UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

DIANE HOWARD et al.,

Plaintiffs,

v.

ALCHEMEE, LLC et al.,

Defendants.

ALAN MONTENEGRO et al.,

Plaintiffs,

v.

CVS PHARMACY, INC. et al.,

Defendants.

ALAN MONTENEGRO et al.,

Plaintiffs,

v.

RB HEALTH US LLC,

Defendant.

Case No. 2:24-cv-01834-SB-BFM
Case No. 2:24-cv-01876-SB-BFM
Case No. 2:24-cv-01878-SB-BFM

ORDER GRANTING MOTIONS TO DISMISS

These are three of the numerous pending putative class actions across the country challenging drug manufacturers' failure to warn consumers about the alleged risks posed by the use of benzoyl peroxide (BPO) in acne medications. In *Howard v. Alchemee, LLC*, No. 2:24-cv-01834-SB, 54 individuals from 13 states assert claims under various state laws challenging the labeling of over-the-counter (OTC) acne treatments produced by Defendants Alchemee, LLC and Taro

Pharmaceuticals U.S.A., Inc. The other two cases, *Montenegro v. CVS Pharmacy, Inc.*, No. 2:24-CV-01876-SB, and *Montenegro v. RB Health US LLC*, No. 2:24-CV-01878-SB, were filed by the same plaintiffs' counsel and involve similar claims. Plaintiffs' central contention is that Defendants failed to warn them that the active ingredient of their products, BPO, degrades into the carcinogen benzene under normal use, handling, and storage conditions. Defendants in all three cases move to dismiss under Rules 12(b)(1) and 12(b)(6).[1] The Court issued a tentative ruling on the motion in *Howard* and held a hearing on all three motions on September 13, 2024.

Because the issues on which the Court rules are indistinguishable among the three cases and the parties presented unified argument on these issues at the hearing, the Court issues a single order addressing all three cases.[2] The Court concludes that Plaintiffs have adequately alleged Article III standing but that their claims are preempted by federal law, which expressly precludes states from imposing labeling requirements that are "different from or in addition to" federal requirements. 21 U.S.C. § 379r(a).

I.

Defendant Alchemee, LLC and its parent company, Defendant Taro Pharmaceuticals U.S.A., Inc., manufacture, market, sell, and distribute OTC topical acne treatment products under the brand name Proactiv. Dkt. No. 45 ¶¶ 2, 72–73 (1st Am Compl.).[3] These products contain BPO. BPO can degrade into benzene, a human carcinogen, as the result of a chemical process, which is accelerated at higher temperatures. *Id.* ¶¶ 9, 13, 18, 113. A laboratory run by third party Valisure, LLC tested some of Defendants' BPO products (along with those of other companies) to determine if they contained benzene. *Id.* ¶¶ 7, 101–02. Before subjecting the products to the testing conditions, Valisure found that 94 of the 99

[1] CVS's motion also argues that the Court lacks personal jurisdiction over the claims of plaintiffs who reside outside of California. At the hearing, however, CVS waived its challenge to personal jurisdiction by accepting a ruling on the merits.

[2] Defendants also requested that the Court take judicial notice of certain documents. Because the Court reaches its conclusions without relying on those documents, it denies the request.

[3] For convenience, the Court cites only the record in *Howard*. The allegations in that case are representative of the other actions, and any differences are immaterial.

BPO products contained some levels of benzene. *Id.* ¶ 8. Valisure then applied heat and humidity to the products, including some of Defendants' products, for extended periods—allegedly to simulate the expected conditions under which the products would be used, handled, distributed, and stored. *Id.* ¶¶ 8, 103. After exposing the BPO products to such conditions, Valisure found benzene in them in various, elevated amounts, which depended both on the product and the duration the product was subjected to higher temperatures. *Id.* ¶¶ 103–06. Valisure filed a citizen's petition with the Food and Drug Administration (FDA) describing its findings and asking the FDA to take action on BPO products. *Id.* ¶ 12.

Shortly after, Plaintiffs, consumers who purchased Defendants' BPO products, filed this putative class action against Defendants. Dkt. No. 1. After Defendants filed a motion to dismiss, Dkt. No. 32, Plaintiffs filed a First Amended Complaint (FAC) adding dozens of additional plaintiffs, Dkt. No. 45. They allege that Defendants knew or should have known of the risk that BPO degrades into benzene, yet never disclosed that risk or that Proactiv contained (or risked containing) benzene. *E.g.*, *id.* ¶¶ 13–14. They also allege they were physically harmed because they applied Defendants' BPO products to their skin and benzene is harmful "even in trace amounts." *Id.* ¶¶ 15, 114, 122, 127, 292. However, Plaintiffs do not allege any specific adverse physical consequences from exposure to benzene and do not seek damages for physical injury. *Id.* ¶ 292. Instead, they assert that they suffered economic injuries because: (1) they bought products they otherwise would not have bought had they known of the risk or actual presence of benzene; and (2) the products were worth less than what they paid for them. *E.g.*, *id.* ¶¶ 15, 18–71, 132–290.

