UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
CIVIL MINUTES—GENERAL

Case No.	**CV 16-7316-DMG (KSx)**	Date	May 25, 2018
Title	***Sara Ebrahimi v. Mentor Worldwide LLC, et al.***	Page	1 of 8

Present: The Honorable DOLLY M. GEE, UNITED STATES DISTRICT JUDGE

KANE TIEN	NOT REPORTED
Deputy Clerk	Court Reporter
Attorneys Present for Plaintiff(s) None Present	Attorneys Present for Defendant(s) None Present

Proceedings: IN CHAMBERS - ORDER RE DEFENDANT'S MOTION TO DISMISS SECOND AMENDED COMPLAINT [29]

On November 14, 2017, Plaintiff Sara Ebrahimi filed a Second Amended Complaint ("SAC") that alleges the following claims against Defendant Mentor Worldwide LLC ("Mentor") relating to silicon gel breast implants: (1) strict product liability—failure to warn, and (2) strict product liability—manufacturing defect. [Doc. #28.] On November 16, 2017, Mentor moved to dismiss Ebrahimi's SAC in its entirety. [Doc. # 29.] The motion has since been fully briefed. [Doc. ## 32, 34, 37, 38, 39.] For the following reasons, the Court **GRANTS** Mentor's motion to dismiss with leave to amend.

I.
REQUEST FOR JUDICIAL NOTICE

In connection with its motion to dismiss, Mentor has submitted a request for judicial notice of the 2011 FDA Update on the Safety of Silicone Gel-Filled Breast Implants. [Doc. # 30.] The Court need not rely upon this document in order to resolve the motion. The Court therefore **DENIES as moot** Mentor's request.[1]

II.
FACTUAL BACKGROUND

In its prior Order that dismissed Ebrahimi's original Complaint, the Court provided a factual summary of the case that need not be repeated here. *See* Order re Def.'s Mot. to Dismiss

[1] Likewise, the Court **DENIES** as **moot** the request for judicial notice included in Defendant's Response to Plaintiff's Notice of Supplemental Authority. [Doc. # 39.]

at 2–3 ("September 15, 2017 Order") [Doc. # 23].[2] To the extent that Ebrahimi's SAC raises any new allegations that are relevant to the instant motion, the Court addresses them *infra* Part IV.

III.
LEGAL STANDARD

The Court set forth the applicable legal standard for motions to dismiss in its prior Order and it applies to the pending motion as well. *See* September 15, 2017 Order at 4.

IV.
DISCUSSION

Mentor argues that Ebrahimi's state law strict product liability claims arising out of the MemoryGel Silicone Gel Breast Implants ("Implants") are either expressly or impliedly preempted by the Medical Device Amendments ("MDA") to the Food, Drug and Cosmetic Act ("FDCA").[3]

A. Strict Product Liability—Failure to Warn

The SAC alleges that Mentor "had a duty to warn [Ebrahimi] and her doctors of the dangers associated with the [Implants]." *See* SAC at ¶ 73. She alleges that the "Implants had the potential to cause injury, through leakage of the silicone gel into the tissues of the user's body, thereby introducing toxic metals and chemicals into those tissues, resulting in serious, dangerous and harmful side effects and complications all to the detriment of the health and well-being of the users of [Mentor's] product[.]" *See id.* at ¶ 66. "Mentor failed to adequately warn or instruct of the potential risk for injury . . . from leakage from the [Implants]." *Id.* at ¶ 71.

[2] All page references herein are to page numbers inserted by the CM/ECF filing system.

[3] Mentor further argues that Ebrahimi's request for injunctive relief is barred by the primary jurisdiction doctrine. *See* Mot. at 13–15. Given the Court's disposition of Mentor's motion, it need not reach this issue. Nonetheless, the Court questions whether Ebrahimi even has Article III standing to request injunctive relief, given that she has not professed any interest in undergoing breast augmentation surgery in the future. *See Campion v. Old Republic Home Prot. Co., Inc.*, 861 F. Supp. 2d 1139, 1147 (S.D. Cal. 2012) (citing *Gest v. Bradbury*, 443 F.3d 1177, 1181 (9th Cir. 2006)) ("A plaintiff seeking to obtain declaratory or injunctive relief must establish that he or she is 'realistically threatened by a repetition of the violation' in order to establish the relief sought would redress the alleged injuries.").

"Mentor failed to warn consumers, healthcare providers, and the FDA that a significant gel bleed was a potential risk, and failed to warn that there were . . . toxic materials in the gel [other than those identified in Mentor's Product Insert Data Sheet] that posed a substantial danger of injury to the Plaintiff."[4] *See id.* at ¶¶ 55, 58. According to the SAC, "[t]he risk of significant gel bleed containing toxic materials was not disclosed or discussed in what Mentor calls its 'Directions for Use' or in its consumer labeling[.]" *Id.* at ¶ 59. Ebrahimi's failure-to-warn claim appears to rely upon two theories: (1) Mentor's failure to report to the FDA "adverse events" resulting from the Implants' use, and (2) Mentor's failure to issue sufficient warnings to patients and doctors.

