UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

CRAIG COUTURIER	**CIVIL ACTION**
VERSUS	**NO. 19-12497**
BARD PERIPHERAL VASCULAR, INC. AND C.R. BARD, INC.	**SECTION: "B"(2)**

ORDER AND REASONS

Before the Court are defendants' motion for summary judgment on all claims (Rec. Docs. 122, 141) and plaintiff's motion for partial summary judgment on defendants' affirmative defenses (Rec. Docs. 102, 124).

After reviewing the motions, supplemental briefings, and oral arguments, **IT IS ORDERED** that the defendants' motion for summary judgment on all claims is **GRANTED IN PART** and **DENIED IN PART.**

IT IS FURTHER ORDERED that the plaintiff's motion for partial summary judgment on defendants' affirmative defenses is **DENIED.**

I. FACTS AND PROCEDURAL HISTORY

This is a products liability action that was remanded to this Court from the multidistrict litigation captioned *In re: Bard IVC Filters Products Liability Litigation*, MDL 2641, in the United States District Court for the District of Arizona. (the "MDL"). The parties agreed that voluminous and comprehensive fact and expert discovery was undertaken in the MDL and that

general fact and expert discovery has been completed and is closed, with two narrow exceptions: (1) any new medical literature published since 2017 may be added to the reliance lists of general experts, and the general experts may expand their trial testimony from the MDL to include a discussion of such new literature[1], and (2) defendants shall supplement their disclosures of adverse event data[2]. No further general fact or expert discovery shall be pursued.

Plaintiff brings this action for personal injuries suffered after being implanted with an Inferior Vena Cava ("IVC") filter medical device manufactured by defendants. Rec. Doc. 6-9 at 25. An IVC filter is a device that is designed to filter or "catch" blood clots that travel from the lower portions of the body to the heart and lungs. *Id.* at 30. IVC filters were originally designed to be permanently implanted in the IVC.[3] *Id.* The IVC is a vein that returns blood to the heart from the lower portions

[1] Defendants have expressly reserved their right to object to the admissibility and/or relevance of any post-implant studies or literature for any and all purposes.

[2] The parties acknowledge and agree that defendants' production and supplementation of adverse event data in this case will be the same as that production by defendants in *Caldera v. C.R. Bard, Inc. et al.*, case no. CV19-4266 PHX DGC pending in the United States District Court of the District of Arizona before Judge David G. Campbell (who oversaw the MDL). Defendants have expressly reserved their right to object to the admissibility and/or relevance of the adverse event date for any all purposes.

[3] Defendant's Simon Nitinol Filter ("SNF") "had a well-established safety record and had been sold for years for permanent implantation only." Rec. Doc. 141-1 at 52.

of the body. *Id.* In certain people, blood clots travel from the vessels in the legs and pelvis, through the vena cava and into the lungs. Deep vein thrombosis ("DVT") occurs when the blood clots develop in the deep leg veins and once these clots reach the lungs, they are considered pulmonary emboli ("PE")—presenting risk to human health, including death. *Id.* IVC filters have been on the market for decades but were limited to patients who could not manage their DVT/PE with prescribed medications. *Id.* at 31. Defendants were the first medical device manufacturer to obtain FDA clearance for marketing a "retrievable" IVC filter in July 2003. *Id.* at 31.

Plaintiff Craig Couturier presented to the emergency room on May 6, 2011 with complaints of "headaches, nausea and vomiting. Rec. Doc. 141-1 at 2. He was diagnosed with severe ear infections and meningitis and underwent surgery to treat the ear infections. *Id.* Following surgery, plaintiff "showed an upper gastrointestinal bleed from a Mallory-Weiss tear[4]." *Id.* Plaintiff required multiple transfusions and was anemic. *Id.* at 3. On May, 2011, a scan of his lungs showed plaintiff had pulmonary emboli

[4] A Mallory-Weiss tear is a tear of the tissue of the lower esophagus and is most often caused by violent coughing or vomiting. Left untreated, it can lead to anemia, fatigue, shortness of breath, and even shock. *Mallory-Weiss Tear*, Johns Hopkins Medicine, CONDITIONS AND DISEASES, https://www.hopkinsmedicine.org/health/conditions-and-diseases/malloryweiss-tear (last accessed June 9, 2021).

in his left lower lobe. *Id.* Because of his anemia and transfusions, plaintiff could not be placed on blood thinners, but needed to be protected from further PE. *Id.*

Dr. Jose Mena[5], a board-certified vascular and cardiothoracic surgeon, discussed potentially implanting an IVC filter with plaintiff as a form of treatment.[6] *Id.* Dr. Mena explained the risks and benefits to plaintiff and his wife and they "voiced understanding and wished to proceed." *Id.* at 7. Plaintiff's wife signed a consent form (that included various risks associated with IVC implant procedures, including "heart problems" and "displacement of device requiring retrieval") on plaintiff's behalf following Dr. Mena's consultation. *Id.* at 9-10. Dr. Mena then implanted an Eclipse® IVC filter[7] in plaintiff under what plaintiff's wife described as "emergent conditions" because it was the only IVC filter available at the hospital. *Id.* at 11-12.

