UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

ALMA R. SUCKOW and EUGENE SUCKOW, Plaintiffs, vs. MEDTRONIC, INC. and DARRELL ROW, Defendants.	Case No.: 2:12-cv-01870-GMN-CWH **ORDER**

Pending before the Court is the Motion to Dismiss (ECF No. 13) filed by Defendant Medtronic, Inc. ("Medtronic"). Plaintiffs Alma Suckow and Eugene Suckow filed a Response (ECF No. 15) and Defendant Medtronic filed a Reply (ECF No. 18). Defendant Medtronic also filed a Notice of Supplemental Authority (ECF No. 14).

I. BACKGROUND

In the Complaint, Plaintiffs allege damages on behalf of Ms. Suckow for physical injuries as a result of the failure of an automatic implantable cardiac defibrillator (AICD) pacemaker with a Sprint Fidelis lead, manufactured by Medtronic. (Compl., Ex. A to Notice of Removal, ECF No. 1-1.) Plaintiffs also allege damages on behalf of Mr. Suckow for loss of consortium. (Id.) Defendant Darrell Row, an individual, was employed by Medtronic as a sales representative. (Row Aff., 2:¶5, Ex. C to Notice of Removal, ECF No. 1-3.)

Plaintiffs allege that the AICD pacemaker with Sprint Fidelis lead was surgically implanted in December 2006, and that on October 22, 2007, Plaintiff received a letter from Medtronic informing her that there was a chance of fractures in the lead but that she was more likely to experience complications with removal than from this problem. (Compl., 2–3:¶8.) Plaintiffs allege that on September 18 through September 23, 2010, Ms. Suckow was admitted

to the hospital for complaints and symptoms related to her cardiac condition and the operation of her Medtronic AICD. (Id. at 3:¶9.) Plaintiffs allege that in September 2010 Defendant Row tested, reviewed, and evaluated the device and informed and advised her and others that it was operating and performing normally and within expected standards, and that it was fit and safe for continued use. (Id. at 3:¶10.) Plaintiffs allege that Ms. Suckow was re-admitted to the hospital on December 22, 2010, on an emergency basis, and surgery was performed to "place temporary heart pacing." (Id. at 3:¶11.) Plaintiffs allege that she "suffered a significant hematoma and other physical injuries as a result of the need for this emergent surgery." (Id.) Finally, Plaintiffs allege that on December 30, 2010, her temporary pacemaker was removed, as well as her Medtronic AICD and Spring Fidelis lead, and that she was subsequently released and discharged on January 4, 2011. (Id. at 3–4:¶12.)

Against Defendant Medtronic, Plaintiffs appear to allege three state law causes of action for: (1) strict product liability; (2) breach of express warranty; and (3) respondeat superior; and against Defendant Row, Plaintiffs appear to allege two state law causes of action for: (1) negligence; and (2) misrepresentation. (Compl., Ex. A to Notice of Removal, ECF No. 1-1.)

Medtronic removed the action to this Court based upon diversity jurisdiction, alleging that Defendant Row was fraudulently joined. (Notice of Removal, ECF No. 1.)

II. DISCUSSION

A. Removal Jurisdiction

As a threshold consideration, the Court must first determine its jurisdiction over this action. If the Court finds that Defendant Row was improperly joined, and that jurisdiction exists over the action, then disposition of Defendant Medtronic's Motion to Dismiss (ECF No. 13) may be proper. As discussed below, the Court finds that it has jurisdiction.

1. Legal Standard

"Federal courts are courts of limited jurisdiction," and "possess only that power

authorized by Constitution and statute, which is not to be expanded by judicial decree." Kokkonen v. Guardian Life Ins. Co. of Am., 511 U.S. 375, 377 (1994) (internal citations omitted). "It is to be presumed that a cause lies outside this limited jurisdiction, and the burden of establishing the contrary rests upon the party asserting jurisdiction." Id. (internal citations omitted).

