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U.S. COURT OF APPEALS

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

KATHRYN MARIE JONES, Plaintiff-Appellant, v. MEDTRONIC, INC., et al., Defendants-Appellees.	No. 15-15653 D.C. No. 2:14-cv-00383 MEMORANDUM*

Appeal from the United States District Court
for the District of Arizona
Steve P. Logan, District Judge, Presiding

Argued and Submitted July 12, 2018
San Francisco, California

Before: GRABER and HURWITZ, Circuit Judges, and LEMELLE,** Senior District Judge.

In October 2010, Plaintiff Kathryn Marie Jones underwent three spinal fusion surgeries (the "spinal procedures"), during which her surgeons implanted several devices manufactured and sold by Medtronic, Inc. Jones' pro se complaint alleged

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

** The Honorable Ivan L.R. Lemelle, Senior United States District Judge for the Eastern District of Louisiana, sitting by designation.

that she was permanently disabled as a result of the spinal procedures, and she asserted various state law claims against Medtronic.

The district court dismissed most of Jones' claims as preempted by the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.* The court dismissed the remainder of Jones' claims, without leave to amend, as inadequately pleaded. We review de novo the district court's preemption rulings and its denial of leave to amend based upon those rulings. *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1227 (9th Cir. 2013) (en banc). We affirm in part, vacate in part, and remand for further proceedings.

1. The express preemption clause in the MDA prevents certain state-law claims concerning medical devices approved by the Food and Drug Administration. 21 U.S.C. § 360k(a). The FDCA also impliedly preempts private attempts to enforce the MDA. *See* 21 U.S.C. § 337(a); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). But there is a narrow gap through which a state-law claim can fit to escape preemption. *Perez v. Nidek Co.*, 711 F.3d 1109, 1120 (9th Cir. 2013). If a state-law claim imposes requirements that are "parallel" to, rather than in addition to or different from, federal requirements, the state-law claim is not preempted. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008); *Perez*, 711 F.3d at 1120.

2. The parties agreed at oral argument that if Jones had plausibly alleged in her complaint that (a) off-label use of the Medtronic devices had caused untoward

results before the spinal procedures were performed; (b) Medtronic failed to report such results to the FDA as required; (c) this failure to report caused the FDA not to issue further warnings; and (d) in turn, this failure to warn caused Jones' injuries, any such claim would not be preempted. *See Stengel*, 704 F.3d at 1233. The parties also agreed that a properly alleged claim of manufacturing defect would not be preempted. Leave to amend should be granted freely when justice so requires. Fed. R. Civ. P. 15(a). Because Jones, now represented by counsel, seeks to amend her complaint to assert such claims, we vacate the judgment below and remand to allow her to attempt to do so.

3. Federal law requires manufacturers of medical devices to update labeling in accordance with new intended uses of approved devices. 21 C.F.R. § 801.4. A claim alleging a parallel Arizona state-law "misbranding" claim would therefore not be preempted. *See Medtronic, Inc., v. Lohr*, 518 U.S. 470 (1996); *Riegel*, 552 U.S. 312; *Buckman,* 531 U.S. at 352–53. Because it does not appear from the record that Jones could not assert such a claim, she may attempt to do so on remand.

4. We affirm the district court's dismissal of Jones' fraud claims. Jones contends that Medtronic fraudulently promoted the Infuse Bone Graft and Infuse Device for off-label use, "thus inducing patients and doctors to use the device in manners that had not been approved by the FDA."

> A claim for fraud requires proof of nine elements by clear and convincing evidence: (1) a representation; (2) its falsity; (3) its

> materiality; (4) the speaker's knowledge of its falsity or ignorance of its truth; (5) the speaker's intent that it be acted upon by the recipient in the manner reasonably contemplated; (6) the hearer's ignorance of its falsity; (7) the hearer's reliance on its truth; (8) the hearer's right to rely on it; (9) the hearer's consequent and proximate injury.

Comerica Bank v. Mahmoodi, 229 P.3d 1031, 1033–34 (Ariz. Ct. App. 2010); *see also Correa v. Pecos Valley Dev. Corp.*, 617 P.2d 767, 771 (Ariz. Ct. App. 1980) (holding that "[t]he requisites of a private cause of action for a statutory fraud are a false promise or a misrepresentation made in connection with the sale or advertisement of merchandise and the consumer's consequent and proximate injury" which "occurs when the consumer relies on the misrepresentation"). We agree that Jones failed to plausibly allege reliance on any alleged Medtronic misrepresentation with the particularity or specificity required by Federal Rule of Civil Procedure 9(b). Indeed, any such allegation is foreclosed by Jones' express allegations that "at no point were any of the Medtronic products mentioned or discussed with her prior to their being implanted in her body during the Spinal Procedure." Consequently, amendment would be futile. *See Krainski v. Nevada ex rel. Bd. of Regents of Nev. Sys. of Higher Educ.*, 616 F.3d 963, 972 (9th Cir. 2010) ("Dismissal without leave to amend is improper unless it is clear, upon *de novo* review, that the complaint could not be saved by any amendment.") (citation omitted). Jones also asserted constructive fraud. The district court liberally construed this as a fraud-by-omission claim, and correctly rejected it as expressly preempted. *See Perez*, 711 F.3d at 1118.

5. We affirm also the district court's rulings that Jones' design defect claims and negligence *per se* claims are preempted. *See Riegel*, 552 U.S. at 325 ("State tort law that requires a manufacturer's [Class III device] to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme . . . ."); *Buckman,* 531 U.S. at 352–53.

AFFIRMED in part, VACATED in part and REMANDED for further proceedings. Each party to bear its own costs.