UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

IRENA MICHAJLUN and JAY MARKOFF, Plaintiffs, vs. BAUSCH & LOMB, INC., Defendant.	CASE NO. 14-cv-1365 JM (JMA) ORDER GRANTING IN PART AND DENYING IN PART BAUSCH & LOMB'S MOTION TO DISMISS PLAINTIFFS' FIRST AMENDED COMPLAINT

This order addresses Defendant Bausch & Lomb's ("B&L's") motion to dismiss Plaintiffs' first amended complaint, (Doc. No. 15), and its request for judicial notice, (Doc. No. 16). The matters were fully briefed and were found suitable for resolution without oral argument pursuant to Local Civil Rule 7.1.d.1. For the reasons set forth below, the court grants B&L's request for judicial notice; denies B&L's motion to dismiss Plaintiffs' claims for strict liability for failure to warn, negligent failure to warn, and loss of consortium; and dismisses, without leave to amend, Plaintiffs' claims for deceptive advertising and deceptive business practices.

BACKGROUND

I. Plaintiffs' Allegations[1]

This case involves a medical device manufactured by B&L called Crystalens. (FAC ¶ 2.) Crystalens is an artificial lens that is surgically implanted in the eye to replace a person's natural lens after it is removed during cataract surgery. (Id.)

[1] Except where noted, the facts in this section are drawn from Plaintiffs' first amended complaint ("FAC") and the attached exhibits, (Doc. No. 14, Exhs. A–F). For purposes of this motion, Plaintiffs' allegations are taken as true to the extent that they are well pleaded.

Plaintiff Michajlun had cataract surgery on April 10, 2012, and had a Crystalens implanted in her left eye. (Id. ¶ 29.) Soon after the surgery, she experienced a condition called "Z syndrome." (Id. ¶ 30.) According to Plaintiffs, Z syndrome occurs when one of Crystalens's arms that attach to the eye muscle detaches and folds forward inside the eye, causing the lens to assume a "Z" shape and to stop functioning. (Id. ¶ 17.) Plaintiffs allege that Michajlun suffered pain, discomfort, and various financial losses, including the cost of surgical procedures to try to correct the problem, and that her husband, Plaintiff Markoff, suffered a loss of consortium. (Id. ¶¶ 30–32.) Michajlun claims that if she and her doctor had known of the risk of Z syndrome, she would not have agreed to having Crystalens implanted, and, on information and belief, her doctor would not have recommended it. (Id. ¶ 46.)

Plaintiffs filed their initial complaint in San Diego Superior Court. (Doc. No. 1.) After B&L removed the case to this court on the basis of diversity jurisdiction, Plaintiffs filed the instant first amended complaint, asserting five causes of action under California law: (1) strict liability for failure to warn; (2) negligent failure to warn; (3) deceptive advertising in violation of California's False Advertising Law ("FAL"), California Business & Professions Code § 17500; (4) deceptive business practices in violation of California's Unfair Competition Law ("UCL"), California Business & Professions Code § 17200; and (5) loss of consortium. (FAC ¶¶ 33–66.) Plaintiffs seek to litigate the third and fourth claims, under the FAL and UCL, as class claims on behalf of individuals who had Crystalens implanted in their eye(s) between April 7, 2010, and April 8, 2014.[2] (Id. ¶¶ 67–69.) Plaintiffs seek money damages on the first, second, and fifth claims, and restitution or disgorgement on the third and fourth claims. (Id. ¶¶ 47, 51, 56, 62, 66.)

[2] Plaintiffs do not identify the significance of these dates.

Plaintiffs set forth the following general allegations: Crystalens is a Class III medical device subject to regulation by the Food and Drug Administration ("FDA"). (Id. ¶ 12.) The FDA's initial premarket approval ("PMA") for Crystalens required B&L, as a condition of continued approval to distribute Cyrstalens, to submit an adverse-reaction report to the FDA within ten days after receiving information concerning any injury attributable to the device if the injury was not addressed by the device's labeling, or if it was addressed by the labeling, if the injury was occurring with unexpected severity or frequency. (Id. ¶ 22.) Similarly, the FDA requires device manufacturers to establish internal procedures for reviewing complaints and event reports, see 21 C.F.R. § 820.198(a),[3] and to report to the FDA within thirty days after becoming aware of information suggesting that one of the manufacturer's devices may have caused or contributed to a death or serious injury, or has malfunctioned and would be likely to cause death or serious injury if the malfunction were to recur, see 21 C.F.R. § 803.50(a).[4] (Id. ¶ 39.)

