UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

JULIA ANN RIDDLEY,	§	
	§	
Plaintiff,	§	
	§	
v.	§	2:24-cv-109-BR
	§	
COOPERSURGICAL, INC. et al.,	§	
	§	
Defendants.	§	

MEMORANDUM OPINION AND ORDER GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTIONS TO DISMISS

Before the Court are Motions to Dismiss filed by Defendants CooperSurgical, Inc. ("CooperSurgical"), (ECF 7), Femcare, Ltd. – UK Subsidiary of Utah Medical Products, Inc. ("Femcare"), (ECF 9), and Utah Medical Products, Inc. ("UTMD"), (ECF 12). The motions have been fully briefed, and after due consideration the Court finds that they should be GRANTED IN PART and DENIED IN PART. The Court holds that venue is proper in this division, that all Defendants are subject to the specific personal jurisdiction of the Court at this stage of proceedings, and that Plaintiff's claims for design defect (Count 1), manufacturing defect (Count 2), and strict liability (Count 4, construed as a claim for marketing defect) should be dismissed, but that Plaintiff's claims for failure to warn (Count 3), negligence (Count 5), violation of consumer protection laws (Count 6), and gross negligence (Count 7) should be allowed to proceed against all Defendants.[1] Any motion by Plaintiff for leave to amend in the interest of repleading causes of action dismissed by this Order shall be filed on or before December 2, 2024.

[1] Although Plaintiff pleads "Exemplary Damages" as Count 8, the Court does not view damages as a separate cause of action, and so does not treat Count 8 apart from Plaintiff's gross negligence cause of action (Count 7).

I. Procedural Background

Plaintiff filed this action to recover under Texas law for damages allegedly resulting from the use of Filshie Clips, a medical device used in tubal ligation surgeries. (ECF 1). In 2009,[2] Plaintiff underwent such a surgery using Filshie Clips intended to permanently prevent future pregnancy. (*Id*. at ¶¶ 29-32). In 2022, Plaintiff discovered that she was pregnant despite the tubal ligation. (*Id*. at ¶¶ 33 & 34).

Plaintiff initially filed her lawsuit in the 320th District Court in Potter County, Texas, and Defendants removed the case to this Federal Court pursuant to 28 U.S.C. § 1446. (ECF 1). Plaintiff's Petition asserts the same seven substantive causes of action against all three Defendants, plus a plea for punitive damages (Count 8). (ECF 1-1 at ¶¶ 49-143). The substantive counts are: (1) design defect, (2) manufacturing defect, (3) failure to warn, (4) strict liability, (5) negligence, (6) violation of consumer protection laws, and (7) gross negligence. (*Id*.).

Each Defendant seeks dismissal of all claims. CooperSurgical moves the Court "to dismiss Plaintiff's lawsuit for lack of personal jurisdiction, improper venue, and for failure to state a claim pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure." (ECF 8[3] at 5). Similarly, Femcare and UTMD move the Court to dismiss "for lack of personal jurisdiction and for failure to state a claim pursuant to Rules 12(b)(2) and 12(b)(6)." (ECF 10 at 6, internal punctuation omitted, *and* ECF 13 at 7). Standards applicable to these grounds for dismissal—(A) improper venue, (B) lack of personal jurisdiction, and (C) failure to state a claim—are detailed below, and then applied to the facts of this case as pleaded by Plaintiff.

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[2] All facts referenced in this Order are drawn from Plaintiff's state-court Petition (sometimes referred to herein as "the Complaint") or from admissions by one or more Defendants and are assumed to be true for the limited purpose of evaluating the merits of the Motions.

[3] Though the only ground for relief listed in CooperSurgical's Motion, (ECF 7), is failure to state a claim subject to Rule 12(b)(6), the Court will also address personal jurisdiction and venue as they relate to CooperSurgical because they are mentioned in that Defendant's Brief in Support, (ECF 8).

II. Legal Standards

Rule 12(b) of the Federal Rules of Civil Procedure establishes multiple defenses that may be asserted by a motion before responding to a pleading in federal courts. Fed. R. Civ. P. 12(b). Each of the three grounds for dismissal urged by the Defendants is established by a subsection of Rule 12(b): improper venue by 12(b)(3), lack of personal jurisdiction by 12(b)(2), and failure to state a claim by 12(b)(6). Fed. R. Civ. P. 12(b)(2)-(3), (6).

When motions under these rules depend on the facts of the case, the plaintiff bears the burden of alleging those facts. *See Umphress v. Hall*, 479 F. Supp. 3d 344, 348 (N.D. Tex. Aug. 14, 2020) (collecting Fifth Circuit district court decisions that the plaintiff bears the burden of proving proper venue to overcome a 12(b)(3) motion) *and Revell v. Lidov*, 317 F.3d 467, 469 (5th Cir. 2002) ("The plaintiff bears the burden of establishing jurisdiction" to defeat a 12(b)(2) motion); *see also Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) *and Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (together setting the standard for a plaintiff's factual allegations to survive a 12(b)(6) motion). However, because these motions must be resolved at the outset of a case, before discovery is completed and findings of fact are made, the burden is a comparatively light one. A plaintiff does not need to prove their case, but rather only to properly plead it.

To determine whether a plaintiff has met this burden, a court must view all well-pleaded facts in the light most favorable to the plaintiff. *See Ambraco Inc. v. Bossclip B.V.*, 570 F.3d 233, 237-8 (5th Cir. 2009) (*cert. denied*, 558 U.S. 1111 (2010)) (regarding 12(b)(3) motions); *Carmona v. Leo Ship Mgmt.*, 924 F.3d 190, 193 (5th Cir. 2019) (regarding 12(b)(2) motions); *and Hodge v. Engleman*, 90 F.4th 840, 843-4 (5th Cir. 2024) (regarding 12(b)(6) motions). The sources to which a court may look for facts depend on the motion in question.

A. Dismissal for Improper Venue

The Federal Rules of Civil Procedure allow defendants to challenge a claim by motion asserting that the claim is being heard in an improper venue. Fed. R. Civ. P. 12(b)(3). *Inter alia*, venue is proper in "a judicial district in which a substantial part of the events or omissions giving rise to the claim occurred." 28 U.S.C. § 1391(b)(2). If the case falls into this category, or one of its alternatives, "venue is proper; if it does not, venue is improper, and the case must be dismissed or transferred." *Atl. Marine Constr. Co. v. U.S. Dist. Ct. for W. Dist. Of Tex.*, 571 U.S. 49, 56 (2013).

In making this determination, a court may "consider more than just [the d]efendants' conduct with regard to the events and omissions at issue in [the] case. That is, a court may also consider the location of the effects of the alleged conduct." *Umphress*, 479 F. Supp. 3d at 352. In other words, if either a substantial part of (1) the relevant acts or omissions of the defendants, or (2) the events resulting from those acts or omissions occurred in this judicial district, a motion to dismiss or to transfer for improper venue should generally be denied. If necessary to resolve the factual question of where the relevant events occurred, a court may look beyond the pleadings, including to evidence submitted by a defendant with their motion or by a plaintiff with their response. *Id*. at 348; *accord Ambraco*, 570 F.3d at 237-8.

