UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

PRIYA SIDHU,

Plaintiff,

v.

BAYER HEALTHCARE PHARMACEUTICALS INC.,

Defendant.

Case No. 22-cv-01603-BLF

ORDER GRANTING IN PART AND DENYING IN PART MOTION TO DISMISS WITH LEAVE TO AMEND IN PART AND WITHOUT LEAVE TO AMEND IN PART

In this case, Plaintiff Priya Sidhu alleges that Defendant Bayer Healthcare Pharmaceuticals Inc. ("Bayer") markets and sells an IUD that significantly increases the risk of breast cancer in users. She brings common law and state statutory claims, and she seeks to represent both a California and a nationwide class.

Now before the Court is Bayer's motion to dismiss under Rules 12(b)(1) and 12(b)(6). ECF No. 17 ("MTD"); *see also* ECF No. 25 ("Reply"). Sidhu opposes the motion. ECF No. 22 ("Opp."). The Court held a hearing on October 27, 2022. For the reasons discussed on the record and explained below, the Court GRANTS IN PART and DENIES IN PART the motion to dismiss WITH LEAVE TO AMEND IN PART and WITHOUT LEAVE TO AMEND IN PART.

I. BACKGROUND

As alleged in the Complaint, Defendant Bayer markets and sells the Mirena intrauterine device ("Mirena" or "the device"). ECF No. 1 ("Compl.") ¶ 1. Mirena is a hormonal IUD, and specifically a levonorgestrel-releasing intrauterine system. *Id.* ¶ 2. The device is inserted into a woman's uterus, where it releases progestin, a hormone that thickens mucus in the cervix to stop sperm from fertilizing an egg; it also thins the uterus lining and partially suppresses ovulation. *Id.* Mirena thus reduces a woman's chance of getting pregnant and reduces menstrual bleeding. *Id.*

Bayer markets the device as birth control. *Id.* ¶ 1.

Sidhu alleges that Mirena "significantly increase[s] the risk of breast cancer in users," and that this information is not disclosed on the packaging, the list of "safety considerations" on the website, or in any other materials that Bayer distributes to doctors or consumers. Compl. ¶ 1, 3-5. She further alleges that Bayer "has long known that the Product significantly increases the risk of breast cancer." *Id.* ¶ 6. Plaintiff cites to several studies, which she alleges show a "significantly increased" risk of breast cancer. *See id.* ¶¶ 7-11.

Sidhu was prescribed and used Mirena between February 2019 and February 2022 in California. Compl. ¶ 15. She paid $50 out-of-pocket for the device. *Id.* She alleges that she reviewed the patient brochure upon first using Mirena, and she further alleges that she would not have purchased Mirena, or would have "paid significantly less," if Bayer had disclosed that Mirena "carried with it a significantly elevated risk of developing breast cancer." *Id.* She finally alleges that Bayer never warned her or her doctor about the elevated breast cancer risk. *Id.*

This lawsuit was filed on March 14, 2022. *See* Compl. The Complaint asserts claims for (1) breach of the implied warranty of merchantability, Compl. ¶¶ 31-40; (2) unjust enrichment, Compl. ¶¶ 41-45; (3) fraud, Compl. ¶¶ 46-53; (4) negligence, Compl. ¶¶ 54-57; (5) violation of all three prongs of the California Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code § 17200 *et seq.*, Compl. ¶¶ 58-71; (6) violation of the California Consumer Legal Remedies Act ("CLRA"), Cal. Civ. Code § 1750 *et seq.*, Compl. ¶¶ 72-92; and (7) violation of the California False Advertising Law ("FAL"), Cal. Bus. & Prof. Code § 17500 *et seq.*, Compl. ¶¶ 93-99. Sidhu seeks to represent a California and nationwide class. *Id.* ¶¶ 21-22.

II. REQUEST FOR JUDICIAL NOTICE

Ordinarily, a district court's inquiry on a Rule 12(b)(6) motion to dismiss is limited to the pleadings. "A court may, however, consider certain materials—documents attached to the complaint, documents incorporated by reference in the complaint, or matters of judicial notice—without converting the motion to dismiss into a motion for summary judgment." *United States v. Ritchie*, 342 F.3d 903, 908 (9th Cir. 2003). Courts may take judicial notice of facts that are "not subject to reasonable dispute." Fed. R. Evid. 201(b). Indisputable facts are those that are

"generally known" or that "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." *Id.*

Defendants request that the Court take judicial notice of 12 exhibits. *See* ECF No. 17-1. These include several scientific studies, FDA information, and several websites. *Id.* Plaintiff did not address the request. While a court may take judicial notice of "matters of public record," it "cannot take judicial notice of disputed facts contained in such public records." *Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 999 (9th Cir. 2018). "The Ninth Circuit has clarified that if a court takes judicial notice of a document, it must specify what facts it judicially noticed from the document." *Edwards Lifescis. Corp. v. Meril Life Scis. Pvt. Ltd.*, No. 19-cv-06593-HSG, 2021 WL 1312748, at *2 (N.D. Cal. Apr. 8, 2021) (citing *Khoja*, 899 F.3d at 999).

Defendant's request for judicial notice is DENIED WITHOUT PREJUDICE. If Bayer requests judicial notice again, it must identify the specific facts within the provided documents that it would like this Court to notice.

III. ARTICLE III STANDING – RULE 12(B)(1)

"[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.* Bayer makes three arguments as to standing.