Accordingly, Plaintiffs assert the following claims: violations of California's Unfair Competition Law and Consumer Legal Remedies Act; false advertising in violation of California, Hawaii, and New York law; deceptive trade practices in violation of the laws of 13 states; breach of express warranty; breach of implied warranty; and unjust enrichment. *Id.* ¶¶ 302–83.

Defendants now move to dismiss the FAC under Rules 12(b)(1) and 12(b)(6). Dkt. No. 54.

II.

A.

A complaint must be dismissed under Rule 12(b)(1) if the plaintiff lacks Article III standing to bring suit. *Maya v. Centex Corp.*, 658 F.3d 1060, 1067 (9th

Cir. 2011). The standing doctrine is derived from Article III's limitation on the judicial power of federal courts to hear only "actual cases or controversies." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 337 (2016) (internal quotation marks omitted). "The doctrine limits the category of litigants empowered to maintain a lawsuit in federal court to seek redress for a legal wrong." *Id.* at 338. Standing "is not dispensed in gross; rather, plaintiffs must demonstrate standing for each claim that they press and for each form of relief that they seek." *TransUnion LLC v. Ramirez*, 594 U.S. 413, 431 (2021). "The irreducible constitutional minimum of standing consists of three elements. The plaintiff must have (1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo*, 578 U.S. at 338 (cleaned up) (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61 (1992)). A plaintiff must show that the injury was "an invasion of a legally protected interest" that is "concrete and particularized" and "actual or imminent, not conjectural or hypothetical." *Lujan*, 504 U.S. at 560 (internal quotation marks omitted).

The party invoking federal jurisdiction bears the burden of demonstrating standing. *TransUnion*, 594 U.S. at 430–31. The quantum of evidence required to meet this burden depends on the stage of litigation. *Maya*, 658 F.3d at 1068. A jurisdictional challenge under Rule 12(b)(1) may be facial or factual. *Safe Air for Everyone v. Meyer*, 373 F.3d 1035, 1039 (9th Cir. 2004). A facial challenge "asserts that the allegations contained in a complaint are insufficient on their face to invoke federal jurisdiction." *Id*. A factual challenge "disputes the truth of the allegations that, by themselves, would otherwise invoke federal jurisdiction." *Id*. In resolving a factual attack, "the district court may review evidence beyond the complaint without converting the motion to dismiss into a motion for summary judgment" and "need not presume the truthfulness of the plaintiff's allegations." *Id*. (citations omitted). Though Defendants do not address the proper framing of their standing challenge, their arguments assume the truth of Plaintiffs' allegations and thus the challenge appears to be facial.

B.

Defendants contend that Plaintiffs have failed to allege a concrete injury in fact because their injury is hypothetical. Although Plaintiffs allege that they have been harmed both physically and economically, they limit their claims in this action to claims for economic harm. Dkt. No. 45 ¶¶ 15–16; *id*. ¶ 292 ("The Class does not seek damages for physical injuries, although Plaintiffs were physically harmed by being exposed to benzene."). Plaintiffs allege that because of

Defendants' "misconduct and consumer deception," Plaintiffs "were economically harmed, as they bought products they otherwise would have never bought, receiving a product that was unfit for human use, i.e., worthless, was not what it was purposed to be, was illegal for sale in the United States, and/or had value below the price paid." *Id*. ¶ 15.

While this allegation implicates multiple theories of economic harm, the Court need only address one to find that Plaintiffs have adequately alleged an Article III injury. The Ninth Circuit has repeatedly held that a plaintiff who purchased a product he would not otherwise have purchased as a result of the defendant's misrepresentation or omission has suffered an Article III injury. Although the Ninth Circuit's discussion of this theory has often been cursory, the court has evidently viewed it as an easy issue. *See, e.g.*, *Maya*, 658 F.3d at 1069 (finding standing based on failure to disclose because allegation that "plaintiffs spent money that, absent defendants' actions, they would not have spent" was "a quintessential injury-in-fact"); *Hinojos v. Kohl's Corp.*, 718 F.3d 1098, 1104 n.3 (9th Cir. 2013) (finding "no difficulty in this case regarding Article III injury in fact" because "when . . . Plaintiffs contend that class members paid more for a product than they otherwise would have paid, or bought it when they otherwise would not have done so[,] they have suffered an Article III injury in fact.") (quoting *Mazza v. Am. Honda Motor Co.*, 666 F.3d 581, 595 (9th Cir. 2012)); *Painters & Allied Trades Dist. Council 82 Health Care Fund v. Takeda Pharms. Co.*, 796 F. App'x 919, 921 n.1 (9th Cir. 2019) ("We have held in the consumer fraud context that where plaintiffs contend that they bought a product when they otherwise would not have done so, because Defendants made deceptive claims and failed to disclose known risks[,] they have suffered an injury in fact sufficient to support Article III standing. Here, Plaintiffs alleged that they purchased Actos, which they would not have done absent Defendants' fraudulent scheme to conceal Actos's risk of bladder cancer. Thus, Plaintiffs have alleged an injury in fact sufficient to support Article III standing.") (cleaned up).

