UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

ANTHONY MORENO, individually, and on behalf of others similarly situated, Plaintiff, v. VI-JON, INC., Defendant.	Case No.: 20cv1446 JM(BGS) **ORDER ON MOTION TO DISMISS**

Presently before the court is Defendant Vi-Jon, LLC's[1] motion to dismiss filed pursuant to Federal Rules of Civil Procedure 9(b), 12(b)(1), and 12(b)(6). (Doc. No. 15.) The motion has been fully briefed and the court finds it suitable for submission on the papers and without oral argument in accordance with Civil Local Rule 7.1(d)(1). For the reasons set forth below, Defendant's motion is granted.

I. BACKGROUND

On July 27, 2020, Plaintiff filed a consumer class action complaint against Defendant, seeking damages and equitable relief for the alleged false and misleading labeling on Defendant's hand sanitizing products. (Doc. No. 1, at ¶¶ 1-8.) The complaint

[1] Defendant notes that the FAC incorrectly identifies it as a Missouri Corporation, (FAC at ¶ 25) when it converted to a Delaware Limited Liability Company as of August 21, 2020. (Doc. No. 16-1, n. 4.)

alleges violations of California's Unfair Competition Law ("UCL"), CAL. BUS. & PROF. CODE § 17200, *et seq;* violation of the California's False Advertising Law ("FAL"), CAL. BUS. & PROF. CODE § 17500, *et seq;* violation of the California Consumer Legal Remedies Act ("CLRA"), CAL. CIV. CODE § 1770, *et seq;* breach of warranty; and quasi-contract.

On September 14, 2020, Plaintiff filed the First Amended Complaint. (Doc. No. 13, "FAC".) The FAC asserts FAL, UCL, CLRA, breach of express warranty, breach of implied warranty, and quasi contract claims against Defendant for misrepresenting and misleading consumers regarding the hand sanitizers (the "Products")[2]. The FAC alleges that the front-facing, primary display panel of each Product contains the statement "kills 99.99% of germs" (the "Representation") when they in fact do not "kill" 99.99% of the organisms that cause disease. (FAC ¶¶ 3, 5.) Plaintiff contends that the Products are ineffective against certain microbes, viruses, protozoa and bacterial spores. (*Id.* ¶¶ 6, 37.) To illustrate his point, Plaintiff points to the Products ineffectiveness against numerous organisms that cause disease including norovirus, polio, polyomavirus, hand, foot, and mouth disease ("HFMD"), human papillomavirus ("HPV"), hepatitis A, cryptosporidium, C. difficile, enterococci, and influenza A. (*Id*. ¶¶ 13, 39-67.) Plaintiff maintains that this list is simply illustrative and is not, however, a comprehensive summary of all microorganisms against which the Products are ineffective. (*Id*. ¶ 38.) Plaintiff claims that "evaluated alone or collectively, the Products are ineffective against more than .01% of 'germs' therefore the uniform Representation that they kill 99.99% of germs is false and misleading." (*Id*. at ¶ 68.) In other words, the germs the Products do not kill, "comprise more than .01% of 'germs' and more than .01% of 'harmful germs.'" (*Id*. at ¶ 33.)

Further, Plaintiff alleges that the Products are misbranded under the law, are legally worthless, and are not capable of being legally sold. (*Id*. ¶¶ 73, 82-84.) Plaintiff purchased

---

[2] The hand sanitizers at issue including the following four brands: (1) CVS Health and/or CVS Pharmacy; (2) Equate (Walmart); (3) Germ-X; (4) Walgreen Co.

each of the branded Products one or more times in stores in San Diego between November 2019 through February 2020[3]. Had the Products not claimed to kill 99.99% of germs, Plaintiff alleges that he would have not purchased them, or alternatively, had he known they did not kill 99.99% of germs and were not legally saleable, he would not have purchased them at the premium price. (*Id.* ¶¶ 89-96.)

Plaintiff seeks to represent a California Class consisting of "all citizens of California who, within four years prior to the filing of the initial Complaint, purchased Defendant's Products and who did not claim any personal injury from using the Products." (*Id*. at ¶ 97.) The FAC's Prayer for Relief includes, among other things, an order for restitution, disgorgement and an award of compensatory, monetary and punitive damages. (*Id.* at 30.[4])

On September 28, 2020, Defendant filed a motion to dismiss. (Doc. No. 15.) Plaintiff filed his opposition to the motion[5], (Doc. No.16) and Defendant filed its reply, (Doc. No. 20).

II. LEGAL STANDARDS

Federal Rule of Civil Procedure 12(b)(1) allows a party to move to dismiss based on the court's lack of subject matter jurisdiction. Fed. R. Civ. P. 12(b)(1). "[T]hose who seek

---

[3] Plaintiff purchased: (1) the CVS product from a CVS store in San Diego for approximately$3.99; (2) the Equate product from a Walmart store in San Diego for approximately $3.97; (3) the Germ-X product from a Walmart store in San Diego for approximately $2.66; and (4) the Walgreens product from a Walgreens store in San Diego for $2.99. FAC at ¶ 88; *see also* Doc. No. 13-1, Declaration of Anthony Moreno, ¶¶ 5, 8-10, 12.

[4] Document numbers and page references are to those assigned by CM/ECF for the docket entry.

