UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF MICHIGAN, SOUTHERN DIVISION

Moussa Kouyate v. L. Perrigo Company, et al.

Kouyate · No. 1:25-cv-1013 · Decided March 3, 2026

SUMMARY

The United States District Court for the Western District of Michigan considers a motion to dismiss claims concerning Perrigo-branded benzoyl peroxide acne products allegedly containing benzene. The court holds that the plaintiff adequately alleged Article III standing, including standing to represent the proposed nationwide class. It dismisses the claims as preempted by the Federal Food, Drug, and Cosmetic Act because they would impose requirements beyond those established by the FDA monograph.

CASE DETAILS

COURT	United States District Court for the Western District of Michigan, Southern Division
WRITING FOR THE COURT	Hala Y. Jarbou
JURISDICTION	United States District Court for the Western District of Michigan, Southern Division
DECIDED	March 3, 2026
DOCKET	1:25-cv-1013
DISPOSITION	dismissed
PROCEDURAL POSTURE	Defendant Padagis US, LLC moved to dismiss the complaint under Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6), asserting that Plaintiff lacked Article III standing, failed to state claims, and was preempted by federal law.
STANDARD OF REVIEW	For a facial Rule 12(b)(1) attack, the court accepts well-pleaded allegations as true and determines whether the complaint establishes subject-matter jurisdiction. Under Rule 12(b)(6), the court construes the complaint in the plaintiff's favor, accepts well-pleaded factual allegations as true, and asks whether the complaint states a facially plausible claim for relief.
PRECEDENTIAL VALUE	persuasive

TOPICS

fda regulation | consumer protection | motions to dismiss | standing | statutory interpretation

PRACTICE AREAS

consumer protection | food and drug law | civil procedure | federal jurisdiction | class actions

QUESTIONS PRESENTED

1. Whether Kouyate adequately alleged an actual injury sufficient for Article III standing when he did not test the specific product units he purchased.
2. Whether Kouyate had standing to assert claims on behalf of a proposed nationwide class involving products purchased in other states and claims arising under other states' laws.
3. Whether Kouyate's state-law claims were expressly or impliedly preempted by the Federal Food, Drug, and Cosmetic Act and its regulations.
4. Whether alleged benzene resulting from benzoyl-peroxide degradation constituted a decomposed substance, a misbranding issue, or an inactive ingredient requiring disclosure under federal law.
5. Whether alleged violations of current good manufacturing practices supplied a non-preempted basis for the state-law claims.

HOLDINGS

1. A plaintiff adequately alleges an actual injury at the pleading stage when the complaint plausibly alleges that the products purchased were contaminated, even though the plaintiff did not test the specific units purchased.
2. Kouyate adequately alleged standing to represent proposed class members whose purchases occurred in other states and whose claims arose under different state laws because the alleged injuries were essentially the same.
3. Kouyate's state-law claims were preempted because success on those claims would impose labeling, ingredient, safety, or manufacturing requirements different from or additional to the requirements established by the FDCA and the FDA's acne-product monograph.
4. Benzene allegedly formed through thermal decomposition of benzoyl peroxide is not a 'decomposed substance' within the natural meaning of 21 U.S.C. § 351(a)(1).
5. The alleged benzene was not an inactive ingredient required to be listed under 21 C.F.R. § 201.66 because it was alleged to be an accidental byproduct rather than an ingredient intended for use in manufacturing the drug product.

KEY QUOTATIONS

> *“In short, to avoid preemption, a plaintiff must bring a claim that (1) would be cognizable under state law regardless of the existence of the FDCA, but (2) is based on actions that violate the FDCA or its associated regulations.”*

> *“In short: to allege standing, Kouyate must assert that benzene degradation is universal; but this assertion entails that BPO is inherently dangerous, and any claims based on the inherent dangers of BPO are preempted by the FDA’s finding to the contrary.”*

> *“Kouyate has standing to sue on behalf of himself and proposed class members, but his claims are preempted because they impose a requirement on Padagis that exceeds those imposed by the FDCA.”*

FACTUAL BACKGROUND

Kouyate alleged that he purchased Perrigo benzoyl-peroxide acne-treatment gel manufactured or sold by Padagis and that the product contained benzene created when benzoyl peroxide degraded under ordinary distribution and storage conditions. He relied primarily on Valisure testing, which allegedly detected benzene in many benzoyl-peroxide products, including a Perrigo product. He claimed that the product was unsafe and economically worthless because its labeling did not disclose the alleged benzene risk, and asserted New York and other state consumer-protection, warranty, misrepresentation, and unjust-enrichment claims on behalf of proposed classes.

PROCEDURAL HISTORY

Kouyate filed a putative nationwide class action concerning Perrigo-branded benzoyl-peroxide acne products allegedly contaminated with benzene. Perrigo was dismissed by stipulation, leaving Padagis as the operative defendant. The district court held that Kouyate adequately alleged individual and putative-class standing but dismissed all claims as preempted by the Federal Food, Drug, and Cosmetic Act.

