FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

NICOLE WEBER, *Plaintiff-Appellant,* v. ALLERGAN, INC., *Defendant-Appellee.*	No. 18-15212 D.C. No. 2:12-cv-02388-SRB OPINION

Appeal from the United States District Court for the District of Arizona Susan R. Bolton, District Judge, Presiding

Argued and Submitted September 13, 2019
Pasadena, California

Filed October 11, 2019

Before: Johnnie B. Rawlinson, John B. Owens, and Mark J. Bennett, Circuit Judges.

Opinion by Judge Owens

COUNSEL

Alan C. Milstein (argued), Sherman Silverstein Kohl Rose & Podolsky P.A., Moorestown, New Jersey, for Plaintiff-Appellant.

GinaMarie Slattery (argued), Slattery Petersen, Tucson, Arizona, for Defendant-Appellee.

OPINION

OWENS, Circuit Judge:

Nicole Weber appeals from the district court's grant of summary judgment in favor of Allergan, Inc. Weber sued Allergan under state law alleging that she suffered injuries when her breast implants bled silicone into her body. We have jurisdiction under 28 U.S.C. § 1291, and we affirm.

I. BACKGROUND

A. Weber's Health Problems

In December 2009, Weber underwent reconstructive surgery after a double mastectomy and received Allergan's Natrelle Style 20 silicone breast implants. Weber then suffered severe health problems, including significant vision loss. In October 2011, Dr. Feng removed the implants and opined that a silicone gel bleed from the implants caused Weber's health issues.

According to a pathology report ordered by Dr. Feng, Weber's right implant had lost roughly 2.8% of its mass.

B. FDA Approval of the Style 20 Implants

In November 2006, the Food and Drug Administration ("FDA") provided Class III pre-market approval for the implants. The Style 20 product label stated that, while silicone could bleed out of intact breast implants, "Allergan performed a laboratory test" in which "[o]ver 99% of the . . . silicones . . . stayed in the implant," and that "[t]he overall body of available evidence supports that the extremely low level of gel bleed is of no clinical consequence." In November 2008, the FDA inspected Allergan's manufacturing facility and concluded that the "procedures seem to be adequate and it seems like no significant change has been made to manufacturing." According to Allergan, Weber's right implant passed testing and inspection to ensure compliance with the FDA's pre-market approval for the Style 20 model.

C. Procedural History

Weber sued Allergan in 2012, and in 2016 filed a Third Amended Complaint alleging claims under Arizona law for (1) strict product liability (manufacturing defect); and (2) negligence.[1] As part of discovery,

---

[1] Prior to the Third Amended Complaint, the district court granted Allergan's motion to dismiss, but we reversed and

Allergan deposed Dr. Feng, Weber's main expert. She testified that the 2.8% mass bleed was a "departure from the manufacturer's specifications" and a "defect." Dr. Feng admitted, however, that she did not "know anything about specifications and how that implant is manufactured" and had "no opinion" about "whether or not Allergan violated any protocols for manufacturing."

After discovery, the district court granted Allergan's motion for summary judgment. The district court explained that Weber's evidence of her health problems coupled with an implant bleed "more than twice the expected amount of gel according to the product's labeling" could have been enough to survive summary judgment if Weber "was required to show only that her implant malfunctioned or was defective." But, according to the district court, that was not the relevant question. Rather, Weber needed to show that Allergan "failed to follow the FDA's regulations and requirements set forth in its pre-market approval of the Natrelle Style 20 implant." Dr. Feng's testimony did not address that question, as her opinion "that the implant was defective because it did not function properly is simply not evidence that it was not manufactured according to pre-market approval specifications." Accordingly, "[e]vidence of a malfunction, without more,

---

remanded. *See Weber v. Allergan, Inc.*, 621 F. App'x 401 (9th Cir. 2015) (unpublished).

is . . . insufficient to withstand summary judgment" for Class III medical devices.[2]

