UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

ROBIN SUMPTER and JOHN SUMPTER,	)	
Plaintiffs,	)	No. 4:17-CV-2289 RLW
v.	)	
ALLERGAN INC. and NUSIL TECHNOLOGY LLC,	)	
Defendants.	)	

MEMORANDUM AND ORDER

This matter is before the court on Defendant Allergan, Inc.'s Motion to Dismiss (ECF No. 15) and Defendant NuSil Technology LLC's Motion to Dismiss (ECF No. 34). These matters are fully briefed and ready for disposition.

BACKGROUND[1]

Plaintiff Robin Sumpter ("Robin") underwent a breast augmentation procedure in 2007. (Amended Petition ("AP"), ECF No. 6, ¶¶17-18). Upon her doctor's advice, Robin received silicone gel-filled breast implants instead of saline implants. (AP, ¶19). Allergan Inc. ("Allergan") distributed the implants throughout the United States, including Missouri. (AP, ¶3). NuSil Technology, LLC ("NuSil") manufactured the silicone used in the implants. (AP, ¶4).

[1] In deciding a motion to dismiss under Rule 12(b)(6), a court assumes all facts in the complaint to be true and construes all reasonable inferences most favorably to the complainant. *U.S. ex rel. Raynor v. Nat'l Rural Utilities Co-op. Fin., Corp.*, 690 F.3d 951, 955 (8th Cir. 2012); *Eckert v. Titan Tire Corp.*, 514 F.3d 801, 806 (8th Cir. 2008).

For years, Robin experienced several problems throughout her body that were similar to multiple sclerosis. Robin had her implants removed on August 27, 2015. (AP, ¶27). Both implants had ruptured. (AP, ¶26). A large fraction of the gel found in Robin's implants deteriorated to reactive silicone-based materials of low viscosity which traversed tissue and invaded surrounding muscles.

STANDARD OF REVIEW

To survive a motion to dismiss, 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, 129 S. Ct. 1937, 1949, 173 L. Ed. 2d 868 (2009) (quoting *Bell Atlantic Corp., v. Twombly,* 550 U.S 544, 570 (2007). A "formulaic recitation of the elements of a cause of action" will not suffice. *Twombly*, 550 U.S. at 555. "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Iqbal,* 556 U.S. at 678 (quoting *Twombly,* 550 U.S. at 556).

DISCUSSION

Plaintiffs have asserted claims for strict product liability, negligence, and loss of consortium against Allergan and NuSil.[2] Allergan and NuSil argue that these claims are preempted by Federal law and are not pleaded with sufficient plausibility or particularity under *Twombly* and *Iqbal.*

[2] Plaintiffs' loss of consortium claim flows from their strict liability and negligence claims. Therefore, Plaintiffs' loss of consortium claim fails if the underlying claims are dismissed. *Johnson v. Anheuser Busch, Inc.*, 876 F.2d 620, 625 (8th Cir. 1989) (citing *Stephen v. Lindell Hosp.*, 681 S.W.2d 503, 508 (Mo. Ct. App. 1984) ("Loss of consortium presents a derivative claim arising out of the tort claims of the injured spouse. When an injured party cannot recover, the spouse claiming loss of consortium is also barred as a matter of law from recovery under that claim.").

Plaintiffs allege Allergen is strictly liable because "[i]n manufacturing the subject implants, Allergan failed to adhere to FDA-approved processes and procedures." (AP, ¶41). Plaintiffs further allege that Allergen was negligent because it "fail[ed] to use reasonable care in designing, manufacturing, labeling, packaging, and selling the subject implants" (AP, ¶47) and "fail[ed] to manufacture the subject implants so as to avoid an unreasonable risk of harm to women in whom the implants are implanted, including the plaintiff[.]" (AP, ¶48(b)). Similarly, Plaintiffs allege NuSil is strictly liable because "[i]n manufacturing the subject silicone, NuSil failed to adhere to FDA-approved processes and procedures." (AP, ¶55). Plaintiffs further allege that NuSil was negligent because it "fail[ed] to use reasonable care in designing, manufacturing, labeling, packaging, and selling the silicone found in the subject implants" (AP, ¶61) and "fail[ed] to manufacture the silicone found in the subject implants so as to avoid an unreasonable risk of harm to women in whom the implants are implanted, including the plaintiff[.]" (AP, ¶62(b)).

