United States District Court
Southern District of Texas
ENTERED
March 06, 2025
Nathan Ochsner, Clerk

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

GIOVANNA BULOX, *et al.*, *Plaintiffs*,	§	
v.	§	Case No. 4:21-cv-2320
COOPERSURGICAL, INC., *et al.*, *Defendants*.	§	

JUDGE PALERMO'S REPORT AND RECOMMENDATION[1]

This is a product liability case involving Filshie Clips, a medical device used for birth control. Before the Court are Defendants Femcare, LTD. ("Femcare") and Utah Medical Products, Inc.'s ("Utah Medical") motions for summary judgment, ECF Nos. 123 & 125, and CooperSurgical, Inc.'s ("CooperSurgical") joinder to Femcare's motion for summary judgment, ECF No. 124. Having carefully reviewed the pleadings, motions, and applicable law, the Court determines that Plaintiffs Giovanna Bulox ("Bulox") and Ahiri Merlo's ("Merlo") state law claims are federally preempted. Therefore, the summary judgment motions should be granted.

I. BACKGROUND

A. The Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act.

The Medical Device Amendments ("MDA") to the Federal Food, Drug, and

[1] On October 18, 2024, the District Judge to whom this case is assigned referred this case for all pretrial proceedings in accordance with 28 U.S.C. § 636.

Cosmetic Act ("FDCA"),[2] promulgated in 1976, bring the regulation of medical devices under the purview of the U.S. Food and Drug Administration ("FDA") and establishes three classes of medical devices and corresponding regulatory requirements. *Morgan v. Medtronic, Inc.*, 172 F. Supp. 3d 959, 964 (S.D. Tex. 2016) (citing *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315 (2008)). Under the MDA, the medical devices receiving the most scrutiny are Class III devices. *Id.* These devices are subject to a rigorous premarket approval ("PMA") process that includes FDA review of their benefits, effectiveness, risks of injury, and proposed labeling. *Id.* (citing 21 U.S.C. § 360c(a)(1)(C)).

Following the device's approval, the manufacturer must inform the FDA of "adverse event reports"—that is, reports of instances in which a device "[m]ay have caused or contributed" to a death or serious injury," *see* 21 C.F.R. § 803.50(a)(1)—and inform the FDA of new clinical investigations or scientific studies concerning the device, *id.* § 814.84(b)(2). Failure to comply with these post-approval requirements may result in the FDA's withdrawal of the device's approval. *Id.* § 814.82(c).

B. Express and Implied Preemption under the MDA.

To ensure the FDA's regulatory authority over medical devices, the MDA includes an express preemption provision that prohibits states from establishing any

[2] 31 U.S.C. § 301, *et seq*.

"requirement" for a medical device

> (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). In *Riegel v. Medtronic, Inc.*, the Supreme Court established a two-step analysis for determining whether a state-law claim is expressly preempted under this provision. *Morgan*, 172 F. Supp. 3d at 965. First, the Court asks whether the federal government established requirements applicable to the medical device. *Id.* Second, the Court determines whether the state-law claim imposes requirements "different from, or in addition to," the federal requirements. *Id.* If the answer to both questions is "yes," then the state-law claim is expressly preempted. *Id.*

However, if the answer to the second question is "no," the claim merely imposes duties that "parallel" the federal requirements and is not expressly preempted. *See id.* Nonetheless, such a claim may be impliedly preempted under 21 U.S.C. § 337(a). *Id.* In *Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), the Supreme Court determined that a parallel state-law claim is impliedly preempted where it "exist[s] solely by virtue" of the federal requirements. *Id.* at 353.

C. Plaintiffs' Causes of Action.

The Filshie Clip is a medical device Femcare manufactured. From 2003 to 2019, CooperSurgical imported, marketed, and distributed the product. In 2011,

Utah Medical acquired Femcare; and, in 2019, Utah Medical acquired the rights to distribute the Filshie Clips from CooperSurgical. ECF Nos. 40 ¶ 19; 123-4 ¶ 11. The Filshie Clip exerts pressure on the fallopian tubes to support fertility control. ECF Nos. 40 ¶ 2; 123-1. In 1992, Femcare sought PMA for the device. ECF No. 123-1. As part of the PMA process, Femcare included in its submissions an adverse clip migration rate of 0.13%. ECF Nos. 123-3; 137-1. In 1996, the FDA approved the warnings and precautions listed in the device's Instructions for Use ("IFU"), including the 0.13% migration rate. ECF Nos. 123-3; 137-1.