A. Injury

Bayer argues that Sidhu does not have standing because she has not suffered an injury. MTD at 7-10. Bayer notes that Sidhu fortunately does not have breast cancer, and it also argues that Sidhu has not shown that Mirena causes a "significantly elevated risk of breast cancer." *Id.* Bayer cites to the five studies cited by Sidhu, as well as one additional study, as support for its contention. *Id.* Sidhu counters that the Court should not get to this question at the pleading stage and further argues that her allegations make plausible that Mirena causes an increased risk of breast cancer, and that she would have found this information material. *Id.* at 4-6.

The Court is not in the position to evaluate the scientific evidence at the pleadings stage. But, as discussed at the hearing, the Court notes that the phrase "significantly elevated risk" is not defined in the Complaint. *See* Compl. In an Amended Complaint, Sidhu is advised to provide more concrete allegations to support her claims regarding the undisclosed or minimized risk of breast cancer for Mirena users.

Bayer's motion to dismiss for lack of standing based on lack of injury is DENIED.

B. Nationwide Class

Bayer argues that Sidhu lacks standing to assert claims on behalf of a nationwide class. MTD at 10. Bayer first argues that the four common law claims should be dismissed because Sidhu does not allege which state law governs. *Id.* Bayer also argues that Sidhu cannot bring claims under the laws of any other states because there is no representative plaintiff for any state other than California. *Id.* Sidhu argues that it is premature to address these issues now. Opp. at 25.

The issues that Bayer raises are properly addressed at the motion to dismiss stage. First, "courts in this district have held that, due to variances among state laws, failure to allege which state law governs a common law claim is grounds for dismissal." *Romero v. Flowers Bakeries, LLC*, No. 14-cv-05189-BLF, 2016 WL 469370, at *12 (N.D. Cal. Feb. 8, 2016) (citing *In re TFT-LCD (Flat Panel) Antitrust Litig.*, 781 F. Supp. 2d 955, 966 (N.D. Cal. 2011)). Sidhu did not do so. *See* Compl. The Court will therefore dismiss the common law claims. In amending these claims, Sidhu should keep in mind that "[c]ourts in the Ninth Circuit have consistently held that a plaintiff in a putative class action lacks standing to assert claims under the laws of states other than those where the plaintiff resides or was injured." *See Jones v. Micron Tech. Inc.*, 400 F. Supp. 3d 897, 908 (N.D. Cal. 2019) (collecting cases). Also, Plaintiff will need to address the issue whether California law can be asserted for class members outside of California.

The motion to dismiss the common law claims for failure to identify which state law applies is GRANTED WITH LEAVE TO AMEND.

C. Injunctive Relief

Bayer also argues that Sidhu lacks standing to pursue injunctive relief because she fails to

allege an intent or willingness to purchase Mirena in the future. MTD at 10-11. Sidhu does not dispute this. *See* Opp.

Bayer's motion to dismiss all claims for injunctive relief is thus GRANTED WITHOUT LEAVE TO AMEND.

IV. FAILURE TO STATE A CLAIM – RULE 12(B)(6)

"A motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief can be granted 'tests the legal sufficiency of a claim.'" *Conservation Force v. Salazar*, 646 F.3d 1240, 1241-42 (9th Cir. 2011) (quoting *Navarro v. Block*, 250 F.3d 729, 732 (9th Cir. 2001)). 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). But 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). While a complaint need not contain detailed factual allegations, it "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is facially plausible when it "allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* 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).

A. Learned Intermediary Doctrine

Bayer argues that the learned intermediary doctrine bars all of Sidhu's claims. MTD at 5-7. "Under California law, when drugs or medical devices are supplied in the context of the physician-patient relationship, the learned intermediary doctrine applies." *Himes v. Somatics, LLC*, No. 21-55517, 2022 WL 989469, at *1 (9th Cir. Apr. 1, 2022) (citing *Webb v. Special Elec. Co., Inc.*, 370 P.3d 1022, 1034 n.10 (2016)). The doctrine 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." *Id.* (quoting *Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227, 1238 (9th Cir. 2017)). Therefore, "the duty to warn runs *to the physician*, not to the patient." *Id.* (quoting *Carlin v. Superior Ct.*, 920 P.2d 1347, 1354 (1996)).

Bayer argues that all of Sidhu's claims should be dismissed because the learned intermediary doctrine applies. MTD at 5-7. Sidhu argues that (1) the learned intermediary doctrine does not apply at the pleadings stage, (2) the learned intermediary doctrine does not apply to its design defect claims, and (3) Bayer did not provide an adequate warning to Sidhu's physician. Opp. at 2-4. The Court will first address whether the learned intermediary doctrine applies at this phase of the proceedings, and it will then turn to the issue of design defect.

Pleadings

Sidhu argues that the learned intermediary doctrine is an affirmative defense that should not be applied at the pleadings stage. Opp. at 2. Bayer argues that the Court can apply the learned intermediary doctrine in deciding the motion to dismiss, and it points the Court to several examples. Reply at 4.

