UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

JOLANDI NICOLE KENNEDY and MARVIN LEVY, individually and as representatives of the Estate of Meaghan Levy,	§	
Plaintiffs,	§	
	§	**CIVIL ACTION NO. 3:16-CV-0065-B**
v.	§	
OXYSURE SYSTEMS, INC., et al.	§	
Defendants.	§	

MEMORANDUM OPINION AND ORDER

Before the Court is Plaintiffs' Motion to Remand (Doc. 9). For the following reasons, the Court **GRANTS** Plaintiffs' Motion.

I.

BACKGROUND

This case arises from the death of Meaghan Levy, allegedly as a result of a malfunction of an OxySure Portable Oxygen Generator, Model 615 ("Model 615"). Doc. 1-5, Original Pet. 8–9. Plaintiffs Jolandi Kennedy and Marvin Levy, individually and as representatives of the Estate of Meaghan Levy, filed suit in state court in Dallas County, Texas, against several defendants involved in the design, manufacture, and distribution of the Model 615.[1] *Id.* at 2–7. Plaintiffs allege several

[1] OxySure Systems, Inc. and Julian Ross are the "Designer and Manufacturer Defendants." Doc. 1-5, Original Pet. 2–3. The "Supplier Defendants" are (1) Activar Construction Products; (2) Branson Ultrasonics Corp.; (3) Brenntag Southwest, Inc.; (4) D.B. Roberts, Inc.; (5) EXFO America, Inc.; (6) Marking Systems, Inc.; and (7) Plastiform, Inc. *Id.* at 3–7.

claims under Texas law. *Id.* at 10–14. First, against the Designer and Manufacturer Defendants, Plaintiffs allege (1) strict products liability; (2) gross negligence; (3) breach of warranty; (4) negligent misrepresentation; (5) fraudulent misrepresentation; and (6) fraud by nondisclosure. *Id.* at 10–14. Second, Plaintiffs allege that *all* Defendants were negligent in the "design, manufacture, marketing, inspecting, and maintenance" of the Model 615. *Id.* at 10–11.

Defendants removed the case to this Court based on "federal preemption and the existence of a substantial federal question raised by Plaintiffs' Petition." Doc. 1, Notice of Removal 1. Defendants allege that Plaintiffs' claims implicate the Food, Drug, and Cosmetic Act (FDCA) and its Medical Device Amendments (MDA), 21 U.S.C. §§ 301–99. *Id.* Plaintiffs moved to remand. Doc. 9, Mot. to Remand 1. The Court must determine whether removal was proper.

II.

LEGAL STANDARD

"'Federal courts are courts of limited jurisdiction,' possessing 'only that power authorized by Constitution and statute.'" *Gunn v. Minton*, — U.S. —, 133 S. Ct. 1059, 1064 (2013) (quoting *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994)). The removal statute authorizes a defendant to remove any state civil action to federal district court if the district court would have had original jurisdiction over the case (e.g., federal question or diversity jurisdiction). 28 U.S.C. § 1441. Removal raises "significant federalism concerns" because it "deprive[s] the state court of an action properly before it." *Gasch v. Hartford Accident & Indem. Co.*, 491 F.3d 278, 281 (5th Cir. 2007) (quoting *Carpenter v. Wichita Falls Indep. Sch. Dist.*, 44 F.3d 362, 365–66 (5th Cir. 1995)). As a result, courts strictly construe the removal statute. *Manguno v. Prudential Prop. & Cas. Ins. Co.*, 276 F.3d 720, 723 (5th Cir. 2002).

Motions for remand are governed by 28 U.S.C. § 1447(c): "If at any time before final judgment it appears that the district court lacks subject matter jurisdiction, the case shall be remanded." When considering a motion to remand, "[t]he removing party bears the burden of showing that federal jurisdiction exists and that removal was proper." *Manguno*, 276 F.3d at 723. Because federal courts are courts of limited jurisdiction, "any doubt about the propriety of removal must be resolved in favor of remand." *Gasch*, 491 F.3d at 281–82.

III.

ANALYSIS

Defendants argue that the Court has federal question jurisdiction based on "federal preemption and the existence of a substantial federal question." Doc. 16, Resp. in Opp'n to Mot. to Remand 1. Plaintiffs, on the other hand, contend that their claims do not present a federal question. Doc. 9, Mot. to Remand 2. The Court agrees with Plaintiffs.