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[3] 21 C.F.R. § 820.198(a) provides:

> (a) Each manufacturer shall maintain complaint files. Each manufacturer shall establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit. Such procedures shall ensure that:
> (1) All complaints are processed in a uniform and timely manner;
> (2) Oral complaints are documented upon receipt; and
> (3) Complaints are evaluated to determine whether the complaint represents an event which is required to be reported to the FDA under part 803 of this chapter, Medical Device Reporting.

[4] 21 C.F.R. § 803.50(a) provides:

> (a) If you are a manufacturer, you must report to us no later than 30 calendar days after the day that you receive or otherwise become aware of information, from any source, that reasonably suggests that a device that you market:
> (1) May have caused or contributed to a death or serious injury; or
> (2) Has malfunctioned and this device or a similar device that you market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.

In November 2008, an article called *Two Cases of Z Syndrome with Crystalens After Uneventful Cataract Surgery* was published. (FAC ¶ 14; Exh. B.) It reported that "[Z syndrome] is a unique complication with this type of hinged accommodating [intraocular lens]," and it suggested steps that could be used to minimize the risk of Z syndrome at the time of implantation. (Id.) According to Plaintiffs, the article indicates that at least four incidents of Z syndrome had occurred by the time the article was published. (Id. ¶ 24.)

In April 2009, B&L submitted an adverse-event report to the FDA reporting an occurrence of Z syndrome. (FAC ¶ 19; Exh. D.)

In April 2010, an article called *Z Syndrome Still Possible with Newer Generation Crystalens* was published. (FAC ¶ 23; Exh. C.) The article stated that Z syndrome had been "reported in newer generations of the lens, including the HD and 5-0," and that one of the doctors quoted in the article, a Dr. Safran, was "working with [B&L] to create an instrument to help aid the surgical correction of Z syndrome." (FAC ¶¶ 18, 23; Exh. C.)

In August 2010, B&L created an advertising circular to promote Crystalens. (FAC ¶ 12; Exh. A.) The circular was placed in opthalmologists' offices throughout California for potential Crystalens buyers to read. (FAC ¶ 21.) It contains two statements that Plaintiffs contend were false or misleading.

First, the circular states: "The risks of implantation with Crystalens are generally the same potential risks that exist for implanting all intraocular lenses." (Id. ¶ 14.) Plaintiffs claim that this statement was false and misleading because, as the 2008 article indicates, Z syndrome is a risk unique to Crystalens. (Id.) According to Plaintiffs, B&L knew that the statement was false because, by the time it created the circular, it had submitted the 2009 adverse-event report to the FDA and, as of 2010, it was working with Dr. Safran to create a surgical tool to correct Z syndrome. (Id. ¶¶ 18–19.) Plaintiffs contend that this statement thus constituted

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misbranding,[5] in violation of 21 U.S.C. § 352(q),[6] 21 C.F.R. § 801.6,[7] and the FAL and UCL. (FAC ¶ 15.)

Second, the circular states: "Only your surgeon . . . can explain the applicable risks." (Id. ¶ 28; Exh. A.) Plaintiffs claim that this statement was false and misleading because B&L had failed to comply with its duty to file adverse-reaction reports for all known incidents of Z syndrome. (FAC ¶¶ 23–28.) Although the 2008 article indicated that there had already been at least four incidents of Z syndrome, and the 2010 article stated that Z syndrome had also occurred in newer models of the lens, and Michajlun herself experienced Z syndrome, Plaintiffs' search of B&L's adverse-reaction reports for Crystalens uncovered only two reports, one dated April 28, 2009 (before the 2010 article), and one dated December 13, 2010 (after the 2010 article).[8] (Id. ¶¶ 23–25.) Plaintiffs contend that B&L's failure to comply with its reporting duty diminished physicians' ability to assess and warn of the risk of Z syndrome, so that this second statement also constituted misbranding in violation of 21 C.F.R. § 801.6. (Id. ¶ 28.)

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[5] Plaintiffs do not identify what the effect of misbranding is under federal law. Their claims appear to be related to 21 U.S.C. § 331(a), which prohibits "[t]he introduction . . . into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or *misbranded*." (Emphasis added.)

[6] 21 U.S.C. § 352(q) provides in relevant part:

> A drug or device shall be deemed to be misbranded . . . [i]n the case of any restricted device distributed or offered for sale in any State, if (1) its advertising is false or misleading in any particular . . . .