B. Dismissal for Lack of Personal Jurisdiction

The Federal Rules of Civil Procedure also allow for a case to be dismissed for lack of personal jurisdiction over a defendant. Fed. R. Civ. P. 12(b)(2). A defendant must raise this defense in its answer or in a pre-answer motion, or else it will be deemed to have waived the defense and voluntarily submitted to the court by future participation in the litigation. Fed. R. Civ. P. 12(h)(1)(B); *see Mullins v. TestAmerica, Inc.*, 564 F.3d 386, 398-400 (5th Cir. 2009) (discussing

waiver and preservation of a personal jurisdiction defense). *See also* Fed. R. Civ. P. 81(c)(2) (establishing the deadlines for defendants to answer or make pre-answer motions in a case that was removed to federal court before that defendant filed a state-court answer).[4]

A court may only exercise personal jurisdiction over a defendant when permitted to do so by both the long-arm statute of the forum State and by the constitutional requirements of due process. *See, e.g.*, *Carmona*, 924 F.3d at 193-4. In Texas, because the applicable long-arm statute reaches to the furthest extent constitutionally permissible, these two requirements collapse into a single inquiry. *Id*. at 193.

There are two kinds of personal jurisdiction that a court may assert over a defendant in keeping with due process requirements: general and specific. *See Bristol-Myers Squibb Co. v. Superior Ct. of Calif.*, 582 U.S. 255, 261-3 (2017). There are some defendants over which a given forum will always have personal jurisdiction, such that those defendants can always be sued in that forum, no matter where the facts of the case occurred. *See, e.g.*, *Ford Motor Co. v. Mont. Eighth Judicial Dist. Ct.*, 592 U.S. 351, 358-9 (2021). General personal jurisdiction of this sort is difficult to establish and is not at issue in this case.

At issue in this case is the more restricted variety: specific personal jurisdiction. Unlike general personal jurisdiction, a court's specific personal jurisdiction over a defendant will extend only to a specific set of claims. *See Ford Motor Co.*, 592 U.S. at 359 (courts in "the forum State may exercise [specific personal] jurisdiction in only certain cases"). These claims must "arise out of or relate to the defendant's contacts with the forum." *Id*. (citing *Bristol-Myers*, 582 U.S. at 262, and collecting cases) (internal punctuation omitted). And those contacts that give rise to the case

[4] Plaintiff has not challenged the timeliness of the Notice of Removal in this case, nor of Defendants' Motions to Dismiss. The Court notes that all three Motions were filed on the seventh day after the Notice of Removal, making them timely under Fed. R. Civ. P. 81(c)(2)(C).

must also constitute a "purposeful availment" by the defendant of the "privilege of conducting activities within the forum State." *Ford Motor Co.*, 592 U.S. at 359. "The guiding principle of specific personal jurisdiction is whether the defendant's conduct and connection with the forum State are such that he should reasonably anticipate being haled into court there." *Shambaugh & Son, L.P. v. Steadfast Ins. Co.*, 91 F.4th 364, 372 (5th Cir. 2024) (quoting *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 287 (1980)) (internal punctuation omitted).

The Fifth Circuit has articulated this standard as a three-prong test. If (1) the defendant has "purposely directed its activities toward the forum State or purposely availed itself of the privileges of conducting activities there" to the extent that establishes the necessary contacts between the defendant and the forum, and (2) the plaintiff's claim "arises out of or" relates to[5] "the defendant's forum-related contacts," and (3) the exercise of personal jurisdiction in the case would be fair and reasonable, then the defendant will be subject to the specific personal jurisdiction of the forum. *Shambaugh & Son*, 91 F.4th at 372 (citing *E. Concrete Materials, Inc. v. ACE Am. Ins. Co.*, 948 F.3d 289, 296 (5th Cir. 2020)).

The burden to meet the first two prongs is on the plaintiff, and the burden to defeat the third is on the defendant. *Id*. The plaintiff's burden at this stage in the pleadings, as stated above, is not to prove the facts underlying the case, but is rather to "make a *prima facie* showing that personal jurisdiction is proper." *Id.* at 369 (citing *E. Concrete Materials*, 948 F. 3d at 295). In determining whether a plaintiff has met this threshold, a court may consider evidence submitted by the parties, but either must resolve any factual conflicts pursuant to an evidentiary hearing or else must treat all facts in the light most favorable to the plaintiff. *Id*.; *see also Irving v. Owens-Corning Fiberglas*

[5] Though the Fifth Circuit here uses the phrase, "arises out of or results from," they elsewhere in the same opinion use the phrase "arise out of or relate to." *Shambaugh & Son*, 91 F.4th at 375. As discussed below, the Supreme Court has made clear that the test is not exclusively a causal one. *Ford Motor Co.*, 592 U.S. at 361-2.

Corp., 864 F.2d 383, 384-5 (5th Cir. 1989) (discussing a district court's reliance on affidavits and depositions to resolve a Rule 12(b)(2) motion).

The first prong, as explained above, is to allege sufficient minimum contacts to support a finding that the defendant has made a purposeful availment of the forum State, and the second prong is to allege that the plaintiff's claims are sufficiently connected to those contacts. The connection in question does not need to be a causal relationship; it may suffice, for example, that a company "serves a market for a product in the forum State and the product malfunctions there," even if the particular product that malfunctions wasn't purchased at the market in the forum state. *Ford Motor Co.*, 592 U.S. at 361-2. There must, however, be a sufficient affiliation between the defendant's forum-directed activities and the plaintiff's claim, such that the defendant should reasonably anticipate being haled into the courts of that State, in connection with those activities, on charges related to the plaintiff's claims. *Shambaugh & Son*, 91 F.4th at 372.

If a plaintiff achieves a *prima facie* showing that the defendant has the necessary contacts with the forum and that the plaintiff's claims arise out of or relate to those contacts, then the defendant must make a "compelling case" that exercise of specific personal jurisdiction would be unfair or unreasonable. *Nuovo Pignone, SpA v. STORMAN ASIA M/V*, 310 F.3d 374, 382 (5th Cir. 2002). There are traditionally five factors that influence this determination: "(1) the burden on the nonresident defendant, (2) the forum State's interests, (3) the plaintiff's interest in securing relief, (4) the interest of the interstate judicial system in the efficient administration of justice, and (5) the shared interest of the several States in furthering fundamental social policies." *E. Concrete Materials*, 948 F. 3d at 298; *see also World-Wide Volkswagen*, 444 U.S. at 292. The weightiest of these factors is the first, the burden on the defendant. *E. Concrete Materials*, 948 F.3d at 299 (citing

Bristol-Myers, 582 U.S. at 263). However, that factor is not always determinative. As the Supreme Court has stated,

> "Restrictions on personal jurisdiction are more than a guarantee of immunity from inconvenient or distant litigation. They are a consequence of territorial limitations on the power of the respective States…Even if the defendant would suffer minimal or no inconvenience from being forced to litigate before the tribunals of another State; even if the forum has a strong interest in applying its law to the controversy; even if the forum State is the most convenient location for litigation, the Due Process Clause, acting as an instrument of interstate federalism, may sometimes act to divest the State of its power to render a valid judgement." *Bristol-Myers*, 582 U.S. at 263 (cleaned up).