[5] Dr. Mena practices at Ochsner Health Center and had experience implanting IVC filters (including the Eclipse®) dating back to 2005. Rec. Doc. 141-1 at 12.

[6] Dr. Mena wanted to prevent another PE from occurring because he could have had significant problems, including death. Rec. Doc. 141-1 at 5. Dr. Mena performed a risk-benefit analysis in determining whether an IVC filter was appropriate for plaintiff and that it was the "best option available." *Id.* at 6.

[7] The FDA cleared the Eclipse® filter on January 14, 2010. Rec. Doc. 6-9 at 53. The Eclipse® filter is the fifth subsequent model of defendant's IVC filters. Predecessor models included the original Recovery® Vena Cava Filter, followed by the G2®, G2® Express, and G2® X filters.

Medical device manufacturers, like defendant, provide an "Instructions for Use" document {"IFU") in the same box with the device. Rec. Doc. 141-1 at 13. According to the Eclipse® filter's IFU, it is a venous interruption device "designed to prevent pulmonary embolism" and is "designated to act as a permanent filter," but "when clinically indicated, … may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure." *Id.* 13-14. The IFU includes several indications for use, warnings, and potential complications such as:

> **Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.**
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> **Movement, migration or tilt of the filter are known complications of vena cava filters. Migration of filters to the heart or lungs has been reported. There have also been reports of caudal migration of the filter. Migration may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots and/or dislodgment due to large clot burdens.** Rec. Doc. 141-1 at 15 (emphasis included).
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> Possible complications include, but are not limited to … [p]erforation or other acute or chronic damage of the IVC wall … [d]istal [e]mbolization … and [o]rgan [i]njury. *Id.* at 17 (internal quotes omitted).

Notably, the parties are contentious about whether Dr. Mena read the IFU prior to implanting the filter in plaintiff; Dr. Mena could not recall whether he read it or not because of the elapsed time between treating plaintiff and his deposition. Rec. Doc. 141-1 at 19. Moreover, the parties argue whether Dr. Mena properly deployed the filter and to what extent did plaintiff follow up with Dr. Mena post-implantation. *Id.* at 23-25.

In October 2016, plaintiff presented at the emergency room and a CT showed that a "linear metallic foreign body" was found in plaintiff's right ventricle of his heart. One was found in his lung in November 2016. Rec. Doc. 141 at 5. Plaintiff consulted with Dr. Mena and a cardiologist, Dr. Ghiath Mikdadi, and both agreed that at that time the fragment in plaintiff's heart was stable and advised plaintiff to "leave it alone." Rec. Doc. 122-2 at 7. Subsequent scans have shown that the fragment is unchanged in position and is stable. *Id.* However, as of December 2019, plaintiff's IVC has been perforated in eight places and he continues to suffer from shortness of breath, irregular heartbeat, and hip pain. *Id.* Because of this, plaintiff alleges he is at risk of the filter further penetrating adjacent organs such as his spine, duodenum, and aorta, which could result in symptomatic or life-threatening hemorrhage, infection, bowel perforation, bowel obstruction, leg

pain, or back pain. Rec. Doc. 141 at 5. Plaintiff further alleges that he is at risk of deadly cardiac complications and further penetration may lead to pericardial tamponade[8], arrythmia and infection. *Id.*

Plaintiff filed his master short complaint for damages in the United States Court for the District of Arizona on July 13, 2017. Rec. Doc. 1 at 4. His short form complaint asserts thirteen causes of action against defendants including strict liability and negligent manufacturing defect (Counts I, V), design defect (Counts III, IV), and failure to warn (Counts II, VII), negligent misrepresentation (Count VIII), negligence per se (Count IX), breach of express and implied warranty (Counts X, XI), fraudulent misrepresentation and concealment (Counts XII, XIII), and violation of state consumer laws (Count XIV). Rec. Doc. 1 at 3. Plaintiff also alleges punitive damages. *Id.* at 4. The case was then transferred to this court on September 9, 2019. Rec. Doc. 5.

[8] Cardiac tamponade happens when extra fluid builds up in the space around the heart. This fluid puts pressure on the heart and prevents it from pumping well. *Cardiac Tamponade*, HEALTH LIBRARY, https://www.cedars-sinai.org/health-library/diseases-and-conditions/c/cardiac-tamponade.html (last accessed June 7, 2021).