[7] 21 C.F.R. § 801.6 provides:

> Among representations in the labeling of a device which render such device misbranded is a false or misleading representation with respect to another device or a drug or food or cosmetic.

[8] B&L asserts that "additional reports were submitted," and it refers the court to the FDA's Manufacturer and User Facility Device Experience ("MAUDE") database, at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm. (Doc. No. 15-1 at 11 n.5.) However, B&L did not provide the court (or Plaintiffs) with copies of the reports or any means of identifying them, and did not explain what the additional reports demonstrate. Accordingly, the court does not address them here.

II. B&L's Motion to Dismiss and Request for Judicial Notice

B&L moved to dismiss Plaintiffs' amended complaint on October 22, 2014, (Doc. No. 15), and filed a separate request for judicial notice, (Doc. No. 16). The hearing, which was initially scheduled for December 15, 2014, was continued for good cause until February 9, 2015. (Doc. No. 20.) Plaintiffs filed an opposition on January 26, 2015, (Doc. No. 22), and B&L replied on February 2, 2015, (Doc. No. 23). Neither party requested oral argument, and the court took the matter under submission on February 3, 2015. (Doc. No. 24.)

DISCUSSION

I. Request for Judicial Notice

B&L asks the court to take judicial notice of two items: (1) the FDA webpage containing links to the original PMA for Crystalens and all applicable supplements; and (2) the FDA-approved patient labeling for Crystalens, which can be downloaded from the FDA's website. (Doc. No. 16 & Exhs. A & B.)

Federal Rule of Evidence 201 provides that courts may take judicial notice of facts that are not subject to reasonable dispute because they are generally known or are capable of accurate and ready determination. See Fed. R. Evid. 201(b). The court may take notice of such facts on its own, and "must take judicial notice if a party requests it and the court is supplied with the necessary information." Fed. R. Evid. 201(c). Matters of public record are proper subjects of judicial notice, but a court may take notice only of the existence and authenticity of an item, not the truth of its contents. See Lee v. City of Los Angeles, 250 F.3d 668, 689–90 (9th Cir. 2001). Under these rules, courts may take judicial notice of "the records and reports of administrative bodies," United States v. Ritchie, 342 F.3d 903, 909 (9th Cir. 2003) (quotation marks omitted), including documents and information posted on the FDA's public website, see Eidson v. Medtronic, Inc., 981 F. Supp. 2d 868, 878–79 (N.D. Cal. 2013) (collecting cases).

Plaintiffs do not oppose B&L's request, and the documents are available

on the FDA's public website and not subject to reasonable dispute. Accordingly, the court grants B&L's request for judicial notice of these items.

II. Motion to Dismiss

B&L contends that Plaintiffs' claims must be dismissed for failure to state a claim because they are expressly preempted by the express-preemption provision of the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360k(a). (Doc. No. 15-1 at 4–13.) Plaintiffs counter that their claims fall within the narrow exception for "parallel" state and federal claims. (Doc. No. 22 at 3–6.) As set forth below, one of Plaintiffs' theories is preempted, but the other is not. Following that discussion, the court addresses B&L's additional arguments and the implications for each of Plaintiffs' causes of action.

A. Legal Standards

A motion to dismiss for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6) challenges the legal sufficiency of the pleadings. To overcome such a motion, the complaint must contain "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 has facial plausibility when the plaintiff pleads factual content that allows 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). Factual pleadings merely consistent with a defendant's liability are insufficient to survive a motion to dismiss because they establish only that the allegations are possible rather than plausible. See id. at 678–79. The court should grant relief under Rule 12(b)(6) if the complaint lacks either a cognizable legal theory or facts sufficient to support a cognizable legal theory. See Balistreri v. Pacifica Police Dep't, 901 F.2d 696, 699 (9th Cir. 1990).

When ruling on a Rule 12(b)(6) motion, the court "must take all of the factual allegations in the complaint as true," but is "not bound to accept as true a legal conclusion couched as a factual allegation." Iqbal, 556 U.S. at 678. Further,

the court "need not accept as true . . . allegations that contradict facts that may be judicially noticed by the court, and may consider documents that are referred to in the complaint whose authenticity no party questions." Shwarz v. United States, 234 F.3d 428, 435 (9th Cir. 2000) (citations omitted). A court may look beyond the complaint to matters of public record, including administrative records, without converting the Rule 12(b)(6) motion into one for summary judgment. See Shawn v. Hahn, 56 F.3d 1128, 1129 n.1 (9th Cir. 1995).

