IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

JAMES BLACKWELL,	§	
	§	
Plaintiff,	§	
	§	
v.	§	2:19-CV-180-Z
	§	
C. R. BARD, INC., and BARD PERIPHERAL VASCULAR, INC.,	§	
	§	
Defendants.	§	

MEMORANDUM OPINION AND ORDER

Before the Court is Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc.'s (collectively "Bard") Motion for Summary Judgment (ECF No. 42). Having considered the Motion, the related pleadings, and the applicable law, the Court finds Defendants' Motion should be **GRANTED**. The Clerk is **DIRECTED** to unseal ECF Nos. 45 and 47. *See* ECF No. 53 (denying without prejudice Defendants' Motion to Seal).

FACTUAL BACKGROUND

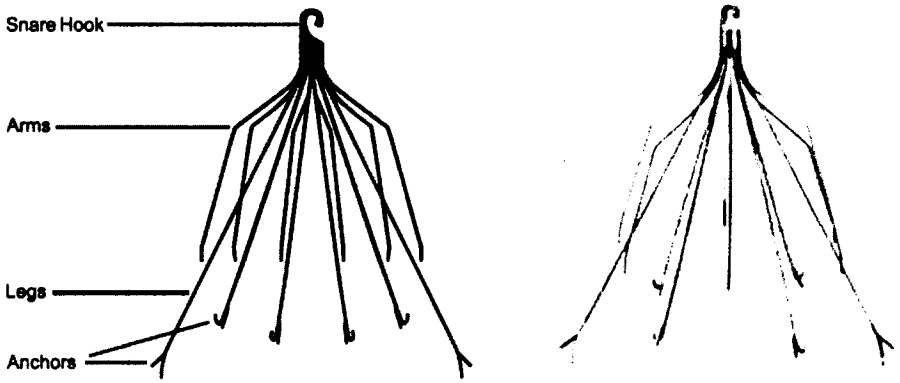
Inferior vena cava ("IVC") filters are prescription medical devices designed to prevent blood clots (or "thrombus") from reaching the heart and lungs to prevent potentially fatal pulmonary embolism ("PE"). IVC filters are placed in the IVC, the large vein leading from the lower extremities to the heart.

Plaintiff James Blackwell was treated with Bard's "Denali" IVC filter after Plaintiff developed deep vein thrombosis ("DVT") while recovering from thoracolumbar surgery. ECF No. 43 at 12.[1] The Denali filter consists of two tiers of struts that make up its "arms" and "legs," and

[1] All citations are to the ECF-generated number at the top of the document, *not* the page numbers in the footer.

can be introduced into the IVC via a small puncture in the jugular vein or the femoral vein. *Id.* at 10. Four of the six legs have cranial anchors; these are designed to keep the Denali from moving towards the head. *Id.* at 10–11. The other two legs have caudal anchors; these are designed to keep the Denali from moving towards the feet. *Id.* at 11. The Denali was designed for permanent or temporary placement. *Id.* The snare hook is used during the removal of the filter.

Denali (2013)



ECF No. 43 at 12; ECF No. 43-1 at 93; ECF No. 46 at 5.

Blackwell was implanted with a Denali filter by Dr. Richard Archer on May 14, 2016. ECF No. 46 at 6. On June 5, 2016, Blackwell returned to the emergency room with bilateral hip pain and worsening left lower swelling as well as mild swelling in the left lower extremity. *Id.* An examination demonstrated "thrombus in the mid and distal femoral veins as well as the popliteal and perineal veins in the left lower extremity." ECF No. 46-1 at 45. An "ultrasound of the iliac veins and inferior vena cava done on the same day demonstrated thrombosis of the right and left common iliac veins and the IVC appears thrombosed." *Id.*

A follow-up venogram on July 3, 2016 revealed Blackwell's left common iliac vein now had chronic occlusion. *Id.* By November 9, 2016, Blackwell was diagnosed with chronic iliocaval thrombus. *Id.* The most recent CT scan on October 1, 2019, showed "significant scarring of the IVC at the level of the filter, with significant collapse of the filter." *Id.*

In other words, Blackwell developed a clot at, near, or directly on the IVC filter. The clot has encased the Denali filter and has spread to the common iliac veins, causing chronic blockage of the iliocaval system. Now, because of the clotting and scarring of the IVC, no doctor in Amarillo will consider removing the Denali filter. ECF No. 46 at 13. As a result, Blackwell suffers from chronic lower extremity pain and swelling related to his chronic venous disease. *Id.*

PROCEDURAL BACKGROUND

On December 2, 2016, Plaintiff direct-filed this suit in the District of Arizona as part of the coordinated or consolidated pretrial proceedings against Defendants. *In re: Bard IVC Filters Products Liability Litigation*, MDL No. 2641. In the MDL, the parties conducted general fact and expert discovery in phases. ECF No. 3 at 9–11. In the second phase, the parties were ordered to produce Rule 26(a)(2) expert disclosures and reports for general expert witnesses whose opinions were common to all cases and to complete depositions of the disclosed general experts. *Id.* at 10.

