United States District Court
Northern District of California

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

PRIYA SIDHU, individually and on behalf of all others similarly situated,

Plaintiff,

v.

BAYER HEALTHCARE PHARMACEUTICALS INC.,

Defendant.

Case No. 22-cv-01603-BLF

ORDER GRANTING IN PART AND DENYING IN PART MOTION TO DISMISS FIRST AMENDED CLASS ACTION COMPLAINT

Re: ECF No. 45

Presently before the Court is Defendant Bayer Healthcare Pharmaceuticals, Inc.'s ("Defendant") Motion to Dismiss ("Motion") Plaintiff Priya Sidhu's ("Plaintiff") First Amended Class Action Complaint ("FAC"). *See* Mot., ECF No. 45. Plaintiff's FAC alleges that Defendant markets and sells an intrauterine device ("IUD"), branded as Mirena ("Mirena IUD"), as suitable for birth control, but that Mirena in fact is not suitable for use as birth control because it increases the risk of breast cancer in users by approximately 20 to 30%. *See* FAC ¶ 1, ECF No. 44. Plaintiff brings this lawsuit as a putative class action on behalf of both a nationwide class and a California subclass, and asserts claims on behalf of the nationwide class for (1) breach of the implied warranty of merchantability; (2) unjust enrichment; and (3) fraud; as well as (on behalf of the California subclass only) (4) violation of California's Unfair Competition Law ("UCL"); (5) violation of California's Consumers Legal Remedies Act ("CLRA"); and (6) violation of California's False Advertising Law ("FAL"). Having considered the parties' written and oral arguments, the Court GRANTS IN PART and DENIES IN PART Defendant's Motion for the following reasons.

I. BACKGROUND

A. Factual Background

The Mirena IUD is a levonorgestrel-releasing intrauterine system ("LNG-IUS"). FAC ¶ 2. Upon insertion into a woman's uterus, the Mirena IUD reduces the chance pregnancy and decreases menstrual bleeding by releasing the hormone progestin, which thickens mucus in the cervix to stop sperm from reaching or fertilizing an egg, thins the lining of the uterus, and partially suppresses ovulation. *Id.* Defendant manufactures, markets, distributes, sells, and makes the Mirena IUD available for prescription throughout the United States and the State of California. *Id.* ¶¶ 26, 39.

The Mirena IUD was first approved for use in the United States in 2000. *Id.* ¶ 20. Plaintiff alleges that five studies published between 2010 and 2020 show that users of the Mirena IUD have approximately 20% to 30% excess risk for breast cancer as compared with non-users of hormonal contraceptives. *See* FAC ¶¶ 9–18. She further alleges that Defendant, despite its knowledge of studies indicating such a risk, has not disclosed to doctors or consumers that the Mirena IUD significantly increases the risk of breast cancer, changed the labeling or prescribing information on the Mirena IUD, or presented it to the FDA to change the product's labeling. *Id.* ¶¶ 5, 9, 19.

Defendant's original prescribing language stated that "[w]omen who currently have or have had breast cancer, or have a suspicion of breast cancer, should not use hormonal contraception because some breast cancers are hormone-sensitive." *Id.* ¶ 20. In 2009, Defendant updated the Mirena IUD's prescribing information to provide: "Spontaneous reports of breast cancer have been received during postmarketing experience with Mirena. Because spontaneous reports are voluntary and from a population of uncertain size, it is not possible to use postmarketing data to reliably estimate the frequency or establish causal relationship to drug exposure. Two observational studies have not provided evidence of an increased risk of breast cancer during the use of Mirena." *Id.* ¶ 21. Most recently, in 2015, Defendant submitted an application to the FDA following the publication of two studies related to the breast cancer risk in Mirena IUD users, resulting in the following update to the prescribing information: "Observational studies of the risk of breast cancer with the use of a LNG-releasing IUS do not

provide conclusive evidence of increased risk." *Id.* ¶ 22.

Plaintiff is a resident and citizen of San Jose who was prescribed and used the Mirena IUD in California between February 2019 and February 2022. FAC ¶ 37. The doctor who prescribed the Mirena IUD to Plaintiff was not aware of the statistically significant increased risk of breast cancer of about 20% to 30% caused by the Mirena IUD, and Defendant did not inform the doctor of the risk. *Id.* The materials provided by Defendant and reviewed by Plaintiff's doctor stated that there was no evidence of an increased risk of breast cancer for women like Plaintiff, *i.e.*, women who had never had breast cancer, a suspicion of having breast cancer, or a family history of breast cancer. *Id.* Accordingly, Plaintiff's doctor prescribed the Mirena IUD to Plaintiff and did not convey any warnings. *Id.* Plaintiff alleges that her doctor would not have prescribed or instructed Plaintiff to use the Mirena IUD had Defendant not mispresented that there was no evidence of an increased risk of breast cancer from using Mirena for patients who never had breast cancer, and had Defendant not failed to disclose to the doctor the statistically significant increased risk of developing breast cancer from using the Mirena IUD. *Id.* ¶ 38. Plaintiff further alleges that she paid $50 out-of-pocket for the Mirena IUD, and that she would not have paid for the Mirena IUD had Defendant not failed to disclose the statistically significant increased risk of developing breast cancer from using the Mirena IUD. FAC ¶¶ 37–38.

B. Procedural Background

Plaintiff filed this action on March 14, 2022, alleging the same claims at issue here. *See* Compl., ECF No. 1. Defendant moved to dismiss in May 2022. *See* ECF No. 17. The Court granted in part and denied in part the motion, and permitted Plaintiff leave to amend all dismissed claims, except those seeking injunctive relief. *See* ECF No. 38 ("Prior Order"). Plaintiff filed the FAC on February 10, 2023. Defendant filed the instant Motion in March 2023, and briefing was complete in June 2023. The Court heard oral argument on the Motion on August 3, 2023.

II. REQUEST FOR JUDICIAL NOTICE

Defendant has requested that the Court take judicial notice of excerpts of seven documents in ruling on the Motion. *See* Req. Jud. Notice ("RJN"), ECF No. 45-1; Decl. of Isabelle L. Ord ("Ord Decl.") ¶¶ 2–8, Exhs. A–G, ECF No. 45-2. Plaintiff does not oppose Defendants' request

for judicial notice. *See* Opp'n 2, ECF No. 48.

The two doctrines that permit district courts to consider material outside the pleadings without converting a motion to dismiss into a motion for summary judgment are (1) judicial notice under Federal Rule of Evidence 201 and (2) incorporation by reference. *Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 998 (9th Cir. 2018). Under the judicial notice doctrine, a court may judicially notice a fact that is "not subject to reasonable dispute," *i.e.*, a fact that is "generally known," or "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b)(1)–(2). If a judicially noticeable document contains disputed facts, the court may notice the document, but not the disputed facts therein. *Khoja*, 899 F.3d at 999 ("[A] court cannot take judicial notice of disputed facts contained in [judicially noticeable] public records.") (citation omitted). "[I]ncorporation-by-reference is a judicially created doctrine that treats certain documents as though they are part of the complaint itself." *Id.* at 1002. Under this doctrine, a court may consider a document "if the plaintiff refers extensively to the document or the document forms the basis of the plaintiff's claim." *United States v. Ritchie*, 342 F.3d 903, 908 (9th Cir. 2003). A court generally "may assume an incorporated document's contents are true for purposes of a motion to dismiss under Rule 12(b)(6)," but "it is improper to assume the truth of an incorporated document if such assumptions only serve to dispute facts stated in a well-pleaded complaint." *Khoja*, 899 F.3d at 1003 (internal quotations omitted).