The federal removal statute provides that a defendant may remove an action to federal court based on federal question jurisdiction or diversity jurisdiction. 28 U.S.C. § 1441. "The 'strong presumption against removal jurisdiction means that the defendant always has the burden of establishing that removal is proper,' and that the court resolves all ambiguity in favor of remand to state court." Hunter v. Philip Morris USA, 582 F.3d 1039, 1042 (9th Cir. 2009) (quoting Gaus v. Miles, Inc., 980 F.2d 564, 566 (9th Cir. 1992) (per curiam)).

"If at any time before final judgment it appears that the district court lacks subject matter jurisdiction, the case shall be remanded." 28 U.S.C. § 1447(c). However, district courts cannot remand sua sponte for non-jurisdictional defects in procedure. Kelton Arms Condominium *Owners Ass'*n, Inc. v. Homestead Ins. Co., 346 F.3d 1190, 1191–93 (9th Cir. 2003).

Under 28 U.S.C. § 1332, complete diversity of citizenship is required, and each plaintiff must be a citizen of a different state than each defendant. Morris v. Princess Cruises, Inc., 236 F.3d 1061, 1067 (9th Cir. 2001). "Nevertheless, one exception to the requirement for complete diversity is where a non-diverse defendant has been 'fraudulently joined.'" Id. "Although there is a general presumption against fraudulent joinder, if the plaintiff fails to state a cause of action against a resident defendant, and the failure is obvious according to the settled rules of the state, the joinder of the resident defendant is fraudulent." Hamilton Materials, Inc. v. Dow Chemical Corp., 494 F.3d 1203, 1206 (9th Cir. 2007) (internal citation and quotation marks omitted). For purposes of removal, "the citizenship of defendants sued under fictitious names shall be disregarded." 28 U.S.C. § 1441(b)(1).

Particularly as applied to the facts here, it is important to note that "a case may not be removed to federal court on the basis of a federal defense, including the defense of preemption, even if the defense is anticipated in the plaintiff's complaint, and even if both parties admit that the defense is the only question truly at issue in the case." Franchise Tax Bd. v. Constr. Laborers Vacation Trust, 463 U.S. 1, 14 (1983).

A preemption defense goes to the merits of a plaintiff's case. Hunter, 582 F.3d at 1045. "When a defendant asserts that the plaintiff's claim is impliedly preempted by federal law, it cannot be said that the plaintiff's failure to state a claim against the resident defendant is 'obvious according to the settled rules of the state.'" Id. (quoting Hamilton Materials, 494 F.3d at 1206). "Rather, the preemption question requires an inquiry into the merits of the plaintiff's claims against all defendants and an analysis of federal law." Id. "In such a case, the defendant has failed to overcome the 'strong presumption against removal jurisdiction.'" Id. (quoting Gaus, 980 F.2d at 566).

2. Analysis

In order to find that jurisdiction is proper, the Court must find that Medtronic has successfully overcome the presumption against removal and that Plaintiffs' failure to state a cause of action against Defendant Row is obvious according to the settled rules of the state of Nevada. Here the Court does so find.

Plaintiffs' negligence claim against Defendant Row consists of allegations that during the period of time between September 18 and September 23, 2010, Row breached "a duty of care to reasonably 'interrogate', [sic] test, review, interpret and evaluate the performance of Plaintiff's Medtronic AICD and Sprint Fidelis leads, and to provide accurate information to [her] and her health care providers." (Compl., 5:¶18.) Furthermore, that Row was negligent in that he knew or should have known that "Plaintiff's Medtronic and Sprint Fidelis leads were not operating in a fit and safe manner during this time, and that said device was likely to fail in

the near future at a time and place in which [she] would be subject to, and at risk for, serious and significant health problems, including death." (Id.) Also, Plaintiffs allege that Row "failed to advise [her] and her medical providers that the replacement and revision of the AICD and leads would best be undertaken under controlled conditions, rather than under the emergent conditions that existed on or about December 22, 2010 when it was learned the device had failed completely." (Id.)