Federal Rule of Civil Procedure Rule 15 provides that courts should freely grant leave to amend when justice requires it. Accordingly, when a court dismisses a complaint for failure to state a claim, "leave to amend should be granted unless the court determines that the allegation of other facts consistent with the challenged pleading could not possibly cure the deficiency." DeSoto v. Yellow Freight Sys., Inc., 957 F.2d 655, 658 (9th Cir. 1992) (internal quotation marks omitted). Amendment may be denied, however, if amendment would be futile. See id.

B. Preemption Under the MDA

Congress enacted the MDA to extend the coverage of the Food, Drug, and Cosmetic Act ("FDCA") to medical devices, after various states enacted laws requiring premarket approval of medical devices. See Riegel v. Medtronic, Inc., 552 U.S. 312, 315–16 (2008). The MDA "imposed a regime of detailed federal oversight." Id. at 316. To that end, the MDA expressly preempts state requirements that are "different from, or in addition to" federal requirements applicable to a device:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
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> (1) which is *different from, or in addition to, any requirement applicable under this chapter to the device*, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a) (emphasis added).[9]

In Riegel v. Medtronic, Inc., the Supreme Court specified a two-step framework for determining whether a state-law claim is preempted under § 360k(a). See 552 U.S. at 321–22. First, the court must determine "whether the Federal Government has established requirements applicable to [the device at issue]." Id. at 321. If it has, the court must then determine whether the plaintiff's claims would impose requirements "different from, or in addition to" the federal requirements. Id. at 322. The MDA's reference to state "requirements" includes not just duties imposed by statute and regulation, but also those imposed by common-law tort doctrines. See id. at 324–25.

Under this framework, the only state-law claims that are not expressly preempted are claims premised on violations of state duties that "parallel" duties imposed by the FDA. Stengel v. Medtronic, Inc., 704 F.3d 1224, 1228 (9th Cir. 2013) (en banc). The MDA thus "provides immunity for manufacturers of new Class III medical devices to the extent that they comply with federal law, but it does not protect them if they have violated federal law." See Bausch v. Stryker Corp., 630 F.3d 546, 553 (7th Cir. 2010).

Claims related to medical devices may also be impliedly preempted by the MDA if they seek to enforce a violation of the medical device provisions and do not rely on traditional state tort law. See Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001); Perez v. Nidek Co., 711 F.3d 1109 (9th Cir. 2013). Because only the FDA is authorized to enforce violations of the FDCA, "private enforcement of the statute is barred." Perez, 711 F.3d at 1119. Consequently, to escape express and implied preemption under the MDA, "[t]he plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted

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[9] The exception in subsection (b) allows the FDA to exempt some state and local requirements from preemption. See Riegel, 552 U.S. at 316. Plaintiffs do not contend that any exception in subsection (b) is relevant to the present analysis.

by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*)." Id. at 1120 (internal quotation marks omitted).

C. Preemption in This Case

1. Federal Requirements Applicable to Crystalens

As noted above, the first step is to ask whether the federal government has established requirements applicable to the device at issue. See Riegel, 552 U.S. at 321. In this case, there is no doubt that it has. Both parties agree that Crystalens is a Class III device that was approved through the premarket approval process. Because the premarket approval process entails a rigorous examination of nearly every aspect of a device's safety, and approval subjects a device to numerous post-approval requirements, it necessarily establishes federal requirements applicable to the device, thus allowing for preemption of state requirements that are "different from, or in addition to" the federal requirements. See Riegel, 552 U.S. at 322–23.

2. Comparison of State and Federal Requirements

The next step is to ask whether Plaintiffs' state-law claims would impose requirements "different from, or in addition to" the federal requirements. See Riegel, 552 U.S. at 322. Plaintiffs' claims rest on two theories. (See Doc. No. 22 at 4.) The court takes each of them in turn.

The first theory is that the advertising circular was false and misleading because of the statements Plaintiffs take issue with: "The risks of implantation with Crystalens are generally the same potential risks that exist for implanting all intraocular lenses," and, "Only your surgeon . . . can explain the applicable risks." (FAC ¶¶13, 28 & Exh. A.) As explained below, any claims premised on this theory are expressly preempted under § 360k(a).

