NOT FOR PUBLICATION

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

BRITTANY A. BILLETTS, an individual; et al., Plaintiffs-Appellants, v. MENTOR WORLDWIDE, LLC; et al., Defendants-Appellees.	No. 19-56398 D.C. No. 5:19-cv-01026-AB-PLA MEMORANDUM* (Filed Feb. 5, 2021)

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

* 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).

approved 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 premarket 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.

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

BRITTANY BILLETTS et al; Plaintiffs, v. MENTOR WORLDWIDE, LLC; NUSIL, LLC; NUSIL TECHNOLOGY, LLC; and DOES 1-100, inclusive. Defendant.	Case No. ED CV 19-01026-AB (PLAx) **ORDER DENYING PLAINTIFFS' MOTION TO REMAND AND GRANTING DEFENDANTS' MOTIONS TO DISMISS** (Filed Aug. 27, 2019)

Before the Court are two motions filed by the parties.

On June 12, 2019 Defendants Mentor Worldwide, LLC. ("Mentor"), NuSil LLC., and NuSil Technology LLC ("NuSil") filed a motion to dismiss (Dkt. No. 10). Plaintiffs Brittany Billets, Vivian Aguiar, Ann Delmonico, Cornelia Ditto and Leah Johnson ("Plaintiffs") opposed the motion (Dkt. No. 20).

Plaintiffs filed a Motion to Remand (Dkt. No. 16) and Defendants opposed the motion (Dkt. No. 18). The Court deemed the matter appropriate for resolution without oral argument, *see* Local Rule 7.15, and took the matter under submission on August 14, 2019. For the following reasons, Plaintiffs' Motion to Remand is **DENIED** and Defendants' Motions to Dismiss is **GRANTED**.

I. BACKGROUND

This lawsuit revolves around injuries Plaintiffs allegedly suffered after receiving surgical implants of Mentors' MemoryGel Silicone Breast Implants ("MemoryGel Implants"). Plaintiffs plead the following in their Complaint ("Compl.," Dkt. No. 1, Exhibit A).

A. The Parties

Billets is a citizen and resident of San Bernardino County, California. Compl. ¶ 1. Aguiar is a citizen and resident of Miami-Dade County, Florida. *Id.* ¶ 2. Delmonico is a citizen and resident of Newport County, Rhode Island. *Id.* ¶ 3. Ditto is a citizen and resident of Seminole County, Florida. *Id.* ¶ 4. Johnson is a citizen of Lee County, Mississippi. *Id.* ¶ 5.

Mentor is a limited liability company incorporated in Delaware with its principal place of business in Santa Barbara, California. *Id.* ¶ 6. Mentor manufactured the MemoryGel Implants at issue. *Id.* ¶ 7.

NuSil LLC is a limited liability company incorporated in California with its principal place of business in Carpinteria, California. *Id.* ¶ 8.

NuSil Technology, LLC is a limited liability company incorporated in Delaware with its principal place of business in Carpinteria, California. *Id.* ¶ 9. NuSil LLC and NuSil Technology are silicone raw material suppliers and allegedly manufactured, produced, supplied, and shipped the silicone used in the MemoryGel Implants. *Id.* ¶11.

B. FDA Regulation of Silicone Breast Implants

In 1976, Congress passed the Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act ("FDCA"). *Id.* ¶ 41. Under the MDA, medical devices, such as the MemoryGel Implants, are subject to three classifications and regulated accordingly. *Id.* ¶ 42. Class I devices require the least and most general oversight, Class II devices are reviewed according to more stringent "special controls," and Class III devices receive the most oversight and require rigorous premarket review and approval. *Id.* The Food and Drug Administration ("FDA") classified silicone breast implants as Class III devices. *Id.* ¶ 43. Accordingly, the FDA requires manufacturers to meet certain requirements for Class III devices. *Id.* On April 10, 1991, the FDA published a final regulation under Section 515(b) of the FDCA requiring that manufacturers of silicone breast implants submit pre-market approval ("PMA") applications with data showing a reasonable assurance of safety and effectiveness of the implants by July 9, 1991. *Id.* ¶ 44.

C. Mentor's FDA Approval

In order to eventually seek PMA for its MemoryGel Implants, Mentor was required to first provide the FDA with sufficient information regarding the safety and efficacy of the medical device. *Id.* ¶ 51. On December 12, 2003, Mentor submitted a request to the FDA for PMA for its MemoryGel Implants. *Id.* ¶ 67. On

November 17, 2006, Mentor received approval subject to certain conditions. *Id.* ¶¶ 68. One of the conditions imposed on Mentor required it to conduct six post-approval studies[1] to further characterize the safety and effectiveness of MemoryGel Implants. *Id.* ¶ 68.

D. Plaintiffs' MemoryGel Procedures

Billets was implanted with MemoryGel Implants on August 15, 2013. *Id.* ¶ 21. Billets alleges that following implantation she experienced fatigue, muscle pain, muscle weakness, joint pain and swelling, vision issues, light sensitivity, numbness, skin rashes, dizziness, nausea, memory loss, shortness of breath, cognitive dysfunction, chest pain, migraines, silicone toxicity, night sweats, and hair loss. *Id.* ¶ 22. On May 26, 2017, Billets was diagnosed with a rupture of her right breast implant. *Id.* ¶ 23.

Aguiar was implanted with MemoryGel Implants on September 8, 2016. *Id.* ¶ 24. Following implantation, Aguiar developed a number of illnesses and symptoms, including, among other things, pain and swelling of the breasts, seromas, and muscle pain. *Id.* ¶ 25. On February 15, 2018, Aguiar underwent an explantation of her implants. *Id.* ¶ 26. A gel bleed/rupture of Aguiar's right implant was discovered during the procedure. *Id.*

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[1] The FDA required Mentor to conduct: the core study, the large post-approval study, the device-failure study, the focus-group study, the informed-decision study, and the adjunct study. *Id.* ¶ 69.

After explantation, various defects were found within Nunn's right breast implant. *Id.* ¶ 27.

Delmonico was implanted with MemoryGel Implants on July 22, 2010. *Id.* ¶ 28. Following implantation, Solano developed a number of illnesses and symptoms., including, among other things, pain and swelling of the breast, seromas, joint pain, swelling, stiffness and fatigue, muscle pain and weakness, memory loss, shortness of breath, cognitive dysfunction, migraines, chest pains, chronic sore throats, itching, nausea, dizziness, numbness in her extremities, issues with her vision, skin rashes, light sensitivity, silicone toxicity, night sweats, and hair loss. *Id.* ¶ 29. On April 28, 2017, Delmonico underwent an explantation of her implants. *Id.* ¶ 30. After explantation, various defects were found within Delmonico's right breast implant. *Id.* ¶ 31.

Ditto was implanted with MemoryGel Implants on October 9, 2007. *Id.* ¶ 32. Following implantation, Watson began to experience, among other things, pain and swelling of the breasts, seromas, fatigue, joint pain, swelling and stiffness, muscle pain and weakness, and migraines. *Id.* ¶ 33. On October 12, 2017, Ditto underwent a bilateral explantation of her implants. *Id.* ¶ 34. A gel bleed/rupture was discovered during the procedure. *Id.* After explantation, various defects were found within Watson's right breast implant. *Id.* ¶ 35.

Johnson was implanted with MemoryGel Implants on September 2, 2010. *Id.* ¶ 36. Following the implantation, Johnson began to experience, among

other things, fatigue, cognitive dysfunction, muscle pain and weakness, joint pain and soreness, dry skin, dry eyes, easy bruising and slow healing wounds, shortness of breath, metallic taste, night sweats, skin rashes, insomnia, swollen and tender lymph nodes in the breast area, numbness, chest pain, fevers, chronic neck and back pain, light sensitivity, vision issues, migraines, chest inflammation, and hair loss. *Id.* ¶ 37. On October 20, 2017, Johnson underwent a bilateral explantation. *Id.* ¶ 38. A gel bleed/rupture was discovered. *Id.* After explantation, various defects were found within Johnson's right breast implant. *Id.* ¶ 39.

E. This Action

On February 22, 2019, Plaintiffs filed a complaint in the Los Angeles County Superior Court asserting causes of action for: (1) negligence/negligence per se; (2) failure to warn; and (3) manufacturing defect. On June 5, 2019, Mentor filed a notice of removal in this Court and then filed a motion to dismiss Plaintiffs' complaint pursuant to Federal Rule of Civil Procedure 12(b)(6). Plaintiffs filed a motion to remand.

II. LEGAL STANDARD

A. Motion to Dismiss Under 12(b)(6)

Federal Rule of Civil Procedure 8 requires a plaintiff to present a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Under Rule 12(b)(6), a defendant may move to dismiss a pleading for "failure to state a claim

upon which relief can be granted." Fed. R. Civ. P. 12(b)(6).

To defeat a motion to dismiss under Rule 12(b)(6), the complaint must provide enough details to "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). The complaint must also be "plausible on its face," allowing 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). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* at 678. Labels, conclusions, and "a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555.

When ruling on a Rule 12(b)(6) motion, "a judge must accept as true all of the factual allegations contained in the complaint." *Erickson v. Pardus*, 551 U.S. 89, 94 (2007). But a court is "not bound to accept as true a legal conclusion couched as a factual allegation." *Iqbal*, 556 U.S. at 678 (internal quotation marks omitted).

B. Leave to Amend

Should a court dismiss certain claims, "[l]eave to amend should be granted unless the district court 'determines that the pleading could not possibly be cured by the allegation of other facts.'" *Knappenberger v. City of Phoenix*, 566 F.3d 936, 942 (9th Cir. 2009) (quoting

Lopez v. Smith, 203 F.3d 1122, 1127 (9th Cir. 2000) (en banc)); *see also Knevelbaard Dairies v. Kraft Foods, Inc.*, 232 F.3d 979, 983 (9th Cir. 2000) ("An order granting such a motion must be accompanied by leave to amend unless amendment would be futile").

C. Removal

Federal courts are courts of limited jurisdiction and possess only that jurisdiction as authorized by the Constitution and federal statute. *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994). Under 28 U.S.C. § 1441(a), a party may remove a civil action only if the district court has original jurisdiction over the issues alleged in the state court complaint. There is a strong presumption that the Court is without jurisdiction until affirmatively proven otherwise. *See Fifty Assocs. v. Prudential Ins. Co. of America*, 446 F.2d 1187, 1190 (9th Cir. 1970). When an action is removed from state court, the removing party bears the burden of demonstrating that removal is proper. *Gaus v. Miles, Inc.*, 980 F.2d 564, 566 (9th Cir. 1992).

Under the diversity statute, 28 U.S.C. § 1332, a federal district court has original jurisdiction when the parties are completely diverse and the amount in controversy exceeds $75,000. *See* 28 U.S.C. § 1332. Pursuant to 28 U.S.C. § 1441(a) and (b), a defendant may remove an action from state court to federal court if the diversity and amount in controversy requirements are satisfied.

A non-diverse party may be disregarded for purposes of determining whether jurisdiction exists if the court determines that the party's joinder was "fraudulent" or a "sham." *Ritchey v. Upjohn Drug Co.*, 139 F.3d 1313, 1318 (9th Cir. 1998). "Fraudulent joinder" occurs, for the purpose of determining diversity jurisdiction, where the plaintiff fails to state a cause of action against the resident defendant, and the failure is obvious according to settled rules of the state. *McCabe v. Gen. Foods Corp.*, 811 F.2d 1336 (9th Cir. 1987). "But if there is a possibility that a state court would find that the complaint states a cause of action against any of the resident defendants, the federal court must find that the joinder was proper and remand the case to the state court." *Grancare, LLC v. Thrower by & through Mills*, 889 F.3d 543, 548 (9th Cir. 2018) (quotations omitted).

The defendant has a high burden of proof when establishing fraudulent joinder. A removing defendant may present evidence to prove fraudulent joinder, but the district court must resolve all disputed questions of fact in the plaintiff's favor. *See Grancare*, 889 F.3d at 549. Thus, a defense should not require "a searching inquiry into the merits of the plaintiff's case, even if that defense, if successful, would prove fatal." *Id.* In this regard, "[r]emand must be granted unless the defendant shows that the plaintiff would not be afforded leave to amend his complaint to cure [a] purported deficiency" in its allegations against the non-diverse defendant. *Padilla v. AT & T Corp.*, 697 F. Supp. 2d 1156, 1159 (C.D. Cal. 2009) (quotations omitted). Ultimately,

"[f]raudulent joinder must be proven by clear and convincing evidence." *Hamilton Materials, Inc. v. Dow Chem. Corp.*, 494 F.3d 1203, 1206 (9th Cir. 2007).

III. DISCUSSION

A. The Court Has Subject Matter Jurisdiction

This dispute raises two issues concerning the Court's subject matter jurisdiction. First, Plaintiffs argue Mentor's Notice of Removal is untimely. Additionally, Defendants contend that complete diversity[2] exists because NuSil LLC, a California corporation, is fraudulently joined. The Court addresses each argument in turn.

1. Mentor's Removal Was Timely

Plaintiffs first argue that Mentor's removal was untimely and improper because it was not based on new grounds or new information. "[A] notice of removal may be filed within 30 days after receipt by the defendant, through service or otherwise, of a copy of an amended pleading, motion, order or other paper from which it may first be ascertained that the case is one which is or has been removable." 28 U.S.C. 1446. The thirty-day period applies even to cases which have been previously been removed and remanded, so long

[2] There is no federal question jurisdiction in this matter as it does not touch upon any area of federal law. Thus this Court only has jurisdiction if all the requirements of diversity jurisdiction are satisfied.

as the latter removal is "based on information not available at the prior removal." *See Sweet v. United Parcel Serv., Inc.*, 2009 WL 1664644 at * 3 (C.D. Cal. June 15, 2009) (permitting subsequent removal and denying motion to remand).

Mentor's successive removal was timely and proper. On May 9, 2019, Edward Scott Mraz, a member of NuSil LLC since August 1, 2005, was deposed. *See* Mentor Notice of Removal (Dkt. No. 1). Mraz testified, among other things, that NuSil was a holding company and had no involvement in the manufacturing of the implants.[3] Plaintiffs argue Mraz's deposition did not reveal additional facts to permit successive removal. To the contrary, Mraz's statements provided further clarity regarding the status of NuSil LLC and its lack of involvement in the production of the silicone used in Mentor's MemoryGel Implants. After Mraz's deposition, Defendants timely removed on the basis of this new information. Accordingly, removal was timely and the Court's inquiry ends there.

2. NuSil LLC is Fraudulently Joined

Plaintiffs also assert there is not complete diversity of citizenship because NuSil LLC and Billets are both California citizens. In their Complaint, Plaintiffs aver that NuSil LLC manufactured a defective component of Mentor's implants. In response, Mentor contends NuSil LLC was fraudulently joined in the action.

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[3] The substance of Mraz's deposition is discussed below.

In a product liability action, a plaintiff must establish "that the defendant produced, manufactured, sold, or was in some way responsible for the [defective] product." *Garcia v. Joseph Vince Co.*, 84 Cal. App. 3d 868, 874 (1984) (quotations omitted). Mentor argues that NuSil LLC was not involved with the production of the silicone used in its MemoryGel implants. Specifically, Mentor argues NuSil LLC is a holding company with no operations, and thus could not have participated in the manufacture of Mentor's allegedly defective implants. In support of this argument, Mentor submitted to the Court the Declaration of Scott Mraz ("Mraz Decl.", Dkt. No. 1-9). Mr. Mraz declares that NuSil LLC (1) is a holding company that transacts no business of its own and whose sole purpose is to hold stock for its members; (2) has not developed, designed, manufactured, supplied, or distributed any products, including the silicone or silicone gel used to manufacture breast implants; and (3) has no ownership interest in or control over the plant, equipment, and supplies that are used to manufacture the silicone raw materials used in breast implants. *See* Mraz Decl. ¶¶ 4-5, 13-14. Plaintiffs also deposed Mr. Mraz. Under oath, Mr. Mraz confirmed that NuSil LLC is an investment holding company that played no role in producing or supplying any products used in the manufacture of breast implants. (*See* Deposition of Scott Mraz ("Mraz Dep.")

Billets produces evidence contrary to Mr. Mraz's position and suggests there is a triable issue. In 2013, NuSil LLC filed a Statement of Information with the Secretary of State of California. The Statement of

Information is a short, two-page document which identifies NuSil LLC as a "Manufacturer of Silicone Products". Mraz signed that Statement of Information as CFO/President of NuSil. Under oath, Mraz testified that he would have reviewed the document for accuracy before signing.

Mentor claims that the 2013 Statement of Information contained a clerical error and points out that NuSil has since filed an amended statement of information wherein it describes itself as an "Investment holding entity." Mentor argues this corrected Statement of Information "conclusively resolve[s]" the factual dispute this Court previously addressed in a related matter.[4]

After a review of the amended Statement of Information and Mr. Mraz's testimony at deposition, the Court concludes that NuSil LLC did not manufacture silicone and was not involved in the development of the MemoryGel Implant. NuSil is not a proper defendant in this lawsuit as there is no possibility that Plaintiff could recover under a theory of product liability against NuSil LLC.

B. Motion to Dismiss

In support of their motions to dismiss, Defendants argue that Plaintiffs' state-law claims are expressly and impliedly preempted by the MDA. Because Plaintiffs'

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[4] *See Vieira v. Mentor Worldwide, LLC, et al.*, No. 2-18-cv-06502-AB (PLAx) (C.D. Cal. Aug. 23, 2018)

claims against Mentor are preempted by the MDA, Mentor's motion to dismiss is **GRANTED**.

