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Attorneys for Defendant VIRGIN SCENT, INC., D/B/A ARTNATURALS, INC.

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

LAUREN SLAUGHTER, etc.

Plaintiffs,

vs.

VIRGIN SCENT, INC., D/B/A ARTNATURALS, INC., and DOES 1-10,

Defendants.

KAILA SAIKI AND RAYMOND SAIKI, etc.,

Plaintiffs,

vs.

VIRGIN SCENT, INC., D/B/A ARTNATURALS, INC.,

Defendant.

Consolidated Case No.: 2:21-cv-02875-VAP-E

Assigned to the Honorable Virginia A. Phillips, Courtroom 8A

DEFENDANT VIRGIN SCENT, INC., D/B/A ARTNATURALS, INC.'S NOTICE OF MOTION AND MOTION TO DISMISS THE SECOND AMENDED COMPLAINT; MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT THEREOF

(*Filed concurrently with Proposed Order thereon*)

Date: April 25, 2022
Time: 2:00 p.m.
Place: Courtroom 8A
350 West 1st Street
Los Angeles, CA 90012

Complaint filed: April 2, 2021
Pretrial Conf.: Not Set
Trial Date: Not Set

TO ALL PARTIES AND TO THEIR COUNSEL OF RECORD:

PLEASE TAKE NOTICE that on April 25, 2022 at 2:00 p.m. or as soon thereafter as the matter maybe heard, in Courtroom 8A of the United States District Court for the Central District of California, the Honorable Virginia A. Phillips presiding, located at 350 W. 1st Street, 8th Floor, Los Angeles, CA 90012, Defendant VIRGIN SCENT, INC., D/B/A ARTNATURALS, INC.'S will and hereby does move the Court pursuant to Federal Rule of Civil Procedure 12(b)(1) and 12(b)(6) to dismiss the Second Amended Complaint of plaintiffs.

The Motion is made upon the grounds that:

1. To survive a Rule 12(b)(6) motion to dismiss, a complaint "must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Pleadings must contain "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). Indeed, "only a complaint that states a plausible claim for relief survives a motion to dismiss." *Iqbal*, 556 U.S. at 679. Unsupported factual allegations and legal conclusions receive no deference. *Id.* In addition, fraud allegations must be stated with particularity. Fed. R. Civ. P. 9(b).
2. The SAC is an impermissible shotgun pleading.
3. All of plaintiffs' claims are impliedly preempted under the FDCA. § 337(a) of the FDCA states that the Food and Drug Administration ("FDA") alone is empowered to enforce alleged FDCA violations. Private citizens cannot substitute themselves for FDA and assert state law claims when those claims are based on violations otherwise left to the FDA to enforce.
4. Plaintiffs' economic loss claims are expressly preempted by § 379(r). Plaintiffs are impermissibly attempting to assert state law claims that would require Artnaturals to include information on the labels of its products that

is in addition to the testing and information actually required by the FDA.

5. Plaintiffs lack standing to represent putative class members from states other than their state of purchase.

6. Plaintiffs' claims are deficient under Fed. R. Civ. P. 8 and Rule 9(b).

The Motion is based on this Notice of Motion and Motion, the attached Memorandum of Points and Authorities, the concurrently filed Proposed Order; and such other and further pleadings and argument to be made at the hearing on the Motion.

Certification: This Motion is made following the conference of counsel pursuant to Local Rule 7-3, which commenced on February 18, 2022 and continued on February 23, 2022. The parties were not able to reach a resolution of their dispute regarding this Motion.

Dated: February 25, 2022

CARLTON FIELDS, LLP
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By: _____
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MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

This is one of four lawsuits filed after a private laboratory allegedly detected the presence of benzene as an impurity in certain alcohol-based hand sanitizer products. Plaintiffs allege in their Second Amended Complaint ("SAC") that the Artnaturals hand sanitizer they purchased contained impermissible levels of benzene that should have been disclosed on the label. Although plaintiffs do not allege that they actually used the product, they assert that it was "worthless" due to the alleged presence of undisclosed benzene. They assert a number of claims—from breach of warranty to fraud to medical monitoring—all based on the fundamental allegation that the failure to include detailed testing information or disclose the presence of benzene on the label violates the federal Food, Drug, and Cosmetic Act ("FDCA") and is actionable under various state laws. But plaintiffs are incorrect, and their SAC should be dismissed for several reasons:

- The SAC is an impermissible shotgun pleading.
- All of plaintiffs' claims are impliedly preempted under the FDCA. § 337(a) of the FDCA states that the Food and Drug Administration ("FDA") alone is empowered to enforce alleged FDCA violations. Private citizens cannot substitute themselves for FDA and assert state law claims when those claims are based on violations otherwise left to the FDA to enforce.
- Plaintiffs' economic loss claims are expressly preempted by § 379(r). Plaintiffs are impermissibly attempting to assert state law claims that would require Artnaturals to include information on the labels of its products that is in addition to the testing and information actually required by the FDA.
- Plaintiffs lack standing to represent putative class members from states other than their state of purchase.
- Plaintiffs' claims are deficient under Fed. R. Civ. P. 8 and Rule 9(b).

For these reasons, discussed below, the SAC should be dismissed.

II. FACTUAL BACKGROUND

A. Plaintiffs' Allegations

Plaintiffs allege that Artnaturals sold hand sanitizer that "contain[s] dangerously high levels of benzene." Doc. 30 ¶ 1. They contend that the presence of benzene made the product "unsafe and worthless" and rendered it "adulterated and misbranded," and as a result, "illegal to sell under federal and state law and therefore worthless." *Id.* ¶ 4. They accuse defendants of "false" and "misleading" labeling because Artnaturals "does not disclose the presence of benzene." *Id.* ¶ 14.

Although plaintiffs allege that the presence of benzene caused defendants' product to be misbranded, they admit that benzene is "a component of crude oil, gasoline, and cigarette smoke, and is one of the elementary petrochemicals." *Id.* ¶ 5. They cite to a webpage that acknowledges that a certain amount of benzene is permissible in gasoline. *Id.* ¶ 5 n.3; *see also Industrial Union Dept., AFL-CIO v. Am. Petroleum Inst.*, 448 U.S. 607, 616 (1980) (observing that "[t]he entire population of the United States is exposed to small quantities of benzene, ranging from a few parts per billion to 0.5 ppm, in the ambient air," "[o]ver one million workers are subject to additional low-level exposures as a consequence of their employment," and "[a]lthough it could conceivably cause harm to a person who swallowed or touched it, the principal risk of harm comes from inhalation of benzene vapors"); *Metro-N. Commuter R.R. v. Buckley*, 521 U.S. 424, 434 (1997) (citing U.S. Dept. of Health & Human Servs., Seventh Annual Report on Carcinogens 71 (1994) for proposition that as of 1994, more than 3 million workers were exposed to benzene in the workplace). Plaintiffs further acknowledge that because of the COVID-19 pandemic, the FDA has issued "Interim Guidance" that permits certain hand sanitizer products to contain benzene up to interim limits of 2 ppm. *Id.* ¶¶ 40-42. They admit that the FDA "established an interim limit of 2 parts per million ('PPM')." *Id.* ¶ 42. They assert that Artnaturals' product does not qualify for this exemption, however, and "its sale is in violation of FDCA laws and

regulations." *Id.* Based on these core allegations, plaintiffs assert 20 assorted claims on behalf of themselves and a nationwide class. They sue for economic damages in the form of a "full refund of their purchase price." *Id.* ¶¶ 16, 18-19. They also allege they "were exposed to a product that resulted in or could result in Plaintiffs and Class Members sustaining bodily injury, sickness or disease resulting from continuous or repeated use of the products…or may suffer personal and bodily injury in the future." *Id.* ¶ 20.