Over the years, Femcare filed supplemental annual reports as part of post-market surveillance of the device. ECF No. 123-4 ¶¶ 4, 5. The 2007 annual report mentioned an academic article containing an estimate that Filshie Clip migration rates could be 25% or higher. ECF Nos. 123-4 ¶ 5; 123-5; 123-6. The FDA did not require that the 0.13% listed in the IFU be changed. ECF No. 123-4 ¶ 6. In the years since the Filshie Clip's PMA, Femcare received numerous complaints about symptoms related to the device's migration. ECF Nos. 123-4 ¶ 7–8; 123-7. Femcare reviewed the complaints but determined that the reporting threshold was not met as to any of them. In its 2019 PMA annual report, Femcare reported its expert determined that, over the last 10 years, "[n]one of the Filshie clip migrations were life-threatening or caused permanent impairment of a body function." ECF No. 123-12 ¶ 21.

Plaintiffs underwent tubal ligation procedures in which they each received Filshie Clip implants, Bulox in 2010 and Merlo in 2009. ECF No. 40 ¶¶ 32, 46. In 2019, Bulox experienced extreme discomfort and was admitted to the hospital and underwent a surgical procedure. *Id.* ¶¶ 39-42. After surgery, she discovered that one of the Filshie Clips had migrated and penetrated her intestine. *Id.* ¶¶ 42-43. In 2020, Merlo also experienced discomfort and discovered through radiology imaging that her implants had migrated as well. *Id.* ¶ 51. She similarly underwent surgery, but the physician could not locate the Filshie Clips. *Id.* ¶ 52. Neither Bulox nor Merlo was informed of the estimate of a 25% or higher migration rate. *Id.* ¶¶ 35, 49.

Plaintiffs bring causes of action for: (1) design defect; (2) failure to warn; (3) strict liability; (4) negligence; (5) gross negligence; and (6) violations of consumer protection laws.[3,4] ECF No. 40 at 17, 20, 22, 24, 27. Defendants, in their motions for summary judgment, argue that Plaintiffs' claims are preempted by the FDA's regulatory authority over medical devices. ECF Nos. 123 at 13-14; 124 at 2-3; 125 at 2-3. The Court previously denied similar arguments in various dispositive

[3] Plaintiffs' strict liability, negligence, and gross negligence claims rely on their manufacturing defect, design defect, and failure to warn theories of the case. *See* ECF No. 40.

[4] Plaintiffs originally also brought a manufacturing defect cause of action but has since abandoned that claim. Response, ECF No. 137 at 19 ("At this point of the litigation, Plaintiffs are no longer asserting their claim for manufacturing defect" (docket citation omitted)). Accordingly, Plaintiffs' manufacturing defect claim and their strict liability, negligence, and gross negligence claims insofar as they are based on the alleged manufacturing defect should be dismissed and summary judgment as to these claims should be denied as moot. *See* ECF No. 40 ¶¶ 108, 114, 118, 119, 122, 146–51.

motions Defendants filed, but now, based on the evidence presented and current briefing, the Court finds that preemption bars all Plaintiffs' claims.

II. LEGAL STANDARD FOR SUMMARY JUDGMENT.

Summary judgment is appropriate when the movant has established that the pleadings, affidavits, and other evidence available to the court demonstrate that no genuine issue of material fact exists, and the movant is thus entitled to judgment as a matter of law. FED. R. CIV. P. 56(c). "A genuine dispute of material fact exists when the 'evidence is such that a reasonable jury could return a verdict for the nonmoving party.'" *Bennett v. Hartford Ins. Co. of Midwest*, 890 F.3d 597, 604 (5th Cir. 2018) (internal quotation omitted). A fact is material "if and only if proof of its existence might affect the outcome of the case." *Roy v. City of Monroe*, 950 F.3d 245, 254 (5th Cir. 2020). The party moving for summary judgment "bears the initial responsibility of informing the district court of the basis for its motion[ ] and identifying those portions of [the record] which it believes demonstrate the absence of a genuine [dispute] of material fact." *MDK Sociedad De Responsabilidad Limitada v. Proplant Inc.*, 25 F.4th 360, 368 (5th Cir. 2022) (quoting *Nola Spice Designs, L.L.C. v. Haydel Enter., Inc.*, 783 F.3d 527, 536 (5th Cir. 2015)).

