

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MINNESOTA

In re Target Corporation BPO Sales and Marketing Litigation

In re Target BPO Sales & Mktg. Litig. · No. No. 24-cv-1323 (ECT/JFD) · Decided January 20, 2026

SUMMARY

The United States District Court for the District of Minnesota addresses Target's motion to dismiss a putative class action involving benzoyl peroxide acne products allegedly containing or degrading into benzene. The court holds that plaintiffs plausibly alleged Article III standing, CAFA jurisdiction, and several state-law claims, while concluding that they lacked standing to seek prospective injunctive or declaratory relief. The court also rejects FDCA preemption and primary-jurisdiction arguments but dismisses or rejects certain theories and claims, including the current-good-manufacturing-practices theory, negligent misrepresentation, and unjust enrichment.

CASE DETAILS

COURT	United States District Court for the District of Minnesota
WRITING FOR THE COURT	Eric C. Tostrud
JURISDICTION	United States District Court for the District of Minnesota
DECIDED	January 20, 2026
DOCKET	No. 24-cv-1323 (ECT/JFD)
DISPOSITION	other
PROCEDURAL POSTURE	Defendants moved to dismiss the consolidated amended class action complaint for lack of subject-matter jurisdiction under Rule 12(b)(1) and, alternatively, for failure to state a claim under Rule 12(b)(6), including challenges based on FDCA preemption, the primary-jurisdiction doctrine, economic-loss rules, unjust enrichment, and Rule 9(b).
STANDARD OF REVIEW	For a facial Rule 12(b)(1) challenge, the court accepts the complaint’s jurisdictional allegations as true and applies protections equivalent to Rule 12(b)(6). Under Rule 12(b)(6), the court accepts well-pleaded factual allegations as true, draws reasonable inferences for the plaintiff, and asks whether the complaint plausibly states a claim. Rule 9(b) requires fraud allegations to plead the circumstances of fraud with particularity.
PRECEDENTIAL VALUE	unpublished district court opinion; persuasive authority only

PARTIES

Target Corporation, Target Brands, Inc. v. Bria Miller, Jordan Judt, Lucinda O'Dea, Grace Navarro

TOPICS

consumer protection standing motions to dismiss class actions civil procedure

PRACTICE AREAS

consumer protection food and drug law products liability class actions civil procedure
federal jurisdiction preemption

QUESTIONS PRESENTED

1. Whether plaintiffs plausibly alleged Article III injury in fact by alleging that the Up&Up products they purchased manifested the alleged benzene defect.
2. Whether plaintiffs had standing to seek prospective injunctive and declaratory relief.
3. Whether the complaint plausibly alleged the Class Action Fairness Act's jurisdictional prerequisites.
4. Whether the FDCA expressly or impliedly preempted plaintiffs' state-law misbranding theory.
5. Whether plaintiffs plausibly pleaded adulteration based on benzene contamination.
6. Whether plaintiffs plausibly pleaded adulteration based on violations of current good manufacturing practices.
7. Whether the primary-jurisdiction doctrine required dismissal or a stay.
8. Whether the economic-loss rules of California, Illinois, and Nebraska barred the negligent-misrepresentation and negligent-omission claims.
9. Whether plaintiffs plausibly pleaded unjust enrichment as an alternative remedy.
10. Whether the complaint satisfied Federal Rule of Civil Procedure 9(b).

HOLDINGS

1. Plaintiffs plausibly alleged Article III injury because the Up&Up products they purchased manifested the alleged benzene defect. The complaint alleged that every tested Up&Up product contained benzene at day zero and that Target manufactured its Up&Up products in the same manner, permitting a plausible inference that the purchased products also contained benzene.
2. Plaintiffs lacked standing to seek forward-looking injunctive or declaratory relief because they alleged no plausible prospect of future interactions with Target, including future purchases.
3. Plaintiffs plausibly alleged the Class Action Fairness Act's jurisdictional prerequisites, including minimal diversity, a proposed class exceeding 100 members, and an amount in controversy exceeding \$5 million.
4. The FDCA did not preempt plaintiffs' state-law theory that Target's Up&Up products were misbranded because their labels failed to disclose the presence of benzene.

5. Plaintiffs' adulteration theory survived dismissal because the complaint plausibly alleged that the Up&Up products they purchased contained benzene.
6. Plaintiffs' current-good-manufacturing-practices theory failed because the complaint alleged only legal conclusions and did not plead facts showing how Target violated particular cGMP requirements.
7. The primary-jurisdiction doctrine did not warrant dismissal or a stay because FDA action on Valisure's Citizen Petition was unlikely to resolve the legal or factual issues in plaintiffs' damages claims, and the issues were not beyond the court's conventional experience.
8. The economic-loss rules of California, Illinois, and Nebraska barred plaintiffs' negligent-misrepresentation and negligent-omission claims because plaintiffs alleged only economic losses from purchasing allegedly defective products and did not seek damages for personal injury or damage to other property.
9. Plaintiffs' unjust-enrichment claim did not survive because they failed to plausibly allege that they might lack an adequate remedy at law.
10. The complaint satisfied Rule 9(b) because it identified the who, what, where, when, and how of the alleged misrepresentations and omissions.

KEY QUOTATIONS

"The law is clear in the Eighth Circuit that purchasers of an allegedly defective product lack an Article III injury—and therefore standing—if the product has not "actually exhibited the alleged defect."" (Part II.B.1)

"The plaintiff must be suing for conduct that violates the FDCA (or else his claim is expressly preempted by § [379r(a)]), but the plaintiff must not be suing because the conduct violates the FDCA (such a claim would be impliedly preempted under Buckman)." (Part III.A)

"The claim must identify who, what, where, when, and how." (Part IV.F)

FACTUAL BACKGROUND

Plaintiffs purchased Target's Up&Up topical acne-treatment products containing benzoyl peroxide. They alleged that the products contained benzene or degraded to form benzene, a carcinogen, and that they would not have purchased the products or would have paid less had they known of the alleged defect. Valisure tested three Up&Up products and reported native benzene at day zero and increased benzene levels after incubation at elevated temperatures. Plaintiffs sought economic damages and equitable relief, but not damages for personal injury.

PROCEDURAL HISTORY

Plaintiffs filed a putative nationwide and state-subclass class action concerning benzoyl-peroxide acne-treatment products sold under Target's Up&Up brand. After filing a consolidated amended complaint, Target moved to dismiss. The court held that most jurisdictional and merits challenges failed, but dismissed without prejudice the negligent-misrepresentation and negligent-omission claims, unjust-enrichment claim, requests for declaratory and injunctive relief, and claims based on the current-good-manufacturing-practices theory.

DISPOSITION

other

CASES CITED

- Branson Label, Inc. v. City of Branson, 793 F.3d 910, 914–15 (8th Cir. 2015)
- Titus v. Sullivan, 4 F.3d 590, 593 (8th Cir. 1993)
- Osborn v. United States, 918 F.2d 724, 729 n.6 (8th Cir. 1990)
- Gorog v. Best Buy Co., 760 F.3d 787, 792 (8th Cir. 2014)
- Bell Atl. Corp. v. Twombly, 550 U.S. 544, 557, 570 (2007)
- Ashcroft v. Iqbal, 556 U.S. 662, 678–79 (2009)
- Zean v. Fairview Health Servs., 858 F.3d 520, 526 (8th Cir. 2017)
- Whitmore v. Arkansas, 495 U.S. 149, 155 (1990)
- Lujan v. Defenders of Wildlife, 504 U.S. 555, 560–61, 564 n.2 (1992)
- Ariz. Christian Sch. Tuition Org. v. Winn, 563 U.S. 125, 146 (2011)
- In re Zurn Pex Plumbing Prods. Liab. Litig., 644 F.3d 604, 616 (8th Cir. 2011)
- O’Neil v. Simplicity, Inc., 574 F.3d 501, 502–03 (8th Cir. 2009)
- Wallace v. ConAgra Foods, Inc., 747 F.3d 1025, 1030 (8th Cir. 2014)
- Briehl v. General Motors Corp., 172 F.3d 623, 628 (8th Cir. 1999)
- In re Polaris Mktg., Sales Pracs., and Prods. Liab. Litig., 9 F.4th 793, 797 (8th Cir. 2021)
- Johannessoehn v. Polaris Indus. Inc., 9 F.4th 981, 987–88 (8th Cir. 2021)
- Park v. Forest Serv. of U.S., 205 F.3d 1034, 1037 (8th Cir. 2000)
- City of Los Angeles v. Lyons, 461 U.S. 95, 101–05, 107 n.8 (1983)
- In re SuperValu, Inc., 870 F.3d 763, 769 (8th Cir. 2017)
- O’Shea v. Littleton, 414 U.S. 488, 495–96 (1974)
- Murthy v. Missouri, 603 U.S. 43, 59 (2024)
- Barclay v. ICON Health & Fitness, Inc., No. 19-cv-2970 (ECT/DTS), 2020 WL 6083704, at *5 (D. Minn. Oct. 15, 2020)
- Arbaugh v. Y&H Corp., 546 U.S. 500, 514 (2006)
- Dart Cherokee Basin Operating Co. v. Owens, 574 U.S. 81, 84–85 (2014)
- Standard Fire Ins. Co. v. Knowles, 568 U.S. 588, 592 (2013)
- Faltermeier v. FCA US LLC, 899 F.3d 617, 621 (8th Cir. 2018)
- Pirozzi v. Massage Envy Franchising, LLC, 938 F.3d 981, 984 (8th Cir. 2019)
- WinRed, Inc. v. Ellison, 59 F.4th 934, 941 (8th Cir. 2023)
- Weber v. Heaney, 995 F.2d 872, 875 (8th Cir. 1993)
- Stursberg v. Morrison Sund PLLC, 648 F. Supp. 3d 1075, 1086 (D. Minn. 2023), aff’d, 112 F.4th 556 (8th Cir. 2024)

