supplement did not *prevent cardiovascular disease* (a disease claim), but the supplement advertised *support for cardiovascular health* (facially a structure/function claim). *Id.* at 848. We implied that the plaintiff had mismatched his evidence, presenting studies alleging that vitamin E did not prevent cardiovascular disease when, based on his claims, he should have presented studies alleging that vitamin E did not support cardiovascular health—the supplement's actual claim. *See id.*

Second, stemming from the supplement label's claim to *promote immune health*, the consumer alleged that the supplement did not *reduce the risk of all-cause mortality*. *Id.* at 849. We held that the FDCA preempted that claim because reducing mortality is a disease claim. *Id.* Third and finally, stemming from the supplement label's claim to *promote immune health*, the consumer alleged that the supplement *increased the risk of all-cause mortality*. *Id.* We held that the FDCA did *not* preempt that claim.[5] *Id.* (stating "the FDCA and California laws have the same labeling requirement with respect to failing to disclose an increased risk of death."). Because the FDCA would not preempt a claim of that nature, we examined the record to see if any evidence existed to create a genuine issue of material fact. *Id.* at 849–50. "Conceivably, evidence that a supplement endangered users by increasing their risk of death could prove that a structure/function claim that omitted the risk was misleading. But the record lacks evidence that vitamin E supplements are actually harmful, as opposed to simply useless at reducing all-cause mortality (which they do not claim to reduce)." *Id.* at 849. Thus, in *Dachauer* we affirmed the district court's grant of summary judgment because the plaintiff failed to meet his burden to create a genuine issue of material fact that the defendant's structure/function claim was misleading. *Id.* at 850.

In *Dachauer*, we stated that "[a]lthough the FDCA requires manufacturers to have substantiation for their structure/function claims, California law does not allow

[5] In the present case, neither Kroessler nor CVS allege that the glucosamine-based supplements present mortality claims in addition to their joint health claims. Therefore, *Dachauer's* holdings concerning the increased or decreased risks of all-cause mortality have little bearing on this case.

private plaintiffs to demand substantiation for advertising claims." *Id.* at 847. But just because California law prohibits private plaintiffs from forcing defendants to substantiate their advertising claims, that does not mean California law prohibits those plaintiffs from attacking defendants' substantiation. The California case governing this issue—*King Bio Pharmaceuticals, Inc.*—held that California state law prohibits private plaintiffs from shifting the burden of production to defendants to substantiate their advertising claims. *King Bio Pharm.*, 133 Cal. Rptr. 2d at 213–14. But it did not hold that plaintiffs cannot challenge a defendant-advertiser's purported substantiation. In fact, that case went to trial but ended with a directed verdict after the plaintiff failed to provide any evidence rebutting the defendant's substantiation. *Id.* at 210. Therefore, under California law, a plaintiff retains the burden of production and the burden of proof but can nevertheless challenge a defendant's substantiation. So, *Dachauer*'s conclusion that a plaintiff cannot demand substantiation did not encompass a challenge to an already substantiated claim. On the contrary, *Dachauer* implicitly supports a plaintiff's ability to challenge both a defendant's initial substantiation and its substantiation produced in rebuttal to a plaintiff's attack, as revealed by the district court allowing the case to proceed to summary judgment rather than granting outright dismissal as a matter of law on the pleadings. *Dachauer*, 913 F.3d at 846.