B. Hand Sanitizer Products Are Actively Regulated By FDA

As the SAC recognizes, hand sanitizer products are considered over-the-counter ("OTC") drugs regulated by the United States Food and Drug Administration ("FDA"). Therefore, plaintiffs' claims must be viewed against the backdrop of FDA's OTC framework and its regulation of hand sanitizers. In 1972, FDA established a "monograph" system for regulating OTC drugs, which allows manufacturers to bypass individualized review provided that their products comply with the monograph. *See* 37 Fed. Reg. 9464; 21 C.F.R. § 330.10; 21 U.S.C. § 355. Under this system, FDA issues a detailed regulation – a "monograph" – for each therapeutic class of OTC drug products. Like a recipe, a monograph "sets out the FDA-approved active ingredients for a given class of TIC drugs and provides the conditions under which each active ingredient is considered" "generally recognized as safe and effective. ('GRAS/E"). *NRDC, Inc. v. FDA*, 710 F.3d 71, 75 (2d Cir. 2013). The FDA regulates the ethyl alcohol-based hand sanitizer at issue as a drug product. In fact, FDA has a long history of close oversight of hand sanitizer, beginning generally in the 1970s, followed by a June 1994 Tentative Final Monograph specific to hand sanitizers (the "1994 TFM"), 59 Fed. Reg. 31402, and thereafter by various rules, deferrals, and guidance issued throughout the years, including in 2013, 2015, 2016, 2017, 2019, 2020, and 2021. Among other things:

- In the 1994 TFM, FDA classified hand sanitizer products made with ethyl alcohol as GRAS/E (59 Fed. Reg. 31402, 31402-03), set forth detailed testing and

labeling requirements for such products, and made clear that hand sanitizer products that met those testing and labeling requirements were not misbranded. *Id.* at 31403, 31407. Notably, the 1994 TFM did not require that detailed testing results or impurity data be included on the label. *See generally id.* at 31407.

- In 2016, after years of ongoing review and evaluation, FDA issued a proposed rule to amend the 1994 TFM "in light of more recent scientific developments and changes in the use patterns of [hand sanitizer] products" and proposed that "additional safety data are necessary to support the safety of antiseptic active ingredients for this use." 81 Fed. Reg. 42912, 42912 (the "2016 TFM"). In the 2016 TFM, FDA changed its initial determination that ethyl alcohol products were GRAS/E, and instead determined that additional studies and safety data were needed. *Id.* Therefore, the 2016 TFM did not "specifically address requirements for anticipated final formulating testing (*i.e.*, testing the mixture of both active and inactive ingredients proposed for marketing) or labeling." *Id.* at 42913. FDA specifically noted that "[f]inal formulation testing could potentially involve both efficacy testing and safety testing to determine absorption" and that "labeling will be addressed as part of the final rule." *Id.* FDA requested more information and noted that improved analytical methods indicated that systemic exposure may be higher than previously thought. *Id.* at 42923. It acknowledged the increased use of hand sanitizer since the 1994 TFM, but noted that it was "unaware of any information that would lead us to conclude that any consumer antiseptic hand rub active ingredient is unsafe." *Id.* at 42914. FDA invited further comment and stated that it would consider requests to defer further rulemaking to allow the submission of new safety or effectiveness data to the record. *Id.* at 42916-17.
- In 2019, FDA issued a final rule indicating that all products covered by the 2016 TFM required the submission of a New Drug Application ("NDA") or Abbreviated New Drug Application ("ANDA"), *except* for those made with ethyl alcohol, isopropyl alcohol, or benzalkonium chloride (the "2019 Rule"). 84 Fed.

Reg. 14847, 14848. Instead, FDA "deferred further rulemaking on these three active ingredients for use in OTC consumer antiseptic rubs to allow for the development and submission to the record of new safety and effectiveness data for these three ingredients." *Id.* The 2019 Rule described "the studies necessary as a scientific matter for the Agency to determine whether an active ingredient is GRAS/E for use in consumer antiseptic rubs" and determined that the monograph status of such products "will be addressed, either after completion and analysis of studies to address the safety and effectiveness data gaps of those ingredients or at another time, if these studies are not completed." *Id.* at 14851, 14861. With respect to ethyl alcohol, specifically, FDA explained that important scientific developments since 1994 "affected [its] evaluation of the safety of the active ingredients in consumer antiseptic rub products, and that this, in turn, had caused [it] to reassess the data necessary to support a GRAS determination." *Id.* at 14854.

- With respect to labeling, FDA made clear that because the three remaining active ingredients in consumer antiseptic rubs were granted deferrals and because FDA had not yet made a GRAS/E determination on those ingredients, it would not address their labeling in the 2019 Rule. *Id.* Rather, "[i]f any of the three active ingredients are subsequently found to be GRAS/GRAE, [FDA] will address the labeling for products containing that active ingredient in the applicable final monograph. *Id.* The 2019 Rule also did not "specifically address requirements for anticipated final formulating testing," which would instead be addressed after the ingredient was found to be GRAS/E. *Id.* FDA also specifically discussed the need for further information regarding potential carcinogenicity risk for drug products that are primarily administered via topical dermal application. *Id.* at 14858.
- Since publishing the 2019 Rule, FDA continued to closely monitor and regulate ethyl alcohol hand sanitizer products, especially in light of the increased demand for and usage of such products due to the COVID-19 pandemic. In FDA's March 2020 Temporary Policy for Preparation of Certain Hand Sanitizer Products

During the Public Health Emergency (COVID-19), Guidance for Industry, which was subsequently updated on March 27, 2020, April 15, 2020, June 1, 2020, August 7, 2020, and February 2021, FDA declared that it was "temporarily providing flexibility with respect to certain impurities at the levels established in Table 1 and Table 2," which table set the 2 ppm limit on benzene. Indeed, FDA continued to update and provide detailed information regarding the testing to be conducted on alcohol-based hand sanitizers, including developing a laboratory analytical procedure to assess the quality of finished products, which FDA determined could be used to evaluate products formulated with ethyl alcohol and screen for potentially harmful impurities and to provide a methodology to help assure hand sanitizer products do not contain harmful levels of impurities. *Id.*; Direct Injection Gas Chromatography Mass Spectrometry (GC-MS) Method for the Detection of Listed Impurities in Hand Sanitizers (Aug. 24, 2020).[1]

- FDA withdrew its temporary policies on October 13, 2021, effective December 31, 2021, because "current data indicate that consumers and healthcare personnel are no longer experiencing difficulties accessing alcohol-based hand sanitizer products, and these temporary policies are no longer needed to help meet demand." 86 Fed. Reg. 56960, 56961.

In sum, FDA continues to actively study and monitor the safety of ethyl alcohol hand sanitizer products, including labeling, testing, and disclosures.

