UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

MICHELLE KINNEE,

Plaintiff,

v.

TEI BIOSCIENCES INC.; INTEGRA LIFESCIENCES CORPORATION; LIFESCIENCE SALES LLC; and DOES 1 through 50, inclusive,

Defendants.

Case No.: 22-CV-604 JLS (DDL)

ORDER (1) GRANTING DEFENDANTS' REQUEST FOR JUDICIAL NOTICE AND (2) GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTION TO DISMISS

(ECF No. 42)

Presently before the Court is Defendants Integra LifeSciences Sales LLC's ("Integra Sales") and Integra LifeSciences Corporation's ("Integra") (collectively, "Defendants") Motion to Dismiss ("Mot.," ECF No. 42). Also before the Court is Defendants' Memorandum of Points and Authorities ("Mem.," ECF No 42-1) and Request for Judicial Notice ("RJN," ECF No. 42-2) in support thereof. Plaintiff Michelle Kinnee filed an Opposition to the Motion ("Opp'n," ECF No. 43), to which Defendants filed a Reply ("Reply," ECF No. 46). The Court then took this matter under submission without oral argument. *See* ECF No. 47. Having carefully reviewed Plaintiff's First Amended Complaint ("FAC," ECF No. 41), the Parties' arguments, and the law, the Court **GRANTS** Defendants' RJN and **GRANTS IN PART AND DENIES IN PART** Defendants' Motion.

BACKGROUND[1]

The Court incorporates the recitations of this action's factual and procedural history contained in its October 24, 2022 and May 18, 2023 Orders (ECF Nos. 23 & 40, respectively). The Court thus sets forth only those facts relevant to the instant Motion.

At issue in this case is the SurgiMend Collagen Matrix ("SurgiMend") device. FAC ¶ 2–3, 6, 10. On April 26, 2017, Plaintiff was implanted with SurgiMend during a ventral hernia repair. *Id.* ¶¶ 10, 31. The SurgiMend device malfunctioned three years later, causing serious complications that necessitated surgery and a week-long hospital stay. *Id.* ¶ 32. Because the device's mesh "had become entwined with and eroded into Plaintiff's bowel," Plaintiff experienced "bowel injury, bowel blockage, bowel perforation, severe inflammatory response, and pain." *Id.*

Plaintiff initiated this action on April 28, 2022, by filing her original Complaint ("Compl., ECF No. 1) against Integra, Intregra Sales, and a third defendant—TEI Biosciences, Inc. ("TEI"). *See generally* Compl. Defendants responded with motions to dismiss, arguing that the Court lacked personal jurisdiction over Defendants and that Plaintiff had failed to state a claim. *See generally* ECF Nos. 10–12. The Court granted Defendants' motions and afforded Plaintiff sixty days to conduct jurisdictional discovery and file an amended complaint. *See generally* ECF No. 23. After some additional back and forth, the Parties dismissed TEI from this case by stipulation. ECF No. 32 at 2.

On May 25, 2023, Plaintiff filed her FAC. In it, Plaintiff alleges that Integra was "involved in overseeing the quality system, post-market surveillance and marketing" of SurgiMend, FAC ¶ 15, while Integra Sales "was involved in the [device's] marketing and sale[]," *id.* ¶ 16. She also states that Defendants' internal data and post-market surveillance showed that SurgiMend's design was not reasonably safe. *Id.* ¶ 19. Nevertheless, Defendants continued marketing SurgiMend to physicians, including Plaintiff's

---

[1] The facts alleged in Plaintiff's FAC are accepted as true for purposes of Defendants' Motion. *See Vasquez v. Los Angeles Cty.*, 487 F.3d 1246, 1249 (9th Cir. 2007) (holding that, in ruling on a motion to dismiss, the Court must "accept all material allegations of fact as true").

prescribing physician. *Id.* ¶¶ 17–18. Per Plaintiff, Defendants' actions in continuing to manufacture, sell, and distribute the device caused her injuries. *See generally id.* On the basis of those allegations, Plaintiff asserts causes of action for strict products liability, negligence, fraudulent concealment, and breach of express warranty. *See generally id.* The FAC also includes a prayer for punitive damages. *See id.* ¶¶ 74–87.

The instant Motion followed.

REQUEST FOR JUDICIAL NOTICE

Defendants request judicial notice of (1) a redlined comparison of the FAC and Plaintiff's original Complaint ("Ex. A," ECF No. 42-3); (2) a report on "Hernia Surgical Mesh Implants" posted on the U.S. Food and Drug Administration ("FDA") website ("Ex. B," ECF No. 42-4); and (3) a different report on "Hernia Surgical Mesh Implants" posted on the FDA website, generated using the WayBack Machine ("Ex. C," ECF No. 42-5). *See generally* RJN. Defendants also ask the Court to consider the "SurgiMend Instructions for Use" ("Ex. D," ECF No. 42-6), pursuant to Federal Rule of Evidence 201 and the incorporation-by-reference doctrine. *See generally id.*

I. Legal Standard

"Generally, district courts may not consider material outside the pleadings when assessing the sufficiency of a complaint under Rule 12(b)(6) of the Federal Rules of Civil Procedure." *Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 998 (9th Cir. 2018) (citing *Lee v. City of Los Angeles*, 250 F.3d 668, 688 (9th Cir. 2001)). "There are two exceptions to this rule: the incorporation-by-reference doctrine, and judicial notice under Federal Rule of Evidence 201." *Id.*

Under the first exception, a document "not attached to a complaint . . . may be incorporated by reference into a complaint" in two ways. *United States v. Ritchie*, 342 F.3d 903, 908 (9th Cir. 2003). First, a document can be incorporated into a complaint if "the plaintiff refers extensively" to the document. *Id.* "[T]he mere mention of the existence of a document is insufficient . . . ." *Khoja*, 899 F.3d at 1002 (quoting *Coto Settlement v. Eisenberg*, 593 F.3d 1031, 1038 (9th Cir. 2010)). Additionally, a document

may be incorporated if it "forms the basis of the plaintiff's claim." *Ritchie*, 342 F.3d at 908. This occurs when "the claim necessarily depend[s] on the [document]." *Khoja*, 899 F.3d at 1002 (citing *Knievel v. ESPN*, 393 F.3d 1068, 1076 (9th Cir. 2005)). "However, if the document merely creates a defense to the well-pled allegations in the complaint, then that document did not necessarily form the basis of the complaint." *Id.*

When a document is incorporated by reference, "the district court may treat such a document as part of the complaint, and thus may assume that its contents are true for purposes of a motion to dismiss under Rule 12(b)(6)." *Ritchie*, 342 F.3d at 908. That said, "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.

Meanwhile, under the second exception, "[t]he court may judicially notice a fact that is not subject to reasonable dispute because it: (1) is generally known within the trial court's territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b). "Accordingly, '[a] court may take judicial notice of matters of public record . . . .'" *Khoja*, 899 F.3d at 999 (alteration in original) (quoting *Lee*, 250 F.3d at 689). "But a court cannot take judicial notice of disputed facts contained in such public records." *Id.*

II. Analysis

A. Redlined Comparison of the FAC Against Plaintiff's Original Complaint

Defendants argue that Exhibit A is properly subject to judicial notice because Plaintiff's initial and amended complaints are pleadings that "are part of the record" and the redlined comparison's accuracy can be "readily determined." RJN at 2. Plaintiff does not contest judicial notice of Exhibit A. *See generally* Opp'n.

