**UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF CALIFORNIA**

# Navarro v. Walgreens Boots Alliance, Inc.

No. 1:24-cv-00290-JLT-SAB (E.D. Cal. May 15, 2025) (findings and recommendations) · No. 1:24-cv-00290-JLT-SAB · Decided May 15, 2025

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**OPINION**

Navarro v. Walgreens Boots Alliance, Inc.
PER CURIAM.
1 2 3 4 5 6 7
UNITED STATES DISTRICT COURT
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9 EASTERN DISTRICT OF CALIFORNIA
10 GRACE NAVARRO, on behalf of themselves, Case No. 1:24-cv-00290-JLT-SAB 11 and all others similarly situated, and the general public, et al., FINDINGS AND RECOMMENDATIONS
12 RECOMMENDING GRANTING
Plaintiffs, DEFENDANT'S MOTION TO DISMISS 13 v. (ECF No. 13) 14
WALGREENS BOOTS ALLIANCE, INC., OBJECTIONS DUE WITHIN FOURTEEN
15 DAYS
Defendant. 16 17 Pending before the Court is Defendant Walgreens Boots Alliance, Inc.'s ("Walgreens") 18 motion to dismiss. On March 26, 2025, the Court held a hearing on the matter. R. Brent Wisner, 19 Esq., appeared for Plaintiffs. Rick Shackelford, Esq., appears for Walgreens. Having considered 20 the moving papers and arguments by counsel, as well as the Court's file, the Court issues the 21 following findings and recommendations recommending granting Walgreen's motion to dismiss. 22 I.
23 REGULATORY BACKGROUND
24 This is a consumer fraud putative class action regarding alleged economic harms caused 25 by the sale of Walgreens' benzol peroxide ("BPO") acne treatment drug products. (ECF No. 1, 26 ¶ 1.) According to Plaintiffs Grace Navarro and Chatham Mullins ("Plaintiffs"), Walgreens sold 27 BPO products that "had unsafe levels of the potent human carcinogen benzene" or that such BPO products "were at risk of degrading further into benzene under normal use." (Id.) Acne 1 treatments are drug products that are regulated by the U.S. Food and Drug Administration 2 ("FDA"), pursuant to the Food, Drug, and Cosmetics Act ("FDCA"). (Id. at ¶¶ 2, 25, 37, 38; see 3 id. at ¶ 4.) Additionally, over-the-counter ("OTC") drugs are regulated by the FDA and must be 4 safe and effective. (Id. at ¶¶ 25, 27, 37, 38.) OTC drugs are subject to federal current Good 5 Manufacturing Practices ("cGMP") regulations. (Id. at ¶¶ 3, 25.) The cGMP regulations require 6 OTC drug products meet safety, quality, purity, identity, and strength standards. 21 U.S.C. § 7

351(a)(2)(B). (Id.) The cGMPs establish 8 minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the 9 manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and 10 has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess. 11 21 C.F.R. § 210.1(a); (see ECF No. 1, ¶¶ 2, 25.). In other words, these regulations cover design, 12 manufacture, and distribution of OTC drug products. Id. Moreover, cGMP regulations set 13 minimum standards for organization and personnel; buildings and facilities; equipment; control 14 of components and drug product containers and closures; production and process controls; 15 packaging and label controls; holding and distribution; laboratory controls; records and reports; 16 and returned and salvaged drug products. See id.; see generally 21 C.F.R. §§ 211, 351(a)(2)(B). 17 For example, the regulations also include that drug product manufacturers have "written 18 procedures" for production and process control designed to comply with cGMPs. 21 C.F.R. 19 § 211.100. A drug product manufacturer's "[l]aboratory controls shall include the establishment 20 of scientifically sound and appropriate specifications, standards, sampling plans, and test 21 procedures designed to assure that components, drug product containers, closures, in-process 22 materials, labeling, and drug products conform to appropriate standards of identity, strength, 23 quality, and purity." 21 C.F.R. § 211.160. "Laboratory records shall include complete data 24 derived from all tests necessary to assure compliance with established specifications and 25 standards, including examinations and assays" and a "statement of the results of tests and how 26 the results compare with established standards of identity, strength, quality, and purity for the 27 component, drug product container, closure, in-process material, or drug product tested." 21 1 C.F.R. § 211.194(a)(6). Should a drug not be manufactured in accordance with cGMPs, the 2 drugs will be considered "adulterated" or "misbranded" and may not be distributed or sold in the 3 United States. 21 U.S.C. §§ 331(a), 351(a)(2)(B); (see ECF No. 1, ¶¶ 3, 25.). 4 An OTC drug monograph establishes conditions, such as active ingredients, uses 5 (indications), doses, routes of administration, labeling, and testing, under which an OTC drug in 6 a given therapeutic category (e.g., sunscreen, antacid, acne product) is generally recognized as 7 safe and effective for its intended use. See Topical Acne Drug Products for Over-the-Counter 8 Human Use; Final Monograph, 56 FR 41008-01, 1991 WL 156981. "Any product which fails to 9 conform to an applicable monograph after its effective date is liable to regulatory action." 21 10 C.F.R. § 330.10(b); (see ECF No. 1, ¶ 25.). In other words, once a final monograph goes into 11 effect, it is illegal to sell a drug that no longer conforms to "each of the conditions contained in 12 this part [330.1] and in an applicable monograph[.]" 21 C.F.R. § 330.1. The "conditions 13 contained in this part" include a requirement that "(a) [t]he product is manufactured in 14 compliance with current good manufacturing practices, as established by parts 210 and 211 of 15 this chapter." 21 C.F.R. § 330.1(a). In turn, parts 210 and 211 describe the cGMPs described 16 above. 17 II.

18 BENZENE, BENZOL PEROXIDE, AND BPO PRODUCT BACKGROUND

19 Made from coal and oil, benzene is a foundational component for many chemicals used 20 to make plastics, resins, synthetic fibers, paints, dyes, detergents, drugs, and pesticides. (Id. at 21 ¶¶ 47, 52.) Benzene is also a known human carcinogen, classified as a Group 1 carcinogen by 22 the International Agency for Research on Cancer. (Id. at ¶¶ 5, 47, 48.) Studies dating to the 23 1800s have led to a consensus within the medical and scientific communities that benzene 24 exposure, even in low amounts, increases the risk of blood cancers and other adverse effects. 25 (Id. at ¶¶ 5, 47.) Medical literature linking benzene to blood cancers date back to the 1930s. (Id. 26 at ¶ 47.) Over time, the use of benzene has declined because of its connection to blood cancers, 27 including acute myelogenous leukemia. (Id. at ¶¶ 47, 48; see also id. at ¶¶ 50, 51.) Benzene has 1 id. at ¶ 55.) Plaintiffs allege that benzene should not be in any drug products. (Id. at ¶ 53.) 2 Fifty million Americans suffer from acne annually, with acne beginning as early as age 3 seven and persisting through adulthood into ages 50s and 60s. (Id. at ¶ 23.) BPO is a drug used 4 to treat acne. (Id. at ¶¶ 2, 25.) Plaintiffs allege that Walgreens' BPO products utilized BPO 5 along with other inactive ingredients to make acne treatment creams, washes, scrubs, and bars. 6 (Id. at ¶ 2.) BPO products should not have benzene in them nor degrade into benzene except 7 under extraordinary circumstances. (Id. at ¶ 3.) Plaintiffs allege that the BPO in products made 8 and sold by Walgreens degrades over time to directly form benzene. (Id. at ¶ 9.) Essentially, 9 Plaintiffs assert that BPO can thermally decompose into benzene radicals that can then produce 10 benzene. (See id. at ¶ 9.) Plaintiffs allege that this process was first reported in scientific 11 literature as early as 1936. (Id. at ¶ 29.) 12 Valisure LLC ("Valisure") is an analytical laboratory and online pharmacy that tests 13 medications and healthcare products to ensure their safety, quality, and consistency. (Id. at ¶ 6.) 14 Valisure is accredited by the International Organization for Standardization ("ISO/IEC") 15 17025:2017 standards for chemical testing (PJLA Accreditation Number 94238) and is registered 16 with the Drug Enforcement Administration (License # RV0484814). (Id. at ¶¶ 6 n.5, 40.) On
17 March 5, 2024, Valisure filed a citizen petition with Federal Food and Drug Administration,
18 requesting a recall and suspension of sales of BPO from the U.S. market. (Id. at ¶¶ 6 n.5, 40, 45; 19 ECF No. 14-1.)1 In layman's terms, Valisure reported that it had tested and detected high levels 20 of benzene in specific batches of BPO products, including the Walgreens Maximum Strength 21 10% BPO Acne Foaming Wash and the Walgreens Daily Creamy BPO Acne Face Wash. (See 22 23 24 1 Plaintiffs have unambiguously incorporated Valisure's citizen petition into the first amended complaint. (ECF No. 1, ¶¶ 6 n.5, 40.) Alongside its motion to dismiss, Walgreens has moved for formal incorporation of Valisure's 25 citizen petition. (ECF Nos. 14, 14-1.) "Even if a document is not attached to a complaint, it may be incorporated by reference into a complaint if the plaintiff refers extensively to the document or the document forms the basis of the plaintiff's claim." United States v. Ritchie, 342 F.3d 903, 908 (9th Cir. 2003). "If the documents are not physically 26 attached to the complaint, they may be considered if the documents' authenticity is not contested and the plaintiff's complaint necessarily relies on them." Lee v. City