III. ARGUMENT

A. The Complaint Is A Shotgun Pleading.

The SAC should be dismissed as a shotgun pleading. A shotgun pleading is "a complaint containing multiple counts where each count adopts the allegations of all preceding counts." *Weiland v. Palm Beach Cnty., Sheriff's Office*, 792 F.3d 1313, 1321-23 (11th Cir. 2015). Shotgun pleadings fail "to give the defendants

[1] https://www.fda.gov/media/141501/download

adequate notice of the claims against them and the grounds upon which each claim rests." *Id.* California federal courts, citing *Weiland,* have condemned shotgun pleadings on multiple occasions. *See*, *e.g.*, *Prostitis v. Riverside Super. Family Law Ct.*, 2020 WL 3843727, *2 (C.D. Cal. Apr. 15, 2020); *Yellowcake, Inc. v. Morena Music, Inc.*, 522 F. Supp. 3d 747, 769 (E.D. Cal. 2021). Shotgun pleadings fail "to give the defendants adequate notice of the claims against them and the grounds upon which each claim rests." *Weiland*, 792 F.3d at 1323.[2]

The SAC is a shotgun pleading. In each count, plaintiffs re-allege and incorporate by reference all allegations of each preceding count. Doc. 30 ¶¶ 99, 111, 117, 125, 133, 150, 161, 168, 177, 189, 201, 215, 226, 239, 250, 268, 282, 294, 305. This practice makes it "exceedingly difficult, if not impossible to know which allegations pertain to that count." *Keith v. DeKalb Cnty., Ga.*, 749 F.3d 1034, 1045 n.39 (11th Cir. 2014). Accordingly, the SAC should be dismissed.

B. Plaintiffs' Claims Are Impliedly and Expressly Preempted.

Under the Supremacy Clause of the Constitution, "state law that conflicts with federal law is without effect." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992). Federal preemption of state law may be express or implied. *See Murphy v. NCAA*, 138 S. Ct. 1461, 1480 (2018). Here, the SAC should be dismissed because the FDCA impliedly and expressly preempts all its claims.

Implied Preemption. In enacting FDCA, Congress declined to create a private cause of action and affirmatively required that any action to enforce the FDCA "shall be by and in the name of the United States." 21 U.S.C. § 337(a). Indeed, the Supreme Court declared that this provision "leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance" with FDCA requirements. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001). As this Court also declared, the absence of a

[2] Unless otherwise indicated, all internal quotations or citations in quotations are omitted.

private right of action to enforce FDCA requirements prohibits the use of state unfair competition laws "as a vehicle to bring a private cause of action that is based on violations of the FDCA." *In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.*, 590 F. Supp. 2d 1282, 1290-91 (C.D. Cal. 2009); *see also Nexus Pharms., Inc. v. US Compounding Inc.*, 2021 WL 342573, *3 (C.D. Cal. Jan. 7, 2021) (unfair competition claims impliedly preempted when plaintiff alleged that defendant was "not following the rules – and those rules are the FDCA rules").

Here, plaintiffs' claims are nothing more than an attempt to evade FDA's exclusive enforcement authority under § 337 of the FDCA by burying their FDCA claims in state-law causes of action. But a close reading of the claims—especially when viewed against the backdrop of FDA's close and continued focus on hand sanitizer products—reveals that they are all dependent on FDCA and FDA regulations. Doc. 30 ¶ 5 (FDA lists Benzene as Class 1 solvent; ¶ 12 ("FDA generally regulates hand sanitizer products as over-the-counter ('OTC') drug products"); *id.* (listing FDCA and "FDA regulations and guidance" as source of duties); ¶ 39 ("Hand sanitizers are considered OTC drug products regulated by FDA," referencing 21 C.F.R. 201.66); *id.* (citing 21 C.F.R. 201.66 labeling requirements); ¶ 42 (product sale "is in violation of FDCA laws and regulations"); ¶ 51 (referencing 201.10); ¶ 130 ("Pursuant to FDA guidance, Defendant was required to engage in impurity testing to ensure that harmful impurities such as benzene were not present in the Product"); ¶¶ 14, 153 (referring 21 U.S.C. § 351(a)(1) as source of duty). Additional examples pervade the SAC.

Thus, the crux of plaintiffs' complaints is that Artnaturals' ethyl alcohol hand sanitizer contained unapproved ingredients and were not properly labeled or tested for safety. But as detailed above, FDA has been closely analyzing the safety of ethyl alcohol products, has considered the impurity and safety testing conducted to date and needed moving forward, and has affirmatively decided that ethyl alcohol products should not yet be considered new, unapproved products requiring

an NDA or ANDA to be sold. Under *Buckman* and the plain language of the myriad relevant FDA TFMs and guidances, it is FDA's job to regulate, study, and enforce safety and impurity issues related to ethyl alcohol hand sanitizers.

In sum, plaintiffs' claims are a transparent attempt to evade FDA's exclusive enforcement authority under § 337. The law is clear that private citizens cannot substitute themselves for the FDA and assert state law claims when those claims are based on violations otherwise left for the FDA to enforce. Plaintiffs' claims are impliedly preempted, and the SAC should be dismissed in its entirety.

Express Preemption. To the extent plaintiffs are attempting to assert state law economic damages claims that would require Artnaturals to include information on the labels of its ethyl alcohol products that are in *addition* to the testing and information that FDA *actually* requires, such claims are expressly preempted by 21 U.S.C. § 379(r). Under the heading "National uniformity for nonprescription drugs," § 379(r) mandates that, except for claims brought under the products liability law of any state, "no State or political subdivision of a State may establish or continue in effect any requirement – (1) that relates to the regulation of a [nonprescription] drug…and (2) that is different from or in addition to, or that is otherwise no identical with, a requirement under [the FDCA]." 21 U.S.C. § 379r(a), (e). § 379r also preempts any common-law duties imposed through civil damages that differ from or add to federal requirements. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 324-25 (2008); *Mills v. Warner-Lambert Co.*, 581 F. Supp. 2d 772, 789 (E.D. Tex. 2008).

To that end, Congress provided in § 379r(c)(2) that "any requirement relating to public information or any other form of public communication relating to a warning of any kind for a drug" shall be deemed a state "requirement" that satisfies § 379r(a). *Carter v. Novartis Consumer Health, Inc.*, 582 F. Supp. 2d 1271, 1282 (C.D. Cal. 2008). "A reasonable reading of § 379(c)(2) is that it expands the universe of potentially preempted state law claims to include those

that require additional warnings in the advertising for nonprescription drugs, and not only on the labeling." *Id*. For purposes of § 379r, a monograph is an FDCA requirement – and a tentative final monograph does not necessarily need to be final to be enforceable. *See* 21 U.S.C. § 355h(b)(8)(A); 21 C.F.R. § 3370.1; *Bailey v. Rite Aid Corp.*, 2019 WL 4260394, *4 (N.D. Cal. Sept. 9, 2019). Here, plaintiffs assert that the labels and testing of Artnaturals' hand sanitizer product is subject to FDA regulations through various tentative final monographs and related FDA actions. Indeed, all plaintiffs' state law claims hinge on their assertion that Artnaturals' hand sanitizer product is unsafe and that the inclusion of additional ingredients – benzene – at undisclosed levels renders the drug unapproved and of lesser quality than that reflected in the versions that allegedly otherwise comply with the monograph and FDA requirements. Plaintiffs attempt to require that Artnaturals conduct testing and include information on its product labels that are different from and in addition to the testing and information that FDA actually requires. Because their economic damages claims would require Artnaturals to take actions that are in addition to or different from FDCA requirements, those claims are expressly preempted under § 379r, no matter how they are styled.