Plaintiffs' misrepresentation claim against Defendant Row consists of allegations that he "represented to [her] and her medical care providers that her Medtronic AICD and Sprint Fidelis lead was fit and safe for continued use, and that it was not necessary at that time to replace and revise the AICD or leads," and that "[she] and her medical providers relied upon such information." (Id. at 5:¶19.) Furthermore, that he "knew, or should have know [sic], that such information and assurance was incorrect and wrong," and that he "knew, or should have known, that [she] and her medical providers would justifiably rely upon such incorrect and wrong information." (Id.) Also, Plaintiffs allege that "as a proximate result of such incorrect and wrong information [she] was released from the hospital at that time without replacement and revision of the Medtronic AICD and Sprint Fidelis leads, and/or without plan to replace and revise the AICD and lead prior to an emergent situation caused by the failure of this pacemaker." (Id.) Finally, Plaintiffs allege that Row "negligently and/or intentionally misrepresented the true facts and conditions surrounding the defective pacemaker." (Id.)

As noted by Medtronic in its Notice of Removal, Plaintiffs' allegations in their Complaint as to manufacturing defect, breach of express warranty, and vicarious liability do not appear to be alleged against Defendant Row. Instead, under a heading of "Claims against Defendant Darrell Row and Does I through X, inclusive," Plaintiffs allege claims for negligence and misrepresentation. (Compl., 5–6.)

In the Notice of Removal, and in an Affidavit from Row, Medtronic argues that

Plaintiffs fail to state a cause of action as to Defendant Row pursuant to the Twombly/Iqbal pleading standard. In a declaration, Defendant Row states that "to the best of my knowledge and recollection, my first encounter with Ms. Alma Suckow occurred when she arrived at Mountain View Hospital in the late December 2010 time period." (Row Decl., 6:¶18.) Furthermore, he states that that any work he performed in interrogating a device was done at the request of a physician, and that it is the physician who interprets any data and makes decisions. (Id. at 7:¶18.) This sworn statement directly contradicts Plaintiffs' allegations of Defendant Row's involvement in September 2010.

Plaintiffs never filed an opposition to Medtronic's Notice of Removal, to Defendant Row's Declaration, or to Medtronic's arguments as to fraudulent joinder. The sole opposition Plaintiffs have filed in this action is as to Medtronic's Motion to Dismiss. (See Response to Mot. to Dismiss, 3, ECF No. 15.)

Medtronic argues in its Motion to Dismiss that Plaintiffs' claims against Medtronic are expressly preempted by 21 U.S.C. § 360k(a)[1]. (Mot. to Dismiss, 11–20, ECF No. 13.) Medtronic also argues that Plaintiffs fail to state a claim for vicarious liability against Medtronic because Plaintiffs' allegations are insufficient to state a negligence claim or a claim for misrepresentation against Defendant Row, and because the learned intermediary doctrine precludes such a finding of liability in any event. (Id. at 20–26.)

In Nevada, to state a claim on a traditional negligence theory a plaintiff must allege that:

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[1] This section of Title 21 was enacted as part of the Medical Device Amendments of 1976 (MDA), 21 U.S.C. § 360c et seq., and provides for federal preemption of certain state laws governing medical devices:

> (a) General rule. Except as provided in subsection (b) of this section, 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.

21 U.S.C. § 360k(a). Subsection (b) permits the Food and Drug Administration to exempt some state and local requirements from preemption. 21 U.S.C. § 360k(b).

(1) the defendant owed the plaintiff a duty of care; (2) the defendant breached that duty; (3) the breach was the legal cause of the plaintiff's injuries; and (4) the plaintiff suffered damages. Foster v. Costco Wholesale Corp., 291 P.3d 150, 153 (Nev. 2012). To state a claim for fraud or intentional misrepresentation, a plaintiff must allege three factors: (1) a false representation by the defendant that is made with either knowledge or belief that it is false or without sufficient foundation; (2) an intent to induce another's reliance; and (3) damages that result from this reliance. See Nelson v. Heer, 163 P.3d 420, 426 (Nev. 2007).