Defendant asserts that Exhibits A through G are both subject to judicial notice and incorporated by reference. RJN 3–4. Exhibits A and B are public FDA documents containing prescribing language and revisions to prescribing language for the Mirena IUD that Plaintiff referenced and quoted in the FAC. *See* RJN 1–2; Ord Decl. ¶¶ 2–3. Exhibits C through G are copies of the five studies cited in the FAC, all of which are publicly available. RJN 2–3; Ord Decl. ¶¶ 4–8. The existence and contents of the FDA documents and public studies is not subject to reasonable dispute and the documents are therefore subject to judicial notice (although the Court does not accept as true any disputed facts within the documents), as well as incorporation by reference, as Plaintiff's claims are based on Defendant's alleged lack of warning, including in

FDA materials, following the publication of the studies. *See Eidmann v. Walgreen Co.*, 522 F. Supp. 3d 634, 642 (N.D. Cal. 2021) ("Documents published on government-run websites are proper for judicial notice given their reliability.") (citation omitted); *Riva v. Pepsico, Inc.*, 82 F. Supp. 3d 1045, 1049 n.1 (N.D. Cal. 2015) ("The Court grants for purposes of the motion to dismiss Pepsi's request for judicial notice over three scientific articles that the [] Plaintiffs specifically relied on in the FAC to provide factual support for the [] Plaintiffs' claims. . . . The Court deems these three articles to be incorporated by reference into the FAC.") (all-caps altered) (citations omitted). Accordingly, the Court GRANTS Defendant's request for judicial notice with respect to Exhibits A through G.

III. LEGAL STANDARDS

A. Article III Standing

"Standing is meant to ensure that the injury a plaintiff suffers defines the scope of the controversy he or she is entitled to litigate." *Melendres v. Arpaio*, 784 F.3d 1254, 1261 (9th Cir. 2015) (emphasis omitted). "[T]he 'irreducible constitutional minimum' of standing consists of three elements." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016) (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992)). "The 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." *Id.* "The plaintiff, as the party invoking federal jurisdiction, bears the burden of establishing these elements." *Id.*

B. Preemption

"Preemption is rooted in the 'fundamental principle of the Constitution . . . that Congress has the power to preempt state law.'" *Ass'n des Éleveurs de Canards & d'Oies du Québec v. Becerra*, 35 F.4th 1107, 1113 (9th Cir. 2022) (quoting *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372 (2000)). Preemption may be express or implied, and implied preemption may be further divided into field preemption and conflict preemption. *Id.* at 1114. Express preemption arises when a federal statute explicitly states Congress's intent to displace state law; field preemption prohibits states from regulating conduct in an area that "Congress . . . has determined must be regulated by its exclusive governance"; and conflict preemption arises when state law

conflicts with a federal statute. *Id.* (citations omitted). One form of conflict preemption, known as impossibility preemption, occurs when "it is impossible for a private party to comply with both state and federal law." *Id.* (quoting *Crosby*, 530 U.S. at 372). Impossibility preemption is a "demanding defense," and the party asserting preemption bears the burden for demonstrating impossibility. *Wyeth v. Levine*, 555 U.S. 555, 573 (2000).

Courts have devised a two-step analysis for evaluating impossibility preemption in the drug-manufacturing context following the Supreme Court's decisions in *Wyeth*, 555 U.S. 555; *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011); and *Mutual Pharmaceutical Co., Inc. v. Bartlett*, 570 U.S. 472 (2013). "First, courts must determine whether a drug manufacturer may independently take action that complies with both state and federal law." *Holley v. Gilead Scis., Inc.*, 379 F. Supp. 3d 809, 821 (N.D. Cal. 2019) (citing *Wyeth*, 555 U.S. at 571); *see also, e.g.*, *Gaetano v. Gilead Scis., Inc.*, 529 F. Supp. 3d 333, 342 (D.N.J. 2021) (substantially same); *Lauderdale v. Organon USA, Inc.*, No. 5:21-CV-5200, 2022 WL 3702113, at *7 (W.D. Ark. Aug. 26, 2022) (same). "An action is independent under this analysis if the manufacturer can take such action without prior FDA approval, even if the FDA may subsequently reject approval of the action post hoc." *Holley*, 379 F. Supp. 3d at 821. "If independent action is not possible, then the state-law claims are preempted. If independent action is possible, then the claims are preempted only if there is clear evidence that the FDA would not grant approval." *Id.*

C. Failure to State a Claim

Under Federal Rule of Civil Procedure 12(b)(6), a court must dismiss a complaint if it fails to state a claim upon which relief can be granted. To survive a Rule 12(b)(6) motion, the plaintiff must 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). A claim is facially plausible when the plaintiff pleads facts that allow the court to "draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation omitted). There must be "more than a sheer possibility that a defendant has acted unlawfully." *Id.* Courts generally do not require "heightened fact pleading of specifics," but a plaintiff must allege facts sufficient to "raise a right to relief above the speculative level." *See Twombly*, 550 U.S. at 555, 570.

A party alleging a fraud-based claim, however, "must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). "Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." *Id.* Rule 9(b) requires that the circumstances constituting any alleged fraud be pled "specific[ally] enough to give defendants notice of the particular misconduct . . . so that they can defend against the charge and not just deny that they have done anything wrong." *Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1124 (9th Cir. 2009) (quoting *Bly-Magree v. California*, 236 F.3d 1014, 1019 (9th Cir. 2001)). Claims of fraud must be accompanied by the "who, what, when, where, and how" of the misconduct alleged. *Id.* If a "claim is said to be 'grounded in fraud' or to 'sound to fraud,' [then] the pleading of that claim as a whole must satisfy that particularity requirement of Rule 9(b)." *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1103-04 (9th Cir. 2003).

When determining whether a claim has been stated, the Court accepts as true all well-pled factual allegations and construes them in the light most favorable to the plaintiff. *Reese v. BP Expl. (Alaska) Inc.*, 643 F.3d 681, 690 (9th Cir. 2011). However, the Court need not "accept as true allegations that contradict matters properly subject to judicial notice" or "allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences." *In re Gilead Scis. Sec. Litig.*, 536 F.3d 1049, 1055 (9th Cir. 2008) (internal quotation marks and citations omitted). On a motion to dismiss, the Court's review is limited to the face of the complaint and matters judicially noticeable. *MGIC Indem. Corp. v. Weisman*, 803 F.2d 500, 504 (9th Cir. 1986); *N. Star Int'l v. Ariz. Corp. Comm'n*, 720 F.2d 578, 581 (9th Cir. 1983).