- *Stephens v. Target Corp.*, 694 F. Supp. 3d 1136, 1141–42 (D. Minn. 2023)
- *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 521 (1992)
- *Merrell Dow Pharms., Inc. v. Thompson*, 478 U.S. 804, 810 (1986)
- *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 353 (2001)
- *Glover v. Bausch & Lomb Inc.*, 6 F.4th 229, 237 (2d Cir. 2021), certified question answered, 275 A.3d 168 (Conn. 2022)
- *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009)
- *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010)
- *Nat. Res. Def. Council, Inc. v. FDA*, 710 F.3d 71, 75 (2d Cir. 2013), as amended (Mar. 21, 2013)
- *Clinger v. Edgewell Pers. Care Brands, LLC*, No. 3:21-cv-1040 (JAM), 2023 WL 2477499, at *10 (D. Conn. Mar. 13, 2023)
- *Access Telecomms. v. Sw. Bell Tel. Co.*, 137 F.3d 605, 608 (8th Cir. 1998)
- *Red Lake Band of Chippewa Indians v. Barlow*, 846 F.2d 474, 476–77 (8th Cir. 1988)
- *Chlorine Inst., Inc. v. Soo Line R.R.*, 792 F.3d 903, 909 (8th Cir. 2015)
- *Alpharma, Inc. v. Pennfield Oil Co.*, 411 F.3d 934, 938 (8th Cir. 2005)
- *Ladore v. Sony Comput. Ent. Am., LLC*, 75 F. Supp. 3d 1065, 1075 (N.D. Cal. 2014)
- *N. Am. Chem. Co. v. Superior Ct.*, 69 Cal. Rptr. 2d 466, 474–75 (Cal. Ct. App. 1997)
- *Prmconnect, Inc. v. Drumm*, No. 15-cv-417, 2016 WL 3014814, at *5 (N.D. Ill. May 26, 2016)
- *Wigod v. Wells Fargo Bank, N.A.*, 673 F.3d 547, 567 (7th Cir. 2012)
- *Lesiak v. Cent. Valley Ag Coop., Inc.*, 808 N.W.2d 67, 81 (Neb. 2012)
- *United States ex rel. Joshi v. St. Luke’s Hosp., Inc.*, 441 F.3d 552, 556 (8th Cir. 2006)
- *United States ex rel. Costner v. United States*, 317 F.3d 883, 888 (8th Cir. 2003)
- *Moua v. Jani-King of Minn., Inc.*, 613 F. Supp. 2d 1103, 1110 (D. Minn. 2009)
- *E-Shops Corp. v. U.S. Bank Nat’l Ass’n*, 678 F.3d 659, 663 (8th Cir. 2012)
- *Payne v. United States*, 247 F.2d 481, 486 (8th Cir. 1957)

OPINION

UNITED STATES DISTRICT COURT DISTRICT OF MINNESOTA IN RE TARGET CORPORATION BPO File No. 24-cv-1323 (ECT/JFD) SALES AND MARKETING LITIGATION OPINION AND ORDER Christopher Devivo, Mark Samuel Reich, and Melissa G. Meyer, Levi & Korsinsky, LLP, New York, NY; Robert K. Shelquist, Cuneo Gilbert Flannery & LaDuca, LLP, St. Louis Park, MN; Krista Freier and Rebecca A. Peterson, George Feldman McDonald, PLLC, Bloomington, MN; and Courtney Maccarone, Kopelowitz Ostrow P.A., Fort Lauderdale, FL, for Plaintiffs Bria Miller and Jordan Judt.

Robert K. Shelquist, Cuneo Gilbert & LaDuca, LLP, St. Louis Park, MN; John Hunter Bryson, Bryson Harris Suci & DeMay PLLC, Raleigh, NC; Nick Suci, III, Bryson Harris Suci & DeMay PLLC, Bloomfield Hills, MI; and Matthew A. Girardi and Philip Lawrence Fraietta,

Bursor & Fisher P.A., White Plains, NY for Plaintiff Lucinda O’Dea. R. Brent Wisner, Hannah Quicksell, and Stephanie Sherman, Wisner Baum LLP, Los Angeles, CA; and Robert K. Shelquist, Cuneo Gilbert & LaDuca, LLP, St. Louis Park, MN for Plaintiff Grace Navarro.

Rick Lynn Shackelford, Greenberg Traurig, P.A., Los Angeles, CA; and Laura Rose Hammargren, Greenberg Traurig, P.A., Minneapolis, MN for Defendants Target Corporation and Target Brands, Inc. This would-be class action concerns over-the-counter acne treatment products that contain benzoyl peroxide.

The suit-prompting products are sold by Defendants Target Corporation and Target Brands, Inc. under the “Up&Up™” brand name. Following the parties’ lead, both Defendants will be referred to together as “Target.” Plaintiffs are four individuals who purchased one or more Up&Up acne treatment products. Plaintiffs’ core allegation is that these products “contain and/or degrade to form high levels of benzene, a known human carcinogen, linked to leukemia and other blood cancers.” Had they known of this problem, Plaintiffs say they would not have purchased the products, or at least they would have paid less for them.

Plaintiffs seek recovery arising out of just their economic losses; they do not seek recovery for personal injuries. Target filed a motion to dismiss the case for lack of subject-matter jurisdiction or, failing that, on various merits-directed grounds. With one exception, there is subject-matter jurisdiction over this case. Plaintiffs allege facts plausibly showing that the products they purchased manifested the claimed defect, meaning Plaintiffs have Article III standing to bring the case, and Plaintiffs plausibly allege the Class Action Fairness Act’s (“CAFA”) jurisdictional prerequisites.

The exception is that Plaintiffs lack standing to seek injunctive or declaratory relief. Regarding the merits, the short version is this: The Federal Food, Drug, and Cosmetic Act (“FDCA”) does not preempt Plaintiffs’ state-law “misbranding” theory because the theory parallels FDCA requirements. Plaintiffs’ “adulteration” theory survives because the at-issue products plausibly contained benzene.

Plaintiffs’ “current good manufacturing practices” theory fails because it is based on mere legal conclusions. The primary-jurisdiction doctrine does not warrant the case’s dismissal. The economic-loss rules of Plaintiffs’ home states bar their negligent-misrepresentation claims. Plaintiffs’ equitable unjust-enrichment claim does not survive because it is not plausibly pleaded as an alternative to Plaintiffs’ legal theories.

And Plaintiffs allege their surviving claims with the particularity required by Federal Rule of Civil Procedure 9(b). Plaintiffs will not be granted leave to amend at this time. Of course, Plaintiffs may ask for time and the opportunity to amend as part of the case management and scheduling process.

I Target manufactures, markets, and sells topical acne treatment products formulated with the active ingredient benzoyl peroxide (or “BPO”).

Compl. [ECF No. 59] ¶¶ 31, 33.1 To manufacture these products, BPO—“a dry white powder”—is “mixed with other ingredients to create topical drug creams, cleansers, scrubs, and washes for use on the face and body.” Id. ¶ 31. All Up&Up BPO acne treatment products are “manufactured in the same manner pursuant to Target’s contracts and specifications.” Id. ¶¶ 32, 34. “Benzene is used primarily as a solvent in the chemical and pharmaceutical industries, as a starting material and intermediate in the synthesis of numerous chemicals.” Id. ¶ 38.

The health risks associated with benzene exposure have been recognized for “over one hundred years,” and it is a known human carcinogen. Id. ¶¶ 39, 44, 46. Benzene exposure has been linked to a variety of long-term adverse health effects and diseases. Id. ¶ 40. These include an increased “risk of developing leukemia and other blood disorders,” id. ¶ 42, and “harm [to] the central nervous system and... reproductive organs,” id. ¶ 45.