Defendants argue that Plaintiffs' claims are preempted. "The Medical Device Amendments of 1976 (MDA) created a scheme of federal safety oversight for medical devices while sweeping back state oversight schemes." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 128 S. Ct. 999, 1000–01, 169 L. Ed. 2d 892 (2008). The MDA preempts claims challenging the safety and effectiveness of premarket approval medical ("PMA") devices. The statute provides that a State shall not "establish or continue in effect with respect to a device intended for human use any requirement—... (1) which is different from, or in addition to, any requirement applicable under [federal law] 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" relevant federal law. 21 U.S.C. § 360k(a). The *Riegel* Court established a two-pronged test for

preemption under the MDA: (1) the court must determine whether the federal government has established the requirements relating to the device, and if so (2) the court must evaluate whether a state claim imposes requirements relating to the safety and effectiveness of the device that are 'different from, or in addition to the federal requirements.'" *Riegel*, 552 U.S. at 321-22 (citing §360k(a)). "The Eighth Circuit has explained that '[w]here a federal requirement permits a course of conduct and the state makes it obligatory, the state's requirement is in addition to the federal requirement and thus is preempted.'" *Blankenship v. Medtronic, Inc.*, 6 F. Supp. 3d 979, 986 (E.D. Mo. 2014) (quoting *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1205 (8th Cir. 2010)).

It is undisputed that the FDA has established regulations and requirements applicable to the relevant silicone implants. Plaintiffs concede that their claims of defective design and failure to warn are expressly preempted by §360k. *See* ECF No. 31 at 4. Plaintiffs' sole remaining theory of liability is for manufacturing defect. Generally, manufacturing defect claims that allege the "manufacturer failed to adhere to the specifications imposed by a device's PMA" are not preempted at the pleading stage. *Hofts v. Howmedica Osteonics Corp.*, 597 F. Supp. 2d 830, 837-38 (S.D. Ind. 2009). Defendants assert that Plaintiffs' manufacturing defect claim nevertheless is preempted because it "attempt to impose responsibilities on [them] that are different from, or in addition to the federal requirements, and is expressly preempted." (ECF No. 16 at 15).

Defendants argue that Plaintiffs' purported manufacturing defect claims are really design and warning claims that are preempted under the FDA. A manufacturing defect occurs when something goes wrong in the manufacturing process and the product is not in its intended condition. *Richcreek v. Gen. Motors Corp.*, 908 S.W.2d 772, 776 (Mo. Ct. App. 1995). The

product is evaluated against the producers' own standards, and compared to like products. *Richcreek*, 908 S.W.2d at 776 (citing *Am Law Prod. Liab.* 3rd § 28:1 p 13). In a design-defect case, however, there is no doubt that the product is in the condition intended by the manufacturer. *Richcreek*, 908 S.W.2d at 776 (citing *Bilotta v. Kelley Co., Inc.*, 346 N.W.2d 616, 621 (Minn. 1984)). In such case, the "defect" lies in a consciously chosen design. *Id.* The manufacturer has deliberately added or omitted the challenged component and has presumably made that decision after balancing a variety of factors. *Id.*; *Richcreek*, 908 S.W.2d at 776 (quoting *Nesselrode v. Executive Beechcraft, Inc.*, 707 S.W.2d 371, 375–77 (Mo. banc 1986) ("To establish liability in a design defect case, the plaintiff bears the burden of demonstrating that the product, as designed, is unreasonably dangerous and therefore 'defective', and that the demonstrated defect caused his injuries."). Defendants contend that Plaintiffs' allegations relate to the dangerous nature of the silicone materials, rather than regarding a specific defect in the assembly or production of the silicone.

