UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

Skylar Williams, individually and on behalf of all others similarly situated *Plaintiff*, v. Galderma Laboratories, L.P., *Defendant*.	No. 24 CV 2222 Judge Lindsay C. Jenkins

MEMORANDUM OPINION AND ORDER

Skylar Williams has sued Galderma Laboratories, L.P., alleging that the benzoyl peroxide in Galderma's Differin line of acne treatments degrades into benzene, a carcinogenic impurity, rendering Differin adulterated and misbranded. And because adulterated products are worthless, Galderma's sale of Differin to unaware consumers violates various state consumer protection statutes, including the Illinois Consumer Fraud and Deceptive Trade Practices Act ("ICFA"). Before the Court is Galderma's motion to dismiss, which primarily argues Williams's claims are preempted because Galderma complies with federal law in the manufacturing and labeling of Differin. For the following reasons, the motion is denied. Williams's ICFA claim may proceed on the theory benzene exists in Differin because Galderma does not adhere to current good manufacturing practices.

I. Background

Galderma manufactures, markets, and sells various over-the-counter ("OTC") acne treatment drugs under its Differin brand. [Dkt. 1 ¶¶ 1, 12, 18-19.] The active ingredient in all Differin products is benzoyl peroxide ("BPO"). [*Id.*] Skylar Williams

purchased Differin 5% BPO cream cleanser from a Walgreens in Illinois at some point in 2023. [*Id.* ¶ 9.] While shopping, Williams reviewed the product's label and noticed it "contained no representation that [it] contained or risked containing benzene." [*Id.* ¶ 10.]

On March 6, 2024, Valisure LLC, an analytical laboratory, announced that its testing revealed BPO in acne treatments is unstable at high temperatures and degrades into benzene, a known carcinogen. [*Id.* ¶¶ 37-38.] The tests involved exposing acne products with BPO, including the Differin product Williams purchased, to at least 37°C (98 degrees Fahrenheit) for several weeks at a time. Valisure then measured the amount of benzene in the product, and found it was well above the 2 parts per million permitted by the FDA. [*Id.* ¶¶ 41-42.] According to Valisure, "the benzene in benzoyl peroxide products is coming from the benzoyl peroxide itself" as opposed to "impurities" in "contaminated ingredients." [*Id.* ¶ 40.] That is, "the specific problem with benzene in benzoyl peroxide products does not appear to be a contamination issue from a specific ingredient, but instead the inherent instability of the benzoyl peroxide molecule that breaks down and forms benzene." [*Id.* ¶ 43.]

Armed with Valisure's findings, Williams sued Galderma. Williams alleges that the latent but inherent presence of benzene in Differin establishes Galderma did not comply with the Food and Drug Administration's ("FDA") current Good Manufacturing Practices ("cGMPs"), which would make the drugs misbranded and adulterated in violation of the Food, Drug and Cosmetics Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, as well as analogous state statutes and regulations. [*Id.* ¶¶ 49-60.]

Williams further alleges Differin was misbranded because its label does not mention benzene, either as a warning or as an ingredient. [*Id.* ¶¶ 61, 71.] Williams contends that she would not have purchased (or at least paid less for) Differin had she known she was purchasing an adulterated or misbranded product. [*Id.* ¶¶ 65, 68-69.] Williams argues Galderma's conduct constitutes both unfair and deceptive practices under ICFA, violates other state consumer protection statutes for the classes she hopes to represent, and that Galderma was unjustly enriched through the sale of Differin. [Dkt. 1 at 26-31.][1] Galderma now moves to dismiss the complaint. [Dkt. 21.]

II. Legal Standard

At the motion to dismiss stage, the Court takes well-pleaded factual allegations as true and draws reasonable inferences in favor of the plaintiff. *Choice v. Kohn L. Firm, S.C.*, 77 F.4th 636, 638 (7th Cir. 2023); *Reardon v. Danley*, 74 F.4th 825, 826-27 (7th Cir. 2023). "To survive a motion to dismiss under Rule 12(b)(6), plaintiff's complaint must allege facts which, when taken as true, plausibly suggest that the plaintiff has a right to relief, raising that possibility above a speculative level." *Cochran v. Ill. State Toll Highway Auth.*, 828 F.3d 597, 599 (7th Cir. 2016) (cleaned up). This occurs when "the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Garrard v. Rust-Oleum Corp.*, 575 F. Supp. 3d 995, 999 (N.D. Ill. 2021) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal citations omitted)).