"Once the moving party has initially shown 'that there is an absence of evidence to support the non-moving party's cause,' the non-movant must come forward with 'specific facts' showing a genuine factual issue for trial." *Houston v.*

Tex. Dep't of Agric., 17 F.4th 576, 581 (5th Cir. 2021) (quoting *TIG Ins. Co. v. Sedgwick James of Washington*, 276 F.3d 754, 759 (5th Cir. 2002)). "Summary judgment cannot be defeated through '[c]onclusional allegations and denials, speculation, improbable inferences, unsubstantiated assertions, and legalistic argumentation.'" *Acker v. Gen. Motors, L.L.C.*, 853 F.3d 784, 788 (5th Cir. 2017) (quoting *Oliver v. Scott*, 276 F.3d 736, 744 (5th Cir. 2002)).

When ruling on a motion for summary judgment, the Court views all facts and inferences in the light most favorable to the nonmoving party and resolves all disputed facts in favor of the nonmoving party. *Rodriguez v. City of Laredo*, 459 F. Supp. 3d 809, 814 (S.D. Tex. 2020). The Court "may not make credibility determinations or weigh the evidence" in ruling on a summary-judgment motion. *Id*. (quoting *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000)).

III. PLAINTIFFS' DESIGN DEFECT CLAIMS ARE PREEMPTED.

Plaintiffs assert that the Filshie Clips were defective in their design "because they failed to perform as safely as persons who ordinarily use the products would have expected at the time of use" and "because Filshie Clips[']s risk of harm exceed their claimed benefits." ECF No. 40 ¶¶ 69, 70. Plaintiffs further allege that "[t]he design was approved by the FDA without the benefit of the knowledge that Filshie Clips had a greater than .13% risk of migration ... Such failure [to report] allowed for the defective design to remain the same." *Id.* ¶ 71.

However, Plaintiffs do not plead that the Filshie Clips used in their surgeries or otherwise currently distributed were designed in a manner other than as the FDA approved. *Riddley v. CooperSurgical, Inc.*, No. 2:24-CV-109-BR, 2024 WL 4557340, at *14 (N.D. Tex. Oct. 23, 2024). Instead, they are alleging that the "FDA-approved design is itself unreasonably dangerous and … impl[y] that the FDA would not have approved the design if they had found the incidence of migration to be 25% rather than 0.13%." *Id.* (docket citations omitted). Because Plaintiffs have not alleged that the product in question was designed in violation of federal standards, they have failed to plausibly state a claim for design defect that would avoid preemption under the MDA. *Id.* (citing *Gomez v. St. Jude Med. Daig Div. Inc.*, 442 F.3d 919, 929-30 (5th Cir. 2006)); *Rodriguez v. Am. Med. Sys., Inc.*, 597 F. App'x 226, 230 (5th Cir. 2014) (holding that plaintiff failed to state a parallel design defect claim because the complaint did not plead a violation of any federal requirement relating to the medical device's design). "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." *Riddley*, 2024 WL 4557340, at *11; *Yosowitz v. Covidien LP*, 182 F. Supp. 3d 683, 695 (S.D. Tex. 2016) (internal citations omitted) (holding that Plaintiffs' claims "necessarily impose requirements that are different from or in addition to federal

requirements because Plaintiffs do not allege here that [Defendant] failed to satisfy federal requirements imposed by the PMA process.").[5]

Plaintiffs' attempt to connect their claim to the adverse event reporting requirement, ECF No. 40 ¶ 71 ("Such failure [to report] allowed for the defective design to remain the same"), is also impliedly preempted under § 337(a), because "[a]lthough embedded in state-law terms, any such claims would 'exist solely by virtue of [federal law].'" *Morgan*, 173 F. Supp. 3d at 970 (quoting *Buckman*, 531 U.S. at 353). "Accordingly, this Court finds that, to the extent [Plaintiffs'] claims are not expressly preempted under 21 U.S.C. § 360k(a), they are impliedly preempted under 21 U.S.C. § 337(a)." *Id.*