of Los Angeles, 250 F.3d 668, 688 (9th Cir. 2001) (cleaned up). 27 Because the citizen petition is a filing with a government agency, and because Plaintiff's claims necessarily rely on the findings detailed therein, the Court incorporates the citizen petition into the first amended complaint. In light of 1 ECF No. 14-1, p. 16;2 ECF No. 1, ¶¶ 6, 41.) More specifically, Valisure stated that "current 2 evidence suggests that on-market BPO products could produce substantial amounts of benzene 3 when stored at above-ambient temperatures, specifically 37°C (98.6°F), 50°C (122°F) and 70°C 4 (158°F)." (ECF No. 14-1, p. 2.) Moreover, Valisure also detected the substantial production of 5 benzene "emanating externally into the air surrounding an unopened benzol peroxide product," 6 which implicates possible inhalation exposure. (Id. at p. 4.) Valisure observed that the problem 7 with benzene in BPO products is seemingly due to the "inherent instability of the benzol 8 peroxide molecule that breaks down and forms benzene." (Id. at p. 9) (emphasis omitted) (see 9 ECF No.1, ¶¶ 7, 43, 44.) 10 The citizen petition acknowledged the most recent guidance from the FDA, which in 11 2011 determined that "that benzoyl peroxide [2.5% to 10%] can be adequately labeled to 12 minimize risks while delivering effective acne treatment." (Id. at p. 4.) Meanwhile prescription- 13 strength BPO products require a warning that: "[t]he role of benzoyl peroxide as a tumor 14 promoter has been well established in several animal species. However, the significance of this 15 finding in humans is unknown." (Id.) 16 Valisure tested 99 different BPO products, both prescription and OTC, including at least 17 two products from Walgreens, incubating the products at 122 degrees Fahrenheit for 18 days. 18 (Id. at pp. 16-19; see ECF No. 1, ¶¶ 6, 41.) Results demonstrated that there was a "substantial 19 instability of BPO and its propensity to form concerningly high levels of benzene in only 18 20 days." (ECF No. 14-1, p. 19.) Valisure noted that 122 degrees Fahrenheit is a reasonable 21 temperature to test because it is a temperature the products may be exposed to during distribution 22 and because it is an "accepted incubation temperature" used in the pharmaceutical industry. (Id. 23 at pp. 18-19.)3 In addition, Valisure stated that it observed evidence that BPO product packaging 24 may be porous to benzene, enabling some of the benzene "to escape into the environment or air 25 around the package." (Id. at p. 23; see ECF No. 1, ¶ 44.) 26 2 All references to pagination of specific documents pertain to those as indicated on the upper right corners via the CM/ECF electronic court docketing system. 27 3 Similar findings were made when Valisure tested certain products, incubating them at 158 degrees Fahrenheit. 1 Valisure offered a possible future remedy to address BPO instability, suggesting the 2 creation of reformulations of BPO-containing acre treatment products. (Id. at p. 26.) 3 Nonetheless, the citizen petition seeks, among other relief, "to have the Commissioner and FDA 4 request recalls and a suspension of sales for products containing the active pharmaceutical 5 ingredient benzoyl peroxide, consistent with FDA's mandate to ensure the safety of prescription 6 and over the counter the drugs in the United States." (Id. at p. 30; see also ECF No. 1, ¶ 45.) 7 Pursuant to FDA guidance, benzene should be restricted to 2 ppm (parts per million) 8 where its use in manufacturing is unavoidable in order to produce a drug product with a 9 significant therapeutic advance. (See ECF No. 1, ¶¶ 6, 53.)4 As a Class 1 solvent, benzene 10

should not be employed in the manufacture of drug substances or drug products except in 11 "limited cases." (Id. at ¶ 48 n.51.) In December 2022, the FDA issued a statement alerting 12 manufacturers to the risk of benzene contamination and 13 remind[ing] drug manufacturers they are required to establish scientifically sound and appropriate specifications and test 14 procedures to assure drug components (active and inactive ingredients) and finished drug product conform to appropriate 15 specifications (21 CFR 211.84, 21 CFR 211.160). This includes testing of raw materials and finished product batches (21 CFR 16 211.165) prior to release to ensure they meet appropriate specifications for identity, strength, quality and purity. 17 (Id. at¶ 37; see also id. at ¶ 31 n.31). The statement also included that "[i]f any drug product 18 batches with benzene above 2 ppm are already in distribution, the manufacturer should contact 19 FDA to discuss the voluntary initiation of a recall[.]" (Id. at ¶ 38.; see also id. at ¶ 31 n.31.) The 20 FDA further warned that if any drug or drug component was subject to deterioration, drug 21 manufactures must have re-testing procedures in place to ensure continued purity and stability. 22 (Id. at ¶ 38.) The FDA put out a substantially similar update in December 2023. (Id. at ¶ 38; see 23 also id. at ¶ 31 n.30.) 24 Beginning in 2020, the FDA started working with companies to identify benzene in 25 products which has resulted in product recalls of hand sanitizers, sunscreens, and deodorants. 26 27 4 In addition to the FDA, the U.S. Environmental Protection Agency regulates the use of benzene where its use may affect water and air emissions. (ECF No. 1, ¶ 52.) Relatedly, the Occupational Safety and Health Administration, 1 (Id. at ¶ 36.) In the last three years, the FDA has announced over a dozen recalls of various drug 2 and cosmetic products containing low levels or even trace levels of benzene, including hand 3 sanitizers, aerosol sunscreens, and aerosol antiperspirants. (See id. at ¶ 36.) 4 III.

5 FACTUAL AND PROCEDURAL BACKGROUND

6 Plaintiffs in this action are Grace Navarro ("Navarro") and Chatham Mullins ("Mullins"). 7 (ECF No. 1, ¶¶ 15, 16.) Navarro is a resident of California, and from June 2022 through

8 September 2022, she purchased multiple Walgreens branded BPO products, including

9 Walgreens' Maximum Strength Acne Foaming Wash. (Id. at ¶¶ 15, 69.) Navarro places a high 10 priority on health and safety, "and on the adverse health consequences of exposure to 11 carcinogens such as benzene." (Id. at ¶ 68.) Navarro states that she was particularly concerned 12 about the effectiveness of the product to treat and prevent acne, and "[she] read the front labeling 13 of the product which encouraged her to purchase the product by Defendant[]." (Id. at ¶ 68.) 14 When making her purchase, Navarro relied upon the label, Walgreens' widely recognized name, 15 and the absence from the product that it contained or might contain carcinogens such as benzene. 16 (Id. at ¶ 68.) In other words, Navarro believed Walgreens' BPO product was "safe to put on her 17 skin." (Id.) Navarro was not aware that when she bought Walgreens' BPO product that it 18 contained or might degrade into benzene. (Id. at ¶ 69.) Had Walgreens informed Navarro of this 19 possibility, "she would not have purchased Walgreens' Maximum Strength Acne Foaming 20 Wash." (Id. at ¶¶ 12, 15, 69, 70.) 21 Mullins is a resident of Massachusetts, and from

