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NOT FOR PUBLICATION

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

KAREN WILLIAMS and ROBERT WILLIAMS, wife and husband, Plaintiffs, vs. ALLERGAN USA, INC., a foreign corporation and successor in interest to Inamed Corporation, a foreign corporation; INAMED CORPORATION, a foreign corporation; DOES 1-XX; BLACK and WHITE CORPORATIONS 1-XX, Defendants.	No. CV-09-1160-PHX-GMS **ORDER**

Pending before the Court are Defendants' Motion for Summary Judgment on Plaintiffs' Claims for Product Liability and Negligence, (Dkt. # 17), Plaintiffs' improperly filed Motion to Amend, (Dkt. # 20), and Defendants' Motion to Strike, and Alternatively Response to, Plaintiffs' Supplemental Statement of Facts, (Dkt. # 29). For the following reasons, the Court grants Defendants' Motion for Summary Judgment, and orders the Clerk to strike Plaintiffs' Motion to Amend for failure to comply with the Local Rules, and denies Defendants' Motion to Strike as moot.

BACKGROUND

This case arises from a ruptured silicone breast implant, which was approved by the Food and Drug Administration ("FDA"). In 1991, McGhan Medical Corporation

("McGhan") (one of Defendants' predecessor corporations) applied for premarket approval for the Style 110 breast implant in accordance with MDA and FDA requirements. The FDA denied approval for use in healthy female breasts, but determined there was a public health need for the devices for reconstruction patients. In 1992, the FDA entered into an agreement with McGhan setting forth requirements for McGhan to conduct clinical trials of implant devices for reconstruction patients. The FDA required McGhan to follow various protocols, including a requirement to get informed consent from all patients. The FDA approved McGhan's study protocol in 1998.

In 1999, Ms. Williams had a left mastectomy and sought reconstructive breast surgery. She executed an informed consent agreement indicating she would take part in the McGhan Medical Corporation's Silicone Filled Breast Implant Adjunct Clinical Study. She then underwent reconstructive breast surgery, during which a McGhan Style 110 breast implant was implanted (the "1999 implant").

In 2004, Ms. Williams's doctors suggested she get a replacement implant. Plaintiffs' Response asserts Ms. Williams never gave informed consent to take part in a study in 2004, but Defendants' Reply includes a copy of what appears to be an informed consent form signed by Ms. Williams in 2004. Ms. Williams then had surgery to replace the 1999 implant with another Style 110 implant (the "2004 implant"). In 2007, Williams's physicians discovered the 2004 implant had ruptured, leaking silicone into Ms. Williams's body.

This lawsuit ensued. Plaintiffs' Complaint alleged strict product liability and negligent manufacture, development, design, production, assembly and merchandising of the breast implant. Defendants now contend Plaintiffs' claims are statutorily preempted by the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act, 21 U.S.C. § 360k(a).

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DISCUSSION

I. Summary Judgment Standard

Summary judgment is appropriate if the evidence, viewed in the light most favorable to the nonmoving party, shows "that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). Substantive law determines which facts are material, and "[o]nly disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986); *see Jesinger v. Nev. Fed. Credit Union*, 24 F.3d 1127, 1130 (9th Cir. 1994). In addition, the dispute must be genuine, that is, the evidence must be "such that a reasonable jury could return a verdict for the nonmoving party." *Anderson*, 477 U.S. at 248.

II. Federal Preemption

"[S]tate law that conflicts with federal law is without effect." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992) (internal quotations omitted); *see* U.S. Const. Art. VI, cl. 2. Congress may indicate preemptive intent either through the statute's express language or through its structure and purpose. *Altria Group, Inc. v. Good*, 129 S. Ct. 538, 543 (2008).

The MDA includes an express preemption section, which states, in pertinent part:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement–
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> > (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> >
> > (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter. 21 U.S.C. § 360k(a).

The Supreme Court has held that the MDA preempts state tort claims if two requirements are met: (1) the FDA has established requirements applicable to the medical device at issue, and (2) the state law claims are based on requirements different from or in addition to any MDA

requirement relating to safety and effectiveness. *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1006–07 (2008). Both requirements are met here.

First, the FDA has established extensive requirements applicable to the Style 110 implant. The Court is aware of only one federal case, *Dorsey v. Allergan, Inc.*, applying the *Riegel* preemption doctrine to breast implants. 2009 WL 703290 (M.D. Tenn. March 11, 2009). That case preempted state product liability claims where the FDA had established extensive premarket approval requirements for the Style 20 implant and where state law claims were based on requirements different from or in addition to MDA/FDA requirements. *Id.* at *5.