II. DISCUSSION

A. Standard of Review

We review de novo a district court's decision to grant summary judgment. *Folkens v. Wyland Worldwide, LLC*, 882 F.3d 768, 773 (9th Cir. 2018). Summary judgment is only appropriate if there is no genuine dispute of material fact, after viewing the evidence in the light most favorable to the nonmoving party. *Id.*

B. Class III Medical Devices

The Food, Drug, and Cosmetic Act ("FDCA") "has long required FDA approval for the introduction of new drugs into the market." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315 (2008). Through the Medical Device Amendments to the FDCA ("MDA"), Congress permitted FDA oversight of medical devices. *Id.* at 316. The MDA established three classes of medical devices, with Class III receiving the most FDA scrutiny. *Id.* at 316–17. "In general, a device is assigned to Class III if . . . [it] is 'purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health,' or 'presents a potential unreasonable

[2] The district court did not reach whether any alleged manufacturing defect caused Weber's health problems, and neither do we.

risk of illness or injury.'" *Id.* at 317 (quoting 21 U.S.C. § 360c(a)(1)(C)(ii)).

The FDA "rigorous[ly]" reviews Class III devices prior to their reaching the market. *Id.* (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996)). This includes a risk-benefit assessment of the device and an analysis of the adequacy of the manufacturer's label. *Id.* at 318. The FDA may "approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives." *Id.* "Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Id.* at 319 (citing 21 U.S.C. § 360e(d)(6)(A)(i)).

C. State Law Claims and the MDA

The MDA expressly preempts state law regulation of medical devices. It provides in relevant part:

> No State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (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).

In *Riegel*, the Supreme Court held that § 360k preempted state law claims challenging the safety and effectiveness of a Class III medical device that had received pre-market approval from the FDA. 552 U.S. at 321–25. Because FDA pre-market approval constitutes federal "requirements," the MDA preempts state laws to the extent they impose standards that are "different from, or in addition to," those federal requirements. *Id.* at 322–23 (quoting 21 U.S.C. § 360k(a)). However, the MDA does not preempt state law requirements that "'parallel,' rather than add to, federal requirements." *Id.* at 330 (quoting *Lohr*, 518 U.S. at 495); *see also Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1228 (9th Cir. 2013) (en banc) (holding that "the MDA does not preempt a state-law claim for violating a state-law duty that parallels a federal-law duty under the MDA"); *Perez v. Nidek Co.*, 711 F.3d 1109, 1120 (9th Cir. 2013) (recognizing a "narrow" preemption exception for parallel state law claims (citation omitted)). In other words, the MDA allows state law claims against a manufacturer of a Class III medical device only if they are "premised on a violation of FDA regulations" relating to the device. *Riegel*, 552 U.S. at 330.

While "[t]he contours of the parallel claim exception were not addressed in *Riegel* and are as-yet ill-defined," *In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation*, 623 F.3d 1200, 1204 (8th

Cir. 2010), the district court in this case applied the same preemption analysis as other courts in our circuit have: to proceed with a state law claim relating to a Class III medical device, such as a product liability or negligence claim, a plaintiff must show a "violation of FDA regulations or requirements related to [the device]." *Erickson v. Bos. Sci. Corp.*, 846 F. Supp. 2d 1085, 1092 (C.D. Cal. 2011); *see also Houston v. Medtronic, Inc.*, 957 F. Supp. 2d 1166, 1174 (C.D. Cal. 2013). Other circuits have similarly held that "to escape express preemption as a parallel claim," a plaintiff must show violation of an FDA requirement applicable to the medical device. *Shuker v. Smith & Nephew, PLC*, 885 F.3d 760, 776 (3d Cir. 2018); *see also*, *e.g.*, *Bass v. Stryker Corp.*, 669 F.3d 501, 512 (5th Cir. 2012); *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1301–02 (11th Cir. 2011).