[5] In his opposition, Plaintiff makes passing objections to the declaration of Alisa Benson, stating a handful of reasons why the court should disregard it. *See* Doc. No. 16. n. 1. Ms. Benson's declaration was filed in support of Defendant's motion to dismiss. (Doc. No. 15-2.) Having not considered Ms. Benson's declaration in ruling on this motion, Plaintiff's objections are denied as moot.

to invoke the jurisdiction of the federal courts must satisfy the threshold requirement imposed by Article III of the Constitution by alleging an actual case or controversy." *City of L.A. v. Lyons,* 461 U.S. 95, 101 (1983). Article III requires that: "(1) at least one named plaintiff suffered an injury in fact; (2) the injury is fairly traceable to the challenged conduct; and (3) the injury is likely to be redressed by a favorable decision." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992) (quotation marks and citation omitted). Plaintiff has the burden of establishing that the court has subject matter jurisdiction over an action. *Ass'n of Med. Colls. v. U.S.*, 217 F.3d 770, 778-79 (9th Cir. 2000). A party may make either a facial or factual attack on subject matter jurisdiction. *See, e.g., Warren v. Fox Family Worldwide, Inc., 328 F.3d 1136, 1139 (9th Cir. 2003)*. To resolve a facial challenge, as Defendant makes here, the court considers whether "the allegations contained in [the] complaint are insufficient on their face to invoke federal jurisdiction." *Safe Air for Everyone v. Meyer*, 373 F.3d 1035, 1039 (9th Cir. 2004). The court must accept the allegations as true and must draw all reasonable inferences in the plaintiff's favor. *Whisnant v. United States*, 400 F.3d 1177, 1179 (9th Cir. 2005); *Wolfe v. Strankman*, 392 F.3d 358, 362 (9th Cir. 2004).

Under Federal Rule of Civil Procedure 12(b)(6), a party may bring a motion to dismiss based on the failure to state a claim upon which relief may be granted. A Rule 12(b)(6) motion challenges the sufficiency of a complaint as failing to allege "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly,* 550 U.S. 544, 570 (2007). This is because a "pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.'" *Ashcroft v. Iqbal,* 556 U.S. 662, 678 (2009) (quoting *Twombly,* 550 U.S. at 555). Ordinarily, for purposes of ruling on a Rule 12(b)(6) motion, the court "accept[s] factual allegations in the complaint as true and construe[s] the pleadings in the light most favorable to the non-moving party." *Manzarek v. St. Paul Fire & Marine Ins. Co.,* 519 F.3d 1025, 1031 (9th Cir. 2008). The court must be able to "draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal,* 556 U.S. at 663. "Determining whether a complaint states a

plausible claim for relief … [is] a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id.* at 679.

Under Federal Rule of Civil Procedure 9(b), a plaintiff must plead fraud with particularity. "Averments of fraud must be accompanied by the who, what, when, where, and how of the misconduct charged." *Vess v. Ciba–Geigy Corp. USA*, 317 F.3d 1097, 1106 (9th Cir. 2003) (internal quotation marks omitted). Even if "fraud is not a necessary element of a [particular] claim," Rule 9(b) will apply if the plaintiff has "allege[d] a unified course of fraudulent conduct and rel[ied] entirely on that course of conduct as the basis of [the] claim." *Id*. at 1103.

III. DISCUSSION

Defendant moves to dismiss all of Plaintiff's claims on the grounds that Plaintiff lacks Article III standing. Defendant also seeks dismissal under Rule 12(b)(6) of the Federal Rules of Civil Procedure, arguing that the FAC fails to allege facts sufficient to state any claim upon which relief can be granted. Further, Defendant claims that Plaintiff has failed to satisfy the heightened pleading requirements of Rule 9(b). Defendant also moves to dismiss on the grounds that federal regulations preempt Plaintiff's claims. Finally, Defendant maintains that Plaintiff's claim for equitable relief should be dismissed. The Court will address each of Defendant's arguments in turn.

A. Rule 12(b)(1)

Defendant moves for dismissal under Rule 12(b)(1), asserting this court lacks subject matter jurisdiction because Plaintiff has not met the Article III standing requirements. It argues that Plaintiff has not pled any injury in fact as a result of his purchases. (Doc. No. 15-1 at 15-17.) In support, Defendant points to the allegations in the FAC that hypothesize the "potential risk of disease – an unrealized risk of harm that could have resulted from use of the Products (or which the Products allegedly failed to prevent), but which Moreno does not claim occurred." (*Id*. at 15.) Relatedly, Defendant argues that Plaintiff is attempting to recast his not cognizable no-injury products liability claims into consumer fraud claims. (*Id.* at 16.) Plaintiff counters that he suffered an injury in fact based on the amount he paid

for the misbranded products. (Doc. No. 16 at 11-13.) Additionally, Plaintiff maintains that his claims are based on Defendant's affirmative misrepresentation and are not a no-injury product liability case. (*Id.* at 13-14.)

"There is no subject matter jurisdiction without standing, and the "irreducible constitutional minimum" of standing consists of three elements." *Romero v. Securus Techs., Inc.,* 216 F. Supp. 1078, 1085 (2016). A plaintiff must have "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robbins*, 136 S. Ct. 1540, 1547 (2016). In a class action, at least one of the named plaintiffs must meet the Article III standing requirements. *Bates v. United Parcel Servs., Inc.,* 511 F. 3d 974, 985 (9th Cir. 2007). Defendant's arguments implicate the first element.