The Court agrees that judicial notice of Exhibit A is appropriate. Generally, courts may take judicial notice of court filings, as such records "are readily verifiable." *Reyn's Pasta Bella, LLC v. Visa USA, Inc.*, 442 F.3d 741, 746 n.6 (9th Cir. 2006). This includes documents "already before the Court." *Clifford v. Regents of Univ. of Cal.*, No. 2:11-CV-02935, 2012 WL 1565702, at *5 (E.D. Cal. Apr. 30, 2012), *aff'd*, 584 F. App'x 431

(9th Cir. 2014). And whether Exhibit A correctly captures the differences and similarities between the original Complaint and the FAC "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned"—*i.e.*, documents previously filed in this case. Fed. R. Evid. 201(b)(2).

The Court also notes that, pursuant to Civil Local Rule 15.1(c), "[a]ny amended pleading filed after the granting of a motion to dismiss . . . with leave to amend, must be accompanied by a version of that pleading that shows—through redlining . . . or similarly effective typographic methods—how that pleading differs from the previously dismissed pleading." Plaintiff's failure to provide such a version of the FAC is yet another reason for the Court to accept Exhibit A. *See Charter Twp. of Clinton Police & Fire Ret. Sys. v. LPL Fin. Holdings Inc.*, No. 16-CV-685-BTM-BGS, 2019 WL 13178511, at *2 (S.D. Cal. Mar. 29, 2019). The Court therefore **GRANTS** Defendants' RJN as to Exhibit A.

B. Discussions Posted on the FDA's Website (Exhibits B and C)

Defendants claim that judicial notice of Exhibits B and C is appropriate because both are available on a governmental agency's website. RJN at 2. Plaintiff does not appear to contest Defendant's RJN as to Exhibit B; instead, she argues only that Exhibit B does little to support Defendants' Motion. *See* Opp'n at 8–9. Plaintiff does not address Exhibit C.

District courts may take judicial notice of information published by government entities when, as here, "neither party disputes the authenticity of the web sites or the accuracy of the information displayed therein." *Daniels-Hall v. Nat'l Educ. Ass'n*, 629 F.3d 992, 998–99 (9th Cir. 2010). This principle applies to documents found on the FDA's website. *See e.g.*, *In re Amgen Inc. Sec. Litig.*, 544 F. Supp. 2d 1009, 1023–24 (C.D. Cal. 2008).

Regarding Exhibit C specifically, "[c]ourts have taken judicial notice of internet archives in the past, including Archive.org's 'Wayback Machine,' finding that Archive.org possesses sufficient indicia of accuracy." *EVO Brands, LLC v. Al Khalifa Grp. LLC*, No. 2:22-CV-03909-AB-MAR, 2023 WL 2768743, at *4 (C.D. Cal. Feb. 23, 2023); *see also United States ex rel. Hong v. Newport Sensors, Inc.*, No. SACV131164JLSJPRX,

2016 WL 8929246, at *3 (C.D. Cal. May 19, 2016) ("[D]istrict courts in this circuit have routinely taken judicial notice of content from the Internet Archive's Wayback Machine . . . ."), *aff'd*, 713 F. App'x 724 (9th Cir. 2018).

As Plaintiff does not contest the accuracy or authenticity of the reports contained within Exhibits B or C, the Court **GRANTS** Defendants' RJN as to both documents. The Court will not, however, take judicial notice of "facts contained therein that may be subject to reasonable dispute." *Mortimer v. Bank of Am., N.A.*, No. C-12-01959 JCS, 2013 WL 1501452, at *1 (N.D. Cal. Apr. 10, 2013).

C. SurgiMend Instructions for Use

Lastly, Defendants argue that Exhibit D is properly subject to judicial notice because it is available on Integra's public website and is incorporated by reference into the FAC. RJN at 2. Plaintiff provides no argument to the contrary. *See generally* Opp'n.

The Court agrees with Defendants. Plaintiff references the Instructions for Use ("Instructions") to establish that Defendants failed to warn prescribing physicians of the risks associated with SurgiMend. *See* FAC ¶¶ 45–46. Plaintiff's claims thus necessarily rely on—and thereby incorporate by reference—the Instructions. *See Roshkovan v. Bristol-Myers Squibb Co.*, No. ED CV 21-8590-FWS-AGR, 2022 WL 3012519, at *5 (C.D. Cal. June 22, 2022).

Accordingly, the Court **GRANTS** Defendants' request for judicial notice of Exhibit D pursuant to the incorporation-by-reference doctrine.

MOTION TO DISMISS

I. Legal Standard

Federal Rule of Civil Procedure 12(b)(6) permits a party to raise by motion the defense that the complaint "fail[s] to state a claim upon which relief can be granted." To survive a 12(b)(6) motion, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is facially plausible when the facts pled "allow[] the court to draw the reasonable inference

that the defendant is liable for the misconduct alleged." *Id.* That is not to say that the claim must be probable, but there must be "more than a sheer possibility that a defendant has acted unlawfully." *Id.* Facts "'merely consistent with' a defendant's liability" fall short of a plausible entitlement to relief. *Id.* (quoting *Twombly*, 550 U.S. at 557).

Though this plausibility standard "does not require 'detailed factual allegations,' . . . it [does] demand[] more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Id.* (quoting *Twombly*, 550 U.S. at 555). In other words, a complaint will not suffice "if it tenders 'naked assertion[s]' devoid of 'further factual enhancement.'" *Id.* (alteration in original) (quoting *Twombly*, 550 U.S. at 557). Put differently, "a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555.

Review under Rule 12(b)(6) requires a context-specific analysis involving the Court's "judicial experience and common sense." *Iqbal*, 556 U.S. at 679. In performing that analysis, "a district court must accept as true all facts alleged in the complaint, and draw all reasonable inferences in favor of the plaintiff." *Wi-LAN Inc. v. LG Elecs., Inc.*, 382 F. Supp. 3d 1012, 1020 (S.D. Cal. 2019). "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not 'show[n]'—'that the pleader is entitled to relief.'" *Iqbal*, 556 U.S. at 679 (second alternation in original). If a complaint does not survive Rule 12(b)(6), a court grants leave to amend unless it determines that no modified contention "consistent with the challenged pleading could . . . possibly cure the deficiency." *Schreiber Distrib. Co. v. Serv-Well Furniture Co.*, 806 F.2d 1393, 1401 (9th Cir. 1986).

II. Analysis

Defendants move to dismiss Plaintiff's FAC in its entirety, contending that the FAC uses boilerplate language and lacks specificity. *See* Mem. at 7–9. Defendants also provide arguments for dismissing each of Plaintiff's individual causes of action, which include claims for strict products liability, negligence, fraudulent concealment, and breach of express warranty, as well as a prayer for punitive damages. *See generally* FAC; Mem. The

Court will address each issue in turn. In so doing, "[b]ecause this is a diversity action," the Court will "apply California substantive law and federal rules of procedure." *Motus v. Pfizer Inc.*, 358 F.3d 659, 660 (9th Cir. 2004).

A. Boilerplate Language

Defendants first contend that Plaintiff's FAC uses "boilerplate" language irrelevant to SurgiMend. Mem. at 7. Defendants claim the FAC resembles pleadings from unrelated cases and suggest that parts of the FAC were "copied and pasted" for reuse in this matter.[2] *Id.* Per Defendants, the FAC is thus "devoid of any facts" pertaining to Plaintiff's own experience with SurgiMend. Reply at 10. And, Defendants argue, as Federal Rule of Civil Procedure 8(a) "does not permit plaintiff to file a boilerplate complaint containing generalized allegations," the FAC should be dismissed and amended. Mem. at 7 (quoting *Heinemann v. Copperhill Apartments*, No. 07-cv-00018, 2007 WL 2225790, at *1 (E.D. Cal. July 31, 2007)).