We adopt this principle as well and hold that, for a state law claim regarding a Class III medical device to survive express preemption by the MDA, a plaintiff must establish that the defendant violated an FDA requirement. As noted above, the protocols and specifications established by the FDA's pre-market approval constitute such requirements. *See Riegel*, 552 U.S. at 321–23. For example, if the FDA's pre-market approval "required 400 degree welds but the manufacturer used a 300 degree welding process," that could show violation of an FDA requirement and establish a parallel state law claim. *In re Medtronic*, 623 F.3d at 1207.

However, the FDA's pre-market approval of the process by which a Class III device is manufactured

"does not guarantee that every device manufactured in that process will work." *Banner v. Cyberonics, Inc.*, No. 08-0741, 2010 WL 455286, at *4 (D.N.J. Feb. 4, 2010) (unpublished). Rather, the FDA performs a cost-benefit analysis and may approve devices knowing that they sometimes will fail. *See Riegel*, 552 U.S. at 318, 325. When it enacted the MDA, Congress struck a balance "in which it determined that the benefit to the many of bringing potentially lifesaving, but risky, medical devices to the public following the rigorous process of FDA approval outweighed the cost to the few of preempting common law claims based on different standards." *Walker v. Medtronic, Inc.*, 670 F.3d 569, 572 (4th Cir. 2012). Thus, the MDA "provides immunity for manufacturers of new Class III medical devices to the extent that they comply with federal law, but it does not protect them if they have violated federal law." *Bausch v. Stryker Corp.*, 630 F.3d 546, 553 (7th Cir. 2010); *see also Williams v. Cyberonics, Inc.*, 654 F. Supp. 2d 301, 306 (E.D. Pa. 2009) ("[A] plaintiff must make some showing that the medical device was not manufactured in accordance with FDA standards."), *aff'd*, 388 F. App'x 169 (3d Cir. 2010) (unpublished). And to survive MDA preemption, a plaintiff cannot simply demonstrate a defect or a malfunction and rely "on *res ipsa loquitur* to suggest only . . . 'that the thing speaks for itself.'" *Funk v. Stryker Corp.*, 631 F.3d 777, 782 (5th Cir. 2011); *see also Clark v. Medtronic, Inc.*, 572 F. Supp. 2d 1090, 1094 (D. Minn. 2008) (rejecting reliance on "res ipsa loquitur for the proposition that full compliance would have resulted in a problem-free device"). Instead, for a state law claim to survive

express preemption under the MDA, a plaintiff must show that the defendant deviated from a particular pre-market approval or other FDA requirement applicable to the Class III medical device.

D. Weber Failed to Show that Allergan Violated a Federal Requirement

Weber's dual attempts to demonstrate that Allergan violated FDA requirements fall short. She first argues that Allergan's product label providing a bleed rate of less than 1% is an FDA pre-market approval requirement, relying heavily on the dissent in the Fourth Circuit's decision in *Walker*.

In *Walker*, the plaintiff's husband died when his internally implanted pump, a Class III medical device, administered a lethal overdose of pain medication. 670 F.3d at 574–75. The plaintiff argued that the pump's pre-market approval materials' statement that the pump had a flow accuracy of "plus or minus 15 percent . . . became a part of the federal requirements governing the device," which the defendant violated because the pump "allegedly infused an amount of medication outside of these parameters." *Id.* at 578. However, the plaintiff conceded that the "pump was designed, manufactured, and distributed in compliance with the terms of the FDA's premarket approval" and that "the plus or minus 15 percent specification is *not* a formal performance standard." *Id.*

The *Walker* majority held that the plus or minus 15 percent specification did not create a federal

requirement, and therefore the plaintiff's state law claims that the pump failed to comply with this specification were preempted. *Id.* at 578–81. "In short, nothing in the . . . pump's premarket approval application—which was approved in its entirety by the FDA—purported that the device would *always* dispense medication within the range of the plus or minus 15 percent flow accuracy." *Id.* at 580 (emphasis added). "Instead, the plus or minus 15 percent specification reflects the . . . pump's output under optimal conditions, but subject to numerous qualifiers that disclose the possibility of infusion outside this range." *Id.* "To the extent that [the plaintiff] interprets the plus or minus 15 percent specification as a guarantee of performance, she seeks to impose a more demanding standard than that of the FDA, rather than a parallel one." *Id.*