Before Plaintiffs filed their opposition (ECF No. 15), Medtronic filed a Notice of Supplemental Authority (ECF No. 14), notifying the Court that one of the district court orders cited in a footnote of their brief was reversed on grounds unrelated to the proposition for which the case was cited. See Stengel v. Medtronic Inc., 704 F.3d 1224 (9th Cir. 2013) (en banc). The Court agrees with Medtronic that the Ninth Circuit Court of Appeals' en banc decision in Stengel does not contradict the proposition for which Medtronic cited the lower court case in a footnote: "(taking judicial notice of 'FDA documents showing the pump and catheter received premarket approval')." (See Mot. to Dismiss, 7 n.3, ECF No. 13.)

Plaintiffs' arguments in opposition are briefly stated in twenty lines of their Response brief. (Response to Mot. to Dismiss, 3, ECF No. 15.) Quoting the holding in the Stengel en banc opinion noted by Medtronic in the Notice of Supplemental Authority, Plaintiffs argue, without analysis, that their claims for defective manufacture and breach of express warranty are not preempted by the Medical Device Amendment Act ("MDA"). (Id. at 3:3–8.) Plaintiffs also argue that their cause of action for strict product liability is supported by Shoshone Coca-Cola Co. v. Dolinski, 420 P.2d 855 (Nev. 1966), "is premised on the violation of the FDA regualtions [sic] regarding the approved manufacturing process," and therefore is not preempted. (Id. at 3:9–15.) Plaintiffs state that the same legal argument applies to their claim for breach of express warranty. (Id. at 3:16.) Plaintiffs also argue that their negligence claim

against Defendant Row "arises from his participation and conduct during the September 2010 evaluation and testing of the Defibrillator," and in "failing to recommend the removal of the Defibriallator [sic] at that time." (Id. at 3:19–22.) Finally, Plaintiffs argue, without analysis, that "[t]he MDA does not preempt a vicarious liability claim." (Id. at 3:24.)

Here, the Court finds that the statements in Defendant Row's Declaration and the failure of Plaintiffs to oppose Medtronic's allegations in the Notice of Removal, along with the absence of jurisdictional arguments in Plaintiffs' Response to the Motion to Dismiss, provides support for a finding that Medtronic has overcome the presumption against removal, and that Plaintiffs' failure to state a cause of action against Defendant Row for negligence and misrepresentation is obvious according to the settled rules of the state of Nevada. Accordingly, the Court finds that the exercise of its jurisdiction here is proper.

B. Motion to Dismiss Analysis

The Court now reaches Medtronic's motion to dismiss, and finds that Plaintiffs' claims against Medtronic may be dismissed pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure.

For its motion, Medtronic relies primarily on the United States Supreme Court opinion in Riegel v. Medtronic, Inc., 552 U.S. 312 (2008), interpreting the preemption clause of the MDA, as codified in 21 U.S.C. § 360k(a), and the corresponding implementing regulation, 21 C.F.R. § 808.1(d). In the Ninth Circuit's recent en banc opinion in Stengel, both the statute and the regulation were considered, along with Riegel and two other Supreme Court cases:

> The Supreme Court has decided three preemption cases under the MDA. The rule that emerges from these cases is that the MDA does not preempt a state-law claim for violating a state-law duty that parallels a federal-law duty under the MDA.

Stengel, 704 F.3d at 1228 (discussing Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996), Buckman *Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), and Riegel v. Medtronic, Inc., 552 U.S. 312 (2008)). This holding does not contradict Medtronic's arguments as to why Plaintiffs fail

to state a legally cognizable claim and the grounds upon which it rests.