"To establish injury in fact, a plaintiff must show that he or she suffered 'an invasion of a legally protected interest' that is 'concrete and particularized' and 'actual or imminent, not conjectural or hypothetical.'" *Spokeo,* 136 S. Ct. at 1547 (quoting *Lujan*, 504 U.S. at 560). To that end, "[a] 'concrete' injury must be '*de facto*'; that is, it must actually exist." *Id.* "Where, as here, a case is at the pleading stage, the plaintiff must 'clearly . . . allege facts demonstrating" the existence of an injury in fact." *Id.* (quoting *Warth v. Seldin*, 422 U.S. 490, 518 (1975)). Thus, for Plaintiff to have Article III standing, the FAC must allege facts demonstrating that Plaintiff has suffered a concrete injury as a result of the violations of the FAL, UCL, CLRA and breach of express warranty, breach of implied warranty, and quasi contract claims alleged in the FAC.

The FAC does not meet this requirement. Pointing to a list of various diseases Plaintiff makes the conclusory allegation that the Products are ineffective against 0.01% of germs and, therefore, the Representation that they kill 99.99% of germs is false and misleading, (*see* FAC ¶¶ 7, 33, 38, 68). Nowhere in the FAC does Plaintiff plead any harm or material risk of harm that he suffered as a consequence of purchasing the hand sanitizers. He has not alleged a negative experience associated with the Products, despite the allegations in the FAC that the Products are not legally saleable. Further, neither in the

FAC nor in his attached declaration, (Doc. No. 13-1), does Plaintiff even allege that he purchased or used the Products to prevent any of the diseases or viruses listed in the FAC. Neither has Plaintiff alleged that he contracted any of the diseases or viruses he alleges that the Products do not purportedly protect against. Moreover, the possibility of contracting one of the listed diseases/viruses because the Products have not killed the germs which cause them, depends on too many outside variables. In other words, Plaintiff does not plead facts to suggest that a palpable risk exists. Setting aside the unassailable reality that the Products do not represent they will kill, for example, polio, HPV, or other serious disease microbes, Plaintiff has done nothing more than "mathematically" calculate that the percentage of serious disease bearing "germs" must, logically, exceed 0.01% of the universe of germs and, therefore, cannot "kill" all of the most serious germs. This argument is insufficient to confer Article III standing. *See, e.g., Birdsong v. Apple,* 590 F.3d 955, 961 (9th Cir.2009) (plaintiff did not adequately allege injury in fact due to false labeling when defendant adequately disclosed potential risks to customers); *Boysen v. Walgreen Co.,* No. C 11- 06262 SI, 2012 WL 2953069, at * 7 (N.D. Cal. July 19, 2012); *Herrington v. Johnson & Johnson Consumer Cos., Inc.,* No. C 09-1597 CW, 2010 WL 3448531, at * 3 (N.D. Cal. Sept. 1, 2010); *In re McNeil Consumer Healthcare,* 877 F. Supp. 2d 254 (E.D. Pa. 2012); *Williams v. Purdue Pharma Co.,* 297 F. Supp. 2d 171 (D.D.C. 2003).[6]

---

[6] *But cf., Degelman v. Advanced Medical Optics*, 659 F.3d 835 (9th Cir. 2011) vacated 699 F.3d 1103 (9th Cir 2012). *Degelman* is, however, easily distinguishable from the instant case. There, the Ninth Circuit reversed a district court's dismissal for lack of standing where plaintiffs purchased contact lens solution that was later recalled due to high incidence of infection, though plaintiffs themselves suffered no such infection. The *Degelman* plaintiffs supported their claims of economic injury with plausible allegations that the product actually performed at a lower level than comparable products and less well than advertised because it caused a serious eye infection. Here, Plaintiff has provided no such plausible allegations, the FDA has not withdrawn the hand sanitizers in question, and Plaintiff makes only passing references to the conclusions of various studies while overlooking the disclosure on the rear of the label.

In sum, Plaintiff has not pled an injury and has failed to allege an injury that "actually exist[ed]" and that affected him in "a personal and individual way." *Spokeo*, 136 S. Ct. at 1548. Rather, Plaintiff has only pled a conjectural and hypothetical injury: that the Products kill 99+% of germs when they do not "kill" certain germs, which comprise more than .01% of "germs" and more than .01% of "harmful germs." *See Lujan*, 504 U.S. at 560 (To establish injury in fact—the relevant element here—the plaintiff must show that he or she suffered "an invasion of a legally protected interest" that is "concrete and particularized" and "actual or imminent, not conjectural or hypothetical") (internal quotations omitted). Consequently, the motion to dismiss the complaint, made pursuant to Rule 12(b)(1), is **GRANTED,** with leave to amend.

B. Sufficiency of Plaintiff's Allegations

Second, Defendant contends that Plaintiff has failed to plead sufficient facts to support his claims, or with the requisite specificity, required by Federal Rules of Civil Procedure 9(b) and 12(b)(6).

1. CLRA, FAL & UCL claims

Defendant makes several arguments in favor of dismissal of these claims. (Doc. No. 15-1 at 21-25.) The court will focus on Defendant's assertion that Plaintiff's claims should be dismissed because the court can conclude as a matter of law that members of the public are not likely to be deceived by the advertisement. (*Id*. at 21.) Relatedly, Defendant argues Plaintiff's reading of the front label is implausible and inconsistent with how a reasonable consumer would understand the Products' function[7]. (*Id*. at 23.) Plaintiff counters that it

---

[7] The court will consider the back labels of the products as depicted in the photographs submitted in Plaintiff's declaration which was attached to the FAC (see Doc. No. 13-1 at 7-8) and described in ¶ 29 of the FAC ("Defendant uniformly states on the back-panel labels of the Products that they are 'Effective at eliminating more than 99.99% of many common harmful germs & bacteria in as little as 15 seconds."). *See, e.g., Knievel v. ESPN,* 393 F.3d 1068, 1076-77 (9th Cir. 2005) (explaining how the incorporation by reference doctrine allows a court, at the motion to dismiss stage, to consider "documents whose contents are not attached to the complaint and whose authenticity no party questions," and

is premature at the pleadings stage to determine whether a reasonable consumer would be deceived by the label. (Doc. No. 16 at 16.) Plaintiff also asserts that this case has not presented the court with one of the rare situations where dismissing a product mislabeling case at the pleadings stage would be appropriate. (*Id.* at 17.) Further, Plaintiff argues that the language on the back panel does not dispel or alleviate the deception. (*Id.* at 17-21.)