D. Motion to Strike

A court may "strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." Fed. R. Civ. P. 12(f). Striking is intended "to avoid the expenditure of time and money that must arise from litigating spurious issues by dispensing with those issues prior to trial." *Whittlestone, Inc. v. Handi-Craft Co.*, 618 F.3d 970, 973 (9th Cir. 2010) (quoting *Fantasy, Inc. v. Fogerty*, 984 F.2d 1524, 1527 (9th Cir. 1993), *rev'd on other grounds by Fogerty v. Fantasy, Inc.*, 510 U.S. 517 (1994)) (internal quotation marks omitted). "While a Rule 12(f) motion provides the means to excise improper materials from pleadings, such

motions are generally disfavored because the motions may be used as delaying tactics and because of the strong policy favoring resolution on the merits." *Barnes v. AT & T Pension Ben. Plan-Nonbargained Program*, 718 F. Supp. 2d 1167, 1170 (N.D. Cal. 2010).

IV. DISCUSSION

Defendant argues at the outset that the five studies forming the foundation for Plaintiff's allegations that the Mirena IUD increases the risk of breast cancer by 20% to 30% do not, in fact, find an increased risk for women who, like Plaintiff, are pre-menopausal and who use LNG-IUS for birth control, so that all of Plaintiff's claims must be dismissed. *See* Mot. 5–7. Plaintiff responds that the pleading stage is not the proper setting in which to litigate the facts and weight of scientific studies, and that the studies in any event support Plaintiff's claims regarding the risk of the Mirena IUD. *See* Opp'n 2–3. The Court acknowledges that the Ninth Circuit has implicitly permitted the review of scientific studies underpinning a plaintiff's allegations, even at the motion to dismiss stage. *See McGee v. S-L Snacks Nat'l*, 982 F.3d 700, 708–09 (9th Cir. 2020) (affirming dismissal for lack of standing following review of studies cited in complaint). However, as the Court indicated at oral argument, it finds that evaluating Defendant's argument with respect to the studies at issue here is more appropriately suited to a later stage of litigation at which the parties and the Court have the benefit of expert opinions. Accordingly, for the purposes of this motion, the Court accepts as true Plaintiff's allegations regarding the studies at issue.

Defendant also argues that Plaintiff lacks Article III standing; the learned intermediary doctrine narrows Plaintiff's claims; federal law preempts Plaintiff's claims; Plaintiff does not sufficiently plead any claim; Plaintiff's equitable claims must be dismissed because there is an adequate legal remedy; Plaintiff's allegations do not entitle her to punitive damages; and, lastly, Plaintiff's class allegations should be stricken. *See* Mot. 7–21. The Court addresses Defendant's standing arguments first, followed by those regarding preemption, the Court's equitable jurisdiction, Plaintiff's failure to state a claim, as affected by the learned intermediary doctrine, the request for punitive damages, and the motion to strike the class allegations.

A. Article III Standing (All Claims)

A plaintiff has Article III standing if she has "(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. Robins*, 578 U.S. 330, 338 (2016) (citations omitted). The latter two requirements are commonly referred to as, respectively, causation and redressability. *See, e.g.*, *Daniel v. Nat'l Park Serv.*, 891 F.3d 762, 767 (9th Cir. 2018). Defendant argues that Plaintiff lacks Article III standing because she (a) fails to allege a sufficient injury-in-fact and (b) has not alleged causation or redressability. Mot. 7–10. Defendant additionally asserts that Plaintiff lacks standing to assert claims on behalf of a nationwide class. The Court addresses these three arguments in turn.

1. Injury-in-Fact

Defendant contends that Plaintiff has not sufficiently alleged an injury-in-fact for Article III standing "because the studies she relies upon do not support her allegation of a 20 to 30% increased risk and she does not allege that she has breast cancer." Mot. 7. That is, Defendant argues that Plaintiff has not alleged a physical injury, and that Plaintiff's allegation of economic injury—*i.e.*, that she would not have paid for the Mirena IUD had she been aware of an elevated risk of breast cancer—should not be credited because it is "based on the implausible allegation that 'the statistically significant increased risk of breast cancer caused by Mirena renders it unsafe and unsuitable for its intended purpose.'" *Id.* at 8–9. Defendant generally seeks to cast Plaintiff's complaint as "the sort of 'no-injury products-liability claims' disguised as 'consumer fraud claims' that courts in this Circuit view with skepticism." *Id.* at 8. Plaintiff counters that neither proof of physical injury nor materialization of the risk of physical injury is necessary to assert a sufficient injury-in-fact, that her cited studies support her allegations of an increased breast cancer risk, and that her allegations that such risk meant that the Mirena IUD did not work as intended and was worth less than her purchase price are sufficient to show injury-in-fact. *See* Opp'n 4–7.

"There is no difficulty . . . regarding Article III injury in fact . . . when, as here, 'Plaintiffs contend that class members paid more for a product than they otherwise would have paid, or bought it when they otherwise would not have done so.'" *Hinojos v. Kohl's Corp.*, 718 F.3d 1098, 1104 n.3 (9th Cir. 2013) (quoting *Mazza v. Am. Honda Motor Co.*, 666 F.3d 581, 595 (9th Cir. 2012), overruled on other grounds by *Olean Wholesale Grocery Cooperative, Inc. v. Bumble Bee*

Foods LLC, 31 F.4th 651, 682 n.32 (9th Cir. 2022)); *see also McGee*, 982 F.3d at 706 ("We have consistently recognized that a plaintiff can satisfy the injury in fact requirement by showing that she paid more for a product than she otherwise would have due to a defendant's false representations about the product."). Plaintiff has alleged that she "would not have paid for the Mirena IUD had Defendant not failed to disclose the statistically significant increased risk of developing breast cancer from using the Mirena IUD." FAC ¶ 37. Although Defendant decries this allegation as "implausible" because the cited studies do not support it, the Court—as noted above—will not here evaluate the scientific studies at issue, and accepts as true for this motion the allegations that users of the Mirena IUD have a statistically significant increased risk of breast cancer by about 20% to 30%. *See, e.g.*, FAC ¶ 1. Further, Defendant's reliance on *McGee* for its argument that Plaintiff is "asserting a no-injury product liability claim," Mot. 8, is misplaced. The plaintiff in *McGee* did not "allege[] that she paid more for a product due to [the defendant's] deceptive conduct [or] that [the defendant] made false representations—or actionable non-disclosures," so that "a key element of our overpayment cases—a defendant's misrepresentations about a product—[was] absent." *McGee*, 982 F.3d at 707. Plaintiff has amply alleged Defendant's non-disclosures and misrepresentations. *See, e.g.*, FAC ¶ 31.

Accordingly, the Court will deny Defendant's motion to dismiss on the ground that Plaintiff has not adequately alleged an injury-in-fact.