Similarly, the Style 110 implant is a Class III medical device subject to FDA regulation, and the FDA does not allow the product on the market until the manufacturer provides the FDA with a "reasonable assurance" that the device is both safe and effective. *See* 21 U.S.C. § 360e(d)(2), *Riegel*, 128 S. Ct. at 1001. To make this showing, manufacturers must submit an extensive application detailing information the FDA might use in assessing the product's safety and effectiveness.[1] "Before deciding whether to approve the application, the agency may refer it to a panel of outside experts, and may request additional data from the manufacturer." *Riegel*, 128 S. Ct. at 1004 (citing 21 U.S.C. § 360e; 21 C.F.R. § 814.44(a)). The FDA's final decision requires not only evaluating the product's safety and effectiveness, but also "weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." 21 U.S.C. § 360c(a)(2); *Riegel*, 128 S. Ct. at 1004. Once the FDA approves a product, the manufacturer may not alter it

[1] The report must include, *at a minimum*, (1) "full reports . . . concerning investigations which have been made to show whether or not such device is safe and effective," (2) "a full statement of the components, ingredients, and properties and of the principle or principles of operation," (3) "a full description of the methods used in, and the facilities and controls used for the manufacture, processing, and . . . packing and installation," (4) "performance standard," (5) "samples of such device and of components," (6) "specimens of the labeling proposed," (7) a special "certification," and (8) "such other information relevant to the . . . application." 21 U.S.C. § 360e(c).

without FDA approval. *Riegel*, 128 S. Ct. at 1004. To get the Style 110 implant approved, therefore, Defendants submitted the device to extensive FDA requirements. This included submitting the appropriate premarket documents and ultimately receiving FDA review and approval.

Second, Plaintiffs' claims would impose different or additional requirements on Defendants. Even though the state law at issue here is not statutory, state tort law imposes "requirements" on manufacturers that may be different from or in addition to FDA requirements because "liability is 'premised on the existence of a legal duty,' and a tort judgment therefore establishes that the defendant has violated a state-law obligation." *Id.* at 1008 (citing *Cipollone*, 505 U.S. at 522). Thus, "state tort law that requires a manufacturer's [products] to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect." *Id.* If state tort law imposes different or additional requirements on manufacturers, then a plaintiff's claims, including claims for negligence and strict liability, are preempted. *See, e.g.*, *id.* at 1007–11 (preempting claims of negligence, strict liability, and implied warranty); *Dorsey*, 2009 WL 703290 at *5–7 (preempting claims of negligence, strict liability, and implied warranty). These state tort requirements are preempted "to the extent that they impose additional requirements on device manufacturers," such that "compliance with federal requirements must preclude state law liability." *Prudhel v. Endologix, Inc.*, 2009 WL 2045559 at *8 (E.D. Cal. July 9, 2009). State requirements are not preempted, however, if claims "parallel," rather than add to, federal requirements, such as where claims are based on a violation of FDA regulations. *Riegel*, 128 S. Ct. at 1011(citing *Lohr*, 518 U.S. 470, 495 (1996)).

In this case, Plaintiffs' Complaint alleges negligence and strict liability based on Defendants' development of the Style 110 implant. Plaintiffs claims would impose different and additional requirements on Defendants because state tort law could require Defendants to meet higher standards of care than the FDA required Defendants to meet. Doing so would disrupt the FDA's ability to determine the Style 110's safety and effectiveness and to weigh its benefits against its risks. Thus, Plaintiffs' claims are preempted.

Plaintiffs contend Defendants did not follow MDA and FDA requirements and thus that preemption should not apply. First, Plaintiffs assert that Ms. Williams did not consent to be a member of Defendants' Style 110 implant study in 2004, but rather consented only in 1999. This seems factually untrue given Defendants' submission of what appears to be an authentic disclosure statement and signed consent form from 2004.[2] (Dkt. # 27, Ex. 1.) The document has Ms. Williams's signature and provides, "I voluntarily agree to participate in the McGahn Medical Corporation Silicone-Filled Breast Implant Adjunct Clinical Study. I have read and understood the patient informed consent form. . . . I understand that breast implant surgery may involve risks which are not currently foreseeable." (*Id.*) The disclosure statement also includes a section explaining the risks of implant rupture. (*Id.*) Second, Plaintiffs assert Defendants failed to follow various other FDA procedural requirements for the Style 110 premarket study, but Plaintiffs offer no evidence for this fact.

Even if Plaintiffs' assertions were true, however, it is unclear why these facts would mean the MDA does not preempt the negligence and strict liability claims *alleged in the Complaint*. Plaintiffs are correct that claims paralleling the MDA are not preempted, such as where state tort claims are based on violations of federal law, but Plaintiffs did not allege any such claims in their Complaint. Rather, Plaintiffs alleged claims based on strict liability and negligence in developing the Style 110 implant.[3] With respect to these claims actually alleged, Defendants are entitled to summary judgment because the FDA enforced regulations

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[2] Defendants submitted this evidence along with their Reply and also faxed the form to Plaintiffs' counsel. Ms. Williams asserts in an affidavit that she signed the signature page of the consent form, but that someone else inserted the 2004 date for her. She also asserts she had not seen the entire consent form previously.