1. There Is No Presumption Against Preemption That Applies Here

The Supremacy Clause of the Constitution provides that federal law preempts state law. Art. VI. cl. 2. However, preemption analysis starts with the assumption that state laws are not preempted unless it was intended by Congress. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). Thus, legislative intent is the "ultimate touchstone" of preemption analysis. *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103 (1963). Congress' intent to preempt state law may be expressed in the statute's language or implied in its statutory framework *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992) (quoting *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977)). When there is an express preemption provision, the court does "not invoke any presumption against pre-emption but instead 'focus[es] on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent.'" *Puerto Rico v. Franklin Cal. Tax-Free Trust*, 136 S. Ct. 1938, 1946 (2016) (quoting *Chamber of Commerce of U.S. v. Whiting*, 536 U.S. 582, 594 (2011)).

Here, Plaintiffs claim Mentor's motion does not overcome this presumption against preemption because Mentor failed to establish that Congress intended to bar redress for injuries caused by Defendants' FDA violations. The Supreme Court in *Puerto Rico* found that

where there is an express preemption provision there is no presumption against preemption. 136 S. Ct. at 1946. "[F]ocus on the plain meaning of the clause which contains the best evidence of Congress's pre-emptive intent." *Id.*

It is well established that the MDA expressly preempts state requirements that are "different from, or in addition to" federal requirements and that was the clear intention of Congress. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008). Plaintiffs also cite to *Medtronic, Inc., v. Lohr*, 518 U.S. 470, 487 (1996) for the proposition that it is difficult to believe that Congress would remove all means of judicial recourse for consumers injured by FDA approved devices. Contrary to Plaintiffs' position, "this is exactly what a pre-emption clause for medical devices does by its terms." *Riegel*, 552 U.S. at 326. Therefore, the presumption against preemption does not apply here.

2. Plaintiffs Do Not Assert A Parallel Claim That Survives Preemption

The MDA contains an express preemption provision that provides, as relevant here:

> "[N]o State . . . may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this Act to the device, and

> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." 21 U.S.C. § 360k(a).

The Supreme Court, in *Riegel*, applied a two-step analysis to determine whether the MDA expressly preempts a state law claim within the meaning of § 360k(a). First, a court must determine whether the FDA has established requirements applicable to the particular medical device at issue. *Riegel*, 552 U.S. at 321-22. Second, a court must determine whether the state law claims are based on state requirements that are "different from, or in addition to" the federal requirements, and relate to safety and effectiveness. *Id.* State "requirements" also include the state's common-law legal duties. *Id.* at 324-325 ("State tort law . . . disrupts the federal scheme no less than state regulatory law to the same effect").

However, the Supreme Court has made clear that "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case parallel, rather than add to, federal requirements." *Id.* at 330; *see also 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").

In order for a state requirement to be parallel to a federal requirement, a plaintiff must show that the requirements are "genuinely equivalent." *Houston v.*

Medtronic, 957 F. Supp. 2d 1166, 1174 (C.D. Cal. July 30, 2013) (quoting *WolickiGables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1300 (11th Cir. 2001)). State and federal requirements are not generally equivalent if a manufacturer could be held liable under state law without having violated federal law. *Id.* at 1174.

The MDA also provides that all actions to enforce FDA requirements "shall be by and in the name of the United States." 21 U.S.C. § 337(a). The Supreme Court interpreted that the provision "leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n. 4 (2001). Thus, to avoid implied preemption, a cause of action must rely on traditional state law and not be based solely on a violation of federal law. *Id.* at 353.

The Ninth Circuit has recognized that there is a 'narrow gap' through which a state-law claim must fit to escape preemption." *Perez v. Nidek Co., Ltd.*, 711 F.3d 1109, 1120 (9th Cir. 2013). "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*)." *Id.* at 1120 (emphasis in original) (citing *In re Medtronic, Inc., Sprint Fidelis Prods. Liab. Litig.*, 623 F.3d 1200, 1204) (8th Cir. 2010). To avoid preemption, a plaintiff must assert a state-law claim that is premised on a violation of federal law but that is not based solely on such violation. *Id.*

Here, Plaintiffs allege Mentor violated federal laws and regulations that are parallel to violations of California state law; however, Plaintiffs have not satisfied their pleading burden. As an initial matter, the Court is not satisfied with Plaintiffs' argument that Mentor violated federal and state law by failing to report adverse events to the FDA. These allegations are merely conclusory. Plaintiffs' Complaint lacks any reference to the specific adverse events that Mentor failed to report. Further, Plaintiffs do not specifically allege that poor performance on post-approval studies is a violation of federal law. Additionally, the Court rejects Plaintiffs' claims that Mentor violated federal regulations and state law by defectively manufacturing MemoryGel Implants. Plaintiffs, in conclusory fashion, allege that Defendants' MemoryGel Implant specifications are inconsistent with federal regulations; however, Plaintiffs fail to allege facts demonstrating that Defendants' specifications are inconsistent or violative of federal standards. In short, a plaintiff "cannot simply incant the magic words" that a defendant violated FDA regulations to avoid preemption. *Simmons v. Boston Scientific Corp.*, 2013 WL 1207421 at *4 (C.D. Cal. Mar. 25, 2018) (quoting *WolickiGables*, 634 F.3d at 1301). Lastly, Plaintiffs fail to allege facts showing how any federal violation caused their claimed injuries. Plaintiffs have not asserted a parallel claim capable of surviving preemption.

Plaintiffs claim that "discovery is necessary" to provide a basis for their claims but Plaintiffs cannot be permitted to engage in discovery when they have not

met the most basic pleading standards. Nothing in Plaintiffs' allegations suggests discovery is needed to resolve this Motion.

3. Plaintiffs Fail to Sufficiently Plead Failure to Report

The FDA requires device manufacturers to report any time its device "may have caused or contributed to a death or serious injury." 21 C.F.R. § 803.50(a). A claim based on the failure to warn the FDA of adverse events is not preempted to the extent state tort law recognizes a parallel duty. *De La Paz v. Bayer Healthcare LLC*, 159 F. Supp. 3d 1085, 1096-97 (N.D. Cal. Feb. 2, 2016). However, a claim based on a failure to warn physicians or patients of adverse events would be preempted. *Id.*; *see also Stengel*, 704 F.3d at 1234. California law recognizes such a duty to warn. *Coleman v. Medtronic, Inc.*, 223 Cal.App.4th 413, 429 (2014). To state a failure to warn claim under California law, a plaintiff "will ultimately have to prove that if [a defendant] had properly reported the adverse events to the FDA as required under federal law, that information would have reached [the plaintiff's] doctors in time to prevent [plaintiff's] injuries." *Id.* at 429-30 (quoting *Stengel*, 704 F.3d at 1234).

Here, Plaintiffs' conclusory allegation that Mentor failed to comply with federal requirements by not reporting adverse events is insufficient. Plaintiffs do not point to any facts supporting their assertion. Plaintiffs have not explained how any purported failure to report

unspecified adverse events caused her injuries. In turn, Plaintiff's allegations are based not on a failure to report actual adverse events from the post-approval studies but rather on a purported failure to properly conduct those studies. "The alleged technical defects in Mentor's post-approval studies, however, do not constitute adverse events." *Ebrahimi v. Mentor Worldwide LLC*, 2018 WL 2448095, at *3 (C.D. Cal. May 25, 2018). Plaintiffs cannot pursue a claim premised on a counterfactual assumption that Mentor would have identified additional adverse events if it had conducted the studies more adequately. Any such claim is impermissibly speculative. Additionally, any claim premised on Mentor's alleged failure to conduct the post-approval studies adequately is impliedly preempted, because there is no state law duty to conduct post-approval studies in the first instance.

Furthermore, Plaintiff's failure to report a claim fails because they do not allege facts showing that the FDA would have exercised its discretion to include additional adverse events in its publicly-accessible adverse-event database had Mentor reported the events. Nor do Plaintiffs allege facts showing that their physicians relied on information in the adverse-event database when making decisions. Without such facts, Plaintiffs cannot establish a causal nexus between their alleged injuries and Mentor's alleged failure to report.

Plaintiffs deduce that if Mentor had conducted follow-up with participants enrolled in clinical studies that there would have been adverse event reports

showing heightened instances of rupture rates. No facts support the conclusion that additional information from patients in post-approval studies would reveal additional adverse events regarding ruptures or would result in the FDA requiring different labeling. Nor have Plaintiffs alleged any facts explaining how Mentor's purported failure to report adverse events from its post-approval studies somehow caused their injuries. Plaintiff's failure to report claim, thus, fails for lack of proximate causation.

4. Plaintiffs' Manufacturing Defect Claims Are Preempted

For manufacturing defects claims to survive preemption, plaintiffs are required to allege "that the manufacturing of the device both fell short of the FDA's requirement for manufacturing and—based on the same deficiency—was defectively manufactured under California law." *Funke v. Sorin Group USA, Inc.*, 147 F. Supp. 3d 1017, 1026 (C.D. Cal. Nov. 24, 2015). The MDA provides that a device is defective if "the methods used in, or the facilities or controls used for, its manufacture . . . are not in conformity" with the FDA's requirements for that device. 21 U.S.C. § 351(h). Next, to escape implied preemption, a plaintiff must allege that the manufacturing defect caused her injuries. *De La Paz*, 159 F. Supp. 3d at 1094; *see also Erickson v. Boston Scientific Corp.*, 846 F. Supp. 2d 1085, 1092 (C.D. Cal. 2011) (stating a plaintiff must establish a "causal nexus between the alleged injury and the violation").

Here, Plaintiffs claim that Mentor's implants differed in some undefined way from the manufacturing and design specifications mandated by the FDA as part of the PMA; that Mentor used unidentified material and components that somehow differed from those approved by the FDA; that Mentor violated unspecified provisions of applicable federal regulations, including the FDA's Quality System Regulations and design control requirements under 21 C.F.R. 820.30. But Plaintiffs "fail[] to adequately allege that the MemoryGel Implants violated the FDA's manufacturing requirements." *Ebrahimi v. Mentor Worldwide LLC*, 2018 WL 6829122, at *2 (C.D. Cal. Dec. 27, 2018). Merely alleging that a defendant violated unspecified "law and regulations" or produced a "noncomforming" device does not sufficiently establish that the defendant violated a federal requirement. Instead a plaintiff must identify specific regulatory violation at issue. In addition, Plaintiffs do not allege how any violation caused their purported injuries; they simply conclude that causation exists without providing any supporting explanation. More is needed.

5. Plaintiffs Fail To Explain How To Cure The Pleading Deficiencies

Valid reasons for denying leave to amend include undue delay, bad faith, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice, and futility. *Foman v. Davis*, 371 U.S. 178, 182 (1962); *see also Klamath-Lake Pharm. Ass'n v. Klamath Med. Serv. Bureau*, 701 F.2d 1276, 1292-93 (9th

Cir. 1983) (holding that while leave to amend shall be freely given, the court need not allow futile amendments). The Court denies leave to amend because Plaintiffs have not explained how further amendment could cure the pleading deficiencies in their Complaint.

IV. CONCLUSION

For the foregoing reasons, Plaintiffs' Motion to Remand is **DENIED**. Defendant Mentor Worldwide's Motion to Dismiss is **GRANTED** as to each of Plaintiffs' claims. As amendment would be futile, Plaintiffs' Complaint is **DISMISSED WITH PREJUDICE**.

IT IS SO ORDERED.

Dated: August 27, 2019 /s/ André Birotte Jr.
HONORABLE
ANDRÉ BIROTTE JR.
UNITED STATES
DISTRICT COURT JUDGE

NOT FOR PUBLICATION

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

KATE NUNN; et al., Plaintiffs-Appellants, v. MENTOR WORLDWIDE, LLC; et al., Defendants-Appellees.	No. 19-56391 D.C. No. 2:19-cv-01484-AB-PLA MEMORANDUM* (Filed Feb. 5, 2021)

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 by the Federal Drug Administration ("FDA")

* 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).

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. The district court properly determined that NuSil, LLC ("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 Scott 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). Because the district court properly

determined that NuSil was fraudulently joined, we do not reach Plaintiffs' argument that Mentor's removal was prohibited by 28 U.S.C. § 1441(b)(2) since Mentor removed before Plaintiffs served NuSil.

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 premarket 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.

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

TAMMI JACOB et al; Plaintiffs, v. MENTOR WORLWIDE, LLC; NUSIL, LLC; NUSIL TECHNOLOGY, LLC; and DOES 1-100, inclusive, Defendant.	Case No. CV 19-01484-AB (PLAx) **ORDER DENYING PLAINTIFFS' MOTION TO REMAND AND GRANTING DEFENDANTS' MOTIONS TO DISMISS** (Filed Aug. 1, 2019)

Before the Court are three motions filed by the Parties.

Defendants, Mentor Worldwide, LLC. ("Mentor"), NuSil LLC., and NuSil Technology LLC ("NuSil") filed motions to dismiss (Dkt. Nos. 19, 23). Plaintiffs Tammi Jacob ("Jacob"), Kate Nunn ("Nunn"), Aluvia Solano ("Solano"), Mary Watson ("Watson"), and April Zimmerman ("Zimmerman") (collectively, "Plaintiffs") opposed the motions (Dkt. Nos. 34, 35), and Defendants replied (Dkt. Nos. 37, 38).

Plaintiffs filed a Motion to Remand (Dkt. No. 21). Mentor opposed the motion (Dkt. No. 33) and Plaintiffs replied (Dkt. No. 39). The Court heard oral argument on July 12, 2019 and took the motions under submission. For the following reasons, Plaintiffs' Motion to Remand is **DENIED** and Defendants' Motions to Dismiss is **GRANTED**.

I. BACKGROUND

This lawsuit revolves around injuries Plaintiffs allegedly suffered after receiving surgical implants of Mentors' MemoryGel Silicone Breast Implants ("MemoryGel Implants"). Plaintiffs plead the following in their Complaint ("Compl.," Dkt. No. 1, Exhibit A).

A. The Parties

Jacob is a citizen and resident of Los Angeles County, California. Compl. ¶ 1. Nunn is a citizen and resident of Collin County, Texas. *Id.* ¶ 2. Solan is a citizen and resident of Bernalillo County, New Mexico. *Id.* ¶ 3. Watson is a citizen of Saline County, Arkansas. *Id.* ¶ 4. Zimmerman is a citizen of Jackson County, Missouri. *Id.* ¶ 5.

Mentor is a limited liability company incorporated in Delaware with its principal place of business in Santa Barbara, California. *Id.* ¶ 6. Mentor manufactured the MemoryGel Implants at issue. *Id.* ¶ 7.

NuSil LLC is a limited liability company incorporated in California with its principal place of business in Carpinteria, California. *Id.* ¶ 8.

NuSil Technology, LLC is a limited liability company incorporated in Delaware with its principal place of business in Carpinteria, California. *Id.* ¶ 9. NuSil LLC and NuSil Technology are silicone raw material suppliers and allegedly manufactured, produced, supplied, and shipped the silicone used in the MemoryGel Implants. *Id.* ¶ 11.

B. FDA Regulation of Silicone Breast Implants

In 1976, Congress passed the Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act ("FDCA"). *Id.* ¶ 41. Under the MDA, medical devices, such as the MemoryGel Implants, are subject to three classifications and regulated accordingly. *Id.* ¶ 42. Class I devices require the least and most general oversight, Class II devices are reviewed according to more stringent "special controls," and Class III devices receive the most oversight and require rigorous premarket review and approval. *Id.* The Food and Drug Administration ("FDA") classified silicone breast implants as Class III devices. *Id.* ¶ 43. Accordingly, the FDA requires manufacturers to meet certain requirements for Class III devices. *Id.* On April 10, 1991, the FDA published a final regulation under Section 515(b) of the FDCA requiring that manufacturers of silicone breast implants submit pre-market approval ("PMA") applications with data showing a reasonable assurance of safety and effectiveness of the implants by July 9, 1991. *Id.* ¶ 44.

C. Mentor's FDA Approval

In order to eventually seek PMA for its MemoryGel Implants, Mentor was required to first provide the FDA with sufficient information regarding the safety and efficacy of the medical device. *Id.* ¶ 51. On December 12, 2003, Mentor submitted a request to the FDA for PMA for its MemoryGel Implants. *Id.* ¶ 67. On

November 17, 2006, Mentor received approval subject to certain conditions. *Id.* ¶ 68. One of the conditions imposed on Mentor required it to conduct six post-approval studies[1] to further characterize the safety and effectiveness of MemoryGel Implants. *Id.* ¶ 68.

D. Plaintiffs' MemoryGel Procedures

Jacob was implanted with MemoryGel Implants in November 2006. *Id.* ¶ 21. Jacob alleges that following implantation she developed pain and swelling of her breasts, experienced fatigue, muscle pain, muscle weakness, joint pain, stiffness and swelling, vision issues, light sensitivity, numbness, dizziness, nausea, memory loss, shortness of breath, cognitive dysfunction, chest pain, migraines, itching, chronic sore throats, night sweats, and hair loss. *Id.* ¶ 22. In July 2018, an MRI scan revealed Jacob's right breast implant had ruptured; Jacob underwent a bilateral explantation of her implants on August 6, 2018. *Id.* ¶ 23. After explantation, various defects were found within Jacob's right breast implant. *Id.* ¶ 24.

Nunn was implanted with MemoryGel Implants in December 2014 and December 2015. *Id.* ¶ 25. Following the implantation, Nunn began to experience, among other things, pain and swelling of the breasts, edema, and muscle pain. *Id.* ¶ 26. On September 17,

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[1] The FDA required Mentor to conduct: the core study, the large post-approval study, the device-failure study, the focus-group study, the informed-decision study, and the adjunct study. *Id.* ¶ 69.

2018, Nunn underwent an explantation of her right breast implant. *Id.* ¶ 27. A gel bleed/rupture was discovered during the procedure. *Id.* After explantation, various defects were found within Nunn's right breast implant. *Id.* ¶ 28.

Solano was implanted with MemoryGel Implants for her left and right breast on April 19, 2011 and August 9, 2011 respectively. *Id.* ¶ 30. Following implantation, Solano developed a number of illnesses and symptoms. *Id.* ¶ 31. On December 13, 2016, Solano underwent an explantation of her ruptured left breast implant. *Id.* ¶ 31. After explantation, various defects were found within Solano's left breast implant. *Id.* ¶ 32.