Earlier this year, the Eastern District of California denied the same argument made by Plaintiff here, noting that "federal courts in California routinely apply the learned intermediary doctrine in dismissing complaints upon motion of defendants." *Kamlade v. LEO Pharma Inc.*, No. 1:21-cv-00522-DAD-EPG, 2022 WL 358429, at *3 n.3 (E.D. Cal. Feb. 7, 2022). In that case, the court decided that because the learned intermediary doctrine applied, plaintiff would need to provide "allegations as to what defendants did or did not tell plaintiff's prescribing physician" in order "to adequately assert" the claim for breach of implied warranty of merchantability. *Id.* at *4. Other courts have reached the same conclusion. In one case, a court dismissed a failure to warn claim under the learned intermediary doctrine where the plaintiff "fail[ed] to allege that her dentist was misled by [the company]." *Buckley v. Align Tech., Inc.*, No. 5:13-cv-02812-EJD, 2015 WL 5698751, at *4 (N.D. Cal. Sept. 29, 2015). In another, the court held that if a doctor had prescribed the product at issue, then plaintiffs would be required to "properly allege a failure to warn Plaintiffs' prescribing physician." *Andren v. Alere, Inc.*, 207 F. Supp. 3d 1133, 1144-45

(S.D. Cal. 2016). And in yet another, a court dismissed a failure to warn claim because the plaintiff "failed to allege that Defendants failed to warn his prescribing physician and failed to allege that if his prescribing physician had been warned, then he would not have prescribed the [product] to Plaintiff." *Tapia v. Davol, Inc.*, 116 F. Supp. 3d 1149, 1158-59 (S.D. Cal. 2015). Relatedly, this Court previously held that "a plaintiff alleging failure to warn regarding a medical device" would need to allege causation as to the physician. *Broge v. ALN Int'l, Inc.*, No. 17-cv-07131-BLF, 2019 WL 2088420, at *2 (N.D. Cal. May 13, 2019).

The Court also notes that in several of the cases relied on by Sidhu, the plaintiff *did* plead facts as to the failure to warn the doctor. *See Baker v. Bayer Healthcare Pharms.*, No. C13-0490 TEH, 2013 WL 6698653, at *5 (N.D. Cal. Dec. 19, 2013); *Wendell v. Johnson & Johnson*, No. C 09-04124 CW, 2010 WL 271423, at *3 (N.D. Cal. Jan. 20, 2010). Other cases cited by Sidhu addressed whether courts would consider the learned intermediary doctrine in deciding fraudulent joinder. *See Kwasniewski v. Sanofi-Aventis U.S., LLC*, 637 F. App'x 405, 406 (9th Cir. 2016); *J.P. ex rel. Plummer v. McKesson Corp.*, No. 2:13-cv-02207-TLN-DAD, 2014 WL 3890326, at *5 (E.D. Cal. Aug. 7, 2014).

For any claims to which the learned intermediary doctrine applies, Sidhu must make allegations as to her physician. She has not adequately done so. *See* Compl. The Court next addresses which claims the learned intermediary doctrine applies to in the Complaint.

Design Defect

Sidhu also argues that even if the learned intermediary doctrine applies to her failure to warn claims, it does not apply to her design defect claims. Opp. at 3-4. Bayer counters that (1) Sidhu does not plead a design defect theory, and instead raises it improperly for the first time in her Opposition, and (2) the learned intermediary doctrine applies to design defect claims. Reply at 4-6. Sidhu identifies paragraphs 54-57 of her Complaint as providing the basis for her design defect theory, which is her count for negligence. *See* Opp. at 3.

As a preliminary matter, "Plaintiff may not use [her] opposition to raise and argue new allegations or claims not in the complaint." *See Minor v. Fedex Office & Print Servs., Inc.*, 182 F. Supp. 3d 966, 977 (N.D. Cal. 2016). The cause of action for negligence does suggest a design

defect claim, *see* Compl. ¶¶ 54-57, but there are no factual allegations elsewhere in the Complaint to form a basis for this claim, *see generally* Compl. Plaintiff must allege her design defect claim more clearly, and she must provide supporting factual allegations. Even if Sidhu does bring a design defect claim, it is not clear she would avoid application of the learned intermediary doctrine. *See Kamlade*, 2022 WL 358429, at *5 (suggesting learned intermediary doctrine may apply to design defect claim); *Andren*, 2018 WL 1920179, at *5 (same).

Conclusion

Bayer's motion to dismiss all counts under the learned intermediary doctrine is GRANTED WITH LEAVE TO AMEND.

B. Preemption

Bayer argues that Sidhu's claims are preempted by the federal Food, Drug, and Cosmetic Act ("FDCA"). MTD at 11-14. The Supreme Court 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 v. Levine, 555 U.S. 555, 568 (2009). "[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).

The Court looks to *Holley v. Gilead Sciences, Inc.*, which laid out a two-step analysis for impossibility preemption in the drug manufacturing context:

> First, courts must determine whether a drug manufacturer may independently take action that complies with both state and federal law. 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. 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.

379 F. Supp. 3d 809, 821 (N.D. Cal. 2019) (citing *Levine*, 555 U.S. at 571). The court in *Holley* discussed preemption as to failure to warn claims and design defect claims. In order to plead a failure to warn claim based on information that came out after the initial drug release, a plaintiff would need to plead "a labeling deficiency that [Defendants] could have corrected using the CBE regulation." *Id.* at 827 (quoting *Gibbons v. Bristol-Myers Squibb Co.*, 919 F.3d 699, 708 (2d Cir. 2019)). The *Holley* court chose not to apply preemption to design defect claims based on drug composition. *Id.* at 821-25. The Court will address each type of claim in turn.