In contrast, the dissent would have held that the plus or minus 15 percent accuracy specification was indeed a federal requirement, rather than a "mere aspirational figure," and therefore the plaintiff's state law claims were not preempted under the MDA. *Id.* at 581 (Wynn, J., dissenting). The dissent reasoned that "[t]he FDA accepted [the] margin [for error], based on [the] Pre-Market Approval application, to be plus or minus 15 percent" and the plaintiff "alone should [not] bear the burden of [the] malfunction" when the pump "instead infused her husband with 258 percent of the appropriate medication dosage, and this extreme overdose killed him." *Id.* at 585.

Here, Weber urges us to follow the *Walker* dissent, and hold that the implant label's statement that a

laboratory test showed that "[o]ver 99% of the . . . silicones . . . stayed in the implant" was a requirement of the FDA's pre-market approval, rather than an "aspirational figure." *Id.* at 581. However, we agree with the *Walker* majority. There is no indication that Allergan purported to the FDA that the implant would "always" bleed less than 1%. *Id.* at 580. To the extent Weber interprets the implant label's statement "as a guarantee of performance, she seeks to impose a more demanding standard than that of the FDA, rather than a parallel one." *Id.*; *see also Rankin v. Bos. Sci. Corp.*, No. 09-177-KSF, 2010 WL 672135, at *4 (E.D. Ky. Feb. 19, 2010) (holding that the manufacturer did not "violate [ ] some federally imposed requirement or regulation" merely because a balloon catheter with a rated burst pressure of 12 atmospheres allegedly ruptured at only 6 atmospheres during a surgical procedure).

Weber also argues that *Walker* is different because there the majority was "compelled to affirm" "[i]n light of [the plaintiff's] concession that the device was designed, manufactured, and distributed in compliance with the terms of its premarket approval," *id.* at 571, a concession that Weber never made. Yet she fails to show that Allergan violated an FDA pre-market approval requirement.

Weber's only evidence that Allergan did not comply with the FDA's pre-market approval is Dr. Feng's opinion that Weber's right implant's gel bleed exceeding the amount specified by its product labeling constituted a "departure from the manufacturer's specifications" and a "defect." However, Dr. Feng's opinion

that the implant was defective and malfunctioned is not evidence that Allergan deviated from the FDA's pre-market approved procedures. *Res ipsa loquitor* is not enough to survive MDA preemption. *See Funk*, 631 F.3d at 782; *Clark*, 572 F. Supp. 2d at 1094. Dr. Feng conceded that she did not "know anything about specifications and how that implant is manufactured" and had "no opinion" about "whether or not Allergan violated any protocols for manufacturing." On the other hand, Allergan provided evidence that Weber's right implant was inspected and complied with the FDA's pre-market approval. In sum, Weber failed to raise a genuine dispute of material fact that Allergan violated a requirement of the FDA's pre-market approval.

Second, Weber argues that Allergan violated the FDA's Current Good Manufacturing Practices or "CGMPs," found in the Quality System Regulations applicable to all medical devices, which "require each manufacturer to put in place processes to test products for compliance with product specifications, to check and document compliance with product specifications before products are accepted for sale and use, and to identify and control nonconforming products." *Bausch*, 630 F.3d at 556 (citing 21 C.F.R. §§ 820.72–820.90).