As part of the premarket approval process, the FDA "must determine that the proposed labeling is neither false nor misleading." See Riegel, 552 U.S. at 318. Once approval has been granted, manufacturers may not make changes to the

labeling without the FDA's permission, see id. at 319, and all advertising must be consistent with the approved labeling, see 21 C.F.R. § 814.80.[10] Although manufacturers may issue additional post-approval safety warnings, they are not required to do so. See 21 C.F.R. § 814.39(d);[11] Stengel, 704 F.3d at 1234 (Watford, J., concurring).

In this case, the FDA-approved patient labeling for Crystalens says essentially what the circular says. As to the comparative risks of Crystalens, it states: "The complications and side effects experienced during the clinical study were similar to those experienced with other intraocular lenses and with routine cataract surgery," and, "The risks of implantation with the Crystalens are the same risks that exist for all intraocular lenses." (Doc. No. 16, Exh. A at 9.) And, regarding surgeons' ability to advise patients of the risks, the approved labeling states, among other things, "Your doctor will perform a thorough examination and fully inform you of any increased risk of a complication." (Id., Exh. A at 14.)

Thus, the only way that Plaintiffs can prevail on the theory that the circular was false and misleading is by showing that B&L had a duty to provide warnings or advisories "different from, or in addition to," those the FDA approved. Such claims

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[10] 21 C.F.R. § 814.80 reads:

> A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device.

[11] 21 C.F.R. § 814.39(d) reads in relevant part:

> (d)(1) After FDA approves a PMA, any change described in paragraph (d)(2) of this section to reflect newly acquired information that enhances the safety of the device or the safety in the use of the device may be placed into effect by the applicant prior to the receipt . . . of a written FDA order approving the PMA supplement . . . .
>
> (d)(2) The following changes are permitted by paragraph (d)(1) of this section:
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> (i) Labeling changes that add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association. . . .

are expressly preempted by § 360k(a) because "[p]remarket approval established the warning requirements applicable to the device and Defendants cannot be made to go beyond those warning requirements." Hawkins v. Medtronic, Inc., 2014 WL 346622, at *14 (E.D. Cal. Jan. 30 2014); see also Eidson, 981 F. Supp. 2d at 883–90 (same); Houston v. Medtronic, Inc., 957 F. Supp. 2d 1166, 1177–78 (C.D. Cal. 2013) (same).

Plaintiffs appear to contend that the PMA has no preemptive effect in this case because the PMA stated that "failure to comply with the conditions of approval invalidates the approval order." (Doc. No. 22 at 6.) But they do not offer any argument or citation to authority to explain why this should affect the analysis.

The court, therefore, concludes that Plaintiffs' claims are expressly preempted to the extent that they rest on the theory that the Cyrstalens advertising should have said something other than what it said.

Plaintiffs' second theory is that B&L failed to comply with its duty to report all adverse events to the FDA. To the extent that Plaintiffs' claims rely on this theory, they are not preempted, as explained below, because they fit within the exception for parallel state and federal claims.

In Stengel v. Medtronic, Inc., the Ninth Circuit held that a claim for negligent failure to warn under Arizona law was not expressly or impliedly preempted because it was premised on the manufacturer's failure to report adverse events to the FDA. See 704 F.3d at 1233. The plaintiff had been paralyzed after receiving treatment with a Class III medical device that had been approved through the premarket approval process. See id. at 1226. He alleged that the manufacturer "had violated a state-law duty of care by failing to report known risks associated with use of its medical device to the [FDA]." Id. His failure-to-warn claim was not preempted because Arizona products-liability law paralleled the FDA's reporting requirement, in that it required manufacturers to warn consumers of known dangers, and a warning to a third party, such as the FDA, would satisfy the duty. See id.

at 1233.

Similarly, in this case, Plaintiffs allege that B&L failed to comply with its duty under federal law to report all adverse events to the FDA and, by doing so, also violated its duty under California law to warn consumers of the risk of Z syndrome. Like Arizona, California requires medical-device manufacturers to warn of known or knowable risks, and they can do so by "fil[ing] adverse event reports with the FDA if that is the only available method to warn doctors and consumers." Coleman v. Medtronic, Inc., 223 Cal. App. 4th 413, 429 (2014) (employing this analysis under Stengel).