2005 through 2023, she purchased 22 multiple Walgreens BPO products, including Walgreens' Daily Creamy Benzoyl Peroxide Acne 23 Face Wash. (Id. at ¶¶ 16, 72.) Like Navarro, Mullins places a high priority on health and safety, 24 "and on the adverse health consequences of exposure to carcinogens such as benzene." (Id. at 25 ¶ 71.) Mullins states that she was particularly concerned about the effectiveness of the product, 26 including resolving skin inflammation. (Id.) Mullins states that "[she] read the front labeling of 27 the product which encouraged her to purchase the product by Defendant[]." (Id.) When making 1 absence from the product that it contained or might contain carcinogens such as benzene. (Id.) 2 Mullins too believed Walgreens' BPO product was "safe to put on her skin." (Id.) Mullins was 3 not aware that when she bought Walgreens' BPO product that it contained or might degrade into 4 benzene. (Id. at ¶ 72.) Had Walgreens informed Mullins of this possibility, "she would not have 5 purchased Walgreens' Daily Creamy Benzoyl Peroxide Acne Face Wash." (Id. at ¶¶ 12, 16, 72, 6 73.) 7 Defendant is Walgreens, a company that is a citizen of Illinois and Delaware with its 8 principal place of business in Deerfield, Illinois. (Id. at ¶ 17.) Plaintiffs state that Walgreens 9 dominates the drug and consumer health care products markets as a pharmacy and retail leader 10 serving millions of customers and patients every day. (Id. at ¶¶ 24, 65.) Walgreens has 11 approximately 13,000 locations worldwide, and it earned 139.1 billion dollars during fiscal year 12 2023. (Id. at ¶ 24.) Walgreens' BPO products are used by children and teenagers as a 13 standalone treatment or in combination with other BPO products. (Id. at ¶ 61.) Walgreens 14 conducted business and derived substantial revenue from its manufacturing, advertising, 15 marketing, distributing, and selling of the BPO products within the State of California. (Id. at 16 ¶ 17.) Walgreens promoted, marketed, and sold its BPO, private label products in California, 17 including within the Eastern District of California. (Id. at ¶¶ 18, 23.) This included marketing to 18 children and teenagers with Walgreens featuring children or teenagers in its advertisements. (Id. 19 at ¶ 62.) Plaintiffs allege that Walgreens' advertising and labeling decisions were prepared 20 and/or approved by Walgreens and thereafter disseminated to consumers, including Plaintiffs. 21 (Id. at ¶ 18.) 22 Plaintiffs allege Walgreen's BPO products did not meet conformity with cGMPs as to 23 quality, safety, and purity specifications. (Id. at ¶ 2.) In particular, Plaintiffs allege that 24 Walgreens did not adequately test and retest its BPO products before marketing and selling them 25 to the public. (Id. at ¶¶ 25, 26, 35.) Plaintiffs assert that Walgreens knew or should have known 26 that BPO products degrade into benzene when exposed to heat or more generally whether their 27 BPO products were chemically and physically stable. (Id. at ¶¶ 9, 28, 30, 31, 32, 64, 67.) 1 used, and stored by distributors, sellers, and consumers under various temperatures . . ." (Id. at 2 ¶¶ 9, 33, 34.) 3 Plaintiffs allege that the BPO products sold by Walgreens "decomposed into benzene 4 rendering them materially different than advertised, i.e., by containing unsafe levels of benzene." 5 (Id. at ¶¶ 5, 57.) However, Walgreens never listed benzene among the ingredients in its BPO 6 products, or anywhere on the products' labels, containers, advertising or on Walgreens' websites. 7 (Id. at ¶¶ 8, 46; see also id. at ¶ 57.) Plaintiffs allege that this "misled" them and the public 8 because the BPO

products were seemingly safe, even giving such products a two- to three-year 9 expiration date. (Id. at ¶¶ 9, 58, 63, 66.) This placed Plaintiffs and the public at "risk of 10 exposure to benzene, and at increased risk of cancer, without their knowledge and consent." (Id. 11 at ¶11.) Plaintiffs alleged that they were exposed to benzene from BPO products by inhalation 12 and/or dermal absorption. (Id. at ¶ 56.) Plaintiffs allege that Walgreens had notice of the 13 dangers of benzene, including notice by the FDA. (Id. at ¶ 66.) 14 On March 8, 2024, Plaintiffs commenced this action, bringing the following claims 15 against Walgreens: 16 1) violation of California's Unfair Competition Law ("UCL"), Cal. Bus. & 17 Prof. Code § 17200, et seq.; 18 2) violation of California's Consumer Legal Remedies Act ("CLRA"), 19 Cal. Civ. Code § 1750, et seq.; 20 3) violation of California's False Advertising Law ("FAL"), Cal. Bus. & 21 Prof. Code §§ 17500, et seq., as well as similar statutes under the 22 laws of Hawaii and New York; 23 4) violation of deceptive trade practices under the laws of Connecticut, 24 Hawaii, Illinois, Maryland, Massachusetts, Missouri, New York, 25 Nevada, Pennsylvania, Ohio, Rhone Island, and Washington State; 26 5) breach of express warranty under the laws of California, Connecticut, 27 Hawaii, Illinois, Maryland, Massachusetts, Missouri, New York, 1 6) breach of implied warranty under the laws of California, Connecticut, 2 Hawaii, Illinois, Maryland, Massachusetts, Missouri, New York, 3 Nevada, Pennsylvania, Ohio, Rhone Island, and Washington State; 4 and 5 7) unjust enrichment under the laws of California, Connecticut, Hawaii, 6 Illinois, Maryland, Massachusetts, Missouri, New York, Nevada, 7 Pennsylvania, Ohio, Rhone Island, and Washington State; 8 (ECF No. 1, pp. 31-41.) For relief, Plaintiffs pray for an order certifying a proposed class; an 9 order declaring Walgreens' conduct violates the laws outline in the causes of action; injunctive 10 and declaratory relief; a court order for Walgreens to disgorge profits and revenues derived from 11 the course of misconduct; compensatory and other damages; punitive damages allowable by law; 12 attorney's fees and costs of suit; statutory pre-judgment and post-judgment interest. (Id. at 13 pp. 44-45; ECF No. 1, ¶ 14.) 14 On May 30, 2024, Walgreens moved to dismiss the action for lack of standing and failure 15 to state a claim, and the district judge referred the motion to the undersigned for the preparation 16 of findings and recommendations. (ECF Nos. 13, 26.) Following litigation not relevant here, the 17 motion has been fully briefed (ECF Nos. 29, 30), and on March 26, 2025, the Court held a 18 hearing on the matter. (ECF No. 34.) 19 IV.

20 LEGAL STANDARDS

21 Under Federal Rule of Civil Procedure 12(b)(1), a complaint must be dismissed if a 22 plaintiff lacks Article III standing to bring suit. Maya v. Centex Corp., 658 F.3d 1060, 1067 (9th

23 Cir. 2011). The standing doctrine is derived from limitation of Article III on the judicial power

24 of federal courts to hear only "actual cases or controversies." Spokeo, Inc. v. Robins, 578 U.S.

25 330, 337 (2016) (internal quotation marks omitted). "The doctrine limits the category of litigants 26 empowered to maintain a lawsuit in federal court to seek redress for a legal wrong." Id. at 338. 27 Standing "is not dispensed in gross; rather, plaintiffs must demonstrate standing for

each claim 1 U.S. 413, 431 (2021). “The irreducible constitutional minimum of standing consists of three 2 elements. The plaintiff must have (1) suffered an injury in fact, (2) that is fairly traceable to the 3 challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial 4 decision.” Spokeo, 578 U.S. at 338 (cleaned up), quoting Lujan v. Defenders of Wildlife, 504 5 U.S. 555, 560-61 (1992). A plaintiff must show that the injury was “an invasion of a legally 6 protected interest” that is “concrete and particularized” and “actual or imminent, not conjectural 7 or hypothetical.” Lujan, 504 U.S. at 560 (internal quotation marks omitted). 8 The party invoking federal jurisdiction bears the burden of demonstrating standing. 9 TransUnion, 594 U.S. at 430-31. A jurisdictional challenge under Rule 12(b)(1) may be facial or 10 factual. Safe Air for Everyone v. Meyer, 373 F.3d 1035, 1039 (9th Cir. 2004). A facial 11 challenge “asserts that the allegations contained in a complaint are insufficient on their face to 12 invoke federal jurisdiction.” Id. The “‘general rule’ for Rule 12(b)(1) motions challenging 13 subject-matter jurisdiction is to take allegations ‘as true unless denied or controverted by the 14 movant.’” Federal Bureau of Investigation v. Fikre, 601 U.S. 234, 237 n.1 (2024), quoting 5C C. 15 Wright & A. Miller, Federal Practice and Procedure § 1363, p. 107 (3d ed. 2004). A factual 16 challenge “disputes the truth of the allegations that, by themselves, would otherwise invoke 17 federal jurisdiction.” Safe Air for Everyone, 373 F.3d at 1039. Generally, in resolving a factual 18 attack, “the district court may review evidence beyond the complaint without converting the 19 motion to dismiss into a motion for summary judgment” and “need not presume the truthfulness 20 of the plaintiff’s allegations.” Id. (citations omitted). However, the Ninth Circuit recently 21 clarified that “when jurisdictional issues are ‘intertwined with an element of the merits of the 22 plaintiff's claim,’ the court must treat the motion like a motion for summary judgment and ‘leave 23 the resolution of material factual disputes to the trier of fact.’” Bowen v. Energizer Holdings, 24 Inc., 118 F.4th 1134, 1143 (9th Cir. 2024), quoting Leite v. Crane Co., 749 F.3d 1117, 1122 (9th 25 Cir. 2014).

