UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

BRYAN CLINGER *et al.*, *Plaintiffs*, v. EDGEWELL PERSONAL CARE BRANDS, LLC, EDGEWELL PERSONAL CARE, LLC, SUN PHARMACEUTICALS, LLC, *Defendants*.	No. 3:21-cv-1040 (JAM)

ORDER GRANTING IN PART AND DENYING IN PART MOTION TO DISMISS

The plaintiffs in this putative class action lawsuit allege that they bought certain "Banana Boat" sunscreen products without knowing that the products were contaminated with benzene. The defendants have moved to dismiss the complaint. I will grant the motion in part and deny it in part.

BACKGROUND

This consolidated lawsuit includes seven named plaintiffs—Sebe Algofi, Monica Barba, Jessica Barton, Luis Chabla, Bryan Clinger, Deborah Jean, and Lisa Zayas. The plaintiffs come from four different States: Florida (Barba and Clinger), New York (Algofi, Barton, and Chabla), Oregon (Jean), and Pennsylvania (Zayas).[1]

The defendants are three companies headquartered in Shelton, Connecticut—Edgewell Personal Care Brands, LLC, Edgewell Personal Care, LLC, and Sun Pharmaceuticals, LLC. These companies manufacture, market, advertise, and distribute nationwide the well-known Banana Boat sunscreen products.[2] There are many different kinds of sunscreen products sold under the Banana Boat name that vary, for example, with respect to whether they are in the form

[1] Doc. #89 at 25-27 (¶¶ 126-132).
[2] *Id.* at 28 (¶¶ 134-36).

of lotions, sprays, or gels and that vary with respect to their strength as measured by a Sun Protection Factor (SPF).[3]

The plaintiffs claim that they bought certain Banana Boat sunscreen products but without knowing that these products contained benzene—a chemical that causes cancer and that they say is unsafe at any level if present in sunscreen.[4] The claims of the plaintiffs critically depend on a third-party study that was issued in May 2021 by Valisure LLC, a company that the plaintiffs describe as "an analytical pharmacy, patient advocacy, and consumer protection organization."[5] The Valisure study surveyed a wide range of sunscreen and after-sun products and found the presence of benzene in 43 out of 234 sunscreens and in 8 out of 48 after-sun products.[6]

Among the sunscreen products which Valisure tested and found benzene were several types of Banana Boat sunscreens. Three of Banana Boat's sunscreens had between .11 and .43 parts per million (ppm) of benzene.[7] Four more Banana Boat sunscreens had detectable amounts of benzene but less than 0.1 ppm.[8] And as indicated in Attachment A to Valisure's petition,

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[3] *Id.* at 6 (¶¶ 20, 23).
[4] *Id.* at 7-10 (¶¶ 29-39).
[5] *Id.* at 10 (¶ 42).
[6] *Ibid.*
[7] *Id.* at 11 (¶ 43). These products were: Kids Max Protect & Play Sunscreen C-Spray SPF 100, UltraMist Deep Tanning Dry Oil Continuous Clear Spray SPF 4, and Ultra Sport Clear Sunscreen Spray SPF 100. Benzene was detected at different levels ranging between .11 and .43 ppm in the Kids Max Protect & Play Sunscreen C-Spray SPF 100. *See also* Valisure's FDA Citizen Petition on Sun Care Products (May 2021), avail. at https://www.valisure.com/wp-content/uploads/Valisure-Citizen-Petition-on-Benzene-in-Sunscreen-and-After-sun-Care-Products-v9.7.pdf [https://perma.cc/NHT6-UV6C]. Because the complaint "relies heavily upon" the report's "terms and effect," the report is a matter integral to the plaintiffs' complaint, and I need not convert this motion to one for summary judgment to consider its findings. *See Palin v. New York Times Co.*, 940 F.3d 804, 811 (2d Cir. 2019).
[8] *Ibid.* These products were: Protective Dry Oil Clear Sunscreen Spray with Coconut Oil SPF 15, Ultra Defense Ultra Mist Clear Sunscreen Spray SPF 100, Kids Sport Sunscreen Lotion Spray SPF 50, and Simply Protect Kids Sunscreen Spray SPF 50+.

benzene was not detected in six other types of Banana Boat sunscreens.[9] According to the complaint, Valisure did not test "the entire product line" of Banana Boat sunscreens.[10]

In addition, the complaint cites results from the "[p]laintiffs' independent testing" but without describing more about the testing process.[11] This testing detected between 1.99 and 2.20 ppm of benzene in two additional Banana Boat sunscreens.[12]

Banana Boat sunscreens do not list benzene as an ingredient.[13] Nor do they warn of the possibility of benzene contamination.[14] Following the release of Valisure's report some sunscreen makers issued voluntary recalls.[15] But the defendants did not.[16]

The complaint alleges that the named plaintiffs bought Banana Boat sunscreen online or at retail stores in their various States of citizenship in 2019, 2020, and 2021 or otherwise during the class period.[17] None of the plaintiffs suspected the sunscreen contained or might contain benzene.[18] They would not have bought the sunscreens if they had known they contained or might contain benzene.[19]

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[9] *See* Doc. #99-1 at 26-43; Attachment A (May 2021), avail. at https://assets-global.website-files.com/6215052733f8bb8fea016220/627293d2966d76b9317a42c9_FDA-2021-P-0497-0003_content.pdf [https://perma.cc/GCY8-X2F7]. These products were: Ultra Sport Sunscreen Lotion SPF 100, Simply Protect Sensitive Mineral Enriched Sunscreen Lotion Spray SPF 50, Kids Mineral Based Sunscreen Lotion SPF 50+, Soothing Aloe After Sun Gel with Aloe Vera, Moisturizing Aloe After Sun Lotion, and Aloe Vera Sun Burn Relief Gel. Valisure's tests also did not detect benzene in two samples from two sunscreens in which benzene *was* detected in different samples—Kids Max Protect & Play Sunscreen C-Spray SPF 100 and Protective Dry Oil Clear Sunscreen Spray with Coconut Oil SPF 15. *Ibid.*

[10] Doc. #89 at 10 (¶ 43).

[11] *Id.* at 12 (¶ 46).

[12] *Ibid.* These additional two products were: Kids Max Clear Sunscreen Spray 100 and Protective Dry Oil Clear Sunscreen Spray 15 with Coconut Oil.

[13] *Ibid.* (¶ 50).

[14] *Ibid.*

[15] *Id.* at 13 (¶ 54).

[16] *Ibid.* (¶ 55).

[17] *Id*. at 25-27 (¶¶ 126-132). The class period is defined by reference to the applicable statute of limitations period, which the complaint does not specify. *Id*. at 5 (¶ 17).

[18] *Id*. at 25-27 (¶¶ 126-132).

[19] *Id*. at 27-28 (¶ 133).

The complaint alleges numerous causes of action including for breach of warranty (Count One), fraudulent concealment or nondisclosure (Count Two), and unjust enrichment (Count Three). It also alleges claims for unfair or deceptive business practices, false advertising, and unlawful omissions under the laws of New York (Counts Four and Five), Pennsylvania (Count Six), Oregon (Counts Seven through Ten), and Florida (Counts Eleven through Thirteen).[20]

The plaintiffs seek monetary damages, an injunctive order requiring the defendants to comply with consumer protection laws, and an injunctive order requiring the defendants to establish a medical monitoring protocol to monitor individual class members for any ailments associated with benzene exposure.[21] The defendants have now moved to dismiss pursuant to Fed. R. Civ. P. 12(b)(1) for lack of jurisdiction and pursuant to Fed. R. Civ. P. 12(b)(6) for failure to state a claim.

DISCUSSION

I will first address the defendants' arguments on standing. Then I will turn to their arguments for dismissal based on preemption, primary jurisdiction, and failure to allege fraud with particularity as required under Fed. R. Civ. P. 9(b). Finally, I will address the defendants' arguments that particular counts of the complaint should be dismissed under Fed. R. Civ. P. 12(b)(6) because they fail to state a plausible claim for relief.