DISPOSITION

dismissed

CASES CITED

- Association of American Physicians & Surgeons v. FDA, 13 F.4th 531, 536 (6th Cir. 2021)
- Murray v. U.S. Department of Treasury, 681 F.3d 744, 748 (6th Cir. 2012)
- Lujan v. Defenders of Wildlife, 504 U.S. 555, 561 (1992)
- Hein v. Freedom from Religion Foundation, Inc., 551 U.S. 587, 598 (2007)
- Kanuszewski v. Michigan Department of Health & Human Services, 927 F.3d 396, 405 (6th Cir. 2019)
- Ohio National Life Insurance Co. v. United States, 922 F.2d 320, 325 (6th Cir. 1990)
- RMI Titanium Co. v. Westinghouse Electric Corp., 78 F.3d 1125, 1134 (6th Cir. 1996)
- Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555, 570 (2007)
- Conley v. Gibson, 355 U.S. 41, 47 (1957)
- Ashcroft v. Iqbal, 556 U.S. 662, 678-79 (2009)
- Parrino v. Price, 869 F.3d 392, 397 (6th Cir. 2017)
- Spokeo, Inc. v. Robins, 578 U.S. 330, 339 (2016)
- Ward v. J.M. Smucker Co., No. 24-3387, 2025 WL 2613489, at *1-*3 (6th Cir. Sept. 10, 2025)

- Howard v. Alchemee, LLC, No. 2:24-CV-01834-SB-BFM, 2024 WL 4272931, at *3, *7-*8 (C.D. Cal. Sept. 19, 2024)
- Huertas v. Bayer US LLC, 120 F.4th 1169, 1179 (3d Cir. 2024)
- Hirsch v. L'Oreal USA, Inc., No. 1:22-cv-06569, 2025 WL 1540857, at *3 (N.D. Ill. May 29, 2025)
- Pineda v. Lake Consumer Products, Inc., No. 5:24-CV-1074-JMG, 2024 WL 5001928, at *5 (E.D. Pa. Dec. 5, 2024)
- Bledsoe v. FCA US LLC, 378 F. Supp. 3d 626, 632 (E.D. Mich. 2019)
- Smith v. Lawyers Title Insurance Corp., No. 07-12124, 2009 WL 514210, at *3 (E.D. Mich. Mar. 2, 2009)
- In re Packaged Ice Antitrust Litigation, 779 F. Supp. 2d 642, 656-57 (E.D. Mich. 2011)
- Generation Changers Church v. Church Mutual Insurance Co., 693 F. Supp. 3d 795, 804 (M.D. Tenn. 2023)
- Walton v. Grammer Industries, Inc., No. 2:20-CV-12298-TGB-RSW, 2021 WL 4458761, at *4 (E.D. Mich. Sept. 29, 2021)
- Generation Changers Church v. Church Mutual Insurance Co., No. 24-5700, 2026 WL 497220, at *3-*4 (6th Cir. Feb. 23, 2026)
- Speerly v. General Motors, LLC, 143 F.4th 306, 340-43 (6th Cir. 2025) (Thapar, J., concurring)
- Blum v. Yaretsky, 457 U.S. 991, 999-1001 (1982)
- Gratz v. Bollinger, 539 U.S. 244, 263 & n.15 (2003)
- Sosna v. Iowa, 419 U.S. 393, 403 (1975)
- Morales v. Trans World Airlines, Inc., 504 U.S. 374, 383 (1992)
- Collaza v. Johnson & Johnson Consumer Inc., No. 24-2568-CV, 2025 WL 2233746, at *2-*3 (2d Cir. Aug. 6, 2025)
- McDaniel v. Upsher-Smith Laboratories, Inc., 893 F.3d 941, 944 (6th Cir. 2018)
- Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341, 353 (2001)
- Loreto v. Procter & Gamble Co., 515 F. App'x 576, 579 (6th Cir. 2013)
- Goldstein v. Walmart, Inc., 637 F. Supp. 3d 95, 113 n.7 (S.D.N.Y. 2022)
- Howard v. Sulzer Orthopedics, Inc., 382 F. App'x 436, 441 (6th Cir. 2010)
- Clinger v. Edgewell Personal Care Brands, LLC, No. 3:21-CV-1040 (JAM), 2023 WL 2477499 (D. Conn. Mar. 13, 2023)
- Smoter v. Mentholatum Co., Inc., No. 24 CV 4155, 2025 WL 273437, at *2 (N.D. Ill. Jan. 17, 2025)
- Williams v. Galderma Laboratories, L.P., No. 24 CV 2222, 2024 WL 4213220, at *4-*5 (N.D. Ill. Sept. 17, 2024)
- Barnes v. Unilever U.S. Inc., No. 21 C 6191, 2023 WL 2456385, at *7 (N.D. Ill. Mar. 11, 2023)
- Navarro v. Walgreens Boots Alliance, Inc., No. 1:24-CV-00290-JLT-SAB, 2025 WL 1411406, at *13 (E.D. Cal. May 15, 2025), adopted, 2025 WL 3485004 (E.D. Cal. Dec. 4, 2025)

OPINION

UNITED STATES DISTRICT COURT WESTERN DISTRICT OF MICHIGAN SOUTHERN DIVISION MOUSSA KOUYATE, Plaintiff, Case No. 1:25-cv-1013 v. Hon. Hala Y. Jarbou L.

PERRIGO COMPANY, et al., Defendants. _____/ OPINION This case is one of a series of class action lawsuits alleging that acne treatment products with benzoyl peroxide ("BPO") as an active ingredient may inadvertently contain benzene, a dangerous carcinogen.

Plaintiff Moussa Kouyate brings this suit on behalf of a proposed class against Defendant Padagis US, LLC, for its manufacture and sale of Perrigo-branded acne treatments. Kouyate asserts claims under New York's General Business Law and various state consumer fraud statutes, as well as claims for breach of implied warranty, negligent misrepresentation, and unjust enrichment.

Padagis now moves to dismiss under Rules 12(b)(1) and 12(b)(6), arguing that Kouyate lacks Article III standing, his complaint fails to state a claim, and his claims are preempted by federal law. As explained below, the Court finds that Kouyate has standing but that his claims are preempted.

Thus, the Court will grant the motion to dismiss. I. BACKGROUND L. Perrigo Company1 sells multiple products containing benzoyl peroxide, including "Perrigo® Benzoyl Peroxide Acne Treatment Gel 5%." (Compl. ¶ 20, ECF No. 1.) Padagis was 1 Perrigo was initially a defendant in this case but has been dismissed by stipulation. (See ECF No. 41.) formerly part of Perrigo and "manufactured, distributed, and/or sold" these BPO products until 2021, when it split off from Perrigo.