26 Additionally, Federal Rule of Civil Procedure 8(a)(2) requires a complaint to include “a 27 short and plain statement of the claim showing that the pleader is entitled to relief.” A complaint 1 12(b)(6). To overcome a Rule 12(b)(6) motion to dismiss, “a complaint must contain sufficient 2 factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” Ashcroft 3 v. Iqbal, 556 U.S. 662, 678 (2009), quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 4 (2007). “A claim has facial plausibility when the plaintiff pleads factual content that allows the 5 court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” 6 Id. “Plausibility requires pleading facts, as opposed to conclusory allegations or the formulaic 7 recitation of the elements of a cause of action, and must rise above the mere conceivability or 8 possibility of unlawful conduct that entitles the pleader to relief.” Somers v. Apple, Inc., 729 9 F.3d 953, 959-60 (9th Cir. 2013) (cleaned up). “Factual allegations must be enough to raise a 10 right to relief above the speculative level.” Twombly, 550 U.S. at 555. 11 In ruling on a Rule 12(b) (6) motion, the court “accept[s] all factual allegations in the 12 complaint as true and construe[s]

the pleadings in the light most favorable to the nonmoving 13 party." Rowe v. Educ. Credit Mgmt. Corp., 559 F.3d 1028, 1029-30 (9th Cir. 2009) (citation 14 omitted). But "allegations that are merely conclusory, unwarranted deductions of fact, or 15 unreasonable inferences" need not be accepted. In re Gilead Scis. Sec. Litig., 536 F.3d 1049, 16 1055 (9th Cir. 2008) (citation omitted). "Dismissal is appropriate when the complaint lacks a 17 cognizable legal theory or sufficient factual allegations to support a cognizable legal theory." 18 Saloojas, Inc. v. Aetna Health of Cal., Inc., 80 F.4th 1011, 1014 (9th Cir. 2023) (cleaned up). 19 V.

20 DISCUSSION AND ANALYSIS

21 Walgreens argues that Plaintiffs have failed to plead an injury-in-fact and therefore lack 22 standing to bring their claims. (ECF No. 13, pp. 17-20.)5 Relatedly, Walgreens then asserts that 23 Plaintiffs fail to state a claim because they have not alleged that that the BPO products they 24 25

5 Walgreens filed its motion to dismiss on May 30, 2024. (ECF No. 13.) The parties then stipulated to stay the case until there was a ruling from the Judicial Panel on Multidistrict Litigation, which eventually denied Plaintiffs' motion. (ECF Nos. 17, 19.) Following litigation not relevant here, on December 20, 2024, Plaintiffs filed their 26 opposition to the motion and included what appears to be responsive arguments to other contentions raised in other motions to dismiss in related cases. (ECF No. 29.) In its reply, Walgreens acknowledged and countered these 27 arguments. (ECF No. 30.) Given the unique briefing schedule and the motion practice in related cases, the Court accepts and will address all arguments the parties have presented, notwithstanding if they first appear in the motion 1 purchased actually contained benzene. (Id. at pp. 17-19.) Even if Plaintiffs were to state a claim, 2 Walgreens argues that their claims are preempted by federal law (or that the FDA has primary 3 jurisdiction). (Id. at pp. 21-25; ECF No. 30, pp. 7-10.) Walgreens also attacks Plaintiffs' claims 4 by arguing that certain fraud claims are barred by statute, the claims fail to satisfy the pleading 5 standard of Rule 9(b), and that Plaintiffs have no cognizable basis for equitable or injunctive 6 relief. (Id. at pp. 25-30.)6 7 Plaintiffs oppose, arguing that they have sufficiently pleaded an economic injury that has 8 been recognized by the Ninth Circuit to confer standing. (ECF No. 29, pp. 11-13.) Moreover, 9 Plaintiffs clarify that their claims are based on alleged omissions by Walgreens and that they 10 adequately allege such claims. (Id. at p. 23.) Regarding preemption, Plaintiffs assert that their 11 state law claims are permissible to proceed notwithstanding federal regulation. (Id. at pp. 14-21.) 12 Plaintiffs then explain how in their view the primary jurisdiction doctrine is inapplicable here. 13 (Id. at pp. 21-22.) Plaintiffs address in turn Walgreens' arguments regarding their fraud claims 14 and pleading standards, as well as injunctive relief. (Id. at pp. 22-26.) Finally, Plaintiffs note 15 that they plead their equitable relief in the alternative, and therefore, there is no reason to dismiss 16 their equitable claims at this early stage of litigation. (Id. at p. 25-26.) 17 The Court first addresses the threshold issue of standing before turning to Walgreens' 18 other arguments. 19 A. Standing 20 The Court begins by observing that Walgreens attack on subject-matter jurisdiction is 21 facial—i.e., Walgreens attacks the allegations in the complaint as well as the incorporated citizen 22

petition from Valisure. See Safe Air for Everyone, 373 F.3d at 1039. Walgreens contends that 23 Plaintiffs have failed to allege an injury-in-fact because the complaint does not contain facts that 24 6 Walgreens makes separate arguments as to how Plaintiffs are unable to state claims on behalf of the putative class. 25 However, it is axiomatic that Plaintiffs themselves must first withstand Walgreens' motion to dismiss before they could represent a class. See Lewis v. Casey, 518 U.S. 343, 357 (1996) ("[E]ven named plaintiffs who represent a class must allege and show that they personally have been injured, not that injury has been suffered by other, 26 unidentified members of the class to which they belong and which they purport to represent.") (internal citation omitted); see also TransUnion LLC, 594 U.S. at 43 ("Every class member must have Article III standing in order to 27 recover individual damages."). Because the Court will recommend that the district judge grant Walgreens' motion to dismiss, the Court finds that any discussion of this argument would be too speculative at this time. See Melendres 1 plausibly demonstrate that their BPO products contained benzene and were actually unsafe and 2 therefore have failed to plead an injury-in-fact, as required for Article III standing. (ECF No. 13, 3 p. 17-19.) 4 However, as also recognized in at least two other district court opinions, the Ninth 5 Circuit's recent decision in Bowen v. Engergizer Holdings, Inc., 118 F.4th 1134 (9th Cir. 2024), 6 dispenses with Walgreens' standing argument. Ottesen v. Hi-Tech Pharmaceuticals, Inc., No. 7 19-cv-07271-JST, 2024 WL 5205539, at *8 (N.D. Cal. Dec. 23, 2024); Bonthon v. Procter & 8 Gamble Company, No. 23-cv-00765-AMO, 2024 WL 4495501, at *7 (N.D. Cal. Oct. 15, 2024); 9 see Howard v. Alchemee, LLC, Nos. 2:24-cv-01834-SB-BFM; 2:24-cv-01876-SB-BFM; 2:24- 10 cv-01878-SB-BFM, 2024 WL 4272931, at *2-*5 (C.D. Cal. Sept. 19, 2024); see also Eisman v. 11 Johnson & Johnson Consumer, Inc., No. 2:24-cv-01982-ODW (AJRx), 2025 WL 241024, at *2 12 (C.D. Cal. Jan. 17, 2025) (acknowledging the defendants' argument regarding standing but 13 analyzing only whether the plaintiff's claims were preempted). 14 In Bowen, the plaintiff brought a putative class action alleging that the defendants' 15 sunscreen products contained an unsafe level of benzene. 118 F.4th at 1140. The plaintiff 16 alleged a myriad of claims, including California state law claims under the FAL, UCL, and 17 CLRA. Id. The plaintiff specifically alleged that she "would have never paid a premium for 18 sunscreen products that contained or were at risk of containing the carcinogen benzene" and that 19 she "suffered economic injury when she spent money to purchase sunscreen products she would 20 not otherwise have purchased, or [would have] paid less for, absent Defendants' misconduct 21 . . . ." Id. at 1141 (modification in original). Relying on an FDA "guideline permitting 2 ppm of 22 benzene in sunscreen," the district court concluded that the plaintiff "[did] not allege facts that 23 tend to show a non-speculative increased health risk or actual economic harm" and granted the 24 defendants' motion to dismiss. Id. 25 The Ninth Circuit reversed. Reaffirming precedent, the Court observed that under a 26 theory of economic harm a plaintiff "need prove only that she 'paid more for [the product] than 27 [she] otherwise would have paid, or bought it when [she] otherwise would not have done so,' 1 representations—or actionable non-disclosures—about [the product].'" Bowen, 118 F.4th at 2 1147, quoting McGee v.