Standing

The defendants first contend that the plaintiffs lack standing because they cannot establish that they suffered an injury-in-fact. Article III of the Constitution limits the jurisdiction of the federal courts to "Cases" and "Controversies." U.S. Const. art. III, § 2, cl. 1. The Supreme Court has ruled that Article III creates a constitutional "standing" requirement—that a federal

[20] *Id*. at 35-63 (¶¶ 155-338).
[21] *Id*. at 63.

court may adjudicate a plaintiff's case only if a plaintiff establishes that they personally suffered a concrete and particularized injury that is actual or imminent and that was likely caused by the defendant's alleged wrongdoing and that would likely be redressed by a grant of judicial relief. *See TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2203 (2021); *Silva v. Farrish*, 47 F.4th 78, 86 (2d Cir. 2022).

At the pleadings stage, a court must accept all factual allegations in support of a plaintiff's standing as true and must draw all reasonable inferences in favor of the plaintiff. *See Calcano v. Swarovski N. Am. Ltd.*, 36 F.4th 68, 72 n.1 (2d Cir. 2022); *Sonterra Cap. Master Fund Ltd. v. UBS AG*, 954 F.3d 529, 533 (2d Cir. 2020). Nevertheless, a plaintiff "bears the burden of establishing standing 'in the same way as any other matter on which [it] bears the burden of proof, *i.e.*, with the manner and degree of evidence required at the successive stages of the litigation.'" *Amidax Trading Grp. v. S.W.I.F.T. SCRL*, 671 F.3d 140, 145 (2d Cir. 2011) (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992)).

Thus, at the motion to dismiss stage, the complaint must allege enough facts to make it plausible to conclude that the plaintiff has standing. *See Maddox v. Bank of New York Mellon Tr. Co., N.A.*, 19 F.4th 58, 65-66 (2d Cir. 2021). "[A]lthough the plausibility requirement is most commonly applied in the context of evaluating whether a complaint substantively states a claim for relief, there is little reason to suppose that it should not equally govern the evaluation of factual allegations that support federal subject matter jurisdiction." *Lapaglia v. Transamerica Casualty Ins. Co.*, 155 F. Supp. 3d 153, 155 (D. Conn. 2016).

What does it mean for factual allegations to be plausible? As the Supreme Court has explained, "[t]he plausibility standard is not akin to a probability requirement, but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft v. Iqbal*, 556 U.S.

662, 678 (2009). Yet "[w]here a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." *Ibid.*

The determination of whether a complaint satisfies the plausibility standard is a "context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id.* at 679. All in all, a court must accept a complaint's factual allegations as true, draw all reasonable inferences in favor of the plaintiffs, and may not dismiss a complaint for lack of standing so long as it alleges enough facts to plausibly show that the plaintiffs have standing.

The defendants argue that the plaintiffs have not alleged enough facts to plausibly show that they were injured—specifically, to show that the Banana Boat products that any of the plaintiffs purchased were contaminated with benzene. After all, the defendants argue, the complaint does not allege that the plaintiffs actually tested for the presence of benzene any of the sunscreen products that they personally bought. Nor does the complaint allege that the sunscreens bought by the plaintiffs came from the same product lot as those found to be contaminated by the testing of Valisure or by the "independent testing" referenced in the complaint.

But the fact that the plaintiffs did not actually test the products that they purchased does not mean that they lack standing. Instead, as the Second Circuit has ruled in a somewhat similar context, a product defect may be plausibly inferred from the fact that a third-party investigation has revealed defects in the same line of such products. In *John v. Whole Foods Market Group, Inc.*, 858 F.3d 732 (2d Cir. 2017), the plaintiff regularly bought certain pre-packaged food products (cheese and cupcakes) from Whole Foods supermarkets, and the price he paid for these products was determined by the weight of the product that Whole Foods identified on the

product label. The plaintiff sued Whole Foods alleging that Whole Foods had overstated the weight of these products. Yet he did not allege that he had actually weighed any of the products he bought; instead, he alleged that a recent third-party investigation had concluded that Whole Foods routinely—89% of the time—overstated the weight of its pre-packaged food products, including for the particular type of products that he had bought and including at the two store locations where he bought the products. The Second Circuit ruled that this was enough to plausibly establish that Whole Foods had overstated the weight of the products bought by the plaintiff. *Id.* at 736-38.

Applying the reasoning of *John v. Whole Foods* here, I conclude that some but not all of the plaintiffs have alleged enough facts to plausibly show that the products they bought were contaminated with benzene. Four of the plaintiffs—Barba, Barton, Chabla, and Clinger—have alleged enough to plausibly establish that they bought Banana Boat sunscreen that contained benzene:

- Barba alleges that she bought Protective Dry Oil Sunscreen Spray SPF 15 and Ultra Sport SPF 30.[22] The testing shows that the Dry Oil Sunscreen Spray contained detectable levels of benzene.[23]
- Barton alleges that she bought UltraMist Deep Tanning Dry Oil Continuous Clear Spray SPF 4 and Ultra Sport Clear Sunscreen Spray SPF 100.[24] The testing shows that these same products contained detectable levels of benzene.[25]

[22] *Id.* at 26 (¶ 129). The Court takes Barba's purchase of Protective Dry Oil Sunscreen Spray SPF 15 to mean that she purchased Protective Dry Oil Clear Sunscreen Spray with Coconut Oil SPF 15.
[23] *Id.* at 10-12 (¶¶ 43, 46); *Valisure Report*, *supra* note 7, at 14.
[24] Doc. #89 at 26 (¶ 127).
[25] *Id.* at 10 (¶¶ 43); *Valisure Report*, *supra* note 7, at 13-14.

- Chabla alleges that he bought Dry Oil Clear Sunscreen Spray with Coconut Oil SPF 15.[26] The testing shows that this same product contained detectable levels of benzene.[27]
- Clinger alleges that he bought Kids Max Protect & Play Sunscreen Spray.[28] The testing shows that this same product contained detectable levels of benzene.[29]

In my view, it is reasonable to assume that benzene did not magically appear in Banana Boat products. It must have appeared by reason of some aspect of the manufacturing process. Of course, if the plaintiffs were able to show that the sunscreen products that they bought came from the very same batch or lot of a sunscreen product that was found to be contaminated with benzene, this would make it highly likely that the product purchased by the plaintiffs also contained benzene. Yet, even in the absence of linkage to a particular batch or lot, it is reasonable to assume that the same product line would involve the same manufacturing process and with the same likelihood of residual benzene contamination even if not every batch is contaminated.[30]

Therefore, if the plaintiffs bought a particular sunscreen product reasonably near in time to the testing positive of that product for the presence of benzene, then it is at least plausible to conclude that the product purchased by the plaintiff was also contaminated with benzene. To be sure, when it comes time for trial, the plaintiffs Barba, Barton, Chabla, and Clinger may have difficulty carrying their burden of proof on this fact issue by a preponderance of the evidence unless they have additional evidence to show a correlation between benzene and particular product lines. But my role at this time is solely to decide if what they have alleged is plausible,

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[26] Doc. #89 at 25-26 (¶ 126).
[27] *Id.* at 10-12 (¶¶ 43, 46); *Valisure Report*, *supra* note 7, at 14.
[28] Doc. #89 at 26 (¶ 128). The Court takes Clinger's purchase of Kids Max Protect & Play Sunscreen Spray to mean he purchased Kids Max Protect & Play Sunscreen C-Spray SPF 100.
[29] *Id.* at 10 (¶¶ 43); *Valisure Report*, *supra* note 7, at 13.
[30] *See* Doc. #99-1 at 14 (Valisure's commentary noting in part "significant variability from batch to batch, even within a single brand").

and I conclude that it is in reliance on the reasoning of the Second Circuit in *John v. Whole Foods*.

The defendants rely on rulings from district courts outside the Second Circuit that have granted motions to dismiss other cases in which other plaintiffs have relied on the Valisure report's testing.[31] But these cases are not persuasive because they are not governed by and do not follow the Second Circuit's decision in *John v. Whole Foods*.