Watson was implanted with MemoryGel Implants in February 2012. *Id.* ¶ 33. Following the implantation, Watson began to experience, among other things, fatigue, muscle weakness, joint stiffness, shortness of breath, itching, dizziness, and night sweats. *Id.* ¶ 34. On January 24, 2017, Watson underwent a bilateral explantation of her implants. *Id.* ¶ 35. A gel bleed/rupture was discovered during the procedure. *Id.* After explantation, various defects were found within Watson's right breast implant.

Zimmerman was implanted with MemoryGel Implants on June 8, 2012. *Id.* ¶ 37. Following the implantation, Zimmerman began to experience, among other things, fatigue, cognitive dysfunction, muscle pain and weakness, joint pain, stiffness, and swelling, memory loss, shortness of breath, chest pain, nausea, dizziness,

fevers, numbness, vision issues, light sensitivity, silicone toxicity, hair loss, dry eyes, dry mouth, chills, sore throat, skin rash, and a metallic taste in her mouth. *Id.* ¶ 38. In May 2017, an MRI scan revealed Zimmerman's right breast implant had ruptured; Zimmerman underwent explantation of her implants on June 21, 2017. After explantation, various defects were found within Zimmerman's right breast implant. *Id.* ¶ 39.

E. This Action

On February 27, 2019, Plaintiffs filed a complaint in the Los Angeles County Superior Court asserting causes of action for: (1) negligence/negligence per se; (2) failure to warn; and (3) manufacturing defect. On February 28, 2019, Mentor filed a notice of removal in this Court and then filed a motion to dismiss Plaintiffs' complaint pursuant to Federal Rule of Civil Procedure 12(b)(6). Plaintiffs filed a motion to remand.

II. LEGAL STANDARD

A. Motion to Dismiss Under 12(b)(6)

Federal Rule of Civil Procedure 8 requires a plaintiff to present a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Under Rule 12(b)(6), a defendant may move to dismiss a pleading for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6).

To defeat a motion to dismiss under Rule 12(b)(6), the complaint must provide enough details to "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). The complaint must also be "plausible on its face," allowing 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). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* at 678. Labels, conclusions, and "a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555.

When ruling on a Rule 12(b)(6) motion, "a judge must accept as true all of the factual allegations contained in the complaint." *Erickson v. Pardus*, 551 U.S. 89, 94 (2007). But a court is "not bound to accept as true a legal conclusion couched as a factual allegation." *Iqbal*, 556 U.S. at 678 (internal quotation marks omitted).

B. Leave to Amend

Should a court dismiss certain claims, "[l]eave to amend should be granted unless the district court 'determines that the pleading could not possibly be cured by the allegation of other facts.' " *Knappenberger v. City of Phoenix*, 566 F.3d 936, 942 (9th Cir. 2009) (quoting *Lopez v. Smith*, 203 F.3d 1122, 1127 (9th Cir. 2000) (en banc)); *see also Knevelbaard Dairies v. Kraft Foods,*

Inc., 232 F.3d 979, 983 (9th Cir. 2000) ("An order granting such a motion must be accompanied by leave to amend unless amendment would be futile").

C. Removal

Federal courts are courts of limited jurisdiction and possess only that jurisdiction as authorized by the Constitution and federal statute. *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994). Under 28 U.S.C. § 1441(a), a party may remove a civil action only if the district court has original jurisdiction over the issues alleged in the state court complaint. There is a strong presumption that the Court is without jurisdiction until affirmatively proven otherwise. *See Fifty Assocs. v. Prudential Ins. Co. of America*, 446 F.2d 1187, 1190 (9th Cir. 1970). When an action is removed from state court, the removing party bears the burden of demonstrating that removal is proper. *Gaus v. Miles, Inc.*, 980 F.2d 564, 566 (9th Cir. 1992).

Under the diversity statute, 28 U.S.C. § 1332, a federal district court has original jurisdiction when the parties are completely diverse and the amount in controversy exceeds $75,000. *See* 28 U.S.C. § 1332. Pursuant to 28 U.S.C. § 1441(a) and (b), a defendant may remove an action from state court to federal court if the diversity and amount in controversy requirements are satisfied. Under 28 U.S.C. § 1441(b)(2), "[a] civil action otherwise removable solely on the basis of the jurisdiction under section 1332(a) of this title may not be removed if any of the parties in interest properly joined

and served as defendants is a citizen of the State in which such action is brought." 28 U.S.C. § 1441(b)(2).

A non-diverse party may be disregarded for purposes of determining whether jurisdiction exists if the court determines that the party's joinder was "fraudulent" or a "sham." *Ritchey v. Upjohn Drug Co.*, 139 F.3d 1313, 1318 (9th Cir. 1998). "Fraudulent joinder" occurs, for the purpose of determining diversity jurisdiction, where the plaintiff fails to state a cause of action against the resident defendant, and the failure is obvious according to settled rules of the state. *McCabe v. Gen. Foods Corp.*, 811 F.2d 1336 (9th Cir. 1987). "But if there is a possibility that a state court would find that the complaint states a cause of action against any of the resident defendants, the federal court must find that the joinder was proper and remand the case to the state court." *Grancare, LLC v. Thrower by & through Mills*, 889 F.3d 543, 548 (9th Cir. 2018) (quotations omitted).

The defendant has a high burden of proof when establishing fraudulent joinder. A removing defendant may present evidence to prove fraudulent joinder, but the district court must resolve all disputed questions of fact in the plaintiff's favor. *See Grancare*, 889 F.3d at 549. Thus, a defense should not require "a searching inquiry into the merits of the plaintiff's case, even if that defense, if successful, would prove fatal." *Id.* In this regard, "[r]emand must be granted unless the defendant shows that the plaintiff would not be afforded leave to amend his complaint to cure [a] purported deficiency" in its allegations against the non-diverse

defendant. *Padilla v. AT & T Corp.*, 697 F. Supp. 2d 1156, 1159 (C.D. Cal. 2009) (quotations omitted). Ultimately, "[f]raudulent joinder must be proven by clear and convincing evidence." *Hamilton Materials, Inc. v. Dow Chem. Corp.*, 494 F.3d 1203, 1206 (9th Cir. 2007).

III. DISCUSSION

A. The Court Has Subject Matter Jurisdiction

This dispute raises two issues concerning the Court's subject matter jurisdiction. First, Plaintiff argues Section 1441(b)(2) precludes removal because NuSil LLC had not been served at the time of Mentor's Notice of Removal. Additionally, Defendants contend that complete diversity[2] exists because NuSil LLC, a California corporation, is fraudulently joined. The Court addresses each argument in turn.

1. Section 1441(b) Does Not Prohibit Removal

Plaintiffs first argue that Section 1441(b) prohibits removal here because Mentor removed to this Court before Plaintiffs had an opportunity to serve any of the Defendants. Plaintiffs also argue the literal

[2] There is no federal question jurisdiction in this matter as it does not touch upon any area of federal law. Thus this Court only has jurisdiction if all the requirements of diversity jurisdiction are satisfied.

interpretation of Section 1441(b) promotes gamesmanship on the part of removing defendants.

The forum defendant rule, articulated in Section 1441(b)(2), provides that "[a] civil action otherwise removable solely on the basis of [diversity] jurisdiction . . . may not be removed if any of the parties in interest properly joined and served as defendants is a citizen of the State in which such action is brought." 28 U.S.C. § 1441(b)(2).

This Court previously held that the above statute precludes removal only when the in-state defendant has been both properly joined and properly served in the action prior to removal. *See Dechow v. Gilead Sci., Inc.*, 358 F. Supp. 3d 1051 (C.D. Cal. 2019) ("The text of § 1441(b)(2) is unambiguous," and "[i]ts plain meaning precludes removal on the basis of in-state citizenship only when the defendant has been properly joined *and served*.")

In *Dechow*, however, the Court also noted that there may be "absurd or bizarre results" that prevent plaintiff from having the opportunity to exact service; in such scenarios, the forum defendant rule may not apply. *Id.*, at 1055.

The Court relied on *Vallejo v. Amgen, Inc.*, 2013 WL 12147584 (C.D. Cal. Aug. 30, 2013) as an example of a possible instance of absurdity. In *Vallejo*, the defendants filed a notice of removal on diversity grounds before the Superior Court made the summons available to plaintiff. On those facts, it was impossible for plaintiff to serve defendants before removal. *Id.* This

distinction required the Court to deviate from adopting the literal interpretation of Section 1441(b)(2). *Id.*

Nothing before the Court suggests it was impossible for Plaintiffs to serve Defendants before removal. Plaintiffs' primary argument is that the short time (less than 24 hours) between the time Plaintiffs filed their complaint and Defendants filed their Notice of Removal made it impossible for Plaintiffs to serve Defendants. Plaintiffs have not provided any indication that they were unable to serve Defendants on the day of filing. The Court recognizes this rule may create a race to serve,[3] but absent any dispositive ruling regarding the forum defendant rule, the Court adopts the plain meaning of statutory text. Section 1441(b)(2) does not bar Mentor's removal because NuSil LLC was not properly served at the time of removal.

2. NuSil LLC is Fraudulently Joined

Plaintiffs assert there is not complete diversity of citizenship because NuSil LLC and Jacob are both California citizens. In their Complaint, Plaintiffs aver that NuSil LLC manufactured a defective component of Mentor's implants. In response, Mentor contends that NuSil LLC was fraudulently joined in the action.

In a product liability action, a plaintiff must establish "that the defendant produced, manufactured, sold,

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[3] Indeed, the rule does nothing to prevent a party from dutifully reviewing a court's docket, and promptly filing a notice of removal the moment a complaint is properly filed in order to dodge a state tribunal.

or was in some way responsible for the [defective] product." *Garcia v. Joseph Vince Co.*, 84 Cal. App. 3d 868, 874 (1984) (quotations omitted). Mentor argues that NuSil LLC was not involved with the production of the silicone used in its MemoryGel implants. Specifically, Mentor argues NuSil LLC is a holding company with no operations, and thus could not have participated in the manufacture of Mentor's allegedly defective implants. In support of this argument, Mentor submitted to the Court the Declaration of Scott Mraz ("Mraz Decl.", Dkt. No. 42 Ex. C), an individual member of NuSil LLC since August 1, 2005. Mr. Mraz declares that NuSil LLC (1) is a holding company that transacts no business of its own and whose sole purpose is to hold stock for its members; (2) has not developed, designed, manufactured, supplied, or distributed any products, including the silicone or silicone gel used to manufacture breast implants; and (3) has no ownership interest in or control over the plant, equipment, and supplies that are used to manufacture the silicone raw materials used in breast implants. *See* Mraz Decl. ¶¶ 4-5, 13-14. Plaintiffs also deposed Mr. Mraz. Under oath Mr. Mraz confirmed that NuSil LLC is an investment holding company that played no role in producing or supplying any products used in the manufacture of breast implants. (*See* Deposition of Scott Mraz ("Mraz Dep.")

Jacob produces evidence contrary to Mr. Mraz's position and suggests there is a triable issue. In 2013, NuSil LLC filed a Statement of Information with the

Secretary of State of California.[4] The Statement of Information is a short, two-page document which identifies NuSil LLC as a "Manufacturer of Silicone Products". Mraz signed that Statement of Information as CFO/President of NuSil. Under oath, Mraz testified that he would have reviewed the document for accuracy before signing.

Mentor claims that the 2013 Statement of Information contained a clerical error and points out that NuSil has since filed an amended statement of information wherein it describes itself as an "Investment holding entity." *See* Hanna Decl., Ex. A (Dkt. No. 33-5). Mentor argues this corrected Statement of Information "conclusively resolve[s]" the factual dispute this Court previously addressed in a related matter.[5] Plaintiffs' position is bolstered by the declaration and deposition testimony of Mr. Mraz.

After a review of the amended Statement of Information and Mr. Mraz's testimony at deposition, the Court concludes that NuSil LLC did not manufacture silicone and was not involved in the development of the MemoryGel Implant. NuSil is not a proper defendant

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[4] The Court **GRANTS** Plaintiffs' request for judicial notice. Dkt. No. 40. The 2013 Statement of Information is a proper subject of judicial notice under Federal Rule of Evidence 201. A court may take judicial notice of matters of public record, and a California Statement of Information is a matter of public record. *Khoury Invs. Inc. v. Nationwide Mut. Ins. Co*, No CV 13-05415-MWF (Ex), 2013 WL 12140449, at *2 (C.D. Cal. Sept. 16, 2013).

[5] *See Vieira v. Mentor Worldwide, LLC, et al.*, No. 2-18-cv-06502-AB (PLAx) (C.D. Cal. Aug. 23, 2018)

in this lawsuit as there is no possibility that Plaintiff could recover under a theory of product liability against NuSil LLC.

3. Plaintiff's Claims Are Properly Joined

Mentor argues in the alternative that Jacob should be severed from the lawsuit. Rule 20 allows courts to join plaintiff's claims that are substantially similar in order to promote judicial economy, and reduce inconvenience, delay, and added expense. Here, both the facts and legal theories of Jacob, as well as the other remaining Plaintiffs are nearly identical. The primary distinction between Plaintiffs' claims is the state in which Plaintiffs underwent surgery. There are no other significant distinctions for each Plaintiff's claims.[6] Nothing supports severing Jacob's claims in what accounts to judicial waste.

B. Motion to Dismiss

In support of their motions to dismiss, Defendants argue that Plaintiffs' state-law claims are expressly and impliedly preempted by the MDA. Because NuSil LLC is not a proper party to this litigation, the Court will only consider arguments from Mentor's motion.

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[6] Mentor asserts that the difference in location, doctor conducting the procedure, and their understanding of the surgery are all significant and support severance. However, those differences appear minor when compared to the underlying background: each woman alleges she received defective breast implants and became ill as a result.

Accordingly, NuSil LLC's motion to dismiss is **DENIED** as **moot** since NuSil was fraudulently joined in this matter.[7] Because Plaintiffs' claims against Mentor are preempted by the MDA, Mentor's motion to dismiss is **GRANTED**.

1. There Is No Presumption Against Preemption That Applies Here

The Supremacy Clause of the Constitution provides that federal law preempts state law. Art. VI. cl. 2. However, preemption analysis starts with the assumption that state laws are not preempted unless it was intended by Congress. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). Thus, legislative intent is the "ultimate touchstone" of preemption analysis. *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103 (1963). Congress' intent to preempt state law may be expressed in the statute's language or implied in its statutory framework *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992) (quoting *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977)). When there is an express preemption provision, the court does "not invoke any presumption against pre-emption but instead 'focus[es] on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent.'" *Puerto Rico v. Franklin Cal. Tax-Free Trust*, 136 S. Ct. 1938,

[7] Plaintiffs raise negligence per se arguments against NuSil LLC, however those arguments will not be addressed as they are inapplicable to the remaining parties.

1946 (2016) (quoting *Chamber of Commerce of U.S. v. Whiting*, 536 U.S. 582, 594 (2011)).

Here, Plaintiffs claim Mentor's motion does not overcome this presumption against preemption because Mentor failed to establish that Congress intended to bar redress for injuries caused by Defendants' FDA violations. The Supreme Court in *Puerto Rico* found that where there is an express preemption provision there is no presumption against preemption. 136 S. Ct. at 1946. "[F]ocus on the plain meaning of the clause which contains the best evidence of Congress's preemptive intent." *Id.*

It is well established that the MDA expressly preempts state requirements that are "different from, or in addition to" federal requirements and that was the clear intention of Congress. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008). Plaintiffs also cite to *Medtronic, Inc., v. Lohr*, 518 U.S. 470, 487 (1996) for the proposition that it is difficult to believe that Congress would remove all means of judicial recourse for consumers injured by FDA approved devices. Contrary to Plaintiffs' position, "this is exactly what a pre-emption clause for medical devices does by its terms." *Riegel*, 552 U.S. at 326. Therefore, the presumption against preemption does not apply here.

2. Plaintiffs Do Not Assert A Parallel Claim That Survives Preemption

The MDA contains an express preemption provision that provides, as relevant here:

> "[N]o State . . . may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this Act to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." 21 U.S.C. § 360k(a).

The Supreme Court, in *Riegel*, applied a two-step analysis to determine whether the MDA expressly preempts a state law claim within the meaning of § 360k(a). First, a court must determine whether the FDA has established requirements applicable to the particular medical device at issue. *Riegel*, 552 U.S. at 321-22. Second, a court must determine whether the state law claims are based on state requirements that are "different from, or in addition to" the federal requirements, and relate to safety and effectiveness. *Id.* State "requirements" also include the state's common-law legal duties. *Id.* at 324-325 ("State tort law . . . disrupts the federal scheme no less than state regulatory law to the same effect").

However, the Supreme Court has made clear that "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case parallel, rather than add to, federal requirements." *Id.* at 330; *see also 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").

In order for a state requirement to be parallel to a federal requirement, a plaintiff must show that the requirements are "genuinely equivalent." *Houston v. Medtronic*, 957 F. Supp. 2d 1166, 1174 (C.D. Cal. July 30, 2013) (quoting *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1300 (11th Cir. 2001)). State and federal requirements are not generally equivalent if a manufacturer could be held liable under state law without having violated federal law. *Id.* at 1174.

The MDA also provides that all actions to enforce FDA requirements "shall be by and in the name of the United States." 21 U.S.C. § 337(a). The Supreme Court interpreted that the provision "leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n. 4 (2001). Thus, to avoid implied preemption, a cause of action must rely on traditional state law and not be based solely on a violation of federal law. *Id.* at 353.