The allegations here are consistent with those the Ninth Circuit has found adequate to allege Article III standing. For each Plaintiff, the FAC identifies the particular Proactiv products that the plaintiff purchased and alleges that the plaintiff "would never have purchased Defendants' BPO Products had Defendants warned about the presence of benzene or that the BPO Products could degrade into benzene . . . ." *E.g.*, Dkt. No. 45 ¶ 18 (allegations as to Plaintiff Diane Howard). Defendants argue, however, that Plaintiffs' economic injuries are speculative because the FAC does not plausibly allege that the Proactiv products Plaintiffs purchased (1) actually contained benzene, (2) were exposed to conditions that

would cause BPO to degrade into benzene, (3) were the same products Valisure tested, or (4) were from the same lots or manufactured close in time to those tested by Valisure. These related arguments fail for two reasons.

First, the thrust of Plaintiffs' complaint is that, because of the inherent propensity of BPO to degrade into benzene under "normal use, handling, and storage" conditions, all acne products with BPO are unsafe because they essentially all contain benzene, and any amount of benzene is dangerous. *See, e.g.*, *id*. ¶¶ 5, 106 ("BPO is a fundamentally unstable molecule that will degrade into benzene—a point illustrated by the identification of benzene in every BPO product tested."); *id.* ¶ 3 (alleging that there is no safe level of human exposure to benzene); *id*. ¶ 8 (alleging that 94 of 99 products tested contained benzene before heat or humidity was applied).[4] Defendants dispute the truth of these allegations, emphasizing that the FDA has concluded otherwise, but the Court must accept the allegations as true for purposes of Defendants' Rule 12(b)(1) facial challenge. *Safe Air for Everyone*, 373 F.3d at 1039.

Because Plaintiffs' allegations of benzene contamination depend on the degradation of BPO, which is in all the Proactiv products Plaintiffs purchased, the cases Defendants rely on—in which there were no allegations of a common risk of contamination—are distinguishable. *Bowen v. Energizer Holdings, Inc.*, No. 2:21-CV-4356-MWF, 2023 WL 1786731, *3–4 (C.D. Cal. Jan. 5, 2023) (plaintiff did not plead economic injury because she failed to allege the results of a study finding benzene in some of defendants' products could be "extrapolated across all of [their] products" to include the product she purchased); *Bodle v. Johnson & Johnson Consumer Inc.*, No. 21-CV-07742, 2022 WL 18495043, at *1–2 (N.D. Cal. Feb. 24, 2022) (finding no injury because plaintiff did not allege either that defendant's products, "other than the specific 23 batches identified in the Valisure

[4] At the hearing, Plaintiffs' counsel suggested that there are chemicals that can be added to Defendants' products to stop the degradation process. To the extent Plaintiffs are suggesting that the degradation of BPO into benzene is not inevitable, Plaintiffs undermine their standing argument, as the Court could not then assume that the named plaintiffs purchased acne products that decompose into benzene without a more specific showing as to each plaintiff. However, when pressed by the Court, Plaintiffs' counsel affirmed Plaintiffs' position that BPO is an inherently unstable chemical that naturally degrades into benzene under normal conditions. This accords with their allegations, which the Court accepts as true for purposes of this motion. *See, e.g.*, Dkt. No. 45 ¶¶ 5–6, 9, 89–91, 93–95, 104, 106.

Petition, contain benzene" or that she purchased a product from one of the contaminated batches).

Moreover, because Plaintiffs allege that benzene is in all BPO acne products (since BPO degrades to benzene under normal conditions),[5] Defendants cannot show Plaintiffs' injury is speculative by citing to cases where courts found no concrete injury based on allegations that a risk might materialize under hypothetical circumstances. *Birdsong v. Apple, Inc.*, 590 F.3d 955, 960 (9th Cir. 2009) (economic injury based on the risk that iPods could cause hearing loss was hypothetical as it depended on the potential that other consumers might listen to music for long periods at unsafe levels); *Cahen v. Toyota Motor Corp.*, 717 F. App'x 720, 723 (9th Cir. 2017) (possibility that vehicles were vulnerable to hacking, which had only been shown in controlled environments, was a speculative risk insufficient for standing); *Lassen v. Nissan N. Am., Inc.*, 211 F. Supp. 3d 1267, 1283 (C.D. Cal. 2016) (allegations that the vehicles posed a safety risk if parked in a particular, dangerous way failed to show a concrete injury).