By permitting discovery and proceeding to summary judgment, the district court in *Dachauer* confirmed that plaintiffs can challenge defendants' substantiation by pointing to "matching evidence" contradicting those claims.[6] That distinction provides the key to understanding

[6] The FDA's guidelines also support this proposition. To meet the FDCA's requirement for "dietary supplement manufacturers to have

Dachauer's previously quoted juxtaposition between the FDCA and California law. *Dachauer* dealt with a "mismatch" of evidence—the plaintiff attempted to dispute the defendant's substantiation that the supplement promoted heart *health* by citing studies showing that the supplement did not prevent heart *disease.* *See id.* at 848. Had we permitted the plaintiff's claims to proceed, we would have forced the defendant to substantiate that the supplement also prevented heart disease. That would have held the defendant to burdens of production and proof different than those required for structure/function claims under the FDCA. Therefore, the FDCA preempted the plaintiff's claim. Importantly, however, *Dachauer* did not hold that the FDCA preempts state law causes of action when a plaintiff attempts

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substantiation that structure/function . . . claims on a dietary supplement product's labeling are truthful and not misleading" the FDA recommends

> that manufacturers possess adequate substantiation *for each reasonable interpretation of the claims*. We intend to apply a standard that is consistent with the FTC standard of "competent and reliable scientific evidence" to substantiate a claim. We consider the following factors important to establish whether information would constitute "competent and reliable scientific evidence": . . . [] If multiple studies exist, do the studies that have the most reliable methodologies suggest a particular outcome? If multiple studies exist, what do most studies suggest or find? Does the *totality of the evidence* agree with the claim(s)?

Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(R) (6) of the Federal Food, Drug, and Cosmetic Act, 2008 WL 10889843, at *15 (emphasis added). This implies that a defendant's substantiation may be evaluated and challenged.

to hold a defendant to the same substantiation standard required by the FDCA.

D.

Here, the district court interpreted *Dachauer* as holding that the FDCA preempts any state-law cause of action seeking to challenge the substantiation of a structure/function claim—including those where the allegations and evidence "match" the structure/function claims—so long as the manufacturer's claims are proper structure/function claims. Because the court concluded that CVS's glucosamine labels presented proper structure/function claims under the FDCA, it held that Kroessler's causes of action were preempted. It stated that Kroessler's citations to studies alleging that glucosamine is "ineffective at supporting or benefiting joint health" ultimately do not matter because CVS is merely required to substantiate its structure/function claims, not defend against a private plaintiff's contradicting evidence. According to the district court, if it permitted Kroessler's state law causes of action then the distinction between structure/function claims and disease claims would be blurred since Kroessler would seek to hold CVS's structure/function claims to the higher standard for disease claims.

The district court erred in so holding. *First*, the court erred in applying *Dachauer* to the present case because this case does not fit within *Dachauer*'s ruling. Kroessler does not allege that CVS's structure/function claims are false either because the supplements do not prevent osteoarthritis or because they do not reduce the risk of all-cause mortality—allegations *Dachauer* clearly proscribed. Nor does he allege that the claims are false because the supplements increase the risk of all-cause mortality—an allegation *Dachauer* clearly permitted. Although he is

occasionally inconsistent throughout the complaint and briefings, Kroessler alleges that CVS's glucosamine claims are false because scientific studies directly refute them. The supplement labels claim, using various terms, to support and maintain joint health, but the scientific studies allegedly conclude that glucosamine is useless for such ends. Therefore, *Dachauer* did not address the scenario in the present case.

Kroessler cited multiple scientific studies in his complaint but he was not able to pursue discovery to obtain evidence that might bolster or rebut them. To be sure, Kroessler's synopses of the studies generally allege that glucosamine is no more effective than a placebo at reducing joint pain, relieving joint stiffness, improving joint function, impacting joint swelling or space width loss, rebuilding joint cartilage, or relieving the symptoms of osteoarthritis or slowing their progression. These allegations do not match the labels containing CVS's structure/function claims, which state that the products maintain and support general joint health. Indeed, many of the studies' titles themselves suggest that they narrowly address glucosamine's effects on osteoarthritis, rather than its wider efficacy in supporting or maintaining joint health.

However, as previously noted, Kroessler also alleges that the contents of the studies support the conclusion that glucosamine is "ineffective" at "supporting, maintaining, or benefiting the health of human joints." Taken as true, those allegations directly refute CVS's claims. Therefore, unlike the plaintiff in *Dachauer*, Kroessler's factual allegations, taken as true, support his claim that CVS violated California law.