The Ninth Circuit has recognized that there is a "'narrow gap' through which a state-law claim must fit to escape preemption." *Perez v. Nidek Co., Ltd.*, 711 F.3d 1109, 1120 (9th Cir. 2013). "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*)." *Id.* at 1120 (emphasis in original) (citing *In re Medtronic, Inc., Sprint Fidelis Prods. Liab. Litig.*, 623 F.3d 1200, 1204) (8th Cir. 2010). To avoid preemption, a plaintiff must assert a state-law claim that is premised on a violation of federal law but that is not based solely on such violation. *Id.*

Here, Plaintiffs allege Mentor violated federal laws and regulations that are parallel to violations of California state law; however, Plaintiffs have not satisfied their pleading burden. As an initial matter, the Court is not satisfied with Plaintiffs' argument that Mentor violated federal and state law by failing to report adverse events to the FDA. These allegations are merely conclusory. Plaintiffs' Complaint lacks any reference to the specific adverse events that Mentor failed to report. Further, Plaintiffs do not specifically allege that poor performance on post-approval studies is a violation of federal law. Additionally, the Court rejects Plaintiffs' claims that Mentor violated federal regulations and state law by defectively manufacturing MemoryGel Implants. Plaintiffs, in conclusory fashion, allege that Defendants' MemoryGel Implant specifications are inconsistent with federal regulations; however, Plaintiffs fail to allege facts demonstrating that Defendants' specifications are inconsistent or violative of federal standards. In short, a plaintiff "cannot simply incant the magic words" that a defendant violated FDA regulations to avoid preemption. *Simmons v. Boston Scientific Corp.*, 2013 WL 1207421 at *4 (C.D. Cal. Mar. 25, 2018) (quoting *Wolicki-Gables*, 634 F.3d

at 1301). Lastly, Plaintiffs fail to allege facts showing how any federal violation caused their claimed injuries. Plaintiffs have not asserted a parallel claim capable of surviving preemption.

Finally, Plaintiffs claim that "discovery is necessary" to provide a basis for their claims but Plaintiffs cannot be permitted to engage in discovery when they have not met the most basic pleading standards. Nothing in Plaintiffs' allegations suggests discovery is needed to resolve this Motion.

3. Plaintiff Nunn Cannot Assert a Failure to Report Claim

"[A] federal court sitting in diversity applies the choice-of-law rules of the forum" state. *Narayan v. EGL*, Inc., 616 F.3d 895, 898 (9th Cir. 2010). California employs a "governmental interest analysis" to resolve choice of law issues. *Offshore Rental Co., Inc. v. Continental Oil Co.*, 22 Cal. 3d 157, 161 (1978). "California courts have tended to apply the law of the place of the injured's domicile, finding that state has the greatest interest." *Kasel v. Remington Arms Co.*, 24 Cal App.3d 711, 734 (1972); *see also Mazza v. Am. Honda Motor Co.*, 666 F.3d 581, 593 (9th Cir. 2012) (confirming that under California's choice of law rules, "the place of the wrong has the predominant interest").

Here, Plaintiff Nunn resided in Texas at all relevant times—her alleged injuries all occurred there. Texas has the greatest interest in the application of its law to Nunn's claims and its law therefore applies.

Thus, Plaintiff Nunn is preempted from making a failure to warn claim, because her home state of Colorado does not recognize such claims. Moreover, Plaintiff Nunn cannot avoid preemption by arguing that California law applies, because California has no comparable interest.

4. The Remaining Plaintiffs Fail to Sufficiently Plead Failure to Report

The FDA requires device manufacturers to report any time its device "may have caused or contributed to a death or serious injury." 21 C.F.R. § 803.50(a). A claim based on the failure to warn the FDA of adverse events is not preempted to the extent state tort law recognizes a parallel duty. *De La Paz v. Bayer Healthcare LLC*, 159 F. Supp. 3d 1085, 1096-97 (N.D. Cal. Feb. 2, 2016). However, a claim based on a failure to warn physicians or patients of adverse events would be preempted. *Id.*; *see also Stengel*, 704 F.3d at 1234. California law recognizes such a duty to warn. *Coleman v. Medtronic, Inc.*, 223 Cal.App.4th 413, 429 (2014). To state a failure to warn claim under California law, a plaintiff "will ultimately have to prove that if [a defendant] had properly reported the adverse events to the FDA as required under federal law, that information would have reached [the plaintiff's] doctors in time to prevent [plaintiff's] injuries." *Id.* at 429-30 (quoting *Stengel*, 704 F.3d at 1234).

Here, Plaintiffs' conclusory allegation that Mentor failed to comply with federal requirements by not

reporting adverse events is insufficient. Plaintiffs do not point to any facts supporting their assertion. Plaintiffs have not explained how any purported failure to report unspecified adverse events caused her injuries. In turn, Plaintiffs allegations are based not on a failure to report actual adverse events from the post-approval studies but rather on a purported failure to properly conduct those studies. "The alleged technical defects in Mentor's post-approval studies, however, do not constitute adverse events." *Ebrahimi v. Mentor Worldwide LLC*, 2018 WL 2448095, at *3 (C.D. Cal. May 25, 2018). Plaintiffs cannot pursue a claim premised on a counterfactual assumption that Mentor would have identified additional adverse events if it had conducted the studies more adequately. Any such claim is impermissibly speculative. Additionally, any claim premised on Mentor's alleged failure to conduct the post-approval studies adequately is impliedly preempted, because there is no state law duty to conduct post-approval studies in the first instance.

Furthermore, Plaintiffs failure to report a claim fails because they do not allege facts showing that the FDA would have exercised its discretion to include additional adverse events in its publicly-accessible adverse-event database had Mentor reported the events. Nor do Plaintiffs allege facts showing that their physicians relied on information in the adverse-event database when making decisions. Without such facts, Plaintiffs cannot establish a causal nexus between their alleged injuries and Mentor's alleged failure to report.

Plaintiffs deduce that if Mentor had conducted follow-up with participants enrolled in clinical studies that there would have been adverse event reports showing heightened instances of rupture rates. No facts support the conclusion that additional information from patients in post-approval studies would reveal additional adverse events regarding ruptures or would result in the FDA requiring different labeling. Nor have Plaintiffs alleged any facts explaining how Mentor's purported failure to report adverse events from its post-approval studies somehow caused their injuries. Plaintiffs failure to report claim, thus, fails for lack of proximate causation.

5. Plaintiffs' Manufacturing Defect Claims Are Preempted

For manufacturing defects claims to survive preemption, plaintiffs are required to allege "that the manufacturing of the device both fell short of the FDA's requirement for manufacturing and—based on the same deficiency—was defectively manufactured under California law." *Funke v. Sorin Group USA, Inc.*, 147 F. Supp. 3d 1017, 1026 (C.D. Cal. Nov. 24, 2015). The MDA provides that a device is defective if "the methods used in, or the facilities or controls used for, its manufacture . . . are not in conformity" with the FDA's requirements for that device. 21 U.S.C. § 351(h). Next, to escape implied preemption, a plaintiff must allege that the manufacturing defect caused her injuries. *De La Paz*, 159 F. Supp. 3d at 1094; *see also Erickson v. Boston Scientific Corp.*, 846 F. Supp. 2d 1085, 1092 (C.D. Cal.

2011) (stating a plaintiff must establish a "causal nexus between the alleged injury and the violation").

Here, Plaintiffs claim that Mentor's implants differed in some undefined way from the manufacturing and design specifications mandated by the FDA as part of the PMA; that Mentor used unidentified material and components that somehow differed from those approved by the FDA; that Mentor violated unspecified provisions of applicable federal regulations, including the FDA's Quality System Regulations and design control requirements under 21 C.F.R. 820.30. But Plaintiffs "fail[] to adequately allege that the MemoryGel Implants violated the FDA's manufacturing requirements." *Ebrahimi v. Mentor Worldwide LLC*, 2018 WL 6829122, at *2 (C.D. Cal. Dec. 27, 2018). Merely alleging that a defendant violated unspecified "law and regulations" or produced a "noncomforming" device does not sufficiently establish that the defendant violated a federal requirement. Instead a plaintiff must identify specific regulatory violation at issue. In addition, Plaintiffs do not allege how any violation caused their purported injuries; they simply conclude that causation exists without providing any supporting explanation. More is needed.

6. Plaintiffs Fail To Explain How To Cure The Pleading Deficiencies

Valid reasons for denying leave to amend include undue delay, bad faith, repeated failure to cure deficiencies by amendments previously allowed, undue

prejudice, and futility. *Foman v. Davis*, 371 U.S. 178, 182 (1962); *see also Klamath-Lake Pharm. Ass'n v. Klamath Med. Serv. Bureau*, 701 F.2d 1276, 1292-93 (9th Cir. 1983) (holding that while leave to amend shall be freely given, the court need not allow futile amendments). The Court denies leave to amend because Plaintiffs have not explained how further amendment could cure the pleading deficiencies in their Complaint.

IV. CONCLUSION

For the foregoing reasons, Plaintiffs' Motion to Remand is **DENIED**. Defendants NuSil LLC and NuSil Technology LLC's Motion to Dismiss is **DENIED** as **moot.** Defendant Mentor Worldwide's Motion to Dismiss is **GRANTED** as to each of Plaintiffs' claims. As amendment would be futile, Plaintiffs' Complaint is **DISMISSED WITH PREJUDICE**.

IT IS SO ORDERED.

Dated: August 1, 2019 /s/ André Birotte Jr.
HONORABLE
ANDRÉ BIROTTE JR.
UNITED STATES DISTRICT
COURT JUDGE

NOT FOR PUBLICATION

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

MARY SEWELL, Wife; et al., Plaintiffs-Appellants, v. MENTOR WORLDWIDE, LLC; et al., Defendants-Appellees.	No. 19-56393 D.C. No. 8:19-cv-01126-AB-PLA MEMORANDUM* (Filed Feb. 5, 2021)

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 by the Federal Drug Administration ("FDA")

* 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).

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 premarket 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.

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

MARY SEWELL et al; Plaintiffs, v. MENTOR WORLWIDE, LLC; NUSIL, LLC; NUSIL TECHNOLOGY, LLC; and DOES 1100, inclusive, Defendant.	Case No. SA CV 19-01126-AB (PLAx) **ORDER DENYING PLAINTIFFS' MOTION TO REMAND AND GRANTING DEFENDANTS' MOTIONS TO DISMISS** (Filed Aug. 27, 2019)

Before the Court are two motions filed by the parties.

On June 13, 2019 Defendants Mentor Worldwide, LLC. ("Mentor"), NuSil LLC., and NuSil Technology LLC ("NuSil") filed a motion to dismiss (Dkt. No. 12). Plaintiffs opposed the motion (Dkt. No. 14).

Plaintiffs filed a Motion to Remand (Dkt. No. 15) and Defendants opposed the motion (Dkt. No. 19). The Court deemed the matter appropriate for resolution without oral argument, *see* Local Rule 7.15, and took the matter under submission on August 9, 2019. For the following reasons, Plaintiffs' Motion to Remand is **DENIED** and Defendants' Motions to Dismiss is **GRANTED**.

I. BACKGROUND

This lawsuit revolves around injuries Plaintiffs allegedly suffered after receiving surgical implants of Mentors' MemoryGel Silicone Breast Implants ("MemoryGel Implants"). Plaintiffs plead the following in their Complaint ("Compl.," Dkt. No. 1, Exhibit A).

A. The Parties

Mary Sewell and Tom Saunders are a married couple and citizens of Orange County, California. Compl. ¶ 1. Carole Little is a citizen and resident of El Dorado County, California. *Id.* ¶ 2. Julia Maceo is a citizen and resident of Sonoma County, California. *Id.* ¶ 3. Aurora Victoria Corona Cattuzzo and Michael Anthony Cattuzzo are a married couple and citizens of Sacramento County, California. *Id.* ¶ 4. Barbara Johncke and Anders Johncke are a married couple and citizens of Fairfield County, Connecticut. *Id.* ¶ 5. Marianne Curry and Joseph Zacharzuk Jr. are a married couple and citizens of Maui County, Hawaii. *Id.* ¶ 6. Tracie Leach and Gregory Leach are a married couple and citizens of Noble County, Indiana. *Id.* ¶ 7. Lenie Valerie is a citizen of Johnson County, Kansas. *Id.* ¶ 8. Deborah Michelle Destasio and Joseph Destasio are a married couple and citizens of Canadian County, Oklahoma. *Id.* ¶ 9. Stacey Holder and Mark Clark Holden are a married couple and citizens of Oklahoma County, Oklahoma. *Id.* ¶ 10. Sheila Mathis and Randy Mathis are a married couple and citizens of Young County, Texas. *Id.* ¶ 11. Kristina

Ruiz and Steve Ruiz are a married couple and citizens of Utah County, Utah. *Id.* ¶ 12.

Mentor is a limited liability company incorporated in Delaware with its principal place of business in Santa Barbara, California. *Id.* ¶ 13. Mentor manufactured the MemoryGel Implants at issue. *Id.* ¶ 14.

NuSil LLC is a limited liability company incorporated in California with its principal place of business in Carpinteria, California. *Id.* ¶ 15.

NuSil Technology, LLC is a limited liability company incorporated in Delaware with its principal place of business in Carpinteria, California. *Id.* ¶ 16. NuSil LLC and NuSil Technology are silicone raw material suppliers and allegedly manufactured, produced, supplied, and shipped the silicone used in the MemoryGel Implants. *Id.* ¶ 18.

B. FDA Regulation of Silicone Breast Implants

In 1976, Congress passed the Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act ("FDCA"). *See generally* FAC. Under the MDA, medical devices, such as the MemoryGel Implants, are subject to three classifications and regulated accordingly. Class I devices require the least and most general oversight, Class II devices are reviewed according to more stringent "special controls," and Class III devices receive the most oversight and require rigorous premarket review and approval. The

Food and Drug Administration ("FDA") classified silicone breast implants as Class III devices. *Id.* Accordingly, the FDA requires manufacturers to meet certain requirements for Class III devices. On April 10, 1991, the FDA published a final regulation under Section 515(b) of the FDCA requiring that manufacturers of silicone breast implants submit pre-market approval ("PMA") applications with data showing a reasonable assurance of safety and effectiveness of the implants by July 9, 1991.

C. Mentor's FDA Approval

In order to eventually seek PMA for its MemoryGel Implants, Mentor was required to first provide the FDA with sufficient information regarding the safety and efficacy of the medical device. *Id.* ¶ 92. On December 12, 2003, Mentor submitted a request to the FDA for PMA for its MemoryGel Implants. *Id.* ¶ 108. On November 17, 2006, Mentor received approval subject to certain conditions. *Id.* ¶ 109. One of the conditions imposed on Mentor required it to conduct six post-approval studies[1] to further characterize the safety and effectiveness of MemoryGel Implants. *Id.*.

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[1] The FDA required Mentor to conduct: the core study, the large post-approval study, the device-failure study, the focus-group study, the informed-decision study, and the adjunct study. *Id.*

D. Plaintiffs' MemoryGel Procedures

Sewell was implanted with MemoryGel Implants on January 3, 2006. *Id.* ¶ 28. Sewell alleges that following implantation she experienced fatigue, muscle pain and weakness, joint pain, swelling and stiffness, vision issues, light sensitivity, numbness, skin rashes, dizziness, nausea, chronic sore throats, chest pain, migraines. *Id.* ¶ 29. On March 13, 2017, Sewell underwent a bilateral explantation of her implants in Newport Beach, California. *Id.* ¶ 30. A gel bleed/rupture of Sewell's right implant was discovered during the procedure. *Id.* After explantation, various defects were found in Sewell's implants. *Id.* ¶ 31.

Little was implanted with MemoryGel Implants in May 2007. *Id.* ¶ 33. Following implantation, Little developed a number of illnesses and symptoms including, among other things, rheumatoid arthritis, fatigue, joint pain and stiffness, memory loss, shortness of breath, cognitive dysfunction, chest pain, itching, nausea, dizziness, numbness, vision issues, light sensitivity, skin rashes, night sweats, dry eyes, metallic taste, poor wound healing, and hair loss. *Id.* ¶ 35. On February 27, 2017, Little underwent a bilateral explantation of her implants. *Id.* ¶ 36. A gel bleed/rupture of Little's implants was discovered during the procedure. *Id.* After explantation, various defects were found within Little's breast implants. *Id.* ¶ 37.

Maceo was implanted with MemoryGel Implants in December 2006. *Id.* ¶ 39. Following implantation, Maceo developed a number of illnesses and symptoms

including, among other things, rheumatoid arthritis, fatigue, joint pain and stiffness, muscle weakness, memory loss, shortness of breath, cognitive dysfunction, chest pain, itching, nausea, dizziness, numbness, vision issues, light sensitivity, skin rashes, night sweats, dry eyes, metallic taste, poor wound healing, and hair loss. *Id.* ¶ 40. On April 26, 2017, Maceo underwent a bilateral explantation. *Id.* ¶ 41. A gel/bleed rupture was discovered during the procedure. *Id.*

Cattuzzo was implanted with MemoryGel Implants on May 21, 2007. *Id.* ¶ 43. Following implantation, Cattuzzo developed a number of illnesses and symptoms, including, among other things, rheumatoid arthritis, autoimmune disorders, fatigue, joint pain and stiffness, muscle weakness, memory loss, itching, and allergies. *Id.* ¶ 44. On August 21, 2017, Cattuzzo underwent a bilateral explantation of her implants. *Id.* ¶ 45. A gel bleed/rupture was discovered during the procedure. *Id.* After explantation, various defects were found within Cattuzzo's implants. *Id.* ¶ 46.

Johncke was implanted with MemoryGel Implants on February 7, 2008. *Id.* ¶ 47. Following implantation, Johncke developed a number of illnesses and symptoms, among other things, arthritis symptoms, chronic fatigue, joint pain and stiffness, fibromyalgia, muscle weakness, memory loss, cognitive dysfunction, debilitating migraines, numbness, light sensitivity, night sweats, autoimmune disorders, and hair loss. *Id.* ¶ 48. On August 25, 2017, Johncke underwent a bilateral explantation. *Id.* ¶ 49. A gel bleed/rupture was

discovered. *Id.* After explantation, various defects were found within Johnson's right breast implant. *Id.* ¶ 50.