(i) Reasonable Consumer

Defendant contends that a cursory review of the entire front label reveals that the language about which Plaintiff complains, "Kills more than 99.99% of germs*" is followed by an asterisk, which alerts the consumer to the language on the rear label: "*Effective at eliminating 99.99% of many common harmful germs and bacteria in as little as 15 seconds." (Doc. No. 15-1 at 21.) Defendant maintains that, when read as whole, the Product packaging and labels would not establish that reasonable consumers could be misled. (*Id*.)

In order to protect its citizens from unfair, deceptive or fraudulent business practices California has enacted a number of consumer protection statutes. The CLRA prohibits "unfair or deceptive acts or practices undertaken by any person in a transaction intended to result or which results in the sale or lease of goods or services to any customer." CAL. CIV. CODE § 1770(a). Similarly, the UCL prohibits any "unlawful, unfair or fraudulent business act or practice," and the FAL prohibits any "unfair, deceptive, untrue or misleading advertising." CAL. BUS. & PROF. CODE §§ 17200, 17500. These claims are governed by the "reasonable consumer" test. *Williams v. Gerber Prods. Co.*, 552 F.3d 934, 938 (9th Cir. 2008). The test requires that plaintiff demonstrate "more than the mere possibility that the label 'might conceivably be misunderstood by some few consumers viewing it in an unreasonable manner.'" *Ebner v. Fresh*, 838 F.3d 958, 965 (9th Cir. 2016) (quoting *Lavie*

---

how the doctrine may be used to incorporate pages and images surrounding the [defamatory] statement when plaintiff has failed to provide the complete context in which the statement was made).

v. Procter & Gamble Co., 105 Cal. App. 4th 496 (2003)). "Rather, the reasonable consumer standard requires a probability that a significant portion of the general consuming public or of targeted consumers, acting reasonably in the circumstances, could be misled." *Id.* (internal quotation marks omitted).

Whether a business practice is deceptive will usually be a question of fact not appropriate for determination at the pleadings stage. *Williams*, 552 F.3d at 938. "However, in certain instances, [and as recognized by *Williams* at 939] a court can properly make this determination and resolve claims based on its review of the product packaging." *Brown v. Starbucks Corp.*, Case No.: 18cv2286 JM (WVG), 2019 WL 996399, at * 3 (S.D. Cal. Mar. 1, 2019) (quoting *Pelayo v. Nestle USA, Inc.* 989 F. Supp. 2d 973, 978 (C.D. Cal. 2013)). Qualifying language in the challenged advertising making the meaning of the alleged misrepresentation clear have led district courts within the Ninth Circuit to grant motions to dismiss. *See, e.g.*, *Freeman v. Time, Inc.*, 68 F.3d 285, 289 (9th Cir. 1995) (affirming the district court's dismissal of the California consumer claim when "[n]one of the qualifying language is hidden or unreadably small" and appears "immediately next to the representations it qualifies"); *Sponchiado v. Apple Inc.*, Case No. 18-cv-07533-HSG, 2019 WL 6117482, at *4 (N.D. Cal. Nov. 18, 2019) (concluding "a reasonable consumer could not be deceived by the iPhone Products' screen size representation, given the qualifying language expressly notifying the consumer that the actual screen area is less than indicated."); *Dinan v. SanDisk LLC*, Case No. 18-CV-05420-BLF, 2020 WL 364277, at *7-8 (N.D. Cal. Jan 22, 2020) (finding a reasonable consumer could not be deceived regarding the number of gigabytes in the product, given the disclosure sought to clarify the use of the term); *Elbaz v. Vitals Int'l Grp.*, Case No. 8:17-cv-01673-JLS-DFM, 2018 WL 5868739 at * 3 (C.D. Cal. Apr. 10, 2018) ("No reasonable consumer would understand the representation 100% Natural Preservative System" to mean that every ingredient in the Shampoo is 100% natural…. A consumer would have to ignore half of the representation in order to conclude that "100% Natural" applies to the Shampoo as a whole."); *Bobo v. Optimum Nutrition, Inc.*, Case No.: 14CV2408 BEN (KSC), 2015 WL 13102417, at *5

(S.D. Cal. Sept. 11, 2015) (dismissing claims when language elsewhere on packaging clarified that "100% WHEY" did not mean "100% protein," because "a reasonable consumer, like the plaintiff in *Freeman*, cannot look at only one statement to the exclusion of everything else and claim he has been misled"); *Garcia v. Sony Computer Entm't Am.*, LLC, 859 F. Supp. 2d 1056, 1065 (N.D. Cal. 2012) (statement on package about product compatibility was accompanied by an asterisk directing consumers to a separate document, but plaintiff selectively omitted portions of the alleged misrepresentation attributable to defendants, leading the court to conclude that the statements were "only partial statements, and do not rise to the level of affirmative misrepresentations.").