In summary, when a defendant raises the defense of lack of personal jurisdiction in a pre-pleading motion to dismiss, they thereby preserve the right to raise that defense in subsequent proceedings, including in their answer, in motions for summary judgment, and at trial. To defeat such a motion to dismiss, a plaintiff must, with all evidence viewed in the light most favorable to them, make a *prima facie* case that the defendant in question had sufficient purposeful contacts with the forum and that the cause of action arises out of or relates to those contacts. If the plaintiff does so, the defendant must in turn make a compelling case that the five factors above would make it unfair or unreasonable to exercise personal jurisdiction over them in the case at hand. If the defendant fails to make such a compelling case, the motion to dismiss must be denied.

C. Dismissal for Failure to State a Claim

Finally, the Federal Rules of Civil Procedure allow for dismissal of a complaint when that complaint fails to state a claim for which relief can be granted. Fed. R. Civ. P. 12(b)(6). To defeat such a motion, a claim must first satisfy the standards of Rule 8 as those standards have been articulated in past jurisprudence. *See* Fed. R. Civ. P. 8(a) *and Iqbal*, 556 U.S. at 678-80 (articulating the plausibility standard associated with Rule 8).

At bottom, a pleading needs "a short and plain statement of the claim showing that the pleader is entitled to relief, in order to give the defendant fair notice of what the claim is and the grounds upon which it rests." *Twombly*, 550 U.S. at 555. Further, the "complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Hodge*, 90 F. 4th at 843 (quoting *Iqbal*, 556 U.S. at 678) (internal quotation marks omitted).

This determination involves a two-step process. *See Waller v. Hanlon*, 922 F.3d 590, 599 (5th Cir. 2019); *see also Iqbal*, 556 U.S. at 679. The first step is to set aside any "conclusory allegations, unwarranted factual inferences, or legal conclusions" made by the plaintiff, which a court cannot assume to be true in ruling on a 12(b)(6) motion. *Hodge*, 90 F. 4th at 843, *and Waller*, 922 F.3d at 599. The second step is to determine whether sufficient allegations remain in the complaint for the court to reasonably infer that the plaintiff's case is plausible, rather than merely possible. *Waller*, 922 F.3d at 599 (citing *Iqbal*, 556 U.S. at 678-9).

Even if a complaint satisfies this Rule 8 standard as to its form and factual plausibility, it may still fail to state a claim for which relief can be granted, such that dismissal pursuant to a Rule 12(b)(6) motion is warranted. *Body by Cook, Inc. v. State Farm Mut. Auto. Ins.*, 869 F.3d 381, 385-6 (5th Cir. 2017). This is the case when the complaint is *legally* insufficient, because the plaintiff "would not be entitled to relief under any set of facts or any possible theory that it could prove consistent with the complaint's allegations." *Id*. at 386. A complaint will be dismissed unless it states one or more claims that are each factually *and* legally sufficient.

A claim might be factually sufficient but legally insufficient, for example, if it asserts and properly pleads a state-law claim that has been preempted by federal law. It is well-established that state laws that conflict with federal laws have no effect. U.S. Const., Art. VI, cl. 2 (the "Supremacy Clause"); *see, e.g.*, *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 479-480 (2013). A

federal law might preempt a state law *expressly*, as by a provision that "States shall not establish" any law of a certain kind, or it might preempt a state law *impliedly* by directly contradicting that state law, like when a federal and a state law impose mutually incompatible duties and an actor cannot simultaneously comply with both. *Id*. at 480. If a claim is legally insufficient for this or any other reason, then it will be dismissed. This is true even if the claim has otherwise satisfied the standards applicable to 12(b)(6) motions, because no relief can be granted for a legally insufficient claim.

A Rule 12(b)(6) motion to dismiss must clear a high threshold before it can be granted. *See, e.g.*, *Hodges*, 90 F.4th at 843 ("Rule 12(b)(6) motions are viewed with disfavor and rarely granted.") (cleaned up). A court must consider all relevant matters in the light most favorable to the plaintiff. Any allegations or evidence asserted by the movant, unless also contained in the complaint, must be excluded from consideration. If any such matter is not excluded, the court must convert the motion to one for summary judgment under Federal Rule of Civil Procedure 56, which requires prior notice to the parties and sufficient opportunity for the plaintiff to respond to the allegations or evidence submitted by the movant. *Id*.

To determine whether the Motions presently before the Court clear this threshold requires analysis of two further groups of legal standards. First is the express and implied preemption of state laws by the federal Medical Device Amendments to the Food, Drug, and Cosmetic Act. Second is the set of legal standards controlling each of Plaintiff's substantive state-law claims. For efficiency, these standards are presented below, alongside application of the law to the instant case.

III. Analysis

Applying the standards articulated above, and for reasons explained below, the Court finds first that this venue is proper for the resolution of this matter, and that all Defendants are properly

subject to the personal jurisdiction of this Court at this stage in the proceedings. Regarding dismissal for failure to state a claim, the Court finds that Counts 1, 2, and 4 of Plaintiff's Complaint, for Design Defect, Manufacturing Defect, and Strict Liability (construed as a claim for Marketing Defect), fail to state a claim for which relief can be granted, and so should be dismissed. Those remaining, Counts 3, 5, 6, and 7, are sufficiently pleaded to survive Defendants' Motions to Dismiss.

After striking all conclusory allegations[6] and unwarranted inferences from Plaintiff's Complaint, the Court relies on the following relevant factual assertions in making the holdings below. CooperSurgical is a Delaware corporation with its principal place of business in Connecticut. (ECF 1-1 at ¶ 4). CooperSurgical also maintains an office and a warehouse in Stratford, Texas. (*Id*. at ¶ 8). UTMD is a Utah corporation with its principal place of business in Utah, and Femcare is a wholly-owned subsidiary of UTMD based in the United Kingdom. (*Id*. at ¶¶ 5-6).

Each of the Defendants is involved in the manufacture, sale, and distribution of Filshie Clips. (*Id*. at ¶ 14). Filshie Clips are used to accomplish tubal ligations by surgical implantation at the fallopian tubes. (*Id*. at ¶¶ 15-16). Filshie Clips have been used this way in the United States since they received Pre-Market Approval ("PMA") from the FDA in 1996. (*Id*. at ¶¶ 17-18). The FDA conditioned PMA on compliance with various requirements, including an obligation to monitor and report adverse events attributable to the use of Filshie Clips. (*Id*. at ¶ 19).

[6] The Court notes that Plaintiff repeatedly conditions her allegations that Defendants violated state law, limiting to those claims to the extent that Defendants violated "parallel" federal law. (*See* ECF 1-1 at ¶¶ 28(a)-(g), 67, 75, 76, 90, 106, 116). As Plaintiff points out in the Responses to each of Defendants' Motions, this was clearly the result of careful drafting, (ECF 24 at 1, 6; ECF 26 at 1; *and* ECF 28 at 1, 8). However, the Court further notes that whether a state-law duty parallels a federal duty is a question of law; consequently, Plaintiff's assertions on this point are not entitled to deference.