1 The operative pleading is titled “Consolidated Amended Class Action Complaint.” ECF No. 59 at 1. For efficiency’s sake, the document will be referred to in this opinion as just the “Complaint” and cited in abbreviated form as “Compl.” Benzene can be absorbed through the skin. Id. ¶ 53–55.

To account for these risks, the Food and Drug Administration (“FDA”) has classified benzene as a “Class 1” solvent that is to be “avoided” in drug manufacturing. Id. ¶ 46. If “unavoidable,” however, FDA guidance allows a drug product to contain up to 2 parts-per-million (or “PPM”) of benzene. Id. Valisure is an “independent laboratory that analyzes the safety of consumer products.” Id. ¶ 4.

In 2023, Valisure tested whether benzene is present in 66 different BPO acne treatment products. Id. ¶ 66; ECF No. 68-2 at 16.2 The tested products included over-the-counter and prescription products from different manufacturers with different brand names. See Compl. ¶ 67; ECF No. 68-2 at 17–19. Valisure tested three of Target’s Up&Up BPO products as part of its study: a “2.5% Up & Up Cream,” a “2.5% Up & Up Lotion, and a “10.0% Up & Up Gel.” ECF No. 68-2 at 17; Compl. ¶¶ 67, 74.

Described at a high level, the testing was straightforward: Valisure “incubated” the 66 different BPO acne treatment products for 18 days at a temperature of 50°C (or 122°F). Compl. ¶ 75; ECF No. 68-2 at 16. Valisure chose that temperature because it is a temperature “the product may be exposed to during distribution and handling by consumers” and because it “is an accepted incubation temperature used by the pharmaceutical industry for performing accelerated stability studies with a duration of at least 3 months.” ECF No. 68-2 at 19–20.

Valisure measured each sample for benzene periodically at days 0 (that is, immediately 2 Citations to pages within a filed document are to pagination assigned by the court’s CM/ECF system,

appearing in a document's upper right corner, not to a document's original pagination. before any sample was incubated at high temperature), 4, 10, 14, and 18. Id. at 16.

The testing showed that "every one of the tested BPO products, including [Target's] BPO Products, contained and/or degraded to form, dangerous levels of benzene well over 2[]ppm, the maximum amount allowed in any U.S. regulated drug." Compl. ¶ 75. Based on its study, Valisure concluded that "all" BPO acne treatment products "seem to be fundamentally unstable and form unacceptably high levels of benzene under normal use, handling, and storage temperatures." Id. ¶ 76.

On March 5, 2024, Valisure submitted a Citizen Petition to the FDA based on its testing of BPO acne treatment products. Id. ¶ 4; see ECF No. 68-2. The Citizen Petition includes a detailed description of Valisure's testing and conclusions. See ECF No. 68-2.

In its Citizen Petition, Valisure "request[ed] the Commissioner of Food and Drugs... to issue a regulation, revise industry guidance, and request a recall and suspend sales of benzoyl peroxide from the US market," among other actions. Id. at 2. Plaintiffs are four individuals who purchased Target Up&Up BPO acne treatment products. Compl. ¶¶ 16–19. Plaintiff Bria Miller is a California citizen who purchased "Up&Up™ Maximum Strength 10% benzoyl peroxide gel" in August 2022.

Id. ¶ 16. Plaintiff Jordan Judt is a Nebraska citizen purchased "Up&Up™ Maximum Strength Effectiveness Acne Spot Treatment 2.5% benzoyl peroxide cream" in December 2022. Id. ¶ 17. Plaintiff Lucinda O'Dea is an Illinois citizen who purchased "Up&Up™ Maximum Strength Effectiveness Acne Spot Treatment 2.5% benzoyl peroxide cream" and "Up&Up™ Maximum Strength Effectiveness Acne Spot Treatment 2.5% benzoyl peroxide lotion" sometime "within the last three years." Id. ¶ 18.

And Plaintiff Grace Navarro is a California citizen who "repeatedly purchased" Target's "Up&Up™ Maximum Strength Effectiveness Acne Spot Treatment 2.5% benzoyl peroxide cream" "[o]ver the last decade." Id. ¶ 19. When Plaintiffs purchased Target's BPO products, each of them "reviewed the accompanying labels and disclosures and understood them as representations and warranties by [Target] that the product was properly manufactured, free from defects, and safe for its intended use." Id. ¶¶ 16–19.

Plaintiffs "relied on these representations and warranties in deciding to purchase" Target's BPO products. Id. Plaintiffs would not have purchased Target's BPO acne treatment products, or would have paid less for them, had they known the products "contain benzene and/or that the BPO Products degrade to form benzene." Id. ¶¶ 13–14. Plaintiffs assert causes of action in nine counts: (1) Count I is a claim under California's Unfair Competition Law, Cal. Bus. & Prof.

Code § 17200 et seq. Compl. ¶¶ 150–61. (2) Count II is a claim under California’s Consumers Legal Remedies Act, Cal. Bus. & Prof. Code § 1750 et seq. Compl. ¶¶ 162–77. (3) Count III is a claim under California’s False Advertising Law, Cal. Bus. & Prof. Code § 17500 et seq. Compl. ¶¶ 178–87.

(4) Count IV includes statutory deceptive-trade-practices claims under California, Illinois, Minnesota, and Nebraska statutes. Compl. ¶¶ 188–202. (5) Count V includes a claim for breach of the implied warranty of merchantability under California law and under the laws of other unspecified states. Id. ¶¶ 203–21.

(6) Count VI is a claim under the Minnesota Prevention of Consumer Fraud Act, Minn. Stat. § 325F.69. Compl. ¶¶ 222–31. (7) Count VII is a claim under the Minnesota Uniform Deceptive Trade Practices Act, Minn. Stat. § 325D.43 et seq. Compl. ¶¶ 232–46.

(8) Count VIII includes negligent-misrepresentation and negligent-omission claims under the common law of California, Illinois, Nebraska, and perhaps other states. Id. ¶¶ 247–61. (9) Count IX includes unjust-enrichment claims under the common law of California, Illinois, Nebraska, and perhaps other states. Id. ¶¶ 262–68. Plaintiffs seek declaratory and injunctive relief, “restitution/damages,” punitive damages, disgorgement, and attorneys’ fees and costs.

Id. at 81–82. And, though it doesn’t matter at this point, Plaintiffs seek to represent a nationwide class, and California, Illinois, and Nebraska subclasses, of persons who purchased Up&Up BPO acne treatment products. See id. ¶¶ 140–49. Each of Plaintiffs’ claims is based on one or more of three theories.

First, Plaintiffs claim the Up&Up products they purchased were misbranded “because of failure to disclose material safety information”—that is, because the products’ labels failed to disclose benzene’s presence in the products. ECF No. 73 at 27; see, e.g., Compl. ¶¶ 127, 155, 173, 181.

Second, Plaintiffs claim the Up&Up products they purchased were adulterated “because of benzene contamination as a result of BPO decomposition.” ECF No. 73 at 27. For this theory’s purposes, Plaintiffs cite that part of the FDCA’s definition of “adulterated” providing that a product is adulterated “if it consists in whole or part of any filthy, putrid, or decomposed substance.” See id. at 29 (quoting 21 U.S.C. § 351(a)(1)).

Third, Plaintiffs claim the Up&Up products they purchased were adulterated “because of failure to comply with” currently good manufacturing practices, or “cGMPs.” ECF No. 73 at 27. For this theory’s purposes, Plaintiffs cite that part of the FDCA’s definition of “adulterated” providing that a product is adulterated if it is not manufactured “in conformity with current good manufacturing practice[s].” See id. at 29 (quoting 21 U.S.C. § 351(a)(1)).

II A Start with Target’s jurisdictional challenge and the familiar Rule 12 standards governing its adjudication. A court reviewing a motion to dismiss for lack of subject- matter jurisdiction must first determine whether the movant is making a “facial” attack or a “factual” attack. *Branson Label, Inc. v. City of Branson*, 793 F.3d 910, 914 (8th Cir. 2015).

As the nomenclature suggests, a facial attack challenges only the complaint’s jurisdictional allegations—that is, it challenges jurisdiction on the face of the complaint. “Conversely, in a factual attack, the existence of subject matter jurisdiction is challenged in fact, irrespective of the pleadings, and matters outside the pleadings... are considered.” *Id.* at 914–15 (citation modified).

Here, Target advances a facial attack to subject-matter jurisdiction. It accepts the truth of the jurisdictional allegations in the Complaint and argues these allegations are insufficient. See ECF No. 68 at 19–23; see *Titus v. Sullivan*, 4 F.3d 590, 593 (8th Cir. 1993).

In a facial attack, “the non-moving party receives the same protections as it would defending against a motion brought under Rule 12(b)(6).” *Osborn v. United States*, 918 F.2d 724, 729 n.6 (8th Cir. 1990) (citations omitted).