At this very early stage of litigation, the Court holds that Plaintiffs have sufficiently alleged claims of manufacturing defects that are not preempted. As stated, Defendants argue that Plaintiffs' claim fails because they have not alleged the "particular defect or flaw in the manufacturing process". (ECF No. 16 at 15, n.9). Plaintiffs, however, alleged a particular defect or flaw in the manufacturing process. Plaintiffs alleged that the silicone implanted in Plaintiffs' differed from NuSil's and the FDA's intended result. (ECF No. 40 at 12 (citing AP, ¶¶41-42); *see also* ECF No. 31 at 12-13). Likewise, Plaintiffs allege that, due to manufacturing defect, the products (the gel and/or the implants) Robin received were not the products approved by the FDA. (ECF No. 40 at 12; *see also* ECF No. 31 at 12). Even though "the precise contours of their theory of recovery have not yet been defined," the Court holds Plaintiffs' allegations

sufficiently allege that Defendants did not adhere to FDA manufacturing requirements. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495, 116 S. Ct. 2240, 2255, (1996).

In addition, Plaintiffs have alleged that the "material fatigue" that led to rupture of the implants was due to manufacturing defect. Defendants ask, without citation, the Court to hold as a matter of law that "all materials are subject to fatigue over time" and that "[m]aterial fatigue is not a manufacturing defect, nor is it suggestive of one." (ECF No. 33 at 4). The Court cannot make such a factual finding on a motion to dismiss. At this stage, the Court is required to draw all reasonable inferences and resolve all factual disputes in favor of the non-moving party. *Coons v. Mineta,* 410 F.3d 1036, 1039 (8th Cir. 2005); *see also Minch Family LLLP v. Buffalo–Red River Watershed Dist.,* 628 F.3d 960, 965 (8th Cir. 2010) ("view[ing] the nonmoving party's facts as true and grant[ing] all reasonable inferences in that party's favor" on review of a grant of a motion for judgment on the pleadings). The Court holds that Plaintiffs have alleged a defect in the manufacturing process and the Court cannot hold as a matter of law at this stage that Plaintiffs' claims are preempted. Accordingly, the Court denies Defendants' motions to dismiss based upon preemption.

Further, the Court holds that Plaintiffs have alleged sufficient facts to support their basic claims of negligence and strict liability. Plaintiffs have not alleged "merely naked assertions that the proper silicone was not used and the correct manufacturing process not followed." *Ortiz v. Allergan, Inc.*, No. 14 CIV. 8188 PAC, 2015 WL 5178402, at *4 (S.D.N.Y. Sept. 4, 2015). Rather, Plaintiffs have extrapolated from the injuries to Robin and the condition of the silicone that there must have been a manufacturing defect. *See, e.g.,* AP, ¶35 ("The characteristics of shell damage are consistent with material fatigue rather than a single event."). Again, Defendants disagree with Plaintiffs' analysis of the damaged implants whether it is indicative of

manufacturing or design defect and assert that Plaintiffs have not pleaded with specificity the alleged manufacturing defect. The Court holds that, at this stage, Plaintiffs have pleaded with sufficient specificity, particularly since they are held to the higher standard of Rule 9. *See In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig.*, 623 F.3d 1200, 1212 (8th Cir. 2010) ("Manufacturing defect claims are not subject, for example, to the 'particularity' pleading requirements of Rule 9."). Therefore, resolving all disputes in favor of the non-moving party, the Court holds that Plaintiffs have plausibly alleged their claims under *Twombly* and *Iqbal* and denies Defendants' motions to dismiss for failure to state a claim.

Accordingly,

IT IS HEREBY ORDERED that Defendant Allergan, Inc.'s Motion to Dismiss (ECF No. 15) and Defendant NuSil Technology LLC's Motion to Dismiss (ECF No. 34) are **DENIED**.

Dated this 11th day of September, 2018.

Ronnie L. White

RONNIE L. WHITE
UNITED STATES DISTRICT JUDGE