S-L Snacks National, 982 F.3d 700, 706 (9th Cir. 2020). 3 Here, Plaintiffs allege that before purchasing Walgreens' BPO products they read and 4 relied on the labeling on the products, including the Walgreens name brand, when deciding to 5 make their purchases; Plaintiffs believed that the products were safe for their skin. Plaintiffs 6 allege that the products they purchased were adulterated or misbranded because the BPO 7 degraded or could degrade into benzene. While Plaintiffs did not have their individual products 8 tested, they allege that Valisure tested Walgreens' Maximum Strength 10% BPO Acne Foaming 9 Wash and Walgreens' Daily Creamy Benzoyl Peroxide Acne Face Wash. Plaintiffs state that 10 would not have purchased Walgreens' BPO products if had known that the products could 11 degrade into benzene. Thus, under Bowen, the Court finds that Plaintiffs have sufficiently 12 alleged economic harm sufficient to confer Article III standing. See 118 F.4th at 1146-47.7 13 The Court will recommend denying Defendant's motion to dismiss insofar as it seeks to 14 dismiss for lack of standing. 15 B. Preemption 16 Walgreens argues that all of Plaintiffs claims are expressly and impliedly preempted by 17 the FDCA. (ECF No. 13, pp. 21-25.) In opposition, Plaintiffs explain that, in their view, their 18 claims are not preempted under any theory of preemption. (ECF No. 29, pp. 14-21.). Further, 19 Plaintiffs note that some of their claims are based on alleged failures by Walgreens to follow 20 cGMPs that may form the basis of a state law "parallel claim," which are not subject to 21 preemption. (Id.) Walgreens responds that essentially none of Plaintiffs claims are in fact 22 parallel, Plaintiffs have failed to allege facts that demonstrate that Walgreens failed to comply 23 with cGMPs. (ECF No. 30, pp. 7-12.) While the parties' briefing seemingly rushes to whether 24 7 The Court notes that in TransUnion LLC the Supreme Court of the United States held that the Article III standing 25 requirement of injury-in-fact requires a plaintiff allege a "concrete" injury "even in the context of a statutory violation." 594 U.S. 413, 426 (2021), quoting Spokeo, 578 U.S. at 341. In other words, "under Article III, an injury in law is not an injury in fact." Id. at 427. For purposes of an injury-in-fact, the Court scrutinized Plaintiff's logic 26 chain that based on the Valisure study—that did not test the actual products Plaintiffs purchased—whether it can be extrapolated that the BPO products Plaintiffs purchased even risked containing benzene. Which, if there were no 27 risk, then there would almost certainly be no economic harm. That said, at this stage of the litigation, the Court accepts as true, as it must, the allegations that there was at least a potential risk that Plaintiffs suffered an economic 1 Plaintiffs have provided allegations that state a claim, the Court must still first address whether 2 Plaintiffs' claims are preempted. 3 A couple preliminaries. Plaintiffs have stated that they rely on a "well-pled omission 4 theory." (ECF No. 29, p. 23.)8 In other words, Plaintiffs assert that they have alleged that 5 Walgreens did not inform consumers that its products contained or could degrade into benzene. 6 In turn, this failure reduced the economic value of the products, which caused Plaintiffs 7 "economic injury." (Id. at p. 11.) Regarding preemption, Plaintiffs begin with the general 8 proposition that so-called state law "parallel claims" are not preempted by the FDCA. (Id. at 9 p. 14.) Plaintiffs then argue, inter alia, that while the Acne Monograph does have set 10

requirements, other regulations (cGMPs) must also be followed. (Id. at p. 15.) It is with this 11 understanding that the Court considers the issue of preemption. 12 1. Preemption Legal Principles 13 "A fundamental principle of the Constitution is that Congress has the power to preempt 14 state law." Crosby v. Nat'l Foreign Trade Council, 530 U.S. 363, 372 (2000). Preemption 15 comes in multiple forms—express, field, and conflict preemption—but the purpose of Congress 16 is "the ultimate touchstone" for all of them. Gilstrap v. United Air Lines, Inc., 709 F.3d 995, 17 1003 (9th Cir. 2013), quoting Cipollone v. Liggett Grp., Inc., 505 U.S. 504, 516 (1992). 18 As relevant here, to ensure uniformity in the regulation of OTC drugs like Walgreens' 19 BPO products, the FDCA contains a broad express preemption provision, which provides that no 20 state "may establish or continue in effect any requirement—(1) that relates to the regulation of a 21 [nonprescription drug]; and (2) that is different from or in addition to, or that is otherwise not 22 identical with, a requirement under" the FDCA. 21 U.S.C. § 379r(a). The statute defines 23 "requirement" to include "any requirement relating to public information or any other form of 24 25 8 Plaintiffs at time characterize their allegations as Walgreens making affirmative statements regarding health and safety as to the BPO products, when the only allegations are that Plaintiffs inferred from the BPO products, seemingly by omissions from Walgreens, that they were safe for their intended use. (See ECF No. 1, ¶¶ 57-60; see 26 also id. at ¶ 63.) Even giving Plaintiffs the benefit of every reasonable inference, the Court finds Plaintiffs' use of the terms affirmations and statements in this context to be conclusory—Plaintiffs have not identified any affirmative 27 statement regarding health or safety made by Walgreens on the product, its packaging, or advertising. Indeed, elsewhere in the complaint, Plaintiffs characterize Walgreens' actions as a deliberate omission, which comports with 1 public communication relating to a warning of any kind for a drug." 21 U.S.C. § 379(c)(2). 2 OTC acne drug products, including Walgreens' products, are governed by a 3 comprehensive set of FDA regulations called a monograph, which includes certain labeling 4 requirements. 21 C.F.R. §§ 330.1, 330.5, 330.10; 333.350. The acne monograph expressly 5 permits BPO to be an active ingredient in these products in an amount from 2.5 to 10 percent. 21 6 C.F.R. § 333.310(a). Section 333.350 provides detailed instructions for labeling covered 7 products, including specific warnings and directions that must be included for products 8 containing BPO. 21 C.F.R. § 333.350(c)(4), (d)(2). The regulations provide that an OTC acne 9 drug product "is generally recognized as safe and effective and is not misbranded if it meets each 10 of the conditions" in the monograph and "each general condition" in 21 C.F.R. § 330.1. Id. at 11 § 333.301. In turn, Section 330.1 specifies that OTC drugs must meet the conditions described 12 therein and must be "labeled in compliance with chapter V" of the FDCA and "the format and 13 content requirements in § 201.66." 21 C.F.R. § 330.1(c)(1). Chapter V of the FDCA prohibits 14 the sale of adulterated or misbranded drugs. 21 U.S.C. §§ 331(a), 351, 352. 15 Consistent with Congress's intent to promote uniform drug regulation, the preemptive 16 effect of Section 379r applies not only to state legislation or regulations but also to claims under 17 state law that would have the effect, if the defendant were liable, of imposing a requirement "at 18 variance with FDA

regulations." Carter v. Novartis Consumer Health, Inc., 582 F. Supp. 2d 19 1271, 1280-83 (C.D. Cal. 2008); see also Morgan v. Albertsons Companies, Inc., No. 22-cv- 20 02948, 2023 WL 3607275, at *4-*5 (N.D. Cal. Mar. 13, 2023). Therefore, "state law claims 21 regarding the labeling or packaging of [OTC drugs] that are not identical to the [FDCA] are 22 expressly preempted." Henning v. Luxury Brand Partners, LLC, No. 22-cv-07011-TLT, 2023 23 WL3555998, at *5 (N.D. Cal., May 11, 2023); see Gisvold v. Merck & Co., 62 F. Supp. 3d 1198, 24 1203 (S.D. Cal. 2014). 25 However, Section 379r does not preempt claims under state law that impose identical or 26 "parallel" requirements to FDA regulations. Riegel v. Medtronic, 552 U.S. 312, 330 (2008); see 27 Ebrahimi v. Mentor Worldwide LLC, 804 Fed. Appx. 871, 872 (9th Cir. 2020) (mem.). As 1 door open to state-law claims 'parallel' to federal requirements." McClellan v. I-Flow Corp., 2 776 F.3d 1035, 1040 (9th Cir. 2015); see Davidson v. Sprout Foods, Inc., 106 F.4th 842, 849 (9th

3 Cir. 2024), discussing Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341 (2021). To

4 avoid preemption, "[t]he plaintiff must be suing for conduct that violates the FDCA (or else his 5 claim is expressly preempted [ ]) but the plaintiff must not be suing because the conduct violates 6 the FDCA (such a claim would be impliedly preempted under Buckman)." Perez v. Nidek Co., 7 Ltd., 711 F.3d 1109, 1120 (9th Cir. 2013) (citation omitted) (emphasis in original).9 8 2. Benzene Warning on Label 9 Notwithstanding that Plaintiffs' claims seem to emanate from a theory of omission, the 10 complaint still sets out that the BPO products Walgreens sold were misbranded under the FDCA 11 because the labels did not disclose or warn that the products contain or might contain benzene. 12 (See ECF No. 1, ¶¶ 8, 12, 15, 46, 57, 69-73.) However, federal labeling regulations do not 13 require such a statement, so Plaintiffs' claims, insofar as they grounded on this basis, are 14 expressly preempted. 15 The upshot of the regulations and the acne monograph, described above, is that a drug 16 that complies with all monograph requirements is not misbranded. 21 C.F.R. § 330.10(a)(1) 17 ("The Commissioner shall . . . evaluate the safety and effectiveness of OTC drugs, to review 18 OTC drug labeling, and to advise him on the promulgation of monographs establishing 19 conditions under which OTC drugs are generally recognized as safe and effective and not 20 misbranded"); see also 21 C.F.R. § 333.301(a) ("An over-the-counter acne drug product in a 21 form suitable for topical application is generally recognized as safe and effective and is not 22 9 Regarding how to interpret express preemption provision, the Court agrees with Walgreens that much of precedent 23 cited by Plaintiffs is inapposite. For example, Plaintiffs cite to Wyeth v. Levine, 555 U.S. 555 (2009), for the general proposition that even in express preemption, the "statutory language should be construed narrowly and not 24 expanded to displace the traditional state sovereignty to enforce their own laws." (ECF No. 29, p. 14.) However, in Wyeth, the Supreme Court was analyzing preemption in a statute where "[Congress] declined to enact [an express 25 preemption] provision for prescription drugs." Id. at 567. Moreover, the Supreme Court has consistently reaffirmed that when a statute "'contains an express pre-emption clause,' [courts] do not invoke any presumption against pre- emption but