II. LAW AND ANALYSIS

Under Federal Rule of Civil Procedure 56, summary judgment is appropriate when "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986) (quoting Fed. R. Civ. P. 56(c)). *See also* T*IG Ins. Co. v. Sedgwick James of Wash.*, 276 F.3d 754, 759 (5th Cir. 2002). A genuine issue of material fact exists if the evidence would allow a reasonable jury to return a verdict for the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The court should view all facts and evidence in the light most favorable to the non-moving party. *United Fire & Cas. Co. v. Hixson Bros. Inc.*, 453 F.3d 283, 285 (5th Cir. 2006). Mere conclusory allegations are insufficient to defeat summary judgment. *Eason v. Thaler*, 73 F.3d 1322, 1325 (5th Cir. 1996).

The movant must point to "portions of 'the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any,' which it believes demonstrate the absence of a genuine issue of material fact." Celotex, 477 U.S. at 323. If and when the movant carries this burden, the non-movant must then go beyond the pleadings and

present other evidence to establish a genuine issue. *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). However, "where the non-movant bears the burden of proof at trial, the movant may merely point to an absence of evidence, thus shifting to the non-movant the burden of demonstrating by competent summary judgment proof that there is an issue of material fact warranting trial." *Lindsey v. Sears Roebuck & Co.*, 16 F.3d 616, 618 (5th Cir. 1994). "This court will not assume in the absence of any proof that the nonmoving party could or would prove the necessary facts, and will grant summary judgment in any case where critical evidence is so weak or tenuous on an essential fact that it could not support a judgment in favor of the [non-movant]." *McCarty v. Hillstone Rest. Grp.*, 864 F.3d 354, 357 (5th Cir. 2017).

A. Defendant's Motion for Summary Judgment

Defendants seek summary judgment on all claims asserting that all of plaintiff's claims fail for lack of causation. Rec. Doc. 122 at 1. Plaintiff cannot survive summary judgment because neither of his experts, Dr. Darren Hurst and Dr. Derek Muehrcke, can connect an alleged defect, negligence, or defendant's conduct to plaintiff's injuries. Rec. Doc. 122-2 at 9. Defendants contend that if the Court grants their motions to exclude or limit opinions of Dr. Hurst and Dr. Muehrcke in their entirety, then the Court should grant summary judgment in their favor for that reason alone.

Rec. Doc. 122-2 at 3. Defendants assert that without these two experts, plaintiff will have no expert who can render an opinion concerning specific causation. *Id.* Even still, defendant argues, neither expert offers the opinion of an allegedly defective condition in the Eclipse® filter that caused plaintiff's injuries. *Id.* A threshold question for the court to answer before considering whether plaintiff can prove causation is whether the court will exclude or limit Dr. Hurst and Dr. Muehrcke's expert opinions.

Defendants argue that Counts IV, VIII, IX, XI, XII, XIII, and XIV and plaintiff's claims for punitive damages fail as a matter of law because these claims are not set forth in the Louisiana Products Liability Act ("LPLA") and the LPLA bars claims based on any theory of liability not set forth within it. Rec. Doc. 122 at 2. Moreover, defendant's argue that plaintiff's manufacturing defect claim must fail because plaintiff has not presented any evidence that his specific IVC filter deviated in a material way from the manufacturer's specifications or performance standards from otherwise identical filters that defendants manufactured at the time the device left defendants' control. *Id.* And defendants contend plaintiffs cannot prove that such a deviation was the proximate cause of his injuries. *Id.*

Louisiana Products Liability Act

The Louisiana Products Liability Act ("LPLA") sets forth the exclusive theories of liability that can be brought against a manufacturer for damage caused by their products. LA. STAT. ANN. § 2800.52 (2020). Circumstances or conduct that will trigger liability of a manufacturer under LPLA constitute fault under LA. CIV. CODE. art. 2315, so that the products action against the manufacturer continues to be in tort. The LPLA provides that a "manufacturer of a product shall be liable to claimant for damage proximately caused by a characteristic of the product that renders the product unreasonably dangerous when such damage arose from a reasonably anticipated use[9] of the product by the claimant or another person or entity." LA. STAT. ANN. § 2800.54 (2020). The LPLA outlines four instances when a product is "unreasonably dangerous" including: (1) in construction or composition, LA. STAT. ANN. § 2800.55; (2) in design, LA. STAT. ANN. § 2800.56; (3) when the manufacturer has not provided an adequate warning about the product, LA. STAT. ANN. § 2800.57; (4) when the product does not conform to an express warranty of the manufacturer about the product, LA. STAT. ANN. § 2800.58.

[9] "Reasonably anticipated use" means a use or handling of a product that the product's manufacturer should reasonably expect of an ordinary person in the same or similar circumstances. La. Stat. Ann. § 2800.53(7) (2020).