2. Causation and Redressability

Defendant next argues that Plaintiff has failed to allege causation or redressability because she does not allege her membership in "certain groups that have specific health risk profiles" that were the focus of the studies on which Plaintiff relies. *See* Mot. 9–10 (relying on *Rivera v. Wyeth-Ayerst Laboratories*, 283 F.3d 315 (5th Cir. 2002)). Specifically, Defendant contends that the studies on which Plaintiff relies "support the conclusion that post-menopausal women, or women who use LNG-IUS to treat certain conditions (rather than for contraception) or for more than 5 years may face marginally elevated risks of breast cancer with LNG-IUS use," *id.* at 9, and that Plaintiff "directs her complaint at pre-menopausal women who use Mirena for birth control, not post-menopausal women or women who use Mirena for other purposes," *id.* at 10. Again, the

Court rejects this argument because it will not at this stage evaluate the contents of the studies. Plaintiff's allegations that the Mirena IUD causes a statistically significant increased risk of breast cancer in women who use it for birth control suffice to show causation and redressability, that Defendant failed to disclose or misrepresented the risk, and that she would not have bought the Mirena IUD had she known the risk, are sufficient to allege causation and redressability. *See Davis v. U.S. Dep't of Housing & Urban Dev.*, 627 F.2d 942, 944 (9th Cir. 1980) ("Causation sufficient to confer standing may result from a defendant's acts or omissions."); *Covington v. Jefferson County*, 358 F.3d 626, 639 (9th Cir. 2004) (finding causation and redressability satisfied where "any violation . . . is directly caused by the [defendant], and any violation can be redressed by requiring the [defendant's] compliance with [applicable law] or by creating a credible deterrent against future violations").

For these reasons, the Court will deny Defendant's motion to dismiss for failure to allege causation and redressability.

3. Nationwide Class

Defendant argues that Plaintiff lacks standing to assert claims for a nationwide class Plaintiff is a California resident—who does not allege that she purchased the Mirena IUD outside of California—and brings her claims under California law. *See* Mot. 10. Plaintiff responds that her ability to represent class members in other states is a question of class certification, rather than standing, under *Melendres v. Arpaio*, 784 F.3d 1254 (9th Cir. 2015), so that Defendant's argument is premature at the pleading stage. *See* Opp'n 8–10.

Plaintiff's common law claims—*i.e.*, her claims for breach of the implied warranty of merchantability, unjust enrichment, and fraud—are brought under the laws of California on behalf of the nationwide class, while her statutory claims are brought on behalf of the California subclass. *See* FAC ¶¶ 54–55, 65–66, 71–72, 80, 93, 113. Accordingly, the question at hand is whether Plaintiff may assert common law claims under California law on behalf of putative class members outside of California.

The cases cited by Defendant are inapposite because they address whether a plaintiff may assert claims under the laws of states outside of the state in which the plaintiff was injured. *See*

Jones v. Micron Tech., 400 F. Supp. 3d 897, 909 (N.D. Cal. 2019) ("Plaintiffs do not have standing to bring claims under the laws of states where they have alleged no injury, residence, or other pertinent connection."); *Corcoran v. CVS Health Corp., Inc.*, No. 15-cv-3504, 2016 WL 4080124, at *2 (N.D. Cal. July 29, 2016) (dismissing claims where "no plaintiff resides in, or alleges to have suffered an injury in, any of the thirty-eight states at issue in defendant's motion"); *Pardini v. Unilever U.S., Inc.*, 961 F. Supp. 2d 1048, 1061 (N.D. Cal. 2013) ("Here, there is only one named plaintiff and she has not alleged that she purchased [the product] outside of California. Thus, Plaintiff does not have standing to assert a claim under the consumer protection laws of the other states named in the Complaint."). Although Defendant's arguments must therefore be rejected, the Court continues the analysis because "[t]he federal courts are under an independent obligation to examine their own jurisdiction, and standing 'is perhaps the most important of [the jurisdictional] doctrines.'" *United States v. Hays*, 515 U.S. 737, 742 (1995) (citation omitted) (alteration in original).

In *Melendres v. Arpaio*, the Ninth Circuit evaluated the defendants' request on appeal to decertify a class because plaintiffs who alleged violations of the Fourth and Fourteenth amendments based on a type of police activity called "saturation patrols" lacked standing to assert the same constitutional claims on behalf of unnamed class members who were not subjected to a saturation patrol effort. 784 F.3d at 1261. The defendants additionally argued that the only named plaintiffs who were stopped outside of a saturation patrol could not establish a Fourth or Fourteenth Amendment violation, so that they too lacked standing to represent the constitutional claims of unnamed class members who were stopped outside of a saturation patrol. *Id.* The Ninth Circuit determined that the defendants' argument "conflate[d] standing and class certification," explaining that standing "is meant to ensure that the injury a plaintiff suffers defines the scope of the controversy he or she is entitled to litigate," while class certification "is meant to ensure that named plaintiffs are adequate representatives of the unnamed class." *Id.* The Ninth Circuit then clarified that it "adopt[ed] the class certification approach" to evaluating dissimilarities between the claims of named and unnamed plaintiffs, meaning that "once the named plaintiff demonstrates her individual standing to bring a claim, the standing inquiry is concluded, and the court proceeds

to consider whether the Rule 23(a) prerequisites for class certification have been met." *Id.* at 1261–62. The court held that all plaintiffs had individual standing to bring their own constitutional claims, and then considered the class certification question of whether the named plaintiffs were adequate class representatives. *Id.* at 1262–63.

Under *Melendres*, because the Court has found Plaintiff has individual standing to bring all of her claims under California law, *see supra*, at Parts IV(A)(1)–(2), the "standing inquiry is concluded." 784 F.3d at 1262. The next step of the analysis is to evaluate plaintiff's adequacy as a class representative, which is a class certification question not suitable for determination at the pleading stage. *See id.*; *see also, e.g., Robinson v. Unilever U.S., Inc.*, No. CV 17-3010, 2018 WL 6136139, at *4 (C.D. Cal. June 25, 2018) (rejecting defendants' argument that named plaintiff lacked standing to assert California law claims on behalf of absent class members outside of California as a question for class certification under *Melendres*).

The Court will therefore deny Defendant's motion to dismiss for lack of standing to assert claims for a nationwide class.

B. Federal Preemption (All Claims)

Defendant argues that it could not have changed the labels or warnings related the Mirena IUD under the federal Food, Drug, and Cosmetic Act of 1938 ("FDCA"). *See* Mot. 11–13 (citations omitted). This argument is essentially one of impossibility preemption, *i.e.*, that Defendant cannot "comply with both the state-law duties underlying [failure-to-warn] claims and its federal labeling duties." *Wyeth*, 555 U.S. at 568. In evaluating impossibility preemption, the Court determines whether Defendant was capable of independently acting to change the labels, and if so, whether there is clear evidence that the FDA would not grant approval. *See Holley*, 379 F. Supp. 3d at 821.