instead ‘focus on the plain wording of the clause, which necessarily contains the best evidence of 26 Congress’ pre-emptive intent.’” Commonwealth of Puerto Rico v. Franklin California Tax-free Trust, 579 U.S. 115, 125 (2016), quoting Chamber of Commerce of United States of America v. Whiting, 563 U.S. 582, 594 (2011). 27 Here, Plaintiffs concede that 21 U.S.C. § 379r contains an express preemption provision. (ECF No. 29, p. 14.) Thus, Plaintiffs reliance on Wyeth and suggestion that Walgreens must present preemption as a ‘demanding 1 misbranded if it meets each of the conditions in this subpart and each general condition 2 established in § 330.1 of this chapter.”). 3 Here, the acne monograph lists BPO as a permitted active ingredient and does not require 4 manufacturers to warn consumers of benzene, or mention benzene in any capacity on the label. 5 U.S. Food & Drug Admin., Over-the-Counter (OTC) Monograph M006: Topical Acne Drug 6 Products for Over-the-Counter Human Use; see also 21 C.F.R. § 333.310(a); 21 C.F.R. 7 § 333.350(c)(4). The FDA’s monograph “allows [topical acne drugs] to be formulated with the 8 active ingredient [BPO] and does not require disclosure that [BPO] may degrade into [benzene].” 9 Williams v. Galderma Laboratories, L.P., No. 24 CV 2222, 2024 WL 4213220, at *3 (N.D. Ill.
10 Sept. 17, 2024), quoting Truss v. Bayer Healthcare Pharms. Inc., No. 21 CV 9845 (VB), 2022
11 WL 16951538, at *4 (S.D.N.Y. Nov. 15, 2022); see Mut. Pharm. Co. v. Bartlett, 570 U.S. 472,
12 488-90 (2013). 13 Therefore, to the extent Plaintiff’s claims are based on allegations that Walgreens should 14 have warned about the presence of benzene on Walgreen’s BPO product labels, that theory is 15 expressly preempted because it would be an “addition” not required by federal law. 21 U.S.C. 16 § 379r(a); see Howard, 2024 WL 4272931, at *7. The Court will recommend granting 17 Walgreen’s motion to dismiss as to this aspect of preemption. 18 Plaintiffs’ other arguments are unavailing. For example, Plaintiffs agree that the Acne 19 Monograph specifies what language must be included on a product label in order to not be 20 misbranded. (ECF No. 29, p. 15.) Plaintiffs then continue, comingling this idea with that certain 21 regulations—notwithstanding the monograph—also require complying with misbranding and 22 adulteration standards. (Id. at p. 16.) The Court views these as separate theories. On the one 23 hand, Walgreens must comply with the Acne Monograph in order to create a product that is not 24 patently misbranded. On the other hand, Walgreens is also subject to other various cGMP 25 regulations that dictate specifics on everything from manufacturing, advertising, and distribution 26 of products. If a company fails to comply with the Acne Monograph, the product is 27 automatically misbranded or adulterated. If a company complies with the Acne Monograph, the 1 compliance with a monograph, there are other regulations that if not followed could lead to a 2 product being found to be misbranded or adulterated. With this understanding, the Court finds 3 that the Acne Monograph itself cannot be used as the basis to force a company to go above and 4 beyond what that monograph prescribes because that is expressly preempted. 5 Likely due to the conflation of theories, many of Plaintiffs’ citations are to cases where 6 there was no monograph, claims arose from an ingredient not expertly permitted by a 7 monograph, and/or the plaintiffs were arguing that affirmative statements on a product were 8 misleading. See, e.g., Henning, 2023

WL3555998 (in the context of cosmetics and no 9 monograph, “to find the labels on the Products to be misleading, the factfinder must necessarily 10 find that an ingredients list that complies with the FDCA is misleading. Such a result would 11 violate the express preemption statute in 21 U.S.C. § 379s.”); Burchfield v. Prestige Consumer 12 Healthcare, Inc., 534 F.Supp.3d 1192 (C.D. Ca. Apr. 16, 2021) (no monograph and discussing 13 preemption in the context of misleading affirmative statement); Cortina v. Goya Foods, Inc., 94 14 F. Supp. 3d 1174 (S.D. Cal. 2015) (beverage; no monograph); Delarosa v. Boiron, Inc., 818 F.
15 Supp. 2d 1177 (C.D. Cal. 2011) (homeopathic drug for which, “unlike . . . non-homeopathic
16 OTC drugs, the FDA has not set up a comprehensive process to evaluate [its] safety or efficacy
17 . . .”); see also Bojko v. Pierre Fabre USA, Inc., No. 22 C 6728, 2023 WL 4204663, at *5 (N.D.
18 Ill. June 27, 2023) (even in context of no monograph, dismissing cosmetics claim based on 19 theory of omission as expressly preempted by the FDCA).10 20 3. Benzene as an Inactive Ingredient 21 22 10 The Court finds Plaintiffs’ alternative argument regarding the First Amendment to be insufficiently analytical. Plaintiffs begin with the proposition that a company retains a First Amendment right to speak regarding the 23 truthfulness of drug products it manufactures. (ECF No. 29, pp. 18-19), citing United States v. Caronia, 703 F.3d 149, 168 (2d Cir. 2012). Thus, Plaintiffs reason that the Constitution overrides preemption in this context because 24 preemption is proscribing free speech if the Acne Monograph forbids a warning regarding BPO and benzene. (Id. at p. 19.) At the hearing, the Court inquired into this alternative basis, but Plaintiffs were unable to provide the Court 25 with a persuasive argument. In particular, the Court remains unsure how to connect the dots between a company’s First Amendment rights to speak about the drugs it manufactures (usually in the context of off-label use) and a plaintiff raising a claim that depends on the company invoking such right. Indeed, the lead cases Plaintiffs provide 26 are in the context of the company itself invoking its own First Amendment right to avoid prosecution under the FDCA. Caronia, 703 F.3d at 168; Amarin Pharma, Inc. v. U.S. Food & Drug Admin., 119 F. Supp. 3d 196, 198 27 (S.D.N.Y. 2015); see also Hawkins v. Medtronic, Inc., 62 F. Supp. 3d 1144, 1151 (E.D. Cal. 2014) (discussing whether off-label promotion can violate the FDCA and noting that the reasoning in Caronia “has gained little 1 Walgreens argues that its BPO products cannot legally list benzene as a possible 2 contaminant because benzene is not a “component” because it is not intended for use in the 3 manufacture or a drug product. (ECF No. 13, p. 22.) Plaintiffs do not directly counter this 4 argument, instead focusing on that a drug may be misbranded if it contains a component that is 5 dangerous to health. (ECF No. 29, p. 16.) Because Walgreens did not intend for benzene to end 6 up in its BPO products, claims based on this theory are preempted. 7 Federal regulations require drug manufacturers to list all active and inactive ingredients 8 on the drug’s label. 21 C.F.R. § 201.66(c). Active ingredients, such as BPO, are those that are 9 “intended to furnish pharmacological activity” in the human body. Id. at § 201.66(b)(2). 10 Inactive ingredients, by contrast, are “any component other than an active ingredient.” Id. at 11 § 201.66(b)(8). 12 Whether Walgreens needed to list benzene as an inactive