Furthermore, even if Plaintiffs' design defect claim was not preempted, Plaintiffs have failed to establish a genuine issue of material fact exists as to this claim. For example, Plaintiffs' evidence of a safer alternative design are two surgeries: cauterizing the fallopian tubes and salpingectomy, removal of the fallopian

[5] For this same reason, insofar as Plaintiffs base their strict liability, negligence, and gross negligence, claims on the purported design defect, these claims are also preempted. ECF No. 40 ¶¶ 104, 105, 108, 110, 114, 118, 119, 122, 146–51. "[A] Texas [strict liability] design defect claim requires [Plaintiffs] to prove that [Defendants] should have used an alternative design—a design different from that approved by the FDA through the PMA process. Such a claim 'disrupts the federal scheme' for regulating Class III medical devices requiring such devices to be 'safer, but hence less effective, than the model the FDA has approved'… Accordingly, the Court finds [the] design defect [claim] expressly preempted." *Morgan*, 172 F.Supp.3d at 968. Similarly, "[n]o negligence claims can be maintained as to devices that complied with the FDA requirements because success on these claims requires a showing that the FDA requirements themselves were deficient." *Gomez*, 442 F.3d at 933.

tubes. ECF No. 137 at 18. "A safer alternative design is one that 'would have prevented or significantly reduces the risk of the [plaintiff]'s personal injury . . . without substantially impairing the product's utility.'" *Pizzitola v. Ethicon, Inc.*, No. 4:20-CV-2256, 2020 WL 6365545, at *4 (S.D. Tex. Aug. 31, 2020) (quoting *In re DePuy Orthopaedics, Inc., Pinnacle Hip Implant Prod. Liab. Litig.*, 888 F.3d 753, 765 (5th Cir. 2018)). "To prove a safer alternative design exists, a plaintiff must prove that the alternative design would have reasonably prevented or significantly reduced the risk of the claimant's injury without substantially impairing the product's utility." *Id.* (citing *Casey v. Toyota Motor Eng'g & Mfg. North America. Inc.*, 770 F.3d 322, 331 (5th Cir. 2014). Plaintiffs must also "prove that the proposed alternative design was economically and technologically feasible at the time the design-defective product was manufactured or sold." *Id.* (citing *Casey*, 770 F.3d at 331).

Here, the proposed alternatives are surgeries or methods different from the Filshie Clip ligation, but under Texas law, Plaintiffs "must propose a safer and feasible alternative design to the alleged defective designs, not different procedures or strategies entirely." *See id.* (citing *Casey*, 770 F.3d at 331; *Caterpillar, Inc. v. Shears*, 911 S.W.2d 379, 384 (Tex. 1995)).

IV. PLAINTIFFS' FAILURE TO WARN CLAIMS ARE PREEMPTED.

Plaintiffs argue that the Filshie Clip IFUs and warnings were inadequate

because they failed to warn Plaintiffs and their prescribing doctor of a 25% overall migration rate, "an unreasonable risk of migration from the implantation site," instead of the FDA-approved 0.13% adverse migration rate. ECF No. 40 ¶¶ 71; 89–100. Because Plaintiffs' complaint does not clarify their failure-to-warn theory of the case,[6] Defendants offer several arguments for various potential theories.

First, if Plaintiffs contend that Defendants failed to give warnings beyond what the FDA required, then Defendants argue that Plaintiffs' failure-to-warn claim is expressly preempted because such a claim would undermine the federal process. ECF Nos. 123 at 19; 124 at 3; 125 at 4. Plaintiffs do not respond to this argument, instead focusing on a "later-acquired-knowledge theory." *See* ECF Nos. 137; 139, 141.