The FDCA does not preempt California false advertising causes of action simply because the challenged label

contains a proper structure/function claim; instead, preemption applies only if the plaintiff's legal claims and factual allegations would hold a defendant to a different "substantiation" standard than the FDCA. *Dachauer* held that the FDCA only preempted causes of action where the evidence to rebut a supplement's structure/function claims did not "match" such claims, but instead related to a disease claim or showed a decreased risk of all-cause mortality.[7] *Dachauer*, 913 F.3d at 848. Thus, *Dachauer* is distinguishable, and applying its analysis here does not lead to the conclusion that the FDCA preempted Kroessler's state law causes of action. Because Kroessler "matched" his evidence with CVS's structure/function claims and he does not otherwise allege effects on the risk of all-cause mortality, his case presents a scenario that *Dachauer* did not explicitly address.

Second, this case is distinguished from *Dachauer* by its procedural posture. *Dachauer* was an appeal from a grant of summary judgment, while this case is an appeal from dismissal on the pleadings. *See id.* at 846. The quality of the evidence in the record—namely, what the scientific studies and expert testimony claimed to prove or disprove—was crucial to our holding in *Dachauer*. There, we noted that the record lacked evidence showing that the supplement increased the risk of all-cause mortality and therefore the plaintiff failed to meet his burden to show a genuine issue of material fact. *Id.* at 850. This court in *Dachauer*, and many other courts, have permitted state-law claims for false

[7] However, *Dachauer* did not hold that *only* cases with "mismatched" evidence are preempted.

advertising to proceed well past the pleading stage.[8] Thus, *Dachauer* implicitly supported the proposition that private plaintiffs should be allowed to sue dietary supplement manufacturers, so long as the state law causes of action impose identical standards as the FDCA, unless the court ultimately determines that the plaintiffs' evidence does not support their claims. Such an evidentiary analysis is not appropriate at the early procedural stage presented in this case.

CVS unsuccessfully attempts to fit Kroessler's factual scenario into the confines of *Dachauer*. It argues that Kroessler's cited scientific studies attempt to prove glucosamine's inefficacy at treating arthritis, while the supplement's labels merely claim to support and maintain normal joint function. Thus, CVS's argument attacks the evidence Kroessler eventually intends to present in this case. At this early stage in the proceedings, however, we will not consider the studies' substance because they are not attached to the pleadings or otherwise part of the record. CVS may attack the sufficiency of Kroessler's evidence at summary judgment or trial—and it may well succeed at those stages. But at this stage, FDCA preemption does not prevent Kroessler's state law claims from proceeding.

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[8] *See, e.g.*, *Hazlin v. Botanical Labs., Inc.*, No. 13cv0618 DMS (JMA), 2013 WL 12076470, at *4 (S.D. Cal. Aug 8, 2013); *Vasic v. Patent Health, LLC.*, No. 13cv849 AJB (MDD), 2014 WL 940323, at *7 (S.D. Cal. Mar. 10, 2014); *Zakaria v. Gerber Prods. Co.*, No. LA CV15-00200 JAK (Ex), 2015 WL 4379743, at *3 (C.D. Cal. July 14, 2015); *In re Clorox Consumer Litig.*, 894 F. Supp. 2d 1224, 1228 (N.D. Cal. 2012); *Fraker v. Bayer Corp.*, No. CV F 08-1564 AWI GSA, 2009 WL 5865687, at *8–9 (E.D. Cal. Oct. 6, 2009); *Stanley v. Bayer Healthcare LLC*, No. 11cv862-IEG (BLM), 2012 WL 1132920, at *3 (S.D. Cal. Apr. 3, 2012).