Here, Plaintiff claims that he and reasonable consumers were deceived by Defendant's Representation that the Products kill 99.99% of germs. (FAC ¶¶ 114, 123, 130, 131, 133, 140, 147.) Plaintiff alleges that "'germs' is defined by Merriam-Webster as amongst other things, 'especially: a microorganism causing disease.'" (*Id*. at ¶ 31.) Further, he alleges that "the Products do not 'kill' certain germs, which comprise more than 0.01% of "germs" and more than .01% of 'harmful germs.'" (*Id*. at ¶ 33.) Yet, Plaintiff entirely ignores the fact that the Products' primary display panel contains an asterisk right next to the 99.99% germs language. This asterisk directs the consumer to the back panel of the Products where the rear label states "*Effective at eliminating 99.99% of many common harmful germs & bacteria." The disclaimer simply confirms and clarifies the expectation raised on the front panel, rather than contradicts it. *See Dinan*, 2020 WL 364277 at *8 ("Asterisks are common in both commerce and elsewhere to denote that the 'reader' should be aware that there is more than meets the eye."). Plaintiff cannot simply look to the statement on the front panel, ignore the asterisk, and claim he has been misled. *Bobo* 2015 WL 13102417 at *5. This is especially true, where as here, there are no other words, pictures or diagrams adorning the packaging that would make the front label statement deceptive. *See Ebner*, 838 F.3d at 966. ("Apart from the accurate weight label, there are no other words, pictures, or diagrams adorning the packaging …from which any inference could be drawn or on which any reasonable belief could be based about how

much of the total lip product can be accessed by using the screw mechanism."). Put another way, Defendant's use of the word germ is clarified by the disclosure on the back panel, namely that the hand sanitizer is effective at eliminating 99.99% of many *common* harmful germs and bacteria. *See Ebner*, 838 F.3d at 966. (taking into consideration how the reasonable consumer's understanding of how the mechanics of the product works).

Further, the court agrees with Defendant that Plaintiff's reading of the front label is implausible and inconsistent with how a reasonable consumer would understand the Products' function. (*See* Doc. No. 15-1 at 23.) Several pages of the FAC are dedicated to recounting various diseases and illnesses, including polio, HPV, C. difficile, enterococci, hepatitis A, and cryptosporidium, which Plaintiff references to support his conclusion that the Products are ineffective against 0.01% of germs. Including polio in the "common germs" count is puzzling since an active case of polio has not been reported in the United States since 1979. *See* https://www.cdc.gov/polio/what-is-polio/polio-us.html. Similarly, Plaintiff refers to HPV, and baselessly alleges that the virus is "transmitted primarily through skin-to-skin contact, including by contact with someone who is carrying the virus on their hands or fingers or by touching something that someone else touched who carried HPV on their hands." (FAC at ¶ 53.) Plaintiff, without providing a citation continues: "A study published by Science Daily states that individuals with current genital infections of HPV also have high levels of HPV DNA on their fingers." (*Id.*) Ordinarily, a court must read a complaint in the light most favorable to the Plaintiff, but this does not mean a court needs to believe out and out falsehoods. HPV can only be spread by ***intimate*** skin on skin contact, in other words through oral, anal or vaginal sex, to allege otherwise is irresponsible. *See* https://www.cdc.gov/std/hpv/stdfact-hpv.htm. Further, Plaintiff points to C. difficile, a germ that causes life-threatening diarrhea, that is usually a side-effect of taking antibiotics. *See* https://www.cdc.gov/HAI/organisms/cdiff/Cdiff_infect.html. This bacterium generally occurs in patients over 65 years of age and older who have been taking antibiotics for a long period of time or who stay in a healthcare or long-term care facility for a long time. *See id.* Likewise, Plaintiff's reference to enterococci, (FAC ¶¶ 65-66), is

interesting because this bacterium lives in the intestines and genital tract and can travel into a person's blood, urine or could do so during surgery causing infection. https://www.cdc.gov/hai/organisms/vre/vre.html#Spread. The bacteria can spread through hospitals if healthcare workers do not wash their hands properly. *Id*. Additionally, hepatitis A is a virus that is normally found in the blood or stool of individuals and is spread when ingested. *See* https://www.cdc.gov/hepatitis/hav/afaq.htm. The virus can be spread from close, personal contact with an infected person, like oral or anal sex, caring for someone who is ill or using recreational drugs. *See id*. Occasionally, in the United States foodborne outbreaks of hepatitis A have occurred from people eating contaminated fresh and frozen imported food products. *Id*. To help contain the spread of the virus, in the 1990's the hepatitis A vaccine became part of regular childhood immunizations, *see* https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/hepa.pdf. Cryptosporidium can be found in water, food, soil or on surfaces or dirty hands that have been contaminated with the feces of humans or animals infected with the parasite. https://www.cdc.gov/parasites/crypto/general-info.html. It can be spread in a variety of ways, including swallowing recreational water, eating undercooked food, touching your mouth with contaminated hands or exposure to an infected person via sexual contact. *Id*.