Insofar as Plaintiffs contend that the FDA-approved labeling was inadequate to warn consumers and the medical community at the time of approval, the claim is preempted. Like their design defect claim, the complaint lacks any allegations that the warnings provided with the Filshie Clip deviated in any way from the FDA-approved language. *See* ECF No. 40. "Federal law squarely preempts any 'claim for failure to provide adequate warnings or instructions . . . that would question the sufficiency of the FDA-approved labeling, warnings, and instructions for the device or require [the manufacturer] to have included different warnings, labels, or

[6] The Court does not suggest that such detail was necessary to meet Rule 8's requirements.

instructions.'" *Hawkins v. Bayer Corp.*, No. 1:21-CV-00646-RP, 2022 WL 2761379, at *4 (W.D. Tex. Feb. 1, 2022), *adopted*, No. 1:21-CV-646-RP, 2022 WL 2718541 (W.D. Tex. Feb. 23, 2022) (quoting *Hughes v. Boston Sci. Corp.*, 631 F.3d 762, 769 (5th Cir. 2011); citing *Gomez*, 442 F.3d at 931 ("To permit a jury to decide [plaintiff's] claims that the information, warnings, and training material the FDA required and approved through PMA process were inadequate under state law would displace the FDA's exclusive role and expertise in this area and risk imposing inconsistent obligations on [the defendant]."")). Therefore, because Plaintiffs do not allege that the IFUs and warnings for the Filshie Clip differed from the approved FDA language, their failure-to-warn claim based on this theory is preempted and should be dismissed. *Hawkins*, 2022 WL 2761379, at *5.

Alternatively, if Plaintiffs proceed based on a "later-acquired-knowledge theory—that the approved warnings were sufficient at the time of PMA, but that Defendants later learned information about the migration risks that should have been included in an amended label," then Defendants argue that the Fifth Circuit has preempted such claims, finding it risks the same interference with the federal regulatory scheme. ECF No. 123 at 19–20 (quoting *Gomez*, 442 F.3d at 931). Defendants explain that Plaintiffs' allegations that the IFU now provides inadequate disclosure of the migration risk because of Defendants' failure to provide required information to the FDA, namely adverse event reports and relevant articles, journals,

and data, is impliedly preempted. This is because although manufacturers must report to the FDA incidents where the device may have caused death or serious injury, there is no parallel duty under Texas law. ECF No. 123 at 20–21. "Because no parallel duty exists, any such claim is necessarily premised on federal law, and is an impermissible 'attempt by private parties to enforce federal reporting requirements, which is foreclosed by § 337(a) as construed in *Buckman*.'" ECF No. 123 at 21 (quoting *Hawkins*, 2022 WL 2761379, at *6).

Relying on *Hughes*, Plaintiffs respond that they escape preemption because they identify both a state law duty to report adverse events and the FDA regulations which Defendants violated. ECF No. 137 at 9–10. Plaintiffs argue that under Texas law, liability for failure to warn consumers is imposed where a manufacturer does not exercise reasonable case in warning of a given danger, and further "in certain scenarios, a defendant's duty to warn is discharged by providing information about the product's dangerous propensities to a third person whom it can reasonably rely on to communicate the information to the ultimate users." ECF No. 137 at 10.

Plaintiffs correctly point out that, "[u]nder federal law, device manufacturers must report any incident to the FDA where their device 'may have caused or contributed to a death or serious injury.'" *Hawkins*, 2022 WL 2761379, at *6 (quoting 21 C.F.R. § 803.50(a)). However, Texas law provides no such parallel duty. *Id.* (citing *Baker v. St. Jude Med., S.C., Inc.*, 178 S.W.3d 127, 138 (Tex. Ct. App.

2005) (directly rejecting the claim that "failure to make these [adverse event] reports, as required by the FDA, gave rise to a common-law cause of action" under Texas law, and holding that the FDA adverse-event reporting regulations do not constitute "a 'parallel federal safety requirement.")). Indeed, under Texas law, manufacturers owe a duty to warn *consumers*, not the FDA, of potential dangers. *Butler v. Juno Therapeutics, Inc.*, 541 F. Supp. 3d 774, 784 (S.D. Tex. 2021) ("Under Texas law, a manufacturer must instruct consumers as to the safe use of its product and warn consumers of the dangers of which it has actual or constructive knowledge at the time the product is sold.") (quoting *Pustejovsky v. Pliva, Inc.*, 623 F.3d 271, 276 (5th Cir. 2010) (citing *Pavlides v. Galveston Yacht Basin, Inc.*, 727 F.2d 330, 338 (5th Cir. 1984))).