Third and finally, the district court erred by greatly expanding the present state of federal preemption jurisprudence under the FDCA, contrary to public policy. No other circuit has held that the FDCA preempts any state law cause of action seeking to challenge the substantiation of a structure/function claim—where the allegations and evidence "match" the structure/function claims—so long as the manufacturer's claims are proper structure/function claims. Rather, it is well established that "supplement makers can be sued for false claims, and no federal preemption exists under the FDCA either by statute or by implication, since the FDA does not occupy the field and its controls are unaffected by private false advertising suits against supplement makers." 1 James T. O'Reilly, *Food and Drug Administration* § 10:112 (Katharine A. Van Tassel, 4th ed. 2020). Adopting the district court's interpretation of *Dachauer* would permit an unprecedented broadening of FDCA preemption, barring nearly all private rights of action under state law against supplement manufacturers.

Furthermore, since the FDCA does not create a private right of action for plaintiffs to sue dietary supplement manufacturers, affirming the district court's ruling would leave federal regulators as the sole enforcers of the FDCA within the Ninth Circuit. *Id.* This contradicts the FDCA's stated purpose of promoting public policy by retaining parallel avenues for private and public enforcement actions against false or misleading statements. 2 James T. O'Reilly, *Food and Drug Administration* § 25:21 (Katharine A. Van Tassel, 4th ed. 2020). Even CVS does not directly argue that the FDCA preempts Kroessler's California claims simply because its glucosamine-based supplements present structure/function claims. It likely understands that such a position would greatly expand the preemption doctrine. The

district court's ruling mistakenly broadened the FDCA preemption doctrine beyond acceptable public policy limits.

II. Leave to Amend the Complaint

The district court dismissed Kroessler's complaint with prejudice, stating in a footnote that any amendment to the complaint would be futile because, as a matter of law, the FDCA would preempt any state law cause of action. Kroessler disagrees, asserting that an amendment would not be futile because he could bolster his "implied disease" claim with further allegations.

In assessing whether leave to amend is proper, courts consider "the presence or absence of undue delay, bad faith, dilatory motive, repeated failure to cure deficiencies by previous amendments, undue prejudice to the opposing party and futility of the proposed amendment." *Moore v. Kayport Package Exp., Inc.*, 885 F.2d 531, 538 (9th Cir. 1989). "Futility of amendment can, by itself, justify the denial of a motion for leave to amend." *Bonin v. Calderon*, 59 F.3d 815, 845 (9th Cir. 1995). If no amendment would allow the complaint to withstand dismissal as a matter of law, courts consider amendment futile. *See Moore*, 885 F.2d at 538–39. Here, the district court concluded that any amendment attempting to state an "implied disease" claim would be futile. As we explain next, this conclusion was in error.

A.

The FDA recognizes that products marketed as supplements may nevertheless *implicitly* claim to impact a disease or the signs of symptoms of a disease. *See* 65 Fed. Reg. at 1012. Differentiating between structure/function and disease claims, the FDA specifies the criteria it uses to classify a supplement's statements as disease claims.

21 C.F.R. § 101.93(g)(2). However, the "criteria are not intended to classify as disease claims statements that refer to the ability of a product to maintain healthy structure or function, *unless the statement implies disease prevention or treatment*." *Id.* (emphasis added). "In determining whether a statement is a disease claim under these criteria, [the] FDA will consider the context in which the claim is presented." *Id*. Therefore, a structure/function claim may also imply a disease claim when considered in context.

The first factor the FDA looks to when considering "the context in which the claim is presented" is the actual label on the supplement. Regarding a supplement's objective representations, the FDA's guidance states that a label claiming the product "reduces the pain and stiffness associated with arthritis" would be a clear disease claim because it explicitly mentions arthritis. 65 Fed. Reg. at 1012. "Implied disease claims do not mention the name of a specific disease, but refer to identifiable characteristics of a disease from which the disease itself may be inferred." *Id.* Implied disease claims need not consist of words alone; "images of people suffering from the disease" are another way to imply a disease claim. *Id.* at 1012. The FDA admits that "[t]he distinction between implied and express disease claims is thus, in many cases, a semantic one . . . ." *Id.* at 1013.