(See id. ¶¶ 16, 20.) BPO is common in over-the-counter acne treatments because of its antiseptic effects. (Id. ¶ 21.) When exposed to sufficient heat, BPO can degrade into benzene. (Id. ¶ 34.)2 This degradation can be caused by the "elevated temperatures... that can be encountered in a hot shipping container, truck, or car." (Id.) Benzene is a chemical that can be found in crude oil, gasoline, and cigarette smoke.

(Id. ¶ 24.) "The Department of Health and Human Services has determined that benzene causes cancer in humans." (Id.) In particular, benzene has been linked to blood cancers like leukemia, as well as anemia and immune system damage. (Id.) According to the Food and Drug Administration (FDA), benzene "should not be employed in the manufacture of drug substances, excipients, and drug products because of [its] unacceptable toxicity." (Id. (alteration in original).)

Benzene can be absorbed through the skin, and FDA studies have indicated that benzene in skincare products can end up in the bloodstream. (Id. ¶¶ 30–32.) Kouyate claims that the BPO in Perrigo's products degrades into benzene under conditions that occur regularly during the distribution process. (See id. ¶ 22.) Kouyate's primary basis for this claim is a series of laboratory tests performed by Valisure, LLC. (Id.)

Valisure monitors the safety of medicines and supplements; it frequently submits citizen petitions to the FDA based on its testing of consumer products, and these petitions have led to eight recalls.

(Id. ¶¶ 42–43.)

In 2024, Valisure tested 99 products containing BPO as an active ingredient and found that 94 contained benzene. (Id. ¶ 48.) The company then tested 66 of these products over a longer period after exposing them to various temperatures. (Id. ¶¶ 55–56.) Valisure's results indicate that 2 To be more specific, a BPO molecule thermally decomposes into two benzoic acid radicals.

(Id. ¶ 35.) The benzoic acid radicals themselves can decompose into benzene radicals and carbon dioxide, and the benzene radicals, through the process of "hydrogen abstraction," can become benzene. (Id.) Perrigo 5% BPO acne treatment gel contained 14 parts per million (ppm) of benzene when initially tested—i.e., before being exposed to additional heat. (Id. ¶ 57.)

Studies suggest that exposure to any quantity of benzene can be harmful (id. ¶ 25), and the FDA has indicated that if benzene is necessary for a "significant therapeutic advance," its quantity should be limited to 2 ppm (id. ¶ 29).

After its testing, Valisure filed a citizen petition with the FDA in March 2024, requesting a recall of the products in which it had found benzene. (Id. ¶ 47.) On March 11, 2025, the FDA indicated that it had tested 95 BPO products and found elevated benzene levels in only 6 of them. (Id. ¶ 62.) Perrigo's product was not one of the six with elevated benzene levels; the FDA did not release a list of the other 89 products that it tested, so it is unclear whether Perrigo's was among them.

(Id.) The companies that made those six products issued voluntary recalls, as did an additional company that found benzene in its own acne treatment product. (Id. ¶¶ 62–63.) Kouyate alleges that he has previously bought Perrigo 5% BPO acne treatment gel, and that the product contained no warnings as to the possible presence of benzene. (Id. ¶ 12.) He avers that because these products contained benzene, they were unsafe and therefore economically worthless.

(Id. ¶ 13.) He seeks to represent a nationwide class of people who have bought Perrigo acne treatment gel, as well as subclasses of people who bought the products in New York or in any of several states with specific consumer fraud statutes. (Id. ¶¶ 107–09.) Kouyate brings claims for deceptive and unfair business practices in violation of New York law, N.Y.

Gen. Bus. Law § 349 (Count I); false advertising in violation of New York law, N.Y. Gen. Bus. Law § 350 (Count II); deceptive and unfair business practices in violation of consumer protection statutes in California, Florida, Illinois, Massachusetts, Michigan, Minnesota, Missouri, New Jersey, and Washington (Count III); breach of implied warranty (Count IV); negligent misrepresentation (Count V); and unjust enrichment (Count VI).

II. LEGAL STANDARD A. Rule 12(b)(1) Article III of the Constitution grants federal courts the authority "to decide 'Cases' or 'Controversies' between litigants." Ass'n of Am. Physicians &

Surgeons v. FDA, 13 F.4th 531, 536 (6th Cir. 2021) (quoting U.S. Const. art. III, § 2). If a plaintiff lacks standing to sue, then a case or controversy does not exist, and the court lacks jurisdiction.

See Murray v. U.S. Dep't of Treasury, 681 F.3d 744, 748 (6th Cir. 2012). "The party invoking federal jurisdiction bears the burden of establishing" standing. Lujan v. Defs. of Wildlife, 504 U.S. 555, 561 (1992). To establish standing, a plaintiff must "allege personal injury fairly traceable to the defendant's allegedly unlawful conduct and likely to be redressed by the requested relief." Murray, 681 F.3d at 748 (quoting Hein v. Freedom from Religion Found., Inc., 551 U.S. 587, 598 (2007)).

Because standing is a jurisdictional issue, it "must be addressed as a threshold matter." Kanuszewski v. Mich. Dep't of Health & Hum. Servs., 927 F.3d 396, 405 (6th Cir. 2019). The standard for evaluating a motion to dismiss under Rule 12(b)(1) depends on the nature of the "attack" on subject matter jurisdiction. A "facial attack" on subject matter jurisdiction "merely questions the sufficiency of the [complaint]." Ohio Nat'l Life Ins.

Co. v. United States, 922 F.2d 320, 325 (6th Cir. 1990). The Court accepts the plaintiff's well-pleaded allegations as true and asks whether subject matter jurisdiction exists based on the complaint. Id. No presumption of truth applies in a "factual attack" on subject matter jurisdiction. Id. Factual attacks challenge the existence of jurisdiction based on facts outside the pleadings.