To prevail under any theory under the LPLA, plaintiff must establish four elements: (1) defendant manufactured the product at issue; (2) plaintiff's injury was proximately caused by a characteristic of the product; (3) this characteristic made the product unreasonably dangerous; and (4) plaintiff's injury arose from a reasonably anticipated use of the product by plaintiff or someone else. *Stewart v. Capital Safety USA*, 867 F.3d 517, 520 (La. 2017) (citing *Stahl v. Novartis Pharm. Corp.*, 283 F.3d 254, 260-61 (5th Cir. 2002)). A "proximate cause" is generally defined as any cause which, in natural and continuous sequence, unbroken by an efficient, intervening cause, produces the result complained of without which the result would not have occurred. *Marable v. Empire Truck Sales of Louisiana, LLC.*, 221 So. 3d 880, 901 (La. Ct. App. 2017). If there is more than one cause of injury, a defendant's conduct is a cause-in-fact, or proximate cause, if it is a substantial factor generating the plaintiff's harm. *Id.* Under Louisiana law, plaintiff bringing products liability action must prove not only causation-in-fact, but also that product was most probable cause of injury. *Wheat v. Pfizer, Inc.*, 31 F.3d 340, 342 (5th Cir. 1994) (citing *Brown v. Parker-Hannafin Corp.*, 919 F.2d 308, 311 and n.9, 312 (5th Cir. 1990).

Plaintiff withdrew any of his claims that are not cognizable under the LPLA and his claims based on manufacturing defects,

rendering defendants' motion moot on these points. Rec. Doc. 141. At 4. Because plaintiff withdrew[10] these claims, he now asserts only five claims against defendants:

- Count III: Strict Products Liability – Design defect
- Count IV: Negligence – Design
- Count II: Strict Products Liability – Information Defect (failure to warn)
- COUNT VII: Negligence – Failure to Warn
- COUNT X: Breach of Express Warranty

Defendant contends that because such claims must be analyzed under the LPLA, plaintiff actually advances only three claims: design defect, inadequate warning, and breach of express warranty. Rec. Doc. 159-1 at 2. This court agrees.

1. *Design Defect*

Defendants argue that plaintiff cannot prevail on his design defect claims because he has not provided any evidence there was a defect in the design of plaintiff's filter, or the design was unreasonably dangerous, which was the cause of his specific injuries. Rec. Doc. 122-2 at 4. Moreover, Dr. Mena was independently aware of the risks associated with the filter at the time of implant. *Id.* at 5. Further, defendant argues the comment K of § 402(A) of the Restatement (Second) of Torts bars plaintiff's design defect claim based on a strict liability theory. *Id.*

[10] Plaintiff submits that defendants' motions with respect to Counts I, V, VIII, IX, XI, XII, XIII, XIV, and punitive damages are moot.

> A product is unreasonably dangerous in design, if at the time the product left its manufacturer's control: (1) an alternative design for the product that was capable of preventing the claimant's damage existed; and (2) the likelihood that the product's design would cause the claimant's damage and the gravity of that damage outweighed the burden of the manufacturer of adopting such alternative design and the adverse effect, if any, of such alternative design on the utility of the product. An adequate warning about a product shall be considered in evaluating the likelihood of damage when the manufacturer has used reasonable care to provide the adequate warning to users and handlers of the product. LA. STAT. ANN. § 2800.56.
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> A manufacturer of a product shall not be liable for damage proximately caused by a characteristic of the product's design if the manufacturer proves that, at the time the product left his control: (1) he did not know and, in light of then-existing reasonably available scientific and technological knowledge, could not have known of the design characteristics that caused the damage or the danger of such characteristic; or (2) he did not know and, in light of then-existing reasonably available scientific and technological knowledge, could not have known of the alternative design identified by the claimant; or (3) the alternative design identified by the claimant was not feasible, in light of then-existing reasonably available scientific and technological knowledge or then-existing economic practicality. LA. STAT. ANN. § 2800.59(A).

To survive a summary judgment on the claim of defective design, the plaintiff must present competent evidence that would enable a trier of fact to conclude at the time the product left the manufacturer's control 1) there existed an alternative design for the product that was capable of preventing the claimant's damage, and 2) the likelihood that the product's design would cause

the claimant's damage and the gravity of that damage outweighed the burden on the manufacturer of adopting the alternative design and the adverse effect, if any, of the alternative design on the utility of the product. Louisiana law does not allow a fact finder to presume an unreasonably dangerous design solely from the fact that injury occurred. *Ashley v. GMC*, 666 So. 2d 1320, 1320 (La. Ct. App. 1996). Known and disclosed risks associated with a particular medical procedure using a certain product cannot be considered a product defect. *See McMillen v. Danek Medical, Inc.*, No. 95-1796, 1999 WL 1117104, at *2-3 (E.D. La. July 16, 1999).