1. Ability to Act Independently

As noted in the Court's order on the previous motion to dismiss, *see* Prior Order 8, the Supreme Court has explained the relevant FDCA provisions as follows:

> The FDA's premarket approval of a new drug application includes the approval of the exact text in the proposed label. *See* 21 U.S.C. § 355; 21 CFR § 314.105(b) (2008). Generally speaking, a manufacturer

> may only change a drug label after the FDA approves a supplemental application. There is, however, an FDA regulation that permits a manufacturer to make certain changes to its label before receiving the agency's approval. Among other things, this "changes being effected" (CBE) regulation provides that if a manufacturer is changing a label to "add or strengthen a contraindication, warning, precaution, or adverse reaction" or to "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product," it may make the labeling change upon filing its supplemental application with the FDA; it need not wait for FDA approval. §§ 314.70(c)(6)(iii)(A), (C).

Wyeth, 555 U.S. at 568. "[A] 2008 amendment [to the CBE regulation] provides that a manufacturer may only change its label 'to reflect newly acquired information.'" *Id.* (quoting 73 Fed. Reg. 49,609). "Newly acquired information" is defined as

> data, analyses, or other information not previously submitted to the Agency, which may include (but is not limited to) data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data (e.g., meta-analyses) if the studies, events, or analyses reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA.

21 C.F.R. § 314.3(b). Further, to change a label without FDA approval, the new information must provide "reasonable evidence of a causal association" between the product and the risk, although "a causal relationship need not have been definitively established." 21 C.F.R. § 201.57(c)(6)(i).

Defendant contends that it could not have changed the Mirena IUD labels because (1) the studies cited by Plaintiff do not plausibly constitute newly acquired information, and (2) Plaintiff fails to plausibly plead evidence of any causal association between use of the Mirena IUD and breast cancer, let alone the alleged 20% to 30% increase in risk. *See* Mot. 11. Plaintiff counters that the studies, published between 2010 and 2020, constitute newly acquired information that Defendant did not provide to the FDA in its submissions in 2000, 2009, and 2015, and that each cited study determined a causal association of an increased risk of breast cancer from use of the Mirena IUD. *See* Opp'n 11–16.

The FAC alleges that Defendant last submitted documentation to the FDA in December 2015 informing the FDA of "two new studies addressing the risk of breast cancer in Mirena users," and that the resulting FDA-approved language stated: "Observational studies of the risk of breast cancer with the use of a LNG-releasing IUS do not provide conclusive evidence of increased risk." FAC ¶ 22; *see id.* ¶ 24. The FAC further alleges that three studies published in

2016, 2017, and 2020, including one meta-analysis, found a statistically significant, 20% to 30% increased risk of breast cancer in Mirena IUD users. *See, e.g.*, *id.* ¶¶ 24, 29. Drawing all inferences in Plaintiff's favor, as is required in deciding a motion to dismiss, the Court concludes that these allegations together show that at least the three post-2015 studies contain data and analyses not previously submitted to the FDA that reveal more severe breast cancer risks from the Mirena IUD than previously included in submissions to the FDA, and thereby constitute newly acquired information. *See* 21 C.F.R. § 314.3(b); *see also, e.g.*, *Wyeth*, 555 U.S. at 570 ("In later years, as amputations continued to occur, Wyeth could have analyzed the accumulating data and added a stronger warning about IV-push administration of the drug."). Further, the allegations indicate that this newly acquired information constituted "reasonable evidence of a causal association" between the Mirena IUD and the harm of an increased risk of breast cancer. Defendant's arguments to the contrary all rest on parsing the contents of the scientific studies at issue, *see* Mot. 12–13, and the Court declines to do so at this stage.

The Court accordingly concludes that Plaintiff has adequately pled that Defendant had an ability to act independently from the FDA to add warning language about the Mirena IUD.

2. Clear Evidence the FDA Would Not Grant Approval

Because the Court finds that Plaintiff has sufficiently pled that independent action was possible, Plaintiff's claims are preempted only if there is "clear evidence" that the FDA would not have granted approval to change the warning language for the Mirena IUD. *See Wyeth*, 555 U.S. at 571 ("[A]bsent clear evidence that the FDA would not have approved a change to Phenergan's label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements"); *Holley*, 379 F. Supp. 3d at 821 (same). Defendant has not submitted any argument regarding this facet of the analysis, nor is there any other material before the Court, let alone clear evidence, that would suggest that the FDA would not have granted approval to change the warning language. The Court will therefore deny Defendant's motion to dismiss Plaintiff's claims as preempted by the FDCA. *See Wyeth*, 555 U.S. at 573 (rejecting manufacturer's preemption argument because it did not carry burden of showing impossibility).

C. Equitable Jurisdiction (Claims 2, 4, 5 (in part), 6)

For a district court to have equitable jurisdiction, and thus entertain a request for equitable relief, the plaintiff must have no adequate legal remedy. *Sonner v. Premier Nutrition Corp.*, 971 F.3d 834, 844 (9th Cir. 2020). Plaintiff asserts a claim for unjust enrichment (Claim 2), and additionally pleads her statutory claims (Claims 4–6) for equitable relief in the alternative. *See* FAC ¶¶ 64–69, 89–90, 108–09, 119–20. Defendant argues that the Court should dismiss the equitable claims because Plaintiff has not demonstrated the inadequacy of a legal remedy. *See* Mot. 18–20. The Court notes at the outset that a CLRA claim does not sound purely in equity, so that Defendant's arguments to dismiss Plaintiff's equitable claims do not affect Plaintiff's ability to pursue legal remedies under the CLRA. *See* Cal. Civ. Code § 1780(a)(1) (permitting recovery of actual damages). Plaintiff argues that she may maintain her equitable claims at the pleading stage. Opp'n 22–24.

It is true that Plaintiff may plead her claims for equitable relief in the alternative, but only if she pleads an inadequate remedy at law. *See, e.g.*, *Freeman v. Indochino Apparel, Inc.*, 443 F. Supp. 3d 1107, 1114 (N.D. Cal. 2020); *Guthrie v. Tranamerica Life Ins. Co.*, 561 F. Supp. 3d 869, 875 (N.D. Cal. 2021). Plaintiff no longer requests injunctive relief, *see generally* FAC, and her only allegation regarding the inadequacy of a legal remedy is that legal remedies are not "equally prompt and certain and in other ways efficient" as equitable relief, *see, e.g.*, *id.* ¶ 90 (citing *American Life Ins. Co. v. Stewart*, 300 U.S. 203, 214 (1937); *United States v. Bluitt*, 815 F. Supp. 1314, 1317 (N.D. Cal. Oct. 6, 1992); *Quist v. Empire Water Co.*, 2014 Cal. 646, 643 (1928)). The Court agrees with other courts in this district that have found nearly identical allegations insufficient to invoke the equitable jurisdiction of the Court. *See, e.g.*, *Sharma v. Volkswagen AG*, 524 F. Supp. 3d 891, 908 (N.D. Cal. 2021). Further, Plaintiff's alleged injury is overpayment for a product she would not have bought but for Defendant's alleged misrepresentations and omissions. *See, e.g.*, FAC ¶ 37. "Post-*Sonner* courts have indicated that this is exactly the type of injury for which legal remedies are appropriate." *Sharma*, 524 F. Supp. 3d at 908.