The MDL plaintiffs produced reports from several general experts and general expert discovery in the MDL closed on July 14, 2017, and the MDL Court subsequently ruled on the parties' *Daubert* motions directed at general experts. ECF No. 3 at 13, 20-21. In its transfer order for this case, the MDL Court conclusively determined that "all general fact and expert discovery has been completed" such that "courts receiving these [transferred] cases need not be concerned with facilitating general expert, corporate, and third-party discovery." *Id.* at 31–32.

This matter was transferred from the MDL to this Court on September 13, 2019. The parties agreed that the scope of discovery in this case would be governed by MDL Judge David Campbell's order in the remanded case *Caldera v. C. R. Bard Inc., et al.*, 2:19-cv-04266-DGC (D. Ariz. Jan. 10, 2020). ECF No. 35 at 4–5. In the *Caldera* order, Judge Campbell ruled that "voluminous

and comprehensive" general expert discovery was completed in the MDL and that general expert discovery was closed except for "narrow exceptions."

On February 10, 2021, Bard moved for summary judgment on all Plaintiff's remaining claims which can be classified in two groups: Warning Claims (Counts II, VII, VIII, XII, and XIV) and Design Claims (Counts III and IV). Plaintiff also maintains an unnumbered claim for punitive damages. Plaintiff has withdrawn his claims for manufacturing defect (Counts I and V), negligence per se (Count IX), fraudulent concealment (Count XIII), and breach of express and implied warranties (Counts X and XI). ECF No. 43 at 1.

On March 5, 2021, Bard moved to strike the opinions in Dr. Garcia's general expert report titled "Expert Report Regarding Matters Related to Bard IVC Filters and Clot Formation." ECF No. 48. The Court granted that motion for the reasons stated in ECF No. 68. On March 17, 2021, Bard also moved to strike Dr. Blackman's Declaration. ECF No. 51. The Court granted that motion as well. ECF No. 69. The Motion for Summary Judgment is now ripe for determination.

LEGAL STANDARDS

In a civil case, "[a] party may move for summary judgment, identifying each claim or defense — or the part of each claim or defense — on which summary judgment is sought." FED. R. CIV. PROC. 56(b). When a summary judgment movant does not have the burden of proof on a claim, it may obtain summary judgment by pointing the Court to the absence of evidence on any essential element of the nonmovant's claim. *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986). Once it does so, the nonmovant must go beyond its pleadings and designate specific facts demonstrating that there is a genuine issue of material fact for trial. *Id.* at 324–25; *Little v. Liquid Air Corp.*, 37 F.3d 1069, 1075 (5th Cir. 1994). A genuine issue of material fact exists if the evidence is such that a reasonable trier of fact could return a verdict for the nonmovant. *Anderson*

v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). Summary judgment is mandatory where the nonmovant fails to meet this burden. *Little*, 37 F.3d at 1076.

To meet this burden, the nonmovant must show more than "some metaphysical doubt as to the material facts" — and may not rely on "conclusory allegations," "unsubstantiated assertions," or "only a scintilla of evidence." *Id.* at 1075 (internal marks omitted). However, summary judgment evidence is to be viewed in the light most favorable to the nonmovant. *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986); *Rosado v. Deters*, 5 F.3d 119, 123 (5th Cir. 1994).

ANALYSIS

Plaintiff's Warning Claims[2] and Design Claims[3] both fail as a matter of Texas state law. Regarding the Warning Claims, Plaintiff has failed to show Bard's warnings were defective. Additionally, even if Plaintiff provided evidence that the warnings were ineffective, Plaintiff has failed to establish causation under the learned-intermediary doctrine. Regarding the Design Claims, Plaintiff has failed to present any admissible evidence of a safer alternative design as required by Texas law. Because all of Plaintiff's named claims fail, Plaintiff's derivative punitive damages claim also fails.

A. The learned-intermediary doctrine bars Plaintiff's Warning Claims (Counts II, VII, VIII, XII, and XIV) because Bard's warnings were not a producing cause of his injuries and Bard provided legally adequate warnings.