Second, even if Plaintiffs' allegations are insufficient to establish the presence of benzene in the Proactiv products they purchased, the actual presence of benzene is not necessary for an injury in fact. Plaintiffs allege not only that they would not have purchased the products had they known they contained benzene, but also that they would not have done so had they known that "BPO Products could degrade into benzene." *E.g.*, *id.* ¶ 18. Courts have found an injury in fact when a plaintiff plausibly alleges a risk that the product she bought is contaminated and that she would not have bought it had she known of the risk of contamination. *Gagetta v. Walmart, Inc.*, 646 F. Supp. 3d 1164, 1173 (N.D. Cal. 2022) (economic injury for standing where plaintiffs plausibly alleged that there was heavy metal contamination (and a risk thereof) and that they would not have bought the products had they been aware of the risk of contamination because the metals were unsafe at any level); *Balistreri v. McCormick & Co., Inc.*, No. 5:22-CV-00349, 2023 WL 5988600, at *5 (N.D. Cal. Sept. 13, 2023) (concrete injury pleaded by allegations that a third party found contamination in the same products plaintiffs

[5] Defendants resist these allegations, suggesting that Valisure's testing does not reflect normal conditions for their products. Dkt. No. 54 at 7, 9. But that is a question of fact not appropriate for resolution on a motion to dismiss. *Cf. Shalikar v. Asahi Beer U.S.A., Inc.*, No. 2:17-CV-02713-JAK, 2017 WL 9362139, at *7 (C.D. Cal. Oct. 16, 2017) (stressing that weighing evidence is inappropriate at the pleading stage, even when a defendant colorably challenges the reliability of a study incorporated into the complaint).

bought, any level of such metals was unsafe, and that plaintiffs would not have purchased the products had they known they "risked containing" heavy metals); *Henning v. Luxury Brand Partners, LLC*, No. 22-CV-07011, 2023 WL 3555998, at *3 (N.D. Cal. May 11, 2023) (finding that plaintiff plausibly alleged a risk of benzene in the sunscreen she bought, given third-party testing of the same product line, and that she would not have purchased the product had she known of the risk because there was no safe level of benzene).

Finally, Defendants argue that Plaintiffs lack standing because they allege that it was well known that BPO degrades to benzene when exposed to heat over time. Defendants' argument misconstrues the case on which they rely, *McGee v. S-L Snacks Nat'l*, 982 F.3d 700 (9th Cir. 2020). In *McGee*, the Ninth Circuit noted that the plaintiff could not rely on the overpayment theory of economic injury because she "does not allege that [the defendant] made false representations—or actionable non-disclosures—about [the product]," and "[t]hus, a key element of our overpayment cases—a defendant's misrepresentations about a product—is absent here." *Id*. at 707. Instead, the plaintiff made the "novel" argument that she could invoke the overpayment theory of standing to challenge a hidden defect in a product even in the absence of any misrepresentation or actionable omission. *Id*. Without deciding the viability of this argument, the Ninth Circuit concluded that it failed on its own terms because the plaintiff did not allege injury on the basis of a "hidden defect," as the product's "nutritional label disclosed the presence of artificial trans fat, and the health risks of consuming artificial trans fat were firmly established by the time of McGee's purchases." *Id*. In contrast, the pleading in this case alleges that Proactiv contains a hidden defect generally unknown to the consuming public (i.e., that the active ingredient, BPO, degrades into benzene). Dkt. No. 45 ¶ 90. *McGee* is therefore distinguishable.

In sum, taking the allegations in the FAC as true, Plaintiffs have sufficiently pleaded an injury in fact because they plausibly allege that (1) Defendants' products contain benzene or risk degrading into benzene, making them unsafe and that (2) Plaintiffs, who place "a high priority on health and safety," would not have purchased the products had Defendants not withheld information about the risks of benzene. *Id.* ¶¶ 132–290; *see Grausz v. Hershey Co.*, 691 F. Supp. 3d 1178, 1189 (S.D. Cal. 2023) (finding economic injury when plaintiff alleged she sought chocolate bars of higher quality and would not have purchased the defendant's bars had it not omitted that they might contain heavy metals). Defendants do not dispute Plaintiff's allegations that benzene is unsafe at any level and poses health risks to those exposed through dermal absorption. Dkt. No. 45 ¶¶ 114–15, 122. Even if they did, the safety of the benzene level to which Plaintiffs were or could

have been exposed is a factual question that would be inappropriate to resolve at the pleading stage. *Rodriguez v. Mondelez Glob. LLC*, 703 F. Supp. 3d 1191, 1205 (S.D. Cal. 2023); *Henning*, 2023 WL 3555998, at *3. Accordingly, Plaintiffs have adequately alleged an injury in fact sufficient to survive a facial attack on their standing, at least as it pertains to their claims for monetary remedies.

C.

Defendants also argue that Plaintiffs lack standing to seek injunctive relief. Plaintiffs concede this issue by failing to respond to this argument in their opposition. *Kerrigan v. Allstate Ins. Co.*, 543 F. Supp. 3d 843, 845–46 (C.D. Cal. 2021), *aff'd*, No. 21-55730, 2022 WL 14476372 (9th Cir. Oct. 25, 2022).