To plead a claim relating to a Class III medical device that survives express preemption, "a plaintiff must allege facts '(1) showing an alleged violation of FDA regulations or requirements related to [the device] and (2) establishing a causal nexus between the alleged injury and the violation.'" *See Erickson v. Boston Sci. Corp.*, 846 F. Supp. 2d 1085, 1092 (C.D. Cal. 2011) (quoting *Cohen v. Guidant Corp.*, No. CV–05–8070–R, 2011 WL 637472, at *1 (C.D. Cal. 2011)). The FDA requires that manufacturers of Class III devices report to the FDA any information "reasonably suggest[ing]" that their device "[m]ay have caused or contributed to a death or serious injury" or "[h]as malfunctioned" in a way that "would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur." *See* 21 C.F.R. § 803.50(a). California law imposes a parallel requirement to that found in 21 C.FR. § 803.50(a) under the common law strict product liability tort of failure to warn. *Coleman v. Medtronic, Inc.*, 223 Cal. App. 4th 413, 428 (2014). To state a parallel failure-to-warn claim under California law, Ebrahimi "will ultimately have to prove that if [Mentor] had properly reported the adverse events to the FDA as required under federal law, that information would have reached [her] doctors in time to prevent [her] injuries." *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1234 (9th Cir. 2013) (*en banc*).

As the Court observed in the Order that dismissed the original Complaint, Ebrahimi's first theory relies upon her contention that Mentor failed to adequately conduct the six post-approval studies mandated by the FDA. *See* Order re Def.'s Mot. to Dismiss at 6–7 [Doc. # 23]; SAC at ¶¶ 28–52. Once again, Ebrahimi points to potential statistical issues associated with the

[4] Although Ebrahimi claims that Mentor failed to warn the FDA that significant gel bleed is a potential risk of the Implants, she does not allege that Mentor failed to reveal to the FDA that the gel contained toxic materials that were not listed on Mentor's Product Insert Data Sheet. *See* SAC at ¶¶ 55–56 (listing fourteen toxic materials that were found in Ebrahimi's body but were not on the Product Insert Data Sheet); *id.* at ¶ 23 (alleging that Mentor's PMA summary of effectiveness listed ten of those materials, and that Mentor's application for premarket approval included five others).

six follow-through studies. For instance, Ebrahimi alleges that Mentor failed to properly conduct a "large post-approval study" because "the actual number of enrolled patients was 41,451, over 500 patients fewer than [the number prescribed by] the [premarket approval ("PMA")] requirements[,]" and "[a]t year 7, the overall follow-up rate was 20.1%[,] . . . leaving 79.9% of the desired statistics unavailable for evaluation."[5] *See* SAC at ¶ 36. In her opposition, Ebrahimi argues that "Mentor failed to report the following adverse events from the six new or ongoing studies commissioned as part of [the] implant's PMA approval, *all of which would have led to reports suggesting the device's contribution to death or serious injury* . . . ." Opp'n at 6 (emphasis added). She then lists the aforementioned statistical deficiencies as if they were "adverse events" that Mentor failed to report to the FDA. *See id.* at 6–7.

The alleged technical defects in Mentor's post-approval studies, however, do not constitute adverse events. Rather, an adverse event is information showing that the Implants "[m]ay have caused or contributed to a death or serious injury" or "[h]as malfunctioned and th[e] device or a similar device that [Mentor] market[s] would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur." *See* 21 C.F.R. § 803.50(a). Furthermore, Ebrahimi merely speculates that, had Mentor conducted these studies properly, the FDA would have discovered "reports suggesting the device's contribution to death or serious injury[.]" *See* Opp'n at 6. Because she fails to identify any unreported ailment or injury resulting from gel bleed, Ebrahimi does not plead sufficient facts to survive the MDA's preemption provision.[6] *See Iqbal*, 556 U.S. at 680 (quoting *Twombly*, 550 U.S. at 570) (internal

[5] In her opposition, Ebrahimi states that her failure-to-warn claim is not "based solely on Mentor's failure to comply with post-approval studies." *See* Opp'n at 13. "Instead, . . . [Ebrahimi] . . . allege[s] that Mentor's failure to provide adverse warnings to [her], her doctors, and the FDA forms the basis for a state-law failure to warn claim[.]" *See id.* Accordingly, the Court need not decide whether the MDA impliedly preempts any claim predicated upon only Mentor's allegedly deficient post-approval studies. *See* Order re Def.'s Mot. to Dismiss at 7 (concluding that any such claim is impliedly preempted) [Doc. # 23].