To the extent Defendants are attempting to derive a bright-line rule against borrowed language from the Federal Rules of Civil Procedure, the Court rejects their argument. The question here is not whether the FAC contains borrowed language, but whether the FAC includes sufficiently well-pled factual allegations so as to "allow[] the court to draw the reasonable inference that the defendant is liable." *Iqbal*, 556 U.S. at 678. This approach is reinforced by the very cases Defendant cites, both of which suggest only that truly generic complaints are too conclusory and non-specific to pass muster under *Iqbal* and *Twombly*. *See Heinemann*, 2007 WL 2225790, at *1 & n.2 (dismissing "boilerplate complaint containing generalized," "broad," and "conclusory allegations"); *Woodson v. Countrywide Home Loans*, No. 09CV2707-LAB (JMA), 2010 WL 2573479, at *5 (S.D. Cal. June 24, 2010) (dismissing complaint that relied on pleading standards pre-dating *Iqbal* and *Twombly*).

[2] Notably, Defendants neither provide citations to—nor ask the Court to take judicial notice of—any such complaints filed in other cases.

The Court therefore declines to dismiss the FAC based on the presence of "boilerplate" language and instead turns to the more pertinent question posed by Defendants' Motion: whether Plaintiff has pleaded sufficient facts to support her claims.

B. Strict Products Liability—Failure to Warn

To sufficiently state a failure-to-warn claim, a plaintiff must establish that (1) the warning provided was inadequate, and (2) an adequate warning would have altered the prescribing physician's conduct. *See Motus*, 358 F.3d at 661. In their Motion, Defendants contend they had no duty to warn physicians of "well-known risks" that may come with the use of SurgiMend. *See* Mem. at 9. Alternatively, Defendants argue they satisfied any duty they might have owed because the warnings provided were adequate. *See id.* Finally, Defendants claim Plaintiff failed to plausibly plead causation. None of Defendants' arguments succeed.

1. Duty to Warn

Defendants claim to fall under an exception to the general rule that, in California, "manufacturers have a duty to warn consumers about the hazards inherent in their products." *Johnson v. Am. Standard, Inc.*, 179 P.3d 905, 910 (Cal. 2008). Specifically, Defendants argue they had no duty to warn of SurgiMend's risks under the sophisticated intermediary and learned intermediary doctrines. Mem. at 9–11.

Under the sophisticated intermediary doctrine, "a supplier may discharge its duty to warn end users" if the supplier "sells to a sophisticated purchaser that it knows is aware or should be aware of the specific danger" posed by a product. *Webb v. Special Elec. Co.*, 370 P.3d 1022, 1034 (Cal. 2016). So, when a "buyer [is] so knowledgeable about the material supplied that it kn[ows] or should [know] about the particular danger," the buyer's "sophistication can be a substitute for actual warnings." *Id.* at 1035.

The related learned intermediary doctrine requires medical manufacturers and suppliers to "warn doctors, not patients, of potential side-effects." *Motus*, 358 F.3d at 661 (citing *Carlin v. Superior Ct.*, 920 P.2d 1347, 1354 (Cal. 1996)); *see also Brown v. Superior Ct.*, 751 P.2d 470, 477 n.9 (Cal. 1988) ("[A] manufacturer fulfills its duty to warn

if it provides adequate warning to the physician.").

Defendants claim they owed no duty to warn Plaintiff or her physicians due to the combined effect of the sophisticated and learned intermediary doctrines. *See* Mem. at 10–11. Defendants cite the learned intermediary doctrine for the premise that they, as device manufacturers, "do not have a duty to warn patients of risks"; instead, that duty "runs to physicians." *Id.* at 10. Defendants then assert that "a physician would be considered a *sophisticated* user" regarding "the risks of hernia surgeries and mesh products generally." *Id.* at 11 (emphasis added). So, per Defendants, Plaintiff's treating physician was a "sophisticated intermediary" that Defendants were not required to warn. *Id.*

Defendants' argument, however, conflates two distinct rules. While both doctrines are "related," they apply in different circumstances. *Webb*, 370 P.3d at 1034 n.10. Where, as here, "drugs or medical devices are supplied in the context of the doctor-patient relationship," California courts apply the *learned*—not the sophisticated—intermediary doctrine. *Id.* As cases discussing one of the doctrines have little bearing on cases applying the other, Defendants' attempt to avoid *any* duty to warn Plaintiff's physicians under the *sophisticated* intermediary doctrine fails. *See Riera v. Mecta Corp.*, No. 2:17-CV-06686-RGK-JC, 2021 WL 2024688, at *5 (C.D. Cal. May 14, 2021), *aff'd in part sub nom. Himes v. Somatics, LLC*, No. 21-55517, 2022 WL 989469 (9th Cir. Apr. 1, 2022).

Under the learned intermediary doctrine, medical device manufacturers have a duty to "adequately warn" physicians of risks that are "known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution." *Carlin*, 920 P.2d at 1351 (quoting *Anderson v. Owens-Corning Fiberglas Corp.*, 810 P.2d 549, 559 (Cal. 1991)). The warning requirement's purpose "is to inform consumers about a product's hazards and faults of which they are unaware, so that they can refrain from using the product altogether or evade the danger by careful use." *Johnson*, 179 P.3d at 910.

True, manufacturers need not warn of risks "which [are] readily known and apparent" to the medical community. *Plenger v. Alza Corp.*, 13 Cal. Rptr. 2d 811, 819

(Ct. App. 1992). In *Plenger*, for example, the argument that a manufacturer failed to adequately warn physicians of the "risk of death" from "pelvic infection" was unsuccessful in part because said risk was "universally known in the medical profession." *Id.*

But *Plenger* has little relevance here. For one thing, "whether the risks and complications were known to the medical community is a question for the jury." *Hurd v. Bos. Sci. Corp.*, No. 5:22-CV-00032-JWH-KK, 2023 WL 3564741, at *3 (C.D. Cal. Apr. 10, 2023) (citation omitted). Further, unlike the death-by-infection risk at issue in *Plender*, the FAC does not discuss the risks associated with SurgiMend in broad terms. Instead, Plaintiff alleges that SurgiMend "posed a significant . . . risk of" complications including "recurrence," "degradation," or "disintegration," and several specific bowel injuries like "blockage," "perforation," and "adhesions." FAC ¶ 38.

Nor is the Court persuaded by Defendants' attempt to use two reports from the FDA's website as evidence that the risks of mesh hernia surgeries were well known. *See id.* (citing RJN Exs. B & C). Indeed, courts have refused to make the "tremendous leap in logic" required to conclude that the "publication of FDA warnings" suffices "to establish that a risk is 'known to the medical community.'" *Hurd*, 2023 WL 3564741, at *3 (quoting *Carlin*, 920 P.2d at 1354).

Here, the FAC adequately pleads that Defendants owed a duty to warn under the learned intermediary doctrine. The FAC alleges SurgiMend was prescribed to—and implanted in—Plaintiff by her physicians. *See* FAC ¶ 48. Defendants thus owed the duty to "adequately warn" Plaintiff's physicians of certain risks associated SurgiMend, which Defendants allegedly failed to do. *See id.* ¶¶ 45–49.

2. Adequacy of Warning

Defendants next argue that the FAC must be dismissed because the warning they provided was adequate. *See* Mem at 12. As a decision on the adequacy of Defendants' warning would be premature, the Court disagrees.