Accordingly, the Court finds that Plaintiff has failed to state a claim for equitable relief, and will grant Defendant's motion to dismiss the unjust enrichment, UCL, and FAL claims, as

well as the CLRA claim to the extent Plaintiff seeks equitable relief. Because the Court dismisses these claims for lack of equitable jurisdiction, it need not and does not address Defendant's other arguments regarding the claims. *See, e.g.*, Mot. 17–18.

D. Failure to State a Claim (Claims 1, 3, 5)

Defendant argues that Plaintiff's remaining claims—namely, breach of the implied warranty of merchantability, fraud, and violation of the CLRA (to the extent Plaintiff seeks legal remedies)—are all insufficiently pled as a matter of law. *See* Mot. 14–20. Defendant additionally argues that the learned intermediary doctrine narrows all of Plaintiff's claims. *See* Mot. 10–11. The Court first addresses the question of narrowing under the learned intermediary doctrine and then turns to the categories of claims that Defendant asserts are insufficiently alleged.

1. Learned Intermediary Doctrine

Defendant argues that all of Plaintiff's claims must be dismissed under the learned intermediary doctrine to the extent they are premised on Defendant's alleged duty—and alleged breach thereof—to warn patients directly. *See* Mot. 11. The learned intermediary doctrine applies "when drugs or medical devices are supplied in the context of the physician-patient relationship," and provides that "manufacturers have a duty to warn physicians of risks that are known or scientifically knowable at the time of the drug's distribution." *Himes v. Somatics, LLC*, No. 21-55517, 2022 WL 989469, at *1 (9th Cir. Apr. 1, 2022) (citations omitted). A manufacturer's duty to warn therefore "runs *to the physician*, not to the patient." *Id.* (quoting *Carlin v. Super. Ct.*, 13 Cal. 4th 1104, 1116 (1996)). Plaintiff argues that the learned intermediary doctrine is inapplicable because the FAC alleges that Defendant failed to warn Plaintiff's doctor, or any doctor, of the alleged increased risk of breast cancer from the use of the Mirena IUD. *See* Opp'n 11.

The parties—and the Court—are in agreement that the learned intermediary doctrine is not a defense to Plaintiff's claims to the extent they are premised on Defendant's duty to warn physicians of the risks of the Mirena IUD. *See* Mot. 11; Opp'n 11; *Himes*, 2022 WL 989469, at *1. However, as Plaintiff concedes, the FAC also alleges that Defendant failed to warn Plaintiff of the alleged increased risk of breast cancer to users of the Mirena IUD. *See* Opp'n 11; *see also, e.g.*, FAC ¶ 8 ("Defendant provided no other warnings to Plaintiff, Class Members, or their

doctors that Mirena use would lead to a statistically significant increased risk of breast cancer."). Plaintiff makes no argument as to why the learned intermediary doctrine does not apply to her claims to the extent they are premised on Defendant's failure to warn Plaintiff and other patients of any risks. *See* Opp'n 11. The Court concludes that the learned intermediary doctrine applies to and bars all of Plaintiff's claims to the extent they are premised on Defendant's alleged duty to warn patients, and will grant Defendant's motion to dismiss on that ground.

2. Fraud-Based Claims (Claims 3, 5)

Plaintiff's claims for common law fraud (Claim 3) and violation of the CLRA (Claim 5), both allege that Defendant misrepresented and failed to disclose[1] the breast cancer risk caused by the Mirena IUD. *See* FAC ¶¶ 73–74, 83–84, 100–104, 115–118. "'The elements of [common law] fraud . . . are (a) misrepresentation (false representation, concealment, or nondisclosure); (b) knowledge of falsity (or "scienter"); (c) intent to defraud, i.e., to induce reliance; (d) justifiable reliance; and (e) resulting damage.'" *Small v. Fritz Cos., Inc.*, 30 Cal. 4th 167, 173 (2003) (citation omitted). The CLRA prohibits "unfair methods of competition and 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 consumer." Cal. Civ. Code §§ 1750, *et seq.* A fraudulent misrepresentation or omission violates the CLRA. *See In re Seagate Tech. LLC Litig.*, 233 F. Supp. 3d 776, 788 (N.D. Cal. 2017).

Defendant argues that Plaintiff's fraud-based claims must be dismissed because Plaintiff does not plead an actionable misrepresentation or an actionable omission. *See* Mot. 14–17. Plaintiff counters that the FAC alleges that Defendant's current language for the Mirena IUD misrepresents that studies since 2015 have found an increased risk of breast cancer, as well as several actionable omissions. *See* Opp'n 16–21. The Court addresses each theory in turn, reviewing Plaintiff's allegations under the heightened pleading standard requiring particularity for fraud-based claims. *See* Fed. R. Civ. P. 9(b).

[1] Plaintiff's original complaint pleaded these claims based only on an alleged failure to disclose. *See* Compl. ¶¶ 46–53, 58–99.

a. Actionable Misrepresentation

"[T]o be actionable as an affirmative misrepresentation, a statement must make a specific and measurable claim, capable of being proved false or of being reasonably interpreted as a statement of objective fact." *Kay v. Copper Cane, LLC*, 549 F. Supp. 3d 1014, 1024 (N.D. Cal. 2021) (citation omitted). Defendant argues that Plaintiff has not plausibly pled an actionable misrepresentation because the alleged misrepresentation is at most an omission, and because the information about the Mirena IUD was accurate. Mot. 14. The label at issue states that "[s]pontaneous reports of breast cancer have been received," and that "[o]bservational studies of the risk of breast cancer with use of a LNG-releasing IUS do not provide conclusive evidence of increased risk." *Id.*; *see also* RJN Exh. A, at 14. Plaintiff contends that these statements on Defendant's label, along with the claim that there is no "conclusive evidence of increased risk of breast cancer" from use of the Mirena IUD, "misrepresent[] that studies since 2015 (the last time Bayer updated the prescribing information) have consistently (and conclusively) found there is an increased risk of breast cancer caused by Mirena." Opp'n 16; *see also* RJN Exh. A, at 14.