First, the plaintiff must show that an alternative design existed for the product at the time it left the manufacturer's control, and the alternative design was capable of preventing the plaintiff's damage. *Bernard v. Ferrellgas, Inc.*, 689 So. 2d 554, 558 (La. Ct. App. 1997). If there was no alternative way to make the product safer, the defendant could not have prevented plaintiff's injuries and therefore, the defendant is not liable under a design defect theory.

Louisiana courts have determined whether an alternative design was capable of preventing plaintiff's damage through a cause-in-fact analysis. Courts which have evaluated cause in fact have applied the "but for" and substantial factors test both

alternatively and in combination to determine cause in fact. *Quick v. Murphy Oil Co.*, 643 So. 2d 1291, 1295 (La. Ct. App. 1994). "Conduct is a cause in fact of harm to another if it was a substantial factor in bringing that harm." *Thomas v. Missouri Pacific R.R. Co.*, 466 So. 2d 1280, 1285 (La. 1985). The requirement that an alternative design be capable of preventing the injury essentially asks whether the defendants' design decisions were a substantial factor in bringing about plaintiff's injuries, *i.e.*, whether plaintiff's injuries would have been prevented "but for" defendant's failure to adopt an alternative design.

If an alternative product capable of preventing plaintiff's damages existed, the court must then weigh the utility of the product against the risk of the harm. *Bernard v. Ferrellgas, Inc.*, 689 So. 2d 554, 558 (La. Ct. App. 1997). The first determination to be made is what risk, if any, the product in question created. *Id.* at 560. The court may consider any effect an adequate warning may have had on the likelihood of damages in assessing this risk. *Id.* Then, the court must determine whether a reasonable person would conclude that the danger-in-fact, whether foreseeable or not, outweighs the utility of the product. *Id.* at 561.

Defendants rely on Dr. Muehrcke and Dr. Mena's concession that all IVC filters can fracture, migrate, embolize, and

perforate. Rec. Doc. 122-2 at 18. Therefore, none of these potential complications can be considered a "defect" and no claim for a design defect can survive summary judgment. *Id.* Defendants also assert that plaintiff's expert evidence is unreliable and otherwise incompetent because neither Dr. Hurst nor Dr. Muehrcke are qualified to testify about product design. *Id.* Regardless, plaintiff failed to set forth a single defect that proximately caused any alleged injuries. Rec. Doc. 159-1 at 3.

In response, plaintiff argues that his experts relied on Dr. McMeeking's engineering expertise in opining that the filter was unreasonably dangerous, and the dangers of this filter outweighed any benefits at the time it was implanted in plaintiff. Rec. Doc. 141 at 19. Further, plaintiff's experts identified the Simon Nitinol filter as a safer alternative permanent filter, and the Gunther Tulip filter as a safe alternative retrievable filter. *Id.* at 19-20. Plaintiff argues summary judgment is inappropriate at this time because there is a genuine question as to a material fact of whether the Eclipse was defectively designed and whether a safer alternative design was available.

Plaintiff's arguments are unconvincing. Plaintiff points to two possible things that could possibly be interpreted as a design defect. First, plaintiff points to defendants' design differences between the Eclipse and previous models of IVC filters and assert that "because no other attributes of the filter were changed … design deficiencies represented by tilt, perforation and migration were left unaffected." Rec. Doc. 141 at 19. Yet, plaintiff still does not describe such design deficiencies or provide any evidence that these deficiencies exist and are the cause of the tilt, perforation, migration, etc. As explained, *supra*, just because an injury has occurred (such as a perforation), does not mean that a defect exists.

Next, plaintiff appears to contend that because defendants allegedly did not follow "professional and industry standards in the engineering activities" there was a design defect in the Eclipse filters. Rec. Doc. 141 at 19. Plaintiff confuses design process with a product defect and does not make a causal link that some misstep in not adhering to these standards lead to a defect in the filters.

Finally, plaintiff failed to provide evidence that any "safer alternative" filter like the Simon Nitinol or Gunther Tulip would have prevented plaintiff's injuries. Plaintiff's experts alleged

the Eclipse filter has higher complication rates[11] but having higher complication rates does not negate the fact that these alternative filters still put patients at risk of the same injuries as the Eclipse filter.

Because plaintiffs fail to provide evidence of a design defect or of an alternative filter that could have prevented his injuries, defendants are entitled to summary judgment on plaintiff's design defect claims.

2. *Failure to Warn*

> A product is unreasonably dangerous because an adequate warning about the product has not been provided if, at the time the product left its manufacturer's control, the product possessed a characteristic that may cause damage and the manufacturer failed to use reasonable care to provide an adequate warning of such characteristic and its danger to users and handlers of the product. LA. STAT. ANN. § 2800.57.
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> A manufacturer of a product shall not be liable for damage proximately caused by a characteristic of the product if the manufacturer proves that, at the time the product left his control, he did not know and, in light of then-existing reasonably available scientific and technological knowledge, could not have known of the characteristics that caused the damage or the danger of such characteristic. LA. STAT. ANN. § 2800.59(B).