It remains only to note that plaintiffs' economic damages claims (Counts I-XVII) are not products liability claims saved by § 379r's savings clause. *See Carter*, 582 F. Supp. 2d at 1286-88 (savings clause inapplicable to claims for economic damages). It is a basic tenet of product liability law that loss of or damage to the product itself is not recoverable. Instead, product liability law encompasses injuries to a person or property. *See id.* at 1286-87 (citing Restatement (Third) of Torts: Prod. Liab. § 1, 21 (1998)). Claims for economic loss are not "product liability" claims for purposes of the savings clause in § 379r(e). *Kanter v. Warner-Lambert Co.*, 99 Cal. App. 4th 780, 790 (Cal. Ct. App. 2002) (stating "injury to the plaintiff from a defective product is an essential element" and "if the damage consists solely of economic losses, recovery on a

products liability theory is unavailable"). Here, too, because Counts I-XVII are not injury claims, they are not saved by § 379r.

C. Plaintiffs Lack Standing To Assert Claims On Behalf Of Putative Class Members From States Other Than Their Own.

The twelve named plaintiffs' claims are governed by Alabama, Illinois, New York, Minnesota, California, Florida, Texas, Washington, Oregon, Idaho, and Pennsylvania law. *See* Doc. 30 ¶¶ 22-33 (describing plaintiffs' states of residence and purchase). Yet they seek to assert nationwide class claims on behalf of purchasers in other states. *E.g.*, *id.* ¶ 73 ("Plaintiffs seek to represent a class defined as all persons in the United States who purchased and used the Hand Sanitizer (the "Class").."). Although plaintiffs limit some of their claims to subclasses of purchasers in a named plaintiff's state (Counts 9-17, 20), they seek to represent class members for all other claims in states in which they do not reside and were not allegedly injured. *Id.* ¶¶ 95, 100, 118, 120, 126, 134, 151, 162, 283, 295, 298. They lack standing to do so. The law is well settled that "at least one named plaintiff must have standing with respect to each claim the class representatives seek to bring." *Webb v. Carter's, Inc.*, 2009 WL 10670244, *10 (C.D. Cal. June 23, 2009). Most California federal courts have applied this principle to dismiss state law claims for states in which none of the named plaintiffs resided or purchased product. *E.g.*, *In re Aftermarket Auto. Lighting Prods. Antitrust Litig.*, 2009 WL 9502003, *6 (C.D. Cal. July 6, 2009) ("Courts routinely dismiss claims where no plaintiff is alleged to reside in a state whose laws the class seeks to enforce.").[3] This Court should do the same.

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[3] *See also Harris v. CVS Pharmacy, Inc.*, 2015 WL 4694047, *4 (C.D. Cal. Aug. 6, 2015) (same); *Los Gatos Mercantile, Inc. v. E.I. DuPont De Nemours & Co.*, 2014 WL 4774611, *3 (N.D. Cal. Sept. 22, 2014) (collecting cases); *Morales v. Unilever U.S., Inc.*, 2014 WL 1389613, *4 (E.D. Cal. Apr. 9, 2014) (noting that if "a representative plaintiff is lacking for a particular state, all claims based on that state's laws are subject to dismissal").

It is no answer to argue that class certification must be addressed first. *See Easter v. Am. West Fin.*, 381 F.3d 948, 962 (9th Cir. 2004) (holding that standing must be addressed prior to class certification); *see also Schertzer v. Bank of Am., N.A.*, 445 F. Supp. 3d 1058, 1072 (S.D. Cal. 2020) (noting "growing trend" after *Easter* to address standing at pleading stage).

Likewise, the argument that plaintiffs have standing as long as the law of other states is materially identical to California law cannot save these claims. This argument conflates the Rule 23 inquiry with plaintiffs' standing to sue in the first place. *Morales*, 2014 WL 1389613, *4. If the named plaintiffs lack standing, the necessary consequence is dismissal, not denial of class certification. *Id.*

D. Plaintiffs Fail To State Claims.

1. **Count 1 For Breach of Express Warranty.**

Count 1 for breach of express warranty should be dismissed for two reasons. First, plaintiffs fail to allege the existence of any actual express warranty. Instead, they allege that Artnaturals "expressly warranted that the Product is a hand sanitizer used for cleaning and/or sterilizing hands, rather than adulterated hand sanitizer containing dangerous chemicals." Doc. 30 ¶ 96. The law is clear that these allegations do not amount to an express warranty, but are actually breach of implied warranty allegations in disguise. *See* UCC § 2-313 cmt 1 (explaining that express warranties "rest on 'dickered' aspects of the individual bargain" but implied warranties "rest so clearly on a common factual situation or set of conditions that no particular language or action is necessary to evidence them").[4]

[4] *See also Barragan v. Gen. Motors LLC*, 2015 WL 5734842, *9 (W.D. Tex. Sept. 30, 2015) (dismissing express warranty claim where plaintiffs alleged warranty "to the public generally" that product "was of merchantable quality and was safe and fit for the purpose intended"); *Anthony v. Country Life Mfg., L.L.C.*, 2002 WL 31269621, *3 (N.D. Ill. Oct. 9, 2002) (dismissing express warranty claim when plaintiff failed to identify affirmative fact or promise because plaintiff "has confused express and implied warranties"), *aff'd sub nom. Anthony v. Country Life*

Second, Slaughter, Duarte, Pichardo, Howe, the Saikis, and Robinson fail to allege privity. Privity is required for express warranty claims under Alabama, California, Florida, Idaho, Illinois, and Texas law.[5] These plaintiffs acknowledge that privity against Artnaturals is absent because they allege they purchased the product from a grocery store, Target, and Walmart. Doc. 30 ¶¶ 22-24, 27-29, 32.

Moreover, no exception applies here for when a manufacturer makes "direct contacts" with and "direct representations" to a consumer. *See Cedars of Lebanon Hosp. Corp. v. Eur. X–Ray Distribs. of Am., Inc.*, 444 So. 2d 1068, 1072, 1072 n.4 (Fla. 3d DCA 1984); *PPG Indus., Inc. v. JMB/Houston Centers Partners L.P.*, 146 S.W.3d 79, 90 (Tex. 2004). The SAC expressly alleges that the product label said nothing about benzene. Doc. 30 ¶ 13.

2. Count 2 for Breach of Implied Warranty.

Plaintiffs' claims in Count 2 for breach of implied warranty should be dismissed.[6] First, the claims of Slaughter, Duarte, Pichardo, Howe, the Saikis,

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Mfg., LLC., 70 F. App'x 379 (7th Cir. 2003); *Byrnes v. Small*, 60 F. Supp. 3d 1289, 1301 (M.D. Fla. 2015) (unspecified representations to general public insufficient).