RMI Titanium Co. v. Westinghouse Elec. Corp., 78 F.3d 1125, 1134 (6th Cir. 1996). Here, because Padagis argues that the complaint is insufficient to establish standing, the Court will treat its motion as raising a facial attack. B. Rule 12(b)(6) Under Rule 12(b)(6) of the Federal Rules of Civil Procedure, a complaint may be dismissed for failure to state a claim if it fails "to 'give the defendant fair notice of what the... claim is and the grounds upon which it rests.'" Bell Atl.

Corp. v. Twombly, 550 U.S. 544, 555 (2007) (alteration in original) (quoting Conley v. Gibson, 355 U.S. 41, 47 (1957)). While a complaint need not contain detailed factual allegations, a plaintiff's allegations must include more than labels and conclusions. Twombly, 550 U.S. at 555; Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) ("Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.").

The Court must determine whether the complaint contains "enough facts to state a claim to relief that is plausible on its face." Twombly, 550 U.S. at 570. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Iqbal, 556 U.S. at 679.

When considering a motion to dismiss under Rule 12(b)(6), courts "construe the complaint in the light most favorable to the plaintiff, accepting all well-pleaded factual allegations as true." Parrino v. Price, 869 F.3d 392, 397 (6th Cir. 2017). III. ANALYSIS A. Standing 1. Individual Claims Padagis contends that Kouyate lacks standing to sue because he has failed to allege an injury that

is “actual or imminent,” as opposed to “conjectural or hypothetical.” Spokeo, Inc. v. Robins, 578 U.S. 330, 339 (2016), as revised (May 24, 2016).

Kouyate’s alleged harms—buying products that were unsafe and therefore worthless, and being deceived by false advertising—rely on the assumption that the Perrigo products he bought contained benzene. But, as Padagis points out, Kouyate did not test any units that he bought. Instead, Kouyate infers that the units he purchased must have contained benzene because Valisure tested a unit of the same product and found benzene.

Padagis argues that such an inference is unwarranted, as the particular unit Valisure tested could have been affected by unique environmental factors that caused the BPO to degrade. Accepting Kouyate’s allegations as true, the Court is satisfied that he has established actual injury. Kouyate alleges that the BPO in Perrigo’s products can degrade to benzene at “temperatures that the Products are exposed to during distribution and handling.” (Compl. ¶ 22.)

He also avers that Padagis “always manufactured, stored and transported the Products in the same manner and all lots are thus prone to the same forms of degradation through temperature and time.” (Id. ¶ 23.) Moreover, Valisure found benzene in almost every BPO product it tested. Putting these facts together, it is reasonable to infer that Valisure’s test was not a fluke, and that benzene can be generally found in Perrigo’s BPO acne treatment products.

Of course, Padagis may dispute this factual claim, and the FDA’s testing suggests that benzene is not as prevalent in BPO products as Valisure’s findings indicate. But these are fact issues that would be improper to resolve on a motion to dismiss. Padagis points to Ward v. J.M. Smucker Co., where the Sixth Circuit held that the plaintiffs failed to establish standing related to a claim of contaminated peanut butter.

No. 24-3387, 2025 WL 2613489, at *3 (6th Cir. Sept. 10, 2025). After a salmonella outbreak that impacted 16 people, defendant J.M. Smucker recalled a product line that contained peanut butter purchased by the plaintiffs. Id. at *1.

The plaintiffs then sued Smucker, alleging that they had purchased contaminated peanut butter. Id. at *2. The Sixth Circuit dismissed the case because the plaintiffs did not “allege facts sufficient to raise a plausible inference of contamination” as to the products they had bought. Id. The court reasoned that “[a] product recall, by itself, does not suffice to raise a plausible inference of contamination,” and noted that “Plaintiffs do not offer any allegations suggesting sufficiently widespread or extensive contamination, such as allegations regarding sampling, testing, or other pertinent data or information.” Id. at *3.

Thus, while “it [was] possible that one or more Plaintiffs purchased contaminated peanut butter,” this “mere possibility [was] not enough” to establish standing. Id. Ward is distinguishable from this case because Kouyate has sufficiently alleged “widespread or extensive contamination.” In

Ward there was no reason to think that the salmonella outbreak extended to every unit Smucker sold.

Here, Kouyate alleges a common cause—exposure to heat during distribution—that would plausibly cause every Perrigo product at issue to suffer the same benzene contamination as the particular unit tested by Valisure. This is enough to reasonably infer that the products purchased by Kouyate were contaminated. See Howard v. Alchemee, LLC, No. 2:24-CV-01834-SB-BFM, 2024 WL 4272931, at *3 (C.D.

Cal. Sept. 19, 2024) (standing existed where plaintiffs alleged "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"). Padagis also cites Huertas v. Bayer US LLC, 120 F.4th 1169 (3d Cir.

2024), a benzene contamination case that was discussed by the Sixth Circuit in Ward, but Huertas provides little support for Padagis's position. There, the district court held that the plaintiffs lacked standing because Valisure's discovery of benzene in some of the defendant's products did not entail that the specific units bought by the plaintiffs also had benzene.

However, the Third Circuit reversed and held that the plaintiffs had sufficiently alleged standing. Padagis argues that Huertas nonetheless supports their position because the Third Circuit only reversed due to additional evidence of widespread benzene contamination that had not been available to the district court— namely, that the defendant had found benzene in its own products.

But the Huertas opinion provides mixed signals as to whether the Third Circuit would have agreed with the district court's holding in the absence of this additional evidence. The Third Circuit acknowledged that, without the additional evidence, it "might still have [had] reservations about the reasonable inferences that could be drawn from Plaintiffs' allegations." Id. at 1179.