Not surprisingly, the Parties define adequacy differently. Per Defendants, the FAC alleges only that SurgiMend entwined with and eroded Plaintiff's bowel, thereby causing

a severe inflammatory response and pain. *See id.* As SurgiMend's Instructions note that "[g]eneral risks" of using the product may include "adhesions," "pain," and "acute or chronic inflammatory reactions," Defendants argue, SurgiMend's warning was adequate as a matter of law. *Id.* (alteration in original). Plaintiff counters that Defendants failed to adequately warn of "the true risk" associated with SurgiMend. Opp'n at 5.

"Whether a warning is adequate is generally a question of fact, which is usually left to the jury." *Woods v. Davol, Inc.*, No. 16-CV-02616-KJM-CKD, 2017 WL 3421973, at *5 (E.D. Cal. Aug. 9, 2017) (citations omitted). Courts thus typically do not resolve the issue of a warning's adequacy at the pleading stage. *See id.* Only when it addresses "in plain and explicit terms" the "specific risk that has caused injury to the plaintiff" may a warning be deemed adequate as a matter of law. *Utts v. Bristol-Myers Squibb Co.*, 251 F. Supp. 3d 644, 673 (S.D.N.Y. 2017) (applying California law), *aff'd sub nom. Gibbons v. Bristol-Myers Squibb Co.*, 919 F.3d 699 (2d Cir. 2019). "Where a warning" is "ambiguous," adequacy remains "a question of fact for the jury." *Miles Lab'ys, Inc. v. Superior Ct.*, 184 Cal. Rptr. 98, 104 (Ct. App. 1982).

Here, the issue of adequacy poses questions of fact that the Court cannot resolve at this stage. Defendants contend that a general warning relating to a plaintiff's injury is "adequate." *See* Mem. at 13. But whether a generalized warning satisfies a manufacturer's duty depends on the facts and circumstances surrounding each case. *See Zetz v. Bos. Sci. Corp.*, 398 F. Supp. 3d 700, 707 (E.D. Cal. 2019) (denying motion to dismiss where "some of the problems associated with [a medical device] were made known to physicians" but "the magnitude and frequency of these problems were not disclosed"); *Woods*, 2017 WL 3421973, at *5 ("[W]hether defendants' general 'adhesions' warning was adequate [is an] issue[] of fact.").

The cases Defendants rely on do not state otherwise. In *Marroquin v. Pfizer, Inc.*, the court found a warning adequate when (1) it extensively discussed the risk of pulmonary toxicity—the "exact danger" that befell the plaintiff—by disclosing the "[p]ercentages of those who experience[d]" and died from such toxicity; (2) the drug's label "clearly state[d]"

that the product was one "of last resort because of its potentially fatal toxicities"; and (3) the plaintiff did not "explain how or why the warnings provided were inadequate." 367 F. Supp. 3d 1152, 1161–63 (E.D. Cal. 2019). *Marroquin* thus bears little resemblance to this case, in which SurgiMend's warning appears to disclose only general risks, and Plaintiff alleges several ways in which said warning was inadequate.

The other cases Defendants cite also involved much more detailed warnings than the one presented here. *See Kearl v. Lederle Lab'ys*, 218 Cal. Rptr. 453, 467 (finding vaccine warning adequate as it described an "alternative vaccine," noted that the alternative carried less risk, and "specifically invited" consumers to "inquire further"); *Utts*, 251 F. Supp. 3d at 675 (holding warning adequate where the "risk of excessive bleeding" and "absence of an antidote" were "fully disclosed," "advice [was] given about" when use of the drug "should be discontinued," and physicians were told "that standard blood tests" would not be "useful in monitoring" for side effects).

The Court must thus decline Defendants' invitation to decide, at this stage, whether SurgiMend's warning was adequate as a matter of law.

3. Causation

In their Reply—but not in their Motion—Defendants appear to argue that their alleged failure to warn did not cause Plaintiff's injury. For support, Defendants cite a case in which the court required a plaintiff to allege "that the inadequacy or absence of the warning caused the plaintiff's injury." *Motus v. Pfizer Inc.*, 196 F. Supp. 2d 984, 991 (C.D. Cal. 2001). Because Plaintiff did not suffer from the specific injuries about which she alleges Defendants ought to have warned her, Defendants argue, her failure to warn claim must fail. *See* Reply at 1.

Defendants' argument is, at best, underdeveloped. Defendants fail to apply the causation standard that courts use when evaluating strict liability failure-to-warn claims. In such cases, a plaintiff must show that the failure to warn was "a substantial factor in causing the plaintiff's harm," meaning that "the prescribing physician's conduct would have changed if an adequate warning had been given." *Crawford v. Zimmer Biomet*

Holdings, Inc., No. 1:21-CV-0988 AWI CDB, 2023 WL 2189425, at *5 (E.D. Cal. Feb. 23, 2023). Defendants make no effort to show how the FAC fails to meet that standard, and the Court declines to develop Defendants' argument for them.

Worse still, Defendants' argument is built on demonstrably incorrect statements. Per Defendants, Plaintiff failed to "plead that the injury she allegedly sustained was not warned of," as she did not claim to have suffered from "a 'bowel blockage[] or perforation,' a 'recurrence, degradation, or disintegration,'" or "an 'inflammatory response.'" Reply at 1 (alteration in original and emphasis omitted). Perhaps Defendants are working off a different document, but to the Court it very much appears Plaintiff *did* make such allegations. *See* FAC ¶ 32 (stating Plaintiff suffered from such complications as "bowel *blockage*, bowel *perforation*," and a "severe *inflammatory response*" (emphases added)).

In light of the above, the Court **DENIES** Defendants' Motion to Dismiss as to Plaintiff's strict liability failure-to-warn claim.

C. Negligence Claim

To state a negligence claim in California, a plaintiff must establish "a legal duty to use due care, a breach of such legal duty, and [that] the breach [is] the proximate or legal cause of the resulting injury." *Kesner v. Superior Ct.*, 384 P.3d 283, 289 (Cal. 2016) (alterations in original) (quoting *Beacon Residential Community Ass'n v. Skidmore, Owings & Merrill LLP*, 327 P.3d 850, 853 (Cal. 2014)). Stating a products liability claim grounded in negligence requires the same showing. *See, e.g.*, *Rodman v. Otsuka Am. Pharm., Inc.*, 564 F. Supp. 3d 879, 893 (N.D. Cal. 2020), *aff'd*, No. 20-16646, 2021 WL 5850914 (9th Cir. Dec. 9, 2021). Plaintiffs must be careful to show "both that a defect caused the injury and 'that the defect in the product was due to negligence of the defendant.'" *Hannan v. Bos. Sci. Corp.*, No. 19-CV-08453-PJH, 2020 WL 2128841, at *8 (N.D. Cal. May 5, 2020) (quoting *Merrill v. Navegar, Inc.*, 28 P.3d 116, 124 (Cal. 2001)).

That Defendants owed a legal duty is not in question. In California, a manufacturer "owes a duty of care to foreseeable users of its products." *Bettencourt v. Hennessy Indus., Inc.*, 141 Cal. Rptr. 3d 167, 179 (Cal. Ct. App. 2012). Defendants instead challenge

Plaintiff's negligence claim on the grounds that the FAC fails to allege (1) "any relevant breach" of a legal duty, and (2) "any causal link between the alleged breach and Plaintiff's alleged injury." Mem. at 13.

Products liability claims sounding in negligence can be premised on three theories: "design defect, manufacturing defect, or failure to warn." *Trejo v. Johnson & Johnson*, 220 Cal. Rptr. 3d 127, 139 (Ct. App. 2017). The causation inquiry remains the same under each theory: a plaintiff must show "that a defect caused the injury." *Marroquin*, 367 F. Supp. 3d at 1164. Specifically, Plaintiff must show that a SurgiMend defect "was a substantial factor in producing [her] injury." *Soule v. Gen. Motors Corp.*, 882 P.2d 298, 312 (Cal. 1994). Each theory, however, comes with its own method for defining breach. *See Marroquin*, 367 F. Supp. 3d at 1164. As Plaintiff appears to invoke all three theories, *see generally* FAC at 12–14, the Court will apply Defendants' arguments to each one.