The FDA granted PMA for Filshie Clips while under the impression that they had a 0.13% incidence rate of migrating from the site of their application. (*Id*. at ¶ 23). At the time of PMA, and in the times since, Defendants have had actual knowledge that the incidence rate of migration is much higher, as high as 25%. (*Id*. at ¶¶ 24, 30, 54). Defendants have not reported this increased migration rate to either the FDA, healthcare providers, or end users. (*Id*. at ¶¶ 27, 36, 41, 54).

Plaintiff underwent a tubal ligation surgery involving Filshie Clips in Amarillo, Texas in 2009. (*Id*. at ¶ 29). In June of 2022, still in Amarillo, Texas, Plaintiff discovered that she had become pregnant despite the surgery. (*Id*. at ¶ 33). It is inferred that one or both Filshie Clips used in Plaintiff's surgery have migrated from their site of application, or else this pregnancy would not have occurred. (*See id*. at ¶ 34).

A. Venue is Proper

Because Plaintiff's surgery using Filshie Clips and Plaintiff's unexpected pregnancy both occurred in Amarillo, Texas, where this Court is located, a substantial portion of the effects resulting from the acts and omissions of the Defendants occurred in this judicial district. Accordingly, the Court holds that venue is proper for this case, and to the extent Defendant CooperSurgical's Motion seeks dismissal or transfer for improper venue, that Motion is DENIED.

B. Defendants are Subject to Specific Personal Jurisdiction

Plaintiff has made the requisite *prima facie* showing that exercise of personal jurisdiction by this Court would be proper with respect to all Defendants, and no Defendant has responded with the requisite showing that such exercise at this stage of the case would be unfair or unreasonable. The Court notes that Defendants have preserved the matter by raising lack of personal jurisdiction in these Motions, and will have opportunities to raise the defense again at future stages of this litigation, where the different legal standards might lead to different results.

1. CooperSurgical is Subject to Specific Personal Jurisdiction

Because Defendant CooperSurgical maintains an office and a warehouse in the State of Texas, from which it may be reasonably inferred that CooperSurgical distributes and sells products within Texas, CooperSurgical has purposely availed itself of the privilege of conducting activities in this State to an extent that establishes the minimum contacts necessary for specific personal jurisdiction.

For the limited purpose of determining personal jurisdiction over CooperSurgical, the Court relies on allegations by Plaintiff, (ECF 24 at 20), Femcare, (ECF 11, "Declaration of Paul Hill," at 2, ¶ 7), and UTMD, (ECF 13 at 11), that are nowhere directly contradicted by CooperSurgical. Specifically, these allegations are that CooperSurgical sells and distributes Filshie Clips, and was the exclusive entity authorized to do so in the United States at the time of Plaintiff's surgery. Viewing these facts in the light most favorable to the Plaintiff, it is reasonable to infer that CooperSurgical distributed the clips used in Plaintiff's surgery from its Texas-based warehouse, or else from its generalized sale and distribution of Filshie Clips in the State, such that the Plaintiff's claims would arise directly out of CooperSurgical's contacts with the State.

Accordingly, and because CooperSurgical has not made the requisite showing that subjecting it to the personal jurisdiction of this Court at this stage of the case would be unfair or unreasonable, the Court holds that CooperSurgical is subject to specific personal jurisdiction in this matter. To the extent CooperSurgical's Motion seeks dismissal for lack of personal jurisdiction, that Motion is DENIED.

2. Femcare is Subject to Specific Personal Jurisdiction

For the limited purpose of determining personal jurisdiction over Femcare, the Court, in addition to the relevant facts listed above, relies on the following facts either asserted by Plaintiff

or admitted by Femcare. Femcare is now, and has been since at least 1996, the primary manufacturer of Filshie Clips. (ECF 24 at 13). It can be reasonably inferred that Femcare manufactured the clips used in Plaintiff's surgery.

Femcare was the original entity to receive PMA from the FDA to sell Filshie Clips in the United States. (*Id*.). Femcare originally established a joint venture for the exclusive purpose of such sale and distribution, and that joint venture was later sold (with associated exclusive distribution rights) to Defendant CooperSurgical. (*Id*. at 13-14). After the sale of distribution rights, Femcare continued to exert significant influence over the marketing, sale, and distribution of Filshie Clips in the United States. (*Id*. at 14). This influence included the provision of promotional materials, the advance authorization of representations regarding the product, and the direct assistance by Femcare employees in the marketing of the products. (*Id*.).

Femcare argues that these activities do not amount to purposeful availment of the privilege of conducting business in the State of Texas. (ECF 34 at 11). To hold otherwise, according to Femcare, would be to endorse the controversial opinion that merely placing products into the "stream of commerce with the expectation that they will be purchased by consumers in the forum state" may establish sufficient minimum contacts to support specific personal jurisdiction. (*Id*.); *cf. World-Wide Volkswagen*, 444 U.S. at 298. As Femcare acknowledges, though Supreme Court Justices have repeatedly expressed their dissatisfaction with it, no binding precedent has rejected this "stream of commerce" test. (ECF 34 at 11-12). The Court does not find it necessary to either endorse or reject the "stream of commerce" test in order to deal with the instant Motions.

Plaintiff has made a *prima facie* case that Femcare intentionally directed its business activities at Texas, among other states, and that her case arises out of these contacts. Femcare has not made the requisite showing that subjecting it to personal jurisdiction in Texas at this stage in

the case would be unduly burdensome or would threaten the shared interests of Texas, the United States, and the United Kingdom in furthering fundamental social policies. Accordingly, the Court holds that Femcare is properly subject to specific personal jurisdiction at this stage of proceedings; thus, to the extent that Femcare's Motion seeks dismissal for lack of personal jurisdiction, that Motion is DENIED.

3. UTMD is Subject to Specific Personal Jurisdiction

For the limited purposes of determining personal jurisdiction over UTMD, the Court, in addition to the relevant facts listed above, relies on the following facts either asserted by Plaintiff or admitted by UTMD. UTMD acquired Femcare in 2011 and purchased rights to distribute Filshie Clips in the United States from CooperSurgical in 2019. (ECF 13 at 11). Since 2019, UTMD has marketed, sold, and distributed Filshie Clips in Texas. (ECF 26 at 19). UTMD was involved in the decision to update the safety materials provided to users of Filshie Clips in 2021. (*Id*. at 20-21).

As a threshold matter, these activities amount to a deliberate availment of the privilege of doing business in Texas, such that the minimum necessary contacts to establish specific personal jurisdiction are present. UTMD urges, however, that these contacts are irrelevant to Plaintiff's claim, because they did not arise until after Plaintiff's surgery. (ECF 33 at 11-14). UTMD points to persuasive authority behind this position, including Moore's Federal Practice and a published First Circuit decision from 2005. (ECF 33 at 11-12). In light of the Supreme Court's decision in *Ford Motor Co.*, however, UTMD's arguments are insufficient to compel dismissal for lack of personal jurisdiction at this stage in the case.