Failure to Warn

Bayer argues that the failure to warn claims are preempted because it could not have changed the warnings on Mirena under the CBE regulation. MTD at 11-14. As discussed above, the CBE regulation provides when a manufacturer can independently change a drug label. The regulation allows a manufacturer to change "the labeling to reflect newly acquired information" in certain circumstances, including "[t]o add or strengthen a contraindication, warning, precaution, or adverse reaction for which the evidence of a causal association satisfies the standard for inclusion in the labeling under § 201.57(c)." 21 CFR § 314.70(c)(6)(iii)(A). In turn, § 201.57(c) requires a change in labeling in accordance with § 314.70 "to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug; a causal relationship need not have been definitely established." 21 CFR § 201.57(c)(6)(i). Finally, the regulations define "newly acquired information" as follows:

> 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 CFR § 314.3(b).

Bayer argues that (1) the studies cited by Sidhu are not "newly acquired information" and (2) the studies do not show "evidence of a causal association" between Mirena and breast cancer.

MTD at 11-14. Sidhu argues that the post-2010 studies she cites do constitute "newly acquired information" and that a preemption analysis is premature. Opp. at 8-10.

The Court will first address whether the identified studies constitute "newly acquired information." In *Holley*, the court noted that it could not tell from the allegations in the complaint "whether – and, if so, when – any such information was provided to the FDA," and it therefore could not tell whether there existed newly acquired information ("data, analyses, or other information *not previously submitted to the [FDA]*") such that the defendant could have changed the label under the CBE regulation. 379 F. Supp. 3d at 829-30 (emphasis in original). The court therefore dismissed the claims for preemption.

The Court here follows that approach. Sidhu has not alleged what information was provided to the FDA and when, and the Court therefore cannot determine whether the post-2010 studies cited by Sidhu constituted "newly acquired information." As in *Holley*, Sidhu has not "plausibly alleged that [Bayer] could have made, under the CBE regulation or any other federal law allowing changes without prior FDA approval," the labeling changes she seeks. *See* 379 F. Supp. 3d at 830. As to "evidence of a causal connection," the Court is not in a position to make that decision at this stage in the proceedings.

Design Defect

Sidhu argues that her design defect claims are not preempted. Opp. at 6-8. As stated above, Sidhu has not adequately alleged a design defect claim. *See supra* Section IV.A. The Court declines to decide at this time whether any such claim would be preempted.

Conclusion

Bayer's motion to dismiss all failure to warn claims as preempted is GRANTED WITH LEAVE TO AMEND.

C. Fraud

1. Rule 9(b)

When a party pleads a cause of action for fraud or mistake, it is subject to the heightened pleading requirements of Rule 9(b). "In alleging fraud or mistake, a party must state *with particularity* the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b) (emphasis

added). "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).

The applicability of Rule 9(b) hinges not on the elements of the claim but rather on the nature of the allegations themselves: "Rule 9(b) applies to 'averments of fraud' in all civil cases in federal district court," including "particular averments of fraud" even when fraud is not an essential element of the claim. *Vess*, 317 F.3d at 1103; *see also Kearns*, 567 F.3d at 1124 ("Where fraud is not an essential element of a claim, only those allegations of a complaint which aver fraud are subject to Rule 9(b)'s heightened pleading standard."). Fraud can thus be averred "by specifically alleging fraud, or by alleging facts that necessarily constitute fraud (even if the word 'fraud' is not used)." *Vess*, 317 F.3d at 1105 (citations omitted).

2. UCL fraud prong, CLRA, FAL, and common law fraud

Plaintiff brings several common law and consumer protection claims that sound in fraud: (1) common law fraud, Compl. Claim III ¶¶ 46-53; (2) violation of the fraud prong of the UCL, *id.* Claim V ¶¶ 58-71; (3) violation of the CLRA, *id.* Claim VI ¶¶ 72-92; and (4) violation of the FAL, *id.* Claim VII ¶¶ 93-99.

"Broadly stated: The UCL prohibits 'any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising and any act prohibited by the FAL' ([Cal. Bus. & Prof. Code] § 17200); the FAL prohibits advertising 'which is untrue or misleading, and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading' ([*id.* at] § 17500); and the CLRA prohibits specified 'unfair methods of

competition and unfair or deceptive acts or practices' ([Cal.] Civ. Code § 1770, subd. (a))." *Hill v. Roll Int'l Corp.*, 195 Cal. App. 4th 1295, 1301 (2011) (alterations omitted). All three statutes prohibit fraudulent misrepresentations and omissions. *See In re Seagate Tech. LLC Litig.*, 233 F. Supp. 3d 776, 788 (N.D. Cal. 2017).

Bayer argues that Sidhu's fraud-based claims should be dismissed because she does not plead an affirmative misrepresentation or an actionable omission. MTD at 14-17. In her Opposition, Sidhu makes clear that her fraud is based on an omission theory. Opp. at 10-14. The Court therefore focuses on fraud by omission.

"Under California law, a claim of fraud by omission requires a showing of (1) the concealment or suppression of material fact, (2) a duty to disclose the fact to the plaintiff, (3) intentional concealment with intent to defraud, (4) justifiable reliance, and (5) resulting damages." *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. App'x 723, 725 (9th Cir. 2021)). Bayer argues that (1) there is no undisclosed fact, as there is no substantially elevated risk of breast cancer; (2) Sidhu has not adequately alleged Bayer's knowledge; (3) Sidhu has not adequately alleged Bayer's intent; and (4) Sidhu has not alleged reliance by her physician. MTD at 15-16.