In any event, Plaintiffs clearly have not established standing to pursue this form of relief. To do so, Plaintiffs must show a "sufficient likelihood that [they] will again be wronged in a similar way," *City of Los Angeles v. Lyons*, 461 U.S. 95, 111 (1983), and that the threat of suffering a concrete injury is "actual and imminent," *Summers v. Earth Island Inst.*, 555 U.S. 488, 493 (2009). Plaintiffs fail to allege any imminent threat of a similar injury. They allege generally that Defendants' conduct is "ongoing and continuing to cause harm." Dkt. No. 45 ¶¶ 16, 309, 325, 361, 376. But they do not allege they intend to buy Defendants' BPO products in the future, nor can they allege that they may be deceived by the products' advertising or labeling in the future. *See Kulp v. Munchkin, Inc.*, 678 F. Supp. 3d 1158, 1165 (C.D. Cal. 2023) (The "threat of future injury is determined by the plaintiff's ability to perceive subsequent misrepresentations based on past experience."). Plaintiffs know that products containing BPO have a risk that they contain benzene and need only look at the label to avoid being misled. *Stewart v. Kodiak Cakes, LLC*, 537 F. Supp. 3d 1103, 1127 (S.D. Cal. 2021) (finding no standing for injunctive relief because the plaintiffs could avoid being misled by checking the product's packaging).

Therefore, Defendants' motion to dismiss is granted with respect to Plaintiffs' claims for injunctive relief.

III.

Defendants next seek dismissal on preemption grounds based on the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*, and the FDA regulations promulgated thereunder. They argue that Plaintiffs' claims are expressly preempted because the FDA regulations prescribe the exact warning and labeling

instructions for OTC acne products and Plaintiffs' claims are inconsistent with those directions.

A.

To survive a motion to dismiss under Rule 12(b)(6), a plaintiff must allege "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim has "facial plausibility" if the facts pleaded "allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). In resolving a Rule 12(b)(6) motion, a court must accept all well-pleaded factual allegations as true, but "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice," and courts "are not bound to accept as true a legal conclusion couched as a factual allegation." *Id.* (quoting *Twombly*, 550 U.S. at 555). Assuming the veracity of well-pleaded factual allegations, a court must "determine whether they plausibly give rise to an entitlement to relief." *Id.* at 679. There is no plausibility "where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct." *Id.*

B.

Before considering the preemption defense, it is important to understand the nature of the misrepresentation claim asserted in this case. Although the FAC contains wide-ranging allegations, Plaintiffs have not identified specific misrepresentations on which they relied, and their opposition makes clear that they advance only an omission theory. *See* Dkt. No. 59 at 15–16 (responding to Defendants' Rule 9(b) argument by asserting that Plaintiffs allege deceptive omissions). Moreover, while Plaintiffs occasionally reference "advertisements," the FAC focuses on the labeling of defendants' products, none of the 54 Plaintiffs identifies any product advertising on which he or she relied other than the front label. *E.g.*, Dkt. No. 45 ¶ 132. Thus, the Court, like the parties, focuses on whether Plaintiffs' claims that Defendants should have disclosed the presence or risk of benzene on their Proactiv products' labels are preempted by the FDCA.

C.

"A fundamental principle of the Constitution is that Congress has the power to preempt state law." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372 (2000). Preemption comes in multiple forms—express, field, and conflict preemption—but the purpose of Congress is "the ultimate touchstone" for all of

them. *Gilstrap v. United Air Lines, Inc.*, 709 F.3d 995, 1003 (9th Cir. 2013) (quoting *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992)). When construing an express preemption clause, courts must begin by examining the clause's plain wording, which contains the best evidence of Congress's preemptive intent. *Sprietsma v. Mercury Marine*, 537 U.S. 51, 62 (2002).

To ensure uniformity in the regulation of OTC drugs like Defendants' BPO products, the FDCA contains a broad express preemption provision, which provides that no state "may establish or continue in effect any requirement—(1) that relates to the regulation of a [nonprescription drug]; and (2) that is different from or in addition to, or that is otherwise not identical with, a requirement under" the FDCA. 21 U.S.C. § 379r(a).[6] The statute defines "requirement" to include "any requirement relating to public information or any other form of public communication relating to a warning of any kind for a drug." *Id.* § 379(c)(2).

OTC acne drug products, including Defendants' Proactiv products, are governed by a comprehensive set of FDA regulations called a monograph, which includes certain labeling requirements. 21 C.F.R. §§ 330.1, 330.5, 330.10; 333.350. The monograph expressly permits BPO to be an active ingredient in these products (in an amount from 2.5 to 10 percent). *Id*. § 333.310(a). Section 333.350 provides detailed instructions for labeling covered products, including specific warnings and directions that must be included for products containing BPO. *Id*. § 333.350(c)(4), (d)(2). The regulations provide that an OTC acne drug product "is generally recognized as safe and effective and is not misbranded if it meets each of the conditions" in the monograph and "each general condition" in 21 C.F.R. § 330.1. *Id.* § 333.301. Section 330.1, in turn, specifies that OTC drugs must meet the conditions described therein and must be "labeled in compliance with chapter V" of the FDCA and "the format and content requirements in § 201.66." *Id*. § 330.1(c)(1). Chapter V of the FDCA prohibits the sale of adulterated or misbranded drugs. 21 U.S.C. §§ 331(a), 351, 352.

