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

SUMMARY*

Medical Device Amendments / Preemption

The panel affirmed the district court's summary judgment in favor of Allergan, Inc. in plaintiff's action under Arizona law alleging that she suffered injuries when her breast implants bled silicone into her body.

Through the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act, Congress permitted the Food and Drug Administration ("FDA") oversight of medical devices. In November 2006, the FDA provided Class III pre-market approval for the implants.

The MDA expressly preempts state law regulation of medical devices. The panel held that 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.

The panel held that plaintiff failed to show that Allergan violated an FDA requirement. Specifically, the panel held plaintiff failed to raise a genuine dispute of material fact that Allergan violated a requirement of the FDA's pre-market approval. The panel further held that plaintiff had not shown a violation of the FDA's Current Good Manufacturing Practices found in the Quality System Regulations applicable to all medical devices. The panel concluded that

* This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

plaintiff failed to raise a genuine dispute of material fact that Allergan violated a federal requirement for its Style 20 implant, which she must have for her state law claims to fit through the narrow exception to MDA preemption.

COUNSEL

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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, 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,

[1] Prior to the Third Amended Complaint, the district court granted Allergan's motion to dismiss, but we reversed and remanded. *See Weber v. Allergan, Inc.*, 621 F. App'x 401 (9th Cir. 2015) (unpublished).

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, 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

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

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 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:

> [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—
>
> > (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).