The Court already addressed Bayer's arguments as to whether there is an increased risk of breast cancer. *See supra* Section III.A. The Court will address each element in turn.

Knowledge and Intent

Bayer argues that Sidhu has not shown its knowledge of the alleged increased risk of breast cancer. MTD at 15. The Court begins by stating, as already noted by Bayer, that Sidhu need not show exclusive knowledge, as the duty to disclose is not at issue here. *See* Reply at 12. But Sidhu does need to show actual knowledge. *See Andren v. Apple Inc.*, 411 F. Supp. 3d 541, 564-65 (N.D. Cal. 2019) ("To state a California fraudulent concealment and UCL claim based on an omission, a defendant must have known of the defect at the time of sale for a plaintiff to state a claim for fraud by omission." (internal quotation marks and citation omitted)); *see also In re Nexus 6P Prod. Liab. Litig.*, 293 F. Supp. 3d 888, 926-27 (N.D. Cal. 2018) ("California law supports this common-sense notion that a defendant cannot disclose facts of which it was

unaware." (internal quotation marks and citation omitted)). She also needs to show "intentional concealment with intent to defraud." *See Edwards*, 2022 WL 1814144, at *3. Sidhu counters that she has adequately pled Bayer's knowledge based on the identified scientific publications, and she argues that Bayer's failure to provide a warning to consumers despite this knowledge is sufficient to show intent. Opp. at 11-13. Under Rule 9(b), a plaintiff need only allege knowledge and intent generally. And Sidhu has done so. She alleges that Bayer had knowledge based on certain identified studies and that Bayer still failed to share this information. Compl. ¶¶ 49. Those allegations are sufficient at this stage.

Reliance

Bayer argues that Sidhu has not pled reliance on the omission by her physician. MTD at 16. Sidhu asserts that she has pled reliance because the learned intermediary doctrine does not apply, and she has pled reliance as to herself. Opp. at 13-14.

As discussed above, the learned intermediary doctrine does apply. Sidhu must therefore plead reliance as to her physician. *See Tapia*, 116 F. Supp. at 1164 (dismissing fraud claim where plaintiff did not "assert facts as to causation alleging that *his own* prescribing physician would not have used the device" if defendants had provided the information[1]); *Fischer v. Boston Sci. Corp.*, No. SACV 19-02106 JVS (DFM), 2020 WL 2300138, at *3 (C.D. Cal. Mar. 25, 2020) (dismissing fraud claim because "it is unclear when the representations were made to [plaintiff's] unnamed physician, where the representations took place, or how they were made").

Conclusion

Bayer's motion to dismiss Sidhu's common law fraud claim, as well as her claims under the fraud prong of the UCL, the CLRA, and the FAL, is GRANTED WITH LEAVE TO AMEND.

D. Other UCL Claims

The UCL prohibits any "unlawful, unfair or fraudulent business practice and unfair, deceptive, untrue or misleading advertising." Cal. Bus. & Prof. Code § 17200. The California

[1] The Court notes that the Ninth Circuit recently certified a question to the California Supreme Court as to the proper standard for causation in a failure-to-warn case. *See Himes v. Somatics, LLC*, 29 F.4th 1125 (9th Cir. 2022). The Court cites *Tapia* only to suggest that Sidhu must plead reliance as to her physician, not for the reliance standard itself.

Supreme Court has clarified that the UCL, because it is "written in the disjunctive," prohibits three separate types of unfair competition: (1) unlawful acts or practices, (2) unfair acts of practices, and (3) fraudulent acts or practices. *Cel-Tech Commc'ns, Inc. v. Los Angeles Cellular Tel. Co.*, 20 Cal. 4th 163, 180 (1999); *accord Davis v. HSBC Bank Nevada, N.A.*, 691 F.3d 1152, 1168 (9th Cir. 2012). To plead a UCL claim, a plaintiff's allegations must show that a defendant's conduct violates one of these three "prongs." *Id.* The Court already addressed Sidhu's claim under the fraudulent prong of the UCL. *See supra* Section IV.C.2. Sidhu also brings claims under the unlawful and unfair prongs of the UCL. *See* Compl. Claim V ¶¶ 58-71.

1. UCL unlawful claim

Sidhu brings a claim under the unlawful prong of the UCL. *See* Compl. ¶ 61. Sidhu bases this claim on her claims asserting fraud, unjust enrichment, negligence, breach of the implied warranty of merchantability, violation of the CLRA, and violation of the FAL. *Id.* Bayer argues that this claim "fails to the same extent as the predicate claims." MTD at 18. Sidhu argues that the UCL unlawful claim stands because the other claims should not be dismissed. Opp. at 16. She also argues for the first time in her Opposition that Bayer's conduct violates the Sherman Food, Drug, and Cosmetic Law. *Id.* at 16-17.

To start, because "Plaintiff may not use [her] opposition to raise and argue new allegations or claims not in the complaint," the Court will not consider Sidhu's argument about the Sherman Act. *See Minor*, 182 F. Supp. 3d at 977. Under the unlawful prong of the UCL, a plaintiff will "base their claims on violations of other causes of actions." *Hammerling v. Google LLC*, No. 21-cv-09004-CRB, 2022 WL 2812188, at *15 (N.D. Cal. July 18, 2022) (citing *S. Bay Chevrolet v. Gen Motors Acceptance Corp.*, 72 Cal. App. 4th 861, 880 (1999)). "If the predicate claims fail, the UCL claim also fails." *Id.* (citing *Davis v. HSBC Bank Nevada, N.A.*, 691 F.3d 1152, 1168 (9th Cir. 2012)). Because the Court dismisses the predicate claims for Sidhu's unlawful UCL claim, it also dismisses this claim.