[5] *See Barre v. Gulf Shores Turf Supply, Inc.*, 547 So. 2d 503, 504 (Ala. 1989) ("[P]laintiff must prove privity of contract in an action on an express warranty where no injuries to natural persons are involved."); *Tapia v. Davol, Inc.*, 116 F. Supp. 3d 1149, 1160 (S.D. Cal. 2015) ("In general, privity is a required element of a breach of express warranty cause of action."); *Fields v. Mylan Pharm., Inc.*, 751 F. Supp. 2d 1257, 1259 (N.D. Fla. 2009) (dismissing warranty claims because complaint did not allege purchase directly from the defendant); *W. Cmty. Ins. v. Burks Tractor Co., Inc.*, 428 P.3d 793, 799 n.2 (Idaho 2018) (noting that trial court held privity is required for express warranty claims); *Caterpillar, Inc. v. Usinor Industeel*, 393 F. Supp. 2d 659, 677 (N.D. Ill. 2005) ("To enforce an express warranty under Illinois law…a party without a warranty assignment alleging purely economic loss must be in privity of contract."); *Well Head Welders, Inc. v. Techalloy Co.*, 1999 WL 314795, *6 (Tex. Ct. App. May 20, 1999) (noting that Texas courts generally require privity for breach of express warranty).

[6] To the extent plaintiffs allege breach of the implied warranty of fitness for a particular purpose, however, such a claim also should be dismissed. *See* UCC § 2-315 cmt 2 ("A 'particular purpose' differs from the ordinary purpose for which the

Pinghera, Scantlin, Sophocles, and Boorman for breach of implied warranty should be dismissed because of a lack of privity. Privity is required under Alabama, California, Florida, Idaho, Illinois, New York, Oregon, and Washington law.[7] As noted above, plaintiffs concede that privity against Artnaturals is absent because they purchased from either a retail store or Amazon.com. Doc. 30 ¶¶ 22-33.

Second, the implied warranty claims of Slaughter, Duarte, Pichardo, Howe, the Saikis, McIntyre, Pinghera, Scantlin, Sophocles, and Robinson should be dismissed because of their failure to give Artnaturals presuit notice. Presuit notice is required under Alabama, California, Florida, Idaho, Illinois, Minnesota, New York, Oregon, Pennsylvania, and Texas law.[8] Although plaintiffs allege they gave presuit notice to Artnaturals in their express warranty claim, Doc. 30 ¶ 98, such an

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goods are used in that it envisages a specific use by the buyer which is peculiar to the nature of his business whereas the ordinary purposes for which goods are used are those envisaged in the concept of merchantability and go to uses which are customarily made of the goods in question."). The SAC fails to allege any "particular purpose." Doc. 30 ¶ 102.

[7] *See Rampey v. Novartis Consumer Health, Inc.*, 867 So. 2d 1079, 1087 (Ala. 2003); *Clemens v. DaimlerChrysler Corp.*, 534 F.3d 1017, 1023 (9th Cir. 2008); *Salmon Rivers Sportsman Camps, Inc. v. Cessna Aircraft Co.*, 544 P.2d 306, 312-13 (Idaho 1975); *Szajna v. Gen. Motors Corp.*, 503 N.E.2d 760, 767 (Ill. 1986); *Mahoney v. Endo Health Sols.*, 2016 WL 3951185, *5 (S.D.N.Y. July 20, 2016); *Davis v. Homasote Co.*, 574 P.2d 1116 (Or. 1978) (en banc); *Tex Enters., Inc. v. Brockway Standard, Inc.*, 66 P.3d 625, 630 (Wash. 2003) (en banc); *Short v. Hyundai Motor Co.*, 444 F. Supp. 3d 1267, 1286 (W.D. Wash. 2020); *Mesa v. BMW of N. Am., LLC*, 904 So. 2d 450, 458 (Fla. 3d DCA 2005).

[8] *See Smith v. Apple, Inc.*, 2009 WL 3958096, *2 (N.D. Ala. Nov. 4, 2009); *Alvarez v. Chevron Corp.*, 656 F.3d 925, 932 (9th Cir. 2011) (California law); *Chapman v. Abbott Lab'ys*, 930 F. Supp. 2d 1321, 1325 (M.D. Fla. 2013); *Murphy v. Etchegaray*, 702 P.2d 852, 854 (Idaho Ct. App. 1985); *Connick v. Suzuki Motor Co.*, 675 N.E.2d 584, 590-91 (Ill. 1996); *Dolan v. Bos. Sci. Corp.*, 2021 WL 698777, *3 (D. Minn. Feb. 23, 2021); *Campbell v. Whole Foods*, 516 F. Supp. 3d 370, 392 (S.D.N.Y. 2021); *Redfield v. Mead, Johnson & Co.*, 512 P.2d 776, 781 (Or. 1973); *Kee v. Zimmer, Inc.*, 871 F. Supp. 2d 405, 410-11 (E.D. Pa. 2012); *McKay v. Novartis Pharm. Corp.*, 751 F.3d 694, 706 (5th Cir. 2014) (Texas law).

allegation is conspicuously absent from their claim for breach of implied warranty.

3. Count 3 for Violation of MMWA.

Count 3 for violation of the Magnuson-Moss Warranty Act ("MMWA") should be dismissed. MMWA claims are only viable if plaintiffs also stated warranty claims under state law. *Clemens v. DaimlerChrysler Corp.*, 534 F.3d 1017, 1022 (9th Cir. 2008). Because plaintiffs failed to state warranty claims for the reasons set forth above, the MMWA claims likewise should be dismissed.

Further, plaintiffs fail to allege breach of a "written warranty," which the MMWA requires and defines as "any written affirmation of fact or written promise made in connection with the sale of a consumer product by a supplier to a buyer which relates to the nature of the material or workmanship and affirms or promises that such material or workmanship is defect free." 15 U.S.C. § 2301(6)(A). Product descriptions on a label do not suffice. *Clancy v. The Bromley Tea Co.*, 2013 WL 4081632, *11 (N.D. Cal. 2013); *Jones v. ConAgra Foods, Inc.*, 912 F. Supp. 2d 889, 904 (N.D. Cal. 2012).

4. Count 4 for "Restitution, Common Counts, Unjust Enrichment, Quasi-Contract and/or Assumpsit".

Count 4 should be dismissed for several reasons. First, Boorman's claim should be dismissed because, in Washington, common law causes of action based on harm caused by products are subsumed by the products liability statute.[9]

Second, Duarte, Pichardo, and McIntyre's unjust enrichment claims should be dismissed because they have an adequate remedy at law. Their claims are duplicative of their express warranty and fraud claims.[10]

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[9] *Wash. Water Power Co. v. Graybar Elec.*, 774 P.2d 1199, 1211 (Wash. 1989) (en banc) (WPLA subsumes common law remedies); *Blangeres v. U.S. Seamless, Inc.*, 725 F. App'x 511, 514 (9th Cir. 2018) (dismissing unjust enrichment claim as preempted by WPLA).

[10] *See Roper v. Big Heart Pet Brands, Inc.*, 510 F. Supp. 3d 903, 924-26 (E.D. Cal. 2020) (dismissing unjust enrichment claim with prejudice because the plaintiff also

Third, Pichardo's and Howe's claims under Florida and Idaho law should be dismissed because they did not confer a "direct benefit" on Artnaturals. *See Marrache v. Bacardi U.S.A., Inc.*, 17 F.4th 1084, 1102 (11th Cir. 2021); *Stevenson v. Windermere Real Est./Cap. Grp., Inc.*, 275 P.3d 839, 840-44 (Idaho 2012). Plaintiffs do not allege compliance with this requirement. Nor can they—Pichardo and Howe purchased the hand sanitizer from Walmart. Doc. 30 ¶¶ 28, 32.