So, for example, in *Bowen v. Energizer Holdings, Inc.*, 2023 WL 1786731 (C.D. Cal. 2023), a California district court recently dismissed a complaint involving three Banana Boat product lines for lack of standing. As to two of the Banana Boat products which were purchased by the plaintiff and were found by the Valisure report to contain benzene, the court ruled that "[p]laintiff does not allege that Valisure's discovery can be extrapolated across all of Defendants' products or to a specific batch which could have ended up in her purchased sunscreen." *Id.* at *4. This reasoning is inconsistent with *John v. Whole Foods* which did not require linkage to a "specific batch," but instead looked to whether the plaintiff alleged he purchased the same type of product that had been found by independent testing to have been defective. In my view, a "specific batch" limitation is overly restrictive, because it is plausible to conclude that, if one specific batch of the same sunscreen product contains benzene, then other batches of the very same product line are manufactured in the same manner and—notwithstanding the possibility of variability from batch to batch—are likely to contain benzene.

The court in *Bowen* went on to conclude that the plaintiff did not have standing even as to one of the products that the plaintiff bought and actually tested to find that it contained 0.29 ppm

[31] *See* Docs. #99 at 27-29, #129, #137, #143; *see, e.g.*, *Schloegel v. Edgewell Pers. Care Co.*, 2022 WL 808694 (W.D. Mo. 2022); *Bodle v. Johnson & Johnson Consumer Inc.*, 2022 WL 18495043 (N.D. Cal. 2022); *Bowen v. Energizer Holdings, Inc.*, 2022 WL 18142508 (C.D. Cal. 2022) (dismissing first amended complaint); *Bowen v. Energizer Holdings, Inc.*, 2023 WL 1786731 (C.D. Cal. 2023) (dismissing second amended complaint).

of benzene. The court reasoned that the plaintiff was not injured because the amount was less than the FDA's limit of up to 2 ppm of benzene. *Id.* at *4-7. But in doing so the court engaged in a highly fact-specific evaluation of the safety risks posed by benzene that is not appropriate for a court to perform at the initial pleadings stage of a lawsuit. *See id.* at *6-7.

Here, I am obliged to credit plaintiff's well-pleaded allegation that benzene is not safe at any level in sunscreen products.[32] It would be premature for me to second-guess this factual allegation or to conclude that the FDA's determination of what is a safe level for benzene is controlling and necessarily negates the plaintiffs' claim of injury for purposes of standing. Whether the FDA's standard is preclusive is a merits question, not a standing question. Likewise, the *Bowen* court's additional conclusion that there is no economic injury is also not persuasive because it depends on a premature fact-based conclusion that there is no safety risk posed by less than 2 ppm of benzene in sunscreen products. *See id.* at *7-9.

The defendants next argue that the lab results on which the plaintiffs rely are "fatally flawed."[33] They contend that Valisure's test methods do not comply with FDA standards, and Valisure "by its own admission disclaimed that its testing provided information about any other sunscreen product other than the specific bottles that were tested."[34] With respect to the independent testing of two other Banana Boat products, the plaintiffs "fail to identify the name of

[32] Doc. #89 at 10 (¶ 39) ("FDA guidance provides that no level of benzene is safe, and benzene is not permitted in these types of sunscreen products. The FDA currently recognizes the high danger of this compound and lists it as a 'Class 1 solvent' that 'should not be employed in the manufacture of drug substances, excipients, and drug products because of their unacceptable toxicity. . . . However, if their use is unavoidable in order to produce a drug product with a significant therapeutic advance, then their levels should be restricted' and benzene is restricted under such guidance to 2 parts per million('ppm')."); *see also id.* at 9 (¶¶ 37-38) (citing testimony of Dr. Christopher Bunick, Associate Professor of Dermatology at Yale University that there is no safe level of benzene for sunscreen products).
[33] Doc. #99 at 33.
[34] *Ibid*.

the laboratory, the lots it tested, and whether the laboratory followed FDA-required" procedures.[35]

None of these arguments are persuasive at this time because "[a]t the pleading stage," a plaintiff "need not prove the accuracy" of an independent investigative study's findings "or the rigor of its methodology." *Whole Foods*, 858 F.3d at 737. In any event, if I were inclined at this time to test the reliability of Valisure's findings, I might take into account that a federal court in Florida has recently approved a class action settlement against another major sunscreen manufacturer that was initially based on the Valisure benzene study and that led the manufacturer to engage in product recalls. *See In re Johnson & Johnson Aerosol Sunscreen Marketing, Sales Practices and Products Liability Litigation*, 2023 WL 2284684, at *1 (S.D. Fla. 2023). The fact that other manufacturers have engaged in product recalls on the basis of the Valisure study is circumstantial evidence that tends to validate Valisure's testing results.

Nor is this a case where the outside study relied on by plaintiffs is not comprehensive in scope and amounts to little more than speculative anecdotal evidence that a product purchased by the plaintiff may be defective. *See, e.g.*, *Gaminde v. Lang Pharma Nutrition, Inc.*, 2019 WL 1338724, *2-3 (N.D.N.Y. 2019) (declining to infer that a bottle of krill oil purchased by the plaintiff was defective because an independent study found a defect in two other bottles); *Fahey on behalf of District of Columbia v. Deoleo USA, Inc.*, 2018 WL 5840664, at *2 (D.D.C. 2018) (declining to infer that a bottle of olive oil purchased in 2018 in D.C. was mislabeled on the basis of a study that tested three bottles of olive oil purchased in California in 2010).

In addition, the plaintiffs Barba, Barton, Chabla, and Clinger need not show that every one of their purchases of sunscreen necessarily contained benzene. Overpayment for mislabeled

[35] *Id.* at 34.

products is a recognized injury-in-fact. *See Patane v. Nestlé Waters North America, Inc. (Patane I)*, 314 F. Supp. 3d 375, 380 (D. Conn. 2018). These four plaintiffs properly claim that they would not have paid as much or anything for their sunscreen had the label warned of the *risk* of benzene contamination—a risk that is plausibly alleged to have existed in the first place in light of the independent testing results for specific product lines that these four plaintiffs purchased. *See, e.g.*, *Barnes v. Unilever U.S. Inc.*, 2022 WL 2915629, at *1 n.1 (N.D. Ill. 2022) (plaintiff's claim that she would not have purchased a product had she known of the risk of benzene contamination "holds water" even if "benzene contamination applied only to some limited lots of [the defendant's] product" because the plaintiff's "theory of injury" is "that she would not have purchased the product had she known of the risk it contained benzene").

Indeed, the FDA requires manufacturers to include a "may contain" label when different alternative ingredients may be present in individual products.[36] And whether benzene is an "alternative ingredient" is a fact in dispute which I must construe in the plaintiffs' favor at this stage of the litigation. And even though the defendants dispute whether the amount of benzene as reported in the studies was enough to make the products unsafe, it is plausible to conclude that a consumer would not wish to purchase and use a product containing a known carcinogen.

In short, I conclude that the plaintiffs Barba, Barton, Chabla, and Clinger have alleged enough facts at this time to show that they have standing. But I cannot reach the same conclusion for the remaining three plaintiffs—Algofi, Jean, and Zayas—who allege that they purchased Banana Boat sunscreen products that are *not* the same as any of the product lines that have been reported by Valisure or the plaintiffs' independent testing to contain benzene. Jean alleges she bought Banana Boat Spray Oil, a product that appears to be a completely different line than any

[36] Doc. #89 at 16-17 (¶ 76).

of the specific product lines alleged to have tested positive for benzene.[37] Algofi bought Banana Boat Kids Clear Spray Sunscreen SPF 50+, and Zayas bought Banana Boat Sport Performance SPF 50+ and Banana Boat Ultra Sport SPF 30.[38] Although these product lines are similar to those product lines that have been reported to contain benzene, they differ with respect to their SPF level.

All these differences are enough to suggest that the products bought by Algofi, Jean, and Zayas were part of a different manufacturing process than the product lines that were found by Valisure or the plaintiffs' independent testing to contain benzene. As plaintiffs concede, not all lines of Banana Boat sunscreen were subject to testing. The Valisure report shows some lines of Banana Boat sunscreen did not test positive for benzene.[39] More generally, the Valisure report found benzene in only 1/6 of sunscreens (43 out of 243 sunscreen products) tested. It would be speculative—rather than plausible—to conclude that benzene was present in Banana Boat product lines for which there are no positive test results for the presence of benzene.