As Plaintiffs point out, under the learned intermediary doctrine, in the case of prescription drugs and medical devices the FDA approved, this duty can generally be discharged by informing the prescribing physician, instead of directing warning the consumer, of the potential dangers. *Id.* at 785, 787 ("As long as the manufacturer sufficiently warns the prescribing or treating physician—the learned intermediary—the manufacturer is not liable for the intermediary's failure to warn the ultimate consumer.") (citing *Ackermann v. Wyeth Pharm.*, 526 F.3d 203, 207 (5th Cir. 2008)); *see also Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 154 (Tex. 2012) (considered whether the doctrine applied in a prescription-drug context). Plaintiffs have not

produced any Texas authority that this duty can be discharged by informing the FDA,[7] which means that Texas failure-to-warn claims impose a different requirement from federal law: warning consumers or prescribing physicians instead of warning the FDA. As a result, this claim is preempted. *See Hawkins*, 2022 WL 2761379, at *6; *see also Purcel v. Advanced Bionics Corp.*, No. 3:07-CV-1777-M, 2010 WL 2679988, at *6 (N.D. Tex. June 30, 2010)[8] ("Plaintiffs cite no federal requirement obligating [the manufacturer] to warn [consumers] that the devices were adulterated. These claims of . . . failure to warn impose a requirement in addition to those approved by the FDA—the duty to warn consumers if devices are adulterated—and are therefore preempted by § 360k(a)."") (citing *Horowitz,* 613 F.Supp.2d at 286–87; *In re Medtronic,* 592 F.Supp.2d at 1160).

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[7] Furthermore, Plaintiffs' cited authority is distinguishable. In *Hughes*, the Fifth Circuit found the plaintiff's failure-to-warn claim did not impose additional or different requirements to the federal regulations, but was parallel to the federal requirements, and based their determination on now defunct Mississippi products liability law. *See Hughes*, 631 F.3d at 771; *see also Knoth v. Apollo Endosurgery US, Inc.*, 425 F. Supp. 3d 678, 694–95 (S.D. Miss. 2019) ("However, the Fifth Circuit's decision in *Hughes* occurred prior the 2014 MPLA amendments and the Mississippi Supreme Court's decision in *Elliott*," 181 So.3d at 269). Moreover, their contention that *Briggs v. Endologix* demonstrates a Texas court's reliance on *Hughes* is misleading—in *Briggs*, the court found Plaintiffs' reliance on *Hughes* [] unavailing," noting that Plaintiffs' case, like here, was distinguishable based on Plaintiffs' failure to allege facts like those present in *Hughes*. *See Briggs v. Endologix, Inc.*, No. 3:22-CV-00290, 2023 WL 2716592, at *5 (S.D. Tex. Mar. 30, 2023), *adopted*, No. 3:22-CV-00290, 2023 WL 3059156 (S.D. Tex. Apr. 24, 2023). Plaintiffs wholly fail to identify how *Hughes*' holding connects to Texas products liability law or even more broadly, identify any parallel duty under Texas state law to report adverse events to the FDA.

[8] The Court is aware that the *Purcel* court found the plaintiffs' claim that Bionics' negligent failure to follow federal law caused B.P.'s injuries is not preempted. 2010 WL 2679988, at *6. Because the *Purcel* court provided little to no explanation for this holding and seemingly based it on an Eastern District of California case, *Prudhel v. Endologix, Inc.,* No. CIV. S–09–066.1 LKK/KJM, 2009 WL 2045559, at *8 (E.D. Cal. July 9, 2009), the Court does not follow this approach.

Further, Texas courts generally reject arguments that reporting statutes give rise to common-law causes of action under Texas law.[9] *Hawkins*, 2022 WL 2761379, at *6 (citing *Doe v. Apostolic Assembly of Faith in Christ Jesus*, 452 F. Supp. 3d 503, 529 (W.D. Tex. 2020); *Moghtader v. GEO Grp., Inc.*, 2020 WL 1557770, at *5 (W.D. Tex. Mar. 31, 2020)). Accordingly, because there is no "parallel" state requirement under Texas law, Plaintiffs' contention that Defendants' failure to warn via failure to report adverse event complaints is "simply an attempt by private parties to enforce" FDA reporting requirements, which is "foreclosed under § 337(a), as construed in *Buckman*." *See id.* (citing *In re Medtronic*, 623 F.3d at 1205-06; *see also Baker*, 178 S.W.3d at 139 ("[A]ppellants are essentially alleging that St. Jude withheld, or unreasonably delayed, in providing the FDA with information that it had regarding adverse effects associated with the Silzone valve. As such, we hold that appellants' fraud claim is really a 'fraud-on-the-FDA claim,' and is, therefore, impliedly preempted.")).