ingredient on its BPO products' 13 labels turns on whether benzene is a "component." That term is not defined in part 201, which 14 relates to labeling requirements. Component is defined, however, in a different portion of the 15 same subchapter related to manufacturing: "Component means any ingredient intended for use 16 in the manufacture of a drug product, including those that may not appear in such drug product." 17 21 C.F.R. § 210.3(b)(3). If this definition is used, then benzene is not an inactive ingredient 18 because it is not intended for use; it is an "unintended contaminant." Williams, 2024 WL 19 4213220, at *4 (internal quotation omitted). 20 The Court finds persuasive the approach taken by multiple district courts in substantially 21 similar contexts regarding how to give effect to the term "component." To begin with, both part 22 210 and part 201 "are within the same subchapter regulating drugs, and 21 C.F.R. § 210.3(b)(3) 23 provides the only definition of 'component' within the subchapter." Williams, 2024 WL 24 4213220, at *4, quoting Barnes v. Unilever United States Inc., No. 21 C 6191, 2023 WL 25 2456385, at *7 (N.D. Ill. Mar. 11, 2023); see Truss, 2022 WL 16951538, at *4. Second, when 26 the FDA added the definition of "inactive ingredient" to part 201, it noted "that the definition 'is 27 identical to the definition in the agency's good manufacturing practice regulations in 21 CFR
1 Reg. 13254, 13258 (Mar. 17, 1999). Therefore, because "the FDA notes that the definitions are
2 identical, it follows that the term 'component' used in both definitions was intended to have the
3 same meaning." Id., quoting Barnes, 2023 WL 2456385, at *7. 4 Accordingly, the Court concludes that it is rational that the FDA would impose consistent 5 requirements and definitions on manufacturers. Williams, 2024 WL 4213220, at *4; see 6 Howard, 2024 WL 4272931, at *8; Barnes, 2023 WL 2456385, at *7; Truss, 2022 WL 7 16951538, at *4; see also Eisman, 2025 WL 241024 at *4 (OTC Coal Tar drug monograph). 8 There are no allegations that Walgreens intended to directly combine benzene into its BPO 9 products; rather, the allegations are that BPO can and does degrade into benzene. Based on the 10 forgoing, the Court concludes that benzene is not an inactive ingredient, and Walgreens was 11 therefore not required to list it on its BPO-product labels. Plaintiffs have not pointed the Court to 12 any authority to the contrary. 13 The Court will recommend granting Walgreens' motion to dismiss insofar as Plaintiffs 14 seek to use the theory of benzene as an inactive ingredient as a basis for their claims. 15 4. Benzene as a Result of cGMP Violations 16 The Court turns to whether Plaintiffs' claims can proceed under the theory that the 17 presence of benzene in Walgreens' BPO products stems from Walgreens' failure to adhere to 18 cGMPs. (See ECF No. 29, pp. 20-21; ECF No. 30, pp. 9-10.) Whether and to what extent 19 cGMPs may form the basis of parallel state-law claims has recently been explored by the Ninth 20 Circuit. In Davidson v. Sprout Foods, Inc., the Ninth Circuit discussed two lines of case. 106 21 F.4th 842 (9th Cir. 2024). The Court first observed the line of cases where private citizens 22 attempted to directly enforce the FDCA but discussed that those claims were held to be impliedly 23 preempted. Id. at 849. Second, the Court noted cases where a private citizen brought state law 24 claims that paralleled duties owed under federal requirements. Id. at 849-50. The Ninth Circuit 25 reaffirmed its position that a plaintiff can potentially raise a parallel state law claim without 26

implicating implied preemption if the state law imposing requirements are identical to those 27 contained in the FDCA, before specifically holding that "the FDCA [did] not impliedly preempt 1 Here, Plaintiffs allege violations of federal law: drugs are considered adulterated when 2 not manufactured in accordance with cGMPs. See 21 U.S.C. § 331(a); 21 C.F.R. § 351(a)(2)(B). 3 To vindicate their rights, Plaintiffs bring various state law consumer fraud and related claims— 4 not relying on the FDCA. In its reply, Walgreens faults Plaintiffs for not using the term cGMP 5 when discussing their contentions that Walgreens failed to abide by regulations that led to 6 adulterated or misbranded products. (ECF No. 30, p. 10.) In giving every reasonable inference 7 to Plaintiffs, the Court finds that Plaintiffs have sufficiently alleged the theory that a basis for 8 their state law claims is violations of regulations or cGMPs. 9 Therefore, the Court concludes that to the extent Plaintiffs' state law claims are parallel 10 claims brought for violations of cGMPs, those claims are not categorically preempted. The 11 Court will recommend denying Walgreens' motion as to this aspect of preemption. 12 C. Failure to State a Claim 13 Walgreens argues that because all of Plaintiffs' claims sound in fraud, which requires a 14 heightened pleading standard, Plaintiffs have failed to state a claim. (ECF No. 13, pp. 25-27.) 15 Plaintiffs oppose, arguing that they have sufficiently alleged that Walgreens deceptively omitted 16 a benzene warning. (ECF No. 29, p. 23-24.) The Court agrees with Walgreens to the extent that 17 Plaintiffs have failed to allege how they were deceived. 18 In alleging a claim grounded in fraud, "a party must state with particularity the 19 circumstances constituting fraud . . . ." Fed. R. Civ. P. 9(b). A court may dismiss a claim for 20 failing to satisfy the heightened pleading requirements of Rule 9(b). Vess v. Ciba-Geigy Corp. 21 USA, 317 F.3d 1097, 1107 (9th Cir. 2003). Under this heightened pleading standard, a party 22 must "identify the who, what, when, where, and how of the misconduct charged, as well as what 23 is false or misleading about the purportedly fraudulent statement, and why it is false." Moore v. 24 Mars Petcare US, Inc., 966 F.3d 1007, 1019 (9th Cir. 2020), quoting Davidson v. Kimberly- 25 Clark, 889 F.3d 956, 964 (9th Cir. 2018). The complaint must contain enough detail to put a 26 defendant on notice of the alleged misconduct so they may "defend against the charge and not 27 just deny that they have done anything wrong." Vess, 317 F.3d at 1106. "[C]laims based on an 1 Miller v. Ford Motor Co., No. 2:20-cv-01796-TLN-CKD, 620 F. Supp. 3d 1045, 1068 (E.D. Cal.
2 Aug. 10, 2022) (citation and internal quotation marks omitted). When a plaintiff alleges a
3 unified course of fraudulent conduct and relies entirely on that course of conduct as the basis of
4 that claim, that claim is said to be "'grounded in fraud' or to 'sound in fraud,' and the pleading 5
. . . as a whole must satisfy the particularity requirement of Rule 9(b)." Kearns v. Ford Motor 6
Co., 567 F.3d 1120, 1125 (9th Cir. 2009) (discussing in context of CLRA and UCL claims). 7
Walgreens attacks Plaintiffs' allegations regarding the "when," "where, and "how." 8 (ECF No.
13, pp. 26-27.) The Court takes these in turn. Beginning with "when," the Court finds 9 that
Plaintiffs have sufficiently alleged with particularity a timeframe. Plaintiff Navarro alleges 10
she purchased a Walgreen's BPO products between June 2022 and September 2022; 11 Plaintiff
Mullins alleges she purchased a Walgreens' products between 2005 to 2023. See 12 United States

v. United Healthcare Insurance Company, 848 F.3d 1161, 1180 (9th Cir. 2016). 13 Walgreens' offered precedent is not persuasive because those cases involved vague timeframe 14 allegations. See Robinson v. Unilever United States, Inc., No. CV 17-3010-DMG (AJWx), 2018 15 WL 6136139, at *6 (C.D. Cal. Jun. 25, 2018) (discussing that the allegation that "[i]n the last 16 several years" was insufficient, in part, to state a claim under Rule 9(b)); Celador Int'l, Ltd. v. 17 Walt Disney Co., 347 F. Supp. 2d 846, 855 (C.D. Cal. 2004) (discussing that the allegation 18 "[p]rior to December 1, 1998," was insufficient to state when because that allegations could 19 "mean anytime-days, months, years-prior to that date"). While the Court notes that 2005 to 2023 20 encompasses 18 years, Walgreens has not provided the Court with any authority that 21 demonstrates that such a long but definite time period would be vague. 22 Next, the Court finds that Plaintiffs have sufficiently alleged "where" they purchased the 23 products. Giving Plaintiffs every reasonable inference, Plaintiff Navarro bought Walgreens 24 Maximum Strength 10% BPO Acne Foaming Wash from Walgreens retail stores in Fresno 25 County, California; Plaintiff Mullins bought the Walgreens' Daily Creamy Benzoyl Peroxide 26 Acne Face Wash product from a Walgreens retail stores located in Suffolk County, 27 Massachusetts. (ECF No. 1, ¶¶ 15, 16, 68, 71.) Again, Walgreens' precedent is not persuasive 1 four cities. Seale v. GSK Consumer Health, Inc., 718 F.Supp.3d 1208, 1228 (C.D. Cal. 2024) 2 ("[The Plaintiff] vaguely states only that she purchased 'various adult's and children's 3 Robitussin products . . . at CVS, Walmart, and/or Walgreens stores in Encino, CA, Tarzana, CA, 4 West Hills, CA, and/or Reseda, CA' without providing which products were purchased where.").