We need not wade into the intercircuit disagreement regarding whether a parallel claim demands that the federal "requirement" must be "device-specific" (such as FDA pre-market approval for a particular medical device) or may be a general FDA regulation applicable to all medical devices (such as the Current Good Manufacturing Practices). *See*, *e.g.*, *Mink v.*

Smith & Nephew, Inc., 860 F.3d 1319, 1331 n.3 (11th Cir. 2017) (agreeing "with our sister circuits that there is no 'sound legal basis' to distinguish these federal requirements because the plain text of § 360k refers to 'any requirement' (quoting *Bausch*, 630 F.3d at 555)); *Bass*, 669 F.3d at 511–13 (noting that "the circuits are not in complete agreement as to what constitutes a sufficient pleading with regard to a CGMP," and holding that allegations based on a CGMP were sufficient at the pleading stage because at trial the plaintiff "will have to prove violations of the more specific, FDA-approved PMA process for this device"); *Bausch*, 630 F.3d at 554–55 (noting that some federal courts have held that "the Quality System Regulations and Current Good Manufacturing Practices are too general to allow juries to enforce them," but rejecting that approach).

Here, even if more general FDA requirements are sufficient, Weber has not shown a violation of the FDA's Current Good Manufacturing Practices. Again, the mere evidence suggesting that her particular breast implant was defective does not show that Allergan failed to comply with the FDA's Current Good Manufacturing Practices. Likewise, evidence that some other implants produced by Allergan were defective does not demonstrate noncompliance. *Cf. Erickson*, 846 F. Supp. 2d at 1093 (stating that "product recalls do not create a presumption that FDA requirements have been violated").

Accordingly, the district court properly granted summary judgment because Weber failed to raise a

genuine dispute of material fact that Allergan violated a federal "requirement" for its Style 20 implant. 21 U.S.C. § 360k(a); *see also Riegel*, 552 U.S. at 330; *Stengel*, 704 F.3d at 1228. We are sympathetic to Weber's health problems. However, she has not shown a violation of an FDA requirement, which she must for her state law claims to fit through the "narrow" exception to MDA preemption. *Perez*, 711 F.3d at 1120 (citation omitted).

AFFIRMED.[3]

[3] Weber also requests that we reverse the district court's cost award. However, Weber "waived her right to appellate review of the cost award" because she neither objected to Allergan's bill of costs nor moved for district court review of the clerk's taxation of costs under Federal Rule of Civil Procedure 54(d)(1). *Mendiola-Martinez v. Arpaio*, 836 F.3d 1239, 1262 (9th Cir. 2016).

NOT FOR PUBLICATION

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

Nicole Weber, Plaintiff, v. Allergan Incorporated, Defendant.	No. CV-12-02388-PHX-SRB **ORDER** (Filed Jan. 25, 2018)

At issue is Defendant's Motion for Summary Judgment ("MSJ") (Doc. 114).

I. BACKGROUND

This case arises out of injuries Plaintiff suffered after the implantation of silicone gel breast implants manufactured by Defendant. (Doc. 124, Pl. Nicole Weber's Resp. to Allergan, Inc.'s Separate Statement of Facts, and Statement of Additional Facts[1] ¶¶ 2, 6.) Plaintiff was diagnosed with breast cancer in March 2009 and underwent reconstructive surgery following a double mastectomy on December 21, 2009. (PSOF ¶ 1-2.) After the procedure, Plaintiff began to suffer severe adverse symptoms, and on October 20, 2011, she

[1] Plaintiff's Statement of Additional Facts begins on page 1, paragraph 1 and will be referred to as "PSOF." Plaintiff's Response to Defendant's Separate Statement of Facts begins on page 9, paragraph 1 and will be referred to as "PRSOF."

underwent an explantation procedure. (PSOF ¶¶ 6-7, 36.) The surgeon who performed the explantation, Dr. Lu-Jean Feng, opined that a gel bleed from Plaintiff's implants caused her adverse symptoms. (PSOF ¶ 8.) At the time of removal, Plaintiff's right implant had lost approximately 2.8% of its volume. (PSOF ¶ 9; Doc. 115, Separate Statement of Facts in Supp. of Mot. for Summ. J. on Behalf of Allergan ("DSOF")[2] ¶ 3.) Plaintiff alleges that the 2.8% gel bleed from her right implant was due to a manufacturing defect. (DSOF ¶¶ 1-3; PRSOF ¶¶ 1-3.)