Once again, Defendant's argument rests on the contents of the studies cited by Plaintiff, *i.e.*, whether the cited studies belie the informational language that there is no "conclusive" evidence of an increased risk of breast cancer from using the Mirena IUD. *See* Mot. 14 ("The Mirena label does not contain any misrepresentations because the statements on the label remain true given the scientific uncertainty acknowledged in the studies."); Aug. 3, 2023 Hr'g Tr. 10:6–10 ("[I]t's our position that those studies that Plaintiff cites are entirely consistent with the label because the studies themselves are not conclusive, and that would certainly jettison an affirmative misrepresentation claim."), ECF No. 58. Because the Court has found a review of the studies to be inappropriate at this procedural juncture, it rejects Defendant's argument that Plaintiff has not pleaded an affirmative misrepresentation. Plaintiff has alleged that the language on the Mirena IUD that "[o]bservational studies of the risk of breast cancer with use of a LNG-releasing IUS do not provide conclusive evidence of increased risk" of breast cancer is false and misleading in light of specific studies finding an increased risk of breast cancer caused by the Mirena IUD, *see* FAC ¶¶ 22, 29, 82; that a reasonable doctor would have been deceived by Defendant's label, *id.* ¶ 84;

that Plaintiff's doctor reviewed the prescribing information, product pamphlet, and other materials provided by Defendant containing the misleading statements when Plaintiff was prescribed the Mirena IUD in February 2019, *see id.* ¶ 37; and that Plaintiff's doctor accordingly did not convey any warning to Plaintiff about the increased risk when prescribing the Mirena IUD, *see id.* The Court finds these allegations sufficient to state an actionable misrepresentation. *See, e.g.*, *Balser v. Hain Celestial Grp., Inc.*, 640 F. App'x 694, 696 (9th Cir. 2016) ("[T]he statements that the products were 'natural' and '100% vegetarian' could be taken as a claim that no synthetic chemicals were in the products, a claim the complaint alleges, in detail, is false.").

b. Actionable Omission

To state a fraud claim based on an alleged omission, a plaintiff must establish: (1) the concealment or suppression of material fact; (2) intentional concealment with intent to defraud; (3) a duty to disclose the fact to the plaintiff; (4) justifiable reliance; and (5) resulting damages. *See, e.g.*, *Edwards v. FCA US LLC*, No. 22-cv-01871-WHO, 2022 WL 1814144, at *3 (N.D. Cal. June 2, 2022) (quoting *Lewis v. Google LLC*, 851 F. Asp's 723, 725 (9th Cir. 2021)). Defendant argues that Plaintiff has not adequately alleged the first three elements, *i.e.*, concealment, intent to defraud, and duty to disclose. *See* Mot. 14–17. The Court addresses each challenged element.

i. Concealment of a Material Fact

Defendant argues that the FAC does not contain particularized allegations of affirmative acts taken by Defendant to conceal a material fact, once more relying upon its characterization of the contents of the studies cited by Plaintiff. *See* Mot. 15 ("As discussed, Plaintiff does not plausibly allege that Bayer concealed any material fact regarding an alleged 20 to 30% increased risk of breast cancer associated with Mirena use because the studies she cites do not demonstrate such a risk for pre-menopausal women using Mirena for birth control, like her."). Because the Court does not here review the cited studies, it rejects Defendant's argument. *See Concorde Equity II, LLC v. Miller*, 732 F. Supp. 2d 990, 996 (N.D. Cal. 2010) ("Whether there is evidence to support these allegations is another matter, but the allegations are sufficient to survive a motion to dismiss.").

ii. Intent to Defraud

Defendant argues that Plaintiff fails to plead non-conclusory facts showing any intent to defraud. *See* Mot. 15. The heightened pleading standard for fraud claims does not apply to state-of-mind allegations. *See In re Seagate Tech.*, 233 F. Supp. 3d at 781 (citing Fed. R. Civ. P. 9(b)). The Court previously found that Plaintiff's allegations that Defendant failed to disclose an increased risk of breast cancer from use of the Mirena IUD, despite knowing of the identified scientific studies, sufficed to plead Defendant's intent to defraud. *See* Prior Order 13. These allegations remain in the FAC, *see, e.g.*, FAC ¶ 74, refuting Defendant's argument that Plaintiff has pleaded nothing more than a formulaic recitation of the elements, *see* Mot. 15. The Court once again finds that Plaintiff has sufficiently pleaded intent to defraud.

iii. Duty to Disclose

A duty to disclose exists "(1) when the defendant is in a fiduciary relationship with the plaintiff; (2) when the defendant had exclusive knowledge of material facts not known to the plaintiff; (3) when the defendant actively conceals a material fact from the plaintiff; and (4) when the defendant makes partial representations but also suppresses some material fact." *LiMandri v. Judkins*, 52 Cal. App. 4th 326, 337 (1997); *see also, e.g.*, *Falk v. Gen. Motors Corp.*, 496 F. Supp. 2d 1088 (N.D. Cal. 2007) (citing same). The FAC alleges Defendant had a duty to disclose because "(i) Defendant had superior knowledge of material facts not known to Plaintiff and Class Members and their doctors, (ii) Defendant actively concealed this material fact from Plaintiff and Class Members and their doctors, and (iii) Defendant made partial representations to Plaintiff and Class Members and their [sic].[2]" FAC ¶ 76. Defendant argues that Plaintiff's omission theory fails because Plaintiff is required to plausibly allege exclusive, rather than superior, knowledge, and because Defendant did not make a partial representation sufficient to create a duty to disclose. *See* Mot. 15–17. Plaintiff counters that courts in fact apply a superior knowledge standard, and that Defendant made misleading partial representations regarding the potential breast cancer risk to some groups, which then required additional disclosures to clarify. Opp'n 18–21.

[2] In light of the grammatical structure of the prior two sections of this quotation, the Court presumes the missing word after "their" is "doctors."

Although the frequently cited standard for a duty to disclose uses the phrase "exclusive knowledge," "courts have held that the concept of 'exclusive knowledge' should not be applied with strict literalism." *Sumer v. Carrier Corp.*, No. 14-cv-4271, 2015 WL 3630972, at *2 (N.D. Cal. June 10, 2015). Rather, "the defendant need not have literally been the sole holder of the knowledge. It is generally sufficient for defendants to have had "superior knowledge" and for the information to have not been reasonably discoverable by the plaintiffs." *Anderson v. Apple Inc.*, 500 F. Supp. 3d 993, 1014–15 (N.D. Cal. 2020) (citation omitted); *see also Falk*, 496 F.Supp.2d at 1096–97 (finding duty to disclose based on "exclusive knowledge" where despite existence of publicly available information online because plaintiff alleged manufacturer's superior knowledge and "[m]any customers would not have performed an Internet search before beginning a car search"). Accordingly, Plaintiff's allegations that Defendant was aware of the studies showing increased risk because it reads literature and studies concerning its own products and commented on certain studies to the FDA in December 2015, FAC ¶ 27, and that doctors—including Plaintiff's own—were not aware of these studies allegedly showing a significantly increased risk of breast cancer in Mirena IUD users, *id.* ¶ 29–30, are sufficient to create a duty to disclose. *See Edwards*, 2022 WL 1814144, at *3 (finding duty to disclose based on exclusive knowledge where plaintiff alleged defendant routinely monitored complaints and received complaints about alleged defect despite defendant's argument that consumer complaints indicated public knowledge).

Because the Court has determined that the FAC adequately alleges a duty to disclose based on Defendant's superior knowledge, it need not and does not address Defendant's other arguments regarding the sufficiency of Plaintiff's duty allegations.

c. Conclusion re Fraud-Based Claims

For the reasons discussed above, the Court will deny Defendant's motion to dismiss Plaintiff's fraud and CLRA claims.