A manufacturer has a continuing statutory duty to warn of any danger inherent in the normal use of its product which is not

[11] The MDL court prevented Dr. Hurst from opining, inter alia, that Bard filters have higher complication rates that other IVC filters. Rec. Doc. 122-2 at 19.

within the knowledge of an ordinary user. *American Cent. Ins. Co. v. Terex Crane*, 861 So. 2d 228, 231 (La. Ct. App. 2003). An "adequate warning" contains two components: "the warning must both lead the ordinary user or handler to contemplate the danger in using the product" and "to either use it safely or decline to use it." *Stahl v. Novartis Pharmaceuticals Corp.*, 283 F.3d 254, 271 (5th Cir. 2002) (quoting Thomas C. Galligan, Jr., *The Louisiana Products Liability Act: Making Sense of it All*, 49 LA. L. REV. 629, 677 (1989)).

Under Louisiana law, a manufacturer of medical drugs and devices generally has no duty to warn consumers directly of any risks or contraindications associated with its product. *McCarthy v. Danek Medical, Inc.*, 65 F.Supp. 2d 410, 413 (E.D. La. 1999) (citing *Mikell v. Hoffman-LaRoche, Inc.*, 649 So. 2d 75, 80 (La. Ct. App. 1994)). Under the "learned intermediary doctrine," the doctor acts as an informed intermediary between the drug company and the patient, and thus, a drug manufacturer has a duty to warn the prescribing doctor, rather than the patient, of potential risks associated with the use of the drug. *Brown v. Glaxo, Inc.*, 790 So. 2d 35, 38 (La. Ct. App. 2000). The drug manufacturer's duty to warn the prescribing doctor under the learned intermediary doctrine is fulfilled when the prescribing doctor is informed of the potential risks from the drug's reasonably anticipated use so

that the physician may intelligently decide on its use with the particular patient, and the doctor must then advise the patient accordingly. *Id.* (citing *Mikell v. Hoffman-LaRoche, Inc.*, 649 So. 2d 75, 79-80 (La. Ct. App. 1994)). To recover for a failure to warn under this doctrine, a plaintiff must show (1) that the defendant failed to warn the physician of a risk associated with the use of product, not otherwise known to the physician, and (2) that the failure to warn the physician was both a cause in fact and the proximate cause of the plaintiff's injury. *Willett v. Baxter Intern., Inc.*, 929 F.2d 1094, 1098 (5th Cir. 1991). Because the defective aspect of the product must cause the injury, the plaintiff must show that a proper warning would have changed the decision of the treating physician, *i.e.*, that "but for" the inadequate warning, the treating physician would not have used or prescribed the product. *Id.* at 1098-99.

A "mere allegation of inadequacy" is insufficient for a plaintiff to survive summary judgment on a failure-to-warn claim. *Anderson v. McNeilab, Inc.*, 831 F.2d 92, 93 (5th Cir. 1987). Plaintiff must go beyond the pleadings and designate specific facts in the record showing that there is a genuine issue for trial to defeat summary judgment.

The Fifth Circuit has held that a warning is not adequate as a matter of law simply because the warning contained a clear and unambiguous reference to the injury plaintiff suffered. *Stahl*, 283 F.3d at 267. For summary judgment of an inadequate warning claim to be appropriate, the plaintiff's physician must also unequivocally testify that the warning was adequate to inform her of the risks involved in prescribing the drug. *Id.* Under Louisiana's learned intermediary doctrine, the treating physician's knowledge is the focus of the inquiry. "The doctor's testimony provides added assurance that the language in the package insert was worded strongly enough to adequately inform him or her of the actual level of risk involved." *Id.* When a particular adverse effect is clearly and unambiguously mentioned in a warning label and the prescribing physician unequivocally states she was adequately informed of that risk by the warning, the manufacturer has satisfied its duty to warn under the learned intermediary doctrine.

Defendants argue that plaintiff's failure to warn claim fails because the content of the IFU was not the proximate cause of plaintiff's injuries. Rec. Doc. 122-2 at 15. Defendants contend because Dr. Mena does not recall reading the IFU, the learned intermediary doctrine requires summary judgment for the manufacturer. *Id.* (citing *Pustejovsky v. Pliva, Inc.*, 623, F. 3d

271, 277 (5th Cir. 2010) (holding plaintiff failed to produce sufficient evidence showing manufacturer's inadequate warning was the producing cause when the prescribing physician testified she did not recall reading the label)). Moreover, Dr. Mena would not have changed his prescribing decision with any other warning. *Id.* Defendant points to the life-and-death situation plaintiff faced as the reason Dr. Mena made the medical decision to implant the filter and the Eclipse was the only type of filter the hospital had. Rec. Doc. 122-2 at 16.