Broadly speaking the allegations regarding these diseases are troubling to the court on four fundamental grounds. First, Plaintiff presupposes that the hand sanitizer Products were meant to be used to "disinfect" after exposure to the harmful germs or to people with these diseases instead of washing with soap and water. But the importance of handwashing is well known, even amongst school children. The widely known concept that washing hands is preferable to using hand sanitizer, is best illustrated by the CDC's own website wherein it:

> recommends washing hands with soap and water whenever possible because handwashing reduces the amounts of all types of germs and chemicals on hands. But if soap and water are not available, using a hand sanitizer with at least 60% alcohol can help you avoid getting sick and spreading germs to others.

https://www.cdc.gov/handwashing/show-me-the-science-hand-sanitizer.html. Second, Plaintiff makes passing references to studies which have purportedly found that hand sanitizer may be relatively ineffective against certain diseases and viruses, (*see* FAC ¶¶ 43-45, 48, 52, 54, 56, 66, 67). Further, Plaintiff hypothesizes that the germs causing these diseases are commonly transferred by hand -to -hand touching. While Plaintiff has "opened the door" for the court to consider the citations it has noted above, Plaintiff has omitted full citations to the studies he cites, has failed to attach copies of them to the FAC, and has failed to provide any other means for the court to establish that the unsubstantiated conclusions are valid or even relevant regarding the Products' effectiveness. Plaintiff's passing references and paraphrased conclusions regarding unsubstantiated study conclusions do not constitute facts. Third, Plaintiff's conclusively assumes these diseases/viruses should be included as part of "99.9% of many common harmful germs & bacteria" referenced on the back of all of the Products, notwithstanding that at least two of the referenced diseases require inoculations and thus can hardly be considered "common harmful germs." As Defendant noted "common sense and logic dictate that a hand sanitizer product will eliminate the germs and bacteria commonly found on hands. With few exceptions, the organisms Plaintiff identifies in the FAC either do not occur on human hands or are not common." (Doc. No 15-1 at 23.) Finally, Plaintiff imagines that the Products will be ineffective at killing some of these germs if used properly without providing any facts to support this assertion. Essentially, the allegations surrounding the ineffectiveness of the Products in relation to these diseases are disjointed and conjectural.

In sum, the court finds nothing on the front label to be deceptive and that it is simply not plausible that the reasonable consumer could be misled into thinking that the Products would kill 99.99% of all germs, including polio, HPV, C. difficile, enterococci and hepatitis A. Furthermore, the court is not persuaded that the reasonable consumer, given the public general awareness around the importance of handwashing, would think that hand sanitizer is a substitute for washing with soap and water. *See Ebner*, 838 F.3d at 966. (concluding "that it is not plausible that 'a significant portion of the general consuming public or of

targeted consumers, acting reasonably in the circumstances, could be misled.'") (citation omitted.) *See also Lavie,* 105 Cal.App.4th at 508 ("likely to deceive" means "more than a mere possibility that the advertisement might conceivably be misunderstood by some few consumers viewing it in an unreasonable manner"). Thus, Plaintiff has failed to state a claim that the packaging on Defendant's Products is misleading under the CLRA, FAL, and UCL.

In accordance with the foregoing, Defendant's motion to dismiss the CLRA, FAL and UCL claims, made pursuant to Rule 12(b)(6), is **GRANTED,** with leave to amend. Having dismissed the CLRA, FAL and UCL claims as a matter of law, the court declines to address Defendant's alternate argument for dismissal of these claims.[8]

(ii) Remaining State Law Claims.

Plaintiff's failure to plausibly allege that Defendant made any misrepresentation or misleading nondisclosure undermines his remaining claims.

"To prevail on a breach of express warranty claim, the plaintiff must prove (the seller's statements constitute an 'affirmation of fact or promise' or a 'description of the goods'; (2) the statement was 'part of the basis of the bargain'; and (3) the warranty was breached." *Weinstat v. Dentsply Int'l, Inc.*, 180 Cal. App 4th 1213, 1227 (2010). *See also Viggiano v. Hansen Natural Corp*., 944 F. Supp. 2d 877, 893 (C.D. Cal. 2013) (adding fourth requirement that "the breach caused injury to the plaintiff."). Here, the court has already concluded that Defendant has not stated the hand sanitizers "kills 99% of all germs" as Plaintiff proposes. Rather, the packaging discloses that Defendant is claiming that the

---

[8] Defendant also argues that the FAC fails to support an FAL claim because there is no basis to infer that Defendant had knowledge of a false statement allegedly made to Plaintiff. (Doc. No. 15-1 at 25.) Further, Defendant asserts that the UCL claim must fail because Plaintiff has not identified any conduct by it that offends an established public policy or violates an underlying law. (*Id*.) Finally, Defendant claims that Plaintiff has failed to plead the claims with the heightened pleading requirements of Rule 9(b). (*Id*. at 18-20.)

Products kill more than 99+% of germs[9], (*see* FAC at 7-8), and that they are "effective at eliminating 99.99% of many common harmful germs and bacteria," (*id* at ¶ 29). Plaintiff has alleged no well-pleaded facts suggesting that Defendant has stated, or expressly warranted, that its hand sanitizer kills 99.9% of all germs known to mankind. As a result, there is no statement by Defendant of any "fact or promise" that it has breached that forms the basis of any bargain. Furthermore, Plaintiff's understanding of the bargain is implausible and inconsistent with the understanding of a reasonable consumer. Plaintiff has failed to plausibly allege that Defendant breached any express warranty. *See Forouzesh v. Starbucks Corp*., Case No. CV-16-3830 PA (AGRx), 2016 WL 4443203, at * 4 (C.D. Cal. Aug. 19, 2016) ("Plaintiff's strained interpretation of Defendant's menu descriptions, which is inconsistent with the understanding of a reasonable consumer, does not form the 'basis of the bargain' that could support a breach of express warranty claim in these circumstances."); *see also Solak v Hain Celestial Grp., Inc.*, 3:17-CV-0704 (LEK/DEP), 2018 WL 1870474, at * 11 (N.D.N.Y. Apr. 17, 2018) ("the caselaw makes clear that for a statement or representation to provide the basis for an express warranty claim, it still must meet the threshold requirement of 'being material to a reasonable consumer.'") (quoting *In re ConAgra Foods, Inc.*, 90 F. Supp. 3d 919, 985) (C.D. Cal. 2015)).