Ford Motor Co. made it clear that the required connection between a defendant's forum contacts and a plaintiff's claims need not entail a causal relationship; rather, the defendant's contacts must result in a reasonable anticipation of being justifiably haled into the forum to defend

against claims like those brought by plaintiff. *See Ford Motor Co.*, 592 U.S. at 361-2. It may well be later found that UTMD's forum-related activity does not make it liable to Plaintiff for her injuries; the question presently before the Court is not whether UTMD is liable in this case, but whether UTMD's Texas-directed activities would *ever* permit the Court to hold it liable if those activities resulted in injuries like those alleged by the Plaintiff.

Finally, the Court notes that the parties have extensively disputed the proper characterization of UTMD's relationship with Femcare. (ECF 13 at 15, ECF 26 at 15-26, & ECF 33 at 15-17). Though the matter may reappear at subsequent stages of the litigation, the Court is able to resolve the request for dismissal for lack of personal jurisdiction without deciding the question of whether Femcare is an alter ego of UTMD, and so makes no findings or holdings on that question at this time.

Plaintiff has made a *prima facie* case that (1) UTMD intentionally avails itself of the privilege of conducting activities in Texas and (2) Plaintiff's claims sufficiently relate to those activities, and UTMD has not responded with a compelling case that subjecting it to personal jurisdiction in Texas would be unduly burdensome or would threaten the shared interests of the several states in furthering fundamental social policies. Accordingly, UTMD is properly subject to specific personal jurisdiction at this stage of proceedings; thus, to the extent that UTMD's Motion seeks dismissal for lack of personal jurisdiction, that Motion is DENIED.

C. Some of Plaintiff's Claims Do Not Survive Dismissal

As noted above and for reasons explained below, the Court finds that Counts 1, 2, and 4 of Plaintiff's Complaint fail to state a claim for which relief can be granted, and should be dismissed. Counts 3, 5, 6, and 7 are sufficiently pleaded to survive Defendants' Motions to Dismiss. The explanation for this holding requires analysis of two particular groups of legal standards. We look

first to the preemption of state laws by the federal Medical Device Amendments to the Food, Drug, and Cosmetic Act, and then to each of Plaintiff's particular state-law claims and their requirements.

1. Preemption Under the MDA

In 1938, Congress passed the Food, Drug, and Cosmetic Act ("FDCA"), now codified at 21 U.S.C. § 301 *et seq*., to broaden existing federal regulations on food, drugs, medical devices, and cosmetics. *See Medtronic Inc. v. Lohr*, 518 U.S. 470, 475-476 (1996). In 1976, the Medical Device Amendments ("MDA") to the FDCA, codified at 21 U.S.C. § 360c *et seq*., further expanded regulatory coverage over medical devices. *Id*. at 476-77; *see also Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315-17 (2008).

As a result of the MDA, the state-law regimes that had previously governed the introduction of medical devices for human use were generally supplanted and replaced with a comprehensive program of federal oversight. The primary mechanism of that replacement was an express pre-emption provision providing:

> "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).[7]

The Supreme Court examined this express preemption provision in *Lohr*, finding that it did not automatically eliminate all common law duties enforceable by actions for damages under state law. *Lohr*, 518 U.S. at 491. The Court revisited the provision in *Riegel* and clarified that it would preempt some such duties if they imposed requirements on the device that were "different from, or in addition to, federal requirements, and that related[d] to the safety or effectiveness of the

[7] There is an exception established in 21 U.S.C. § 360k(b) that allows the FDA to empower state or local requirements that meet certain standards. That exception is not at issue in this case.

device or to any other matter included in a [federal] requirement applicable to the device." *Riegel*, 552 U.S. at 323.

To determine whether a particular state-law claim is barred by the MDA's express preemption provision, courts have distilled Supreme Court jurisprudence into a two-prong test. *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 767-8 (5th Cir. 2011). The first prong is whether the FDA has set requirements for the device, such as by granting a business pre-market approval to make and sell the device under certain circumstances. *Id.*; *accord Riegel*, 552 U.S. at 322. The second prong is whether the state law giving rise to the claim imposes any requirements on the device that differ from or are additional to the FDA's requirements. *Hughes*, 631 F.3d at 768. A state law claim will be dismissed if it imposes such requirements and the requirements relate to the safety or effectiveness of the device, or to any matter otherwise regulated by federal requirements. 21 U.S.C. § 360k(a)(2).

Even if a state law claim survives this two-prong test, it may still be impliedly preempted by the MDA. As stated above, a state law is impliedly preempted by a federal law if it directly conflicts with the terms of that federal law, such as when it would not be possible to simultaneously satisfy the requirements of both. For example, suppose that the FDA required a device to be sold with a particular label, and a plaintiff asserted a failure-to-warn tort claim against the marketer on the sole grounds that the FDA-approved label inadequately disclosed a certain risk. *See Bartlett*, 570 U.S. at 475. In that case, it would be impossible for the marketer to simultaneously perform the duty asserted by the plaintiff and the duty to use the FDA-approved label, so the plaintiff's claim would be impliedly preempted.

The FDCA also includes a provision that, though it does not expressly abrogate any particular state laws, may imply preemption of a state law claim by barring suits to privately

enforce requirements imposed by the FDCA or MDA. 21 U.S.C. § 337(a) ("All such proceedings for the enforcement, or to restrain violations, of this Act shall be by and in the name of the United States."). For example, if the hypothetical plaintiff above instead based their failure-to-warn claim solely on the grounds that the marketer had deliberately concealed evidence of the risk from the FDA during the pre-market approval process, their claim would conflict with 337(a) by attempting to privately enforce FDCA procedures, and so would be impliedly preempted. *See Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341, 343-4 (2001).

Despite these multiple forms of preemption by the MDA, courts have been clear that the law does not result in complete immunity for federally-regulated medical device companies. To survive preemption, a claim based in state law must:

(1) exist independently of the MDA, such that the complained-of behavior would still have violated state law even if the MDA had never been passed;[8]

(2) leave space for the defendant to have avoided liability under state law without having breached federal law in the process,[9] *and*

(3) impose no additional or differing requirements on a federally-regulated device in the areas of safety, effectiveness, or any area covered by the federal regulations.[10]

One shorthand summary of these elements is that a State may provide "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. Therefore, an independent state-law duty may form the

[8] Otherwise, the claim would be impliedly preempted by 337(a) as an attempt to privately enforce the Act. *Hughes*, 631 F.3d at 775.

[9] Otherwise, the claim would be impliedly preempted by directly conflicting with the requirements of the FDA. *Bartlett*, 570 U.S. at 479-80.

[10] Otherwise, the claim would be expressly preempted by 360k(a). *Riegel*, 552 U.S. at 353-4.

basis of a tort claim for which violations of the FDCA may be presented as evidence of breach." *Spano v. Whole Foods, Inc.*, 65 F.4th 260, 264 (5th Cir. 2023).