[1] Citations to docket filings generally refer to the electronic pagination provided by CM/ECF, which may not be consistent with page numbers in the underlying documents.

III. Analysis

Galderma argues Williams's ICFA claim should be dismissed for two reasons. First, it is preempted because Galderma complied with all applicable federal law while manufacturing and labeling Differin. Second, it fails on the merits because Williams has not adequately alleged which cGMPs Galderma did not follow and how that caused Differin to contain benzene. And because her ICFA claim fails, so too must her other claims. The Court reviews each in turn.

A. Preemption

Galderma contends Williams's ICFA claim is preempted by federal law. Preemption is grounded in the Constitution's Supremacy Clause, and Congress has the authority to define how broadly its enactments preclude state law. *Novotney v. Walgreen Co.*, 683 F.Supp.3d 785, 788-89 (N.D. Ill. 2023) (citing *English v. Gen Elec. Co.*, 496 U.S. 72, 78 (1990)). Preemption is an affirmative defense, which plaintiffs need not anticipate or circumvent in their pleadings. *Bausch v. Stryker Corp.*, 630 F.3d 546, 561 (7th Cir. 2010). However, if "the allegations of the complaint itself set forth everything necessary to satisfy" preemption, then dismissal at the pleading stage is appropriate. *Sidney Hillman Health Ctr. of Rochester v. Abbott Lab'ys, Inc.*, 782 F.3d 922, 928 (7th Cir. 2015).

The FDCA governs the manufacturing, marketing, and labeling of OTC drugs such as Differin. 21 U.S.C. § 301 *et seq*. The FDCA's preemptive power is strong: states are prohibited from enforcing legislation that would impose requirements on drug manufacturers that are "different from … in addition to, or … otherwise not identical with, a requirement under the" FDCA. 21 U.S.C. § 379r(a); *see also Harris*

v. Topco Assocs., LLC, 538 F. Supp. 3d 826, 831 (N.D. Ill. 2021) (a plaintiff's right to bring state-law claims in this area "is tightly circumscribed by the FDCA's express preemption of state-law theories that impose requirements 'not identical' to its own requirements") (quoting *Benson v. Fannie May Confections Brands, Inc.*, 944 F.3d 639, 645 (7th Cir. 2019)). But preemption only extends to manufacturers that comply with federal law; state-law claims that are premised on a "parallel" violation of federal law may proceed. *Medtronic v. Lohr*, 518 U.S. 470, 495 (1996) (claims based on state law are permissible where the statute's duties "parallel federal requirements"); *Bausch*, 630 F.3d 546, at 552; *Barnes v. Unilever United States Inc.*, 2023 WL 2456385, at *5 (N.D. Ill. Mar. 11, 2023).

Put differently, whether Williams's ICFA claims are preempted turns on whether she has alleged Galderma's conduct is inconsistent with federal law. Williams points to three purported failures: (1) Galderma did not warn consumers of the presence of benzene on Differin's label; (2) Galderma did not list benzene as an inactive ingredient on the label; and (3) the presence of benzene in Differin is the result of Galderma not following cGMPs.

1. Benzene on the Label

Williams argues that Differin is misbranded under the FDCA because its label does not disclose or warn that it contains benzene. [Dkt. 26 at 12.] Federal labeling regulations do not require such a statement, however, so her ICFA claim on this basis is preempted.

The FDA is vested with "authority to promulgate regulations for the efficient enforcement" of the FDCA. 21 U.S.C. § 371(a); 21 U.S.C. § 393; *see also Novotney*, 683 F.Supp.3d at 789. Pursuant to this authority, the FDA allows manufacturers of OTC drugs to sell products without FDA review so long as the manufacturer adheres to the relevant monograph. 21 C.F.R. § 330.10. A monograph is a "recipe"; a "detailed regulation … for each therapeutic class of OTC drug products" that "sets out the FDA-approved active ingredients for a given therapeutic class of OTC drugs and provides the conditions under which each active ingredient is" generally recognized as safe and effective by the FDA. *NRDC v. FDA*, 710 F.3d 71, 75 (2d Cir. 2013). That is, for each drug type—such as OTC acne treatments—the FDA delineates approved active ingredients, and accompanying labeling and other requirements to which manufacturers must adhere. This process allows the FDA to provide comprehensive parameters for a certain class of drugs instead of approving each drug individually.