Therefore, I will grant the defendants' motion to dismiss as to Algofi, Jean, and Zayas. Because Zayas is the sole named plaintiff with respect to claims arising under Pennsylvania law (Count 6), and because Jean is the sole named plaintiff with respect to claims arising under Oregon law (Counts 7 through 10), I will dismiss these counts for lack of standing.

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[37] *Id.* at 27 (¶ 131).
[38] *Ibid.* (¶¶ 130, 132).
[39] Valisure's testing did not detect benzene in ten samples of Banana Boat sunscreens representing eight unique product lines. *See Attachment A*, *supra note* 9; Doc. #99 at 24 n.7. Two of those samples were from the same product line—Moisturizing Aloe After Sun Lotion. Two other samples were from the Soothing Aloe After Sun Gel with Aloe Vera product line. And as explained above, another two of those ten samples were of Protective Dry Oil Clear Sunscreen Spray with Coconut Oil SPF 15 and the Kids Max Protect & Play Sunscreen C-Spray SPF 100. But testing of other samples from those same product lines did detect benzene. *See supra* note 9. Benzene was detected by Valisure in three other samples of Kids Max Protect & Play Sunscreen C-Spray SPF 100 and one other sample of Protective Dry Oil Clear Sunscreen Spray with Coconut Oil SPF 15. *See supra* notes 7, 9. And the plaintiffs' independent lab also detected benzene in its tests of the Protective Dry Oil Clear Sunscreen Spray with Coconut Oil SPF 15. *See supra* note 12.

The defendants also challenge the plaintiffs' standing to seek: (1) an order requiring the defendants to comply with consumer protection laws in their future manufacturing practices, and (2) a blood testing program to monitor the plaintiffs for future adverse effects from benzene exposure.[40] A plaintiff "must demonstrate standing separately" for "each form of relief sought." *Nicosia v. Amazon.com, Inc.*, 834 F.3d 220, 239 (2d Cir. 2016) (citing *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 185 (2000)). "Although past injuries may provide a basis for standing to seek money damages, they do not confer standing to seek injunctive relief unless the plaintiff can demonstrate that [they are] likely to be harmed again in the future in a similar way." *Ibid.*

With respect to the plaintiffs' compliance order, "purchasers of a consumer product who claim to be deceived by that product's packaging . . . have, at most, alleged a past harm." *Berni v. Barilla S.p.A.*, 964 F.3d 141, 147 (2d Cir. 2020). Past purchasers are unlikely to be deceived anew if they buy the product again, since they already know of the alleged defect in the product's packaging. *Id.* 147-48. The four remaining plaintiffs are now on notice that Banana Boat sunscreens may contain benzene. Even if, as they allege, they would like to or do buy Banana Boat sunscreen in the future, they are unlikely to be harmed by any continued deception from mislabeling. Accordingly, they have not shown a likelihood of future harm, and I will dismiss their claim for injunctive relief.

As to the plaintiffs' request for medical monitoring, the plaintiffs have alleged that benzene is a health hazard and can lead to blood cancer, such as leukemia.[41] At this point in the litigation, these allegations are sufficient to establish that the plaintiffs are at a risk of future injury based on their past exposure to benzene. *See, e.g.*, *In re Valsartan, Losartan, and*

[40] Doc. #89 at 63 (¶ A).
[41] *Id.* at 4 (¶¶ 4-6).

Irbesartan Prods. Liab. Litig., 2021 WL 100204, at *12 (D.N.J. 2021) ("It is well settled that exposure to toxic substances is sufficient for purposes of Article III standing" on a medical monitoring claim); *Giordano v. Solvay Specialty Polymers USA, LLC*, 522 F. Supp. 3d 26, 34-35 (D.N.J. 2021) (dismissing medical monitoring claim would be premature where "allegations support the plausibility of Plaintiffs' claims" that exposure to carcinogenic chemicals put them "at risk for serious physical injuries and diseases").

The defendants argue the plaintiffs' request for medical monitoring must fail because they have not alleged physical injury.[42] But as the defendants themselves acknowledge, the Connecticut Supreme Court case on which they rely "did not settle [the] central issue" of whether "to permit medical monitoring in the absence of some present manifestation of a physical injury."[43] *See also Dougan v. Sikorsky Aircraft Corp.*, 337 Conn. 27, 45-46 (2020). And so I will decline at this time to "require[e] plaintiffs to manifest physical symptoms before receiving medical monitoring," which would seem to "defeat the purpose of that remedy." *See Baker v. Saint-Gobain Performance Plastics Corp.*, 232 F. Supp. 3d 233, 252 (N.D.N.Y. 2017).

Preemption

The defendants next argue that the plaintiffs' state law claims are preempted by the Federal Drug and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq*. Federal law may preempt state law in various ways. Sometimes Congress expressly preempts state law by statute, and other times state law may be impliedly preempted if Congress has occupied an entire field or if a state law somehow conflicts with or otherwise stands as an obstacle to the purpose of a federal law. *See generally Oneok, Inc. v. Learjet, Inc.*, 575 U.S. 373, 376-77 (2015); *Marentette v. Abbott Labs.*, Inc., 886 F.3d 112, 117 (2d Cir. 2018). In general, for a court to conclude that Congress

[42] Doc. #99 at 85-86.
[43] *Id.* at 85.

has preempted state law, Congress's intent to preempt—whether express or implied—must be "clear and manifest." *Wyeth v. Levine*, 555 U.S. 555, 565, (2009); *New York State Rest. Ass'n v. New York City Bd. of Health*, 556 F.3d 114, 123 (2d Cir. 2009) (discussing preemption principles in context of the FDCA).

The defendants focus on two provisions of the FDCA. First, section 379r(a) *expressly* preempts States from imposing "any requirement" related to the regulation of nonprescription drugs "that is different from or in addition to, or that is otherwise not identical with, a requirement under" the FDCA. 21 U.S.C. § 379r(a). Second, under section 337(a) "[a]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a). Because this provision means only the federal government may sue to enforce violations of the FDCA, courts have understood this provision to *impliedly* preempt state law causes of action for the violation of the FDCA. *See Patane I*, 314 F. Supp. 3d at 385 (citing *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001)).

Taken together, § 379r(a) and § 337(a) have a broad preclusive effect. For express preemption, "the FDCA preempts not only those state laws that are in conflict with it (*i.e.*, any law that is 'different from' the FDCA), but also *any* state law that provides for labeling requirements that are not *exactly the same* as those set forth in the FDCA and its regulations (*i.e.*, any law that is 'in addition to' the FDCA)." *Critcher v. L'Oreal USA, Inc.*, 959 F.3d 31, 35–36 (2d Cir. 2020). For implied preemption, the FDCA preempts any state law that amounts to no more than an effort to provide a state law enforcement mechanism for a violation of the FDCA. What remains is a "narrow gap" of state law claims that may escape the perils of either express or implied preemption. *Glover v. Bausch & Lomb Inc.*, 6 F.4th 229, 237 (2d Cir. 2021). I will first address the arguments for express preemption before turning to implied preemption.

Express preemption

The defendants first argue in accordance with the express preemption provision of § 379r(a) of the FDCA that the plaintiffs' claims are expressly preempted by Food and Drug Administration (FDA) regulations which limit how drug manufacturers may list active or inactive ingredients on its products. The FDCA requires a product's label to list its active and inactive ingredients. *See* 21 U.S.C. § 352(e)(1)(A); 21 C.F.R. § 201.66(c). An active ingredient is "any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of humans." 21 C.F.R. § 201.66(b)(2). An inactive ingredient is "any component other than an active ingredient." *Id.* § 201.66(b)(8).