Texas has adopted the learned-intermediary doctrine, which applies to products-liability claims involving implantable medical devices like IVC filters. *See Pustejovsky v. Pliva, Inc.*, 623 F.3d 272, 276 (5th Cir. 2010) ("Under the doctrine, the manufacturer may rely on the doctor —

[2] Specifically, Count II is a strict-products-liability failure-to-warn claim. Count VII is a negligent failure-to-warn claim. Count VIII is a negligent misrepresentation claim. Count XII is a fraudulent misrepresentation claim. Count XIV is a Texas Deceptive Trade Practice Consumer Protection Act ("DTPA") claim. ECF No. 1 at 3.

[3] Count III is a strict-products-liability design defect claim. Count IV is a negligent design claim. ECF No. 1 at 3.

the learned intermediary — to pass on its warnings."); *see also Bean v. Baxter Healthcare Corp.*, 965 S.W.2d 656, 663 (Tex.App.—Houston [14th Dist.] 1998, no pet.) (applying the learned intermediary doctrine in an implantable medical device case). And the parties agree that this doctrine applies to all the Warnings Claims in this case.[4]

"In order to recover for a failure to warn under the learned intermediary doctrine, a plaintiff must show: (1) the warning was defective; and (2) the failure to warn was a producing cause of the plaintiff's injury." *Porterfield v. Ethicon, Inc.*, 183 F.3d 464, 468 (5th Cir. 1999). It is the Plaintiff's burden to raise a triable issue of fact on each element. *Centocor, Inc., v. Hamilton*, 372 S.W.3d 140, 165–66 (Tex. 2012). Here, Plaintiff fails raise a genuine issue of material fact on both elements.

1. Bard's warnings are legally adequate as a matter of law

Under Texas law, "adequate warnings and instructions are those given in a form that could be reasonably expected to catch the attention of a reasonably prudent" physician. *Bean*, 965 S.W.2d at 664. The question whether warnings are adequate is normally a fact question for the jury. But where "a warning specifically mentions the circumstances complained of, then the warning is adequate as a matter of law." *Ackermann v. Wyeth Pharm.*, 526 F.3d 203, 208 (5th Cir. 2008).

Plaintiff alleges Bard, in order to market the Denali filter, published and disseminated Instructions for Use ("IFU") which was packaged with the filter, a Denali product brochure, and a Denali patient brochure.[5] ECF No. 46-1 at 55–61, 16–21, 88–89. Plaintiff further alleges each of

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[4] *See, e.g., Ebel v. Eli Lilly & Co.*, 536 F. Supp. 2d 767, 773 (S.D. Tex. 2008) (applying Texas law) ("Where the crux of the suit is based on a failure to adequately warn, the learned intermediary doctrine may apply to strict liability, negligence, misrepresentation, and breach of warranty claims.").

[5] Plaintiff failed to disclose the patient brochure during discovery and did not actually disclose the brochure until after Bard had filed its motion for summary judgment. Plaintiff provided no consistent explanation for this late disclosure. The Court frowns upon this litigation tactic, but, as it does not affect the outcome, proceeds to analyze the evidence as properly disclosed. *Cf.* FED. R. CIV. P. 37(c).

these contain inadequate warnings about the potential complications and risks of using the device. The Court will only consider Plaintiff's allegations regarding the IFU and the patient brochure. Plaintiff has made no argument why the product brochure is relevant to this case.[6]

The IFU that accompanied Plaintiff's filter "specifically mentions the circumstances complained of." *Ackermann*, 526 F.3d at 208. Plaintiff alleges that his filter failed due to "occlusion of the IVC filter." ECF No. 43-1 at 31, 69. And Dr. Blackman, Plaintiff's expert, stated that Plaintiff's filter induced "thrombosis [and] led to venous occlusion." *Id.* at 67. Under the bolded heading "**Potential Complications**," the IFU warns "Caval thrombosis/occlusion," "Deep vein thrombosis," and "Occlusion of small vessels." ECF No. 46-1 at 58–59. Additionally, the IFU stated in bold text that these complications "**have been associated with serious adverse events such as medical intervention and/or death**." *Id.* at 59. Because the IFU specifically warns of the circumstances complained of, the warnings are adequate as a matter of law.

Plaintiff's arguments to the contrary are unpersuasive and rely heavily on non-admissible testimony. The expert report of John Ladisa Jr. cited in footnotes 51 and 53 of Plaintiff's Response is hearsay. Dr. Garcia's report cited in footnotes 52, 53, and 54 has been excluded by this Court's Order. *See* ECF No. 68. Dr. Blackman's Declaration cited in footnote 55 has also been excluded by this Court's Order. *See* ECF No. 69. Lastly, Plaintiff argues "[m]ultiple courts presented with

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[6] As explain in part A.2, under Texas law, the physician is required to have read or encountered the allegedly defective warnings. Plaintiff has offered *zero* evidence on if, when, where, or how Plaintiff's implanting physician, Dr. Archer, encountered the product brochure. Thus, the materials in the product brochure are irrelevant to this case.