A supplement label's objective representations are not the only factors the FDA will consider when determining "the context in which the claim is presented" for purposes of identifying implied disease claims. 21 C.F.R. § 101.93(g)(2). "[I]n appropriate circumstances, [the] FDA may find that a dietary supplement for which only structure/function claims are made in labeling may nevertheless [claim to treat disease] if there is *other evidence*

of intended use to prevent or treat disease." 65 Fed. Reg. at 1006 (emphasis added). We need not delineate what types of evidence courts may consider when evaluating implied disease claims. It is sufficient to state that many other courts have considered extra-label material when identifying implied disease claims and that those considerations are best made by district courts on a case-by-case basis.[9]

B.

In this case, the district court considered only the objective representations on the label of the glucosamine-based supplement that Kroessler purchased, which is similar to the labels on CVS's other glucosamine-based supplements identified in the complaint. It concluded that CVS's representations did not make disease claims since they did not purport to reduce or improve anything or otherwise mention joint pain. The district court concluded that they were proper structure/function claims that were consistent with federal requirements. The court appears to have foreclosed Kroessler from asserting an implied disease claim based on its incorrect determination that the presence of a structure/function claim causes the FDCA to preempt California causes of action. In a footnote at the end of its order, the court stated that "[it] does not find that any amendment to this claim could possibly cure the deficiency." The footnote is attached to a sentence concluding that the

[9] District courts within this circuit have considered factors such as the product's advertisements, the consumer's experience with the product, and market research showing consumer's typical uses of the product. *See, e.g., Mullins v. Premier Nutrition Corp.*, 178 F. Supp. 3d 867, 899 (N.D. Cal. 2016). District courts in other circuits have similarly considered various extra-label factors. *See United States v. Kasz Enters., Inc.*, 855 F. Supp. 534, 540–44, *amended*, 862 F. Supp. 717 (D.R.I. 1994).

FDCA preempts all of Kroessler's claims. By denying Kroessler leave to amend his complaint to include allegations of extra-label evidence supporting an implied disease claim, the court concluded that only a supplement's label can imply disease claims.

The court erred in denying Kroessler leave to amend his complaint on the grounds of futility. It attached its preemption holding to Kroessler's implied disease claim and considered only the labels on CVS's glucosamine-based supplements, concluding that they present structure/function claims that necessarily trigger the FDCA's preemption of Kroessler's California causes of action. But even if the district court's preemption reasoning is disentangled from its denial of leave to amend, it still erred in denying leave. The current state of FDCA law, as clarified by the FDA's guidance and various courts' rulings, both cited above, allows courts examining implied disease claims to consider extra-label evidence. The district court should have given Kroessler the chance to present such evidence and allegations.

C.

The district court correctly concluded, however, that CVS's glucosamine-based supplements do not present implied disease claims on the face of the label alone. None of the words on the labels fit within the FDA's guidance on telltale implied disease claims. On the contrary, most of the labels' representations perfectly match the FDA's examples of proper structure/function claims. Furthermore, as Kroessler himself notes, the images on the labels show an elderly couple leisurely walking along a beach, far from suffering with the symptoms of arthritis. The labels do not present these pictures as "before and after" comparisons, implying the healing of arthritic patients. Therefore, based

on the FDCA, enabling regulations, and the FDA's accompanying guidance, CVS's glucosamine-based supplements do not present implied disease claims on the face of the labels alone.

Because Kroessler may have been able to "bolster" his complaint with allegations of extra-label evidence showing that CVS's glucosamine-based supplements present implied disease claims, the court erred by denying him leave to amend his complaint based on futility.

CONCLUSION

The district court erred in concluding that the FDCA preempts Kroessler's state law causes of action simply because CVS's glucosamine-based supplements present only structure/function claims, and erred in dismissing the complaint without granting Kroessler leave to amend to add allegations regarding an implied disease claim.

REVERSED and REMANDED.