B&L contends that Stengel is distinguishable because here, unlike in Stengel, the FDA has not found any violation or taken any action against B&L. (Doc. No. 23 at 3–4.) The court need not address the argument because it was raised for the first time in B&L's reply brief, and it is unsupported by any authority or explanation. See Zamani v. Carnes, 491 F.3d 990, 997 (9th Cir. 2007) ("The district court need not consider arguments raised for the first time in a reply brief."). Regardless, at least one circuit has expressly rejected the contention that FDA action is an "implicit precondition" to this kind of suit. Hughes v. Boston Scientific Corp., 631 F.3d 762, 772–73 (5th Cir. 2011). The court is not, therefore, persuaded that this is a meaningful distinction.

Accordingly, the court concludes that under Stengel, Plaintiffs' claims are not expressly or impliedly preempted to the extent that they are premised on B&L's alleged failure to comply with its parallel state and federal duties to report adverse events to the FDA. "Most lower courts—both federal and state—that have analyzed and applied Stengel to [such claims] have held that the claims escape both express and implied preemption." Eidson v. Medtronic, Inc., — F. Supp. 2d —, 2014 WL 1996024, at *20 (N.D. Cal. May 13, 2014) (citing examples).

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D. Causation

Causation is an essential element of a products-liability claim, see Bunch v. Hoffinger Indus., 123 Cal. App. 4th 1278, 1302 (2004), and a prerequisite for standing to sue under the UCL and FAL, see Cal. Bus. & Prof. Code §§ 17204, 17535. Because the only unpreempted theory is that B&L failed to warn the FDA (as opposed to warning consumers or doctors directly), there is a "causation hurdle that would not otherwise exist." Stengel, 704 F.3d at 1234 (Watford, J., concurring). "To prevail, [Plaintiffs] will ultimately have to prove that if [B&L] had properly reported the adverse events to the FDA as required under federal law, that information would have reached [Michajlun's] doctors in time to prevent [her] injuries." Id.

As to causation, Plaintiffs allege that if B&L had communicated the adverse-event reports to the FDA as required, it "would have effectively warned surgeons, including [Michajlun's] surgeon of those adverse events . . . both directly and through discussion of those events that would have followed in the literature and at meetings [her] surgeon attended, as well as more complete information through the FDA's MAUDE database, which is available to the public at large." (FAC ¶ 44.) Further, she "would not have agreed to the Crystalens implant, and, upon information and belief, [her] surgeon would not have recommended [it] but for [B&L's] underreporting adverse events with the Crystalens, *i.e.*, Z syndrome." (Id. ¶ 46.)

B&L contends that although Plaintiffs generally allege that the failure to submit the additional adverse event reports caused the injury, they "do not state with any specificity *how* it caused the injury." (Doc. No. 15-1 at 11.) Specifically, they contend, Plaintiffs "have not alleged how the four (at most) incidents that [B&L] purportedly did not report had any causal effect on her injuries." (Id.) As support, B&L cites Hawkins, 2014 WL 346622, at *8, and Eidson, 981 F. Supp. 2d at 889, which dismissed failure-to-report claims because the plaintiffs in those cases had

not identified the relevant dates of the failures to report, so that there was no way to evaluate the causal connection.

This case does not suffer from a similar defect, as Plaintiffs have alleged relevant date ranges for the allegedly unreported adverse events that occurred prior to Michajlun's surgery. And B&L does not explain how these cases otherwise inform the present analysis. Based on the court's own research, some courts have found causal allegations resembling Plaintiffs' plausible. See Eidson, 2014 WL 1996024, at *20; Comella v. Smith & Nephew, Inc., 2013 WL 6504427, at *4 (N.D. Ill. Dec. 11, 2013). In the court's view, the limited number of unreported incidents alleged provides a thin causal connection, but a plausible connection nonetheless. Perhaps these cases are distinguishable because they involved allegations of large-scale failures to report, but that is an issue for a later date. At this point, construing the allegations in the light most favorable to Plaintiffs, and in light of B&L's failure to offer any authority to the contrary, the court declines to dismiss Plaintiffs' claims for insufficient causal allegations.

E. B&L's Additional Arguments

In addition to the arguments addressed above, B&L contends that Plaintiffs' claims must all be dismissed because the advertising circular's statements were not misleading as a matter of law and because the allegations do not meet the heightened pleading standards for averments of fraud under Federal Rule of Civil Procedure 9(b). (Doc. No. 15-1 at 13–16.)