Curry was implanted with MemoryGel Implants on April 11 2007. *Id.* ¶ 51. Following implantation, Curry developed a number of illnesses and symptoms including, among other things, tremors and other central nervous system problems, neurocognitive issues, fatigue, Hashimoto's thyroiditis, endocrine system disorders, vision problems, dry eyes, headaches, neck and shoulder pain, elbow and thumb pain, breast pain, breathing difficulties, and articular problems. *Id.* ¶ 52. On May 5, 2017, Curry underwent a bilateral explantation. *Id.* ¶ 53. A gel bleed/rupture was discovered in Curry's left breast implant. *Id.* After explantation, various defects were found within Johnson's right breast implant. *Id.* ¶ 55.

Leach was implanted with MemoryGel Implants in 2006. *Id.* ¶ 56. Following implantation, Leach developed a number of illnesses and symptoms including, among other things, rheumatoid arthritis, fatigue, joint pain and stiffness, muscle weakness, memory loss, cognitive dysfunction, chest pain, itching, nausea, dizziness, numbness, vision issues, light sensitivity, skin rashes, and hair loss. *Id.* ¶ 57. On March 20, 2017, Leach underwent a bilateral explantation. *Id.* ¶ 58. A gel bleed/rupture was discovered in Curry's left breast implant. *Id.* After explantation, various defects were found within Curry's implants. *Id.* ¶ 59.

Lenie was implanted with MemoryGel Implants on July 29, 2008. *Id.* ¶ 60. Following implantation,

Lenie developed a number of illnesses and symptoms including, among other things, fatigue, muscle pain and weakness, joint pain, swelling and stiffness, ocular migraines, memory loss, shortness of breath, dizziness, numbness, vision issues, light sensitivity, skin rashes, and night sweats. *Id.* ¶ 61. On September 26, 2017, Lenie underwent a bilateral explantation. *Id.* ¶ 62. A gel bleed/rupture was discovered in Lenie's left breast implant. *Id.* After explantation, various defects were found within Lenie's implants. *Id.* ¶ 63.

Destasio was implanted with MemoryGel Implants on September 6, 2007. *Id.* ¶ 64. Following implantation, Destasio developed a number of illnesses and symptoms including, among other things, lupus, rheumatoid arthritis, fatigue, muscle weakness, joint pain and stiffness, memory loss, itching, nausea, dizziness, vision issues, light sensitivity, skin rashes, night sweats, dry eyes, and chronic pain. *Id.* ¶ 65. On February 23, 2017, Destasio underwent a bilateral explantation. *Id.* ¶ 66. A gel bleed/rupture was discovered in Destasio's right breast implants. *Id.* After explantation, various defects were found within Destasio's implant. *Id.* ¶ 67.

Holden was implanted with MemoryGel Implants on August 27, 2013. *Id.* ¶ 68. Following implantation, Holden developed a number of illnesses and symptoms including, among other things, fatigue, muscle weakness, joint pain and stiffness, memory loss, itching, skin rashes, autoimmune dysfunction, and hair loss. *Id.* ¶ 69. On November 10, 2017, Holden underwent a bilateral explantation. *Id.* ¶ 70. A gel bleed/rupture

was discovered in Holden's left breast implant. *Id.* After explantation, various defects were found within Holden's implants. *Id.* ¶ 71.

Mathis was implanted with MemoryGel Implants on January 7, 2007. *Id.* ¶ 71. Following implantation, Mathis developed a number of illnesses and symptoms including, among other things, rheumatoid arthritis, fatigue, joint pain and stiffness, muscle weakness, memory loss, shortness of breath, cognitive dysfunction, chest pain, itching, nausea, dizziness, numbness, vision issues, light sensitivity, skin rashes, night sweats, dry eyes, metallic taste, poor wound healing, and hair loss. *Id.* ¶ 73. On May 16, 2017, Mathis underwent a bilateral explantation. *Id.* ¶ 74. A gel bleed/rupture was discovered in Mathis's left breast implant. *Id.* After explantation, various defects were found within Mathis's implants. *Id.* ¶ 75.

Ruiz was implanted with MemoryGel Implants on May 27, 2010. *Id.* ¶ 76. Following implantation, Mathis developed a number of illnesses and symptoms including, among other things, rheumatoid arthritis, fatigue, joint pain and stiffness, muscle weakness, memory loss, shortness of breath, cognitive dysfunction, chest pain, itching, nausea, dizziness, numbness, vision issues, light sensitivity, skin rashes, night sweats, dry eyes, metallic taste, poor wound healing, and hair loss. *Id.* ¶ 77. On December 27, 2016, Ruiz underwent a bilateral explantation. *Id.* ¶ 78. A gel bleed/rupture was discovered during explantation. *Id.* After explantation, various defects were found within Mathis's implants. *Id.* ¶ 79.

Plaintiffs allege that the exposure to silicone gel due to the rupture and leakage into their bodies caused significant injuries. *Id.* ¶ 80. Plaintiffs further allege they would not have received MemoryGel Implants if they were aware of the true risks associated with rupture rate and injury. *Id.* ¶ 81.

E. This Action

On June 6, 2019, Plaintiffs filed a complaint in the Orange County Superior Court asserting causes of action for: (1) negligence/negligence per se; (2) failure to warn; and (3) manufacturing defect. On June 6, 2019, Mentor filed a notice of removal in this Court and then filed a motion to dismiss Plaintiffs' complaint pursuant to Federal Rule of Civil Procedure 12(b)(6). Plaintiffs filed a motion to remand.

II. LEGAL STANDARD

A. Motion to Dismiss Under 12(b)(6)

Federal Rule of Civil Procedure 8 requires a plaintiff to present a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Under Rule 12(b)(6), a defendant may move to dismiss a pleading for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6).

To defeat a motion to dismiss under Rule 12(b)(6), the complaint must provide enough details to "give the defendant fair notice of what the . . . claim is and the

grounds upon which it rests." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). The complaint must also be "plausible on its face," allowing 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). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* at 678. Labels, conclusions, and "a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555.

When ruling on a Rule 12(b)(6) motion, "a judge must accept as true all of the factual allegations contained in the complaint." *Erickson v. Pardus*, 551 U.S. 89, 94 (2007). But a court is "not bound to accept as true a legal conclusion couched as a factual allegation." *Iqbal*, 556 U.S. at 678 (internal quotation marks omitted).

B. Leave to Amend

Should a court dismiss certain claims, "[l]eave to amend should be granted unless the district court 'determines that the pleading could not possibly be cured by the allegation of other facts.' " *Knappenberger v. City of Phoenix*, 566 F.3d 936, 942 (9th Cir. 2009) (quoting *Lopez v. Smith*, 203 F.3d 1122, 1127 (9th Cir. 2000) (en banc)); *see also Knevelbaard Dairies v. Kraft Foods, Inc.*, 232 F.3d 979, 983 (9th Cir. 2000) ("An order granting such a motion must be accompanied by leave to amend unless amendment would be futile").

C. Removal

Federal courts are courts of limited jurisdiction and possess only that jurisdiction as authorized by the Constitution and federal statute. *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994). Under 28 U.S.C. § 1441(a), a party may remove a civil action only if the district court has original jurisdiction over the issues alleged in the state court complaint. There is a strong presumption that the Court is without jurisdiction until affirmatively proven otherwise. *See Fifty Assocs. v. Prudential Ins. Co. of America*, 446 F.2d 1187, 1190 (9th Cir. 1970). When an action is removed from state court, the removing party bears the burden of demonstrating that removal is proper. *Gaus v. Miles, Inc.*, 980 F.2d 564, 566 (9th Cir. 1992).

Under the diversity statute, 28 U.S.C. § 1332, a federal district court has original jurisdiction when the parties are completely diverse and the amount in controversy exceeds $75,000. *See* 28 U.S.C. § 1332. Pursuant to 28 U.S.C. § 1441(a) and (b), a defendant may remove an action from state court to federal court if the diversity and amount in controversy requirements are satisfied. Under 28 U.S.C. § 1441(b)(2), "[a] civil action otherwise removable solely on the basis of the jurisdiction under section 1332(a) of this title may not be removed if any of the parties in interest properly joined and served as defendants is a citizen of the State in which such action is brought." 28 U.S.C. § 1441(b)(2).

A non-diverse party may be disregarded for purposes of determining whether jurisdiction exists if the

court determines that the party's joinder was "fraudulent" or a "sham." *Ritchey v. Upjohn Drug Co.*, 139 F.3d 1313, 1318 (9th Cir. 1998). "Fraudulent joinder" occurs, for the purpose of determining diversity jurisdiction, where the plaintiff fails to state a cause of action against the resident defendant, and the failure is obvious according to settled rules of the state. *McCabe v. Gen. Foods Corp.*, 811 F.2d 1336 (9th Cir. 1987). "But if there is a possibility that a state court would find that the complaint states a cause of action against any of the resident defendants, the federal court must find that the joinder was proper and remand the case to the state court." *Grancare, LLC v. Thrower by & through Mills*, 889 F.3d 543, 548 (9th Cir. 2018) (quotations omitted).

The defendant has a high burden of proof when establishing fraudulent joinder. A removing defendant may present evidence to prove fraudulent joinder, but the district court must resolve all disputed questions of fact in the plaintiff's favor. *See Grancare*, 889 F.3d at 549. Thus, a defense should not require "a searching inquiry into the merits of the plaintiff's case, even if that defense, if successful, would prove fatal." *Id.* In this regard, "[r]emand must be granted unless the defendant shows that the plaintiff would not be afforded leave to amend his complaint to cure [a] purported deficiency" in its allegations against the non-diverse defendant. *Padilla v. AT & T Corp.*, 697 F. Supp. 2d 1156, 1159 (C.D. Cal. 2009) (quotations omitted). Ultimately, "[f]raudulent joinder must be proven by clear and

convincing evidence." *Hamilton Materials, Inc. v. Dow Chem. Corp.*, 494 F.3d 1203, 1206 (9th Cir. 2007).

III. DISCUSSION

A. The Court Has Subject Matter Jurisdiction

This dispute raises two issues concerning the Court's subject matter jurisdiction. First, Plaintiffs argue Mentor's Notice of Removal is untimely. Additionally, Defendants contend that complete diversity[2] exists because NuSil LLC, a California corporation, is fraudulently joined. The Court addresses each argument in turn.

1. Mentor's Removal Was Timely

Plaintiffs first argue that Mentor's removal was untimely and improper because it was not based on new grounds or new information. "[A] notice of removal may be filed within 30 days after receipt by the defendant, through service or otherwise, of a copy of an amended pleading, motion, order or other paper from which it may first be ascertained that the case is one which is or has been removable." 28 U.S.C. 1446. The thirty-day period applies even to cases which have been previously been removed and remanded, so long as the latter removal is "based on information not

[2] There is no federal question jurisdiction in this matter as it does not touch upon any area of federal law. Thus this Court only has jurisdiction if all the requirements of diversity jurisdiction are satisfied.

available at the prior removal." *See Sweet v. United Parcel Serv., Inc.*, 2009 WL 1664644 at * 3 (C.D. Cal. June 15, 2009) (permitting subsequent removal and denying motion to remand).

Mentor's successive removal was timely and proper. On May 9, 2019, Edward Scott Mraz, a member of NuSil LLC since August 1, 2005, was deposed. *See* Mentor Notice of Removal (Dkt. No. 1). Mraz testified, among other things, that NuSil was a holding company and had no involvement in the manufacturing of the implants.[3]

Plaintiffs argue Mraz's deposition did not reveal additional facts to permit successive removal. To the contrary, Mraz's statements provided further clarity regarding the status of NuSil LLC and its lack of involvement in the production of the silicone used in Mentor's MemoryGel Implants. After Mraz's deposition, Defendants timely removed on the basis of this new information. Accordingly, removal was timely and the Court's inquiry ends there.

2. NuSil LLC is Fraudulently Joined

Plaintiffs also assert there is not complete diversity of citizenship because NuSil LLC and Sewell are both California citizens. In their Complaint, Plaintiffs aver that NuSil LLC manufactured a defective

[3] The substance of Mraz's deposition is discussed below.

component of Mentor's implants. In response, Mentor contends NuSil LLC was fraudulently joined in the action.

In a product liability action, a plaintiff must establish "that the defendant produced, manufactured, sold, or was in some way responsible for the [defective] product." *Garcia v. Joseph Vince Co.*, 84 Cal. App. 3d 868, 874 (1984) (quotations omitted). Mentor argues that NuSil LLC was not involved with the production of the silicone used in its MemoryGel implants. Specifically, Mentor argues NuSil LLC is a holding company with no operations, and thus could not have participated in the manufacture of Mentor's allegedly defective implants. During his deposition, Mraz was asked questions regarding NuSil LLC's corporate structure. Mraz Mraz confirmed that NuSil LLC is an investment holding company that played no role in producing or supplying any products used in the manufacture of breast implants. Mraz clarified that the description of NuSil LLC as a manufacturer of silicone products was a clerical error that was subsequently corrected on corporate filings.

Sewell produces evidence contrary to Mr. Mraz's position and suggests there is a triable issue. In 2013, NuSil LLC filed a Statement of Information with the Secretary of State of California. The Statement of Information is a short, two-page document which identifies NuSil LLC as a "Manufacturer of Silicone Products". Mraz signed that Statement of Information as CFO/President of NuSil. Under oath, Mraz testified

that he would have reviewed the document for accuracy before signing.

Mentor claims that the 2013 Statement of Information contained a clerical error and points out that NuSil has since filed an amended statement of information wherein it describes itself as an "Investment holding entity." Mentor argues this corrected Statement of Information "conclusively resolve[s]" the factual dispute this Court previously addressed in a related matter.[4]

After a review of the amended Statement of Information and Mr. Mraz's testimony at deposition, the Court concludes that NuSil LLC did not manufacture silicone and was not involved in the development of the MemoryGel Implant. NuSil is not a proper defendant in this lawsuit as there is no possibility that Plaintiff could recover under a theory of product liability against NuSil LLC.

B. Motion to Dismiss

In support of their motions to dismiss, Defendants argue that Plaintiffs' state-law claims are expressly and impliedly preempted by the MDA. Because Plaintiffs' claims against Mentor are preempted by the MDA, Mentor's motion to dismiss is **GRANTED**.

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[4] *See Vieira v. Mentor Worldwide, LLC, et al.*, No. 2-18-cv-06502-AB (PLAx) (C.D. Cal. Aug. 23, 2018)

1. There Is No Presumption Against Preemption That Applies Here

The Supremacy Clause of the Constitution provides that federal law preempts state law. Art. VI. cl. 2. However, preemption analysis starts with the assumption that state laws are not preempted unless it was intended by Congress. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). Thus, legislative intent is the "ultimate touchstone" of preemption analysis. *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103 (1963). Congress' intent to preempt state law may be expressed in the statute's language or implied in its statutory framework *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992) (quoting *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977)). When there is an express preemption provision, the court does "not invoke any presumption against pre-emption but instead 'focus[es] on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent.' " *Puerto Rico v. Franklin Cal. Tax-Free Trust*, 136 S. Ct. 1938, 1946 (2016) (quoting *Chamber of Commerce of U.S. v. Whiting*, 536 U.S. 582, 594 (2011)).

Here, Plaintiffs claim Mentor's motion does not overcome this presumption against preemption because Mentor failed to establish that Congress intended to bar redress for injuries caused by Defendants' FDA violations. The Supreme Court in *Puerto Rico* found that where there is an express preemption provision there is no presumption against preemption. 136 S. Ct. at 1946. "[F]ocus on the plain meaning of the clause

which contains the best evidence of Congress's pre-emptive intent." *Id.*

It is well established that the MDA expressly preempts state requirements that are "different from, or in addition to" federal requirements and that was the clear intention of Congress. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008). Plaintiffs also cite to *Medtronic, Inc., v. Lohr*, 518 U.S. 470, 487 (1996) for the proposition that it is difficult to believe that Congress would remove all means of judicial recourse for consumers injured by FDA approved devices. Contrary to Plaintiffs' position, "this is exactly what a pre-emption clause for medical devices does by its terms." *Riegel*, 552 U.S. at 326. Therefore, the presumption against preemption does not apply here.

2. Plaintiffs Do Not Assert A Parallel Claim That Survives Preemption

The MDA contains an express preemption provision that provides, as relevant here:

> "No State . . . may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this Act to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to

> the device under this chapter." 21 U.S.C. § 360k(a).

The Supreme Court, in *Riegel*, applied a two-step analysis to determine whether the MDA expressly preempts a state law claim within the meaning of § 360k(a). First, a court must determine whether the FDA has established requirements applicable to the particular medical device at issue. *Riegel*, 552 U.S. at 321-22. Second, a court must determine whether the state law claims are based on state requirements that are "different from, or in addition to" the federal requirements, and relate to safety and effectiveness. *Id.* State "requirements" also include the state's common-law legal duties. *Id.* at 324-325 ("State tort law . . . disrupts the federal scheme no less than state regulatory law to the same effect").

However, the Supreme Court has made clear that "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case parallel, rather than add to, federal requirements." *Id.* at 330; *see also 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").

In order for a state requirement to be parallel to a federal requirement, a plaintiff must show that the requirements are "genuinely equivalent." *Houston v. Medtronic*, 957 F. Supp. 2d 1166, 1174 (C.D. Cal. July 30, 2013) (quoting *WolickiGables v. Arrow Int'l, Inc.*,

634 F.3d 1296, 1300 (11th Cir. 2001)). State and federal requirements are not generally equivalent if a manufacturer could be held liable under state law without having violated federal law. *Id.* at 1174.

