NOT FOR PUBLICATION

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U.S. COURT OF APPEALS

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

KIMBERLY WEAVER and JAMES WEAVER, Plaintiffs-Appellants, v. ETHICON, INC. and DOES, 1-20, inclusive, Defendants-Appellees.	No. 17-55350 D.C. No. 3:16-cv-00257-GPC-BGS MEMORANDUM*

Appeal from the United States District Court
for the Southern District of California
Gonzalo P. Curiel, District Judge, Presiding

Submitted June 8, 2018**
Pasadena, California

Before: LIPEZ,*** TALLMAN, and OWENS, Circuit Judges.

Appellants Kimberly and James Weaver ("Appellants") appeal the district

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* This disposition is not appropriate for publication and is not precedent except as provided by Ninth Circuit Rule 36-3.

** The panel unanimously concludes this case is suitable for decision without oral argument. *See* Fed. R. App. P. 34(a)(2).

*** The Honorable Kermit V. Lipez, United States Circuit Judge for the First Circuit, sitting by designation.

court's dismissal with prejudice of their Third Amended Complaint ("TAC"). We have jurisdiction under 28 U.S.C. § 1291, and we review "a district court's determination of whether a plaintiff's complaint complied with the notice pleading requirements" *de novo*. *Lehman v. Nelson*, 862 F.3d 1203, 1211 (9th Cir. 2017) (quoting *Pickern v. Pier 1 Imp. (U.S.), Inc.*, 457 F.3d 963, 968 (9th Cir. 2006)).

Appellees Ethicon, Inc., and other defendants (collectively, "Ethicon"), produce the Surgiflo Hemostatic Matrix Kit ("Surgiflo"), a Class III medical device subject to the Food and Drug Administration's ("FDA") rigorous premarket approval regulations. Surgiflo acts as a self-absorbing wound packing to control bleeding after surgery. In 2012, Ethicon voluntarily conducted two recalls of Surgiflo packs based on issues with the sterility of the packaging. Both recalls were completed by September 2014. The oldest recalled Surgiflo packs had expiration dates of June 2013.

On November 24, 2014, Kimberly Weaver underwent sinus surgery and a Surgiflo pack was used to control the bleeding. On December 4, however, Weaver underwent a second surgery due to an infection resulting from the Surgiflo's alleged failure to reabsorb. Appellants sued Ethicon under a variety of theories, and the district court ultimately dismissed with prejudice Appellants' TAC alleging manufacturing defects, a failure to warn, and loss of consortium.

I

Through the Medical Device Amendments ("MDA"), 21 U.S.C. § 360 *et seq.*, Congress replaced a patchwork of state laws that had previously governed medical devices with a uniform federal regulatory regime. Under § 360k(a), state laws "which relate[] to the safety or effectiveness of the device" and are "different from, or in addition to" federal requirements under the MDA, are expressly preempted. To avoid preemption, state laws must be "equal to, or substantially identical to, requirements imposed by or under the [MDA]." 21 C.F.R. § 808.1(d)(2). *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321–22 (2008). Therefore, to survive dismissal, a plaintiff must plead sufficient factual allegations to show that the state-law claims fall within the "narrow" parallel exception to preemption. *Perez v. Nidek Co.*, 711 F.3d 1109, 1120 (9th Cir. 2013). A plaintiff must also plead the necessary elements of the state-law claims with "sufficient factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). This requires Appellants to plead "more than an unadorned, the-defendant-unlawfully-harmed-me accusation. *Id.*[1]

[1] We observe that the district court's order appears to conflate the MDA preemption inquiry with the inquiry into whether the plaintiffs have stated a claim under state law. Because "we may affirm based on any ground supported by the record," *Johnson v. Riverside Healthcare Sys., LP*, 534 F.3d 1116, 1121 (9th Cir. 2008), we resolve this case based on the Weavers' failure to plead

A

Appellants first contend that the district court erred by dismissing their manufacturing defect claim at the pleadings stage because the information the court required them to plead could only be obtained through discovery. Under California law, a manufacturing defect occurs when the product "differs from the manufacturer's intended result or from other ostensibly identical units from the same product line[,]" *Barker v. Lull Eng'g Co.*, 573 P.2d 443, 454 (Cal. 1978), and the alleged defect causes the plaintiff's injury, *Soule v. Gen. Motors Corp.*, 882 P.2d 298, 303 (Cal. 1994). Here, Appellants' manufacturing defect claim fails because even assuming they have pled a parallel state claim, they failed to adequately allege (1) factual, non-conclusory support for the claim that Weaver's doctor used a recalled Surgiflo pack or (2) the nature of the manufacturing defect. Accordingly, Appellants did not plead the necessary facts to support the causation element, and we affirm the district court's dismissal of Appellants' manufacturing defect claim.

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necessary elements of their state law claims. We note, however, that the MDA preemption inquiry examines a plaintiff's possible expansion of the scope of the defendant's duty under existing federal law, *see Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1228 (9th Cir. 2013) (en banc) ("[T]he MDA does not preempt a state-law claim for violating a state-law *duty* that parallels a federal-law *duty* under the MDA.") (emphases added), not whether the plaintiff adequately plead the elements of a state law claim.

B

To prevail on their failure to warn claim, Appellants must plead facts to support their claim that if Ethicon "had properly reported the adverse events to the FDA as required under federal law, that information would have reached [Weaver's] doctors in time to prevent h[er] injuries." *See Stengel*, 704 F.3d at 1234 (Watford, J., concurring). Here, Appellants proffer two events that allegedly triggered Ethicon's duty to report: first, a third-party's 2010 report on a public website that an element of the Surgiflo pack would not reconstitute,[2] and second, her own injury.

Again assuming (1) the Weavers have pled a parallel state claim and (2) the 2010 report was rationally related to the same defect allegedly at issue here, the fact that Weaver's doctor had access to that report on a public database maintained by the FDA negates her claim. For even if Ethicon had a duty to report the 2010 issue to the FDA and failed to do so, Weaver's physician could have viewed the report independently, considered the alleged issue's effect on his recommendation, informed the Weavers, and elected not to use Surgiflo. Nor can Ethicon's failure to report Weaver's injury logically be the cause of her injury as well.

[2] The 2010 report was filed on the FDA's Manufacturer and User Facility Device Experience ("MAUDE") website, which is publicly available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=1691379&pc=LMF.

Consequently, Appellants failed to plead a necessary element of the failure to warn claim, and the district court's dismissal was correct. We also agree that after three tries, further amendment would have been futile.

C

Because Appellants' loss of consortium claim is derivative of the manufacturing defect and failure to warn claims, *see Riegel*, 552 U.S. at 321, we affirm the district court's dismissal of that claim as well.

Costs are awarded to Appellees.

AFFIRMED.