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[6] The preemption provision contains a number of exceptions not relevant here. 21 U.S.C. § 379r(d)–(e). One exception is for product liability actions under state law, *id*. § 379r(e), which is inapplicable because Plaintiffs pursue only their economic loss theory. *See Kanter v. Warner-Lambert Co.*, 99 Cal. App. 4th 780, 790 (2002) (finding FDCA preemption of California claims based on drug labeling where no personal injury was alleged because "if the damage consists solely of economic losses, recovery on a products liability theory is unavailable").

Consistent with Congress's intent to promote uniform drug regulation, the preemptive effect of § 379r applies not only to state legislation or regulations, but also to claims under state law that would have the effect, if the defendant were liable, of imposing a requirement "at variance with FDA regulations." *Carter v. Novartis Consumer Health, Inc.*, 582 F. Supp. 2d 1271, 1280–83 (C.D. Cal. 2008); *see also Morgan v. Albertsons Companies, Inc.*, No. 22-CV-02948, 2023 WL 3607275, at *4–5 (N.D. Cal. Mar. 13, 2023) (same). Thus, "state law claims regarding the labeling or packaging of [OTC drugs] that are not identical to the [FDCA] are expressly preempted." *Henning*, 2023 WL 3555998, at *5; *accord Gisvold v. Merck & Co.*, 62 F. Supp. 3d 1198, 1203 (S.D. Cal. 2014) (finding express preemption under § 379r where "the proposed disclaimer plainly adds to and is not identical with the FDA's requirements"). On the other hand, § 379r does not preempt claims under state law that impose identical or "parallel" requirements to FDA regulations. *Riegel v. Medtronic*, 552 U.S. 312, 330 (2008); *Fagan v. Neutrogena Corp.*, No. 5:13-CV-01316-SVW, 2014 WL 92255, at *1 (C.D. Cal. Jan. 8, 2014) (opining that state law claims imposing liability for misleading product labels impose parallel requirements and thus are not preempted).

D.

Plaintiffs' claims seek relief that is fundamentally at odds with the FDA's monograph. As explained above, Plaintiffs' allegations boil down to a claim that all acne drugs containing BPO are unsafe because they contain benzene, or will degrade into benzene under normal conditions, and benzene is unsafe in any amount. In fact, Plaintiffs' showing of standing depends on this theory, since they have not even attempted to demonstrate that the specific products they used have been tested and shown to contain benzene. Plaintiffs' theory is, therefore, essentially an attack on the FDA's determination that OTC acne drugs containing BPO are "generally recognized as safe and effective" and "not misbranded" if they comply with the monograph. 21 C.F.R. §§ 333.301(a), 333.310(a). Indeed, Plaintiffs' disagreement with the FDA, as clarified at the hearing, could not be more stark. They argued that the acne products are "adulterated" because they contain BPO, that it is "a crime" to sell such products, and that Defendants should be enjoined from doing so. In other words, Plaintiffs are not genuinely seeking a warning that the product is unsafe—which would be stark enough—but rather are pursuing a ban on selling what they believe is an "adulterated," illegal product. In these circumstances, Plaintiffs cannot claim that they seek to impose requirements that are identical or parallel to the FDCA and the FDA's regulations.

When confronted with this apparent conflict at the hearing, Plaintiffs denied that they were asking the Court to second-guess the FDA, arguing that unlike Defendants, the FDA was ignorant of the risk that BPO degrades into benzene under normal conditions when it concluded BPO was safe. That argument, however, cannot be squared with the repeated allegations in the FAC that the scientific community has known of BPO's degradation into benzene for almost 90 years. *See* Dkt. No. 45 ¶ 13 ("BPO is known, within the scientific community . . . to degrade into benzene according to the mechanism below."); *id*. ¶ 90 ("It is well known in the scientific community . . . that BPO degrades to benzene when exposed to heat over time. This process was first reported in the scientific literature as early as 1936."); *id*. ¶ 91 (alleging that "[t]he degradation of BPO to benzene was known or should have been known to the Defendants" based on their employment of "high-level scientists, chemists, and researchers"). Thus, the FAC precludes any suggestion that Defendants were aware of the degradation risk because they employed scientists working on drug products, but the FDA—a federal agency that depends on its "scientific expertise" to regulate drug safety—was ignorant of a chemical process commonly known among scientists. *See United States v. 1,638 Cases of Adulterated Alcoholic Beverages & Other Articles of Food*, 624 F.2d 900, 902 (9th Cir. 1980) (noting the "scientific expertise of the FDA"). To state the argument is to refute it.

E.