5 Rule 9(b) does not require a plaintiff to "describe in detail a single specific transaction," United
6 Healthcare Ins. Co., 848 F.3d at 1180, and the Court finds that Plaintiffs has satisfied "where" 7 they purchased their products. 8 However, the Court finds that Plaintiff have not sufficiently alleged "how" they were 9 deceived. To begin, the Court notes that Plaintiffs come to this point in their opposition with the 10 understanding that, in their view, their mislabeling theory of liability is not preempted. (ECF

11 No. 29, p. 23.) Notwithstanding, the Court finds that Plaintiffs have argued throughout their
12 opposition (and alleged in their complaint) that Walgreens has potentially violated regulations or 13 cGMPs. Even with this reasonable inference, the Court finds that Plaintiffs have not alleged 14 facts that either establish that Walgreens violated cGMPs, or even if Walgreens did violate the 15 cGMPs, how those violations ultimately deceived Plaintiffs. 16 The parties' discussion on Williams merits discussion. 2024 WL 4213220. While up to 17 this point the Court has agreed with analysis of Williams, a district court opinion from the 18 Northern District of Illinois, regarding preemption and that cGMPs may for the basis of state 19 parallel claims, the Court parts ways regarding pleading with particularity as required by Rule 20 9(b). Similar to here, in Williams, the plaintiff alleged that the defendant, a manufacturing 21 laboratory, manufactured an OTC acne product that degraded into benzene, utilizing the same 22 Valisure study implicated in this case. Id. at *1. Among other claims, the plaintiff brought 23 unfair and deceptive practices

claim under the Illinois Consumer Fraud and Deceptive Business 24 Practices Act (the same law as Plaintiff Bolyard brings part of her claims here). Id. As relevant 25 here, regarding potential parallel state law claims, the district court discussed that in its view 26 another district court opinion, from the Northern District of Illinois, was instructive and 27 essentially adopted that court's reasoning. Id., citing Barnes, 2023 WL 2456385. 1 Barnes, the plaintiffs sued alleging that the defendant manufactured antiperspirant aerosol and 2 spray products that contained benzene and distributed those products in retail stores in the United
3 States. 2023 WL 2456385, at *1. Not unlike this case, the plaintiffs relied upon a study
4 produced by Valisure that found that certain antiperspirant aerosol products contained benzene 5 when tested. Id. Critically, "[t]he amended complaint also identifie[d] several statements 6 regarding product safety and testing from [the defendant's] website that [the plaintiffs] allege[] 7 are false and misleading." Id. at *2. In its analysis of under Rule 9(b), the court in Barnes 8 focused on that the plaintiff's claims were premised on "the [defendant] website's safety 9 statements," which the plaintiffs had alleged were false. Id. at *4. The Barnes court then relied 10 upon Seventh Circuit authority, in a trademark deception case, that observed that a "complaint 11 [wa]s sufficient" where it "allege[d] precisely the statement . . . that is asserted to be false, and 12 the exact reason . . . why the statement was false." Id., quoting Vincent v. City College of 13 Chicago, 485 F.3d 919, 925 (7th Cir. 2007). In other words, while the plaintiffs in Barnes were 14 bringing parallel state law claims regarding potential violations of cGMPs as to aerosol 15 antiperspirant sprays, the plaintiffs also alleged that the defendant had affirmatively made false 16 statements on their website. Id. By contrast, here, Plaintiffs have alleged, and explicitly 17 endorsed, that they proceeding on a theory of omission—i.e., Walgreens failed to inform 18 consumers that its products contained or could degrade into benzene. Therefore, the analysis in 19 Barnes and Vincent is inapposite to the case at bar. See Bojko, 2023 WL 4204663, at *7-*8 20 (contrasting affirmative statements against omissions). And because Williams relied upon these 21 cases for its determination that the plaintiff had met Rule 9(b) pleading standards, the Court finds 22 Williams to not be persuasive.11 23 24 11 The Court also addresses a potential logical fallacy that Walgreens has identified. (ECF No. 30, p. 10 n.2.) Walgreens observes that Plaintiffs are proceeding under two theories that are seemingly in conflict with each other. 25 On the one hand, Plaintiffs operate from the position that all of Walgreens BPO products break down into benzene, perhaps due to BPO's inherent instability, which gives them standing insofar as this would create an economic injury sufficient for standing. On the other hand, Plaintiffs at the same time assert that it was Walgreens' failure to 26 comply with cGMPs that led to benzene in its products. However, for that to be true, benzene contamination in Walgreens' BPO products would not have been an inevitability but rather a by-product of Walgreens' manufacturing 27 process. This premise would potentially undermine Plaintiffs' standing premise that all BPO products necessarily degrade into benzene. Moreover, Walgreens posits that should Plaintiffs rely on cGMPs as a basis for their injury, 1 In sum, the Court finds that Plaintiffs have failed to state a

claim regarding those claims 2 not preempted. Therefore, the Court will recommend granting Walgreens' motion to dismiss as 3 to state law parallel claims not preempted. 4 D. Primary Jurisdiction Doctrine 5 In the alternative, Walgreens argues that the Court should stay or dismiss this action 6 under the primary jurisdiction doctrine. (ECF No. 30, p. 12.) "Primary jurisdiction is a 7 prudential doctrine that permits courts to determine 'that an otherwise cognizable claim 8 implicates technical and policy questions that should be addressed in the first instance by the 9 agency with regulatory authority over the relevant industry rather than by the judicial branch.'" 10 Astiana v. Hain Celestial Grp., Inc., 783 F.3d 753, 760 (9th Cir. 2015) (citation omitted). "[T]he 11 doctrine of primary jurisdiction is committed to the sound discretion of the court when 12 'protection of the integrity of a regulatory scheme dictates preliminary resort to the agency which 13 administers the scheme.'" Syntek Semiconductor Co. v. Microchip Tech. Inc., 307 F.3d 775, 14 781 (9th Cir. 2002) (citation omitted). Given that the Court has found that Plaintiffs have failed 15 to state a claim, the Court finds that addressing the issue of primary jurisdiction would be 16 premature. 17 E. Injunctive and Equitable Relief. 18 Separately, Walgreens argues that Plaintiff have failed to plead allegations that would 19 afford them standing for injunctive relief and that Plaintiffs may not plead equitable relief in the 20 alternative when they have an adequate remedy in law. (ECF No. 13, pp. 27-30.) Again, 21 because the Court has found that Plaintiffs have failed to state a claim, the Court finds that 22 discussion of these issues would be premature. 23 F. Leave to Amend. 24 Under Rule 15(a) of the Federal Rules of Civil Procedure, leave to amend shall be freely 25 given when justice so requires. Fed. R. Civ. P. 15(a)(2). "In the absence of . . . undue delay, bad 26 faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by 27 need not reach this issue at this moment because the Court has found that Plaintiffs have otherwise failed to state a 1 amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of 2 the amendment, futility of amendment, etc.—the leave sought should . . . be 'freely given.'" 3 Foman v. Davis, 371 U.S. 178, 182 (1962), quoting Fed. R. Civ. P. 15(a). In other words, 4 "[a]bsent prejudice, or a strong showing of any of the remaining Foman factors, there exists a 5 presumption under Rule 15(a) in favor of granting leave to amend." Eminence Capital, LLC v. 6 Aspeon, Inc., 316 F.3d 1048, 1052 (9th Cir. 2003). 7 The Court finds that leave to amend should be granted in its entirety. The Court observes 8 that Plaintiffs operated in their complaint from the understanding that certain theories were not 9 preempted by federal law, which allowed them to bring an aspirational complaint in terms of 10 theories and relief. Even with the Court's conclusions regarding preemption and the plausibility 11 of Plaintiffs' claims as presently pleaded, the Court will recommend granting leave to amend 12 with the understanding that Plaintiffs will do so only to the extent they believe in good faith they 13 can plead additional factual material that could satisfy the legal standards and deficiencies 14 identified above. See Fed. R. Civ. P. 15(a)(2); Lopez v. Smith, 203 F.3d 1122, 1130 (9th Cir. 15 2000). 16 VI.

17 CONCLUSION AND RECOMMENDATION

18 Based on the foregoing, IT IS HEREBY RECOMMENDED that Defendants' motion to 19 dismiss (ECF No. 13) be GRANTED as follows: 20 1. The motion to dismiss as to standing be DENIED; 21 2. The motion to dismiss as to preemption of theories of failure to include a warning 22 label of benzene and failure to include benzene as an inactive ingredient be 23 GRANTED with leave to amend; 24 3. The motion to dismiss as to preemption on the theory that cGMPs may form the basis 25 of state parallel claims be DENIED; 26 4. The motion to dismiss as to failure to state a claim be GRANTED with leave to 27 amend; and 1 These findings and recommendations are submitted to the district judge assigned to this 2 | action, pursuant to 28 U.S.C. § 636(b)(1)(B) and this Court's Local Rule 304. Within fourteen 3 | (14) days of service of this recommendation, any party may file written objections to these 4 | findings and recommendations with the court and serve a copy on all parties. Such a document 5 | should be captioned "Objections to Magistrate Judge's Findings and Recommendations." The 6 | district judge will review the magistrate judge's findings and recommendations pursuant to 28 7 | U.S.C. § 636(b)(1)(C). The parties are advised that failure to file objections within the specified 8 | time may result in the waiver of rights on appeal. Wilkerson v. Wheeler, 772 F.3d 834, 839 (9th 9 | Cir. 2014), citing Baxter v. Sullivan, 923 F.2d 1391, 1394 (9th Cir. 1991). 10 i IT IS SO ORDERED. FA. ee 12 | Dated: _ May 15, 2025
STANLEY A. BOONE
13 United States Magistrate Judge 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28