The MDA also provides that all actions to enforce FDA requirements "shall be by and in the name of the United States." 21 U.S.C. § 337(a). The Supreme Court interpreted that the provision "leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n. 4 (2001). Thus, to avoid implied preemption, a cause of action must rely on traditional state law and not be based solely on a violation of federal law. *Id.* at 353.

The Ninth Circuit has recognized that there is a 'narrow gap' through which a state-law claim must fit to escape preemption." *Perez v. Nidek Co., Ltd.*, 711 F.3d 1109, 1120 (9th Cir. 2013). "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*)." *Id.* at 1120 (emphasis in original) (citing *In re Medtronic, Inc., Sprint Fidelis Prods. Liab. Litig.*, 623 F.3d 1200, 1204) (8th Cir. 2010). To avoid preemption, a plaintiff must assert a state-law claim that is premised on a violation of federal law but that is not based solely on such violation. *Id.*

Here, Plaintiffs allege Mentor violated federal laws and regulations that are parallel to violations of California state law; however, Plaintiffs have not satisfied their pleading burden. As an initial matter, the Court is not satisfied with Plaintiffs' argument that Mentor violated federal and state law by failing to report adverse events to the FDA. These allegations are merely conclusory. Plaintiffs' Complaint lacks any reference to the specific adverse events that Mentor failed to report. Further, Plaintiffs do not specifically allege that poor performance on post-approval studies is a violation of federal law. Additionally, the Court rejects Plaintiffs' claims that Mentor violated federal regulations and state law by defectively manufacturing MemoryGel Implants. Plaintiffs, in conclusory fashion, allege that Defendants' MemoryGel Implant specifications are inconsistent with federal regulations; however, Plaintiffs fail to allege facts demonstrating that Defendants' specifications are inconsistent or violative of federal standards. In short, a plaintiff "cannot simply incant the magic words" that a defendant violated FDA regulations to avoid preemption. *Simmons v. Boston Scientific Corp.*, 2013 WL 1207421 at *4 (C.D. Cal. Mar. 25, 2018) (quoting *WolickiGables*, 634 F.3d at 1301). Lastly, Plaintiffs fail to allege facts showing how any federal violation caused their claimed injuries. Plaintiffs have not asserted a parallel claim capable of surviving preemption.

Plaintiffs claim that "discovery is necessary" to provide a basis for their claims but Plaintiffs cannot be permitted to engage in discovery when they have not

met the most basic pleading standards. Nothing in Plaintiffs' allegations suggests discovery is needed to resolve this Motion.

3. Plaintiffs Fail to Sufficiently Plead Failure to Report

The FDA requires device manufacturers to report any time its device "may have caused or contributed to a death or serious injury." 21 C.F.R. § 803.50(a). A claim based on the failure to warn the FDA of adverse events is not preempted to the extent state tort law recognizes a parallel duty. *De La Paz v. Bayer Healthcare LLC*, 159 F. Supp. 3d 1085, 1096-97 (N.D. Cal. Feb. 2, 2016). However, a claim based on a failure to warn physicians or patients of adverse events would be preempted. *Id.*; *see also Stengel*, 704 F.3d at 1234. California law recognizes such a duty to warn. *Coleman v. Medtronic, Inc.*, 223 Cal.App.4th 413, 429 (2014). To state a failure to warn claim under California law, a plaintiff "will ultimately have to prove that if [a defendant] had properly reported the adverse events to the FDA as required under federal law, that information would have reached [the plaintiff's] doctors in time to prevent [plaintiff's] injuries." *Id.* at 429-30 (quoting *Stengel*, 704 F.3d at 1234).

Here, Plaintiffs' conclusory allegation that Mentor failed to comply with federal requirements by not reporting adverse events is insufficient. Plaintiffs do not point to any facts supporting their assertion. Plaintiffs have not explained how any purported failure to report

unspecified adverse events caused her injuries. In turn, Plaintiffs allegations are based not on a failure to report actual adverse events from the post-approval studies but rather on a purported failure to properly conduct those studies. "The alleged technical defects in Mentor's post-approval studies, however, do not constitute adverse events." *Ebrahimi v. Mentor Worldwide LLC*, 2018 WL 2448095, at *3 (C.D. Cal. May 25, 2018). Plaintiffs cannot pursue a claim premised on a counterfactual assumption that Mentor would have identified additional adverse events if it had conducted the studies more adequately. Any such claim is impermissibly speculative. Additionally, any claim premised on Mentor's alleged failure to conduct the post-approval studies adequately is impliedly preempted, because there is no state law duty to conduct post-approval studies in the first instance.

Furthermore, Plaintiffs failure to report a claim fails because they do not allege facts showing that the FDA would have exercised its discretion to include additional adverse events in its publicly-accessible adverse-event database had Mentor reported the events. Nor do Plaintiffs allege facts showing that their physicians relied on information in the adverse-event database when making decisions. Without such facts, Plaintiffs cannot establish a causal nexus between their alleged injuries and Mentor's alleged failure to report.

Plaintiffs deduce that if Mentor had conducted follow-up with participants enrolled in clinical studies that there would have been adverse event reports

showing heightened instances of rupture rates. No facts support the conclusion that additional information from patients in post-approval studies would reveal additional adverse events regarding ruptures or would result in the FDA requiring different labeling. Nor have Plaintiffs alleged any facts explaining how Mentor's purported failure to report adverse events from its post-approval studies somehow caused their injuries. Plaintiff's failure to report claim, thus, fails for lack of proximate causation.

4. Plaintiffs' Manufacturing Defect Claims Are Preempted

For manufacturing defects claims to survive preemption, plaintiffs are required to allege "that the manufacturing of the device both fell short of the FDA's requirement for manufacturing and—based on the same deficiency—was defectively manufactured under California law." *Funke v. Sorin Group USA, Inc.*, 147 F. Supp. 3d 1017, 1026 (C.D. Cal. Nov. 24, 2015). The MDA provides that a device is defective if "the methods used in, or the facilities or controls used for, its manufacture . . . are not in conformity" with the FDA's requirements for that device. 21 U.S.C. § 351(h). Next, to escape implied preemption, a plaintiff must allege that the manufacturing defect caused her injuries. *De La Paz*, 159 F. Supp. 3d at 1094; *see also Erickson v. Boston Scientific Corp.*, 846 F. Supp. 2d 1085, 1092 (C.D. Cal. 2011) (stating a plaintiff must establish a "causal nexus between the alleged injury and the violation").

Here, Plaintiffs claim that Mentor's implants differed in some undefined way from the manufacturing and design specifications mandated by the FDA as part of the PMA; that Mentor used unidentified material and components that somehow differed from those approved by the FDA; that Mentor violated unspecified provisions of applicable federal regulations, including the FDA's Quality System Regulations and design control requirements under 21 C.F.R. 820.30. But Plaintiffs "fail[] to adequately allege that the MemoryGel Implants violated the FDA's manufacturing requirements." *Ebrahimi v. Mentor Worldwide LLC*, 2018 WL 6829122, at *2 (C.D. Cal. Dec. 27, 2018). Merely alleging that a defendant violated unspecified "law and regulations" or produced a "noncomforming" device does not sufficiently establish that the defendant violated a federal requirement. Instead a plaintiff must identify specific regulatory violation at issue. In addition, Plaintiffs do not allege how any violation caused their purported injuries; they simply conclude that causation exists without providing any supporting explanation. More is needed.

5. Plaintiffs Fail To Explain How To Cure The Pleading Deficiencies

Valid reasons for denying leave to amend include undue delay, bad faith, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice, and futility. *Foman v. Davis*, 371 U.S. 178, 182 (1962); *see also Klamath-Lake Pharm. Ass'n v. Klamath Med. Serv. Bureau*, 701 F.2d 1276, 1292-93 (9th

Cir. 1983) (holding that while leave to amend shall be freely given, the court need not allow futile amendments). The Court denies leave to amend because Plaintiffs have not explained how further amendment could cure the pleading deficiencies in their Complaint.

IV. CONCLUSION

For the foregoing reasons, Plaintiffs' Motion to Remand is **DENIED**. Defendant Mentor Worldwide's Motion to Dismiss is **GRANTED** as to each of Plaintiffs' claims. As amendment would be futile, Plaintiffs' Complaint is **DISMISSED WITH PREJUDICE**.

IT IS SO ORDERED.

Dated: August 27, 2019 /s/ André Birotte Jr.
HONORABLE
ANDRÉ BIROTTE JR.
UNITED STATES DISTRICT
COURT JUDGE

NOT FOR PUBLICATION

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* (Filed Feb. 5, 2021)

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

* 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).

breast implants at issue are a Class III medical device approved 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 premarket 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.

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

NICOLE VIEIRA, an individual; EMILIA BAROZZI, an individual; Plaintiffs, v. MENTOR WORLDWIDE, LLC; NUSIL, LLC; NUSIL TECHNOLOGY, LLC; and DOES 1-100, inclusive, Defendants.	Case No. CV 19-04939-AB (PLAx) **ORDER DENYING PLAINTIFFS' MOTION TO REMAND AND GRANTING DEFENDANTS' MOTION TO DISMISS** (Filed Aug. 1, 2019)

Before the Court are two motions filed by the Parties.

Defendants Mentor Worldwide, LLC ("Mentor"), NuSil, LLC, and NuSil Technology, LLC ("NuSil Technology") (collectively, "Defendants") filed a Motion to Dismiss ("MTD," Dkt. No. 12). Plaintiffs Nicole Vieira ("Vieira") and Emilia Barozzi ("Barozzi") (collectively, "Plaintiffs") filed an opposition ("Opp'n.," Dkt. No. 16) and Defendants filed a reply (Dkt. No. 17). The Court heard oral argument on July 12, 2019 and took the motion under submission.

Plaintiffs filed a Motion to Remand (Dkt. No. 18). Mentor opposed the motion (Dkt. No. 24) and filed supplemental authority in support of their opposition (Dkt. No. 26). The Court took the motion under submission on July 31, 2019. For the following reasons,

Plaintiffs' Motion to Remand is **DENIED** and Defendants' Motions to Dismiss is **GRANTED**.

I. BACKGROUND

This lawsuit revolves around injuries Plaintiffs allegedly suffered after surgically receiving Mentor's MemoryGel Silicone Breast Implants ("MemoryGel Implants"). Plaintiffs plead the following in their First Amended Complaint ("FAC," Dkt. No. 1, Ex. A).

A. The Parties

Vieira is a citizen and resident of Solano County, California. FAC ¶ 1. Barozzi is a citizen and resident of Arapahoe County, Colorado. *Id.* ¶ 2.

Mentor is a limited liability company incorporated in Delaware with its principal place of business in Santa Barbara, California. *Id.* ¶ 3. Mentor manufactured the MemoryGel Implants at issue. *Id.* ¶ 4.

NuSil LLC is a limited liability company incorporated in California with its principal place of business in Carpinteria, California. *Id.* ¶ 6. NuSil Technology is a limited liability company incorporated in Delaware with its principal place of business in Carpinteria, California. *Id.* ¶ 7. NuSil LLC and NuSil Technology are silicone raw material suppliers and allegedly manufactured, produced, supplied, and shipped the silicone used in the MemoryGel Implants. *Id.* ¶ 9.

B. FDA Regulation of Silicone Breast Implants

In 1976, Congress passed the Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act ("FDCA"). *Id.* ¶ 36. Under the MDA, medical devices, such as the MemoryGel Implants, are subject to three classifications and regulated accordingly. *Id.* ¶ 37. Class I devices require the least and most general oversight, Class II devices are reviewed according to more stringent "special controls," and Class III devices receive the most oversight and require rigorous premarket review and approval. *Id.* The Food and Drug Administration ("FDA") classified silicone breast implants as Class III devices. *Id.* ¶ 38. Accordingly, the FDA requires manufacturers to meet certain requirements for Class III devices. *Id.* On April 10, 1991, the FDA published a final regulation under Section 515(b) of the FDCA requiring that manufacturers of silicone breast implants submit pre-market approval ("PMA") applications with data showing a reasonable assurance of safety and effectiveness of the implants by July 9, 1991. *Id.* ¶ 39.

C. Mentor's FDA Approval

In order to eventually seek PMA for its MemoryGel Implants, Mentor was required to first provide the FDA with sufficient information regarding the safety and efficacy of the medical device. *Id.* ¶ 46. On December 12, 2003, Mentor submitted a request to the FDA for PMA for its MemoryGel Implants. On

November 17, 2006, Mentor received approval subject to certain conditions. *Id.* ¶¶ 62-63. One of the conditions imposed on Mentor required it to conduct six post-approval studies[1] to further characterize the safety and effectiveness of MemoryGel Implants. *Id.* ¶ 63.

D. Plaintiffs' MemoryGel Procedures

Vieira was implanted with MemoryGel Implants on April 16, 2007. *Id.* ¶ 19. Vieira alleges that following implantation she developed Hashimoto's disease, experienced fatigue, memory loss, hair loss, light sensitivity, skin rashes, vision issues, numbness, dizziness, nausea, chronic sore throats, chest pain, migraines, joint pain, stiffness and swelling, muscle pain and weakness.[2] *Id.* ¶¶ 20-21. Vieira was unaware as to what triggered her symptoms. *Id.* ¶ 21. Vieira's injuries caused her to be bedridden; she subsequently moved to her parent's household in Vacaville, California for home care. *Id.* ¶ 22. On June 27, 2016, Vieira underwent a bilateral explantation of her implants in Los Angeles, California. *Id.* ¶ 23. A gel bleed was discovered in the right implant during the procedure. *Id.* Within six months of explantation, Vieira saw relief of

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[1] The FDA required Mentor to conduct: the core study, the large post-approval study, the device-failure study, the focus-group study, the informed-decision study, and the adjunct study. *Id.* ¶ 64.

[2] At the time of her implantation and during the onset of her symptoms, Vieira resided in Los Angeles County. *Id.* ¶ 21.

approximately 80% of her symptoms and is now in remission from her Hashimoto's disease. *Id.* ¶ 24.

Barozzi received MemoryGel Implants on April 12, 2012. *Id.* ¶ 26. Barozzi alleges that following implantation, she developed a rash on her chest and abdomen along with dry eyes and mouth, experienced recurrent sore throats, ear infections, and bladder infections. *Id.* ¶ 28. Barozzi's pain increased over time. *Id.* Barozzi also developed rheumatoid arthritis, experienced fatigue, joint pain and stiffness, muscle weakness, memory loss, shortness of breath, cognitive dysfunction, chest pains, itching, nausea, dizziness, numbness, vision issues, light sensitivity, night sweats, metallic taste, poor wound healing, and hair loss. *Id.* ¶ 27. Barozzi was unaware as to what caused her injuries. *Id.* ¶ 28. On August 2, 2016, Barozzi underwent a bilateral explantation of her implants. *Id.* ¶ 29. A gel bleed was discovered during the procedure. *Id.* ¶ 29. After explantation, various defects were found in Barozzi's implants. *Id.* ¶ 30.

E. This Action

Plaintiffs filed a FAC in the Los Angeles County Superior Court asserting causes of action for: (1) negligence/negligence per se; (2) failure to warn; and (3) manufacturing defect. Defendants filed a notice of removal in this Court and then filed a motion to dismiss Plaintiffs' FAC pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim. Plaintiffs filed a motion to remand.

II. LEGAL STANDARD

A. Motion to Dismiss Under 12(b)(6)

Federal Rule of Civil Procedure 8 requires a plaintiff to present a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Under Rule 12(b)(6), a defendant may move to dismiss a pleading for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6).

To defeat a motion to dismiss under Rule 12(b)(6), the complaint must provide enough details to "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). The complaint must also be "plausible on its face," allowing 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). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* at 678. Labels, conclusions, and "a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555.

When ruling on a Rule 12(b)(6) motion, "a judge must accept as true all of the factual allegations contained in the complaint." *Erickson v. Pardus*, 551 U.S. 89, 94 (2007). But a court is "not bound to accept as true a legal conclusion couched as a factual allegation." *Iqbal*, 556 U.S. at 678 (internal quotation marks omitted).

B. Leave to Amend

Should a court dismiss certain claims, "[l]eave to amend should be granted unless the district court 'determines that the pleading could not possibly be cured by the allegation of other facts.'" *Knappenberger v. City of Phoenix*, 566 F.3d 936, 942 (9th Cir. 2009) (quoting *Lopez v. Smith*, 203 F.3d 1122, 1127 (9th Cir. 2000) (en banc)); *see also Knevelbaard Dairies v. Kraft Foods, Inc.*, 232 F. 3d 979, 983 (9th Cir. 2000) ("An order granting such a motion must be accompanied by leave to amend unless amendment would be futile").

C. Removal

Federal courts are courts of limited jurisdiction and possess only that jurisdiction as authorized by the Constitution and federal statute. *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994). Under 28 U.S.C. § 1441(a), a party may remove a civil action only if the district court has original jurisdiction over the issues alleged in the state court complaint. There is a strong presumption that the Court is without jurisdiction until affirmatively proven otherwise. *See Fifty Assocs. v. Prudential Ins. Co. of America*, 446 F.2d 1187, 1190 (9th Cir. 1970). When an action is removed from state court, the removing party bears the burden of demonstrating that removal is proper. *Gaus v. Miles, Inc.*, 980 F.2d 564, 566 (9th Cir. 1992).

Under the diversity statute, 28 U.S.C. § 1332, a federal district court has original jurisdiction when the parties are completely diverse and the amount in

controversy exceeds $75,000. *See* 28 U.S.C. § 1332. Pursuant to 28 U.S.C. § 1441(a) and (b), a defendant may remove an action from state court to federal court if the diversity and amount in controversy requirements are satisfied. Under 28 U.S.C. § 1441(b)(2), "[a] civil action otherwise removable solely on the basis of the jurisdiction under section 1332(a) of this title may not be removed if any of the parties in interest properly joined and served as defendants is a citizen of the State in which such action is brought." 28 U.S.C. § 1441(b)(2).

