NOT FOR PUBLICATION

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MOLLY C. DWYER, CLERK
U.S. COURT OF APPEALS

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

REBECA LAWRENCE, Plaintiff-Appellant, v. MEDTRONIC, a foreign corporation, Defendant-Appellee.	No. 18-55621 D.C. No. 2:16-cv-07289-DSF-AS MEMORANDUM*

Appeal from the United States District Court
for the Central District of California
Dale S. Fischer, District Judge, Presiding

Argued and Submitted December 12, 2019
Pasadena, California

Before: BOGGS,** WARDLAW, and BEA, Circuit Judges.

Rebeca Lawrence sued Medtronic, alleging a variety of state-law tort claims stemming from her use of Medtronic's SynchroMed II drug-infusion pump ("the Pump"), which is a Class III medical device subject to the Food and Drug Administration's ("FDA") pre-market approval process ("PMA"). She appeals the

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

** The Honorable Danny J. Boggs, United States Circuit Judge for the U.S. Court of Appeals for the Sixth Circuit, sitting by designation.

district court's dismissal of her product-defect and failure-to-warn claims for failure to state a claim and its dismissal of her misrepresentation claims at summary judgment. We have jurisdiction under 28 U.S.C. § 1291, and we affirm.

1. The district court did not err in dismissing Lawrence's claims that were based on Medtronic's failure to ship her old Pumps back to company headquarters for further analysis because such claims are preempted. State-law claims for devices that have undergone PMA are preempted "to the extent that they [impose requirements that] are 'different from, or in addition to' the requirements imposed by federal law." *Riegel v. Medtronic*, *Inc.*, 552 U.S. 312, 330 (2008) (quoting 21 U.S.C. § 360k(a)(1)). To avoid preemption, a plaintiff bringing a state tort claim must allege that the state-law duty at issue parallels a federal requirement. *Id.* Lawrence identifies no federal authority that requires medical-device manufacturers to send removed medical devices anywhere for evaluation. Indeed, there is no federal regulation mandating any analysis of removed medical devices, and thus a tort claim premised on such a course of conduct would impose a requirement that is "different from" and "in addition to" what is required under federal law. *See id.*

2. The district court did not err in dismissing Lawrence's claims to the extent they were based on Medtronic's alleged failure to report adverse events to the FDA because they failed to state plausible claims for relief. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). To prevail, Lawrence must plausibly allege that had

Medtronic "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." *See Stengel v. Medtronic*, 704 F. 3d 1224, 1234 (9th Cir. 2013) (en banc) (Watford, J., concurring). Lawrence cannot plausibly allege that the purported absence of adverse-event reports regarding her own pumps caused her any injury. Moreover, contrary to Lawrence's assertions, the record indicates that Medtronic did in fact file the reports at issue. Medtronic included the reports, which were the proper subjects of judicial notice, in several attached exhibits to its motion to dismiss. *See* Fed. R. Evid. 201. Accordingly, Lawrence's allegations are facially implausible and are not enough for us to "draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678.

3. The district court did not err in dismissing Lawrence's claims that were based on product-defect theories of recovery. Although such theories are not preempted if the claim is that Medtronic failed to comply with a federal requirement, Lawrence's First Amended Complaint contains only conclusory allegations, which fail to identify any specific federal requirement that was violated or the specific nature of the Pump's purported defects. Several of our sister circuits have not permitted such product-defect theories to proceed if the plaintiff cannot plausibly allege either the violation of a specific requirement or the specific nature of the defect. *See Funk v. Stryker Corp.*, 631 F.3d 777, 782 (5th Cir. 2011) (affirming

dismissal when the complaint failed to "specify a causal connection between the failure of the specific manufacturing process and the specific defect in the process that caused the personal injury"); *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1206 (8th Cir. 2010) (affirming dismissal when the "[p]laintiffs failed to identify any specific federal requirement in the PMA approval . . . for an unpreempted parallel claim"). Lawrence does neither and thus the district court properly dismissed the claims associated with these theories.

4. The district court did not err in dismissing Lawrence's claims for negligent and intentional misrepresentation at summary judgment because Lawrence failed to demonstrate a genuine dispute of material fact over whether she justifiably relied on any statement made by Medtronic. *Weber v. Allergan*, 940 F.3d 1106, 1110 (9th Cir. 2019) (standard of review). Under California law, a plaintiff claiming either intentional or negligent misrepresentation must prove justifiable reliance to prevail. *Small v. Fritz Cos., Inc.*, 30 Cal. 4th 167, 173–74 (2003). During Lawrence's deposition, she admitted that she did not rely on Medtronic's statements when she decided to continue using the Pumps. She further admitted that she agreed to get each pump without knowing whether her doctor had received any analysis of the explanted pumps, and before it would have been possible for any analysis of the previous pump to be completed. Notwithstanding this lack of information, Lawrence was most concerned about the "potential benefits" of the Pumps and

continued using the Pumps without the analysis from Medtronic. The district court's grant of summary judgment was thus proper.

AFFIRMED.