[3] Plaintiffs strict liability claim is based on the "manufacture, design, development, production, assembly, testing, inspection, wholesaling, retailing . . . implantation, and [failure] to meet reasonable expectations of safety . . . and [the fact that] any benefits . . . were substantially outweighed by the risk of harm." (Dkt. # 1, Ex. 1 at 4.) Plaintiffs also alleged negligence based on Defendants' "duty not to unreasonably manufacture, develop, design, process, produce, assemble, wholesale, retail, or otherwise place into the stream of commerce the 2004 implant." (*Id.* at 6)

and approved the Style 110 implant and because inflicting state tort law on Defendants would impose different or additional requirements external from federal requirements. Whether Ms. Williams consented and whether Defendants followed every FDA requirement does not negate the fact that the FDA ultimately concluded the Style 110 implant was fit for public use.

For the first time in their Response, Plaintiffs suggest Defendants' noncompliance with FDA requirements disrupted the FDA's approval process and contributed to the product's lack of safety. Without commenting on the merits of such a claim, the Court recognizes such a claim might parallel the MDA and thus avoid preemption. Even construing the Complaint broadly, however, Plaintiffs alleged no facts regarding FDA requirements, the premarket approval process, the study, or Ms. Williams's consent. The Complaint also did not assert any of these arguments in either the count for strict liability or for negligence. This is insufficient to assert a justiciable claim based on Defendants' noncompliance with the MDA and FDA. *See Clemens v. DaimlerChrysler Corp.*, 534 F.3d 1017, 1022 (9th Cir. 2008) (quoting *Twombly*, 550 U.S. at 570) (holding that while "a complaint need not contain detailed factual allegations . . . it must plead 'enough facts to state a claim to relief that is plausible on its face.'").

In addition to this argument, Plaintiffs suggest, without citing any authority, that preemption does not apply because the FDA approved the Style 110 implant over two years after the product was implanted. This distinction is inapposite. *Dorsey* addressed this very question. 2009 WL 703290 at *2. There, plaintiff received Style 20 implants over one year before the implants received premarket approval. *Id.* Citing *Riegel*, the court concluded "the subsequent approval by the FDA is a bar to Plaintiff's strict liability claim because the FDA has determined that the implants at issue are reasonably safe for consumers and there is no suggestion that the implants she received were somehow different than those ultimately approved by the FDA." Here, the fact that the FDA did not approve the Style 110 implant until after Ms. Williams received the implants does not affect preemption as long as Ms.

Williams's implant was essentially the same as the one ultimately approved. Plaintiffs have asserted no facts to the contrary.

Finally, Plaintiffs argue that preemption does not apply because the 1999 consent form Ms. Williams signed stated, "You should understand that you have not waived any of your legal rights by signing this Patient Informed Consent." (Dkt. # 18 Ex. 6.) Reliance on the waiver clause is misplaced. This form addresses whether Ms. Williams waived legal rights, not whether federal law preempts any rights she might otherwise have.

III. Plaintiffs' Alternative Motion to Amend

On September 15, 2009, Plaintiffs improperly filed their Response as a "Response . . . Or in the Alternative, Motion to Amend Complaint" (Dkt. # 20) and also filed an Amended Complaint (Dkt. # 19). The Clerk issued a notice of deficiency to Plaintiffs because Plaintiffs did not seek the Court's leave, file a redline/strikeout version of the proposed amended complaint, or properly lodge the proposed amended complaint in the electronic filing system. (Dkt. # 23.) The Clerk ordered Plaintiffs that they had one day to comply. Instead, Plaintiffs did not re-file a proper version of their amended complaint. Plaintiffs re-filed an identical response, simply deleting the phrase "Or in the Alternative, Motion to Amend Complaint" from the caption. Thus, Plaintiffs' essentially withdrew their Motion to Amend, and the motion should be stricken. Plaintiffs' failure to re-file correctly does not preclude the Court from granting Defendants' Motion for Summary Judgment.

IV. Defendants' Motion to Strike

Pursuant to Local Rule of Civil Procedure 7.2(m)(1), Defendants move to strike Plaintiffs' supplemental statement of facts, which Plaintiffs' filed nine days late in violation of the Court's case management order, (Dkt. # 16). Because summary judgment is appropriate even considering Plaintiffs' supplemental facts, the Court denies Defendants' Motion to Strike as moot. Therefore,

IT IS HEREBY ORDERED that Defendants' Motion for Summary Judgment (Dkt. # 17) is **GRANTED**.

IT IS FURTHER ORDERED that Plaintiffs' Motion to Amend (Dkt. # 20) is **STRICKEN**.

IT IS FURTHER ORDERED that Defendants' Motion to Strike (Dkt. # 29) is **DENIED** as moot.

IT IS FURTHER ORDERED directing the Clerk of the Court **TERMINATE** this action.

DATED this 14th day of October, 2009.

G. Murray Snow
United States District Judge