In sum, Plaintiffs' failure to warn claim regarding Defendants' failure to report

[9] For this same reason, Plaintiffs' DTPA claims, which are based entirely on failure to warn and labeling violations, ECF No. 40 ¶¶ 127–45, and insofar as Plaintiffs base their negligence, gross negligence, and strict liability claims on Defendants' purported failure to warn, ECF No. 40 ¶¶ 107, 114–16, 122, 146–51, are similarly preempted. *See Phares v. Actavis-Elizabeth LLC*, 892 F. Supp. 2d 835, 841 (S.D. Tex. 2012) (dismissing plaintiff's claims of negligence, negligent misrepresentation, strict liability, breach of the implied warranty of merchantability, breach of warranty for a particular purpose, and deceptive trade practices because "[n]o matter how she casts her claims, Plaintiff essentially alleges that Actavis failed to warn her that metoclopramide causes tardive dyskinesia.").

adverse events to the FDA is preempted because Plaintiffs do not identify in either the submitted evidence or briefing any parallel duty under state law to report adverse events to the FDA—they essentially contend that Defendants should be liable under Texas law because they allegedly violated the ongoing adverse event reporting requirements, which is impliedly preempted. *See Hawkins*, 2022 WL 2761379, at *6; *see also ARNOLD v. COOPERSURGICAL, INC., et al.*, No. 2:22-CV-1951, 2025 WL 622075, at *10 (S.D. Ohio Feb. 26, 2025) ("The Court's conclusion that Ms. Arnold's failure-to-warn claim based on a failure-to-report-adverse-events theory of liability is preempted by federal law aligns with decisions of other courts who have considered similar arguments about Filshie Clips.") (citing *Mack v. CooperSurgical, Inc.*, No. 1:22-CV-54-RAH, 2024 WL 4427846, at *8 (M.D. Ala. Oct. 4, 2024) (granting summary judgment to the defendants on plaintiff's failure-to-warn claim); *Farson v. Coopersurgical, Inc.*, No. 3:22 CV 716, 2023 WL 5002818, at *11 (N.D. Ohio Aug. 4, 2023) (granting motions to dismiss similar claims as preempted); *Froman v. Coopersurgical, Inc.*, No. 2:22-CV-00110-AKK, 2022 WL 2657117, at *6 (N.D. Ala. July 8, 2022) (holding similar claims preempted); *Watters v. CooperSurgical, Inc.*, 655 F. Supp. 3d 376, 386 (E.D.N.C. 2023) (holding similar claims preempted)).

Defendants are entitled to summary judgment on Plaintiffs' failure to warn

claim.[10]

V. CONCLUSION

Therefore, the Court **RECOMMENDS** that Defendants' motions for summary judgment, ECF Nos. 123, 124, 125, be **DENIED AS MOOT** as to Plaintiff's manufacturing defect claims and **GRANTED** as to all remaining claims. Because summary judgment should be granted on all Plaintiffs' claims, the Court **RECOMMENDS** that Defendant's motion to exclude evidence related to past and future medical expenses, lost wages, and lost earning capacity, ECF No. 127, and Plaintiffs' motions for summary judgment, ECF No. 134, 135 be **DENIED AS MOOT**.

The Parties have fourteen days from service of this Report and Recommendation to file written objections. 28 U.S.C. § 636(b)(1)(C); FED. R. CIV. P. 72(b). Failure to file timely objections will preclude review of factual findings or legal conclusions, except for plain error. *Quinn v. Guerrero*, 863 F.3d 353, 358 (5th Cir. 2017).

Signed on March 6, 2025, at Houston, Texas.

Dena Palermo

Dena Hanovice Palermo
United States Magistrate Judge

[10] Because all Plaintiffs' claims are federally preempted, the Court does not reach the remaining arguments.