Because the product brochure is irrelevant, the Court has no need to address Plaintiff's allegations that the product brochure is misleading because of the font size and location of the warnings included therein. *But even if* the Court considered Plaintiff's allegations, they are unsupported by any admissible expert testimony. *See Gen. Motors Corp. v. Saenz*, 873 S.W.2d 353, 360 (Tex. 1993) ("Every warning can always be made bigger, brighter and more obvious."); *see also Goodyear Tire & Rubber Co. v. Rios*, 143 S.W.3d 107, 117–18 (Tex.App.—San Antonio 2004, pet. denied) ("A jury could not have determined, without the benefit of expert testimony, which, among many, warnings and instructions should be printed on a sidewall. When a lay person's general experience and common sense will not enable that person to determine the issue, expert testimony is required.") (citing Tex. R. Evid. 702).

a similar record . . . have rejected Bard's arguments that its warnings through the IFUs are adequate as a matter of law." ECF No. 46 at 16. Yet, Plaintiff offers no explanation on how these other court records were similar. Moreover, *none* of these other cases involved a Denali filter and, more importantly, all of them but one were decided under the *laws of other states*. The only case cited that applied Texas law contains no reasoning or precedential value. *See Sweezey v. C.R. Bard, Inc.*, No. 3:19-CV-2172-S (N.D. Tex. Mar. 12, 2020), ECF No. 125 at 3 (Mem. and Order). Plaintiff's concluding statement that "Bard's failure to provide adequate warning in its IFU and brochures about the specific risks and circumstances complained of here is evidence of its inadequacy" is a circular argument that does nothing more than argue that Bard's failure to warn is evidence of its failure to warn. ECF No. 46 at 16–17.

2. Plaintiff has failed to show that Bard's warnings were a producing cause of his injuries

Even if Plaintiff had produced evidence of an inadequate warning, Plaintiff still would have to show, under the second prong of the learned-intermediary doctrine, that "the failure to warn was a producing cause of the plaintiff's injury." *Porterfield*, 183 F.3d at 468. "Causation entails *two distinct factual predicates*: first, that the doctor would have read or encountered the adequate warning; and second that the adequate warning would have altered his treatment decision for, or risk-related disclosures to, the patient." *In re DePuy Orthopaedics, Inc., Pinnacle Hip Implant Prod. Liab. Litig.*, 888 F.3d 753, 775 (5th Cir. 2018) (emphasis in original).

Bard argues that it is entitled to summary judgment on Plaintiff's failure to warn claims because Plaintiff failed to depose the implanting physician, Dr. Archer,[7] and therefore there is no evidence regarding whether Dr. Archer *ever* encountered the warnings. The Court agrees.

[7] Plaintiff offers no explanation for failing to depose Dr. Archer. As Bard noted in its Reply, this is not a case where Plaintiff was unable to locate Dr. Archer. A quick internet search shows that Dr. Archer still practices in Amarillo, Texas (where he implanted Plaintiff's filter) and is still affiliated with the same facility where he implanted Plaintiff's

Plaintiff failed to meet the first "factual predicate" for establishing causation because he presented no record evidence that Dr. Archer read or encountered any warning from Bard. Plaintiff does not allege that Dr. Archer ever read the IFU or product brochure. *Supra*, n. 5. Instead, as in *In re DePuy*, Plaintiff relies on his own statements in lieu of the implanting physician's testimony, which is a losing argument. *See In re Dupuy*, 888 F.3d at 775 ("[P]laintiffs cite only their own statements for support . . . But these snippets say nothing of how the doctors came to hold their respective views. . . . The jury was left to guess, and plaintiffs' claims fail as a result.").

Plaintiff's sole attempt to distinguish *In re Dupuy* fares no better. In addition to Plaintiff's own testimony about the conversations between Dr. Archer and himself,[8] Plaintiff alleges Dr. Archer provided Plaintiff with a Denali patient brochure that appears to have been signed by Dr. Archer the day of the procedure.[9] ECF No. 46-1 at 88–89. But there is no evidence that Dr. Archer ever *read* the brochure. Plaintiff's counter-argument — that Dr. Archer's alleged signature on the brochure equates with Dr. Archer having read the brochure — is pure speculation. The signature does not establish that Dr. Archer read the brochure or relied upon it. Nor does it establish where Dr. Archer received the brochure, whether he received it from Bard or some other source, when he received it, or the circumstances under which he received it.[10]

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filter—Baptist St. Anthony Hospital. ECF No. 50 at 6 n. 16 (citing U.S. NEWS &WORLD REPORT, https://health.usnews.com/doctors/richard-archer-308373 (last visited Mar. 3, 2021); ECF No. 43-1 at 69.