In light of the preemption analysis, however, it is unnecessary to address these arguments. At this point, the remaining theory is completely uncoupled from the advertising circular,[12] so whether the statements were misleading does not matter. And, as set forth in the next section, simple products-liability claims for

[12] Although it would not change the analysis, the court notes that Plaintiffs do not allege that the circular would have read differently if B&L had reported the adverse events as required, and, as B&L points out, they also do not allege that Michajlun ever saw the circular or relied on it.

failure to warn are all that remain. These causes of action, which are for strict liability and negligence, do not depend upon intentional deceit.

F. Plaintiffs' Causes of Action

With these discussions in mind, the court addresses each of Plaintiffs' causes of action.

1. Strict Liability for Failure to Warn

To state a claim for strict products liability for failure to warn, a plaintiff must allege that the defendant failed to adequately warn of a known or knowable risk and that the failure caused the plaintiff's injuries. See Chavez v. Glock, Inc., 207 Cal. App. 4th 1283, 1304 (2012).

On this claim, Plaintiffs allege that Crystalens was defective and unreasonably dangerous because of inadequate post-PMA warnings; that B&L had parallel duties to warn physicians and Michajlun about the risk of Z syndrome, which were known to B&L; and that B&L breached those duties by failing to submit adverse-reaction reports to the FDA as required. (FAC ¶¶ 36–38.) B&L counters that this claim fails for the reasons addressed above.

This claim is expressly preempted to the extent that it rests on the theory that Cyrstalens advertising should have said something other than what it said. It is not preempted to the extent that it rests on the theory that B&L failed to comply with its duty to file adverse-event reports with the FDA, and at the same time breached its state-law duty to warn of dangerous product defects. The surviving aspect of this claim is supported by plausible causal allegations, so B&L's motion to dismiss it is denied.

2. Negligent Failure to Warn

To state a claim for negligent failure to warn, the plaintiff must allege "that a manufacturer or distributor did not warn of a particular risk for reasons which fell below the acceptable standard of care, *i.e.*, what a reasonably prudent manufacturer would have known and warned about." Id. at 1305 (internal quotation marks

omitted). The same analysis that applies to Plaintiffs' strict-liability claim applies here. Accordingly, B&L's motion to dismiss this claim is also denied.

3. Deceptive Advertising

California's False Advertising Law prohibits any "unfair, deceptive, untrue, or misleading advertising." Cal. Bus. & Prof. Code § 17500. To prevail on this claim, Plaintiffs would have to show that B&L should have provided warnings to the public "different from, or in addition to" those approved by the FDA. This claim is expressly preempted by the MDA, and nothing remains. It is, therefore, dismissed without leave to amend.

4. Deceptive Business Practices

California's Unfair Competition Law prohibits any "unlawful, unfair or fraudulent business act or practice." Cal. Bus. & Prof. Code § 17200. This claim is subject to the same analyses that apply to Plaintiffs' products-liability claims. Here, however, two additional considerations not relevant to the common-law claims compel the conclusion that this claim must be dismissed without leave to amend.

First, B&L contends that this claim must be dismissed without leave to amend[13] because the equitable relief Plaintiffs seek is unavailable as a matter of law. (Doc. No. 15-1 at 16–17.) It argues that the UCL provides only equitable relief; equitable relief is available only when money damages are inadequate; California courts have extended this principle to claims under the UCL; and Plaintiffs have not shown that money damages would be inadequate. (Id.) In support, B&L cites a case that dismissed a UCL claim because money damages would adequately redress the plaintiffs' injuries if they were to prevail on other causes of action. See Rhynes v. Stryker Corp., 2011 WL 2149095, at *3–4 (N.D. Cal. May 31, 2011). That case, in turn, relied on Prudential Home Mortgage Co. v. Superior Court, 66 Cal. App.

[13] B&L asserts that dismissal should be with prejudice, which the court construes as a request for dismissal without leave to amend.

4th 1236 (1998), which held that statutory relief under the UCL "is subject to fundamental equitable principles, including inadequacy of the legal remedy." Id. at 1249.

Plaintiffs counter only that B&L has mischaracterized Plaintiffs' claims as claims for money damages, when in reality they seek restitutionary disgorgement of the profits B&L earned from its sales of Crystalens. (Doc. No. 22 at 12.) Plaintiffs do not address Rhynes and do not attempt to explain why money damages on their common-law claims will not adequately redress their injuries.