In response, plaintiff argues that defendants had multiple avenues to warn Dr. Mena—aside from the IFU—including the sales representatives visiting the hospital and the letters Bard wrote to doctors about their filters. Rec. Doc. 186 at 24. Plaintiff vigorously argues that the Eclipse filter had significantly higher rates of fracture, migration, and perforation, than other filters and these "non-obvious risks" of injury were not disclosed in defendants' warnings. *Id.* 25-26. Moreover, defendants conducted the studies and analyses themselves and the risk of failure was statistically significantly higher. *Id.* at 26. Dr. Mena testified that had he been provided with this information, he would have gone to the hospital to get a different filter to use. *Id.* at 33.

Because a manufacturer's duty to warn is a continuing one, a genuine issue of material fact exists whether the increased rate of failure of the Eclipse filter rendered defendants' warnings inadequate. Therefore, summary judgment is inappropriate at this time and this question should be left for the jury to decide.

3. *Breach of Express Warranty*

> A product is unreasonably dangerous when it does not conform to an express warranty made at any time by the manufacturer about the product if the express warranty has induced the claimant or another person or entity to use the product and the claimant's damage was proximately caused because the express warranty was untrue. LA. STAT. ANN. § 2800.58.

To survive summary judgment on an express warranty claim under LPLA, plaintiff is required to demonstrate or provide evidence to create genuine issue of material fact regarding whether (1) manufacturer made an express warranty regarding the product, (2) plaintiff was induced to use the product because of that warranty, (3) the product failed to conform to that express warranty, and (4) plaintiff's damages were proximately caused because the express warranty was untrue. *Broussard v. Procter & Gamble Co.*, 463 F. Supp. 2d 596 (W.D. La. 2006). It is not necessary for a plaintiff to cite to a specific express warranty in order to state claim for breach of express warranty under LPLA, but he must make more than a general reference to them. *Baudin v. AstraZeneca Pharms. LP*, 413 F.Supp. 3d 498, 511 (W.D. La. 2017).

Plaintiff points to multiple statements within the IFU but does not provide evidence that such statements ever induced Dr. Mena, him, or his wife to use the Eclipse filter. In fact, Dr. Mena testified that the only factor causing him to use the specific filter was the fact that it was the only IVC filter the hospital had available. Rec. Doc. 159-1 at 9. Therefore, plaintiff's breach of express warranty claim must fail.

B. Plaintiff's Motion for Partial Summary Judgment

Plaintiff moves this court for partial summary judgment on six of defendants' affirmative defenses: (1) sole proximate cause; (2) assumption of the risk; (3) failure to mitigate; (4) contributory negligence and/or comparative fault of plaintiff; (5) comparative fault of non-parties; and (6) superseding and/or intervening causes. Rec. Doc. 102 at 1. For the following reasons, this court finds summary judgment inappropriate at this time.

Under Louisiana law, a tort victim has an affirmative duty to make every reasonable effort to mitigate his or her damages. *Campbell v. Robinson*, 10 So. 3d 346, 349 (La. Ct. App. 2009) (citing to La. Civ. Code art. 2002); *MB Industries, LLC v. CNA Insurance Co.*, 74 So. 3d 1173, 1181 (La. 2011). This duty to mitigate requires that the plaintiff take reasonable steps to

minimize the consequences of his injuries. *Id.* A patient may breach their duty to mitigate by failing to follow reasonable orders from their physician. *Bacle v. Wade*, 607 So. 2d 927, 935 (La. Ct. App. 1992). Plaintiff argues that the record shows he routinely sought medical care for the medical conditions he experienced and there is no evidence that anything he did or failed to do caused his injuries. Rec. Doc. 102-1 at 4. But plaintiff did not seek medical treatment related to his Filter for five years following implantation. Even after the fractured strut was identified through CT imaging, Plaintiff disregarded his treating physician's advice to schedule a subsequent CT scan in three months and did not schedule another imaging study until three years later. Further, on December 19, 2019, Plaintiff's treating physician recommended Plaintiff schedule further follow-up imaging in six months. To date, Plaintiff still has not scheduled any follow-up imaging despite his physician's recommendation fifteen months ago, and his bringing these claims.

Under Louisiana law, assumption of risk as an affirmative defense is subsumed into Louisiana's comparative negligence regime. *Murray v. Ramada Inns, Inc.*, 521 So. 2d 1123, 1132- 33 (La. 1988) ; La. Civ. Code art. 2323 (applying comparative negligence "to any claim for recovery of damages for injury,

death, or loss asserted under any law or legal doctrine or theory of liability, regardless of the basis of liability."). Assumption of the risk looks at Plaintiff's conduct and is "in reality a form of contributory negligence." *Murray*, 521 So. 2d at 1125. The fact that a plaintiff was aware of the risk(s) is a factor to be considered in assessing percentages of fault. Id. at 1134.