Bayer's motion to dismiss the unlawful claim under the UCL is GRANTED WITH LEAVE TO AMEND.

2. UCL unfair claim

Sidhu brings a claim under the unfair prong of the UCL. Compl. ¶¶ 58-71. Bayer argues that this claim should be dismissed because the other UCL claims do not survive, and Sidhu has not alleged why its conduct is unfair. MTD at 17-18. Sidhu argues that the unfair UCL claim stems from Mirena's design defect, as opposed to its fraudulent omissions, and that the design defect constitutes unfair conduct because the harm of the product outweighs any benefits. Opp. at 14-16.

The Court notes that "the UCL does not define 'unfair,' and the definition in consumer cases is in flux." *Hammerling*, 2022 WL 2812188, at *15 (citing *Hodsdon v. Mars, Inc.*, 891 F.3d 857, 866 (9th Cir. 2018)). But "[i]n this District, when plaintiff's claim under the unfair prong overlaps entirely with the conduct alleged in the fraudulent and unlawful prongs of the UCL, 'the unfair prong of the UCL cannot survive if the claims under the other two prongs . . . do not survive.'" *Eidmann v. Walgreen Co.*, 522 F. Supp. 3d 634, 647 (N.D. Cal. 2021) (quoting *Hadley v. Kellogg Sales Co.*, 243 F. Supp. 3d 1074, 1105 (N.D. Cal. 2017)). Despite Sidhu's arguments to the contrary in the Opposition, the unfair UCL claim as pled in the Complaint is based on the same conduct underlying the other two UCL claims, and it must therefore be dismissed. *See* Compl. ¶¶ 58-71; *see also Minor*, 182 F. Supp. 3d at 977 ("Plaintiff may not use [her] opposition to raise and argue new allegations or claims not in the complaint.").

Bayer's motion to dismiss the unfair claim under the UCL is GRANTED WITH LEAVE TO AMEND.

E. Unjust Enrichment

Sidhu asserts a claim for unjust enrichment, alleging that Bayer unlawfully accepted payment for Mirena while failing to disclose the breast cancer risk, and it would be "unjust and inequitable" for Bayer to retain that benefit. Compl. Claim II ¶¶ 41-45. Bayer argues that the Court should dismiss this claim because Sidhu failed to state claims under the California consumer protection statutes. MTD at 19. Sidhu clarifies that she is bringing an independent claim for unjust enrichment. Opp. at 21. In Reply, Bayer only argues that the claim must be dismissed because Sidhu does not allege an inadequate remedy at law. Reply at 14.

The Court first notes it is not clear from the Complaint under what state law the unjust enrichment claim is brought. The Court will apply California law, as that is where Sidhu resides and was injured. There has been significant confusion over whether California law provides for a standalone cause of action for unjust enrichment. *See, e.g.*, *Falk v. Gen. Motors Corp.*, 496 F. Supp. 2d 1088, 1099 (N.D. Cal. 2007). In 2015, the Ninth Circuit indicated that, "in California, there is not a standalone cause of action for 'unjust enrichment,' which is synonymous with 'restitution.'" *Astiana v. Hain Celestial Grp., Inc.*, 783 F.3d 753, 762 (9th Cir. 2015). But in 2017, the Ninth Circuit recognized that the California Supreme Court later "clarified California law, allowing an independent claim for unjust enrichment to proceed." *Bruton v. Gerber Prods. Co.*, 703 F. App'x 468, 470 (9th Cir. 2017) (citing *Hartford Cas. Ins. Co. v. J.R. Mktg., LLC*, 61 Cal. 4th 988, 1000 (2015)). Therefore, the Court rejects Bayer's argument that the claim for unjust enrichment fails because Sidhu did not state claims under the consumer protection statutes. The Court will address the equitable jurisdiction argument below.

Bayer's motion to dismiss the unjust enrichment claim based on Sidhu's failure to state other claims is thus DENIED.

F. Implied Warranty of Merchantability

Sidhu brings a claim alleging that Bayer breached the implied warranty of merchantability. Compl. Claim I ¶¶ 31-40. Bayer argues that the Court should dismiss this claim. MTD at 19-20. It is not clear from the Complaint under what state law Sidhu is bringing this claim, but in the Opposition, she indicates that she is bringing the claim under California law, as she cites to the Song-Beverly Act. Opp. at 21-22. She argues that Mirena is unmerchantable because it creates a safety hazard for the consumer. *Id.* at 22. Bayer counters that Sidhu does not show Mirena is unmerchantable because she cannot show that Mirena is not fit for its intended use, which is birth control. Reply at 13. Bayer also notes that all prescription drugs have associated risks. *Id.*

"Unless excluded or modified [], a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind." Cal. Com. Code § 2314(1). 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)); *see also Thomas v. Costco Wholesale Corp.*, No. 12-cv-02908-BLF, 2014 WL 5872808, at *3 (N.D. Cal. Nov. 12, 2014) (dismissing claim for breach of implied warranty of merchantability where plaintiff did not allege the products "lacked a basic degree of fitness for ordinary use, or would in some way be unsafe for consumption").

