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U.S. COURT OF APPEALS

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UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

LORI SPELLMAN, Plaintiff–Appellant, v. SMITH & NEPHEW, INC., a Tennessee Corporation, Defendant–Appellee.	No. 17-15351 D.C. No. 3:16-cv-08080-JWS MEMORANDUM*

Appeal from the United States District Court
for the District of Arizona
John W. Sedwick, District Judge, Presiding

Argued and Submitted February 12, 2018
San Francisco, California

Before: KLEINFELD and TALLMAN, Circuit Judges, and JACK,** District Judge.

Lori Spellman sued Smith & Nephew, Inc., the manufacturer of her two hip implants, alleging violations of Arizona state law. Spellman claims that Smith & Nephew failed to warn the FDA of problems with the implants. She also claims

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

** The Honorable Janis Graham Jack, United States District Judge for the Southern District of Texas, sitting by designation.

that the implants suffered from manufacturing defects. The district court granted Smith & Nephew's motion to dismiss and denied Spellman leave to file an amended complaint. We have jurisdiction under 28 U.S.C. § 1291 and reverse.

1. Spellman's proposed amended complaint sufficiently alleges a failure-to-warn claim under Arizona law. Insofar as the state-law duty to warn parallels a federal-law duty under the Medical Device Amendments to the Food, Drug, and Cosmetic Act, 21 U.S.C. § 360c et seq., that claim is not preempted. Stengel v. Medtronic Inc., 704 F.3d 1224, 1233 (9th Cir. 2013) (en banc). Spellman alleges that after the hip implants went on the market, Smith & Nephew "became aware of wide evidence that the BHR system[] was wearing down more quickly and severely than anticipated." Despite receiving "hundreds of adverse reports regarding the BHR system," Smith & Nephew "delayed its reporting to the FDA" and "failed to properly communicate adverse events to the FDA." When it did make reports, Smith & Nephew "underreported" and "withheld information" about how likely the implants were to fail. All of this happened after Smith & Nephew "became aware of defects in the BHR [system] and harm it was causing" but before Spellman's surgeries. Neither Spellman nor her doctor knew about the problems associated with the implants. These factual allegations plausibly suggest

entitlement to relief on the claim that Smith & Nephew failed to warn the FDA of problems with the implants. Together with the reasonable inferences drawn from them, they sufficiently state a claim that Smith & Nephew's failure to warn the FDA of problems with the implants caused Spellman's injuries. See id. at 1234–35 (Watford, J., concurring) ("To prevail, [the plaintiff] will ultimately have to prove that if [the defendant] had properly reported the adverse events to the FDA as required under federal law, that information would have reached [her] doctors in time to prevent [her] injuries. But at this juncture—a request for leave to amend the[] complaint—the [plaintiff's] allegations of causation are adequate.") (citation omitted).

2. Although the manufacturing defect allegations in Spellman's proposed amended complaint fail to state a plausible claim for relief, see Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009), the district court erred by dismissing her complaint with prejudice. Spellman alleges that Smith & Nephew failed to "identify the component discrepancy" and failed to "capture the component discrepancy or defect during their Final Acceptance Activities." Those failures, she claims, violated regulations designed in part to ensure that her implants conformed to the design that the FDA approved. See 21 C.F.R. § 820.80. Spellman may be alleging

that problems in the manufacturing process resulted in deviations from the FDA-approved design, causing her to suffer "an adverse metal reaction." A manufacturing defect claim premised upon sufficient factual allegations of that nature would be plausible and, insofar as the relevant state-law duty parallels a federal-law duty under the Medical Device Amendments to the Food, Drug, and Cosmetic Act, would not be preempted. See Mink v. Smith & Nephew, Inc., 860 F.3d 1319, 1329–31 (11th Cir. 2017) (holding that a complaint against the manufacturer of a Class III medical device sufficiently stated a manufacturing defect claim that was not preempted where it alleged that the device was not manufactured according to FDA premarket approval requirements and federal regulations); Bausch v. Stryker Corp., 630 F.3d 546, 556–63 (7th Cir. 2010) (same, and noting that at the motion to dismiss stage, some details about the manufacture of a Class III medical device remain in the hands of the manufacturer, preventing more detailed factual pleading). Spellman's proposed amended complaint does not identify the "component discrepancy or defect" that she believes caused her injuries. Nevertheless, although the district judge in the multidistrict litigation dismissed a similar manufacturing defect claim on Rule 8 grounds, see In re Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Prods. Liab. Litig., No. CCB–17–2775, 2018 WL 1471684, at *13 (D. Md. Mar. 26, 2018), it remains

possible for Spellman to amend her complaint to add factual allegations that are sufficient to state a claim that will survive a motion to dismiss. See Mink, 860 F.3d at 1329–31; Bausch, 630 F.3d at 556–63; Eminence Capital, LLC v. Aspeon, Inc., 316 F.3d 1048, 1052 (9th Cir. 2003) ("Dismissal with prejudice and without leave to amend is not appropriate unless it is clear on de novo review that the complaint could not be saved by amendment.").

REVERSED and REMANDED.