The upshot of these regulations is that a drug that complies with all monograph requirements is not misbranded. 21 C.F.R. § 330.10(a)(1) ("The Commissioner shall … evaluate the safety and effectiveness of OTC drugs, to review OTC drug labeling, and to advise him on the promulgation of monographs establishing conditions under which OTC drugs are generally recognized as safe and effective and not misbranded"); *see also* 21 C.F.R. § 333.301(a) ("An over-the-counter acne drug product in a form suitable for topical application is generally recognized as safe and effective and is not misbranded if it meets each of the conditions in this subpart and each general condition established in § 330.1 of this chapter.")

The relevant monograph for acne drugs lists BPO as a permitted active ingredient and does not require manufacturers to warn consumers of benzene, or mention benzene in any capacity on the label.[2] U.S. Food & Drug Admin., Over-the-Counter (OTC) Monograph M006: Topical Acne Drug Products for Over-the-Counter Human Use[3]; *see also* 21 C.F.R. § 333.310(a); 21 C.F.R. § 333.350(c)(4). The FDA's monograph "allows [topical acne drugs] to be formulated with the active ingredient [BPO] and does not require disclosure that [BPO] may degrade into [benzene]." *Truss v. Bayer Healthcare Pharms. Inc.*, 2022 WL 16951538, at *4 (S.D.N.Y. Nov. 15, 2022).

Williams's allegation that Galderma should have warned about the presence of benzene on Differin's label is therefore preempted because it would be an "addition" not required by federal law. 21 U.S.C. § 379r(a); *Turek v. General Mills, Inc.*, 662 F.3d 423, 427 (7th Cir. 2011) (plaintiff's demand for a statement on the label was preempted because it was "not identical to the labeling requirements imposed on such products by federal law"); *Bell v. Publix Super Markets, Inc.*, 982 F.3d 468, 484 (7th Cir. 2020) ("the FDCA preempt[s] the plaintiffs' attempt to use state law to require that disclosure language be added to a food label when federal regulations did not explicitly require it"); *Harris*, 538 F.Supp.3d 826 at 833 (preemption is proper where plaintiff "is asking more than what [federal regulations] require"); *Novotney*, 683 F.Supp.3d 785 (same).

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[2] The Court may take judicial notice of regulatory materials such as monographs. *Perez v. Staples Contract & Commer. LLC*, 31 F.4th 560, 574 n. 6 (7th Cir. 2022).

[3] https://www.accessdata.fda.gov/drugsatfda_docs/omuf/OTC%20Monograph_M006-Topical%20Acne%20drug%20products%20for%20OTC%20Human%20Use%2011.23.2021.pdf

2. Benzene as an Inactive Ingredient

Williams next contends Galderma violated federal law when it did not list benzene as an inactive ingredient on Differin's label. [Dkt. 26 at 7-9.] Because Galderma does not intend for benzene to end up in Differin, however, this argument fails.

Federal regulations require drug manufacturers to list all active and inactive ingredients on the drug's label. 21 C.F.R. § 201.66(c). Active ingredients, such as BPO, are those that are "intended to furnish pharmacological activity" in the human body. *Id.* (b)(2). Inactive ingredients, by contrast, are "any component other than an active ingredient." *Id.* (b)(8).

Whether Galderma needed to list benzene as an inactive ingredient on Differin's label turns on whether benzene is a "component." That term is not defined in part 201, which relates to labeling requirements. Component is defined, however, in a different portion of the same subchapter related to manufacturing: "Component means any ingredient intended for use in the manufacture of a drug product, including those that may not appear in such drug product." 21 C.F.R. § 210.3(b)(3). If this definition is used, then benzene is not an inactive ingredient because it is not intended for use; it is an "unintended contaminant." *Barnes*, 2023 WL 2456385, at *7 (citing *Truss*, 2022 WL 16951538, at *4)).