The plaintiffs posit that, because the "term *ingredient* applies to any substance in the drug," 21 C.F.R. § 201.10(b) (emphasis added), any substance in sunscreen must be either an active ingredient or an inactive ingredient. They argue that, as testing has shown, some Banana Boat sunscreens contain benzene, and so Banana Boat sunscreen is therefore mislabeled. They also note that even if not all Banana Boat sunscreen bottles contain benzene, FDA guidance still recommends that labels include ingredients that may or may not be contained in each individual drug product.[44]

The defendants respond that a component is "any ingredient intended for use in the manufacture of a drug product, including those that may not appear in such drug product." 21 C.F.R. § 210.3(b)(3). The defendants maintain that benzene was "never intended for use" in Banana Boat sunscreens and is therefore not a "component" and cannot be an active or inactive ingredient that is required to be listed on the label.

[44] *Id*. at 16-17 (¶¶ 76-77) (quoting FDA, Guidance for Industry: Labeling OTC Human Drug Products (May 2009) at 9, 12-13, avail. at https://www fda.gov/media/76481/download [https://perma.cc/QGS2-PSAU]).

But even accepting defendants' restrictive view of the regulation, whether benzene was intended for use in sunscreen is a question of fact which cannot be resolved on a motion to dismiss. "[W]hen considering a preemption argument in the context of a motion to dismiss, the factual allegations relevant to preemption must be viewed in the light most favorable to the plaintiff." *Galper v. JP Morgan Chase Bank, N.A.*, 802 F.3d 437, 444 (2d Cir. 2015). Assuming therefore that benzene is intended for use in sunscreens, the plaintiffs' requested label would not be preempted by existing FDA guidance.

The defendants next argue that requiring Banana Boat sunscreen to include benzene on the label would violate the FDA's prohibition on listing residual manufacturing solvents as an ingredient. There are a number of problems with this argument. First, it assumes that benzene is a residual manufacturing solvent. But benzene's role in sunscreen remains unresolved. Second, the defendants do not cite authority to show that the FDA prohibits the listing of residual manufacturing solvents. In fact, their own definition of "component" encompasses ingredients "that may not appear" in the final drug product, which would seem to include such solvents. 21 C.F.R. § 210.3(b)(3).

As for the plaintiffs' claim that Banana Boat sunscreen labels should state the sunscreen "may contain" benzene, the defendants say the plaintiffs have misconstrued the FDA's labeling guidance. They claim that the "may contain" label is reserved for substitute or alternative ingredients, which benzene is not. The defendants also point out that the FDA has expressly warned manufacturers not to list "too many alternative ingredients" which "could be misleading and may cause consumer confusion."[45] The defendants suggest that reading this guidance to

[45] *See* Questions and Answers, FDA.gov (Dec. 2008) at 10-11, avail. at https://www fda.gov/media/72441/download [https://perma.cc/NHU9-UCJK].

include substances unintentionally added or a residual solvent like benzene would contravene the FDA's guidance.

But again the defendants presuppose the answer to a fact question. Whether benzene is a substitute or alternative ingredient or one "unintentionally added" is an unresolved question of fact which I cannot properly resolve in the defendants' favor at this time. And as to the concern about overlong ingredients lists, the FDA also has a solution: a second set of labels.[46]

The defendants next argue that the plaintiffs are seeking additional warnings not required by or permitted under federal law. They allege that "the entire universe of warning statements" that can be included on an over-the-counter (OTC) drug product's label is circumscribed by two regulations. First, 21 C.F.R. § 201.66(c)(5) describes the warnings which "shall" be included on drug labels, including "[a]ny required warnings in an applicable OTC drug monograph, other OTC drug regulations, or approved drug application that do not fit within one of the categories listed." Second, 21 C.F.R. § 201.327(d) provides specific warnings sunscreen products must include (*e.g.*, a warning to stop use if rash occurs). The defendants say that, because plaintiffs' proposed benzene warnings do not fall under either regulation, such a warning is preempted by the FDCA.

But neither regulation purports to foreclose other warnings necessary for health and safety. And in fact, the disclosure of a benzene warning may be required in certain cases. Section 201.66(c)(5) mandates warnings when required by "an applicable OTC drug monograph." OTC Monograph M020 deems sunscreen to not be misbranded only if it meets "each general condition established in 21 CFR 330.1." In turn, 21 C.F.R. § 330.1(c)(1) and (e) require sunscreen to be

[46] Guidance for Industry Labeling: OTC Human Drug Products, *supra* note 44, at 13.

"labeled in compliance with chapter V of the Federal Food, Drug, and Cosmetic Act" and to "contain[] only suitable inactive ingredients which are safe in the amounts administered."

Also, Chapter V of the FDCA prohibits a manufacturer from using a label which "fails to reveal facts material in the light of [other] representations or material with respect to consequences which may result from the use of the article under such conditions of use as are customary or usual," or to include an ingredient "dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. §§ 352(a)(1), (j); 21 U.S.C. § 321(n). And so taking as true the allegations that benzene is present in some sunscreens at levels "dangerous to health" when used in the manner recommended, the regulations would seem to require a benzene warning.

The defendants respond that the FDA *does* allow manufacturers to sell drug products with trace levels of benzene. They point to recent FDA instructions that "[d]rug manufacturers with a risk for benzene contamination should test their drugs accordingly and should not release any drug product batch that contains benzene above 2 ppm."[47] They claim that this implies that products with less than 2 ppm of benzene are safe for use. *See also Bowen*, 2023 WL 1786731, at *5 ("The FDA's alert, stating that manufacturers should not release products that contain over 2 ppm of benzene, implies that manufacturers . . . may continue to release products that are adequately tested and contain less than 2 ppm of benzene.").

I do not read the new FDA guidance so definitively. The FDA has released subsequent guidelines which reiterate that "[m]anufacturers should not use benzene in the manufacture of

[47] Frequently Asked Questions on Benzene Contamination in Drugs, FDA.gov (June 9, 2022), https://www.fda.gov/drugs/drug-safety-and-availability/frequently-asked-questions-benzene-contamination-drugs [https://perma.cc/B8W7-7U2G]. Both the plaintiffs and the defendants cite to a version of the FAQs from June 6, 2022. However, the URL provided in both briefs links to a page updated on June 9, 2022. Because the Court is unable to access the June 6 version of the webpage, all citations will be to the June 9 version.

drugs."[48] This implies that the use of benzene at any level should be avoided. And where "benzene use is unavoidable to produce a drug product with a significant therapeutic advance," then it is limited to 2 ppm.[49] Viewing the facts in the light most favorable to plaintiffs, because only some Banana Boat sunscreens contain benzene, its use is not unavoidable, and the defendants cannot claim the "unavoidable use" exception.

The defendants protest that the "unavoidable" test applies only when benzene is purposefully used in the manufacturing process.[50] They say that benzene is a residual solvent and not purposefully used in the production of Banana Boat sunscreen. Therefore, according to the defendants, its presence does not trigger the test, and the defendants need not show that the use of benzene is unavoidable to take advantage of the 2-ppm safe harbor.

But the defendants' position would mean that the FDA has irrationally prohibited or strictly limited the *purposeful* use of benzene in drug manufacturing while greenlighting the presence of benzene if it is *accidentally* introduced into a product. And even assuming the defendants have correctly interpreted the guidance, they must still wish away a factual dispute as to whether benzene is a purposefully used ingredient. So this is not a case where the FDA has "addressed the substance of the plaintiff's claim" and reached a different conclusion, and dismissal for preemption is not appropriate at this time. *See Canale v. Colgate-Palmolive Co.*, 258 F. Supp. 3d 312, 323 (S.D.N.Y. 2017).