With respect to the implied warranty of merchantability, the court is not satisfied that Plaintiff has plausibly alleged that the Products he purchased are unfit for the ordinary purpose of hand sanitizers. *See* CAL. COM. CODE § 2314(2) (the implied warranty may be violated if (1) the product does not "[p]ass without objection in the trade under the contract description," (2) is not "fit for the ordinary purposes for which such good [is] used," or (3) does not "[c]onform to the promises or affirmations of fact made on the container or

---

[9] Specifically, the statements on each of four Products claim to either: (1) "kills more than 99.99% of germs;" (2) "kill 99.99% of germs;" (3) "kills more than 99.99% of germs; " or (4) "kills 99.9% of harmful germs." (*see* FAC at 7-8).

label if any"); *Mocek v Alfa Leisure, Inc*., 114 Cal. App. 4th 402, 204 (2003) ("a breach of the implied warranty of merchantability means the product did not possess even the most basic degree of fitness for ordinary use."). This conclusion is further buttressed by the fact that none of the products listed in the complaint appear on the FDA's website of hand sanitizers consumers should not use. *See* https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-hand-sanitizers-consumers-should-not-use.

Plaintiff has failed to plead a quasi-contract claim because, as explained above, there was no false representation. Plaintiff's quasi-contract claim is asserted under the theory of unjust enrichment and seeks restitution and/or disgorgement. But with no false representation appearing on the Products, and no apparent fraud on the part of Defendant, there can be no unjust enrichment. *See Astiana v. Hain Celestial Grp., Inc.*, 783 F.3d 753, 762 (9th Cir. 2015) (To bring an action based on a quasi-contract, a plaintiff must allege "that a defendant has been unjustly conferred a benefit through mistake, fraud, coercion, or request."). *See also Myers-Taylor v. Ornau Foods N. Am., Inc*., Case No.: 3:18- cv- 01538- H-MDD, 2019 WL 424703**,** * 6 (S.D. Cal. Feb. 4, 2019) (in order to successfully plead a quasi-contract claim based on unjust enrichment, a plaintiff must show some fraud.); *First Nationwide Sav. v. Perry*, 11 Cal. App. 4th 1657, 1670 (1992) ("A quasi-contract action, in the form of a common count for money had and received, to recover money obtained by fraud (waiver of tort) or mistake, is governed by the fraud statute."). Likewise, the absence of a fraudulent and misleading representation means that Plaintiff's claim for restitution is not supported by sufficient facts at this time. *Pulaski & Middleman, LLC v. Google, Inc*., 802 F.3d 979, 989 (9th Cir. 2015) ("[I]n calculating restitution under the UCL and FAL, the focus is on the difference between what was paid and what a reasonable consumer would have paid at the time of purchase without the fraudulent or omitted information."); *Astiana v. Kashi Co.,* 291 F.R.D. 493, 506 (S.D. Cal. 2013) (the various California consumer protection laws provide the court with "very broad discretion to determine an appropriate remedy as long as it is supported by the evidence

and is consistent with the purpose of restoring to the plaintiff the amount that the defendant wrongfully acquired.") (internal citation omitted).

In accordance with the foregoing, the court **GRANTS** Defendant's motion to dismiss the breach of warranty, breach of implied warranty, and quasi-contract claims, with leave to amend.

C. Preemption Issues

Finally, Defendant asserts that Plaintiff is seeking to impose duties on Defendant that are different than those imposed by federal law and moves for dismissal on these grounds, arguing Plaintiff's state law claims are exclusively and impliedly preempted by the Food and Drug Administration. (Doc. No. 15-1 at 25-31.) In opposition, Plaintiff counters that (1) his claims are all based on violations of California's consumer law and are, therefore, not preempted; (2) there is no express preemption in relation to consumer claims based on drug products; and (3) there is no conflict between any federal law and his state law claims. (Doc. No. 16 at 24-32.)

The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, confers on the United States Food and Drug Administration ("FDA") the responsibility for protecting the public health by ensuring drugs and cosmetics are safe, effective and properly labeled. 21 U.S.C. § 393(b)(2)(B)-(D). Before a new drug may enter interstate commerce the FDA must first determine that it is generally recognized as safe and effective (GRAS/E) for the particular use described in its product labeling. *See* 21 U.S.C. § 321 (p)(1) (a "new drug" is defined as one that "is not generally recognized, among experts … as safe and effective for use under the conditions" noted in the drug's labeling); *id*. § 355(a) (prohibiting a "new drug" from entering interstate commerce without FDA approval). And 21 U.S.C. § 352 provides "[a] drug or device shall be deemed to be misbranded…(a) false or misleading label **(**1**)** If its labeling is false or misleading in any particular."

The alcohol-based hand sanitizers at issue here are regulated under the FDA's over-the counter ("OTC") drug review. In 1972, the FDA established a "monograph" system

for regulating OTC drugs. *See* 21 C.F.R. § 330.10; 37 Fed. Reg. 9464 (May 11, 1972). This allows manufacturers to bypass individualized review. *See* 21 C.F.R. § 330.10; *see also*21 U.S.C. § 355. Under this system, the FDA issues a detailed regulation—a "monograph"—for each therapeutic class of OTC drug products. The monograph provides the FDA-approved active ingredients for a given therapeutic class of OTC drugs and sets forth the conditions under which each active ingredient is GRAS/E. *See NRDC, Inc. v. FDA*, 710 F. Supp. 71, 75 (2d Cir. 2013) ("Like a recipe, each monograph sets out the FDA-approved active ingredients for a given therapeutic class of OTC drugs and provides the conditions under which each active ingredient is GRAS/E.") Active ingredients deemed not GRAS/E or about which there is insufficient information are excluded from the FDA's monographs.