In reviewing a motion to dismiss for failure to state a claim under Rule 12(b)(6), a court must accept as true all the factual allegations in the complaint and draw all reasonable inferences in the plaintiff’s favor. *Gorog v. Best Buy Co.*, 760 F.3d 787, 792 (8th Cir. 2014) (citation omitted). Jurisdictional allegations, like any other allegations in a complaint, are subject to Rule 8(a)’s standard of “a short and plain statement of the grounds for the court’s jurisdiction.” *Fed.*

R. Civ. P. 8(a)(1). To meet this requirement, a plaintiff must satisfy the plausibility standard of *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007) and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009). See *Penrod v. K&N Eng’g, Inc.*, No. 18-cv-2907 (ECT/LIB), 2019 WL 1958652, at *3–4 (D. Minn. May 2, 2019) (applying the *Twombly/Iqbal* plausibility standard to jurisdictional allegations); *Hawse v. Page*, 7 F.4th 685, 688–89 (8th Cir.

2021) (same); *Auer v. Trans Union, LLC*, 902 F.3d 873, 878 (8th Cir. 2018) (same). In other words, the complaint must contain “enough facts” to nudge the showing of subject-matter jurisdiction “across the line from conceivable to plausible.” *Twombly*, 550 U.S. at 570. “[N]aked assertion[s]’ devoid of ‘further factual enhancement’” will not suffice. *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 557).

A complaint must include “factual content that allows the court to draw the reasonable inference” that there is subject-matter jurisdiction. *Id.* at 678– 79 (describing this as a “context-specific task” that requires the court “to draw on its judicial experience and common sense”). Ordinarily, a federal court does not consider matters outside the pleadings in resolving a Rule 12(b)(6) motion or, it follows, in resolving a facial challenge to subject- matter jurisdiction.

See Fed. R. Civ. P. 12(d); *Zean v. Fairview Health Servs.*, 858 F.3d 520, 526 (8th Cir. 2017). Regardless, the law is clear that several categories of documents beyond a pleading's allegations appropriately may be considered in this procedural context. These include "matters incorporated by reference or integral to the claim, items subject to judicial notice, matters of public record, orders, items appearing in the record of the case, and exhibits attached to the complaint whose authenticity is unquestioned." *Zean*, 858 F.3d at 526 (citation omitted).

Here, the Complaint repeatedly quotes from and refers to the Citizen Petition that Valisure filed with the FDA. See, e.g., Compl. ¶¶ 41, 64–76. It seems fair to say the Citizen Petition is integral to Plaintiffs' claims—the case appears to be derived from it. Reinforcing this conclusion, Target filed the Citizen Petition with its motion, ECF No. 68-2, both sides discuss it without any objection from the other, and Plaintiffs' counsel confirmed at the hearing that the Citizen Petition appropriately may be considered in adjudicating Target's motion.

B 1 The primary disputed issue underlying Target's jurisdictional challenge is whether Plaintiffs alleged facts plausibly showing that benzene contaminated the Up&Up items they purchased. This issue is rooted in Eighth Circuit cases addressing Article III standing in defective-products claims.

The standing doctrine "serves to identify those disputes which are appropriately resolved through the judicial process"—in other words, those disputes that qualify as "Cases" or "Controversies" under Article III. *Whitmore v. Arkansas*, 495 U.S. 149, 155 (1990). A plaintiff meets "the irreducible constitutional minimum of standing" when (1) he has suffered an "injury in fact," (2) there is "a causal connection between the injury and the conduct complained of" that is "fairly traceable to the challenged action of the defendant," and (3) it is "likely... that the injury will be redressed by a favorable decision." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61 (1992) (citation modified).

The Supreme Court has instructed that "[i]n an era of frequent litigation [and] class actions... courts must be more careful to insist on the formal rules of standing, not less so." *Ariz. Christian Sch. Tuition Org. v. Winn*, 563 U.S. 125, 146 (2011).

The law is clear in the Eighth Circuit that purchasers of an allegedly defective product lack an Article III injury—and therefore standing—if the product has not "actually exhibited the alleged defect." *In re Zurn Pex Plumbing Prods. Liab. Litig.*, 644 F.3d 604, 616 (8th Cir. 2011) (quoting *O'Neil v. Simplicity, Inc.*, 574 F.3d 501, 503 (8th Cir. 2009)); see also *Wallace v. ConAgra Foods, Inc.*, 747 F.3d 1025, 1030 (8th Cir.

2014) (same). As the Eighth Circuit has explained, no tort claim for economic damages lies when a product is merely at risk of failing. In *Briehl v. General Motors Corp.*, 172 F.3d 623 (8th Cir. 1999), for example, this Court concluded that a purported class of General Motors vehicle owners

had failed to state a claim for relief when the alleged defect in the braking system had not manifested itself in the vehicles they owned.

Id. at 628. Similarly, in *O’Neil v. Simplicity, Inc.*, 574 F.3d 501 (8th Cir. 2009), the plaintiffs brought suit against a crib manufacturer premised on an alleged hardware defect in a crib that “made it possible for the drop- side to detach from the crib, creating a dangerous gap in which a child could get caught.” *Id.* at 502.

The Court reiterated that no cause of action lies for products merely at risk for manifesting a defect. *Id.* at 503. Under our precedent, a cognizable tort claim arises when a defective product has actually malfunctioned or failed, not merely when a defect poses a risk or possibility of injury or damage. *Penrod v. K&N Eng’g, Inc.*, 14 F.4th 671, 673–74 (8th Cir.

2021). Though the *Penrod* panel phrased its discussion of the issue in Rule 12(b)(6) “failure to state a claim” parlance, the Eighth Circuit has made clear that the issue must be “viewed... through the lens of Article III.” *In re Polaris Mktg., Sales Pracs., and Prods. Liab. Litig.*, 9 F.4th 793, 797 (8th Cir. 2021).

In the defective-products context, a plaintiff does not show Article III injury by alleging “that a product is at risk for manifesting [a] defect.” *Id.* (citation omitted); see *Johannessohn v. Polaris Indus. Inc.*, 9 F.4th 981, 987–88 (8th Cir. 2021) (same).

Here, Plaintiffs allege facts plausibly showing that the Up&Up BPO acne treatment products they purchased contained benzene and, therefore, manifested the alleged defect. Plaintiffs make this showing two ways. First, the front-line theory underlying the Complaint is that any amount of benzene renders a BPO acne-treatment product defective. See Compl. ¶¶ 39, 41, 51– 53, 59a, 77, 80, 107.

As Valisure explained in its Citizen Petition, Valisure found “native benzene” present in 94 of the 99 products it tested, ECF No. 68-2 at 16, including all three Up&Up products Valisure tested, *id.* at 17. And, Plaintiffs allege, all Target BPO acne treatment products “are manufactured in the same manner.” Compl. ¶ 34.

In other words, even without the high-temperature incubation testing Valisure performed, every Target BPO product it tested contained benzene. And, by virtue of their “same” manufacturing, Target’s BPO products are sufficiently comparable to infer—at least at this motion-to-dismiss stage—that this result would have held across the Up&Up BPO acne treatment product line.

Accepting these allegations as true, it is plausible that the Up&Up products Plaintiffs purchased manifested the alleged defect. Second, in addition to alleging that any amount of benzene renders a BPO acne treatment product defective, Plaintiffs allege that benzene amounts exceeding 2 ppm are especially hazardous. *Id.* ¶¶ 46–47, 49–50, 95. Valisure’s high-temperature incubation testing

showed benzene was present in amounts greater than 2 ppm in the three tested Up&Up products at day 4, and the testing showed the amount of benzene in the Up&Up products generally increased after that to quantities far exceeding 2 ppm.

ECF No. 68-2 at 17. Valisure’s incubation testing replicated real-world distribution and consumer-handling conditions and was consistent with pharmaceutical industry testing standards. *Id.* at 19–20. And again, paired with the allegation that Target’s Up&Up products “are manufactured in the same manner,” Compl. ¶ 34, these allegations permit the plausible inference that the products Plaintiffs purchased manifested the above-2ppm defect in the same way.

Considered against these allegations, the arguments Target advances to show that Plaintiffs lack Article III standing are not persuasive. Target first argues that “Plaintiffs allege nothing showing benzene in their BPO products.” ECF No. 68 at 19 (emphasis in original). This contention is correct in the sense that Plaintiffs have not alleged the specific items they purchased were tested for benzene.

Regardless, for the reasons discussed in the preceding paragraph, Plaintiffs’ allegations permit the plausible inference that the items they purchased contained benzene—i.e., that they manifested the alleged defect.

The short of it is that Valisure’s testing reflected real-world conditions and showed benzene was in Up&Up BPO products that were sufficiently comparable to the Up&Up BPO products Plaintiffs purchased to plausibly expect benzene’s presence in the items Plaintiffs purchased.

