UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

MARY SEWELL et al;

Plaintiffs,

v.

MENTOR WORLWIDE, LLC; NUSIL, LLC; NUSIL TECHNOLOGY, LLC; and DOES 1-100, inclusive,

Defendant.

Case No. SA CV 19-01126-AB (PLAx)

ORDER DENYING PLAINTIFFS' MOTION TO REMAND AND GRANTING DEFENDANTS' MOTIONS TO DISMISS

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.*.

[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 available at

[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.

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 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

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

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:

> "[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.

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.

Plaintiffs 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

HONORABLE ANDRÉ BIROTTE JR.
UNITED STATES DISTRICT COURT JUDGE