The Natrelle Style 20 implant that was used in Plaintiff's reconstructive surgery is a Class III medical device, subject to regulation by the Food and Drug Administration ("FDA"). (DSOF ¶ 7; PRSOF ¶ 7.) The FDA approved Defendant's pre-market approval application to manufacture the Style 20 implant in November 2006. (*Id.*) Defendant's product labeling stated that after testing "[o]ver 99% of the [low molecular weight] silicones and platinum stayed in the implant." (PRSOF ¶ 10.) It further stated that "[t]he overall body of available evidence supports that the extremely low level of gel bleed is of no clinical consequence." (*Id.* (emphasis omitted).) The FDA conducted an inspection at Defendant's manufacturing facility in November 2008, and the inspector concluded that "the procedures seem to be adequate and it seems like no significant change

---

[2] Defendant filed an additional statement of facts with its Reply. (Doc. 132) Reply statements of fact are not permitted under the Local Rules. LRCiv 56.1(b). Therefore, the Court will not consider Defendant's additional filing.

has been made to manufacturing." (DSOF ¶ 16; PRSOF ¶ 16.) Defendant alleges that Plaintiff's right implant was subject to testing and inspection by Defendant in 2009 to ensure its compliance with the FDA's pre-market approval, and it passed this inspection and was approved for distribution in late 2009.[3] (DSOF ¶ 19, 21.)[4] Defendant alleges that Plaintiff's

---

[3] Although Defendant's Statement of Facts states that the implant was approved for distribution in early 2010, the expert report that supports this allegation states that it was approved for distribution in late 2009. (Doc. 115, Ex. A- Expert Report of Nelson Rodriguez at 2.)

[4] Plaintiff argues that the expert report of Nelson Rodriguez, which supports the above allegation, is inadmissible because it is not an affidavit or declaration, and it refers to other documents not cited by Defendant. (Doc. 123, Pl.'s Mem. in Opp'n to MSJ ("Resp.") at 10.) A motion for summary judgment may be supported by:

> materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion), admissions, interrogatory answers, or other materials.

Fed. R. Civ. P. 56(c)(1)(A). Expert reports constitute "other materials" that are routinely cited by parties to support or respond to motions for summary judgment. Furthermore, experts are permitted to rely upon facts or data that are not admissible if they would reasonably rely on them in forming an opinion on the subject. Fed. R. Evid. 703. Mr. Rodriguez's report discloses that he relied on the Device History Report for the right implant, the Operative Report, the Pathology Report, the Complaint, and the 2008 FDA Inspection Report in concluding that Plaintiff's right implant was subjected to and passed product testing. (Doc. 114, Ex-A, Expert Report of Nelson Rodriguez at 1.) These all strike the Court as reasonable data for Mr. Rodriguez to rely on in forming his conclusions. Plaintiff's objections to the report are therefore rejected. Furthermore, Plaintiff has the burden to cite

implant was manufactured and labeled according to FDA specifications; Plaintiff argues that the gel bleed constitutes evidence of a deviation from the manufacturing specifications. (DSOF ¶ 22; PRSOF ¶ 22.)

Dr. Feng examined the implant following the explantation procedure and testified that although she could not see any defects, the implant's volume was "unusually low." (DSOF ¶ 23; PRSOF ¶ 23.) In Dr. Feng's expert report, Dr. Feng opined that the bleed from Plaintiff's implants constitutes a departure from the manufacturer's specifications and that it did have a clinical consequence for Plaintiff. (DSOF ¶¶ 25-26; PRSOF ¶¶ 25-26.) The parties do not dispute that Dr. Feng has no knowledge concerning how the Natrelle Style 20 implant is manufactured or the manufacturing protocols required. (DSOF ¶ 23; PRSOF ¶ 23.) Dr. Feng also testified that she has no opinion regarding whether Defendant followed the proper manufacturing specifications and protocols when manufacturing Plaintiff's right implant, but she did opine that the implant's bleed of more than two times the amount specified by Defendant in its product labeling constituted a defect. (*Id.*) The parties agree that Dr. Feng was never provided the manufacturing specifications for Natrelle implants, the FDA Update on Silicone Gel-Filled Breast Implants, the February 2009 FDA Inspection Report, or the Device History Report for Plaintiff's right implant. (DSOF ¶ 27; PRSOF ¶ 27.) Although Dr.