But it also "conclude[d] that the District Court's reasoning was flawed" because it improperly "require[d] a showing that all products in the recall were contaminated," which "would impose a heightened standard requiring that it be more likely than not—or probable—that Plaintiffs purchased a defective product." Id. Thus, Huertas arguably supports Kouyate's position rather than Padagis's.

Moreover, here Kouyate has a stronger case for standing because he alleges a specific cause of benzene contamination— namely, the presence of BPO in Padagis's products. In Huertas, by contrast, the source of the contamination was apparently unknown, making it unclear whether test results from a few units could be extrapolated to the entire product line.

For similar reasons, the other cases cited by Padagis are distinguishable. In Hirsch v. L'Oreal USA, Inc., the court dismissed the case because the plaintiff did not "plead facts suggesting that contamination of [the defendant's] products was sufficiently systemic and widespread to plausibly affect any given unit." No. 1:22-cv-06569, 2025 WL 1540857, at *3 (N.D.

Ill. May 29, 2025) (cleaned up). Similarly, in Pineda v. Lake Consumer Products, Inc., the court observed that "nothing in the Complaint indicates that the contamination was so widespread that the Court can make a reasonable inference that Plaintiff purchased contaminated products." No. 5:24-CV-1074- JMG, 2024 WL 5001928, at *5 (E.D. Pa. Dec. 5, 2024).

Here, as explained above, Kouyate has sufficiently alleged widespread contamination. Finally, in Bledsoe v. FCA US LLC, the court reasoned that "testing of a single truck[] under poorly-defined parameters" was insufficient to plausibly indicate a general issue with trucks in that product line. 378 F. Supp. 3d 626, 632 (E.D. Mich. 2019).

Here, by contrast, Kouyate alleges that the tests were conducted by an independent company with a reliable methodology. In sum, Kouyate has sufficiently alleged that the product he purchased plausibly contained benzene, and thus has established standing to sue. 2. Class Claims Padagis contends that even if Kouyate has standing to sue on his own behalf, he lacks standing to sue on behalf of a nationwide class.

Kouyate's own claims arise under New York law, whereas the claims of class members potentially arise under the laws of all 50 states. Padagis argues that Kouyate lacks standing to bring claims based on products sold in other states because Kouyate's injuries are only traceable to Padagis's actions in New York. Padagis cites several cases where courts have held that a plaintiff bringing individual claims under the law of a particular state lacks standing to bring class claims under the laws of other states.

See, e.g., Smith v. Lawyers Title Ins. Corp., No. 07-12124, 2009 WL 514210, at *3 (E.D. Mich. Mar. 2, 2009); In re Packaged Ice Antitrust Litig., 779 F. Supp. 2d 642, 656–57 (E.D. Mich. 2011) (collecting cases). Other courts have disagreed, reasoning that a plaintiff's ability to bring class claims on behalf of members in different states is an issue of Rule 23 class certification rather than Article III standing.

See, e.g., Generation Changers Church v. Church Mut. Ins. Co., 693 F. Supp. 3d 795, 804 (M.D. Tenn. 2023); Walton v. Grammer Indus. Inc., No. 2:20-CV-12298-TGB-RSW, 2021 WL 4458761, at *4 (E.D. Mich. Sept. 29, 2021).

The Sixth Circuit has acknowledged that it is an open "'question whether the relevance of [ ] variation' between a named plaintiff's claims and the putative class's claims 'is a matter of Article III standing at all or whether it goes to the propriety of class certification pursuant to Federal Rule of Civil Procedure 23(a).'" Generation Changers Church v. Church Mut.

Ins. Co., No. 24-5700, 2026 WL 497220, at *3 (6th Cir. Feb. 23, 2026) (alteration in original) (quoting Gratz v. Bollinger, 539 U.S. 244, 263 (2003)). Padagis urges the Court to adopt the standing approach, whereas Kouyate relies on the Rule 23 approach. "Under the standing approach, a named plaintiff may litigate only on behalf of those whose harms are a close match for the harms he suffered." Id. (quoting Speerly v. Gen.

Motors, LLC, 143 F.4th 306, 340 (6th Cir. 2025) (Thapar, J., concurring)). Thus, if there is a significant difference between the injury suffered by the named plaintiff and those suffered by the class members, the plaintiff lacks standing to sue on their behalf.

The logic of this approach is that "'a plaintiff who has been subject to injurious conduct of one kind' does not 'possess by virtue of that injury the necessary stake in litigating conduct of another kind, although similar, to which he has not been subject.'" Id. (quoting Blum v. Yaretsky, 457 U.S. 991, 999 (1982)).

The standing approach derives support from Blum, where the Supreme Court held that named plaintiffs who were subject to a particular harm—transfer to a medical facility with lower levels of care—lacked standing to bring claims on behalf of class members subject to a different type of harm—transfer to a facility with higher levels of care. 457 U.S. at 1000-01; but see Gratz, 539 U.S. at 263 n.15 (citing Blum and acknowledging "tension in [the Supreme Court's] prior cases" on this issue).

The Rule 23 approach, by contrast, treats any variation between the claims of the named plaintiff and the class members as a matter for class certification rather than standing. Under this approach, if "'a named plaintiff... has standing to bring a claim,'" "'the standing inquiry is at an end,' and the court then 'compare[s] the harms of the named representative and the would-be unnamed class members... through the lens of Rule 23, not justiciability." Generation Changers Church, 2026 WL 497220, at * 4 (alteration in original) (quoting Speerly, 143 F.4th at 342 (Thapar, J., concurring)).

This approach relies on the premise that variation between claims does not "ha[ve] anything to do with Article III's case or controversy requirement." Speerly, 143 F.4th at 341 (Thapar, J., concurring). As long as the named plaintiff has standing, a case or controversy exists, and the plaintiff's ability to represent other class members is merely a question of claim aggregation under Rule 23.