By failing to address B&L's argument in any meaningful way, Plaintiffs have effectively waived the issue. See Stichting Pensioenfonds ABP v. Countrywide Fin. Corp., 802 F. Supp. 2d 1125, 1132 (S.D. Cal. 2011) ("[I]n most circumstances, failure to respond in an opposition brief to an argument put forward in an opening brief constitutes waiver or abandonment in regard to the uncontested issue." (internal quotation marks omitted)).

Second, although not raised by the parties, the court concludes that the surviving theory cannot support a cognizable claim under the UCL. As discussed above, all that remains is the theory that B&L violated its duty under California law to warn the FDA (a common-law claim), and at the same time ran afoul of FDA reporting requirements (a claim that B&L violated FDA regulations). Plaintiffs assert that this theory "has nothing to do with false or misleading ad literature," and is brought under the "unlawful" prong of the UCL. (Doc. No. 22 at 9–10.)

At first glance, this approach should work. According to California courts, the "unlawful" prong of the UCL proscribes "anything that can be properly called a business practice and that at the same time is forbidden by law." Farmers Ins. Exchange v. Superior Court, 2 Cal. 4th 377, 383 (1992). It prohibits "any practices forbidden by law, be it civil or criminal, federal, state, or municipal, statutory, regulatory, or *court-made*." Saunders v. Superior Court, 27 Cal. App. 4th 832, 838–39 (1994) (emphasis added).

But, despite this sweeping language, courts have held that common-law claims unaccompanied by a violation of some other law cannot support a claim under the "unlawful" prong of the UCL. See Shroyer v. New Cingular Wireless Servs., Inc., 622 F.3d 1035, 1044 (9th Cir. 2010) ("[A] common law violation such as breach of contract is insufficient [to allege a violation of the "unlawful" prong of the UCL]."); TreeFrog Devs., Inc. v. Seidio, Inc., 2013 WL 4028096, at *5 (S.D. Cal. Aug. 6, 2013) ("Because Defendant's allegation of Plaintiff's 'unlawful' act rests entirely on common law theories, Defendant fails to sufficiently allege a UCL claim under the 'unlawful' prong."). For this reason, some courts have rejected UCL "unlawful" claims premised on products-liability claims. See Hartless v. Clorox Co., 2007 WL 3245360, at *5 (S.D. Cal. Nov. 2, 2007) (common-law products-liability claim was insufficient to support a UCL claim); Klein v. Earth Elements, Inc., 59 Cal. App. 4th 965, 969 (1997) (same).

Here, Plaintiffs combine products-liability claims with alleged violations of FDA regulations. They thus appear to present the kind of allegations that can support a claim under the "unlawful" prong of the UCL.

The problem, however, is that private claims to enforce violations of the FDCA are impliedly preempted because the FDA alone is empowered to enforce it. See Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001); Perez v. Nidek Co., 711 F.3d 1109 (9th Cir. 2013). "Although citizens may petition the FDA to take administrative action, private enforcement of the statute is barred. . . ." Perez, 711 F.3d at 1119 (citation omitted).

Because common-law claims cannot be the basis of a UCL "unlawful" claim, and private actions to enforce the FDCA are barred, combining them cannot result in a viable claim under the "unlawful" prong of the UCL. See Cel-Tech Commc'ns, Inc. v. Los Angeles Cellular Tel. Co., 20 Cal. 4th 163, 182 (1999) ("A plaintiff may . . . not plead around an absolute bar to relief simply by recasting the cause of action as one for unfair competition.") (internal quotation marks omitted).

Accordingly, for both of the reasons discussed above, this claim is dismissed without leave to amend.

5. Loss of Consortium

Markoff's claim for loss of consortium is contingent on Michajlun's claims. See Tucker v. CBS Radio Stations, Inc., 194 Cal. App. 4th 1246, 1256 (2011). Because two of Michajlun's claims remain, this claim also remains.

CONCLUSION

B&L's request for judicial notice, (Doc. No. 16), is GRANTED. Its motion to dismiss Plaintiffs' first amended complaint, (Doc. No. 15), is GRANTED IN PART AND DENIED IN PART as follows:

1. B&L's motion to dismiss Plaintiffs' claims for strict liability for failure to warn, negligent failure to warn, and loss of consortium is DENIED. These claims survive to the extent that they are premised on B&L's alleged failure to warn the FDA.
2. B&L's motion to dismiss Plaintiffs' putative class claims under the FAL and UCL is GRANTED. These claims are dismissed without leave to amend.

IT IS SO ORDERED.

DATED: March 11, 2015

Hon. Jeffrey T. Miller
United States District Judge