On Plaintiffs’ case theory, and in the context of a facial challenge to subject-matter jurisdiction, that is enough. Target next attempts to use one of Plaintiffs’ own allegations to show the absence of Article III standing.

As Target points out, Plaintiffs allege that “[b]enzene contamination is not inevitable in BPO-based acne treatments.” ECF No. 68 at 19–20 (quoting Compl. ¶ 119). If that is true, Target’s argument goes, then Plaintiffs “cannot distinguish their BPO Products from those that were tested and found to be benzene-free.” *Id.* at 20.

As I understand things, this argument misconstrues the Complaint and the Valisure Citizen Petition. Plaintiffs allege that, as manufactured, benzene contamination was inevitable and occurred in Target’s BPO acne treatment products. Though Plaintiffs allege it is possible to manufacture and store a BPO product in a way or ways that do not result in benzene contamination, they do not allege Target did those things.

See Compl. ¶¶ 118–19, 125. And, contrary to Target’s assertion, no Up&Up product was “tested and found to be benzene-free” as part of the Valisure study. ECF No. 68 at 20; see ECF No. 68-2 at 17. To be clear, Target had a reasonable basis to challenge Plaintiffs’ Article III standing.

The Complaint's most common allegation by far is that BPO acne treatment products "contain and/or degrade" or "degrade" to form benzene. See Compl. ¶¶ 1, 9, 11, 13, 35–36, 75, 77, 95, 97, 100, 101, 110–12, 121, 125–26, 131, 134, 157–58, 170, 192, 212, 214, 226, 228–29, 234–37, 244, 251, 264.

The most natural understanding of this oft-repeated allegation is that some BPO acne treatment products contain benzene or degrade to contain it, but others do not, either because they have not yet "degraded" or would not degrade. Some allegations in the pleading support this interpretation. Plaintiffs allege, for example, "that the BPO Products could degrade to form benzene." Compl. ¶ 158 (emphasis added).

In this understanding of Plaintiffs' liability theory, their Article III standing would seem doubtful—if benzene contamination represented merely a risk, then we would have nothing to show that the items Plaintiffs purchased manifested benzene contamination. But I don't understand Plaintiffs to allege a mere possibility of degradation or contamination.

As discussed, Plaintiffs' primary theory is that any amount of benzene renders a BPO acne treatment product defective. Plaintiffs allege facts plausibly showing that benzene was present in every tested Up&Up BPO acne treatment product at day 0, before Valisure conducted its high-temperature incubation testing. And the comparability of Up&Up BPO acne treatment products permits the plausible inference that the items Plaintiffs purchased manifested this same defect.

The same logic holds for Plaintiffs' theory that Up&Up BPO products inevitably degraded to contain benzene in amounts above 2 ppm. Plaintiffs have shown that they possess Article III standing to prosecute this case.² The second disputed jurisdictional issue is whether Plaintiffs have alleged facts plausibly showing they possess standing to seek forward-looking injunctive or declaratory relief.

When a plaintiff seeks injunctive relief, "the 'injury in fact' element of standing requires a showing that the plaintiff faces a threat of ongoing or future harm." *Park v. Forest Serv. of U.S.*, 205 F.3d 1034, 1037 (8th Cir. 2000); see also *City of Los Angeles v. Lyons*, 461 U.S. 95, 101–05, 107 n.8 (1983) (stating that the threat of future injury must be "real and immediate"). "In future injury cases, the plaintiff must demonstrate that the threatened injury is certainly impending, or there is a substantial risk that the harm will occur." *In re SuperValu, Inc.*, 870 F.3d 763, 769 (8th Cir.

2017) (citation modified); see *Lujan*, 504 U.S. at 564 n.2 ("Although imminence is concededly a somewhat elastic concept, it cannot be stretched beyond its purpose, which is to ensure that the alleged injury is not too speculative for Article III purposes—that the injury is certainly impending." (citation modified)). "Past exposure to illegal conduct does not in itself show a

present case or controversy regarding injunctive relief... if unaccompanied by any continuing, present adverse effects.” *O’Shea v. Littleton*, 414 U.S. 488, 495–96 (1974).

In this context, “past injuries are relevant only for their predictive value.” *Murthy v. Missouri*, 603 U.S. 43, 59 (2024). In other words, past injuries do not by themselves show a plaintiff’s standing to seek prospective relief, but they may “serve as evidence of threatened future injury.” *Id.* (citing *O’Shea*, 414 U.S. at 495–96).

Here, Target argues that Plaintiffs lack standing to seek injunctive relief because they claim no intent to purchase Up&Up BPO products again. ECF No. 68 at 35. Courts are split regarding this issue. Some conclude that there can be no threat of injury unless the plaintiff has specific plans to purchase the product in the future. See, e.g., *Kelly v. Cape Cod Potato Chip Co.*, 81 F. Supp. 3d 754, 763 (W.D.

Mo. 2015). If the injury is being fooled by misleading sales practices, the analysis goes, then a plaintiff who isn’t going to buy anything faces no threat of suffering the injury again. See *id.* Courts on the other side of the split typically focus on policy concerns: they observe that depriving plaintiffs who avoid a given product because of the deceptive sales practices surrounding it of standing would “denigrate” consumer-protection statutes, likely preventing plaintiffs from ever obtaining injunctive relief in this type of case.

Belfiore v. Procter & Gamble Co., 94 F. Supp. 3d 440, 445 (E.D.N.Y. 2015); see also *Yeldo v. MusclePharm Corp.*, 290 F. Supp. 3d 702, 713–14 (E.D. Mich. 2017). For these courts, a defendant’s continuing deceptive trade practices are themselves an ongoing injury sufficient to confer Article III standing to seek injunctive relief. See *Leiner v. Johnson & Johnson Consumer Cos.*, 215 F. Supp. 3d 670, 672–73 (N.D.

Ill. 2016). In an earlier case, I concluded that, to demonstrate standing to seek injunctive relief in this situation, “there must be some plausible prospect of future interactions between Plaintiffs and Defendants, even if there need not be specific plans to purchase again.” *Barclay v. ICON Health & Fitness, Inc.*, No. 19-cv-2970 (ECT/DTS), 2020 WL 6083704, at *5 (D.

Minn. Oct. 15, 2020). “Otherwise, it is difficult to see how the allegedly deceptive practices that occurred at the time Plaintiffs purchased their [products] will affect them at all going forward.” *Id.* Plaintiffs here have identified no reason to second-guess this earlier conclusion. All of Plaintiffs’ purchases occurred in the past. See Compl. ¶¶ 16–19. And Plaintiffs do not allege facts plausibly showing a prospect of future interactions, whether those might be product purchases or something else.

This means Plaintiffs lack standing to seek forward-looking injunctive or declaratory relief. 3 A third jurisdictional issue deserves discussion, though no party raised it. The issue is whether Plaintiffs have alleged facts plausibly showing CAFA’s jurisdictional prerequisites. A federal court

has “an independent obligation to determine whether subject-matter jurisdiction exists, even in the absence of a challenge from any party.” *Arbaugh v. Y&H Corp.*, 546 U.S. 500, 514 (2006) (citation omitted). “CAFA gives federal courts jurisdiction over certain class actions, defined in § 1332(d)(1), if the class has more than 100 members, the parties are minimally diverse, and the amount in controversy exceeds \$5 million.” *Dart Cherokee Basin Operating Co. v. Owens*, 574 U.S. 81, 84–85 (2014) (citing 28 U.S.C. § 1332(d)(2), (5)(B)).

The task of determining whether a case meets CAFA’s \$5 million threshold is not intended to be difficult. “[T]he claims of the individual class members shall be aggregated to determine whether the matter in controversy exceeds the sum or value of \$5,000,000, exclusive of interest and costs.” 28 U.S.C. § 1332(d)(6). CAFA “tells the District Court to... add[] up the value of the claim of each person who falls within the definition of [the] proposed class and determine whether the resulting sum exceeds \$5 million.” *Standard Fire Ins.*

Co. v. Knowles, 568 U.S. 588, 592 (2013); *Faltermeier v. FCA US LLC*, 899 F.3d 617, 621 (8th Cir. 2018) (“A district court aggregates the claims of all named or unnamed persons who fall within the definition of the proposed or certified class.” (citation modified)).

Here, I conclude Plaintiffs have done just enough to plausibly allege CAFA’s jurisdictional prerequisites. The first two elements are clearly established. (1) Plaintiffs allege there is minimal diversity between them and Target. Plaintiffs are California, Nebraska, and Illinois citizens, Compl. ¶¶ 16–19, and they allege Target “is a Minnesota corporation” that maintains its principal place of business in Minneapolis, *id.* ¶ 22.

(2) And Plaintiffs allege facts plausibly showing that the would-be nationwide class has more than 100 members. Plaintiffs allege that every Up&Up-branded product is fair game for this case, see *id.* ¶ 1, and that “hundreds of thousands” of consumers purchased Up&Up products, *id.* ¶ 144.3. In its opening brief, Target argued that Plaintiffs lacked Article III standing to assert claims regarding Target BPO products they did not purchase.