1. Design Defect

There are two tests for negligent design. The risk-benefit test "involves a balancing of the likelihood of harm to be expected from . . . a given design and the gravity of harm if it happens against the burden of the precaution which would . . . avoid the harm." *Merrill*, 28 P.3d at 125 (quoting *Pike v. Frank G. Hough Co.*, 467 P.2d 229, 232 (Cal. 1970)). Meanwhile, the consumer expectations test asks whether "the product has failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner." *Barker v. Lull Eng'g Co.*, 573 P.2d 443, 446 (Cal. 1978).

To survive a motion to dismiss, plaintiffs must identify what aspects of a product make it defective. *Marroquin*, 367 F. Supp. 3d at 1164. A plaintiff should also "identify which design defect theory is being utilized and allege facts to support that theory." *In re Toyota Motor Corp.*, 754 F. Supp. 2d 1208, 1220 (C.D. Cal. 2010). A "bare allegation" that the product "suffered from a 'design defect'" will not suffice. *Lucas v. City of Visalia*, 726 F. Supp. 2d 1149, 1155 (E.D. Cal. 2010) (citing *Iqbal*, 556 U.S. at 680–81).

Plaintiff meets these requirements. The FAC alleges a variety of ways in which SurgiMend is defective. For example, Plaintiff alleges that SurgiMend lacked "any design

feature to prevent the mesh from becoming entwined with and eroding into the bowel." FAC ¶ 41. Plaintiff further claims that the "small pore size of [SurgiMend] rendered it more likely to cause and/or harbor infection and negative inflammatory response." *Id.* ¶ 54(g). Plaintiff thus also sufficiently pleads causation, as she alleges that—after being implanted with SurgiMend—she suffered from those same complications. *See id.* ¶ 32.

Plaintiff also invokes the risk-benefit test, claiming that SurgiMend's defects posed a risk of harm that outweighed the burden of taking additional safety measures. *See id.* ¶ 56(i). She supports this theory by alleging that "other available devices" were not similarly defective. *Id.* ¶ 54(b). The Court can thus reasonably infer that the risk and magnitude of harm associated with SurgiMend's design outweighed the potential burden that Defendants would have incurred by attempting to prevent such harm.

Further, Plaintiff sufficiently pleads that SurgiMend's alleged defects were caused by Defendants' negligence. The FAC states that Defendants "designed, manufactured, distributed or conducted post-market surveillance of" SurgiMend." *Id.* ¶ 51. Plaintiff also alleges that medical studies showed SurgiMend was "substantially weaker" than other "hernia mesh devices," and that SurgiMend could "disintegrate in a matter of weeks." *Id.* ¶ 20. Plaintiff thus claims Defendants knew or should have known about SurgiMends design defects but failed to correct them. *See id.* ¶¶ 54–55.

Allegations like those described above are sufficient to state a negligent design claim. *See Hannan*, 2020 WL 2128841, at *10; *Smith v. Medtronic, Inc.*, No. 22-CV-09179-JSW, 2023 WL 4849432, at *3–4 (N.D. Cal. July 28, 2023); *Hammarlund v. C.R. Bard, Inc.*, No. 215CV05506SVWJEM, 2015 WL 5826780, at *3 (C.D. Cal. Oct. 2, 2015).

2. Manufacturing Defect

"Under a 'manufacturing defect' theory, 'a defective product is one that differs from the manufacturer's intended result or from other ostensibly identical units of the same product line.'" *In re Toyota*, 754 F. Supp. 2d at 1222 (quoting *Lucas*, 726 F. Supp. 2d at 1154). The "traditional definition[]" of a manufacturing defect in California thus "presuppose[s] that a suitable design is in place, but that the manufacturing process has in

some way deviated from that design." *In re Coordinated Latex Glove Litig.*, 121 Cal. Rptr. 2d 301, 315 (Ct. App. 2002), *as modified on denial of reh'g* (July 15, 2002). To comply with federal pleading standards, "plaintiffs should '*identify/explain how* the [product] either deviated from [defendant's] intended result/design or *how* the [product] deviated from other seemingly identical [product] models.'" *In re Toyota*, 754 F. Supp. 2d at 1222 (alterations in original) (quoting *Lucas*, 726 F. Supp. 2d at 1155).

Plaintiff has not adequately alleged breach under a manufacturing defect theory. The FAC states that Defendants failed "to use reasonable care in manufacturing [SurgiMend] and producing a product that differed from their design . . . or from other typical units from the same product line." FAC ¶ 56(iv). But restating the claim's elements does not suffice under *Iqbal* and *Twombly*. True, the FAC could be read to imply that Defendants manufactured SurgiMend in unsafe conditions. *See id.* ¶ 21. But the FAC fails to discuss *how* any SurgiMend units ultimately differed from Defendants' designs. And even if Plaintiff had sufficiently pleaded breach, she fails to establish causation. The FAC discusses only how SurgiMend's defective design and inadequate warning—and not the alleged unsafe manufacturing conditions—led to her injury. *See generally id.*

Plaintiff has thus failed to state a negligence claim under a manufacturing defect theory. Notably, Plaintiff does not argue otherwise. *See* Opp'n at 9–12 (discussing Plaintiff's negligence claim only in the context of design and warning defects).

3. Failure to Warn

In a negligent failure-to-warn case, a plaintiff must establish that a manufacturer did not adequately warn of a risk that "a reasonably prudent manufacturer would have known and warned about." *Carlin*, 920 P.2d at 1351 (quoting *Anderson*, 810 P.2d at 558). The negligence form of a warning claim thus differs from its strict-liability counterpart in that Plaintiff must show that Defendants' failure to warn fell below the acceptable standard of case. *See id.* Under either theory, the duty to warn "runs to the physician." *Marroquin*, 367 F. Supp. 3d at 1164.

/ / /

Here, Plaintiff adequately alleges a breach of Defendants' duty to warn. For the same reasons stated in Section II.B.2, *supra*, the FAC contains factual allegations sufficient to show that SurgiMend's warning was inadequate. Furthermore, Plaintiff alleges that medical studies revealed risks inherent to the use of SurgiMend, *see* FAC ¶ 20, and that "Defendants knew from internal testing and their post-market investigations" that SurgiMend "creates a high risk of injury to the bowel" and is "more likely to cause . . . negative inflammatory response," *id.* ¶ 40. These allegations support the inference that a reasonably prudent manufacturer would have known and warned of the risks associated with SurgiMend, but Defendants did not.

As to causation, the Court again notes that—as in a strict liability case—Plaintiff must show that "the prescribing physician's conduct would have changed if an adequate warning had been given." *Crawford*, 2023 WL 2189425, at *5. Defendants once more make no effort to show how the FAC fails to meet that standard, and the Court remains disinclined to develop Defendants' argument for them. The Court notes, however, that Plaintiff alleges that her physicians "would not have prescribed and used" SurgiMend "had Defendants not failed to provide adequate warnings." FAC ¶ 49.

Given the foregoing, the Court **GRANTS** Defendants' Motion to dismiss Plaintiff's negligence claim to the extent the FAC relies on a manufacturing defect theory. Defendants' Motion is otherwise **DENIED**.