Like the plaintiff in *Barnes*, Williams argues that the definition of component in the manufacturing subpart should not be applied in the labeling context.[4] [Dkt. 26

[4] The Court notes there is substantial overlap between Williams's counsel in this case, and counsel for the plaintiff in *Barnes*.

at 8-9.] According to Williams, there is a salient difference between manufacturing and labeling because the former "is about the process", whereas the latter is "about the final result." [*Id.* at 9.] Williams asks the Court to instead apply the common definition of "component", which would include benzene (and, theoretically, every other conceivable chemical compound that may be present in Differin). [*Id.*]

The Court is unpersuaded for the same reasons as those articulated in *Barnes*. First, both part 210 and 201 "are within the same subchapter regulating drugs, and 21 C.F.R. § 210.3(b)(3) provides the only definition of 'component' within the subchapter." *Barnes*, 2023 WL 2456385, at *7. Second, when the FDA added the definition of "inactive ingredient" to part 201, it noted "that the definition 'is identical to the definition in the agency's good manufacturing practice regulations in 21 CFR 210.3(b)(8)." *Id.* (quoting Over-The-Counter Human Drugs; Labeling Requirements, 64 Fed. Reg. 13254, 13258 (Mar. 17, 1999)). And because "the FDA notes that the definitions are identical, it follows that the term 'component' used in both definitions was intended to have the same meaning." *Id.* The Court disagrees with Williams that the mere fact that manufacturing and labeling are different steps in the process of bringing a drug to market means that the FDA wanted to use distinct definitions for the same term. Rather, the Court believes it makes more sense for the FDA to impose consistent requirements and definitions on manufacturers, and Williams does not point to any authority to the contrary.

Accordingly, benzene is not an inactive ingredient under federal law, and Galderma was therefore not required to list it on Differin's label. Williams's ICFA claim cannot proceed on that basis.

3. Benzene as a result of cGMP Violations

The Court now turns to Williams's argument that the presence of benzene in Differin stems from Galderma's failure to adhere to cGMPs. [Dkt. 26 at 10-11.] A state-law claim based on this theory is not preempted because it alleges a violation of federal law; drugs are considered adulterated when not manufactured in accordance with cGMPs. *See* 21 U.S.C. § 331(a); 21 C.F.R. § 351(a)(2)(B).

The Seventh Circuit has held that parallel state claims can proceed based on general cGMP violations, and that a plaintiff need not point to a drug-specific requirement. *Bausch*, 630 F.3d 546, at 554-56 ("Current Good Manufacturing Practices adopted by the FDA under its delegated regulatory authority are legally binding requirements" and can support a state-law claim); *Barnes*, 2023 WL 2456385, at *5-6 (plaintiff's allegations that defendant violated cGMPs in manufacturing drug "are accordingly parallel to federal law under *Bausch* because the claims do not impose any requirements that differ from federal law … [and] are not preempted under 21 U.S.C. § 379r(a).")

Galderma concedes that cGMP violations can serve as the foundation for a parallel claim, but argues Williams cannot do so here because she has not adequately alleged Galderma failed to comply with cGMPs or how that failure caused her harm.

[Dkt. 22 at 11-12.] This argument goes to the merits of Williams's claims, which the Court addresses below.

In sum, Williams's ICFA claim is preempted to the extent she argues Galderma should have mentioned benzene on Differin's label—either as a warning or as an inactive ingredient—but is not preempted based on Galderma's alleged failure to comply with cGMPs.[5]

B. Merits of ICFA Claim

Having determined which of Williams's ICFA theories survive preemption, the Court turns to whether Williams has adequately alleged that theory on the merits. The Court concludes she has.

A plaintiff may bring an ICFA claim based on either unfair or deceptive practices, which are to be construed "liberally." *Robinson v. Toyota Motor Credit Corp.*, 775 N.E. 2d 951, 960 (Ill. 2002). In determining whether a practice is "unfair", courts are instructed to look to three factors: "(1) whether the practice offends public policy; (2) whether it is immoral, unethical, oppressive, or unscrupulous; [or] (3) whether it causes substantial injury to consumers." *Id.* at 961; *see also Vanzant v. Hill's Pet Nutrition, Inc.*, 934 F.3d 730, 738-39 (7th Cir. 2019). "A plaintiff need not satisfy all three factors; a practice may be unfair because of the degree to which it meets one of the criteria or because to a lesser extent it meets all three." *Vanzant*,

[5] Because a violation of cGMPs is not "specifically authorized by laws administered by any regulatory body or officer acting under statutory authority of this State or the United States", ICFA's safe harbor is inapplicable. *See* 815 ILCS 505/10b(1); [Dkt. 22 at 11-12.]

934 F.3d 730, at 739. Public policy may be "established by statutes, the common law, or otherwise." *Drs. Direct Ins., Inc. v. Bochenek*, 2015 IL App (1st) 142919, ¶ 34.