3. Breach of Implied Warranty of Merchantability (Claim 1)

Plaintiff asserts a claim for breach of the implied warranty of merchantability, alleging that the "the statistically significant increased risk of breast cancer caused by Mirena renders it unsafe and unsuitable for its intended purpose" of birth control, so that the Mirena IUD "was not fit for its

intended purpose when it left the exclusive control of Defendant . . . [and] constitute[d] an unreasonable safety hazard for consumers." FAC ¶¶ 18, 59. To state a claim under the implied warranty of merchantability, a party must plead that the product in question "lacks 'even the most basic degree of fitness for ordinary use.'" *Birdsong v. Apple, Inc.*, 590 F.3d 955, 958 (9th Cir. 2009) (quoting *Mocek v. Alfa Leisure, Inc.*, 114 Cal. App. 4th 402, 406 (2003)). "[F]itness is shown if the product is in safe condition and substantially free of defects[.]" *T & M Solar & Air Conditioning, Inc. v. Lennox Int'l Inc.*, 83 F. Supp. 3d 855, 878 (N.D. Cal. 2015) (quoting *Mexia v. Rinker Boat Co., Inc.*, 174 Cal. App. 4th 1297, 1303 (2009)).

Defendant argues that "Plaintiff has not plausibly pled a causal association between Mirena use and breast cancer, let alone a significantly elevated risk of 20 to 30% for pre-menopausal women, like Plaintiff." Mot. 20. Because this argument requires a review of the contents of the studies the Court has deemed inappropriate for this stage of litigation, the Court will deny Defendant's motion to dismiss the breach of implied warranty of merchantability claim.

E. Punitive Damages

Defendant argues that Plaintiff's request for punitive damages should be dismissed because her fraud claims are deficient, and restates its request to strike Plaintiff's demand. Mot. 20. Plaintiff responds that her fraud claims are now adequately pled, so that her punitive damages request survives. Opp'n 24–25. She further requests that the Court not deviate from its prior holding premature Defendant's request to strike Plaintiff's demand for punitive damages. *Id.* at 25; *see* Prior Order 18–20.

"To support punitive damages, the complaint . . . must allege ultimate facts of the defendant's oppression, fraud, or malice." *Cyrus v. Haveson*, 65 Cal. App. 3d 306, 316-17 (1976). "[A] plaintiff may include a short and plain prayer for punitive damages that relies entirely on unsupported and conclusory averments of malice or fraudulent intent." *Union Pac. R.R. Co. v. Hill*, No. 21-cv-03216-BLF, 2021 WL 5964595, at *6 (N.D. Cal. Dec. 16, 2021) (quoting *Rees v. PNC Bank, N.A.*, 308 F.R.D. 266, 273 (N.D. Cal. 2015)). Plaintiff alleges that punitive damages are warranted "[a]s a result of Defendant's willful and malicious conduct." FAC ¶ 78. This allegation, together with Plaintiff's surviving claims for fraud and violation of the CLRA, are

sufficient to state a request for punitive damages.

Defendant's motion to dismiss Plaintiff's claim for punitive damages will be denied. And because the Court finds that Plaintiff has properly pled punitive damages, it will likewise deny Plaintiff's request to strike the demand.

F. Motion to Strike Class Allegations

Defendant again moves to strike Plaintiff's class allegations, arguing that the learned intermediary doctrine's application would require individualized causation inquiries such that a class could not be certified. Mot. 20–21. Plaintiff counters that the motion to strike is premature, and that the FAC's allegations that Defendant failed to warn physicians of an increased risk of breast cancer from use of the Mirena IUD negates the requirement for individualized inquiries. Opp'n 25.

As this Court previously noted, "[t]here is a split in this District as to whether a motion to strike class action allegations may be entertained at the motion to dismiss stage." Prior Order 21 (quoting *Ogala v. Chevron Corp.*, No. 14–cv–173–SC, 2014 WL 4145408, at *2 (N.D. Cal. Aug. 21, 2014) (collecting cases)). If a motion to strike class allegations is even considered at the pleading stage, such allegations are struck in "rare circumstances" where "the complaint demonstrates that a class action cannot be maintained on the facts alleged." *Tasion Commc'ns, Inc. v. Ubiquiti Networks, Inc.*, No. C–13–1803, 2014 WL 1048710, at *3 (citation omitted).

Plaintiff has alleged a nationwide class defined as "all persons in the United States who were prescribed and used the Mirena IUD," as well as a state subclass defined as "all persons who reside in the state of California and who were prescribed and used the Mirena IUD." FAC ¶¶ 43–44. Plaintiff further alleges that Defendant failed to warn doctors of the alleged increased risk of breast cancer caused by the Mirena IUD by failing to update prescribing information after December 2015, despite the publication of studies allegedly showing the increased risk. *Id.* ¶¶ 29–34. The Court cannot say that no class action can be maintained on these allegations. Nor do Defendant's cited cases suggest a different result. Two of the decisions arise out of a procedural posture beyond class certification, and both accordingly evaluate the parties' positions with the benefit of relevant facts obtained in discovery. *See Andren v. Alere, Inc.*, No. 16-cv-1255, 2018

WL 1920179, at *5 (S.D. Cal. Apr. 24, 2018) (motion for reconsideration of class certification decision); *In re Vioxx Class Cases*, 180 Cal. App. 4th 116, 134 (2009) (appeal of class certification decision). The third decision cited by Defendant involved a complaint described as containing no allegations beyond formulaic recitations that the plaintiff's claims were "typical of the claims of all class members," which is not the case with Plaintiff's FAC. *See Guerra v. United Natural Foods, Inc.*, No. 19-cv-01684, 2019 WL 13203781, at *12 (N.D. Cal. Nov. 8, 2019).

Accordingly, the Court will deny Defendant's motion to strike Plaintiff's class allegations.

V. ORDER

For the foregoing reasons, the Court hereby ORDERS as follows:

1. Defendant's motion to dismiss on the ground that Plaintiff lacks Article III standing, including standing to assert claims on behalf of a nationwide class, is DENIED;
2. Defendant's motion to dismiss on the ground that Plaintiff's claims are preempted by the FDCA is DENIED;
3. Defendant's motion to dismiss Plaintiff's equitable claims on the ground that the Court lacks equitable jurisdiction is GRANTED. Plaintiff's claims for unjust enrichment and violations of the UCL and FAL are DISMISSED, as is Plaintiff's CLRA claim to the extent Plaintiff seeks equitable relief.
4. Defendant's motion to dismiss Plaintiff's claims, to the extent the claims are premised on a duty to warn patients (rather than physicians), on the ground that the learned intermediary doctrine bars such claims is GRANTED.
5. Defendant's motion to dismiss Plaintiff's remaining claims—*i.e.*, breach of implied warranty of merchantability, fraud, and violation of the CLRA (to the extent Plaintiff seeks legal remedies)—for failure to state a claim is DENIED.
6. Defendant's motion to dismiss or strike Plaintiff's claim for punitive damages is DENIED.

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7. Defendant's motion to strike Plaintiff's class allegations is DENIED.

IT IS SO ORDERED.

Dated: October 5, 2023

BETH LABSON FREEMAN
United States District Judge

United States District Court
Northern District of California