D. Fraudulent Concealment Claim

Defendants next contend that Plaintiff's fraudulent concealment claim should be dismissed because it fails to satisfy the heightened pleading standard of Federal Rule of Civil Procedure 9(b). Mem. at 15. To that end, Defendants argue that (1) Plaintiff's allegations are conclusory and lack facts to support them, *id.* at 16; and (2) Plaintiff impermissibly lumps Defendants together, failing to allege specific facts pertaining to each defendant's conduct, *id.* at 17. The Court agrees.

/ / /

/ / /

1. Rule 9(b) and Fraudulent Concealment Claims

Defendants are correct that Rule 9(b) applies to Plaintiff's fraudulent concealment claim. Under Rule 9(b), a party alleging fraud must "state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). That "particularity requirement applies to state-law causes of action" based on fraud, *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1103 (9th Cir. 2003), including fraudulent concealment claims brought under California law, *see Engalla v. Permanente Med. Grp., Inc.*, 938 P.2d 903, 917 (Cal. 1997); *Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1125–26 (9th Cir. 2009). Plaintiff does not dispute that Rule 9(b) applies. *See generally* Opp'n.

To satisfy Rule 9(b), "allegations of fraud must be 'specific enough to give defendants notice of the particular misconduct . . . so that they can defend against the charge." *Bly-Magee v. California*, 236 F.3d 1014, 1019 (9th Cir. 2001) (quoting *Neubronner v. Milken*, 6 F.3d 666, 672 (9th Cir. 1993)). Such allegations must thus be "accompanied by 'the who, what, when, where, and how' of the misconduct charged." *Kearns*, 567 F.3d at 1124 (quoting *Vess*, 317 F.3d at 1106). "[N]eutral facts necessary to identify the transaction" are not enough; a plaintiff "must set forth what is false or misleading about a statement, and why it is false." *In re GlenFed, Inc. Sec. Litig.,* 42 F.3d 1541, 1548 (9th Cir. 1994), *superseded by statute on other grounds*.

As fraudulent concealment alleges "a failure to act instead of an affirmative act," district courts in the Ninth Circuit have found that such claims "can succeed without the same level of specificity required by a normal fraud claim." *Baggett v. Hewlett-Packard Co.,* 582 F. Supp. 2d 1261, 1267 (C.D. Cal. 2007) (quoting *Falk v. Gen. Motors Corp.*, 496 F. Supp. 2d 1088, 1098–99 (N.D. Cal. 2007)). That said, "[w]here a fraudulent omission is at issue, the requirements of Rule 9(b) are relaxed, but not eliminated." *UMG Recordings, Inc. v. Glob. Eagle Ent., Inc.*, 117 F. Supp. 3d 1092, 1107 (C.D. Cal. 2015).

2. Sufficiency of Plaintiff's Allegations

To state a claim for fraudulent concealment, a plaintiff must show: "(1) concealment or suppression of a material fact; (2) by a defendant with a duty to disclose the fact to the

plaintiff; (3) the defendant intended to defraud the plaintiff by intentionally concealing or suppressing the fact; (4) the plaintiff was unaware of the fact and would not have acted as he or she did if he or she had known of the concealed or suppressed fact; and (5) plaintiff sustained damage as a result of the concealment or suppression of the fact." *Graham v. Bank of Am.*, 172 Cal. Rptr. 3d 218, 228 (Ct. App. 2014).

Defendants' challenge appears to focus mostly on fraudulent concealment's first element. Defendants argue that the FAC does not identify the "what" of the alleged fraud—*i.e.*, what specific material fact should have been disclosed—nor "provide factual allegations as to *when* material information was . . . concealed, *how* it was concealed, or *where* it was concealed." Mem. at 16 (emphases added).

The Court first turns to the question of *what* material facts Defendants allegedly concealed. "To plead the existence of an omission sufficient to support a fraudulent concealment claim, a plaintiff 'must describe the content of the omission . . . .'" *Tapia v. Davol, Inc.*, 116 F. Supp. 3d 1149, 1163 (S.D. Cal. 2015) (quoting *Erickson v. Boston Sci. Corp.*, 846 F. Supp. 2d 1085, 1092 (C.D. Cal. 2011)). An omitted fact is deemed material if "a reasonable man would attach importance to its existence or nonexistence in determining his choice of action in the transaction in question." *Engalla*, 938 P.2d at 919 (quoting Restatement (Second) Torts § 538(2)(a)).

Defendants argue that Plaintiff failed to identify "a specific safety hazard or defect that should have been warned against," Mem. at 16, but the Court disagrees. Per the FAC, Defendants knew that SurgiMend "did not contain any design feature to prevent the mesh from" damaging a patient's bowel, FAC ¶ 41; that absent such a safety mechanism, SurgiMend posed a higher risk of complications than similar devices, *see id.* ¶¶ 41, 60; and that SurgiMend often led to bowel injuries, *see id.* The foregoing allegations sufficiently identify an omitted material fact. *See, e.g.*, *Shimy v. Wright Med. Tech., Inc.*, No. 2:14-CV-04541-CAS, 2014 WL 3694140, at *3 (C.D. Cal. July 23, 2014).

On the other hand, the FAC provides fewer details regarding the *where* and *how* of Defendants' alleged omission. Beyond the omission's content, Plaintiff must describe

"where the omitted information should or could have been revealed." *Tapia*, 116 F. Supp. 3d at 1163 (quoting *Erickson*, 846 F. Supp. 2d at 1092). The FAC states that Plaintiff and her health care providers "reviewed and relied on" the "product inserts Defendants distributed with" SurgiMend. FAC ¶¶ 64–65. But Plaintiff does not state what specific information Defendants omitted from said inserts. Nor does she describe the actual contents of the inserts, thereby failing to explain *how* Defendants allegedly concealed or miscommunicated the dangers of SurgiMend.

The FAC's bare allegations thus do not satisfy Rule 9(b)'s particularity requirement. *See Hill v. Davol Inc.*, No. 516CV01759ODWKK, 2016 WL 10988657, at *8 (C.D. Cal. Nov. 16, 2016) (dismissing claim where the plaintiff "neither identified a specific advertisement that either he or his physician viewed nor provided even a vague outline of the specific language used to make these representations"); *Sukonik v. Wright Med. Tech., Inc.*, No. CV1408278BROMRWX, 2015 WL 10682986, at *16 (C.D. Cal. Jan. 26, 2015) (finding insufficient the allegation "that Plaintiff and his healthcare providers 'relied on [defendant's] incomplete and inaccurate representations as to the safety and performance of the device'"); *Jager v. Davol Inc.*, No. EDCV161424GBKKX, 2016 WL 6157942, at *6 (C.D. Cal. Oct. 20, 2016) (dismissing claim where "[n]othing in the Complaint point[ed] to specific content in [d]efendants' marketing materials . . . that were allegedly false").

3. Rule 9(b) and Multiple Defendants

Defendants also argue that the FAC improperly lumps Defendants together without specifying each defendant's specific role in the alleged fraudulent concealment. Mem. at 17–18. Defendants are correct.

Rule 9(b) "require[s] plaintiffs to differentiate their allegations when suing more than one defendant." *Swartz v. KPMG LLP*, 476 F.3d 756, 764 (9th Cir. 2007) (alteration in original) (quoting *Haskin v. R.J. Reynolds Tobacco Co.*, 995 F. Supp. 1437, 1439 (M.D. Fla. 1998)). A complaint must provide each defendant with information sufficient to allow them "to know what misrepresentations are attributable to them and what fraudulent conduct they are charged with." *Tapia*, 116 F. Supp. 3d at 1163 (quoting *Vega*

v. JPMorgan Chase Bank, N.A., 654 F. Supp. 2d 1104, 1115 (E.D. Cal. 2009)).