See id. at 341, 343. This approach finds support in Sosna v. Iowa, 419 U.S. 393 (1975), where the Supreme Court explained that once the named plaintiff has established standing, "the focus of examination [shifts] from the elements of justiciability to the ability of the named representative to 'fairly and adequately protect the interests of the class.'" Id. at 403 (quoting Fed.

R. Civ. P. 23(a)); see Speerly, 143 F.4th at 342 (Thapar, J., concurring). In Generation Changers Church, the Sixth Circuit chose "not [to] resolve which approach is appropriate." 2026 WL

497220, at *3. On the other hand, one Sixth Circuit judge has suggested that the class certification approach was already adopted in Fallick v. Nationwide Mutual Insurance Co., 162 F.3d 410, 422 (6th Cir.

1998), see Speerly, 143 F.4th at 342 (Thapar, J., concurring), though the Sixth Circuit "ha[s] yet to explicitly endorse this view [of Fallick] in a published decision," Generation Changers Church, 2026 WL 497220, at *3 n. 2.

In Fallick, the district court held that a plaintiff allegedly injured by the defendant's activities regarding a particular retirement plan lacked standing to represent class members injured by the defendant's activities regarding a different retirement plan. See 162 F.3d at 421.

The Sixth Circuit reversed, finding the district court's analysis "fundamentally flawed" because it "confuse[d] the issue of a plaintiff's standing under Article III vis-a-vis a defendant with the relationship between a potential class representative and absent class members, which is governed by Rule 23 of the Federal Rules of Civil Procedure." Id. at 422.

The Sixth Circuit noted that once a plaintiff has established their own standing to sue, their ability to represent class members is not a matter of standing but rather "depends solely on whether [they are] able to meet the additional criteria encompassed in Rule 23." Id. It is unnecessary for the Court to determine which approach (standing or Rule 23) to follow here because both entail the same result.

If the variation between Kouyate's claims and the proposed class members' claims is a Rule 23 issue, it should be postponed until the class certification stage. And if the variation is a matter of standing, it is a small enough variation that Article III is satisfied. Kouyate and the proposed class members all suffered essentially the same alleged injury: they bought Perrigo products that were falsely marketed and worthless because they contained benzene.

See Fallick, 162 F.3d at 422 (no significant variation existed between the claims of the plaintiff and those of the class members because "the gravamen of the plaintiff's challenge [wa]s to the general practices which affect[ed] all of the [retirement] plans").

The fact that Kouyate's injury occurred in a different state than the injuries of many class members does not create variation sufficient to undermine standing. See Generation Changers Church, 2026 WL 497220, at *4 (rejecting argument that "because [the class representative] does not allege that it owns property or suffered damages outside of Tennessee, it must lack standing to pursue the non- Tennessee class claims").

Similarly, the fact that Kouyate's claims arise under the laws of different states than those of some class members does not mean that he lacks standing to represent the class. See id. In sum, Kouyate has sufficiently alleged standing to represent the proposed class. B. Preemption Padagis argues

that Kouyate's claims are preempted by the FDCA. Federal law may preempt state law either explicitly or impliedly.

Morales v. Trans World Airlines, Inc., 504 U.S. 374, 383 (1992). Explicit preemption is based on statutory language; implied preemption is based on statutory structure and purpose. Id. Here, both types of preemption are at issue.

The FDCA contains an explicit preemption clause regarding the regulation of nonprescription drugs: "no State or political subdivision of a State may establish or continue in effect any requirement... that is different from or in addition to, or that is otherwise not identical with, a requirement under this chapter...." 21 U.S.C. § 379r(a).

Thus, a plaintiff cannot assert a state law claim against a defendant who has complied with federal law, because such a claim imposes requirements in addition to the FDCA's.3 See Collaza v. Johnson & Johnson Consumer Inc., No. 24-2568-CV, 2025 WL 2233746, at *2–3 (2d Cir. Aug. 6, 2025). But even if a plaintiff alleges that a defendant has violated both state law and the FDCA, their claim may still be impliedly preempted.

This is because a state law claim is preempted if "the existence of [the FDCA] is a critical element in [the plaintiff's] case." McDaniel v. Upsher-Smith Lab'ys, Inc., 893 F.3d 941, 944 (6th Cir. 2018) (quoting Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 353 (2001)).

In other words, a plaintiff cannot bring a state law claim that "would not exist in the absence of the FDCA." Loreto v. Procter & Gamble Co., 515 F. App'x 576, 579 (6th Cir. 2013). In short, to avoid preemption, a plaintiff must bring a claim that (1) would be cognizable under state law regardless of the existence of the FDCA, but (2) is based on actions that violate the FDCA or its associated regulations.

Kouyate meets the first requirement because his claims are brought under state consumer law and are not inherently tied to the FDCA. As explained below, however, Kouyate does not meet the second requirement. Kouyate attempts to satisfy the second requirement by arguing that Padagis's labeling and sale of the products at issue violated FDA regulations.

For certain over-the-counter drugs, including the products at issue here, the FDA issues "monographs" that specify what information 3 The preemption provision has an exception for state law products liability claims. See 21 U.S.C. § 379r(e). But Kouyate does not contend that any of his claims can be classified as products liability claims. See Goldstein v. Walmart, Inc., 637 F. Supp. 3d 95, 113 n.7 (S.D.N.Y.

2022) (products liability claims must involve allegation of physical rather than economic harm). must be included on the product's label. Such a drug "is generally recognized as safe and effective

and is not misbranded if it meets each of the conditions contained in [21 C.F.R. § 330.1] and each of the conditions contained in any applicable monograph." 21 C.F.R. § 330.1.

The FDA has issued a monograph for acne products that includes specific warnings for products containing benzoyl peroxide. See id. § 333.350(c)(4). In issuing the monograph, the FDA recognized that benzoyl peroxide is "generally recognized as safe and effective" when used as an active ingredient in topical acne products. 75 Fed. Reg. 9767, 9767 (Mar. 4, 2010).