Federal law regulates medical devices through the MDA, 21 U.S.C. §§ 351–60, which contains an express preemption provision:

> 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). Despite this provision, the MDA "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." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008) (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996)). In addition, Congress chose not

to create a private cause of action in the statute, which "prevents a private litigant from enjoining, or seeking damages under federal law for, FDCA violations." *Purcel v. Advanced Bionics Corp.*, No. 3:07-CV-1777, 2010 WL 2679988, at *5 (N.D. Tex. June 30, 2010); *see* 21 U.S.C. § 337(a).

A. Preemption

Defendants' preemption defense provides no basis for removal. In determining whether there is federal question jurisdiction, courts follow the well-pleaded complaint rule, according to which "federal jurisdiction exists only when a federal question is presented on the face of the plaintiff's properly pleaded complaint." *Caterpillar Inc. v. Williams*, 482 U.S. 386, 392 (1987). In other words, "a defendant may not [generally] remove a case to federal court unless the *plaintiff's* complaint establishes that the cause 'arises under' federal law."[2] *Aetna*, 542 U.S. at 207 (quoting *Franchise Tax Bd. of State of Cal. v. Constr. Laborers Vacation Trust for S. Cal.*, 463 U.S. 1, 10 (1983)). In this case, even if Plaintiffs' claims are preempted, that is no basis for removal because preemption arises only as a defense to Plaintiffs' claims and, thus, not in Plaintiffs' well-pleaded complaint. *See Metro. Life Ins. Co. v. Taylor*, 481 U.S. 58, 63 (1987). Therefore, Defendants' preemption argument fails to support federal question jurisdiction.

B. Substantial Federal Question

Plaintiffs' claims also do not present a substantial federal question. A substantial federal question may exist "where the vindication of a right under state law necessarily turn[s] on some

[2] Complete preemption is an exception to this rule. *See Aetna Health Inc. v. Davila*, 542 U.S. 200, 207 (2004) ("[W]hen a federal statute wholly displaces the state-law cause of action through complete preemption,' the state claim can be removed." (quoting *Beneficial Nat'l Bank v. Anderson*, 539 U.S. 1, 8 (2003))). The exception does not apply here because Defendants do not argue for "complete field preemption." *See* Doc. 16, Resp. in Opp'n to Mot. to Remand 1.

construction of federal law." *Franchise Tax Bd.*, 463 U.S. at 9. This is a "'special and small category' of cases." *Gunn*, 133 S. Ct. at 1064 (quoting *Empire Healthchoice Assurance, Inc. v. McVeigh*, 547 U.S. 677, 699 (2006)). "[F]ederal jurisdiction over a state law claim will lie if a federal issue is: (1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in a federal court without disrupting the federal-state balance approved by Congress." *Id.* at 1065; *see also Singh v. Duane Morris LLP*, 538 F.3d 334, 338 (5th Cir. 2008). All four requirements must be met for federal jurisdiction to be proper. *Gunn*, 133 S. Ct. at 1065.

In this case, even assuming a federal issue is necessarily raised and actually disputed, the federal issue is not substantial. The Supreme Court has explained that "it is not enough that the federal issue be significant to the particular parties in the immediate suit; that will *always* be true when the state claim 'necessarily raise[s]' a disputed federal issue." *Id.* at 1066. Rather, "[t]he substantiality inquiry . . . looks instead to the importance of the issue to the federal system as a whole." *Id.* The following factors weigh in favor of finding a substantial federal issue:

> (1) . . . the case presents a nearly pure issue of law that would control many other cases rather than an issue that is fact-bound and situation-specific; (2) . . . the federal government has an important interest in the issue, particularly if the case implicates a federal agency's ability to vindicate its rights in a federal forum; and (3) . . . a determination of the federal question will be dispositive of the case.

Marren v. Stout, 930 F. Supp. 2d 675, 683 (W.D. Tex. 2013) (citing *Empire Healthchoice*, 547 U.S. at 700–01).