---

evidence showing that Defendant failed to abide by its pre-market approval requirements even in the absence of Mr. Rodriguez's report.

Feng is a highly experience [sic] medical authority on breast implants, she has never held a position within the FDA or participated in the pre-market approval process for a Class III medical device. (DSOF ¶ 29; PRSOF ¶ 29.)

Defendant argues that it is entitled to summary judgment on Plaintiff's negligence and strict product liability claims because Plaintiff has failed to adduce any evidence that her right implant was not manufactured according to the specifications and protocols outlined in the Natrelle Style 20 pre-market approval. (MSJ at 1.)[5] Plaintiff argues that Dr. Feng's expert report regarding the extent of the gel bleed and its consequences for Plaintiff constitute sufficient evidence of a manufacturing defect to withstand summary judgment. (Resp. at 2.)

II. LEGAL STANDARD AND ANALYSIS

Under Federal Rule of Civil Procedure 56, summary judgment is properly granted when: (1) there is no genuine dispute as to any material fact; and (2) after viewing the evidence most favorably [sic] to the non-moving party, the movant is clearly entitled to prevail as a matter of law. Fed. R. Civ. P. 56(a); *Celotex*

[5] Defendant also argues that Plaintiff has failed to adduce sufficient evidence to show that any alleged manufacturing defect caused her adverse symptoms. (MSJ at 1.) Because the Court agrees that Plaintiff has failed to adduce any evidence that Defendant did not follow the specifications and protocols required by its pre-market approval when manufacturing her breast implants, it need not address this argument.

Corp. v. Catrett, 477 U.S. 317, 322-23 (1986); *Eisenberg v. Ins. Co. of N. Am.*, 815 F.2d 1285, 1288-89 (9th Cir. 1987). A fact is "material" when, under the governing substantive law, it could affect the outcome of the case. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A genuine dispute of material fact arises if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.* In considering a motion for summary judgment, the court must regard as true the non-moving party's evidence if it is supported by affidavits or other evidentiary material, and "all inferences are to be drawn in the light most favorable to the non-moving party." *Eisenberg*, 815 F.2d at 1289; *see also Celotex*, 477 U.S. at 324. However, the non-moving party may not merely rest on its pleadings; it must produce some significant probative evidence tending to contradict the moving party's allegations, thereby creating a material question of fact. *Anderson*, 477 U.S. at 256-57 (holding that the plaintiff must present affirmative evidence to defeat a properly supported motion for summary judgment); *First Nat'l Bank of Ariz. v. Cities Serv. Co.*, 391 U.S. 253, 289 (1968).

The Natrelle Style 20 breast implants at issue in this case are a Class III medical device approved by the FDA pursuant to a pre-market approval. As such, state law claims with requirements different from or in addition to the requirements imposed by the FDA during the pre-market approval process are preempted by the Medical Device Amendments to the Food, Drug, and Cosmetic Act. 21 U.S.C. § 301-399f; *Riegel v. Medtronic,*

Inc., 552 U.S. 312, 321-23 (2008). Therefore, in order to proceed with a products liability or negligence claim relating to a Class III medical device, a plaintiff must show (1) a "violation of FDA regulations or requirements related to [the device]" and (2) "a causal nexus between the alleged injury and the violation." *Erickson v. Bos. Scientific Corp.*, 846 F. Supp. 2d 1085, 1092 (C.D. Cal. 2011) (citations omitted); *see also Bass v. Stryker Corp.*, 669 F.3d 501, 512 (5th Cir. 2012). Plaintiff has failed to provide sufficient evidence of a violation of FDA regulations or requirements related to the Natrelle Style 20 silicone gel breast implant to withstand summary judgment.