That said, a plaintiff need not provide "every detail" of each defendant's participation in a fraudulent scheme. *Swartz*, 476 F.3d at 764. Rather, "a plaintiff must, at a minimum, 'identif[y] the role of [each] defendant[].'" *Id.* at 765 (alterations in original) (quoting *Moore v. Kayport Package Express, Inc.*, 885 F.2d 531, 541 (9th Cir.1989)). Conversely, "a complaint need not distinguish between defendants that had the exact same role in a fraud." *United States ex rel. Silingo v. WellPoint, Inc.*, 904 F.3d 667, 677 (9th Cir. 2018).

Here, Plaintiff has not adequately delineated the roles played by each defendant. The FAC alleges that Integra oversaw "the post-market surveillance and marketing" of SurgiMend, FAC ¶ 2, while Integra Sales was "involved in the marketing and sale of Plaintiff's [SurgiMend] device," *id.* ¶ 3. But the rest of the FAC suggests Defendants played identical roles. Each of the FAC's remaining allegations refer generically to "Defendants"—even when discussing an activity that allegedly falls within a specific defendant's remit. *See, e.g.*, *id.* ¶ 37 ("Defendants, including DOES 1 through 50, and each of them, also engaged in *post-market surveillance*, quality control, marketing, and distribution . . . ." (emphasis added)). Similarly, all allegations listed in the FAC's fraudulent concealment section refer to "Defendants." *See, e.g.*, *id.* ¶ 60 ("In marketing and selling the device, Defendants concealed material facts from Plaintiff . . . .").

As Plaintiff neither "differentiate[s] which facts pertain to which defendant" nor "note[s] each defendant's role," *Sivilli v. Wright Med. Tech., Inc.*, No. 18-CV-2162-AJB-JLB, 2019 WL 3803808, at *4 (S.D. Cal. Aug. 13, 2019), the FAC fails to plead a fraudulent concealment claim with the particularity required by Rule 9(b). The Court thus **GRANTS** Defendants' Motion to dismiss Plaintiff's fraudulent concealment claim.

E. Express Warranty Claim

Plaintiff's fourth cause of action is for breach of express warranty. FAC ¶¶ 68–73. To plead an express warranty claim under California law, a plaintiff must allege that the seller "(1) made an affirmation of fact or promise or provided a description of its goods;

(2) the promise or description formed part of the basis of the bargain; (3) the express warranty was breached; and (4) the breach caused injury to the plaintiff." *Loomis v. Slendertone Distrib., Inc.*, 420 F. Supp. 3d 1046, 1087 (S.D. Cal. 2019) (quoting *Viggiano v. Hansen Nat. Corp.*, 944 F. Supp. 2d 877, 893 (C.D. Cal. 2013)).

Defendants mount two attacks on the FAC's warranty claim. Neither succeeds.

1. Contents and Location of the Warranties

Defendants first attack Plaintiff's warranty claim by arguing that Plaintiff did not "allege the exact terms of the alleged warranties" or "identify the specific materials, packaging inserts, or advertisements that contain[ed]" the warranties. Mem. at 19.

As to the terms of the alleged warranties, the Court finds Plaintiff's pleadings sufficient. Per the FAC, Defendants represented that SurgiMend "was safe for its intended use; did not pose serious health hazards when used appropriately; was safer and more effective than alternative mesh devices; had been adequately tested for its intended use; and would not cause injury after implantation." FAC ¶ 70. Other courts have found similar statements adequate. *See, e.g.*, *Tapia*, 116 F. Supp. 3d at 1162 (holding warranty terms sufficiently plead where complaint alleged that "[d]efendants expressly warranted that the [product] was safe and fit for use by consumers, was of merchantable quality, did not produce dangerous side effects, and was adequately tested"); *Kent v. Pfizer Inc.*, No. 17-CV-0604 DMS (MDD), 2017 WL 11672334, at *4 (S.D. Cal. Aug. 16, 2017) (finding alleged representation that a product "was effective proper [sic] and safe for its intended use" sufficient to plead warranty terms).

Defendants' argument regarding the "location" of the warranties also fails. Defendants cite no case law to support the contention that Plaintiff must describe the materials through which Defendants' representations were allegedly made in greater detail than does the FAC.[3] *See* FAC ¶ 70 (explaining that Defendants' representations were made

[3] Defendants also do not argue that Rule 9(b)'s particularity requirement applies to Plaintiff's express warranty claim.

through SurgiMend's "packaging inserts and media advertisements"). And indeed, several courts have found that representations made on a product's label or packaging can constitute an express warranty. *See Anderberg v. Hain Celestial Grp., Inc.*, No. 321CV01794RBMNLS, 2023 WL 419268, at *7 (S.D. Cal. Jan. 26, 2023); *Thurston v. Bear Naked, Inc.*, No. 11-CV-02890-H-BGS, 2012 WL 12845621, at *8 (S.D. Cal. July 16, 2012). The only case Defendants provide has little relevance here, as it focuses on a complaint's failure to plead other elements—like breach and causation—of an express warranty claim, rather than on the terms or location of the warranties themselves. *See Bogart v. Glenmark Generics, Inc., USA*, No. 14-CV-778 LAB DHB, 2014 WL 5800577, at *6 (S.D. Cal. Nov. 7, 2014).

2. Reliance

Defendants next make two reliance-based arguments.

First, Defendants contend that "the warranties Plaintiff alleges were breached are neither specific nor measurable as required under California law." Mem. at 19. In support, Defendants cite *Southland Sod Farms v. Stover Seed Co.*, which, the Court notes, discusses the idea that mere puffery is not actionable under the Lanham Act—not California law. *See* 108 F.3d 1134, 1145 (9th Cir. 1997). Specifically, the Ninth Circuit explained in *Southland* that "exaggerated advertising . . . is not actionable" because "no reasonable buyer would rely" on it. *Id.* Defendants' remaining cases make similar points, albeit in the context of express warranty claims. *See Azoulai v. BMW of N. Am. LLC*, No. 16-CV-00589-BLF, 2017 WL 1354781, at *8 (N.D. Cal. Apr. 13, 2017); *Marrujo v. Coloplast Corp.*, No. 319CV01588AJBNLS, 2020 WL 3791637, at *3 (S.D. Cal. July 7, 2020).

Presuming Plaintiff must plead reliance,[4] the Court rejects Defendants' first argument. Defendants' proffered caselaw does them few favors. As *Southland* explained,

[4] Whether a plaintiff must sometimes—or ever—establish reliance to state an express warranty claim is unsettled under California law. *See, e.g.*, *Watkins v. MGA Ent., Inc.*, 574 F. Supp. 3d 747, 757–58 (N.D. Cal. 2021) (summarizing three-way split in authority). However, Plaintiff herself states that she must plead reliance, *see* Opp'n at 16, and Defendants do not disagree, *see generally* Mem.; Reply. The Court will thus proceed under the assumption that reliance remains an element of Plaintiff's claim.

"[a] specific and measurable advertisement claim of product superiority based on product testing is not puffery." 108 F.3d at 1145. Such a statement can be actionable even where no "direct comparison to a competitor" is made. *Id.* (quoting *Castrol Inc. v. Pennzoil Co.*, 987 F.2d 939, 946 (3d Cir. 1993)). And here, Plaintiff alleges that she relied on Defendant's representation that SurgiMend was "safer and more effective than alternative mesh devices" and "had been adequately tested." FAC ¶ 70. This representation, in the Court's view, is sufficiently specific such that Plaintiff and her physicians could rely on it.