The relevant portion of § 360k(a) is the language barring any state law requirement "which is different from, or in addition to, any requirement applicable under this chapter to the device," and "which relates to the safety or effectiveness of the device or to any other matter" under the MDA.

Pointing to the premarket approval process to show the existence of federal requirements under the MDA applicable to its pacemaker, Medtronic's argument is that Plaintiffs' claims are preempted under the language of § 360k(a) because they are brought pursuant to Nevada laws that do not "parallel[] a federal-law duty under the MDA," but instead are "different from, or in addition to," requirements under the MDA that "relate[] to the safety or effectiveness of" the Medtronic pacemaker. The Court agrees.

"Absent other indication, reference to a State's 'requirements' includes its common-law duties." Riegel, 552 U.S. at 324. "[C]ommon-law liability is 'premised on the existence of a legal duty,' and a tort judgment therefore establishes that the defendant has violated a state-law obligation." Id. (quoting Cipollone v. Liggett Group, Inc., 505 U.S. 504, 522 (1992)). Here, the Court does not find that the claims alleged by Plaintiffs against Medtronic are an exception to this standard.

In Nevada, the doctrine of strict liability has been judicially adopted to apply to manufacturers of certain defective products. See, e.g., Allison v. Merck & Co., 878 P.2d 948 (Nev. 1994) (extending the doctrine of strict liability to a manufacturer of a vaccine); Shoshone Coca-Cola Bottling Co. v. Dolinski, 420 P.2d 855 (Nev. 1966) (extending the doctrine of strict liability to a manufacturer of a bottled beverage); see also Calloway v. City of Reno, 993 P.2d 1259 (Nev. 2000) (declining to extend the doctrine of strict liability to buildings).

As discussed in Riegel, premarket approval imposes "requirements" under the MDA specific to individual devices, and is focused on safety, and is therefore "in no sense an

exemption from federal safety review – it is federal safety review." 552 U.S. at 323.

Here, therefore, the Court finds that Plaintiffs cannot show that the Supplemental Premarket Approval application is insufficient to preempt Plaintiffs' product defect claims pursuant to § 360k(a). Accordingly, the Court must find that Plaintiffs have failed to state a legally cognizable claim and the grounds upon which it rests.

Likewise, Plaintiffs' claim for breach of express warranty fails, because of both preemption and failure to state a claim under Nevada law. As discussed by Medtronic in its motion, Plaintiffs' claim for breach of express warranty appears to arise pursuant to Nevada statute, which requires a seller of goods to conform its product to any "affirmation of fact or promise" or to any "description" made to the buyer. See Nev. Rev. Stat. § 104.2313. In their Complaint, Plaintiffs allege that Medtronic expressly warranted that its devices "were mechantable, [sic] fit and safe for their intended uses," and that it "expressly promoted and assured the fitness and safety" of the devices "beyond the FDA approved statements." (Compl., 4:20–24.) To the extent that Plaintiffs' allegations contradict the FDA's conclusions in the PMA process, these claims are preempted by § 360k(a). To the extent that Plaintiffs' allegations go further than this, Plaintiffs fail to allege sufficient facts to show a plausible violation on the part of Defendants or to give Defendants fair notice of a legally cognizable claim and the grounds upon which it rests. Therefore, the Court must dismiss this claim.

As discussed by Medtronic in its motion, because Plaintiffs' loss of consortium claim is premised upon the success of their insufficient claims for product defect and for breach of express warranty, this claim fails as well, and must be dismissed.

III. CONCLUSION

IT IS HEREBY ORDERED that the Motion to Dismiss (ECF No. 13) is **GRANTED**. Plaintiffs' Complaint is **DISMISSED without prejudice**. If Plaintiffs intend to amend their pleading so as to cure the deficiencies described in this Order, they may do so by **Friday,**

October 11, 2013. Failure to do so by this deadline will result in dismissal of this action with prejudice.

DATED this 20th day of September, 2013.

Gloria M. Navarro
United States District Judge