While the claim for breach of implied warranty of merchantability is not a model of clarity, Sidhu does allege that Mirena is "not fit for its intended purpose" and causes a "significantly elevated risk of breast cancer." *See* Compl. ¶¶ 36, 39. Such a risk, if proven, would constitute a safety hazard.

Bayer's motion to dismiss Sidhu's claim for a breach of implied warranty of merchantability for failure to state a claim is DENIED.

G. Negligence

Sidhu also brings a claim for negligence. Compl. Claim IV ¶¶ 54-57. Bayer argues that Sidhu's negligence claim should be dismissed under the economic loss rule. MTD at 20-21. Sidhu contested that one of the exceptions to the economic loss doctrine may apply in this case. Opp. at 23. At hearing, Plaintiff's counsel noted that Plaintiff would likely concede this claim. Regardless, the Court will address it.

The Court first notes it is not clear under what state law the negligence claim is brought, but it will apply California law. "The 'economic loss rule requires a purchaser to recover in contract for purely economic loss due to disappointed expectations, unless he can demonstrate harm above and beyond a broken contractual promise.'" *Ladore v. Sony Comput. Entm't Am., LLC*, 75 F. Supp. 3d 1065, 1075 (N.D. Cal. 2014) (quoting *Tasion Commc'ns v. Ubiquiti Networks, Inc.*, No. C-13-1803 EMC, 2013 WL 4530470, at *3 (N.D. Cal. Aug. 26, 2013)). "[T]he 'economic loss rule has been applied to bar a plaintiff's tort recovery of economic damages unless such damages are accompanied by some form *of physical harm* (i.e., personal injury or

property damage).'" *Id.* (quoting *N. Am. Chem. Co. v. Superior Ct.*, 59 Cal. App. 4th 764, 777 (1997)). Therefore, "in actions arising from the sale or purchase of a defective product, plaintiffs seeking economic losses must be able to demonstrate that either physical damage to property (other than the defective product itself) or personal injury accompanied such losses"; otherwise "they would be precluded from any tort recovery in strict liability or negligence.'" *Id.* (quoting *N. Am. Chem. Co.*, 59 Cal. App. 4th at 780).

Sidhu does not dispute that the economic loss rule applies here. Opp. at 23. Instead, she argues that an exception may apply. *Id.* But Sidhu must allege facts supporting such an exception. *See Gardiner v. Walmart, Inc.*, No. 20-cv-04618-JSW, 2021 WL 4992539, at *6 (N.D. Cal. July 28, 2021) (dismissing negligence claim because Plaintiff failed to allege facts to support an exception). As noted by Bayer, Sidhu has not done so. Reply at 14.

Bayer's motion to dismiss the negligence claim is GRANTED WITH LEAVE TO AMEND.

H. Punitive Damages

Bayer argues that Sidhu does not adequately plead punitive damages because she does not plead oppression, fraud, or malice. MTD at 21. Sidhu, noting that courts often decline to address this question at the motion to dismiss stage, also argues that she has pled oppression, fraud, or malice. Opp. at 23-24. In its Reply, Bayer seeks to dismiss or, in the alternative, to strike the request for punitive damages because it is based on "insufficient and conclusory allegations in connection with her fraud-based claims." Reply at 14-15.

"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)). Here, Plaintiff has done so. Sidhu states, "As a result of Defendant's willful and malicious conduct, punitive damages are warranted." Compl. ¶ 53. However, the punitive damages are based on Sidhu's fraud claims,

which have been dismissed. Therefore, although there is no pleading deficiency as to punitive damages, because the Court has dismissed the predicate fraud claims, it will dismiss the request for punitive damages as well.

Bayer's motion to dismiss the request for punitive damages is GRANTED WITH LEAVE TO AMEND. The request to strike the request for punitive damages is addressed below.

V. EQUITABLE JURISDICTION

Even if a district court has subject matter jurisdiction, "[t]here remains the question of equitable jurisdiction." *Schlesinger v. Councilman*, 420 U.S. 738, 753-54 (1975). Both are required for a federal court to hear the merits of an equitable claim. *Guzman v. Polaris Indus. Inc.*, No. 21-55520, 2022 WL 4543709, at *5 (9th Cir. Sept. 29, 2022). "Subject matter jurisdiction regards 'whether the claim falls within the limited jurisdiction conferred on the federal courts' by Congress, while equitable jurisdiction regards 'whether consistently with the principles governing equitable relief the court may exercise its remedial powers.'" *Id.* (quoting *Schlesinger*, 420 U.S. at 754). 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).

Bayer argues that the UCL, FAL, and unjust enrichment claims should be dismissed because they are equitable claims, and Plaintiff has not established that she lacks an adequate remedy at law. MTD at 18-19. Sidhu argues that she has alleged that she lacks an equitable remedy at law. Opp. at 18-19. She further argues that she has no adequate remedy at law to rectify Bayer's violations of the Sherman Act. Opp. at 19-20.