[6] Ebrahimi also avers "[u]pon information and belief, a Mentor chemist of 15 years reported to the FDA that the implants are more likely to break than the company reported." SAC at ¶ 52. She cites Exhibit 9 to the SAC for that proposition, *see id.*, which appears to be an error because that document is Mentor's Product Data Safety Sheet. *See* SAC, Ex. 9 [Doc. # 28-9]. She further claims that "[i]t has also been reported that the silicone is more likely to leak, even when the implants are intact, and that platinum used in the implants is more dangerous than reported." SAC at ¶ 52. The relevance of these allegations is unclear because it seems that these dangers were reported to the FDA, albeit not by Mentor. Additionally, these allegations fail to provide Mentor with fair notice as to which adverse events (*i.e.*, instances of death, serious bodily injury, or malfunction) it should have reported to the FDA. *See Lehman v. Nelson*, 862 F.3d 1203, 1211 (9th Cir. 2017) (quoting *Pickern v. Pier 1 Imports (U.S.), Inc.*, 457 F.3d 963, 968 (9th Cir. 2006)) (internal quotation marks omitted) ("Federal Rule of Civil Procedure 8(a)(2) requires that the allegations in the complaint give the defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests.").

quotation marks omitted) (Rule 8 requires a plaintiff to "nudge[] [his or her] claims . . . across the line from conceivable to plausible").

Furthermore, the SAC does not sufficiently allege a causal nexus between Ebrahimi's injuries and Mentor's failure to report adverse events to the FDA. In particular, she does not allege any specific facts showing that had Mentor not "covered up" these purported adverse events, the FDA would have required Mentor to modify its labeling and marketing materials or otherwise warn patients and doctors that "significant gel bleed was a potential risk" and that "there were . . . toxic chemicals in the gel [other than those already disclosed to doctors and patients] that posed a substantial danger of injury." *See* SAC at ¶¶ 52, 58. Therefore, Ebrahimi's failure-to-warn claim cannot escape express preemption because she has not shown that Mentor's failure to report adverse events to the FDA resulted in her injury. *See Erickson*, 846 F. Supp. 2d at 1092.

Lastly, the MDA expressly preempts any claim premised on a duty to make disclosures to doctors or patients that are not required by the statute or the FDA's implementing regulations (*e.g.*, the FDA's labeling and marketing requirements). *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321–22 (2008) (quoting 21 U.S.C. § 360k(a)(1)) (a state common-law claim is expressly preempted if it is "based upon [state] requirements with respect to the device that are 'different from, or in addition to,' the federal ones, and that relate to safety and effectiveness"). Thus, Ebrahimi's failure-to-warn claim fails.

Accordingly, the Court **GRANTS** Mentor's motion to dismiss Ebrahimi's strict product liability failure-to-warn claim.

B. Strict Product Liability—Manufacturing Defect

For a manufacturing defect claim to survive MDA preemption, courts have "required specific allegations that the manufacturing of the device both fell short of the FDA's requirements for manufacturing and—based on the same deficiency—was defectively manufactured under California law." *De La Paz v. Bayer Healthcare LLC*, 159 F. Supp. 3d 1085, 1092 (N.D. Cal. 2016) (quoting *Funke v. Sorin Grp. USA, Inc.*, 147 F. Supp. 3d 1017, 1026–27 (C.D. Cal. 2015)) (internal quotation marks omitted) (collecting cases). In *Erickson*, the court held that a plaintiff cannot simply allege that the defendant violated FDA regulations in order to avoid preemption. *See Erickson*, 846 F. Supp. 3d at 1092. Instead, "a plaintiff must allege that the defendant violated a particular federal specification referring to the device at issue, or identify specific PMA requirements that have been violated." *Id.* (citation omitted)

(internal quotation marks omitted) (quoting *Ilarraza v. Medtronic, Inc.*, 677 F. Supp. 2d 582, 589 (E.D.N.Y. 2009)).

In the SAC, Ebrahimi alleges that the Implants were surgically removed from her body, and that they and her "capsules" were thereafter sent to Dr. P. Blais's laboratory for analysis. *See* SAC at ¶ 24. She further contends:

> Dr. Blais made the following *preliminary findings*: (1) capsular contracture, a response of the immune system to toxic materials, which develops when internal scar tissue forms a tight or constricting capsule around a breast implant, contracting it until it becomes misshapen and hard; (2) poor quality of workmanship and patch defects; (3) shell failure, as the shell failed to confine the gel which contained materials; and (4) evidence of intracapsular bleeding.