A non-diverse party may be disregarded for purposes of determining whether jurisdiction exists if the court determines that the party's joinder was "fraudulent" or a "sham." *Ritchey v. Upjohn Drug Co.*, 139 F.3d 1313, 1318 (9th Cir. 1998). "Fraudulent joinder" occurs, for the purpose of determining diversity jurisdiction, where the plaintiff fails to state a cause of action against the resident defendant, and the failure is obvious according to settled rules of the state. *McCabe v. Gen. Foods Corp.*, 811 F.2d 1336 (9th Cir. 1987). "But if there is a possibility that a state court would find that the complaint states a cause of action against any of the resident defendants, the federal court must find that the joinder was proper and remand the case to the state court." *Grancare, LLC v. Thrower by & through Mills*, 889 F.3d 543, 548 (9th Cir. 2018) (quotations omitted).

The defendant has a high burden of proof when establishing fraudulent joinder. A removing defendant may present evidence to prove fraudulent joinder, but the district court must resolve all disputed questions

of fact in the plaintiff's favor. *See Grancare*, 889 F.3d at 549. Thus, a defense should not require "a searching inquiry into the merits of the plaintiff's case, even if that defense, if successful, would prove fatal." *Id.* In this regard, "[r]emand must be granted unless the defendant shows that the plaintiff would not be afforded leave to amend his complaint to cure [a] purported deficiency" in its allegations against the non-diverse defendant. *Padilla v. AT & T Corp.*, 697 F. Supp. 2d 1156, 1159 (C.D. Cal. 2009) (quotations omitted). Ultimately, "[f]raudulent joinder must be proven by clear and convincing evidence." *Hamilton Materials, Inc. v. Dow Chem. Corp.*, 494 F.3d 1203, 1206 (9th Cir. 2007).

III. DISCUSSION

A. Motion to Remand

1. Removal Was Timely And Proper

"A notice of removal may be filed within 30 days after receipt by the defendant, through service or otherwise, of a copy of an amended pleading, motion, order or other paper from which may first be ascertained that the case is one which is or has become removable." 28 U.S.C. § 1446. There are two thirty-day periods for removal and the "second thirty-day period . . . enters the picture only when . . . the original complaint does note evidence its removability." *Kuxhausen v. BMW Financial Services NA LLC*, 707 F.3d 1136, 1141 (9th Cir. 2013). "A second removal petition based on the same grounds [as the first removal] does not 'reinvest' the court's jurisdiction." *Seedman v. U.S. Dist. Court for*

Cent. Dist. of California, 837 F.2d 413, 414 (9th Cir. 1988). Nevertheless, the second thirty-day period applies even to cases which have previously been removed and remanded, so long as the latter removal is "based on information not available at the prior removal." *See Sweet v. United Parcel Serv., Inc.*, 2009 WL 1664644, at *3 (C.D. Cal. June 15, 2009). Successive removals are also permissible if "the first remand was on grounds that subsequently became incorrect." *Taylor v. Cox Commc'ns Cal., LLC*, 673 F. App'x 734, 735 (9th Cir. 2016) (internal quotation marks omitted).

Here, Mentor's successive removal was timely and proper as it was filed within thirty days of receipt of Mr. Mraz's deposition transcript. Following the prior notice of removal, Mr. Mraz's deposition provided evidence that NuSil LLC is a holding company and not a manufacture of silicone. Mr. Mraz's deposition seriously undermines Plaintiff's argument that NuSil LLC is a properly named defendant and belongs in the case. Plaintiffs were afforded the opportunity to test the sufficiency of Mr. Mraz's statements. *See*, *e.g.*, *Costa v. Cnty. of Ventura*, 680 F. App'x 545, 547 (9th Cir. 2017) (explaining that a party must be afforded opportunity to "test . . . declarations through depositions"). Yet, Plaintiffs have not demonstrated that the information contained in Mr. Mraz's deposition is false. The Court is satisfied that additional discovery will not change the fact that NuSil LLC was not in the manufacture of silicone products and is an improperly named defendant.

2. NuSil LLC is Fraudulently Joined

Plaintiffs assert there is not complete diversity of citizenship because NuSil LLC and Vieira are both California citizens. In their Complaint, Plaintiffs aver that NuSil LLC manufactured a defective component of Mentor's implants. In response, Mentor contends that NuSil LLC was fraudulently joined in the action.

In a product liability action, a plaintiff must establish "that the defendant produced, manufactured, sold, or was in some way responsible for the [defective] product." *Garcia v. Joseph Vince Co.*, 84 Cal. App. 3d 868, 874 (1978) (quotations omitted). Mentor argues that NuSil LLC was not involved with the production of the silicone used in its MemoryGel implants. Specifically, Mentor argues NuSil LLC is a holding company with no operations, and thus could not have participated in the manufacture of Mentor's allegedly defective implants. In support of this argument, Mentor submitted to the Court the Deposition of Scott Mraz ("Mraz Dep.", Dkt. No. 1 Ex. M), an individual member of NuSil LLC since August 1, 2005. Mr. Mraz testified that NuSil LLC (1) is a holding company that transacts no business of its own and whose sole purpose is to hold stock for its members; (2) has not developed, designed, manufactured, supplied, or distributed any products, including the silicone or silicone gel used to manufacture breast implants; and (3) has no ownership interest in or control over the plant, equipment, and supplies that are used to manufacture the silicone raw materials used in breast implants. *See* Mraz Dep. at 18:7-21, 40:8-12, 40:2-7.

Vieira produces evidence contrary to Mr. Mraz's position and suggests there is a triable issue. In 2013, NuSil LLC filed a Statement of Information with the Secretary of State of California.[3] The Statement of Information is a short, two-page document which identifies NuSil LLC as a "Manufacturer of Silicone Products". Mraz signed that Statement of Information as CFO/President of NuSil. Under oath, Mraz testified that he would have reviewed the document for accuracy before signing.

Mentor claims that the 2013 Statement of Information contained a clerical error and points out that NuSil has since filed an amended statement of information wherein it describes itself as an "Investment holding entity." *See* Dkt. No. 1 Ex. N. Mentor argues this corrected Statement of Information "conclusively resolve[s]" the factual dispute this Court previously addressed in a related matter.[4] Plaintiffs' position is bolstered by the declaration and deposition testimony of Mr. Mraz.

After a review of the amended Statement of Information and Mr. Mraz's testimony at deposition, the

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[3] The Court GRANTS Plaintiffs' request for judicial notice. Dkt. No. 1 Ex. N. The 2013 Statement of Information is a proper subject of judicial notice under Federal Rule of Evidence 201. A court may take judicial notice of matters of public record, and a California Statement of Information is a matter of public record. *Khoury Invs. Inc. v. Nationwide Mut. Ins. Co*, No. CV 13-05415-MWF (Ex), 2013 WL 12140449, at *2 (C.D. Cal. Sept. 16, 2013).

[4] *See Vieira v. Mentor Worldwide, LLC, et al.*, No. 2-18-cv-06502-AB (PLAx) (C.D. Cal. Aug. 23, 2018)

Court concludes that NuSil LLC did not manufacture silicone and was not involved in the development of the MemoryGel Implant. NuSil is not a proper defendant in this lawsuit as there is no possibility that Plaintiff could recover under a theory of product liability against NuSil LLC.

B. Motion to Dismiss

Defendants argue that Plaintiffs' state-law claims are expressly and impliedly preempted by the MDA. Because Plaintiffs' claims against Mentor are preempted by the MDA, Mentor's motion to dismiss is **GRANTED.**

1. There Is No Presumption Against Preemption That Applies Here

The Supremacy Clause of the Constitution provides that federal law preempts state law. Art. VI. cl. 2. However, preemption analysis starts with the assumption that state laws are not preempted unless it was intended by Congress. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). Thus, legislative intent is the "ultimate touchstone" of preemption analysis. *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103 (1963). Congress' intent to preempt state law may be expressed in the statute's language or implied in its statutory framework. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992) (quoting *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977)). When there is an express preemption provision, the court does "not invoke any presumption

against pre-emption but instead 'focus[es] on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent.' " *Puerto Rico v. Franklin Cal. Tax-Free Trust*, 136 S. Ct. 1938, 1946 (2016) (quoting *Chamber of Commerce of U.S. v. Whiting*, 563 U.S. 582, 594 (2011)).

Here, Plaintiffs claim Defendants' motion does not overcome this presumption against preemption because Defendants failed to establish that Congress intended to bar redress for injuries caused by Defendants' FDA violations. The Supreme Court in *Puerto Rico* found that where there is an express preemption provision there is no presumption against preemption. 136 S. Ct. at 1946. "[F]ocus on the plain meaning of the clause which contains the best evidence of Congress's pre-emptive intent." *Id.* It is well established that the MDA expressly preempts state requirements that are "different from, or in addition to" federal requirements and that was the clear intention of Congress. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008). Plaintiffs also cite to *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 487 (1996) for the proposition that it is difficult to believe that Congress would remove all means of judicial recourse for consumers injured by FDA approved devices. Contrary to Plaintiffs' position, "this is exactly what a pre-emption clause for medical devices does by its terms." *Riegel*, 552 U.S. at 326. Therefore, the presumption against preemption does not apply here.

2. Plaintiffs Do Not Assert A Parallel Claim That Survives Preemption

The MDA contains an express preemption provision that provides, as relevant here:

> "[N]o State . . . may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this Act to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." 21 U.S.C. § 360k(a).

The Supreme Court, in *Riegel*, applied a two-step analysis to determine whether the MDA expressly preempts a state law claim within the meaning of § 360k(a). First, a court must determine whether the FDA has established requirements applicable to the particular medical device at issue. *Riegel*, 552 U.S. at 321-22. Second, a court must determine whether the state law claims are based on state requirements that are "different from, or in addition to" the federal requirements, and relate to safety and effectiveness. *Id.* State "requirements" also include the state's common-law legal duties. *Id.* at 324-325 ("State tort law . . . disrupts the federal scheme no less than state regulatory law to the same effect").

However, the Supreme Court has made clear that "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case parallel, rather than add to, federal requirements." *Id.* at 330; *see also 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").

In order for a state requirement to be parallel to a federal requirement, a plaintiff must show that the requirements are "genuinely equivalent." *Houston v. Medtronic*, 957 F. Supp. 2d 1166, 1174 (C.D. Cal. 2013) (quoting *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1300 (11th Cir. 2011)). State and federal requirements are not generally equivalent if a manufacturer could be held liable under state law without having violated federal law. *Id.* at 1174.

The MDA also provides that all actions to enforce FDA requirements "shall be by and in the name of the United States." 21 U.S.C. § 337(a). The Supreme Court interpreted that the provision "leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n. 4 (2001). Thus, to avoid implied preemption, a cause of action must rely on traditional state law and not be based solely on a violation of federal law. *Id.* at 353.

The Ninth Circuit has recognized that there is a "'narrow gap' through which a state-law claim must fit to escape preemption." *Perez v. Nidek Co., Ltd.*, 711 F.3d 1109, 1120 (9th Cir. 2013). "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*)." *Id.* at 1120 (emphasis in original) (citing *In re Medtronic, Inc., Sprint Fidelis Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010)). To avoid preemption, a plaintiff must assert a state-law claim that is premised on a violation of federal law but that is not based solely on such violation. *Id.*

Here, Plaintiffs allege Mentor violated federal laws and regulations that are parallel to violations of California state law; however, Plaintiffs have not satisfied their pleading burden. As an initial matter, the Court is not satisfied with Plaintiffs' argument that Mentor violated federal and state law by failing to report adverse events to the FDA. These allegations are merely conclusory. Plaintiffs' Complaint lacks any reference to the specific adverse events that Mentor failed to report. Further, Plaintiffs do not specifically allege that poor performance on post-approval studies is a violation of federal law. Additionally, the Court rejects Plaintiffs' claims that Mentor violated federal regulations and state law by defectively manufacturing MemoryGel Implants. Plaintiffs, in conclusory fashion, allege that Defendants' MemoryGel Implant specifications are inconsistent with federal regulations;

however, Plaintiffs fail to allege facts demonstrating that Defendants' specifications are inconsistent or violative of federal standards. In short, a plaintiff "cannot simply incant the magic words" that a defendant violated FDA regulations to avoid preemption. *Simmons v. Boston Scientific Corp.*, 2013 WL 1207421 at *4 (C.D. Cal. Mar. 25, 2013) (quoting *Wolicki-Gables*, 634 F.3d at 1301). Lastly, Plaintiffs fail to allege facts showing how any federal violation caused their claimed injuries. Plaintiffs have not asserted a parallel claim capable of surviving preemption.

Finally, Plaintiffs claim that "discovery is necessary" to provide a basis for their claims but Plaintiffs cannot be permitted to engage in discovery when they have not met the most basic pleading standards. Nothing in Plaintiffs' allegations suggests discovery is needed to resolve this Motion.

3. Plaintiff Barozzi Cannot Assert a Failure to Report Claim

"[A] federal court sitting in diversity applies the choice-of-law rules of the forum" state. *Narayan v. EGL, Inc.*, 616 F.3d 895, 898 (9th Cir. 2010). California employs a "governmental interest analysis" to resolve choice of law issues. *Offshore Rental Co., Inc. v. Continental Oil Co.*, 22 Cal. 3d 157, 161 (1978). "California courts have tended to apply the law of the place of the injured's domicile, finding that state has the greatest interest." *Kasel v. Remington Arms Co.*, 24 Cal App.3d 711, 734 (1972); *see also Mazza v. Am. Honda Motor*

Co., 666 F.3d 581, 593 (9th Cir. 2012) (confirming that under California's choice of law rules, "the place of the wrong has the predominant interest").

Here, Plaintiff Barozzi resided in Colorado at all relevant times—her alleged injuries all occurred there. Colorado has the greatest interest in the application of its law to Barozzi's claims and its law therefore applies. Thus, Plaintiff Barozzi is preempted from making a failure to warn claim, because her home state of Colorado does not recognize such claims. Moreover, Plaintiff Barozzi cannot avoid preemption by arguing that California law applies, because California has no comparable interest.

4. The Remaining Plaintiffs Fail to Sufficiently Plead Failure to Report

The FDA requires device manufacturers to report any time its device "may have caused or contributed to a death or serious injury." 21 C.F.R. § 803.50(a). A claim based on the failure to warn the FDA of adverse events is not preempted to the extent state tort law recognizes a parallel duty. *De La Paz v. Bayer Healthcare LLC*, 159 F. Supp. 3d 1085, 1096-97 (N.D. Cal. 2016). However, a claim based on a failure to warn physicians or patients of adverse events would be preempted. *Id.*; *see also Stengel*, 704 F.3d at 1234. California law recognizes such a duty to warn. *Coleman v. Medtronic, Inc.*, 223 Cal. App. 4th 413, 429 (2014). To state a failure to warn claim under California law, a plaintiff "will ultimately have to prove that if [a defendant] had properly

reported the adverse events to the FDA as required under federal law, that information would have reached [the plaintiff's] doctors in time to prevent [plaintiff's] injuries." *Id.* at 429-30 (quoting *Stengel*, 704 F.3d at 1234).

Here, Plaintiffs' conclusory allegation that Mentor failed to comply with federal requirements by not reporting adverse events is insufficient. Plaintiffs do not point to any facts supporting her assertion. Plaintiffs have not explained how any purported failure to report the unspecified adverse events caused her injuries. In turn, Plaintiffs allegations are based not on a failure to report actual adverse events from the post-approval studies but rather on a purported failure to properly conduct those studies. "The alleged technical defects in Mentor's post-approval studies, however, do not constitute adverse events." *Ebrahimi v. Mentor Worldwide LLC*, 2018 WL 2448095, at *3 (C.D. Cal. May 25, 2018). Plaintiffs cannot pursue a claim premised on a counterfactual assumption that Mentor would have identified additional adverse events if it had conducted the studies more adequately. Any such claim is impermissibly speculative. Additionally, any claim premised on Mentor's alleged failure to conduct the post-approval studies adequately is impliedly preempted, because there is no state law duty to conduct post-approval studies in the first instance.

Furthermore, Plaintiffs' failure to report a claim fails because they do not allege facts showing that the FDA would have exercised its discretion to include additional adverse events in its publicly-accessible

adverse-event database had Mentor reported the events. Nor do Plaintiffs allege facts showing that their treating physicians even relied on information in the adverse event database making decisions. Without such facts, Plaintiffs cannot establish a causal nexus between their alleged injuries and Mentor's alleged failure to report.

Plaintiffs deduce that if Mentor had conducted follow-up with participants enrolled in clinical studies that there would have been adverse event reports showing heightened instances of rupture rates. No facts support the conclusion that additional information from patients in post-approval studies would reveal additional adverse events regarding ruptures or would result in the FDA requiring different labeling. Nor has Plaintiff Vieira alleged any facts explaining how Mentor's purported failure to report adverse events from its post-approval studies somehow caused her injuries. Plaintiff Vieira's failure to report claim, thus, fails for lack of proximate causation.

5. Plaintiffs' Manufacturing Defect Claims Are Preempted

For manufacturing defects claims to survive preemption, plaintiffs are required to allege "that the manufacturing of the device both fell short of the FDA's requirement for manufacturing and—based on the same deficiency—was defectively manufactured under California law." *Funke v. Sorin Group USA, Inc.*, 147 F. Supp. 3d 1017, 1026 (C.D. Cal. 2015). The MDA

provides that a device is defective if "the methods used in, or the facilities or controls used for, its manufacture . . . are not in conformity" with the FDA's requirements for that device. 21 U.S.C. § 351(h). Next, to escape implied preemption, a plaintiff must allege that the manufacturing defect caused her injuries. *De La Paz*, 159 F. Supp. 3d at 1094; *see also Erickson v. Boston Scientific Corp.*, 846 F. Supp. 2d 1085, 1092 (C.D. Cal. 2011) (stating a plaintiff must establish a "causal nexus between the alleged injury and the violation").