Fourth, the claims of Slaughter, Duarte, the Saikis, Pinghera, Scantlin, and Robinson should be dismissed because the alleged benefit they conferred on Artnaturals is too attenuated. In Alabama, California, Illinois, New York, Oregon, and Texas, the detriment suffered by the plaintiff and the benefit conferred on the defendant must not be too attenuated. *See In re Takata Airbag Prod. Liab. Litig.*, 462 F. Supp. 3d 1304, 1326-31 (S.D. Fla. 2020) (dismissing unjust enrichment claims under Alabama, Illinois, and New York law against vehicle manufacturers because buyers purchased vehicles at independent dealers); *In re Takata Airbag Prod. Liab. Litig.*, 255 F. Supp. 3d 1241, 1260-64 (S.D. Fla. 2017) (same under Alabama, California, Florida, Oregon, and Texas law). Like in *Takata Airbag*, plaintiffs purchased the hand sanitizer from dealers unaffiliated with Artnaturals. Doc. 30 ¶¶ 22-33. Therefore, these plaintiffs' claims should be dismissed because the alleged benefit they conferred upon Artnaturals is "too attenuated."

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alleged express warranty claim and noting that "Rule 8 does not allow a plaintiff invoking state law to assert an unjust enrichment claim while also alleging an express contract"); *Leonhart v. Nature's Path Foods, Inc.*, 2014 WL 1338161, *9 (N.D. Cal. 2014) (dismissing unjust enrichment claim duplicative of deceptive practices claims); *Prohias v. Pfizer, Inc.*, 490 F. Supp. 2d 1228, 1237 (S.D. Fla. 2007) (dismissing unjust enrichment claim in part because it sought "recovery for the exact same wrongful conduct as [the] consumer fraud act claim"); *cf. Southtown Plumbing, Inc. v. Har-Ned Lumber Co., Inc.*, 493 N.W.2d 137 (Minn. Ct. App. 1992) (dismissing unjust enrichment claim against lender under Minnesota law in part because subcontractor had an adequate remedy at law, a breach of contract claim, against the general contractor).

Fifth, Sophocles' unjust enrichment claim should be dismissed because he fails to specify whether he is proceeding under quasi-contract or a "wrongful enrichment" tort theory, as required by Pennsylvania law. *See Whitaker v. Herr Foods, Inc.*, 198 F. Supp. 3d 476, 492-95 (E.D. Pa. 2016) (explaining the two theories and dismissing unjust enrichment claim for failure to specify the theory). On the one hand, Sophocles uses terms like "illegal," "unlawful," "misleading," "fraud," "wrongful," and requests exemplary damages—which are available only in tort. Doc. 30 ¶¶ 119-21, 124. On the other, Sophocles uses terms like "implied-at-law," "quasi-contract," "restitution," and requests to be "restore[d]...to [his] former position"—which indicates a quasi-contractual theory. *Id.* ¶¶ 118, 120-22.

5. Count 5 for "Fraud and Deceit" And Counts 6 Through 17 for Violation of Consumer Protection Laws.

Count 5 (fraud) and Counts 6 through 17 (consumer protection laws) should be dismissed because they fail to plead fraud with the particularity required by Fed. R. Civ. P. 9(b). Count 5 should be dismissed for the additional reason that its fraud claims are, with the exception of the Idaho, Illinois, Minnesota, Oregon, and Washington claims, barred by the economic loss rule.

To satisfy Rule 9(b), "the complaint must include an account of the time, place, and specific content of the false representations as well as the identities of the parties to the misrepresentations. In other words, the pleading must identify the who, what, when, where, and how of the misconduct charged." *Depot, Inc. v. Caring for Montanans, Inc.*, 915 F.3d 643, 668 (9th Cir. 2019).

Because the SAC "alleges a unified fraudulent course of conduct"—Artnaturals allegedly deceived purchasers about benzene in their hand sanitizer product—all of its claims "are grounded in fraud." *Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1127 (9th Cir. 2009). The "entire complaint must therefore be pleaded with particularity"—including the consumer protection law claims. *Id.*

None of Counts 5 through 17 comes close to satisfying Rule 9(b). Like all

claims grounded in fraud, those claims must be premised on alleged statements or omissions. As to statements, plaintiffs fail to allege the "*specific content* of the false representations" they attribute to Artnaturals. *Depot*, 915 F.3d at 668 (emphasis added). Paragraph 127 exemplifies this failing, alleging as it does that Artnaturals "provided Plaintiffs…with materially false or misleading information about the Hand Sanitizer." Plaintiffs purport to offer specificity with the next sentence of this paragraph by alleging that Artnaturals "marketed the Hand Sanitizer as safe for human use." But that allegation (and others like it in the operative complaint) is anything but specific, and thus plaintiffs have not alleged any fraudulent statements with the requisite particularity. *See id.* (affirming dismissal of a number of claims grounded in fraud because while plaintiffs generally alleged that defendants made misrepresentations—including that the alleged misrepresentations were made "in the course of marketing" to plaintiffs—plaintiffs did not allege "the details of these misrepresentations," including "when defendants made them" and "the specific contents of the misrepresentations").

As to omissions, they also must be pled with particularity. *Marolda v. Symantec Corp.*, 672 F. Supp. 2d 992, 1002 (N.D. Cal. 2009). In *Marolda*, like here, the plaintiffs complained that they were deceived into purchasing a product. Indeed, here, one of the supposedly common questions alleged by plaintiffs in support of class certification was "whether the marketing, advertising, packaging, labeling, and other promotional materials for the Hand Sanitizer are deceptive." Doc. 30 ¶ 90(i). *Marolda* explains that, in such a case, "to plead the circumstances of omission with specificity, plaintiff must describe the content of the omission and where the omitted information should or could have been revealed, as well as provide representative samples of advertisements, offers, or other representations that plaintiff relied on to make her purchase and that failed to include the allegedly omitted information." 672 F. Supp. 2d at 1002. Here, plaintiffs have not provided representative samples of any of the "marketing, advertising, packaging, labeling,

and other promotional materials" that they say were deceptive, and thus they have not alleged any fraudulent omissions with the requisite particularity.

Moreover, as to both statements and omissions, plaintiffs have not alleged reliance with particularity. In ¶¶ 22-35, for example, plaintiffs generally allege that they reviewed and relied on the product label, but without alleging what specifically any of them relied on in purchasing the product. That is not enough to satisfy Rule 9(b). *See Gutierrez v. Johnson & Johnson Consumer Inc.*, 2021 WL 822721, *5 (S.D. Cal. Jan. 22, 2021) (plaintiffs did not allege reliance with particularity when they generally alleged reliance on statements made on bottles of baby powder without alleging specifically what statements they relied on).