Id. at ¶ 25 (emphasis in original). The SAC also avers that Mentor failed to adhere to multiple FDA regulations relating to the manufacture of the Implants (*e.g.*, the quality system requirements imposed by 21 C.F.R. § 820.20 *et seq.*), *see* SAC at ¶¶ 53.c–h, but it is unclear how Dr. Blais's findings demonstrate that the Implants did not adhere to these generalized regulations. Instead of clarifying this point in her opposition, Ebrahimi merely argues in a conclusory fashion that "[i]f taken as true, [these allegations] show a clear violation of the Code of Federal Regulations sections cited in the SAC that require documentations and procedures for correcting defective products that do not confirm to otherwise suitable designs." *See* Opp'n at 15.

The defects Dr. Blais identified in the Implants are simply too vague to plausibly show that they deviated from FDA requirements. *See Iqbal*, 556 U.S. at 678 ("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."). The "capsular contracture" appears to concern the body's response to the Implants, and not necessarily any specific defect therein. *See* SAC at ¶ 25. The SAC's reference to "poor quality of workmanship and patch defects" constitutes a factual conclusion that sheds little light on how the manufacturing of the Implants failed to adhere to FDA specifications. *See id.* The existence of "shell failure" may or may not amount to a manufacturing defect, depending upon whether and to what extent a product designed according to FDA specifications has a risk of failure. *See id.* Lastly, without any factual allegations regarding Mentor's FDA-approved design specifications and procedures, the Court is unable to determine if "evidence of intracapsular bleeding" has any bearing on whether Mentor failed to adhere to FDA regulations in the course of manufacturing the Implants. *See id.* Therefore, Ebrahimi's manufacturing defect claim does not survive express preemption because

she has not advanced "specific allegations [showing] that the manufacturing of the device both fell short of the FDA's requirements for manufacturing and—based on the same deficiency—was defectively manufactured under California law."[7] *See De La Paz*, 159 F. Supp. 3d at 1092 (quoting *Funke*, 147 F. Supp. 3d at 1026–27) (internal quotation marks omitted).

The Court therefore **GRANTS** Mentor's motion to dismiss Ebrahimi's strict product liability manufacturing defect claim.

C. Leave to Amend

Valid reasons for denying leave to amend include undue delay, bad faith, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice, and futility. *Foman v. Davis*, 371 U.S. 178, 182 (1962); *see also Klamath-Lake Pharm. Ass'n v. Klamath Med. Serv. Bureau*, 701 F.2d 1276, 1292–93 (9th Cir. 1983) (holding that while leave to amend shall be freely given, the court need not allow futile amendments). Ebrahimi's failure-to-warn cause of action fails for essentially the same reasons that it failed to survive Mentor's motion to dismiss her original Complaint. *Compare supra* Part IV.A, *with* Order re Def.'s Mot. to Dismiss at 6–8 [Doc. # 23]. Furthermore, because Ebrahimi failed to timely oppose Mentor's motion to dismiss her First Amended Complaint, she impliedly agreed that it failed to state a failure-to-warn claim. *See* Order re Def.'s Mot. to Dismiss the FAC [Doc. # 25]; C.D. Cal. L.R. 7-12 (providing that the failure to timely oppose a motion may be deemed consent to granting it). As Ebrahimi has had three opportunities to properly plead her failure-to-warn claim, the Court concludes that granting further leave to amend that cause of action would be futile. Therefore, the Court **DISMISSES** that claim **with prejudice**.

On the other hand, Ebrahimi could plead a plausible manufacturing defect claim if she adds more detailed factual allegations regarding, for example, the "poor workmanship[,]" "patch defects[,]" and "shell failure" of the Implants, and if she connected those deficiencies to violations of particular FDA requirements that resulted in her injuries. Therefore, the Court **GRANTS** Ebrahimi leave to amend to replead her manufacturing defect cause of action.

[7] Although Mentor concedes that "the Court must take the well-pleaded allegations of the [SAC] as true for purposes of a Rule 12(b)(6) motion," Mentor claims that "[Ebrahimi's] attempted reliance on work by Dr. Pierre Blais should give this Court pause" because "[h]e has been excluded in virtually every breast implant case since the 1990s in which he has attempted to testify because what he does is not science and his opinions are creation for litigation." *See* Reply 7 n.2. Mentor is advised that it is imprudent to present such inflammatory accusations when they are wholly irrelevant on a motion to dismiss.

IV.
CONCLUSION

In light of the foregoing, Mentor's motion to dismiss is **GRANTED**. Within 21 days from the date of this Order, Ebrahimi shall file an amended complaint consistent with this Order that raises only the manufacturing defect claim, or notify Mentor and the Court of her intention not to do so. Mentor's response shall be filed within 21 days after the service and filing of the third amended complaint.

IT IS SO ORDERED.