2. Standards Governing Plaintiff's State-Law Claims

To determine which of Plaintiff's state law claims may be preempted by the MDA requires an analysis of the law controlling each claim, to find whether any of them, as a matter of law and in light of the well-pleaded facts alleged in the Complaint,[11] passes the tests articulated above. As stated, the seven substantive claims at issue in this case are (1) design defect, (2) manufacturing defect, (3) failure to warn, (4) strict liability, (5) negligence, (6) violation of consumer protection laws, and (7) gross negligence.

i. Design Defect

Under Texas law, a products liability claim for design defect is grounded both in statute and in the common law. *Nester v. Textron, Inc.*, 888 F.3d 151, 156, n. 1 (5th Cir. 2018). To recover, a plaintiff pleading design defect must show that "(1) the product was defectively designed so as to render it unreasonably dangerous; (2) a safer alternative design existed; and (3) the defect was a producing cause of the injury for which the plaintiff seeks recovery." *Goodner v. Hyundai Motor Co.*, 650 F.3d 1034, 1040 (5th Cir. 2011); *see also* Tex. Civ. Prac. & Rem. Code § 82.005.

Whether a design is unreasonably dangerous is generally a question of fact, and courts considering the question rely on a set of common-law factors to guide their analysis. *Goodner*, 650 F.3d at 1040. The ultimate purpose of these factors is to balance the benefit or utility of the product, the probability and severity of injuries that might result from its use, and the costs that would be borne by intended users, by the manufacturer, and by the public at as a whole if the product were required to be adapted to a less dangerous design. *Id*.

[11] As stated above, the Court sometimes refers to Plaintiff's state-court Petition as her "Complaint," so that the terminology in this Opinion is consistent with federal law.

Similarly, a plaintiff must show as a matter of fact that an alternative design would have reasonably reduced the risk of injury and was feasible as an alternative when the device left the defendant's control. *Id*. at 1042. In other words, to return a verdict for the plaintiff on a Texas products liability claim for design defect, a trier would have to find that the product design was dangerous in ways that were not justified by the utility of the product or by the economics of the matter *and* that the product could have been designed in another, better way. To survive a Rule 12(b)(6) motion to dismiss, then, a plaintiff's complaint must plausibly allege these facts (as well as causation). *See Rodriguez v. Am. Med. Sys., Inc.*, 597 Fed. App'x 226, 230 (5th Cir. 2014) (unpublished).

The parties have not pointed to, and the Court is not aware of, any directly controlling precedent on the question of whether Texas design defect claims are preempted as a matter of law for device designs that have received pre-market approval ("PMA") under the MDA. The Court notes, however, that the matters balanced by a Texas design defect decision (i.e., the risks and benefits associated with the design as compared to potential alternatives) are exactly the matters administratively adjudicated by the FDA when making a PMA determination under the MDA.

The Court holds that for a claim of strict liability for design defect under Texas law to survive preemption by the MDA, the plaintiff must show that the product alleged to be defective was designed in a manner differing from the design approved by the FDA. If the FDA has approved the design actually used by the defendant to manufacture the product at issue, then to permit a design defect claim to proceed would necessarily allow state law to impose requirements on the device that add to or differ from those imposed by federal law. Accordingly, any claim that a device was defectively designed despite compliance with the design standards established by the FDA is necessarily preempted under the MDA. *Accord Gomez v. St. Jude Med. Daig Div., Inc.*,

442 F.3d 919, 929-30 (5th Cir. 2006).

ii. Manufacturing Defect

A products liability claim for manufacturing defect under Texas common law[12] requires a plaintiff to show that "a product deviates, in its construction or quality, from the specifications or planned output in a manner that renders it unreasonably dangerous," and that the deviation or defect "existed at the time the product left the manufacturer's possession" and was "a producing cause of the plaintiff's injuries." *Johnston v. Ferrellgas, Inc.*, 96 F.4th 852, 858 (5th Cir. 2024) (cleaned up). These are generally factual questions, and significant emphasis is placed on avoiding speculation and conclusory determinations. *See id*.

At the pleading stage, a plaintiff must allege sufficient facts to meet the *Twombly* plausibility standard for these elements. *See Bass v. Stryker Corp.*, 669 F.3d 501, 509 (5th Cir. 2012). Further, in contexts where the specifications for manufacturing a device are established by the federal government under the MDA, the plaintiff must allege "manufacturing defects resulting from violations of federal regulations." *Bass*, 669 F.3d at 510. As always, the plaintiff need not prove these facts to defeat a Rule 12(b)(6) motion, but must at least allege them sufficiently to make their case facially plausible and more than speculative.

If a plaintiff's well-pleaded facts pass the *Iqbal-Twombly* two-step standard, the Fifth Circuit has explicitly held that a Texas manufacturing defect claim is not preempted by the MDA as a matter of law. Bass, 669 F.3d at 509-510. If a plaintiff can show that a manufacturing process failed in a manner that violated FDA requirements and produced a deviation in construction or

[12] The Court notes that the Plaintiff's state-court Petition associates this count with Chapter 82 of the Texas Civil Practice and Remedies Code, but that statute has not modified the common-law cause of action for manufacturing defect.

quality resulting in an unreasonably dangerous product, that plaintiff may be entitled to recover damages under state law.

iii. Failure to Warn (Negligence)

Under Texas law, both manufacturers and product suppliers have a duty[13] to warn of dangers that they know or have reason to know are likely to apply to users who may not, absent the warning, otherwise recognize those dangers. *Garcia v. United States*, 986 F.3d 513, 534-5 (5th Cir. 2021); *see also Bristol-Myers Co. v. Gonzales*, 561 S.W.2d 801, 804 (Tex. 1978) (hereafter "*Gonzales*" to avoid confusion with the personal jurisdiction case cited above). This duty may sometimes be satisfied by providing the necessary warnings to intermediaries who can then be relied on to relay those warnings to the final user. *See Humble Sand & Gravel Inc. v. Gomez*, 146 S.W. 3d 170, 172 (Tex. 2004). If a defendant breaches such a duty and thereby causes damages, that defendant may be liable for negligent failure to warn.

Federal regulation under the MDA intersects with the applicable common-law[14] elements of negligent failure to warn in both the areas of duty and of causation. When receiving PMA for a device, a manufacturer may be required to report adverse events to the FDA on an ongoing basis, which imposes a specific duty that may parallel common-law duties imposed by state law. *Hughes*, 631 F.3d at 769-71. Additionally, FDA restrictions imposed on a device may impact the tort law requirement of causation by restricting a company's possible actions and interposing discretionary agency decisions into hypothetical sequences of events. *See Hughes*, 631 F.3d at 776.

If a plaintiff's well-pleaded facts carry a negligent failure to warn claim past the *Iqbal-Twombly* two-step plausibility test, then that claim might not be preempted by the MDA, so long

[13] Manufacturers may also be strictly liable for failure to warn if their product is unreasonably dangerous; this is addressed below under Claim 4: Strict Liability.