See ECF No. 68 at 21. However, Target did not defend this contention in its reply brief, see ECF No. 75 at 4–5, and Target confirmed at the hearing that this issue is appropriate for resolution at the class-certification stage.

(3) The problem is that Plaintiffs have nowhere identified “the value of the claim of each person who falls within the definition of [the] proposed class.” *Knowles*, 568 U.S. at 592. The Complaint makes clear that the measure of damages is the price paid to purchase each Up&Up acne treatment product or some lesser amount that accounts for each product’s defective character.

See, e.g., Compl. ¶¶ 14, 135. But Plaintiffs don’t say what that is. The pleading contains no allegations regarding either the purchase price or the claimed discounted amount for any single Up&Up product. See *id.* And Plaintiffs nowhere identify the aggregate amount in controversy, see

id., other than to plead the statutory requirement that it “exceeds \$5,000,000 exclusive of interest and costs,” id. ¶ 25.

Without more, repeating this CAFA element amounts to “a legal conclusion not entitled to a presumption of truth.” Penrod, 2019 WL 1958652, at *4.4 I nonetheless conclude that Plaintiffs’ allegations are enough. With “hundreds of thousands” of potential class members, the purchase price of any Up&Up product need not be substantial to reach CAFA’s \$5 million threshold.

And on top of that, Plaintiffs seek to recover punitive damages on behalf of some class members and attorneys’ fees. Compl. ¶ 138; see *Pirozzi v. Massage Envy Franchising, LLC*, 938 F.3d 981, 984 (8th Cir. 2019) (recognizing that these amounts count toward determining whether CAFA’s \$5 million amount-in- 4 The Complaint includes allegations regarding market conditions and revenue.

The pleading alleges, for example, that “Target generated total revenues of \$24.8 billion during fiscal year 2023,” that Target’s more than 2,000 “private and exclusive brand products represent approximately one third of their overall sales,” that acne treatment products are a “billion-dollar industry,” and that Target is “a leader” in this market. Compl. ¶¶ 29, 30, 31, 32.

These high-level allegations do not contribute to showing the amount in controversy on Plaintiffs’ damages theories. controversy threshold is met). From Plaintiffs’ allegations regarding the nature of the at- issue products, the products’ intended use, and the additional sums plausibly associated with Plaintiffs’ punitive-damages and attorneys’ fees requests in this complex case, it plausibly follows that this case meets CAFA’s amount-in-controversy threshold.

That Target raised no challenge to CAFA jurisdiction reinforces this conclusion. The presence of subject-matter jurisdiction enables consideration of the merits as challenged by Target. III Target’s first merits-directed challenge is that the FDCA preempts Plaintiffs’ theory that Target’s Up&Up products are misbranded because they omit a benzene warning. Though preemption is an affirmative defense, it will subject the Complaint to dismissal under Rule 12(b)(6) if that pleading or materials that appropriately may be considered, construed in a light most favorable to Plaintiffs, establish the defense.

See *United States ex rel. Louderback v. Sunovion Pharms., Inc.*, 703 F. Supp. 3d 961, 971 (D. Minn. 2023); see also *Stephens v. Target Corp.*, 694 F. Supp. 3d 1136, 1141 (D. Minn. 2023) (first citing *Wuebker v. Wilbur-Ellis Co.*, 418 F.3d 883, 886 (8th Cir. 2005); and then citing *Noble Sys. Corp. v. Alorica Cent., LLC*, 543 F.3d 978, 983 (8th Cir. 2008)); *Dougherty v. Source Nats., Inc.*, 148 F. Supp. 3d 831, 835 (E.D.

Mo. 2015) (citing *Brinkley v. Pfizer, Inc.*, 772 F.3d 1133, 1139 (8th Cir. 2014)). Here, answering the preemption question requires the consideration of (A) the FDCA’s preemption rules and (B)

the federal regulatory regime governing nonprescription BPO acne treatment products, and then (C) the application of those authorities to Plaintiffs' misbranding theory.

A "Congress can preempt state law in one of three ways: (1) expressly [through] statutory language like a preemption clause; (2) implicitly when a state law 'conflicts with' or stands as an obstacle to federal law; or (3) implicitly by 'occupying a legislative field,' leaving no room for state law." *WinRed, Inc. v. Ellison*, 59 F.4th 934, 941 (8th Cir. 2023) (citation modified) (quoting *Weber v. Heaney*, 995 F.2d 872, 875 (8th Cir.

1993)); see *Stursberg v. Morrison Sund PLLC*, 648 F. Supp. 3d 1075, 1086 (D. Minn. 2023) (identifying and differentiating preemption doctrines), *aff'd*, 112 F.4th 556 (8th Cir. 2024). There seem to be as many ways to explain the scope of FDCA preemption as there are cases addressing the subject.

For this case's purposes, the FDCA falls in the first, "express preemption" category because the statute contains a preemption clause that governs the availability of state claims regarding nonprescription or over-the-counter ("OTC") drugs.

The clause provides in relevant part that a state may not "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 this chapter." 21 U.S.C. § 379r(a).

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." 21 U.S.C. § 379r(c)(2). This definition "encompass[es] regulatory and common-law requirements." *Stephens*, 694 F. Supp. 3d at 1142 (citing *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 521 (1992)). "[S]tates are free under § 379r(a) to impose and enforce their own OTC-drug requirements, so long as those requirements are substantively identical to what the FDA requires pursuant to the FDCA." *Id.* The Supreme Court also has interpreted the FDCA to fall in the third, "implied preemption" category.

The FDCA has no private right of action. See *Merrell Dow Pharms., Inc. v. Thompson*, 478 U.S. 804, 810 (1986). "The FDCA provides that 'all... proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States.'" *Glover v. Bausch & Lomb Inc.*, 6 F.4th 229, 237 (2d Cir. 2021) (quoting 21 U.S.C. § 337(a)), certified question answered, 275 A.3d 168 (Conn.

2022). In *Buckman Co. v. Plaintiffs' Legal Committee*, the Supreme Court held that the FDCA impliedly preempts claims that "exist solely by virtue of the FDCA... requirements," including state-created claims where an FDCA violation "is a critical element." 531 U.S. 341, 353 (2001); see *Davidson v. Sprout Foods, Inc.*, 106 F.4th 842, 848–49 (9th Cir. 2024), cert. denied, 145 S. Ct.

1922 (2025). To get past Buckman, “the conduct on which the claim is premised must be the type of conduct that would... give rise to liability under state law even if the FDCA had never been enacted.” *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009).

As our Eighth Circuit Court of Appeals has explained, the combination of these express- and implied-preemption principles leaves a narrow gap through which a plaintiff’s state-law claim must fit if it is to escape express or implied preemption.

The plaintiff must be suing for conduct that violates the FDCA (or else his claim is expressly preempted by § [379r(a)]), but the plaintiff must not be suing because the conduct violates the FDCA (such a claim would be impliedly preempted under Buckman).

In *re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010) (quoting *Riley*, 625 F. Supp. 2d at 777). It is true that the Eighth Circuit described this “narrow gap” by reference to an express-preemption provision applicable in the medical-device context, 21 U.S.C. § 360k(a).

In *re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d at 1204. But it doesn’t matter. Section 379r(a) parallels § 360k(a). See *Stephens*, 694 F. Supp. 3d at 1142–43; see also *Kouyate v. Harvard Drug Grp. LLC*, No. 1:24-cv-6223-GHW, 2025 WL 2773159, at *9 & n.9 (S.D.N.Y. Sep. 26, 2025). B Under the FDCA, the FDA regulates the sale of over-the-counter drugs through the monograph system. “While FDA must generally approve drugs as [generally recognized as safe and effective (“GRAS/E”)] individually, the monograph system allows manufacturers to bypass individualized review.” *Nat.*

Res. Def. Council, Inc. v. FDA, 710 F.3d 71, 75 (2d Cir. 2013), as amended (Mar. 21, 2013). “Like a recipe, each monograph 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 GRAS/E.” *Id.* The “FDA excludes from its monographs any active ingredients or uses of active ingredients that it has determined either not to be GRAS/E or for which there is insufficient data to confirm whether they are GRAS/E.” *Id.* The monograph system includes general rules with which all OTC drugs must comply to be “generally recognized as safe and effective and... not misbranded.” 21 C.F.R. § 330.1.

These rules include that each product must (1) meet “each of the conditions contained in any applicable monograph,” (2) be “manufactured in compliance with current good manufacturing practices,” (“cGMPs”) and (3) “labeled in compliance with chapter V of the [FDCA]” and “the format and content requirements in § 201.66.” *Id.* § 330.1(a), (c)(1). “The cGMP regulations require OTC drug products meet safety, quality, purity, identity, and strength standards.” *Navarro v. Walgreens Boots All., Inc.*, No. 1:24-cv- 00290, 2025 WL 1411406, at *1 (E.D.