A plaintiff cannot state a claim for equitable relief "if the pleading does not demonstrate the inadequacy of a legal remedy." *Sharma v. Volkswagen AG*, 524 F. Supp. 3d 891, 907 (N.D. Cal. 2021). In arguing that she has pled the inadequacy of a legal remedy, Sidhu points to two paragraphs of the Complaint. Opp. at 19 (citing Compl. ¶¶ 69, 91). In one of these, Plaintiff alleges the necessity of injunctive relief. *See* Compl. ¶ 91. Because the Court has dismissed all claims for injunctive relief, Sidhu cannot rely on this allegation. The second identified paragraph does not refer to injunctive relief specifically, but it is ahead of two paragraphs that explain the

need for injunctive relief. *See* Compl. ¶¶ 69-71. Sidhu again cannot rely on this allegation. And the Court will not consider Plaintiff's arguments as to the Sherman Act, as they are not mentioned anywhere in the Complaint. *See Minor*, 182 F. Supp. 3d at 977.

Bayer's motion to dismiss the UCL, FAL, and unjust enrichment claims for lack of equitable jurisdiction is GRANTED WITH LEAVE TO AMEND.

VI. MOTION TO STRIKE

Federal Rule of Civil Procedure 12(f) permits a court to "strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." Fed. R. Civ. P. 12(f). "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). "If there is any doubt whether the portion to be stricken might bear on an issue in the litigation, the court should deny the motion." *Platte Anchor Bolt, Inc. v. IHI, Inc.*, 352 F. Supp. 2d 1048, 1057 (N.D. Cal. 2004). "Ultimately, whether to grant a motion to strike lies within the sound discretion of the district court." *Cruz v. Bank of N.Y. Mellon*, No. 12-CV-00846-LHK, 2012 WL 2838957, at *2 (N.D. Cal. July 10, 2012).

A. Punitive Damages

Bayer argues that the Court should strike the request for punitive damages. Reply at 14-15. This request is improperly raised for the first time in the Reply. *See* MTD. Regardless, the request fails on the merits. Federal Rule of Civil Procedure 12(f) allows a court to "strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." Fed. R. Civ. P. 12(f). Bayer has not met this standard. Sidhu may be able to properly plead punitive damages in an Amended Complaint. The motion to strike the request for punitive damages is DENIED.

B. Class Allegations

Bayer finally seeks to strike Sidhu's class allegations. MTD at 21-23. Bayer argues that because the learned intermediary doctrine applies, individual issues will necessarily predominate

over class issues, and therefore the class allegations should be stricken. *Id.* Sidhu asserts that Bayer's arguments are premature. Opp. at 25.

"There 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." *Ogala v. Chevron Corp.*, No. 14–cv–173–SC, 2014 WL 4145408, at *2 (N.D. Cal. Aug. 21, 2014) (collecting cases). Even those courts that have considered such a motion early in the proceedings "have applied a very strict standard to motions to strike class allegations on the pleadings." *Id.* "Only if the court is convinced that any questions of law are clear and not in dispute, and that under no set of circumstances could the claim or defense succeed may the allegations be stricken." *Id.* (internal quotation marks and citation omitted). Thus, even if a motion to strike class allegations is considered at the pleading stage, it may only be granted under "rare circumstances" where "the complaint demonstrates that a class action cannot be maintained on the facts alleged." *Tasion*, 2014 WL 1048710, at *3 (citation omitted).

The Court is granting Sidhu leave to amend on all of her claims. The Court cannot say that a class action could not be maintained under the facts alleged in an Amended Complaint. Therefore, Bayer's motion to strike the class allegations is DENIED.

VII. ORDER

For the foregoing reasons, IT IS HEREBY ORDERED that:

1. Bayer's request for judicial notice is DENIED WITHOUT PREJUDICE;

2. Bayer's motion to dismiss for lack of standing based on lack of injury is DENIED;

3. Bayer's motion to dismiss the common law claims for failure to identify which state law applies is GRANTED WITH LEAVE TO AMEND;

4. Bayer's motion to dismiss all claims for injunctive relief for lack of standing is GRANTED WITHOUT LEAVE TO AMEND;

5. Bayer's motion to dismiss all claims under the learned intermediary doctrine is GRANTED WITH LEAVE TO AMEND;

6. Bayer's motion to dismiss all failure to warn claims as preempted is GRANTED WITH LEAVE TO AMEND;

7. Bayer's motion to dismiss the fraud-based claims (common law fraud, UCL fraud claim, CLRA claim, and FAL claim) for failure to state a claim is GRANTED WITH LEAVE TO AMEND;

8. Bayer's motion to dismiss the UCL unlawful and unfair claims for failure to state a claim is GRANTED WITH LEAVE TO AMEND;

9. Bayer's motion to dismiss the unjust enrichment claim based on the failure to state other claims is DENIED;

10. Bayer's motion to dismiss the implied warranty claim for failure to state a claim is DENIED;

11. Bayer's motion to dismiss the negligence claim for failure to state a claim is GRANTED WITH LEAVE TO AMEND;

12. Bayer's motion to dismiss the request for punitive damages is GRANTED WITH LEAVE TO AMEND;

13. Bayer's motion to dismiss the UCL, FAL, and unjust enrichment claims for lack of equitable jurisdiction is GRANTED WITH LEAVE TO AMEND;

14. Bayer's motion to strike the request for punitive damages is DENIED; and

15. Bayer's motion to strike the classwide allegations is DENIED.

Plaintiffs SHALL file an amended complaint within 60 days of this order. Failure to meet the deadline to file an amended complaint or failure to cure the deficiencies identified on the record or in this order will result in a dismissal of the deficient claims with prejudice. Plaintiff's amendments shall not exceed the scope allowed by the Court in this order.

Dated: November 22, 2022

BETH LABSON FREEMAN
United States District Judge