The Alabama, California, Florida, New York, Pennsylvania, and Texas fraud claims in Count 5 also should be dismissed because they are barred by the economic loss rule. While the rule is not entirely identical in those jurisdictions, in essence it "prohibits parties from recovering tort damages for what is essentially a breach of contract claim." *Zhejiang Crafab Elec. Co. v. Advantage Mfg., Inc.*, 2018 WL 6177952, *5-6 (C.D. Cal. Apr. 23, 2018). Here, plaintiffs have not alleged harm caused by fraud that is distinct from the economic loss they allegedly suffered due to breach of contract. Indeed, their fraud claims are premised on the same allegations as their contract claims and merely allege that plaintiffs suffered "damages." Doc. 30 ¶ 131. The Alabama, California, Florida, New York, Pennsylvania, and Texas fraud claims in Count 5 are therefore barred by the economic loss rule. *See Blake v. Bank of Am., N.A.*, 845 F. Supp. 2d 1206, 1210 (M.D. Ala. 2012) ("Alabama does not recognize a tort-like cause of action for the breach of a duty created by contract."); *Zhejiang*, 2018 WL 6177952, *6 (finding that fraud claim was barred by California's economic loss rule because it arose "from the same alleged conduct that gives rise to its cause of action for breach of contract"); *Thompson v. Procter & Gamble Co.*, 2018 WL 5113052, *3 (S.D. Fla. Oct. 19, 2018) (Florida's economic loss rule bars fraud claims in "a products

liability case where only economic damages are alleged"); *Orlando v. Novurania of Am., Inc.*, 162 F. Supp. 2d 220, 225 (S.D.N.Y. 2001) ("New York's economic loss rule restricts plaintiffs who have suffered 'economic loss,' but not personal or property injury, to an action for the benefit of their bargain. If the damages are the type remedial in contract, a plaintiff may not recover in tort."); *Silva v. Rite Aid Corp.*, 416 F. Supp. 3d 394, 401 (M.D. Pa. 2019) (Pennsylvania's economic loss rule "prohibits plaintiffs from recovering in tort economic losses to which their entitlement flows only from a contract"); *Yumilicious Franchise, L.L.C. v. Barrie*, 819 F.3d 170, 177-78 (5th Cir. 2016) ("In Texas, the economic loss rule generally precludes recovery in tort for economic losses resulting from the failure of a party to perform under a contract.").

6. Counts 18-19 (Negligence, Negligence *Per Se*).

All the plaintiffs' negligence and negligence *per se* claims should be dismissed. Slaughter, Pichardo, the Saikis, Pinghera, Scantlin, Sophocles, and Robinson's claims should be dismissed because they fail to allege facts showing that they have suffered an actual present injury.[11] Alabama, Florida, Illinois, New York, Oregon, Pennsylvania, and Texas require an actual present injury—neither increased risk of cancer, nor fear of cancer, is sufficient to state a negligence claim.[12] Here, plaintiffs allege only that they "suffered injury, or may suffer

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[11] Plaintiffs may attempt to argue that paragraph 22 of the SAC alleges a specific injury to Slaughter and her child. Doc. 30 ¶ 22 ("Further, Plaintiff Slaughter was pregnant during the time period when she was using the Product, causing injury and/or increased risk of cancer not only to herself but also her unborn child or may suffer such personal and bodily injury in the future as a result of such exposure."). However, that paragraph discusses only speculative or anticipated injury.

[12] *Griffin v. Unocal Corp.*, 990 So. 2d 291, 293 (Ala. 2008) (in Alabama, a cause of action in toxic exposure case "accrues only when there has occurred a manifest, present injury"); *Eagle–Picher Indus., Inc. v. Cox*, 481 So. 2d 517, 522-29 (Fla. 3d DCA 1985); *Berry v. City of Chicago*, 2020 IL 124999, ¶ 38 (Ill. 2021) ("[P]laintiff may not recover solely for the defendant's creation of an increased risk

personal and bodily injury in the future." Doc. 30 ¶¶ 292, 303. That is a legal conclusion not entitled to a presumption of correctness. *See, e.g.*, *Heinen v. Royal Caribbean Cruises Ltd.*, 2019 WL 4059911, *2 (S.D. Fla. Aug. 28, 2019) (merely alleging that "Plaintiffs were injured" and "suffered physical and emotional damage" was insufficient to state a claim), *aff'd*, 806 F. App'x 847 (11th Cir. 2020). Plaintiffs do not specify what type of injuries they have suffered, when they suffered those injuries, or whether and, if so, when they received treatment for those injuries. There is no indication that plaintiffs have suffered from any disease in particular, and if plaintiffs contend that they have contracted cancer, there is no indication of what type of cancer.

Second, McIntyre and Howe's claims of negligence and negligence *per se* should be dismissed because they fail to adequately allege a negligence claim based on either present injury or increased risk of future injury. They fail to allege a negligence claim based on present injury for the same reasons, explained above, that Slaughter, Pichardo, the Saikis, Pinghera, Scantlin, Sophocles, and Robinson fail to adequately allege a negligence claim based on present injury. These plaintiffs also fail to state a claim for increased risk of future disease.[13] In

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of harm."); *Caronia v. Philip Morris USA, Inc.*, 5 N.E.3d 11, 14 (N.Y. 2013); *Lowe v. Philip Morris USA, Inc.*, 183 P.3d 181, 185 (Or. 2008) (exposure to toxic substances that lead to a significantly increased risk of cancer insufficient to give rise to negligence claim); *Simmons v. Pacor, Inc.*, 674 A.2d 232, 240 (Pa. 1996) (awarding damages for increased risk and fear of cancer contrary to established jurisprudence of Commonwealth); *In re Rezulin Prod. Liab. Litig.*, 361 F. Supp. 2d 268, 276 (S.D.N.Y. 2005) (citing *Temple-Inland Forest Prod. Corp. v. Carter*, 993 S.W.2d 88, 92-93 (Tex. 1999)) ("Texas limits recovery for fear of future injury to cases where plaintiffs have suffered a manifest physical injury" and "it is unlikely that Texas would allow recovery for a subcellular injury absent any clinically manifest detriment as a compensable injury.").

[13] It is unclear whether Minnesota or Idaho law allows recovery for increased risk of future disease in the absence of a present physical injury at all. The standard enunciated in *Bryson* and *Mansfield* applied to "increased risk" claims of future

Minnesota, a plaintiff cannot recover for increased risk of future disease unless he proves (1) that future harm is more likely than not to occur; and (2) that future damages are not too speculative. *Bryson v. Pillsbury Co.*, 573 N.W.2d 718, 720-21 (Minn. Ct. App. 1998). In Idaho, a plaintiff cannot recover for increased risk of future disease unless the disease is "medically reasonably certain to follow....mere conjecture or even possibility does not justify the court awarding damages for a future disability which may never materialize." *Mansfield v. United States*, 2019 WL 6868965, *4 (D. Idaho Dec. 16, 2019). McIntyre and Howe failed to allege that it is more likely than not that they will contract cancer. They make no allegation at all regarding the magnitude of the alleged increased risk. *See* Doc. 30 ¶¶ 292, 303 (alleging merely that plaintiffs "suffered injury, or may suffer personal and bodily injury in the future as a result of such exposure"). Their claims for negligence and negligence *per se* should be dismissed.

Duarte's negligence and negligence *per se* claims should be dismissed because she fails to allege an actual injury for the same reasons discussed above, and she also fails to sufficiently allege medical monitoring.[14] *See Riva v. Pepsico, Inc.*, 82 F. Supp. 3d 1045, 1053-64 (N.D. Cal. 2015) (dismissing claims for failure to allege facts supporting factors enunciated in *Potter v. Firestone Tire & Rubber Co.*, 863 P.2d 795, 804-25 (Cal. 1993)). Duarte failed to allege the significance and extent of her exposure; the amount of increased risk caused by the exposure, and

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damages where there was already a physical injury. Nevertheless, McIntyre and Howe's claims fail even under those standards.