Cal. May 15, 2025), R. & R. adopted, 2025 WL 3485004 (E.D. Cal. Dec. 4, 2025); see 21 C.F.R. § 210.1(a). The cGMPs provide minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess.

21 C.F.R. § 210.1(a). Chapter V of the FDCA prohibits the sale of adulterated, 21 U.S.C. § 351, or misbranded, *id.* § 352, drugs. *Id.* § 331(a). Under § 351, a drug is adulterated if: (1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2) (A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

21 U.S.C. § 351(a). A product is misbranded “[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.” *Id.* § 352(a) (1), (j). Section 201.66 of the Code of Federal Regulations lists format and content labeling requirements for OTC drugs.

21 C.F.R. § 201.66. Among other things, the regulation mandates that warnings, active ingredients, and inactive ingredients be included on the labels. *Id.* § 201.66(c)(2), (c)(5), (c)(8). The monograph system includes regulations specific to OTC topical acne treatment products, and more that apply specifically to such products that contain BPO. Kouyate, 2025 WL 2773159, at *7 (citing 21 C.F.R. §§ 333.301–333.350 (the “Acne Monograph”)).

These regulations provide that “a topical, OTC drug product ‘is generally recognized as safe and effective and is not misbranded if it meets’ (1) ‘each of the conditions’ that apply only to topical acne drug products and (2) ‘each general condition’ applicable to all OTC drugs to be ‘generally recognized as safe and not misbranded.’” *Id.* (quoting 21 C.F.R. § 333.301). “Any product which fails to conform to each of the conditions” contained in 21 C.F.R. § 330.1 “and in an applicable monograph is liable to regulatory action.” 21 C.F.R. § 330.1.

The Acne Monograph expressly permits that BPO—in an amount from “2.5 to 10 percent”—may be an active ingredient in OTC topical acne treatment products. 21 C.F.R. § 333.310(a); see *Howard v. Alchemee, LLC*, No. 2:24-cv-01834 et al., 2024 WL 4272931, at *6 (C.D. Cal. Sep. 19, 2024).

The Acne Monograph also provides “detailed instructions for labeling covered products, including specific warnings and directions that must be included for products containing BPO.” Howard, 2024 WL 4272931, at *6; see 21 C.F.R. § 333.350(c)(4), (d)(2). C Though the answer seems reasonably debatable, I conclude that Plaintiffs’ misbranding theory—i.e., that the Up&Up products they purchased were misbranded because of the failure to disclose benzene’s presence in the products—is not preempted by operation of 21 U.S.C. § 379r(a).

The theory parallels the FDCA. Under the regulations, Target’s Up&Up acne treatment products are not misbranded merely because their labeling complies with the applicable monograph. 21 C.F.R. § 330.1. The product must also be “labeled in compliance with Chapter V of the [FDCA].” 21 C.F.R. § 330.1(c)(1). Chapter V includes a general prohibition against labeling that “is false or misleading in any particular.” 21 U.S.C. § 352(a)(1).

And in answering whether an OTC drug is “misbranded because the labeling or advertising is misleading,” “material” omissions regarding the “consequences which may result from the use of the article” count. 21 U.S.C. § 321(n). Plaintiffs’ state-law misbranding theory tracks these requirements. They plausibly allege that benzene is present in Up&Up acne treatment products and that benzene causes adverse health consequences.

Accepting those allegations as true, the FDCA plausibly would have required Target to disclose benzene’s presence in the Up&Up acne treatment products’ labeling. See *Clinger v. Edgewell Pers. Care Brands, LLC*, No. 3:21-cv-1040 (JAM), 2023 WL 2477499, at *10 (D. Conn. Mar. 13, 2023). Target fairly disputes this conclusion.

As Target points out, most courts to have addressed this issue stop with the monograph. That is, they hold that, because Plaintiffs’ misbranding theory would add a labeling requirement that is not in the applicable monograph, the theory is expressly preempted under § 379r(a). E.g., *Navarro v. Walmart, Inc.*, No. 1:24-cv-00288-JLT-SAB, 2025 WL 3563471, at *12–13 (E.D.

Cal. Dec. 12, 2025); *Kouyate*, 2025 WL 2773159, at *10–13; *Bodunde v. Walgreens Boots All., Inc.*, No. 1:24-cv-00985-JLT-SAB, 2025 WL 1411306, at *12 (E.D. Cal. May 15, 2025); *Navarro v. Walgreens Boots All., Inc.*, No. 1:24-cv-00290-JLT-SAB, 2025 WL 1411406, at *11 (E.D. Cal. May 15, 2025); *Howard*, 2024 WL 4272931, at *8; *Eisman v. Johnson & Johnson Consumer, Inc.*, No. 2:24-cv-01982-ODW (AJRx), 2025 WL 241024, at *4–6 (C.D.

Cal. Jan. 17, 2025); *Smoter v. Mentholatum Co.*, No. 24 CV 4155, 2025 WL 273437, at *2 (N.D. Ill. Jan. 17, 2025); see also *Stephens*, 694 F. Supp. 3d at 1142 (explaining that, under 21 U.S.C. § 379r(a), “state law cannot prohibit a statement on an OTC drug label that a monograph expressly authorizes, or require a warning or other statement that the applicable monograph does not require”).

I have carefully reviewed each of these cases. Perhaps owing to the precise liability theories asserted in those cases, none addresses the regulations' additional requirement that, to be "not misbranded," an OTC product's labeling must also comply with 21 C.F.R. § 330.1, including Chapter V's more general proscription against "false or misleading" labeling, 21 U.S.C. § 352(a)(1).

And no reason or explanation has been identified to show why the monograph might trump § 352(a)(1)'s more general requirement. Target argues that "any deviation from" the monograph would render its Up&Up BPO acne treatment products misbranded. ECF No. 68 at 24.

As support for this argument, Target cites Federal Register entries and BPO-specific subsections within the acne drug products monograph. *Id.* These authorities do not expressly forbid (or say anything about) additional warnings or representations a manufacturer might wish to place on an acne treatment product's label, or that a manufacturer might be required to place on a label to comply with other applicable FDCA provisions, including 21 U.S.C. § 352(a)(1).

IV A Plaintiffs' "adulteration" theory survives because the at-issue products plausibly contained benzene. Target did not address this theory specifically in its opening brief. See ECF No. 68 at 23–30. In its reply brief, Target argued that the theory fails because Plaintiffs do not allege facts plausibly showing "benzene contamination in their products." ECF No. 75 at 8 (emphasis in original).

As explained in addressing the Article III injury question, Plaintiffs allege facts plausibly showing that the Up&Up BPO acne treatment products they purchased contained benzene. See *supra* Part II.B.1. Considering the factual nature of Target's challenge, that is enough for Plaintiffs' adulteration theory to survive. B Plaintiffs' cGMP theory fails because it is based on mere legal conclusions.

Again, the gist of this theory is that benzene's presence in Target's Up&Up BPO acne treatment products resulted from Target's violations of cGMPs. See Compl. ¶¶ 84–99. Plaintiffs do not, however, allege facts regarding any cGMP violations. They allege only that "[t]he presence of benzene above 2 ppm... upon information and belief, resulted from Defendants' failure to comply with cGMPs." *Id.* ¶ 95.

And Plaintiffs identify 23 cGMPs they allege Target violated by quoting the regulation in which the cGMP appears. See *id.* ¶ 94(a)–(w). This pleads legal conclusions, and legal conclusions do not plausibly show liability. *Iqbal*, 556 U.S. at 678 ("[T]he tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions."); *Warmington v. Bd. of Regents of Univ. of Minn.*, 998 F.3d 789, 796 (8th Cir.

2021) (same). C "Primary jurisdiction is a common-law doctrine that is utilized to coordinate judicial and administrative decision making." *Access Telecomms. v. Sw. Bell Tel. Co.*, 137 F.3d

605, 608 (8th Cir. 1998) (citing *Red Lake Band of Chippewa Indians v. Barlow*, 846 F.2d 474, 476 (8th Cir. 1988)).

Under the doctrine, a district court may refer a disputed issue “to the appropriate administrative agency for a ruling in the first instance, even when the matter is initially cognizable by the district court.” *Id.* (citing *Iowa Beef Processors, Inc. v. Ill. Cent. Gulf R.R. Co.*, 685 F.2d 255, 259 (8th Cir. 1982)). A district court may invoke the doctrine and “leave an issue for agency determination when [the issue] involves the special expertise of the agency and would impact the uniformity of the regulated field.” *Chlorine Inst., Inc. v. Soo Line R.R.*, 792 F.3d 903, 909 (8th Cir.