Examining the more specific arguments raised by the parties confirms that Plaintiffs seek relief that is in addition to—or, more accurately, contrary to—the FDA's labeling requirements. First, insofar as Plaintiffs' claims would require Defendants to disclose benzene as an ingredient of Proactiv, they are incompatible with the FDCA—as Plaintiffs conceded at the hearing. The FDA mandates disclosure of the active and inactive ingredients on the label, 21 C.F.R. § 201.66, 333.310, and benzene does not fit the definition of any type of ingredient, *id.* §§ 201.66(b)(2), (b)(8), 210.3(b)(3), because it is not a purposefully added component of the drug, Dkt. No. 45 ¶¶ 81, 331; *see Truss v. Bayer Healthcare Pharms. Inc.*, No. 21-CV-9845, 2022 WL 16951538, at *4 (S.D.N.Y. Nov. 15, 2022) (byproduct of active ingredient's degradation is neither an active nor inactive ingredient and need not be disclosed as an ingredient under the FDCA); *Barnes v. Unilever U.S. Inc.*, No. 21-CV-6191, 2023 WL 2456385, at *9 (N.D. Ill. Mar. 11, 2023) ("The FDA's regulations permit the exclusion of unintended ingredients from the product's label.").

Second, the Court is not persuaded by Plaintiffs' argument that their claims are parallel to the FDCA's general prohibition on misbranded drugs, which prohibits labels that are "false or misleading in any particular," including by "fail[ing] to reveal facts . . . material with respect to consequences which may result from the use of the article . . . under such conditions of use as are customary or usual." 21 U.S.C. §§ 321(n), 352(a). Plaintiffs contend that it is misleading for Defendants not to include in their label a warning about the risks of benzene. But the monograph sets forth in detail the exact warnings that must be on the labels of OTC acne drug products, including warnings that are only necessary for the subset containing BPO. 21 C.F.R. § 333.350(c)(4), (d)(2). Those warnings do not include any mention of benzene or its risks. Given that the FDA has specifically identified the warnings that must be provided when an acne drug contains BPO, Plaintiffs' contention that the presence of BPO requires a warning about benzene seeks to impose an *additional* labeling requirement that is not identical to the FDA's requirements and is therefore preempted by § 379r(a).[7]

That said, when a drug manufacturer makes additional affirmative statements about the product that are not required by the specific labeling instructions in a monograph, the FDCA's mislabeling provisions provide an additional restriction that may overlap with state claims for misrepresentations or false advertising, such that the state claims are not preempted. *See e.g.*, *Burchfield v. Prestige Consumer Healthcare, Inc.*, 534 F. Supp. 3d 1192, 1203–05 (C.D. Cal. 2021) (claims based on representation that a product was formulated specifically for infants not preempted); *Davis v. The Kroger Co.*, No. 2:22-CV-02082-MEM, 2023 WL 9511156, at *7–8 (C.D. Cal. Sept. 22, 2023) (claims based on "non-drowsy" label not preempted); *Fagan*, 2014 WL 92255, at *1 (claims based on "100% naturally sourced" language not preempted). As the court in *Davis* explained, Chapter V of the FDCA provides "a set of background requirements" that prohibit drugmakers, whose products otherwise comply with the monograph,

[7] In *Clinger v. Edgewell Personal Care Brands, LLC*, the district court—after accepting the truth of the disputed allegation that benzene is an intended ingredient of sunscreen—found that the FDA's required warnings for OTC drugs did not preempt claims that other warnings about the risks of benzene in sunscreen were required. No. 3:21-CV-1040, 2023 WL 2477499, *9-10 (D. Conn. Mar. 13, 2023). The regulations at issue in *Clinger* did not approve the use of, or mandate warnings about, an ingredient in sunscreen that was the alleged source of the benzene. *Clinger* is therefore distinguishable.

from making misleading statements that the monograph does not expressly ban. 2023 WL 9511156, at *8.

Here, however, Defendants are not alleged to have made affirmative misrepresentations outside the scope of the monograph. Instead, Plaintiffs allege that the Proactiv labels are misleading because they omit a warning that the monograph does not require. Courts have repeatedly found such claims preempted, notwithstanding the background requirements of Chapter V, because they would impose obligations not identical to those under the FDCA. *Youngblood v. CVS Pharmacy*, No. 2:20-CV-06251-MCS, 2021 WL 3700256, at *3 (C.D. Cal. Aug. 17, 2021) ("Adjudicating Plaintiffs' claims in their favor would penalize Defendants for declining to include labeling representations beyond what the [monograph] requires."); *Seale v. GSK Consumer Health, Inc.*, No. 2:23-CV-00842-ABM, 2024 WL 1040854, at *7 (C.D. Cal. Feb. 27, 2024) (omission-based claims preempted because they would impose "an actual requirement of . . . explicit disclosure" not mandated by FDA regulations); *Patora v. Vi-Jon, LLC*, No. 22-CV-6678, 2023 WL 5610300, at *5 (S.D.N.Y. Aug. 30, 2023) (claims that laxatives labels failed to include a warning for bacteria contamination preempted because the FDCA required no such warning); *Harris v. Topco Assocs., LLC*, 538 F. Supp. 3d 826, 831–33 (N.D. Ill. 2021) (claims alleging misleading omission of disclaimers not required by the monograph preempted). Here, too, Plaintiffs' claims based on the omission of warnings not required by the monograph are preempted because they "seek[] to impose a specific labeling requirement . . . that is not imposed by the FDA's monograph." *Seale*, 2024 WL 1040854, at *7.[8]