[14] Pichardo, the Saikis, Pinghera, and Sophocles also seek medical monitoring damages as part of their negligence claims. However, medical monitoring is an independent cause of action in Florida and Pennsylvania. Therefore, Pichardo and Sophocles' medical monitoring claims are addressed in section (g) below. Furthermore, in Illinois and New York, medical monitoring damages are available only if the plaintiff has suffered a current, manifest physical injury. *See Berry*, 2020 IL 124999, ¶ 38; *Caronia*, 5 N.E.3d at 18. Therefore, Pinghera and the Saikis are not entitled to medical monitoring damages.

the clinical value of early detection and diagnosis. *Potter*, 863 P.2d at 824-25.

Boorman's claims should be dismissed because, in Washington, negligence claims based on harm caused by products are subsumed by the products liability statute. *See Mensonides Dairy, LLC v. Agri-King Nutrition, Inc.*, 2017 WL 8777386, *2-5 (E.D. Wash. Dec. 27, 2017).

Duarte, Pichardo, McIntyre, and Robinson's negligence *per se* claims should be dismissed because negligence *per se* cannot be based on the FDCA or its regulations. *See Blinn v. Smith & Nephew Richards*, 55 F. Supp. 2d 1353, 1361 (M.D. Fla. 1999) ("Under Florida law...Plaintiff cannot use a negligence *per se* claim to create a private cause of action for Defendant's alleged violations of the FDCA."); *Simien v. C. R. Bard*, 2020 WL 4922331, *10 (E.D. Tex. Aug. 20, 2020) ("Texas courts...refuse to recognize a cause of action for negligence *per se* based on violations of the [FDCA] and FDA regulations."); *Connelly v. St. Jude Med.*, 2017 WL 3619612, *5 (N.D. Cal. Aug. 23, 2017) (same); *Kapps v. Biosense Webster*, 813 F. Supp. 2d 1128, 1152 (D. Minn. 2011) (same).

Negligence *per se* is not an independent cause of action in Alabama, California, Idaho, New York, Oregon, Pennsylvania, Texas, and Washington.[15] Therefore, the negligence *per se* claims of Slaughter, Duarte, Howe, Pinghera, Scantlin, Sophocles, Robinson, and Boorman should be dismissed.

Negligence *per se* claims only are permitted in Illinois if the statute provides for strict liability if violated. *See Test Drilling Serv. Co. v. Hanor Co.*, 322 F. Supp.

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[15] *See Prickett v. BAC Home Loans*, 946 F. Supp. 2d 1236, 1247 (N.D. Ala. 2013); *Millard v. Biosources, Inc.*, 68 Cal. Rptr. 3d 177, 188 n.2 (Cal. Ct. App. 2007); *Johnson v. Enriquez*, 460 S.W.3d 669, 673 (Tex. Ct. App. 2015); *Rizzo v. State Farm Ins.*, 305 P.3d 519, 528 (Idaho 2013); *Hammond v. The Bank of New York Mellon Corp.*, 2010 WL 2643307, *10 n.14 (S.D.N.Y. June 25, 2010); *Abraham v. T. Henry Constr., Inc.*, 249 P.3d 534, 538 n.5 (Or. 2011); *Simmons v. Simpson House, Inc.*, 224 F. Supp. 3d 406, 417 (E.D. Pa. 2016); *Atherton Condo. Apartment-Owners Ass'n Bd. of Directors v. Blume Dev. Co.*, 799 P.2d 250, 262 n.13 (Wash. 1990) (en banc).

2d 957, 964 (C.D. Ill. 2003). The Saikis claims are based on "Chapter 410, Illinois Statutes §§ 620/3.1 and /14(a)(2)(B)." Doc. 30 ¶ 298. Those statutes do not provide for strict liability. Therefore, the Saikis' claims should be dismissed.

7. Count 20 for Medical Monitoring.

Count 20 for medical monitoring, brought by Pichardo and Sophocles under Florida and Pennsylvania law, should be dismissed. The elements of medical monitoring under both Florida and Pennsylvania law are: (1) exposure greater than normal background levels; (2) to a proven hazardous substance; (3) caused by the defendant's negligence; (4) as a proximate result of the exposure, plaintiff has a significantly increased risk of contracting a serious latent disease; (5) a monitoring procedure exists that makes the early detection of the disease possible; (6) the prescribed monitoring regime is different from that normally recommended in the absence of the exposure; and (7) the prescribed monitoring regime is reasonably necessary according to contemporary scientific principles. *Petito v. A.H. Robins Co.*, 750 So. 2d 103, 106-07 (Fla. 3d DCA 1999); *Redland Soccer Club, Inc. v. Dep't of the Army & Dep't of Def. of the U.S.*, 696 A.2d 137, 146 (Pa. 1997). Pichardo and Sophocles fail to allege these requirements.

Pichardo and Sophocles allege that they have "an increased risk of developing cancer above the normal base-level risk," Doc. 30 ¶ 307, but they fail to allege that they have a "*significantly* increased risk." Plaintiffs must allege that the risk is "significant enough that a treating physician would prescribe a monitoring regime." *See In re Zantac (Ranitidine) Prod. Liab. Litig.*, 2021 WL 2682659, *11 (S.D. Fla. June 30, 2021) (dismissing medical monitoring claims based on exposure to ranitidine in Zantac, which allegedly transformed into a cancer-causing molecule, NDMA). In *Zantac*, the court observed that "every human being consumes NDMA through eating, drinking, and even breathing." *Id.* *13. In light of this, it was incumbent of plaintiffs upon repleading to allege that amount of exposure above baseline levels that would require medical monitoring.

Id. *13-17; *see also In re Zantac (Ranitidine) Prod. Liab. Litig.*, 2021 WL 4593943, *5 (S.D. Fla. Oct. 6, 2021) (denying second round of motions to dismiss when plaintiffs alleged with greater specificity, among other things, the "frequency and dosage of each Plaintiff's ranitidine use, levels of NDMA that were above FDA's daily limit).

Here, as well, benzene is commonly present in many products purchased and used by consumers. In light of this, Pichardo and Sophocles must, consistent with *Twombly*, plausibly allege that their specific exposure to benzene from Artnaturals' hand sanitizer product was above threshold levels and placed them at a significantly increased risk, which would include allegations regarding frequency and dosage. The FAC does not come close to satisfying this standard.

Also, Pichardo and Sophocles allege that because "benzene-associated cancer screenings may not be conducted with the frequency necessary to identify cancer," the prescribed monitoring regime is different from that normally recommended. Doc. 30 ¶ 307. Merely alleging that cancer screenings "may" not be conducted with the frequency necessary is insufficient. They must allege that "the prescribed monitoring regime *is* different from that normally recommended in the absence of the exposure." They also completely fail to allege that they were exposed to benzene in amounts "greater than normal background levels." Finally, they completely fail to allege that "the prescribed monitoring regime is reasonably necessary according to contemporary scientific principles." Therefore, Pichardo and Sophocles' medical monitoring claims should be dismissed.

IV. CONCLUSION

For the foregoing reasons, the SAC should be dismissed.

Dated: February 25, 2022

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