The defendants further argue that basing their liability on results from Valisure and an independent lab—neither of which adhere to FDA current good manufacturing practices—would

[48] FDA alerts drug manufacturers to the risk of benzene contamination in certain drugs, FDA.gov (Dec. 23, 2022), https://www.fda.gov/drugs/pharmaceutical-quality-resources/fda-alerts-drug-manufacturers-risk-benzene-contamination-certain-drugs [https://perma.cc/AZH3-2HMF].
[49] *Ibid*.
[50] Doc. #99 at 47; Doc. #131 at 9.

impose new and different testing requirements on manufacturers.[51] They rely on cases where courts have found labeling claims to be preempted because they were based on testing results using methods other than those specified by the FDA. But all those cases involved highly regimented testing methods mandated by the FDA. *See, e.g.*, *Forouzesh v. CVS Pharmacy, Inc.*, 2019 WL 652887 (C.D. Cal. 2019) (SPF levels); *Anglin v. Edgewell Pers. Care Co.*, 2018 WL 6434424, at *11 (E.D. Mo. 2018) (same, noting that "the governing FDA regulation imposes a specific, lengthy, and very detailed methodology for testing the products, including the specific number of subjects to be tested, timelines for testing, etc."); *Mee v. I A Nutrition, Inc.*, 2015 WL 2251303 (N.D. Cal. 2015) (amount of protein in protein powder).

Here, the FDA has not "prescribed a specific methodology for determining whether a particular [benzene]-content statement made on a label is false." *Melendez v. ONE Brands, LLC*, 2020 WL 1283793, at *5 (E.D.N.Y. 2020). Because the FDA has not provided the exclusive means to detect and disclose the presence of benzene, the plaintiffs are not preempted from relying on Valisure's testing or other independent testing to plead their claims. Ultimately, the validity of such testing becomes a question of fact not properly resolved at this stage. All in all, I am unable to conclude at the pleadings stage that the plaintiffs' claims are expressly preempted by the FDCA or related FDA regulations.

Implied preemption

The defendants next argue that the plaintiffs' claims are impliedly preempted pursuant to § 337(a) of the FDCA. As noted above, because the FDCA makes it the exclusive responsibility of the federal government to prosecute claims for violations of the FDCA, the FDCA impliedly preempts state law claims that rely solely on a violation of the FDCA rather than on a violation

[51] Doc. #99 at 48-52; Doc. #129 at 15

of an independent duty under state law. As I have previously observed in a similar context, "[i]n order to survive preemption, a state law claim must rely on an independent state law duty that parallels or mirrors the FDCA's requirement for [sunscreen products], but must not solely and exclusively rely on violations of the FDCA's own requirements." *Patane I*, 314 F. Supp. 3d at 386.

Put differently, "[w]here a state law claim would not exist but for a FDCA regulation, § 337(a) impliedly preempts the claim." *Id.* at 387. That is because "there can be no state law cause of action if a plaintiff's 'true goal is to privately enforce alleged violations of the FDCA.'" *Id.* at 385 (quoting *PDK Labs, Inc. v. Friedlander*, 103 F.3d 1105, 1113 (2d Cir. 1997)).

I now review the counts of the complaint to ascertain if they do no more than seek to enforce the FDCA rather than any independent duty under state law. As an initial matter, I need not consider Count One because the plaintiffs have withdrawn this count.[52] Turning to Count Two, it alleges a state law claim for fraudulent concealment or non-disclosure. Whether under New York law or Florida law, a claim for common law fraud involving failure to disclose requires proof that the defendant omitted disclosure of a material fact, that the defendant omitted the fact for the purpose of inducing another party to rely on its omission, that there was justifiable reliance of the other party, and that the plaintiff was injured. *See, e.g.*, *Consigli & Assocs., LLC v. Maplewood Senior Living, LLC,* 2023 WL 1818401, at *13 (S.D.N.Y. 2023) (New York law); *Frayman v. Douglas Elliman Realty, LLC*, 515 F. Supp. 3d 1262, 1281 n.8 (S.D. Fla. 2021) (Florida law). This count is not impliedly preempted because proof of these elements does not require the plaintiffs to prove that there was a violation of the FDCA.

[52] Doc. #128.

Count Three makes a claim for unjust enrichment. Whether under New York law or Florida law or even Connecticut law, a claim for unjust enrichment requires a plaintiff to show that the defendant unjustly received a benefit to the plaintiff's detriment. *See Merco Holdings, LLC v. Bousbib*, 2022 WL 673579, at *11 (D. Conn. 2022); *Cooper v. Anheuser-Busch, LLC*, 553 F. Supp. 3d 83, 115 (S.D.N.Y. 2021); *Carriuolo v. Gen. Motors LLC*, 72 F. Supp. 3d 1323, 1326 (S.D. Fla. 2014). The complaint alleges that the defendants received a benefit from the plaintiffs—the price they paid for the Banana Boat sunscreens—greater than the value of the goods the plaintiffs got in return. This count is not impliedly preempted because it does not depend on any showing of a violation of the FDCA.

Counts Four and Five allege claims for deceptive business practices and false advertising under N.Y. Gen. Bus. Law §§ 349 and 350. To assert a claim under either law, "a plaintiff must allege that a defendant has engaged in (1) consumer-oriented conduct that is (2) materially misleading and that (3) plaintiff suffered injury as a result of the allegedly deceptive act or practice." *Orlander v. Staples, Inc.*, 802 F.3d 289, 300 (2d Cir. 2015).

The plaintiffs have pled facts showing that the label on Banana Boat sunscreens do not contain a benzene warning, that this omission is misleading in light of the risk of benzene contamination, and that the plaintiffs suffered economic and other injury as a result. Thus, Counts Four and Five "appear to be of a vintage that would exist under New York State law even if the FDCA had never been enacted" and are not preempted. *Booker v. E.T. Browne Drug Co., Inc.*, 2021 WL 4340489, at *7 (S.D.N.Y. 2021).

Counts Eleven, Twelve, and Thirteen all allege violations of Florida's Deceptive and Unfair Trade Practices Act (FDUTPA) in three different ways. Florida law provides that violations of FDUTPA include violations of "[a]ny law, statute, rule, regulation, or ordinance

which proscribes unfair methods of competition, or unfair, deceptive, or unconscionable acts or practices." Fla. Stat. § 501.203(3)(c). To state a claim under FDUTPA, a plaintiff must allege (1) a deceptive act or unfair trade practice; (2) causation; and (3) actual damages. *Dolphic LLC v. WCI Cmtys., Inc.*, 715 F.3d 1243, 1250 (11th Cir. 2013).

Count Eleven alleges a violation of FDUTPA insofar as the defendants have violated *both* the federal FDCA and the Florida Drug and Cosmetic Act, Fla. Stat. § 499.005. To the extent that this count explicitly relies on the federal FDCA as the basis for a state law duty, I conclude that Count Eleven is impliedly preempted. *See Patane I*, 314 F. Supp. 3d at 384-89 (state law claims precluded that explicitly relied on violation of FDCA); *Reid v. GMC Skin Care USA Inc.*, 2016 WL 403497, at *10 (N.D.N.Y. 2016) (same).

On the other hand, to the extent that Count Eleven additionally relies on the Florida Drug and Cosmetic Act, *see* Fl. Stat. § 499.005(1)-(5), which independently prohibits misbranding any drug or cosmetic, then Count Eleven is not preempted. *See Patane v. Nestle Waters N. Am., Inc*. (*Patane II*), 369 F. Supp. 3d 382, 389-95 (D. Conn. 2019) (state law claims not precluded to the extent that they rely on independent state law provisions that mirror FDCA requirements); *Reid*, 2016 WL 403497, at *10 (same as to provisions of California and Washington statutes prohibiting misbranding).

Counts Twelve and Thirteen allege additional FDUTPA violations based on unfair practices and deceptive conduct. The defendants' omission of a benzene warning is an allegedly unfair and deceptive act under the Florida Drug and Cosmetic Act, *see* Fl. Stat. § 499.005(1)-(5), and which caused the plaintiffs to purchase Banana Boat sunscreen for more money than they otherwise would have paid. Such claims are not impliedly preempted because they rely on independent duties under state law not to engage in unfair trade practices or deceptive conduct.

In short, the plaintiffs' remaining claims are not expressly or impliedly preempted except for part of Count Eleven which impermissibly seeks to enforce by means of state law a violation of the federal FDCA. Accordingly, I will dismiss Count Eleven to the extent that it relies on a violation of federal law under the FDCA.