Plaintiff, through his wife, provided all appropriate consent to the implant of an inferior vena cava filter following a discussion with Dr. Mena about the risks of the procedure. The consent specifically acknowledged Dr. Mena informed Plaintiff of "the risks of the proposed treatment/surgery" as well as the "risks of no treatment." Plaintiff accepted these risks by choosing to go forward with the Filter procedure.

Moreover, Plaintiff's continued failure to abide by his treating physician's recommendations to undergo imaging studies, as well as his failure to seek medical treatment for his alleged anxiety and heart palpitations—the injuries alleged to be attributable to the Filter—prevented Plaintiff from discovering the condition of the Filter earlier in time and from receiving medical care for the injuries he alleges to have suffered in this case.

In product liability cases, a plaintiff must bring forth clear and definite proof establishing the cause of his injury. *Todd v. State Through Dep't of Soc. Servs.*, 699 So. 2d 35, 43 (La. 1997). Mere possibilities and speculation are insufficient to prove causation to a reasonable degree of medical probability. *Richard v. Artigue*, 87 So. 3d 997, 1005 (La. Ct. App. 2012). Where there is more than one possible cause to a plaintiff's alleged injuries, a defendant is permitted to present evidence as to any potential alternative and/or intervening causes. In a product liability case with a failure to warn claim at issue, the learned intermediary doctrine applies, and a plaintiff must prove that the defendant failed to warn (or inadequately warned) the physician of a risk associated with the product that was not otherwise known to the physician, and this failure to warn the physician was the proximate cause of the plaintiff's injuries. *Stahl*, 283 F. 3d at 265-266. To prove a design defect, a plaintiff must show that his injury was proximately caused by a characteristic of the product that renders the product unreasonably dangerous in design. Id. at 261. And any alleged alternative intervening causes that break the chain of causation are relevant and admissible to Plaintiff's claims, whether they be for alleged defect or alleged failure to warn.

Bard's expert Dr. Sarac opines that "it is more likely than not that the implant procedure was not performed within the standard of care and in accordance with the IFU for the Eclipse device and was the cause of any resultant complication." Dr. Sarac further explains that "[d]espite Dr. Mena's incorrect implantation, the medical records reveal that no efforts were made at the time of the procedure to rectify this by removing the Filter and placing another one." Plaintiff's own case-specific experts agree that Dr. Mena improperly placed the filter, which increased the risk of complications.

Under Louisiana law, a superseding intervening cause exonerates a defendant in a products liability or negligence action—whether the action is based on allegations of design defect or failure to warn. *See Guille v. Comprehensive Addiction Programs, Inc.*, 735 So. 2d 775, 778 (La. Ct. App. 1999). A proximate cause is any cause, which in natural and continuous sequence is unbroken by any intervening cause. *Hutto v. McNeil-PPC, Inc.*, 79 So. 3d 1199, 1213 (La. Ct. App. 2011). Dr. Sarac opined to a reasonable degree of medical probability and/or certainty that the improper placement of the Filter was not performed within the standard of care and "was the cause of any resultant complication."

Under Louisiana's comparative fault regime, a plaintiff's recovery is reduced in accordance with the degree of negligence is attributable to the person suffering the injury. La. Civ. Code art. 2323(A). "Louisiana state courts and federal courts have routinely held that pure comparative fault applies to LPLA cases". *Allen v. C & H Distribs., LLC*, 2013 WL 4506233, at *3 (W.D. La. Aug. 22, 2013) (citations omitted).

Dr. Mena conceded he did not follow the IFU in several material ways. Dr. Mena conceded that he did not measure Plaintiff's inferior vena cava prior to implanting the Filter. SOMF at ¶36. Plaintiff's expert, Dr. Hurst, opined that the Filter should not be deployed unless the IVC has been properly measured. Id. at ¶72. Dr. Mena conceded at his deposition that he could not remember the amount of pressure that was used when injecting the contract medium through the dilator and thus could not confirm if it was more or less than 800 psi. Dr. Mena did not see Plaintiff for any follow-up after the implantation and conceded he, therefore, could not have had a discussion with the Plaintiff about potential removal of the filter.

III. CONCLUSION

IT IS ORDERED that defendants' motion for summary judgment is **GRANTED IN PART** and **DENIED IN PART.** All claims against

defendants, except the claim for failure to warn, are hereby **DISMISSED.**

IT IS FURTHER ORDERED that plaintiff's motion for partial summary judgment on affirmative defenses is **DENIED.**

New Orleans, Louisiana this 8th day of July, 2021

SENIOR UNITED STATES DISTRICT JUDGE