More broadly, Plaintiff alleges that she and her physicians relied on Defendants' representations regarding SurgiMend's safety and effectiveness in deciding whether to use the device. FAC ¶ 69. Similarly worded allegations have been held sufficient to establish reliance at the 12(b)(6) stage. *See Kent*, 2017 WL 11672334, at *4; *Kanfer v. Pharmacare US, Inc.*, 142 F. Supp. 3d 1091, 1104 (S.D. Cal. 2015) (finding reliance adequately stated where plaintiff allegedly relied on "specific statements made on [a product's] packaging"). The Court thus concludes that Plaintiff's allegations of reliance are sufficient.

Defendants' final argument fares no better. Defendants point out that the learned intermediary rule applies in express warranty claims, meaning Plaintiff must "allege that [her] *prescribing physician* read and relied on the purported warranties." Reply. at 9 (citing *Tapia*, 116 F. Supp. 3d at 1162). Plaintiff failed to do so here, per Defendants, as the FAC "alleges only that her '*treating* physicians' relied on the purported warranties." *Id.* (emphasis added) (quoting FAC ¶ 69). Defendants do not explain, however, why such a deviation in language—particularly between two words that could be used synonymously in this context—should prove dispositive against Plaintiff. Defendants' argument is particularly unpersuasive given that the Court must draw all reasonable inferences in Plaintiff's favor at this stage of the litigation.

Consequently, the Court **DENIES** Defendants' Motion to dismiss Plaintiff's breach of express warranty claim.

/ / /

/ / /

F. Punitive Damages

Defendants' final challenge is to Plaintiff's prayer for punitive damages. California law permits a plaintiff to recover punitive damages when there is "clear and convincing evidence that the defendant has been guilty of oppression, fraud, or malice." Cal. Civ. Code § 3294(a).

Before addressing the merits of Defendants' argument, the Court must clarify the applicable standard. Defendants seem to suggest that California's "clear and convincing evidence" requirement creates a heightened pleading standard. *See* Mem. at 19–20; Reply at 9. However, "federal courts sitting in diversity jurisdiction apply state substantive law and federal procedural law." *Gasperini v. Center for Humans., Inc.*, 518 U.S. 415, 427 (1996). So, Plaintiff need only plead facts sufficient to state a plausible claim for punitive damages, as required by *Iqbal* and *Twombly*.[5] *See Omni King, Inc. v. Accelerant Speciality Ins. Co.*, No. 523CV00048SSSKKX, 2023 WL 6881824, at *3 (C.D. Cal. Apr. 19, 2023).

Defendants contend that Plaintiff has failed to allege any facts to support a claim for punitive damages. Mem. at 20. Defendants repeat many of the same arguments made regarding Plaintiff's fraud claim, asserting that because "Plaintiff has failed to adequately allege fraudulent concealment," her "prayer for punitive damages should also be dismissed." *Id.* Defendants do not, however, argue that Rule 9(b) applies here.

The Court is not convinced that Plaintiff's prayer for punitive damages must rise or fall with her fraudulent concealment claim. The Court dismisses the latter claim, *supra*, for its failure to sufficiently plead the "where" and "how" of the alleged fraudulent scheme, not for any failure to plead facts relating to Defendants' mental states. And even if Rule

---

[5] There is some disagreement in the caselaw as to whether—post-*Iqbal* and *Twombly*—a plaintiff must plead facts to support an allegation of a defendant's mental state in establishing a § 3294 claim. *See Omni King*, 2023 WL 6881824, at *3 (describing the different conclusions reached by district courts). However, an emerging majority of courts appear to require complaints to include such facts. *See, e.g.*, *id.*; *Kelley v. Corr. Corp. of Am.*, 750 F. Supp. 2d 1132, 1147 (E.D. Cal. 2010); *Ducre v. Veolia Transp.*, No. CV1002358MMMAJWX, 2010 WL 11549862, at *4–5 (C.D. Cal. June 14, 2010). The Parties do not address this issue in their briefs. As the Court finds that the FAC survives Defendant's Motion even under the standard set by *Iqbal* and *Twombly*, the Court adopts the majority's approach here.

9(b) applied, said rule treats the circumstances surrounding fraud differently from conditions of a defendant's mind. The former must be stated "with particularity," but "[m]alice, intent," and "knowledge . . . may be alleged generally." Fed. R. Civ. P. 9(b). So, while plaintiffs must allege facts to support an allegation relating to a defendant's state of mind, they need not clear the "elevated" bar set by Rule 9's particularity requirement. *Iqbal*, 556 U.S. at 686–87.

The Court thus turns to § 3294's mental state requirements. Allegations of malice support a § 3294(a) claim. Malice can be shown through "despicable conduct," or conduct that is "carried on by the defendant with a willful and conscious disregard of the rights or safety of others." Cal. Civ. Code § 3294(c)(1). Despicable conduct "is conduct 'so vile, base, contemptible, miserable, wretched or loathsome that it would be looked down upon and despised by most ordinary decent people.'" *Hardeman v. Monsanto Co.*, 997 F.3d 941, 971 (9th Cir. 2021) (quoting *Pac. Gas & Elec. Co. v. Super. Ct.*, 235 Cal Rptr. 3d 228, 236 (Ct. App. 2018)). Meanwhile, conscious disregard "requires that the defendant 'have *actual knowledge* of the risk of harm it is creating and, in the face of that knowledge, fail to take steps it knows will reduce or eliminate the risk of harm.'" *Id.* (quoting *Pac. Gas*, 235 Cal. Rptr. 3d at 228).

Here, Plaintiff sufficiently pleads malice. Plaintiff alleges that Defendants, through reports from patients and healthcare providers, knew SurgiMend had higher reported rates of recurrence, patient injury, and other complications compared to alternative hernia repair devices. *See* FAC ¶¶ 76, 79. She also alleges that despite knowing that SurgiMend "was not safe for intrabdominal placement," *id.* ¶ 78, Defendants continued advertising, selling, and distributing SurgiMend without performing further testing or notifying users of these risks, *id.* ¶¶ 82, 84–86. As the FAC's factual allegations allow the Court to reasonably infer malice, Plaintiff has sufficiently stated her punitive damages claim. *See, e.g.*, *Omni King*, 2023 WL 6881824, at *4; *Doe 1 v. United Airlines, Inc.*, No. CV2005554RSWLAGRX, 2021 WL 4595766, at *6 (C.D. Cal. Apr. 22, 2021).

/ / /

The Court thus **DENIES** Defendants' Motion to dismiss Plaintiff's prayer for punitive damages.

CONCLUSION

For the reasons stated above, the Court **GRANTS** Defendants' Request for Judicial Notice and **GRANTS IN PART AND DENIES IN PART** Defendants' Motion to Dismiss (ECF No. 42). Specifically, the Court **GRANTS** Defendants' Motion as to the FAC's negligence claim—but only to the extent it is based on a manufacturing defect theory—and fraudulent concealment claim; these two claims are **DISMISSED WITHOUT PREJUDICE**. The Court otherwise **DENIES** Defendant's Motion.

Plaintiff **MAY FILE** a second amended complaint within thirty (30) days of the date of this Order. Should Plaintiff elect to file a second amended complaint, it must cure the deficiencies noted herein and be complete in itself without reference to Plaintiff's prior complaints. *See* S.D. Cal. CivLR 15.1. Any claims not realleged in the second amended complaint will be considered waived. *See Lacey v. Maricopa Cty.*, 693 F.3d 896, 925, 928 (9th Cir. 2012). If Plaintiff fails to file an amended complaint, this action will proceed with Plaintiff's remaining claims.

IT IS SO ORDERED.

Dated: November 27, 2023

Janis L. Sammartino
Hon. Janis L. Sammartino
United States District Judge