The monograph for alcohol-based hand sanitizers is yet to be finalized. The Tentative Final Monograph ("TFM") for Health Care Antiseptic Drug Products dated June 17, 1994 represents the FDA's current thinking on these products. *See* 59 Fed. Reg. 31402, §333.455. On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") deemed currently marketed OTC drugs as GRAS/E if they are classified as Category I. PL 116–136, Subtitle F-Over-the Counter-Drugs, sec. 505-G. The CARES Act did not impact the labeling requirements as outlined in the 1994 TFM.

The court is not persuaded by Defendant's express or implied preemption arguments. Defendant argues that Plaintiff is violating 21 U.S.C. § 337(a) of the FDCA. In part section 337(a) provides: "(a) Except as provided in subsection (b) of this section, all 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).

For a court to conclude that Congress has preempted a state law, its intent to do so, must be "clear and manifest." *Wyeth* v. *Levine*, 555 U.S. 555, 565, (2009). Generally, courts have found that claims based on parallel state laws that mirror the relevant sections of the FDCA are not preempted by the Act. *See, e.g., Khasin v. Hershey Co*., No. 5:12- CV- 0862 EJD, 2012 WL 5471153, at * 4 (N.D. Cal. Nov. 9, 2012). As a result,

consumer fraud claims alleging material misrepresentations have been found to be permissible under the FDCA. *See Wyeth,* 555 U.S. at 574, 577-78 (2009) (the FDCA creates a floor but not a ceiling for warning labels regarding prescription drugs and recognizing that "[i]f Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express preemption provision at some point during the FDCA's 70-year history"); *Summit Tech. v. High-Line Medical Instruments Co*., 922 F. Supp. 299, 307 (C.D. Cal. 1996) ("*Summit I*")("a plaintiff may bring a Lanham Act cause of action for affirmatively mispresenting facts, even if the truth of those facts may be governed by FDA regulations.").

Here Plaintiff is alleging violations of various state consumer protection laws. To the extent that Plaintiff's claims simply require the court to make factual determinations as to whether the statements are false, such claims do not give rise to preemption. *See, e.g., Astiana,* 783 F.3d at 757 ("we have little difficulty concluding that the FDCA does not preempt state laws that allow consumers to sue cosmetics manufacturers that label or package their products in violation of federal standards"); *Morgan v. Wallaby Yogurt Co., Inc.,* Case No. 13-cv-00296–WHO, 2013 WL 5514563, at *4 (N.D. Cal. Oct.4, 2013) (whether a label is misleading is within the ability of the Court and frequently determined by courts)*; In re Epogen & Aransep Off-Label Mktg. & Sales Practices Litig.,* 590 F. Supp. 2d. 1282, 1291 (C.D. Cal. 2008) (state consumer fraud claims based on allegation that statements were false are not barred by FDCA); *Summit I, Summit Tech., Inc. v. High-Line Medical Instruments*, Co, 933 F. Supp. 918, 933 (C.D. Cal. 1996) ("Summit II") (noting that "false statements are actionable under the Lanham Act, even if their truth may be generally within the purview of the FDA."). Plaintiff is alleging Defendant's Products are "misbranded under identical federal and California laws," (FAC at ¶ 17), and is suing because Defendant's conduct allegedly violates California's Sherman Law, the UCL,

CLRA and FAL[10], all of which "could have imposed the exact same regulations even if the FDCA was never passed." *See Gustavson v. Wrigley Sales Co.*, 961 F. Supp. 2d 1100, 1119 (N.D. Cal. 2013).

Aside from section 337(a), the only regulation cited by Defendant is the TFM regulating Health Care Antiseptic Drug Products. However, because the TFM regarding the labeling requirements of hand sanitizers has never been adopted, it only has the legal status of a proposed rule. The opening summary of the TFM clearly states: "the FDA is issuing a notice of proposed rulemaking in the form of an amended tentative final monograph that would establish conditions under which over-the-counter (OTC) topical health-care antiseptic drug products are generally recognized as safe and effective and not misbranded." 59 Fed. Reg. 31402. Further, the TFM contains the following clarifying language: "The legal status of each tentative final monograph, however, is that of a proposed rule." *Id*. at 31403. *See also Won Kyung Hwang v Ohso Clean, Inc*., No. C- 12- 06355 JCS, 2013 WL 1632697, at * 17 (N.D. Cal. Apr. 16, 2013) (declining to find plaintiff's FAL, CLRA, UCL impliedly preempted because the TFM only has the status of a proposed rule.).

Accordingly, at this stage of the proceedings, the court cannot say that Plaintiff's argument is preempted. Therefore, Defendant's motion to dismiss on these grounds is **DENIED**.

IV. CONCLUSION

In accordance with the foregoing, the court **GRANTS** Defendant's motion to dismiss, with leave to amend. (Doc. No. 15.) Plaintiff has up to an including ***March 24,***

///

///

---

[10] In fact, the FAC specifically avers that "Plaintiff does not bring this action pursuant to any FDA regulation, but under the applicable consumer protection laws and common law, which require that Defendant truthfully and accurately label the Products." (FAC at ¶ 19.)

2021, to file an amended complaint.

IT IS SO ORDERED.

Dated: March 3, 2021

Hon. Jeffrey T. Miller
United States District Judge