Here, Plaintiffs claim that Mentor's implants differed in some undefined way from the manufacturing and design specifications mandated by the FDA as part of the PMA; that Mentor used unidentified material and components that somehow differed from those approved by the FDA; that Mentor violated unspecified provisions of applicable federal regulations, including the FDA's Quality System Regulations and design control requirements under 21 C.F.R. 820.30. But Plaintiffs "fail[] to adequately allege that the Implants violated the FDA's manufacturing requirements." *Ebrahimi v. Mentor Worldwide LLC*, 2018 WL 6829122, at *2 (C.D. Cal. Dec. 27, 2018). Merely alleging that a defendant violated unspecified "law and regulations" or produced a "noncomforming" device does not sufficiently establish that the defendant violated a federal requirement. Instead a plaintiff must identify specific regulatory violation at issue. In addition, Plaintiffs do not allege how any violation caused their purported injuries; they simply conclude that causation exists

without providing any supporting explanation. More is needed.

6. Plaintiffs Fail To Explain How To Cure The Pleading Deficiencies

Valid reasons for denying leave to amend include undue delay, bad faith, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice, and futility. *Foman v. Davis*, 371 U.S. 178, 182 (1962); *see also Klamath-Lake Pharm. Ass'n v. Klamath Med. Serv. Bureau*, 701 F.2d 1276, 1292-93 (9th Cir. 1983) (holding that while leave to amend shall be freely given, the court need not allow futile amendments). The Court denies leave to amend because Plaintiffs have not explained how further amendment could cure the pleading deficiencies in their Complaint. As Plaintiffs have had two opportunities to properly plead their claims, the Court concludes that granting further leave to amend would be futile. *See Cafasso v. Gen. Dynamics C4 Sys., Inc.*, 637 F.3d 1047, 1058 (9th Cir. 2011) ("[T]he district court's discretion to deny leave to amend is particularly broad where plaintiff has previously amended the complaint.") (quoting *Ascon Props., Inc. v. Mobil Oil Co.*, 866 F.2d 1149, 1160 (9th Cir. 1989)).

IV. CONCLUSION

For the foregoing reasons, Plaintiffs' Motion to Remand is **DENIED**. Defendant Mentor Worldwide's Motion to Dismiss is **GRANTED** as to each of Plaintiffs'

claims. As amendment would be futile, Plaintiffs' Complaint is **DISMISSED WITH PREJUDICE**.

IT IS SO ORDERED.

Dated: August 1, 2019 /s/ André Birotte Jr.
HONORABLE
ANDRÉ BIROTTE JR.
UNITED STATES DISTRICT
COURT JUDGE

RELEVANT STATUTORY AND REGULATORY PROVISIONS

21 U.S.C. § 337. Proceedings in name of United States; provision as to subpoenas

(a) Except as provided in subsection (b), all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States. Subpoenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any proceeding under this section.

(b)(1) A State may bring in its own name and within its jurisdiction proceedings for the civil enforcement, or to restrain violations, of section 341, 343(b), 343(c), 343(d), 343(e), 343(f), 343(g), 343(h), 343(i), 343(k), 343(q), or 343(r) of this title if the food that is the subject of the proceedings is located in the State.

(2) No proceeding may be commenced by a State under paragraph (1) –

> **(A)** before 30 days after the State has given notice to the Secretary that the State intends to bring such proceeding,
>
> **(B)** before 90 days after the State has given notice to the Secretary of such intent if the Secretary has, within such 30 days, commenced an informal or formal enforcement action pertaining to the food which would be the subject of such proceeding, or
>
> **(C)** if the Secretary is diligently prosecuting a proceeding in court pertaining to such food, has

settled such proceeding, or has settled the informal or formal enforcement action pertaining to such food.

In any court proceeding described in subparagraph (C), a State may intervene as a matter of right.

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21 U.S.C. § 360h. Notification and other remedies

(a) Notification

If the Secretary determines that –

(1) a device intended for human use which is introduced or delivered for introduction into interstate commerce for commercial distribution presents an unreasonable risk of substantial harm to the public health, and

(2) notification under this subsection is necessary to eliminate the unreasonable risk of such harm and no more practicable means is available under the provisions of this chapter (other than this section) to eliminate such risk,

the Secretary may issue such order as may be necessary to assure that adequate notification is provided in an appropriate form, by the persons and means best suited under the circumstances involved, to all health professionals who prescribe or use the device and to any other person (including manufacturers, importers, distributors, retailers, and device users) who should properly receive such notification in order to eliminate such risk. An order under this subsection shall require that the individuals subject to the risk with respect to

which the order is to be issued be included in the persons to be notified of the risk unless the Secretary determines that notice to such individuals would present a greater danger to the health of such individuals than no such notification. If the Secretary makes such a determination with respect to such individuals, the order shall require that the health professionals who prescribe or use the device provide for the notification of the individuals whom the health professionals treated with the device of the risk presented by the device and of any action which may be taken by or on behalf of such individuals to eliminate or reduce such risk. Before issuing an order under this subsection, the Secretary shall consult with the persons who are to give notice under the order.

(b) Repair, replacement, or refund

(1)(A) If, after affording opportunity for an informal hearing, the Secretary determines that –

> **(i)** a device intended for human use which is introduced or delivered for introduction into interstate commerce for commercial distribution presents an unreasonable risk of substantial harm to the public health,
>
> **(ii)** there are reasonable grounds to believe that the device was not properly designed or manufactured with reference to the state of the art as it existed at the time of its design or manufacture,
>
> **(iii)** there are reasonable grounds to believe that the unreasonable risk was not caused by failure of a person other than a manufacturer, importer,

distributor, or retailer of the device to exercise due care in the installation, maintenance, repair, or use of the device, and

(iv) the notification authorized by subsection (a) would not by itself be sufficient to eliminate the unreasonable risk and action described in paragraph (2) of this subsection is necessary to eliminate such risk,

the Secretary may order the manufacturer, importer, or any distributor of such device, or any combination of such persons, to submit to him within a reasonable time a plan for taking one or more of the actions described in paragraph (2). An order issued under the preceding sentence which is directed to more than one person shall specify which person may decide which action shall be taken under such plan and the person specified shall be the person who the Secretary determines bears the principal, ultimate financial responsibility for action taken under the plan unless the Secretary cannot determine who bears such responsibility or the Secretary determines that the protection of the public health requires that such decision be made by a person (including a device user or health professional) other than the person he determines bears such responsibility.

(B) The Secretary shall approve a plan submitted pursuant to an order issued under subparagraph (A) unless he determines (after affording opportunity for an informal hearing) that the action or actions to be taken under the plan or the manner in which such action or actions are to be taken under the plan will not

assure that the unreasonable risk with respect to which such order was issued will be eliminated. If the Secretary disapproves a plan, he shall order a revised plan to be submitted to him within a reasonable time. If the Secretary determines (after affording opportunity for an informal hearing) that the revised plan is unsatisfactory or if no revised plan or no initial plan has been submitted to the Secretary within the prescribed time, the Secretary shall (i) prescribe a plan to be carried out by the person or persons to whom the order issued under subparagraph (A) was directed, or (ii) after affording an opportunity for an informal hearing, by order prescribe a plan to be carried out by a person who is a manufacturer, importer, distributor, or retailer of the device with respect to which the order was issued but to whom the order under subparagraph (A) was not directed.

(2) The actions which may be taken under a plan submitted under an order issued under paragraph (1) are as follows:

> **(A)** To repair the device so that it does not present the unreasonable risk of substantial harm with respect to which the order under paragraph (1) was issued.
>
> **(B)** To replace the device with a like or equivalent device which is in conformity with all applicable requirements of this chapter.
>
> **(C)** To refund the purchase price of the device (less a reasonable allowance for use if such device has been in the possession of the device user for one year or more –

(i) at the time of notification ordered under subsection (a), or

(ii) at the time the device user receives actual notice of the unreasonable risk with respect to which the order was issued under paragraph (1),

whichever first occurs).

(3) No charge shall be made to any person (other than a manufacturer, importer, distributor or retailer) for availing himself of any remedy, described in paragraph (2) and provided under an order issued under paragraph (1), and the person subject to the order shall reimburse each person (other than a manufacturer, importer, distributor, or retailer) who is entitled to such a remedy for any reasonable and foreseeable expenses actually incurred by such person in availing himself of such remedy.

(c) Reimbursement

An order issued under subsection (b) with respect to a device may require any person who is a manufacturer, importer, distributor, or retailer of the device to reimburse any other person who is a manufacturer, importer, distributor, or retailer of such device for such other person's expenses actually incurred in connection with carrying out the order if the Secretary determines such reimbursement is required for the protection of the public health. Any such requirement shall not affect any rights or obligations under any contract to which the person receiving reimbursement or the person making such reimbursement is a party.

(d) Effect on other liability

Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.

(e) Recall authority

(1) If the Secretary finds that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, the Secretary shall issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the device) –

> **(A)** to immediately cease distribution of such device, and
>
> **(B)** to immediately notify health professionals and device user facilities of the order and to instruct such professionals and facilities to cease use of such device.

The order shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of the issuance of the order, on the actions required by the order and on whether the order should be amended to require a recall of such device. If, after providing an opportunity for such a hearing, the Secretary determines that

inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

(2)(A) If, after providing an opportunity for an informal hearing under paragraph (1), the Secretary determines that the order should be amended to include a recall of the device with respect to which the order was issued, the Secretary shall, except as provided in subparagraphs (B) and (C), amend the order to require a recall. The Secretary shall specify a timetable in which the device recall will occur and shall require periodic reports to the Secretary describing the progress of the recall.

(B) An amended order under subparagraph (A) –

(i) shall –

(I) not include recall of a device from individuals, and

(II) not include recall of a device from device user facilities if the Secretary determines that the risk of recalling such device from the facilities presents a greater health risk than the health risk of not recalling the device from use, and

(ii) shall provide for notice to individuals subject to the risks associated with the use of such device.

In providing the notice required by clause (ii), the Secretary may use the assistance of health professionals who prescribed or used such a device for individuals. If a significant number of such individuals cannot be

identified, the Secretary shall notify such individuals pursuant to section 375(b) of this title.

(3) The remedy provided by this subsection shall be in addition to remedies provided by subsections (a), (b), and (c).

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21 U.S.C. § 360i. Records and reports on devices

(a) General rule

Every person who is a manufacturer or importer of a device intended for human use shall establish and maintain such records, make such reports, and provide such information, as the Secretary may by regulation reasonably require to assure that such device is not adulterated or misbranded and to otherwise assure its safety and effectiveness. Regulations prescribed under the preceding sentence –

> **(1)** shall require a device manufacturer or importer to report to the Secretary whenever the manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices –
>
> > **(A)** may have caused or contributed to a death or serious injury, or
> >
> > **(B)** has malfunctioned and that such device or a similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur, which report under this subparagraph –

(i) shall be submitted in accordance with part 803 of title 21, Code of Federal Regulations (or successor regulations), unless the Secretary grants an exemption or variance from, or an alternative to, a requirement under such regulations pursuant to section 803.19 of such part, if the device involved is –

(I) a class III device;

* * *

(2) shall define the term "serious injury" to mean an injury that –

(A) is life threatening,

(B) results in permanent impairment of a body function or permanent damage to a body structure, or

(C) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure;

(3) shall require reporting of other significant adverse device experiences as determined by the Secretary to be necessary to be reported;

(4) shall not impose requirements unduly burdensome to a device manufacturer or importer taking into account his cost of complying with such requirements and the need for the protection of the public health and the implementation of this chapter;

(5) which prescribe the procedure for making requests for reports or information shall require that each request made under such regulations for submission of a report or information to the Secretary state the reason or purpose for such request and identify to the fullest extent practicable such report or information;

(6) which require submission of a report or information to the Secretary shall state the reason or purpose for the submission of such report or information and identify to the fullest extent practicable such report or information;

* * *

(b) User reports

(1)(A) Whenever a device user facility receives or otherwise becomes aware of information that reasonably suggests that a device has or may have caused or contributed to the death of a patient of the facility, the facility shall, as soon as practicable but not later than 10 working days after becoming aware of the information, report the information to the Secretary and, if the identity of the manufacturer is known, to the manufacturer of the device. In the case of deaths, the Secretary may by regulation prescribe a shorter period for the reporting of such information.

(B) Whenever a device user facility receives or otherwise becomes aware of –

(i) information that reasonably suggests that a device has or may have caused or contributed to

the serious illness of, or serious injury to, a patient of the facility, or

(ii) other significant adverse device experiences as determined by the Secretary by regulation to be necessary to be reported,

the facility shall, as soon as practicable but not later than 10 working days after becoming aware of the information, report the information to the manufacturer of the device or to the Secretary if the identity of the manufacturer is not known.

(C) Each device user facility shall submit to the Secretary on an annual basis a summary of the reports made under subparagraphs (A) and (B). Such summary shall be submitted on January 1 of each year. The summary shall be in such form and contain such information from such reports as the Secretary may require and shall include –

(i) sufficient information to identify the facility which made the reports for which the summary is submitted,

(ii) in the case of any product which was the subject of a report, the product name, serial number, and model number,

(iii) the name and the address of the manufacturer of such device, and

(iv) a brief description of the event reported to the manufacturer.

(D) For purposes of subparagraphs (A), (B), and (C), a device user facility shall be treated as having

received or otherwise become aware of information with respect to a device of that facility when medical personnel who are employed by or otherwise formally affiliated with the facility receive or otherwise become aware of information with respect to that device in the course of their duties.

* * *

(3) No report made under paragraph (1) by –

(A) a device user facility,

(B) an individual who is employed by or otherwise formally affiliated with such a facility, or

(C) a physician who is not required to make such a report,

shall be admissible into evidence or otherwise used in any civil action involving private parties unless the facility, individual, or physician who made the report had knowledge of the falsity of the information contained in the report.

(4) A report made under paragraph (1) does not affect any obligation of a manufacturer who receives the report to file a report as required under subsection (a).

* * *

(6) For purposes of this subsection:

(A) The term "device user facility" means a hospital, ambulatory surgical facility, nursing home, or outpatient treatment facility which is not a physician's office. The Secretary may by regulation

include an outpatient diagnostic facility which is not a physician's office in such term.

(B) The terms "serious illness" and "serious injury" mean illness or injury, respectively, that –

(i) is life threatening,

(ii) results in permanent impairment of a body function or permanent damage to a body structure, or

(iii) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

* * *

(e) Device tracking

(1) The Secretary may by order require a manufacturer to adopt a method of tracking a class II or class III device –

(A) the failure of which would be reasonably likely to have serious adverse health consequences; or

(B) which is –

(i) intended to be implanted in the human body for more than one year, or

(ii) a life sustaining or life supporting device used outside a device user facility.

(2) Any patient receiving a device subject to tracking under paragraph (1) may refuse to release, or refuse

permission to release, the patient's name, address, social security number, or other identifying information for the purpose of tracking.

* * *

(g) Reports of removals and corrections

(1) Except as provided in paragraph (2), the Secretary shall by regulation require a manufacturer or importer of a device to report promptly to the Secretary any correction or removal of a device undertaken by such manufacturer or importer if the removal or correction was undertaken –

(A) to reduce a risk to health posed by the device, or

(B) to remedy a violation of this chapter caused by the device which may present a risk to health.

A manufacturer or importer of a device who undertakes a correction or removal of a device which is not required to be reported under this paragraph shall keep a record of such correction or removal.

(2) No report of the corrective action or removal of a device may be required under paragraph (1) if a report of the corrective action or removal is required and has been submitted under subsection (a).

(3) For purposes of paragraphs (1) and (2), the terms "correction" and "removal" do not include routine servicing.

(h) Inclusion of devices in the postmarket risk identification and analysis system

(1) In general

(A) Application to devices

The Secretary shall amend the procedures established and maintained under clauses (i), (ii), (iii), and (v) of section 355(k)(3)(C) of this title in order to expand the postmarket risk identification and analysis system established under such section to include and apply to devices.

(B) Exception

Subclause (II) of clause (i) of section 355(k)(3)(C) of this title shall not apply to devices.

(C) Clarification

With respect to devices, the private sector health-related electronic data provided under section 355(k)(3)(C)(i)(III)(bb) of this title may include medical device utilization data, health insurance claims data, and procedure and device registries.

(2) Data

In expanding the system as described in paragraph (1)(A), the Secretary shall use relevant data with respect to devices cleared under section 360(k) of this title or approved under section 360e of this title, including claims data, patient survey

data, and any other data deemed appropriate by the Secretary.

* * *

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21 U.S.C. § 360k. State and local requirements respecting devices

(a) General rule

Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(b) Exempt requirements

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if –

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement –

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

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21 C.F.R. § 803.50 If I am a manufacturer, what reporting requirements apply to me?

(a) If you are a manufacturer, you must report to us the information required by § 803.52 in accordance with the requirements of § 803.12(a), no later than 30 calendar days after the day that you receive or otherwise become aware of information, from any source, that reasonably suggests that a device that you market:

(1) May have caused or contributed to a death or serious injury or

(2) Has malfunctioned and this device or a similar device that you market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.

(b) What information does FDA consider "reasonably known" to me?

(1) You must submit all information required in this subpart E that is reasonably known to you. We consider the following information to be reasonably known to you:

(i) Any information that you can obtain by contacting a user facility, importer, or other initial reporter;

(ii) Any information in your possession; or

(iii) Any information that you can obtain by analysis, testing, or other evaluation of the device.

(2) You are responsible for obtaining and submitting to us information that is incomplete or missing from reports submitted by user facilities, importers, and other initial reporters.

(3) You are also responsible for conducting an investigation of each event and evaluating the cause of the event. If you cannot submit complete information on a report, you must provide a statement explaining why this information was incomplete and the steps you took to obtain the information. If you later obtain any required information that was not available at the time you filed your initial report, you must submit this information in a supplemental report under § 803.56 in accordance with the requirements of § 803.12(a).