Kouyate does not contest that Padagis's products contained the label required by the monograph. Rather, he argues that the products violated the following conditions contained in 21 C.F.R. § 330.1: (1) a product must be "labeled in compliance with chapter V of the Federal Food, Drug, and Cosmetic Act"; (2) a product must be labeled in accordance with the "content requirements in [21 C.F.R.] § 201.66"; and (3) a product must be "manufactured in compliance with current good manufacturing practices." 21 C.F.R. § 330.1(a), (c)(1).

As to the first condition, Kouyate points to two provisions of Chapter V that Padagis allegedly violated. Chapter V contains 21 U.S.C. § 351, which states that a drug is "adulterated"— and therefore its sale is prohibited by 21 U.S.C. § 331—"[i]f it consists in whole or in part of any filthy, putrid, or decomposed substance." 21 U.S.C. § 351(a)(1). Kouyate argues that the benzene found in Padagis's products is a "decomposed substance." In a technical sense, he is correct that the benzene is "decomposed" because it is formed through the process of thermal decomposition.

But words in a statute must be given their natural meaning in context. Sw. Airlines Co. v. Saxon, 596 U.S. 450, 455 (2022). Based on its proximity to "filthy" and "putrid," the word "decomposed" naturally denotes organic decomposition.

Thus, "decomposed substance" describes rotted organic matter; it does not encompass every chemical that forms from the breakdown of other chemicals. Because benzene is not rotted organic matter, it is not a "decomposed substance" and Kouyate's products were not "adulterated" under § 351. Next, Kouyate cites 21 U.S.C. § 352, which states that a drug is "misbranded"—and, again, prohibited from being sold under 21 U.S.C. § 331—"[i]f its labeling is false or misleading in any particular" or "[i]f it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 352(a)(1), (j).

Kouyate argues that the products at issue were dangerous to health, and that their labeling was misleading because they failed to disclose this danger. But both arguments are foreclosed by the monograph, which explicitly recognizes that a BPO-based acne product in compliance with the monograph "is not misbranded." 21 C.F.R. § 330.1. Kouyate's claim boils down to the contention that, contrary to the FDA's finding, BPO is inherently unsafe.

Because such a claim adds an additional requirement that the FDA has not imposed, it is preempted. See Howard, 2024 WL 4272931, at *8 ("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....").

Kouyate argues that his claim does not rely on the assertion that BPO is inherently unsafe, just that it is unsafe given the conditions under which Padagis was manufacturing, storing, and/or transporting it. But Kouyate does not point to any particular reason why Padagis's manufacturing, storage, or transportation processes were conducive to the degradation of BPO into benzene.

Rather, the crux of his claim is that BPO degrades into benzene under normal conditions as products are manufactured, transported, stored, and ultimately sold to consumers. Presumably the FDA was aware of the standard conditions to which acne products are subject when it approved the use of BPO in these products.

Therefore, Kouyate's contention that BPO is dangerous under standard conditions conflicts with the FDA's findings. It is true that the FDA's finding as to the safety of BPO does not plausibly extend to every possible scenario: if a manufacturer caused its products to degrade into benzene by subjecting them to extremely high temperatures, a state law claim against the company would not necessarily be preempted because the success of that claim would not contradict the FDA's finding that BPO is generally safe.

But here, Kouyate claims that BPO is unsafe under the sorts of standard conditions that the FDA would have anticipated when it crafted its rule. Kouyate does allege that Padagis could have made its products safe by including "certain antioxidants" in them. (Compl. ¶ 40.) But insofar as Kouyate's "theory of the case would" require Padagis to have "added a separate ingredient appearing nowhere in the monograph," that theory "would impose a further state law requirement on" Padagis.

Smoter v. Mentholatum Co., Inc., No. 24 CV 4155, 2025 WL 273437, at *2 (N.D. Ill. Jan. 17, 2025). So the success of Kouyate's claim would contradict the FDA's finding that BPO itself is safe. See Howard, 2024 WL 4272931, at *7 (plaintiffs' claims regarding benzene degradation were preempted because "Plaintiffs' theory is... 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.").

To avoid this conclusion, Kouyate contends that he is not directly challenging the FDA's findings as to the safety of BPO. He points out that some of the BPO products tested by Valisure did not contain benzene, indicating that the presence of benzene may be affected by companies' individual practices.

Thus, he contends, his claim only implicates the safety of Padagis's practices, not BPO in general. But as discussed above, Kouyate's theory of standing depends on the allegation that BPO degradation into benzene is common under standard manufacturing and storage conditions. If he instead were to assert that BPO only degrades into benzene under certain (unknown) conditions, then the fact that benzene was detected in a single Perrigo product would not support the inference that it was present in the products purchased by Kouyate.

As the district court explained in Howard: 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. 2024 WL 4272931, at *7.

In short: to allege standing, Kouyate must assert that benzene degradation is universal; but this assertion entails that BPO is inherently dangerous, and any claims based on the inherent dangers of BPO are preempted by the FDA's finding to the contrary. Kouyate cites Clinger v. Edgewell Personal Care Brands, LLC, No. 3:21-CV-1040 (JAM), 2023 WL 2477499 (D. Conn.

Mar. 13, 2023), where the court held that the plaintiffs' state law claims based on a failure to include benzene on a sunscreen label were not preempted. But that case is distinguishable because the plaintiffs did not allege that the benzene in the sunscreen was the result of BPO degradation. Rather, the benzene had allegedly been added either intentionally or unintentionally at some stage of the manufacturing process.

A monograph contains the FDA's determination that specific ingredients are safe; the promulgation of a monograph does not necessarily foreclose claims that a manufacturer is adding additional unsafe ingredients to its products, as in Clinger. But a monograph does foreclose claims that the very ingredients approved as safe by the FDA are harmful.