[8] *Knight v. Kellogg Brown & Root Inc.*, 333 F. App'x 1, 6 (5th Cir. 2009) ("[S]ummary summary judgment evidence cannot be based on inadmissible hearsay."); *Fowler v. Smith*, 68 F.3d 124, 126 (5th Cir. 1995) ("Evidence on summary judgment may be considered to the extent not based on hearsay or other information excludable at trial.").

[9] This is the same brochure that was not produced in discovery even though Bard requested it on several occasions. *Supra*, n. 5; *cf.* FED. R. CIV. P. 37(c).

[10] Moreover, the signature on the brochure appears to be hearsay. Plaintiff's argument is that Dr. Archer's signature is tantamount to Dr. Archer writing "I, Dr. Archer, read this document." But that would clearly be hearsay. So too then is the shorter, simpler statement of "Dr. Archer."

B. Plaintiff's Design Claims (Counts III and IV) fail because Plaintiff lacks *any* evidence of a safer alternative design.

To prevail on a design defect claim in Texas, a plaintiff must prove by a preponderance of the evidence that, among other elements, a safer alternative design existed. *In re Dupuy*, 888 F.3d at 753. A safer alternative design is one that "would have prevented or significantly reduced the risk of the [plaintiff]'s personal injury . . . without substantially impairing the product's utility." *Id.* at 765. The plaintiff must prove that a safer alternative design was economically and technologically feasible at the time the allegedly defective product was manufactured. *Casey v. Toyota Motor Eng'g &Mfg. North America, Inc.*, 770 F.3d 322, 331 (5th Cir. 2014). For a design to be technologically feasible, the plaintiff must prove that the proposed design existed at the time the allegedly defective product was manufactured. *Id.* at 334.

Furthermore, the Fifth Circuit has stated "[u]nder Texas law, 'expert testimony is generally encouraged if not required to establish a products liability claim.'" *Norman v. Grove Cranes U.S., LLC*, 750 Fed. App'x 269, 273 (5th Cir. 2018) (quoting *Sims v. Kia Motors of Am., Inc.*, 839 F.3d 393, 409 (5th Cir. 2016)); *id.* ("Moreover, numerous intermediate Texas courts and federal district courts have granted judgments in favor of defendants where no admissible expert testimony was offered to prove the existence of a safer alternative design.").

Plaintiff argues that the ALN filter is a safer alternative device. But Plaintiff has *no* admissible expert evidence to support this claim. The Court struck Dr. Blackman's Declaration — Plaintiff's only expert report on this topic — for good cause. *See* ECF No. 69.

> Plaintiff's argument that the Declaration merely supplements his existing opinions is unavailing. The two opinions offered in the Declaration relate to a safer alternative design. These opinions are an entirely new topic that was not addressed in his original expert report *or* during his deposition. Nowhere in his original report does Dr. Blackman mention "safer," "alternate" or "alternative," or "different" designs. Nor does his original report identify any other filter designs or models he believes would have been safer for Plaintiff than his Denali filter.

> Likewise, Dr. Blackman did not identify or discuss a safer alternative design during his deposition, except to say that he is "not suggesting that [Plaintiff] should have any filter in particular."

Id. at 3.

Without expert evidence, Plaintiff is unable to meet his burden to show a safer alternative design at the summary judgment stage and his Design Claims thus fail. Because both Plaintiff's Warning and Design Claims have failed, Plaintiff's derivative punitive-damages claim must fail as well.[11]

CONCLUSION

For the reasons explained above, the Court determines there are no genuine issues of material facts on any of Plaintiff's claims. Accordingly, the Court **GRANTS** Defendants' Motion for Summary Judgment (ECF No. 42) in its entirety. Plaintiff's claims are **DISMISSED WITH PREJUDICE**.

SO ORDERED.

June 9, 2021

MATTHEW J. KACSMARYK
UNITED STATES DISTRICT JUDGE

[11] Because Plaintiff lacks any evidence of a safer alternative design, the Court need not decide whether comment k to the Restatement (Second) of Torts § 402A applies to the Denali filter. For the same reason, the Court need not decide if Texas Civil Practice and Remedy Code § 82.008 establishes a presumption of non-liability as to all of Plaintiff's claims.