Primary jurisdiction

The defendants' next argument is that the plaintiffs' claims are subject to the primary jurisdiction of the FDA and therefore improper for adjudication by this Court. "The doctrine of primary jurisdiction allows a court to stay litigation and refer issues to an administrative agency when a case involves issues that fall within the special competence of that agency." *Seneca Nation of Indians v. New York*, 988 F.3d 618, 629 (2d Cir. 2021). Accordingly, "whenever enforcement of the claim requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body," the court should defer decision to that agency. *Ellis v. Tribune Television Co.*, 443 F.3d 71, 81 (2d Cir. 2006).

Yet "primary jurisdiction is not required when a referral to the agency would significantly postpone a ruling that a court is otherwise competent to make." *Astiana v. Hain Celestial Grp., Inc.*, 783 F.3d 753, 761 (9th Cir. 2015). The Second Circuit has cautioned that the doctrine has a "relatively narrow scope," and does not apply when the claim involves matters within the "traditional realm of judicial competence." *Goya Foods, Inc. v. Tropicana Prods., Inc.,* 846 F.2d 848, 851 (2d Cir. 1988).

A court considering whether to defer to an agency decisionmaker must consider "(1) whether the question at issue is within the conventional experience of judges or whether it involves technical or policy considerations within the agency's particular field of expertise; (2) whether the question at issue is particularly within the agency's discretion; (3) whether there

exists a substantial danger of inconsistent rulings; and (4) whether a prior application to the agency has been made." *Seneca Nation*, 988 F.3d at 629.

The defendants argue that the FDA is in the process of applying its expertise and discretion to craft a response to the issue of benzene contamination in sunscreen. The agency has issued an alert to consumers and manufacturers and has announced plans to respond to the Valisure report by formulating a new OTC monograph for sunscreen. The defendants insist that any ruling a court may issue on the topic would potentially conflict with these updated regulations.

However, the plaintiffs primarily seek economic damages for past labeling practices. That the FDA is currently formulating its future response to benzene contamination need not conflict with whether the plaintiffs are entitled to retrospective relief. Neither does the FDA have any special expertise in assessing whether the absence of a benzene warning would prove deceptive to a reasonable consumer, which requires the application of bread-and-butter tort principles best suited for a judge and jury. *See Langan v. Johnson & Johnson Consumer Companies, Inc.*, 95 F. Supp. 3d 284, 292-93 (D. Conn. 2015). Nor does the FDA have authority to award monetary damages to deceived purchasers. Accordingly, none of the factors weigh in favor of deferring to the FDA on the plaintiffs' remaining claims for relief.

Failure to plead fraud with particularity

The defendants next argue as to some of the plaintiffs' remaining claims that they do not meet Rule 9(b)'s heightened pleading standard for claims involving fraudulent conduct. "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). A claim sounding in fraud must "(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where

and when the statements were made, and (4) explain why the statements were fraudulent." *United States ex rel. Chorches for Bankr. Est. of Fabula v. Am. Med. Response, Inc.*, 865 F.3d 71, 81 (2d Cir. 2017).

While "[m]alice, intent, knowledge, and other conditions of a person's mind may be averred generally," this "leeway is not a 'license to base claims of fraud on speculation and conclusory allegations.'" *Eternity Glob. Master Fund Ltd. v. Morgan Guar. Tr. Co. of N.Y.*, 375 F.3d 168, 187 (2d Cir. 2004). The complaint must allege facts to show "that the defendants had both motive and opportunity to commit fraud," or "that constitute strong circumstantial evidence of conscious misbehavior or recklessness." *Ibid*.

The defendants argue that the plaintiffs have not satisfied Rule 9(b)'s requirements for their claim of fraudulent non-disclosure as alleged in Count Two. I agree. The plaintiffs allege in a conclusory fashion that the defendants "had knowledge that the Products contained benzene or may contain benzene and that the Products were not safe and healthy for use."[53] But they do not allege that the defendants knew about benzene in Banana Boat sunscreen before the release of the Valisure report or other third-party testing.

In response, the plaintiffs argue that "[t]he omissions were fraudulent because testing determined the Product contains—or risks containing—benzene."[54] But this argument misunderstands the basic essence of fraud—that a misrepresentation or omission has been made *with knowledge at the time it was made* that it was false or misleading. Therefore, a fraud claim that relies merely on the fact that an untrue statement or omission has been made does not satisfy Rule 9(b)'s pleading requirements. Accordingly, I will dismiss Count Two for failure to satisfy Rule 9(b)'s particularity requirement.

[53] Doc. #89 at 38 (¶ 166).
[54] Doc. #102 at 59.

As to the remaining counts that have not otherwise been dismissed, the defendants further argue that Counts Twelve and Thirteen do not allege fraud with particularity as required by Rule 9(b). As noted above, Counts Twelve and Thirteen allege claims for unfair and deceptive conduct in violation of the Florida Deceptive and Unfair Trade Practices Act (FDUTPA). The defendants' argument fails because a claim for relief under FDUTPA does not necessarily require a showing of fraud, and so "the requirements of Rule 9(b) do not apply to claims under FDUTPA." *Lewis v. Mercedes-Benz USA, LLC*, 530 F. Supp. 3d 1183, 1231 (S.D. Fla. 2021); *see also Bluegreen Vacations Unlimited, Inc. v. Timeshare Laws. P.A.*, 2021 WL 3552175, at *7 (S.D. Fla. 2021) (same).

Failure to state a claim

Lastly, the defendants move to dismiss pursuant to Rule 12(b)(6) for failure to state a claim. For reasons of judicial economy, I will address only those counts that have not been previously dismissed in this ruling.

Count Three alleges a claim for unjust enrichment. I assume for present purposes that Connecticut law applies to the unjust enrichment claim because the parties cite and discuss only Connecticut law.[55]

Unjust enrichment is "essentially equitable, its basis being that in a given situation it is contrary to equity and good conscience for one to retain a benefit which has come to him at the expense of another." *Vertex, Inc. v. City of Waterbury*, 278 Conn. 557, 573 (2006). In order to make a claim of unjust enrichment, a plaintiff must establish: "(1) that the defendant was benefited, (2) that the defendant unjustly did not pay the plaintiff for the benefit, and (3) that the

[55] Doc. #99 at 70-71; Doc. #102 at 69-70.

failure of payment was to the plaintiff's detriment." *Merco Holdings*, 2022 WL 673579, at *11 (cleaned up).

The plaintiffs have plausibly alleged that the defendants sold a product which, because of its actual or risk of benzene contamination, was worth less than its purchase price. When the plaintiffs overpaid for the product, the defendants therefore unjustly received an unearned benefit, leaving the plaintiffs out the difference.

The defendants disagree. They first argue that the products the plaintiffs purchased are not worthless because the detected benzene level is within the FDA's guidelines.[56] But this fails for the same reasons as explained above. Whether, and which, of the FDA's guidance applies to Banana Boat sunscreen depends on questions of fact unresolved at this stage of the litigation.

The defendants next argue that the plaintiffs got the benefit of their bargain: they purchased sunscreen to protect them from the risks of sun exposure, and that is what the product did.[57] This argument misses the point. The plaintiffs' claim is that the presence of benzene in sunscreen undermines its protective function by exposing them to carcinogenic benzene. In other words, the sunscreen was defective in some way and therefore worth less than the price the plaintiffs paid for it. *See Zeigler v. Sony Corp. of America*, 48 Conn. Supp. 397, 405 (2004) ("It is disingenuous . . . to argue that, because the plaintiff got a Sony DVD player, he received the benefit of his bargain when the player he got is alleged to have been defective.").

The defendants next contend that, because the plaintiffs paid third-party retailers for the sunscreen and not the defendants directly, they received no benefit from the plaintiffs' purchases.[58] As the defendants argue, "[a]bsent the conferring of a benefit by the plaintiff

[56] *See* Doc. #99 at 70.
[57] *Ibid.*
[58] *Id.* at 70-71.

directly, no action for unjust enrichment . . . is valid." *Granito v. Int'l Bus. Machines*, 2003 WL 1963161, at *2 (Conn. Super. Ct. 2003).