2015) (quoting *DeBruce Grain, Inc. v. Union Pac. R.R. Co.*, 149 F.3d 787, 789 (8th Cir. 1998)). A case is considered to call for an agency’s special expertise when it “raise[s] issues of fact not within the conventional experience of judges.” *Alpharma, Inc. v. Pennfield Oil Co.*, 411 F.3d 934, 938 (8th Cir. 2005) (quoting *Access Telecomms.*, 137 F.3d at 608). “The doctrine is to be ‘invoked sparingly, as it often results in added expense and delay.’” *Id.* (quoting *Red Lake Band*, 846 F.2d at 477).

The primary-jurisdiction doctrine does not warrant the case’s dismissal. (1) Target points out that this case is derived from the Valisure Citizen Petition and argues this case should be dismissed or stayed in deference to the FDA’s adjudication of the Citizen Petition. ECF No. 68 at 31. But Target identifies no authority suggesting that FDA action—even a decision reaffirming the acne drug product monograph’s current content— might have some dispositive or other legal consequence regarding Plaintiffs’ claims in this case.

In other words, it is difficult to see how FDA action might resolve any issue here. (2) Target says that “Plaintiffs’ allegations challenge the safety of an entire category of acne drugs and call for their removal from the market.” *Id.* If that was true initially, it isn’t anymore. I determined that Plaintiffs lack Article III standing to seek forward-looking relief, meaning this is a damages case.

(3) Target argues that “[t]here is a real risk that courts and juries could reach inconsistent rulings on whether the OTC and BPO acne drug claims are permissible under state law.” *Id.* This is true. Courts (and juries) routinely reach different judgments in defective-products cases. But Target identifies no issue the FDA might resolve that would eliminate that risk across the universe of defective-products cases involving BPO acne treatment products.

(4) The legal and factual issues this case presents may be complex, but they are not beyond a court’s conventional experience. D The economic-loss rules of Plaintiffs’ home states bar their negligent- misrepresentation claims.

As Target points out, California, Illinois, and Nebraska each bars negligence claims based on a purchase of goods when the claimed injury is purely economic. *Ladore v. Sony Comput. Ent. Am., LLC*, 75 F. Supp. 3d 1065, 1075 (N.D. Cal. 2014) (“[I]n actions arising from the sale or purchase

of a defective product, plaintiffs seeking economic losses must be able to demonstrate that either physical damage to property (other than the defective product itself) or personal injury accompanied such losses; if they cannot, then they would be precluded from any tort recovery in strict liability or negligence.” (quoting *N. Am.*

Chem. Co. v. Superior Ct., 69 Cal. Rptr. 2d 466, 474–75 (Cal. 1997)); *Prmconnect, Inc. v. Drumm*, No. 15-cv-417, 2016 WL 3014814, at *5 (N.D. Ill. May 26, 2016) (recognizing that, under Illinois law, the economic-loss doctrine “bars recovery in tort for purely economic losses arising out of a” sale of goods (quoting *Wigod v. Wells Fargo Bank, N.A.*, 673 F.3d 547, 567 (7th Cir.

2012))); *Lesiak v. Cent. Valley Ag Coop., Inc.*, 808 N.W.2d 67, 81 (Neb. 2012) (“[T]he economic loss doctrine precludes tort remedies only where the damages caused were limited to economic losses and where either (1) a defective product caused the damage or (2) the duty which was allegedly breached arose solely from the contractual relationship between the parties.”).

Here, Plaintiffs allege only economic harms arising from their purchase of Target’s Up&Up acne treatment products as support for their negligent-misrepresentation claims. Specifically, Plaintiffs allege that Target’s “breaches of its duties were a direct and proximate cause of the economic harms to Plaintiffs and the California, Illinois, and Nebraska Subclass members.” Compl. ¶ 260 (emphasis added).

Plaintiffs defend their negligent-misrepresentation claims with two arguments, but neither is convincing. First, Plaintiffs claim they “seek damages based on [Target’s] intentional misrepresentations and omissions,” and they point out that the economic-loss rule does not bar fraudulent- inducement claims. ECF No. 73 at 50. These observations may be accurate with respect to other claims Plaintiffs assert, but they are not true of the negligent-misrepresentation claims.

These claims are not based on “intentional” conduct or “fraud”; they are negligence claims. Second, Plaintiffs argue that Nebraska’s economic-loss rule does not bar the negligent-misrepresentation claims because “Plaintiffs claim that [Target’s] defective products increased their risk of getting cancer and created risk of harm to the consumers themselves.” *Id.* Again, this is true in one sense—Plaintiffs allege benzene is dangerous and increases the risk of developing cancer in those exposed to it.

See, e.g., Compl. ¶ 42. But Plaintiffs nowhere seek to recover damages for their exposure to these risks. See *id.* ¶¶ 259–60. The absence of any personal-injury claim means the economic-loss rule applies. E Plaintiffs assert their equitable unjust-enrichment claim as an alternative to their legal claims. See ECF No. 73 at 51. “Alternative” unjust-enrichment claims are plausible if a plaintiff plausibly alleges that she may lack an adequate remedy at law.

Stephens, 694 F. Supp. 3d at 1148. Plaintiffs do not allege that here, see Compl. ¶¶ 262–68, and it is difficult to envision how they might. The unjust-enrichment claim will be dismissed on this basis. F Target argues that Plaintiffs’ claims must be dismissed because they were not alleged with the particularity required by Rule 9(b). Rule 9(b)’s basic requirements are familiar. “In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake.” Fed.

R. Civ. P. 9(b). To satisfy the particularity requirement of Rule 9(b), the complaint must plead such facts as the time, place, and content of the defendant’s false representations, as well as the details of the defendant’s fraudulent acts, including when the acts occurred, who engaged in them, and what was obtained as a result. *United States ex rel. Joshi v. St. Luke’s Hosp., Inc.*, 441 F.3d 552, 556 (8th Cir.

2006). “The claim must identify who, what, where, when, and how.” *United States ex rel. Costner v. United States*, 317 F.3d 883, 888 (8th Cir. 2003). While Rule 9(b) requires particularity in pleading, “a complaint need not be filled with precise detail.” *Moua v. Jani-King of Minn., Inc.*, 613 F. Supp. 2d 1103, 1110 (D. Minn. 2009). Rather, “Rule 9(b) is to be read in the context of the general principles of the Federal Rules, the purpose of which is to simplify pleading.

Thus, the particularity required by Rule 9(b) is intended to enable the defendant to respond specifically and quickly to the potentially damaging allegations.” *Costner*, 317 F.3d at 888. “The level of particularity required depends on the nature of a case,” *E-Shops Corp. v. U.S. Bank Nat’l Ass’n*, 678 F.3d 659, 663 (8th Cir. 2012), and to determine whether a party has satisfied Rule 9(b), courts look to “the complexity or simplicity of the transaction or occurrence, the relationship of the parties and the determination of how much circumstantial detail is necessary to give notice to the adverse party and enable him to prepare a responsive pleading,” *Payne v. United States*, 247 F.2d 481, 486 (8th Cir.

1957) (internal quotation omitted). The Complaint satisfies Rule 9(b). It alleges the who (Target), the what (the intentional failure to disclose benzene’s presence in the Up&Up acne treatment products), the where (in Target stores and, more specifically, on the products’ labeling), the when (from March 8, 2020), and the how (the relationship between BPO and benzene as described in the Valisure Citizen Petition).

Target challenges only the “how.” See ECF No. 68 at 32. It argues Plaintiffs haven’t alleged that the items they purchased “contained or degraded to form benzene” in the way Rule 9(b) requires. *Id.* For the same reasons I determined Plaintiffs plausibly alleged Article III injury, I disagree.

The short of it is that the Valisure Citizen Petition—and, to the extent it recounts the Citizen Petition, the Complaint—describe how the tested Up&Up BPO products were found to contain benzene at day 0, how those benzene amounts increased with incubation testing designed to mimic

real-world conditions, and how those products are sufficiently comparable to the products Plaintiffs purchased to expect the same result with those products.

The Citizen Petition's detailed descriptions more than satisfy Rule 9(b)'s particularity-in-pleading requirement. ORDER Therefore, based on the foregoing, and on all the files, records, and proceedings herein, IT IS ORDERED THAT Defendants' Motion to Dismiss [ECF No. 63] is GRANTED IN PART and DENIED IN PART as follows: 1.

The Motion is GRANTED WITHOUT PREJUDICE with respect to Plaintiffs' negligent-misrepresentation and negligent-omission claims (Count VIII), Plaintiffs' unjust-enrichment claim (Count IX), Plaintiffs' requests for declaratory and injunctive relief, and all claims to the extent they are based on Plaintiffs' cGMP theory. 2.

The Motion is in all other respects DENIED. Dated: January 20, 2026 s/ Eric C. Tostrud Eric C. Tostrud United States District Court