The Supreme Court has ruled that "alleging a violation of a federal statute as an element of a state cause of action, when Congress has determined that there should be no private, federal cause of action for the violation, does not state a claim 'arising under the Constitution, laws, or treaties of the United States.'" *Merrell Dow Pharm. Inc. v. Thompson*, 478 U.S. 804, 817 (1986) (quoting 28

U.S.C. § 1331). In *Merrell Dow*, consumers sued a manufacturer and distributor of a drug that allegedly caused deformities. *Id.* at 805. The complaint alleged, among other things, that the drug was misbranded in violation of the FDCA. *Id.* at 805–06. The Supreme Court concluded that "[t]he novelty of an FDCA issue is not sufficient to give it status as a federal cause of action; nor should it be sufficient to give a state-based FDCA claim status as a jurisdiction-triggering federal question." *Id.* at 817. Further, the Fifth Circuit has summarized the *Merrell Dow* decision thusly: "where Congress has provided no private remedy for the violation of a federal drug regulatory statute, the fact that violation of the statute is an element of a state tort claim is insufficient to establish a substantial federal interest." *Singh*, 538 F.3d at 338–39.

A Texas federal district court recently found a similar federal issue to be insubstantial. *See Maher v. Vaughn, Silverberg & Assocs., LLP*, 95 F. Supp. 3d 999, 1010–11 (W.D. Tex. 2015). In *Maher*, the plaintiff sued fertility clinics that used the wrong sperm for her *in vitro* fertilization procedure. *Id.* at 1002–03. She alleged negligence *per se*, negligent hiring, promissory estoppel, battery, and intentional infliction of emotional distress. *Id.* at 1003. The plaintiff argued that federal jurisdiction was proper because the defendants had purportedly violated FDA regulations. *Id.* at 1004–05. The court determined that the federal issue was not substantial because, first, "whether [the] [d]efendants violated the FDA regulations when they mistakenly used the wrong sperm . . . and subsequently failed to report the incident [was] a fact-bound, situation-specific set of determinations." *Id.* at 1010. Second, "the federal government [did] not have an important interest in the outcome of [the] lawsuit" because "the FDA [was] ' . . . not a party to [the] case and accordingly would not be bound by a court's determination of' any issues presented at trial or in a pre-trial proceeding." *Id.* at 1011 (quoting *Marren*, 930 F. Supp. 2d at 687). Third, "resolution of

[the] 'federal issue' [would] not be dispositive of [the] case" because "[e]ven if [the plaintiff] ultimately established [the] [d]efendants violated the relevant FDA regulations, she would still need to establish additional elements of her claim in order to dispose of the case." *Id.*

In the present case, the federal issue is not substantial because, first, "whether Defendants violated the FDA regulations" and misrepresented that the appropriate testing had been conducted on the Model 615 is mostly a "fact-bound, situation-specific set of determinations." *See id.* at 1010; Doc. 1-5, Original Pet. 8–10, 12–14. While the issue pertaining to the Model 615 in this case is less "situation-specific" than the issue in *Maher*, it is still a question of fact, rather than a "nearly pure issue of law." *See Marren*, 930 F. Supp. 2d at 683. Furthermore, the remaining factors unequivocally demonstrate that the federal issue is not substantial. Regarding the second factor, the FDA is not a party to this case. Instead, Plaintiffs challenge the actions of designers, manufacturers, and distributors of the Model 615. Doc. 1-5, Original Pet. 2–7. Thus, "the federal government does not have an important interest in the outcome of this lawsuit" because "the FDA . . . would not be bound by a court's determination of any issues presented at trial or in a pre-trial proceeding." *See Maher*, 95 F. Supp. 3d at 1011 (internal quotation marks omitted) (quoting *Marren*, 930 F. Supp. 2d at 687). Third, resolving the federal issue will not dispose of this case because "[e]ven if [Plaintiffs] ultimately establish[] Defendants violated the relevant FDA regulations, [they] would still need to establish additional elements of [their claims] in order to dispose of the case." *See Maher*, 95 F. Supp. 3d at 1011; *see also* Doc. 1-5, Original Pet. 10–14. Plaintiffs' claims, therefore, do not present a substantial federal question, which means that this Court lacks federal question jurisdiction. Accordingly, removal was improper, and the case must be remanded.

IV.

CONCLUSION

Based on the foregoing, the Court **GRANTS** Plaintiffs' Motion to Remand (Doc. 9).

SO ORDERED.

DATED: June 28, 2016.

JANE J. BOYLE
UNITED STATES DISTRICT JUDGE