Once again, the Court finds *Barnes* instructive. In that case, the plaintiff alleged an OTC deodorant contained benzene because its manufacturer failed to comply with cGMPs related to testing and screening, rendering the product adulterated. *Barnes*, 2023 WL 2456385, at *1-2. The court held "allegations that Unilever put adulterated and therefore dangerous products into the marketplace without adequate testing or screening—which is the gist of Barnes's claim—are sufficient to state a claim for an unfair practice violative of the ICFA." *Id.* at *2. The court noted that a violation of cGMP requirements is a violation of federal law and therefore offends public policy. *Id.* at *3.

Williams's allegations in this case track closely to Ms. Barnes's. Here, Williams contends Galderma's failure to adhere to cGMPs in manufacturing Differin is the reason Differin contains benzene. [Dkt. 1 ¶ 60 ("[t]he mere presence of benzene—which, upon information and belief, resulted from Defendant's failure to comply with cGMPs—renders the Products both adulterated and misbranded under the FDCA").] That is, the violation of at least one federal regulation caused Williams's harm.

As mentioned above, Galderma argues dismissal is required because Williams has not alleged which cGMP regulations Galderma violated, and how that violation led to benzene in Differin.[6] [Dkt. 22 at 12.] But reviewing the complaint as a whole

[6] Galderma also argues that Williams has failed to allege Galderma knew Differin contained benzene, but this argument is limited to an ICFA claim based on a deceptive practice. [Dkt. 22 at 13-14.] Williams's unfair practice claim related to cGMPs is not based

and drawing reasonable inferences in Williams's favor, *Garrard*, 575 F. Supp. 3d 995, at 999, the Court finds she has met her pleading burden.

Williams alleges that the scientific community has known for at least the past 30 years that BPO can decompose into benzene at warm temperatures, and that the presence of certain antioxidants can retard benzene formation. [Dkt. 1 ¶¶ 25-26.] Acknowledging benzene's harmful impact on humans, the FDA prohibits the use of benzene in drugs unless it is unavoidable (which is not the case for topical acne treatments), and only then at 2 parts per million. [*Id.* ¶¶ 29-30.] Valisure's testing—which included placing Differin at a temperature equivalent to the inside of the human body or a storage container for a few weeks—showed benzene in concentrations well above FDA-approved levels. [*Id.* ¶¶ 41-42.]

Williams's complaint also cites to federal cGMP requirements demonstrating that Galderma has an obligation to ensure its drugs meet "the requirements of the act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess." [*Id.* ¶ 50]; 21 C.F.R. § 210.1(a). Williams points to specific cGMPs regarding laboratory controls, tests, and testing records, which also demand product safety and quality. [*Id.* ¶¶ 53-55.] In essence, Williams argues that given the known link between BPO and benzene, Galderma could not have complied with cGMP testing and safety requirements because had they done so, Galderma would have detected benzene. While the Court

on a deceptive omission. *See Barnes*, 2023 WL 2456385, at *5-6 ("Barnes's unfair practices claims arise from the manufacturer's alleged failure to use reasonable care in the production of the product.") (citation omitted).

appreciates Galderma's position that Williams's argument relies to some extent on "*ipso facto* reasoning", [Dkt. 22 at 11], the facts alleged plausibly suggest Williams is entitled to relief. *Cochran*, 828 F.3d 597, at 599; *see also Barnes*, 2023 WL 2456385 at *2.

C. Other Consumer Protection Statutes and Unjust Enrichment

Briefly, because Galderma's ICFA claim survives, so too do her claims for the consumer protection laws of other states and unjust enrichment. *See e.g., Bojko v. Pierre Fabre USA Inc.*, 2023 WL 4204663, at *9 (N.D. Ill. June 27, 2023) (declining to dismiss consumer protection states from other states where ICFA claim survived); *Vanzant*, 934 F.3d 730, at 740 (a claim for unjust enrichment under Illinois law is "a condition brought about by fraud or other unlawful conduct" and is therefore "tied to the fate of the [ICFA] claim.")

IV. Conclusion

For the reasons stated herein, Galderma's motion to dismiss is denied, although Williams will only be permitted to proceed on the theory that Galderma's failure to comply with cGMPs was an unfair practice under ICFA.

Enter: 24 CV 2222
Date: September 17, 2024

Lindsay C. Jenkins
United States District Judge