Plaintiff argues that her expert, Dr. Feng, provides sufficient evidence that Defendant violated the FDA regulations and requirements related to her right implant because Dr. Feng testified that the implant bled more than twice the expected amount of gel according to the product's labeling. (Resp. at 13-14.) She also argues that her adverse symptoms are evidence that the bleed in question did in fact have clinical consequences despite the label's indication to the contrary. (Resp. at 13.) This evidence may indeed be sufficient to withstand summary judgment if Plaintiff was required to show only that her implant malfunctioned or was defective. It is insufficient, however, to create a material dispute of fact concerning whether Defendant failed to follow the FDA's regulations and requirements set forth in its pre-market approval of the Natrelle Style 20 implant.

Defendant objects that Dr. Feng's opinion that the gel bleed is evidence of a manufacturing defect is conclusory and lacks sufficient foundation given Dr. Feng's admitted lack of manufacturing expertise and that she did not review any of the manufacturing documentation. (MSJ at 10-11). The Court agrees. Plaintiff admits that Dr. Feng was never provided any information concerning the manufacturing specifications and protocols of the implants, and Dr. Feng testified that she has no knowledge concerning the creation of the Natrelle implant. (Doc. 114, Ex. F- Lu-Jean Feng Dep. Mar. 27, 2017 131:15-17 ("Right. I don't know anything about specifications and how that implant is manufactured.").) Dr. Feng's opinion that the implant was defective because it did not function properly is simply not evidence that it was not manufactured according to pre-market approval specifications. The FDA does not approve Class III medical devices because they are completely safe; rather, it "must 'weig[h] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.'" *Riegel*, 552 U.S. at 318 (quoting 21 U.S.C. § 360c(a)(2)(C)). "It may thus approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives." *Id.* Therefore, it is entirely possible that a Class III device could be manufactured according to specifications and still cause injury or fail to function as expected. *See*, *e.g.*, *Walker v. Medtronic, Inc.*, No. 2:07-00317, 2010 WL 4822135, *5 (S.D. W. Va. Nov. 24, 2010), affirmed by *Walker v. Medtronic, Inc.*, 670 F.3d 569 (4th Cir. 2012) (pain pump that was manufactured in accordance with the terms

of its pre-market approval over-infused patient with a lethal dose of pain medication) ("An alleged deviation from manufacturing performance specifications for a device that has received premarket approval is not the same thing as noncompliance with the FDA or its regulations."). Evidence of a malfunction, without more, is therefore insufficient to withstand summary judgment in favor of Defendant in this case.

III. CONCLUSION

The Court grants Defendant's Motion for Summary Judgment because Plaintiff failed to produce evidence creating a material dispute of fact concerning whether Defendant failed to follow FDA requirements when manufacturing the Natrelle Style 20 implant Plaintiff received.

IT IS ORDERED granting Defendant's Motion for Summary Judgment (Doc. 114).

IT IS FURTHER ORDERED directing the Clerk to enter Judgment in favor of Defendant.

Dated this 24th day of January, 2018.

/s/ Susan R. Bolton
Susan R. Bolton
United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

Nicole Weber, Plaintiff, v. Allergan Incorporated, Defendant.	**NO. CV-12-02388-PHX-SRB** **JUDGMENT IN A CIVIL CASE** (Filed Jan. 25, 2018)

Decision by Court. This action came for consideration before the Court. The issues have been considered and a decision has been rendered.

IT IS ORDERED AND ADJUDGED that, pursuant to the Court's Order filed January 25, 2018, which granted Defendant's Motion for Summary Judgment, judgment is entered in favor of defendant and against plaintiff. Plaintiff to take nothing, and the complaint and action are hereby dismissed.

Brian D. Karth
District Court Executive/Clerk of Court

January 25, 2018

s/ A. Duran
By Deputy Clerk