Finally, Plaintiffs' claims are not parallel or identical to the FDCA's bar on the sale of adulterated drugs, 21 U.S.C. § 331(a) (prohibiting "[t]he introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded"); *see also id.* § 351(a)(1) (defining adulterated drugs to include those that "consist[] in whole or in part of any filthy, putrid, or decomposed substance"). Plaintiffs do not allege that Defendants violated state law by *introducing* into the market a product (Proactiv) that was contaminated with benzene. While the FAC includes

[8] Contrary to Plaintiffs' argument at the hearing, the Court does not read out the "and" in 21 C.F.R. § 333.301, which requires an OTC drug product to comply with the monograph "and each general condition" in § 330.1, including Chapter V's misbranding bar in § 352(a). As explained above, Chapter V still prohibits Defendants from making misrepresentations about the safety of their drugs when they elect to go beyond the statements prescribed by the monograph.

allegations about adulterated drugs, Plaintiffs' claims are for failing to *disclose* the adulteration or risk thereof (i.e., the risk of benzene in the product). Dkt. No. 45 ¶¶ 305, 317–24, 331, 343, 345, 366, 372. Despite their claims, Plaintiffs argued at the hearing that Defendants are selling an inherently adulterated product—amounting to a criminal act—because BPO degrades into benzene. Not only is that argument inconsistent with the FDA's approval of BPO, it also contradicts the central theory of their FAC (i.e., false advertising for failure to warn) because no additional warning could transform a criminally adulterated drug into a legal, commercial product. Thus, the state laws prohibiting misleading advertisements on which Plaintiffs rely are not parallel or identical to the FDCA's prohibition on selling adulterated drugs.[9]

In sum, Plaintiffs seek to require Defendants to make disclosures not required under the FDCA that would conflict with the FDA's conclusion that BPO is safe and effective. Because Plaintiffs' claims would impose requirements that differ from and are in addition to those in the FDCA, they are preempted under § 379r.[10]

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[9] After the hearing, Plaintiffs filed a notice of the recent decision in *Williams v. Galderma Laboratories, L.P.*, No. 24-CV-2222, 2024 WL 4213220 (N.D. Ill. Sept. 17, 2024), which found that the plaintiff's claims were preempted to the extent they were based on a failure to warn of the presence of benzene on the product label or a failure to list benzene as an inactive ingredient on the product label. *Id.* at *3–4. However, the court found that the claim was not preempted under Seventh Circuit law to the extent that the complaint adequately alleged that "the reason [the product] contains benzene" was because the defendant failed to manufacture the product in compliance with the practices mandated by federal law. *Id.* at *5–6. Even assuming that this legal theory is viable under Ninth Circuit law, Plaintiffs have not alleged that the "presence of benzene in [Proactiv] stems" from the manufacturing process. *Id.* at *5. On the contrary, they allege that the cause is the inevitable degradation of BPO. *See supra* p. 6 and note 4 (describing allegations of the inherent instability of BPO and propensity to degrade into benzene).

[10] Plaintiffs briefly argue that their claims are not preempted because an FDA prohibition on warning consumers about the risks of BPOs would violate Defendants' First Amendment rights to speak truthfully about their products. The Court questions whether Plaintiffs have standing to raise Defendants' First Amendment rights as asserted—a question neither party has raised. Regardless, this case does not involve an FDA prohibition on speech Defendants wish to make.

IV.

In their opposition, Plaintiffs requested leave to amend. Dkt. No. 59 at 18. "The court should freely grant leave [to amend] when justice so requires." Fed. R. Civ. P. 15(a)(2). Leave may be denied, however, for reasons such as "undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, [or] futility of amendment." *Foman v. Davis*, 371 U.S. 178, 182 (1962).

As the Court concludes that Plaintiffs' claims are preempted by § 379r because their theory is fundamentally at odds with the FDA's conclusions about the safety of using BPOs in acne medications, it is not clear that Plaintiffs would be able to amend their pleading to state any viable claim. The Court noted this problem in its tentative order and directed that "Plaintiffs should be prepared at the hearing to identify the specific facts they intend to plead in a Second Amended Complaint and to explain why amendment would not be futile." At the hearing, Plaintiffs neither raised their request for leave to amend nor identified any facts that they would allege in an amended complaint that could overcome preemption. Because Plaintiffs have not even attempted to show that amendment would not be futile, the Court denies the conclusory request for leave to amend in their opposition, which they effectively abandoned at the hearing.

V.

Accordingly, the Defendants' motion to dismiss is granted. Plaintiffs' claims for injunctive relief are dismissed for lack of standing, and Plaintiffs' claims are otherwise dismissed on the merits as preempted.

The Court will separately issue a final judgment in each case.

Date: September 19, 2024

Stanley Blumenfeld, Jr.
United States District Judge

Cf. United States v. Caronia, 703 F.3d 149, 168–69 (2d Cir. 2012) (holding that prosecuting a drugmaker "for [truthful] speech promoting the lawful, off-label use of an FDA-approved drug" violates the First Amendment).