[14] Though Plaintiff's state-court Petition associates Count 3 with Chapter 82 of the Texas Civil Practice and Remedies Code, that statute does not control products liability claims for either negligent or strict-liability failure to warn.

as maintenance of the claim merely provides a damages remedy for a breach of a duty that also violated federal law.

iv. Strict Liability (Marketing Defect)

In addition to the duty to report dangers of which a company knows or has reason to know, Texas law may impose strict liability for failure to warn[15] when the product in question is unreasonably dangerous. *See Humble Sand*, 146 S.W.3d at 181, n. 17 & 18 (clarifying differences between negligent and strict liability failure to warn claims). To sustain this claim, a plaintiff must show (1) using the product involved a risk of harm, (2) the defendant knew or should have reasonably foreseen the risk, (3) the defendant did not adequately warn of the risk or provide instructions for safe use, (4) the lack of adequate warning made the product unreasonably dangerous, and (5) the failure to warn caused the plaintiff's damages. *See Wright v. Ford Motor Co.*, 508 F.3d 263, 275 (5th Cir. 2007) (hereafter "*Wright*" to avoid confusion with the personal jurisdiction case cited above).

Unlike a claim for negligence, which focuses on the conduct of the defendant, a strict liability claim focuses on the product itself, and in the context of a marketing defect claim, this encompasses the warnings, labels, and instructions provided with the product. *See Humble Sand*, 146 S.W.3d at 181, *and Bass*, 669 F.3d at 515. The adequacy of warnings is generally a matter of fact for determination by the jury.

Accordingly, a strict liability claim for marketing defect will be preempted by the MDA to the extent that the claim imposes requirements for the marketing of a device that are different from or additional to the requirements imposed by federal law. *See Hughes*, 631 F.3d at 768-9. As with

[15] Though Plaintiff's fourth claim was advanced under the heading of "strict liability" without qualification, and though Texas law imposes strict liability in three situations—design defect, manufacturing defect, and marketing defect—the first two of these have been independently asserted as Counts 1 & 2, so the Court construes Count 4 of the state-court Petition as asserting a strict liability claim for marketing defect specifically.

strict liability for design defect or manufacturing defect, however, a marketing defect claim will not be preempted to the extent it is premised on violations of the marketing requirements imposed by the FDA. *Id*. at 769-70.

v. Negligence

Under Texas law, a claim for negligence in a products liability suit will be subsumed into the plaintiff's defective product claims unless the plaintiff has alleged some negligence unrelated to the product being unreasonably dangerous when sold. *Shaun T. Mian Corp. v. Hewlett-Packard Co.*, 237 S.W.3d 851, 857 (Tex. App.--Dallas 2007, pet. denied). Unless so subsumed, whether a negligence claim will survive a Rule 12(b)(6) motion depends primarily on whether it plausibly alleges breach of a duty of care resulting in damages. If it clears facial plausibility, it will not necessarily be preempted by the MDA; to the extent it merely provides a damages remedy for violation of a state-law duty that parallels federal requirements, it will be allowed to proceed. *Spano*, 65 F.4th at 264.

vi. Violation of Consumer Protection Laws

As explained by the Fifth Circuit,

> "The Texas Deceptive Trade Practices & Consumer Protection Act ["DTPA"][16] protects a consumer from false, misleading, or deceptive acts or practices, from an unconscionable action or course of action by any person, and from the breach of an implied or express warranty in the conduct of any trade or commerce that is the producing cause of actual damage. To sustain a claim under the Act, a plaintiff must show that (1) the plaintiff was a consumer; (2) the defendant either engaged in false misleading, or deceptive acts, or engaged in an unconscionable action or course of action; and (3) the Act's laundry-list violation or unconscionable action was a producing cause of the plaintiff's injury." *Huynh v. Walmart Inc.*, 30 F.4th 448, 453 (5th Cir. 2022) (cleaned up).

[16] Though the Plaintiff's state-court Petition alleges "violation of state and Federal consumer protection statutes," (ECF 1-1 at ¶ 119), the DTPA is the only specific grounds on which the Plaintiff alleges to be entitled to relief.

The DTPA, codified at Texas Business & Commerce Code § 17.41 *et seq*., non-exhaustively lists many acts qualifying as "false, misleading, or deceptive," including for example, "representing that goods or services have…characteristics…uses, [or] benefits which they do not have." Tex. Bus. & Com. Code § 17.46(b)(5). The DTPA also defines an "unconscionable action" as one that "to a consumer's detriment, takes advantage of the lack of knowledge, ability, experience, or capacity of the consumer to a grossly unfair degree." *Id*. at § 17.45(5).

Whether a claim under the DTPA is preempted by the MDA depends on whether the claim imposes requirements that are different from or additional to federal requirements. For example, if a DTPA claim categorizes as "deceptive" actions that were explicitly approved by the FDA, that claim will be preempted by federal law. If, however, a claim under the DTPA merely provides a damages remedy for actions by the defendant that violated federal requirements, that claim will not necessarily be preempted. *Spano*, 65 F.4th at 264.

vii. Gross Negligence

Under Texas law, a finding of gross negligence requires an act or omission that involves an extreme degree of risk of which the actor was actually aware, but to which they were consciously indifferent. *Marsillo v. Dunnick*, 683 S.W.3d 387, 392-3 (Tex. 2024) *and* Tex. Civ. Prac. & Rem. Code § 41.001(11). The existence of the risk is an objective question of fact that requires a likelihood of serious injury, over and beyond even a mere probability of minor harm. *Marsillo*, 683 S.W.3d at 393. The actual knowledge of the plaintiff is a question of subjective fact, and once such knowledge is established, the defendant's acts or omissions can be taken as demonstrations of the requisite conscious indifference. *Id*.

A claim for gross negligence does not necessarily impose any requirements on a federally-regulated medical device. To the extent that a claim for gross negligence pursues a state-law-

permitted damages remedy for a duty that parallels federal requirements, and to the extent that violations of the duty are also violations of the federal requirements, a gross negligence claim is not preempted by the MDA. *Spano*, 65 F.4th at 264.

