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FILED

FEB 5 2021

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U.S. COURT OF APPEALS

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

NICOLE VIEIRA; EMILIA BAROZZI, Plaintiffs-Appellants, v. MENTOR WORLDWIDE, LLC; et al., Defendants-Appellees.	No. 19-56394 D.C. No. 2:19-cv-04939-AB-PLA MEMORANDUM*

Appeal from the United States District Court
for the Central District of California
Andre Birotte, Jr., District Judge, Presiding

Submitted February 3, 2021**
Pasadena, California

Before: GOULD, OWENS, and VANDYKE, Circuit Judges.

Plaintiffs appeal from the district court's judgment dismissing their action alleging state law claims arising out of injuries they suffered after the implantation of MemoryGel Silicone Breast Implants manufactured by Mentor Worldwide, LLC ("Mentor"). The breast implants at issue are a Class III medical device approved

* 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).

by the Federal Drug Administration ("FDA") under the pre-market approval process of the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA"). We review de novo a district court's denial of a motion to remand. *Canela v. Costco Wholesale Corp.*, 971 F.3d 845, 849 (9th Cir. 2020). We review de novo a district court's dismissal for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6), and for abuse of discretion the denial of leave to amend. *Curry v. Yelp Inc.*, 875 F.3d 1219, 1224 (9th Cir. 2017). As the parties are familiar with the facts, we do not recount them here. We affirm.

1. The district court properly denied Plaintiffs' motion to remand. Mentor's removal was timely under 28 U.S.C. § 1446(b)(3) because the deposition transcript of Scott Mraz revealed sufficiently new information about NuSil, LLC ("NuSil") to trigger the removal. *See Fritsch v. Swift Transp. Co. of Ariz., LLC*, 899 F.3d 785, 789 (9th Cir. 2018); *Carvalho v. Equifax Info. Servs., LLC*, 629 F.3d 876, 887 (9th Cir. 2010).

The district court properly determined that NuSil was fraudulently joined, and therefore diversity jurisdiction existed. Fraudulent joinder may be established "if a defendant shows that an 'individual[] joined in the action cannot be liable on any theory.'" *Grancare, LLC v. Thrower ex. rel. Mills*, 889 F.3d 543, 548 (9th Cir. 2018) (citation omitted). "Fraudulent joinder must be proven by clear and convincing evidence." *Hamilton Materials, Inc. v. Dow Chem. Corp.*, 494 F.3d

1203, 1206 (9th Cir. 2007). Based on Mraz's deposition testimony and the amended Statement of Information, Mentor showed by clear and convincing evidence that NuSil was not involved in manufacturing or supplying the silicone used in Mentor's allegedly defective implants, and thus there was no possibility Plaintiffs could recover against NuSil. *See DiCola v. White Brothers Performance Prods., Inc.*, 69 Cal. Rptr. 3d 888, 897 (Ct. App. 2008).

2. The district court also properly dismissed Plaintiffs' state law claims as preempted by the MDA. The MDA expressly preempts state law claims unless they are premised on a "parallel" federal requirement. *See* 21 U.S.C. § 360k(a); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008). Even if a state law claim is not expressly preempted by the MDA, it may be impliedly preempted. *See* 21 U.S.C. § 337(a); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352-53 (2001). Thus, to escape preemption, a state law claim must fit through a "narrow gap": "The plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*)." *Perez v. Nidek Co., Ltd.*, 711 F.3d 1109, 1120 (9th Cir. 2013) (citation omitted).

Plaintiffs' failure to warn claims are primarily based on Mentor's alleged failure to report adverse events related to its MemoryGel Silicone Breast Implants

to the FDA. In states that recognize failure to report claims, such as California, a manufacturer's failure to report adverse events to the FDA can form the basis of a parallel claim that survives preemption. *See Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013) (en banc); *Coleman v. Medtronic, Inc.*, 167 Cal. Rptr. 3d 300, 311-12 (Ct. App. 2014).

Here, however, Plaintiffs fail to allege actual adverse events that Mentor did not report to the FDA. Rather, Plaintiffs speculate that if Mentor had conducted its post-approval studies differently (e.g., increased follow-up with participants), then Mentor would have identified additional adverse events that it would have reported to the FDA. These conclusory and speculative allegations are insufficient to state a parallel failure to warn claim. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Moreover, to the extent Plaintiffs base their failure to warn claims on Mentor's alleged failure to properly conduct the post-approval studies, Plaintiffs' claims are impliedly preempted because Plaintiffs do not identify a parallel state law duty to conduct post-approval studies. In addition, to the extent Plaintiffs argue that Mentor failed to warn them or their doctors directly, such claims are preempted because there are no such federal requirements. *See Stengel*, 704 F.3d at 1234 (Watford, J., concurring).

For their manufacturing defect claims to survive express preemption under the MDA, Plaintiffs must allege that Defendants "deviated from a particular pre-

market approval or other FDA requirement applicable to the Class III medical device." *Weber v. Allergan, Inc.*, 940 F.3d 1106, 1112 (9th Cir. 2019). They "cannot simply demonstrate a defect or a malfunction and rely on *res ipsa loquitur* to suggest only . . . that the thing speaks for itself." *Id.* (citation and internal quotation marks omitted).

Here, Plaintiffs fail to allege that Defendants violated a particular FDA requirement. For example, Plaintiffs vaguely allege that Mentor's MemoryGel Silicone Breast Implants contained unidentified materials that differed from those approved by the FDA. Further, Plaintiffs' mere allegations "suggesting that [their] particular breast implant[s] w[ere] defective do[] not show that [Defendants] failed to comply with the FDA's Current Good Manufacturing Practices." *Id.* at 1114.

While we are sympathetic to Plaintiffs' health problems, they have not sufficiently alleged a state law claim that squeezes through the "narrow gap" to escape MDA preemption. *Perez*, 711 F.3d at 1120 (citation omitted).

3. Finally, the district court did not abuse its discretion by dismissing Plaintiffs' action without leave to amend based on its determination that any amendment would be futile. *See Ebner v. Fresh, Inc.*, 838 F.3d 958, 968 (9th Cir. 2016).

AFFIRMED.