But other Connecticut courts have rightly declined to require that the plaintiff confer a benefit "directly" to the defendant to make a claim for unjust enrichment. They have upheld claims where, as here, the plaintiffs purchased the products through a third-party retailer. *See, e.g.*, *Zeigler*, 48 Conn. Supp. at 404–05 ("[C]learly the purchase of DVD players conferred a benefit upon the defendants" even though they were the manufacturers rather than the sellers of the product); *Stefan v. P.J. Kids, LLC*, 2005 WL 834208, at *3 (Conn. Super. Ct. 2005) ("Nor is the court persuaded . . . [that] the parties must have a direct relationship (as opposed to buying from a retailer as here)."). Thus, as the Connecticut Supreme Court has acknowledged, "[a]lthough unjust enrichment typically arises from a plaintiff's direct transfer of benefits to a defendant, it also may be indirect, involving, for example, a transfer of a benefit from a third party to a defendant when the plaintiff has a superior equitable entitlement to that benefit." *Geriatrics, Inc. v. McGee*, 332 Conn. 1, 25 (2019).

Therefore, the plaintiffs do not have to show that they "directly" conferred a benefit on the defendants. It is enough for plaintiffs to show, as they do here, that the defendants benefitted from their purchase of the sunscreen from a retail seller. *See also In re Takata Airbag Prod. Liab. Litig.*, 462 F. Supp. 3d 1304, 1327 (S.D. Fla. 2020) (applying Connecticut law to conclude that no direct benefit required); *Melnick v. TAMKO Bldg. Prod., Inc.*, 469 F. Supp. 3d 1082, 1099 (D. Kan. 2020) (same). Accordingly, I will deny the defendants' motion to dismiss the unjust enrichment claim as alleged in Count Three.

The defendants additionally argue that the plaintiffs' remaining statutory consumer protection claims as alleged in Counts Four and Five (New York General Business Law §§ 349, 350) and Counts Eleven to Thirteen (FDUTPA) fail to state a claim.

First, the defendants argue that the plaintiffs have failed to establish that their label was misleading, because no reasonable consumer would believe that Banana Boat sunscreens could never contain trace amounts of a substance not on the ingredients list.[59] But this argument is overbroad. The question is whether any reasonable consumer could believe that Banana Boat sunscreens contain *benzene* when it is not on the ingredients list. Assuming the truth of the plaintiffs' claim that exposure to even low levels of benzene carries serious health risks, it is plausible that most consumers would not expect their sunscreen to contain such an ingredient without a warning label. And ultimately what a reasonable consumer would expect is "a question of fact that is not readily susceptible to resolution on a motion to dismiss." *Langan*, 95 F. Supp. 3d at 289.

The defendants next contend that the plaintiffs' New York law claims for false advertising based on a material omission fail, because the plaintiffs have not alleged that "the business alone possesse[d] material information that is relevant to the consumer."[60] *Harris v. Pfizer*, 586 F. Supp. 3d 231, 244 (S.D.N.Y. 2022). But other courts have found that a plaintiff "claiming an omission constitutes actional deception must show *either* that the business alone possessed the relevant information, *or* that a consumer could not reasonably obtain the information."[61] *Kyszenia v. Ricoh USA, Inc.*, 583 F. Supp. 3d 350, 360 (E.D.N.Y. 2022)

[59] *See* Docs. #99 at 71-76; #131 at 11-12.
[60] The defendants make this argument citing to only New York state law. Doc. #99 at 74-75. As such I will construe the defendants' material omission argument to apply only to the New York state law claims.
[61] The defendants' standard would also have the perverse effect of rewarding businesses who do not conduct routine quality checks and remain ignorant of defects in their products while punishing businesses that do have routine quality checks and therefore face increased opportunities to discover materially relevant information.

(emphasis added); *Braynina v. TJX Companies, Inc.*, 2016 WL 5374134, at *6 (S.D.N.Y. 2016). Here, the plaintiffs have satisfied the latter requirement. Testing is prohibitively expensive, and impractical at the point of purchase. It is certainly plausible that consumers lack the ability to test or independently ascertain whether their own bottles of sunscreen contain benzene.[62]

The defendants next argue that because the plaintiffs have not shown that they read the labels before purchasing the sunscreen, they cannot have "justifiably relied" on its omissions. They say that any mislabeling was therefore not the cause of the plaintiffs' injury. But the cases cited by the defendants involve statements made in materials not attached to the physical product. *See, e.g.*, *Oden v. Boston Scientific Corporation*, 330 F. Supp. 3d 877, 902 (E.D.N.Y. 2018) (website and separate product brochure); *Goldemberg v. Johnson & Johnson Consumer Companies, Inc.*, 8 F. Supp. 3d, 467, 480 (S.D.N.Y. 2014) (Facebook and website posts). When the deceptive label is affixed to the product, courts do not require plaintiffs to affirmatively show that they read the language at issue. *See, e.g.*, *id.* at 479. The defendants do not contest that the ingredients label was attached to the sunscreen bottles. That is enough to plausibly establish that the plaintiffs did indeed see the label and rely on its contents when making their purchase.

The defendants go on to object that the plaintiffs have not pled their economic injury with sufficient specificity.[63] As the defendants contend, the plaintiffs must allege "what the premium was, what price they paid for the products, or the price of potential comparator products."[64] But neither New York nor Florida law are so demanding. Courts have routinely upheld claims under the New York law where, as here, the plaintiffs allege that they "would not have purchased, or paid a price premium for," the mislabeled products, without requiring the plaintiffs to name a

[62] Doc. #89 at 7 (¶ 26).
[63] *See* Doc. #99 at 78-79, 83-84.
[64] *Id.* at 79.

dollar figure. *See Koenig v. Boulder Brands, Inc.*, 995 F. Supp. 2d 274, 288 (S.D.N.Y. 2014). Even the primary case on which the defendants rely acknowledges that "[u]nder New York law, a premium could constitute an actual injury." *See Colella v. Atkins Nutritionals, Inc.*, 348 F. Supp. 3d 120, 142 (E.D.N.Y. 2018). And under Florida state law, actual damages exist where a product is "deemed adulterated and cannot lawfully be sold" and therefore "has no value." *See Debernardis v. IQ Formulations, LLC*, 942 F.3d 1076, 1084-85 (11th Cir. 2019). The complaint has at least plausibly alleged why contaminated sunscreen is a valueless good.

Finally, in supplemental briefing, the defendants argue that the plaintiffs' FDUTPA claims fail because the plaintiffs have not plausibly alleged a misleading statement, there was no unfair practice because the plaintiffs got what they paid for, the plaintiffs have not alleged actual damages, and the plaintiffs' claims fall into FDUTPA's safe harbor provision.[65] Of these points only the safe harbor provision remains unaddressed. The safe harbor provision prevents an act or practice from serving as the basis for a FDUTPA claim where that act or practice is permitted under federal law.[66] But whether federal law permits the act in question depends on whether the defendants' labeling practices complied with FDCA regulations—an unresolved question of fact as discussed at length above.

Restitution

One last issue: the defendants argue that because the plaintiffs have an adequate remedy at law, their request for restitution as a form of equitable relief fails.[67] But at this stage of the litigation a party "may state as many separate claims or defenses as it has, regardless of consistency." Fed. R. Civ. P. 8(d)(3). And so the plaintiffs are "not required to elect between

[65] Doc. #131 at 12-14.
[66] Docs. #99 at 82-83, #131 at 14.
[67] Doc. #99 at 86.

legal and equitable relief." *Capax Discovery, Inc. v. AEP RSD Investors, LLC*, 285 F. Supp. 3d 579, 593 (W.D.N.Y. 2018).

CONCLUSION

For the reasons stated above, I will GRANT the defendants' motion to dismiss with respect to Counts Two, Six, Seven, Eight, Nine, Ten, Eleven (in part), and the plaintiffs' request for an injunctive order requiring the defendants to comply with the at-issue consumer protection laws. I will DENY the defendants' motion to dismiss with respect to Counts Three, Four, Five, Eleven, Twelve, and Thirteen. The plaintiffs have previously withdrawn Count One.

It is so ordered.

Dated at New Haven this 13th day of March 2023.

/s/ ***Jeffrey Alker Meyer***
Jeffrey Alker Meyer
United States District Judge