Here, the FDA has specifically approved the use of BPO in acne products, so Kouyate's claim that BPO is inherently harmful would directly contradict that approval. See Howard, 2024 WL 4272931, at *8 n.7 (distinguishing Clinger from a case regarding BPO contamination on this basis). Kouyate argues next that Padagis' products were not labeled in accordance with 21 C.F.R. § 201.66, which requires that the label list "each inactive ingredient." 21 C.F.R. § 201.66(c)(8).

The parties disagree as to whether benzene qualifies as an inactive ingredient in the products at issue. Section 201.66 defines "inactive ingredient" as "any component other than an active ingredient." Id. § 201.66(b)(8). Section 201.66 does not define "component," and Kouyate argues that the term's plain meaning refers to any constituent element of the product, which would include benzene.

On the other hand, Padagis points to 21 C.F.R. § 210.3, which states that—as used in "parts 211, 225, and 226 of this chapter"—"[c]omponent means any ingredient intended for use in the manufacture of a drug product." Id. § 210.3(b)(3). Padagis contends that benzene does not fit this definition because it is (as alleged by Kouyate) an accidental byproduct, not something Padagis "intended" to be in their products.

Kouyate responds that § 210.3's definition of "component" does not apply to § 201.66, so the term should be given its ordinary meaning (i.e. "any constituent element") when used in that section. The Court agrees with Padagis that benzene is not an inactive ingredient under § 201.66. While the definition of "component" in § 210.3 does not explicitly apply to § 201.66, that definition still provides insight as to the meaning of "component" (and thus "inactive ingredient") as used in § 201.66.

There is ample evidence that the terms used in these closely related regulations were meant to have a consistent meaning. For example, § 210.3 incorporates all definitions used in Section 201. See id. § 210.3. And the preamble of the FDA's final rule regarding § 201.66 states that "[t]he definition for inactive ingredient [in § 201.66] is identical to the definition in...

210 C.F.R. § 210.3(b)(8)." 64 Fed. Reg. 13254, 13258 (Mar. 17, 1999). The definition of "inactive ingredient" in § 210.3(b)(8) to which the FDA is referring is the same as that in § 201.66: "any component other than an active ingredient." 21 C.F.R. § 210.3(b)(8). But because § 210.3 includes a definition of "component," the full definition of "inactive ingredient" in § 210.3(b)(8) becomes "any [ingredient intended for use in the manufacture of a drug product] other than an active ingredient." Benzene is thus not an "inactive ingredient" under § 210.3(b)(8) and, because § 201.66 uses the same definition of "inactive ingredient" as § 210.3(b)(8), benzene is also not an "inactive ingredient" under § 201.66.

In short, § 201.66 does not require Padagis to list benzene on its products' labels. See Howard, 2024 WL 4272931, at *8 ("The FDA mandates disclosure of the active and inactive ingredients on the label, and benzene does not fit the definition of any type of ingredient, because it is not a purposefully added component of the drug." (citations omitted)); Williams v. Galderma Lab'ys, L.P., No. 24 CV 2222, 2024 WL 4213220, at *4 (N.D.

Ill. Sept. 17, 2024); Barnes v. Unilever U.S. Inc., No. 21 C 6191, 2023 WL 2456385, at *7 (N.D. Ill. Mar. 11, 2023). Finally, Kouyate contends that Padagis has not complied with the "current good manufacturing practices" (cGMPs) detailed in 21 C.F.R. § 211. Kouyate lists numerous cGMPs and alleges that the presence of benzene supports an inference that these cGMPs were violated.

Many of the cited cGMPs require manufacturers "to assure that the[ir] drug products have the identity, strength, quality, and purity they purport or are represented to possess," 21 C.F.R. §

211.100(a), or contain similar language. Kouyate also cites a requirement that manufacturers test their products under appropriate conditions, such as “after storage for long periods or after exposure to air, heat or other conditions that might adversely affect the component, drug product container, or closure.” Id. § 211.87.

But Kouyate’s reliance on the cGMPs suffers from the same problems as his previous arguments. Insofar as Kouyate alleges that Padagis must have violated the testing requirements in the cGMPs because otherwise it would have discovered BPO’s widespread degradation, this theory is barred by the FDA’s determination that BPO is safe. And if instead Kouyate alleges that a violation of the cGMPs caused BPO to degrade in some unique, unusual circumstances, he has not explained what that violation might have been or justified an inference that the violation affected the products he purchased.

Kouyate cites two out-of-circuit district courts that have allowed similar claims premised on BPO degradation to proceed based on alleged violations of the cGMPs. See Williams, 2024 WL 4213220, at *5; Navarro v. Walgreens Boots All., Inc., No. 1:24-CV-00290-JLT-SAB, 2025 WL 1411406, at *13 (E.D. Cal. May 15, 2025), adopted, No. 1:24-CV-00290-JLT-SAB, 2025 WL 3485004 (E.D.

Cal. Dec. 4, 2025). The Court does not disagree with the general principle that cGMPs can serve as a basis for avoiding preemption. See Howard v. Sulzer Orthopedics, Inc., 382 F. App’x 436, 441 (6th Cir. 2010). But it finds Williams and Navarro unpersuasive because they fail to engage with the argument laid out above: that the cGMPs cannot be used to avoid preemption when the theory underlying the cGMP violations is in direct conflict with an FDA- issued monograph.

In sum, Kouyate’s claims are preempted by the FDCA because they would impose requirements in addition to those established by federal law. IV. CONCLUSION Kouyate has standing to sue on behalf of himself and proposed class members, but his claims are preempted because they impose a requirement on Padagis that exceeds those imposed by the FDCA.

Thus, the Court will grant Padagis’s motion to dismiss. An order and judgment will enter consistent with this Opinion. Dated: March 3, 2026 /s/ Hala Y. Jarbou HALA Y. JARBOU CHIEF UNITED STATES DISTRICT JUDGE