3. Application to Plaintiff's Claims

For reasons set forth in order below, application of the standards articulated above to Plaintiff's claims, as pleaded in her state-court Petition, requires that her strict liability claims—for design defect (Count 1), manufacturing defect (Count 2), and marketing defect (Count 4, as construed by the Court) be dismissed for failure to state a claim that would survive preemption by the MDA. Plaintiff's other claims, however, are adequately pleaded and are not preempted as a matter of law.

i. Design Defect

Plaintiff has not pleaded that the Filshie Clips used in her surgery or otherwise currently distributed by the Defendants are designed in a manner other than that approved by the FDA. Rather, Plaintiff has alleged that the FDA-approved design is itself unreasonably dangerous, and has implied that the FDA would not have approved the design if they had found the incidence of migration to be 25% rather than 0.13%. (ECF 1-1, ¶¶ 53-4). Because Plaintiff has asserted a claim for design defect but has not alleged that the product in question was designed in violation of federal standards, she has failed to plausibly state a claim for design defect that would avoid preemption by the MDA. *See St. Jude Med. Daig Div., Inc.*, 442 F.3d at 929-30. Accordingly, to the extent that Defendants' Motions seek dismissal of Count 1 of Plaintiff's state-court Petition for failure to state a claim upon which relief can be granted, those Motions are GRANTED.

ii. Manufacturing Defect

Plaintiff has not alleged that the process of manufacturing Filshie Clips has failed in any manner that violates FDA standards. On the contrary, Plaintiff alleges that her injury is due to dangerousness inherent in the product as designed and manufactured in the manner approved by the FDA. (ECF 1-1, ¶¶ 53-4). Because Plaintiff has asserted a claim for manufacturing defect but has not alleged that the product in question was manufactured in violation of federal standards, she has failed to state a claim that would avoid preemption by the MDA. *See Bass*, 669 F.3d at 510. Accordingly, to the extent Defendants' Motions seek dismissal of Count 2 of Plaintiff's state-court Petition for failure to state a claim, those Motions are GRANTED.

iii. Failure to Warn (Negligence)

Plaintiff has alleged that Defendants had a common-law duty to warn of dangers associated with the use of Filshie Clips in tubal ligation surgeries. Plaintiff has further alleged that Defendants were aware of such a danger, that they could have discharged their duty by reporting the danger to the FDA, and that by failing to do so they both breached their common-law duty and violated FDA requirements. These allegations establish plausible grounds for a damages remedy that merely parallels, and does not add to or differ from, federal requirements; accordingly, Plaintiff's claim for negligent failure to warn is not preempted by the MDA. *Hughes*, 631 F.3d at 769-71. Thus, to the extent Defendants' Motions seek dismissal of Count 3 of Plaintiff's state-court Petition for failure to state a claim, those Motions are DENIED.

iv. Strict Liability (Marketing Defect)

As mentioned above, Plaintiff has pleaded a claim for strict liability, and the Court construes this Count as one for marketing defect specifically, because claims for design defect and manufacturing defect were separately pleaded in Counts 1 and 2. Plaintiff does not allege that

Filshie Clips have been marketed in a manner that violates FDA requirements. On the contrary, Plaintiff argues that the product marketing and the warnings, labels, and instructions provided with the Filshie Clips were inadequate despite their compliance with federal requirements. (ECF 1-1, ¶ 79). If Plaintiff's claim were successful, it would necessarily involve state law imposing marketing requirements on the Filshie Clips that were different from and additional to federal requirements, so Plaintiff's claim is preempted by the MDA. *Hughes*, 631 F.3d at 768-9. Accordingly, to the extent Defendants' Motions seek dismissal of Count 4 of Plaintiff's state-court Petition for failure to state a claim, those Motions are GRANTED.

v. Negligence

Plaintiff has pleaded negligence by the Defendants that resulted in Filshie Clips being unreasonably dangerous when sold, but has also pleaded subsequent negligence by the Defendants in failing to adequately warn of known dangers. Accordingly, Plaintiff's claim for negligence is not completely subsumed into her products liability claims. Further, the subsequent negligence plausibly alleged by Plaintiff may have independently violated both federal law and parallel duties imposed by state law. Accordingly, Plaintiff's claim for negligence is sufficiently pleaded, and to the extent Defendants' Motions seek dismissal of Count 5 of Plaintiff's state-court Petition for failure to state a claim, those Motions are DENIED.

vi. Violation of Consumer Protection Laws

Plaintiff has alleged that Defendants knowingly withheld information about a significant risk associated with their product, and that by doing so they violated both FDA-imposed requirements and the Texas DTPA. (ECF 1-1 at ¶ 119). Because Plaintiff does not claim that conduct authorized by the FDA is nevertheless prohibited under the DTPA, but instead seeks a damages remedy under state law for conduct that also violated federal requirements, her claim is

not preempted by the MDA. *Spano*, 65 F.4th at 264. Accordingly, to the extent Defendants' Motions seek dismissal of Count 6 of Plaintiff's state-court Petition for failure to state a claim, those Motions are DENIED.

vii. Gross Negligence

Finally, Plaintiff has alleged that Defendants had actual knowledge that the incidence rate of migration from the site of application for their product was substantially higher than originally reported, that this increased rate resulted in an extreme degree of risk, and that Defendants acted with conscious indifference in reckless disregard of that risk. (ECF 1-1 at ¶ 130). Accordingly, Plaintiff has sufficiently pled a facially plausible claim for gross negligence. Further, because Plaintiff has alleged that the grossly negligent acts and omissions of Defendants also violated FDA requirements, Plaintiff's claim does not impose restrictions on Defendants or on Filshie Clips that add to or differ from federal requirements, but instead seeks only a damages remedy under state law that parallels federal law. *Spano*, 65 F.4th at 264. Accordingly, to the extent Defendants' Motions seek dismissal of Count 7 of Plaintiff's state-court Petition for failure to state a claim, those Motions are DENIED.

The Court further notes that because Plaintiff's claim for gross negligence survives Defendants' Motions to Dismiss, Plaintiff's plea for exemplary damages ("Count 8" of Plaintiff's Petition) remains live in this proceeding. *See* Tex. Civ. Prac. & Rem. Code § 41.003(a)(3).

IV. Conclusion

In summary, the Court holds that venue is proper in this judicial district, and that all three defendants—CooperSurgical, Femcare, and UTMD—are subject to the personal jurisdiction of the Court at this stage of the pleadings. The Court further holds that Plaintiff's strict liability claims

for design defect, manufacturing defect, and marketing defect are inadequately pleaded to survive preemption by federal law.

For the foregoing reasons, CooperSurgical's Motion to Dismiss, (ECF 7), Femcare's Motion to Dismiss, (ECF 9), and UTMD's Motion to Dismiss, (ECF 12), are hereby GRANTED IN PART and DENIED IN PART. Counts 1, 2, and 4 of Plaintiff's state-court Petition, (ECF 1-1), are hereby DISMISSED without prejudice to repleading in connection with factual allegations that would permit those claims to survive preemption by federal law. If Plaintiff wishes to so replead, it is hereby ORDERED that she shall file a Motion for Leave to Amend **on or before December 2, 2024**.[17] Counts 3, 5, 6, 7, and 8 shall be allowed to proceed against all three Defendants.

IT IS SO ORDERED.

ENTERED October 23, 2024.

Lee Ann Reno

LEE ANN RENO
UNITED STATES MAGISTRATE JUDGE

[17] The Court notes that under the current Scheduling Order in this case, Plaintiff has until May 12, 2025 to request leave to file an Amended Complaint; the deadline established in the present Order controls only as regarding requests to replead causes of action dismissed by this Order. The Court notes that leave will not be granted to replead dismissed claims unless they are accompanied by factual allegations that would permit those claims to survive preemption by federal law. Finally, the Court notes that nothing in this Order prohibits Plaintiff from requesting an extension of her December 2, 2024 deadline if necessary; the Court will evaluate any such requests in light of the four good-cause factors that control any Scheduling Order modification. (*See* ECF 41 at 1-2).