IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

LEONARDO GOMEZ,	§	
	§	
Plaintiff,	§	
	§	
v.	§	CIVIL ACTION NO. H-19-3852
	§	
ALN INTERNATIONAL, INC and	§	
ALN IMPLANTS CHIRURGICAUX,	§	
	§	
Defendants.	§	

MEMORANDUM AND OPINION

The late Leonardo Gomez brought this action to recover for injuries allegedly caused by a retrievable inferior vena cava (IVC) filter manufactured by ALN International, Inc. and ALN Implants Chirurgicaux.[1] Gomez's amended complaint brought thirteen claims based on Texas common law and the Texas Deceptive Trade Practices Act. (Docket Entry No. 19). The court previously dismissed ALN Implants for lack of personal jurisdiction and several claims of the amended complaint for failure to state a claim. (Docket Entry No. 38). The court allowed Gomez's claims for failure to warn, design defect, negligent design, negligent failure to warn, negligent misrepresentation, and violations of the Texas Deceptive Trade Practices Act (counts II, III, IV, VII, VIII, and XIII) to proceed. (*Id.*). The remaining defendant, ALN International, now moves for summary judgment on all of Gomez's remaining claims. After considering the parties' briefing, the record, and the relevant law, the court grants the motion for the following reasons.

[1] After Gomez's passing, his sister, Esperanza Gomez Gutierrez, was substituted as the plaintiff. (Docket Entry No. 44). The court refers to Mr. Gomez as the plaintiff for convenience and because it reflects the case caption.

I. Background

A. Factual and Procedural Background

This case involves a retrievable vena cava filter, a device designed to filter out blood clots that would otherwise travel from the lower body to the heart and lungs, where they may carry fatal consequences. Retrievable filters differ from permanent IVC filters because they may be removed from the body, making them suitable for temporary, prophylactic use. (Docket Entry No. 21 ¶¶ 24–25, 29). The FDA cleared ALN's filter in January 2008 through the 510(k) fast-track process, which permits approval without additional clinical or laboratory studies for devices that are "substantially equivalent" to another device already on the market. (*Id.* ¶¶ 29–30). The ALN filters were granted 510(k) approval on the basis that they were substantially similar to certain approved permanent filters. (*Id.*).

In February 2017, Dr. Polina Kyriakides implanted ALN's retrievable IVC filter into Gomez. (*Id.* ¶ 39). Gomez presented with a pulmonary embolism, placing him at risk of heart failure. (Docket Entry No. 55-1 at 12:20–13–8). Although treatment with anticoagulation medications, commonly referred to as blood thinners, are preferable, Dr. Rana Afifi testified that an IVC filter is "usually second best to an anticoagulation if you want to prevent pulmonary emboli if you can't get the anticoagulation.". (Docket Entry No. 55-1 at 52:1–14). Gomez had a preexisting condition, a subdural hematoma, that meant he could not take blood thinners. (Docket Entry No. 49-1 at 27:16–20).

The procedure to implant Gomez with an IVC filter was conducted as part of a study led by Dr. Alan Cohen. In June 2017, Gomez's physicians learned that one of the filter's struts was penetrating Gomez's vena cava wall. (Docket Entry No. 49-2 at 63:7–20). The filter was nonetheless still functioning as intended, and Gomez's physicians apparently made the decision

to not remove it at that time because they were concentrating on his other medical issues. (*Id.* at 63:21–64:14).

In February or March 2017, Gomez's sister, Esperanza Gutierrez, obtained power of attorney over her brother's care. (Docket Entry No. 55-6 at 24:8–25). Gutierrez had signed the consent form regarding Dr. Cohen's study, either immediately prior to or after obtaining power of attorney, because her brother was "basically in a coma" at that time. (*Id.* at 28:6–12). In October 2017, Gomez was again hospitalized. Dr. Cohen testified that his medical records indicated that this hospitalization was for pain related to kidney stones. (Docket Entry No. 49-2 at 140:15–24). Dr. Cohen testified that Gomez no longer suffered from the condition for which the filter was implanted. (*Id.* at 117:23–118:2). During that hospital stay, the filter, which was still penetrating the vena cava wall, was removed by Dr. Afifi. (Docket Entry No. 50-1 at 35–37). Mr. Gomez's pain and other symptoms persisted after the removal of the filter. (Docket Entry No. 55-6 at 57:11–16).

In October 2019, Gomez brought this suit. (Docket Entry No. 1). The court granted ALN's motion to dismiss two counts of the original complaint and granted Gomez leave to amend. (Docket Entry No. 19). Gomez filed an amended complaint in March 2020. (Docket Entry No. 21). The court granted in part the defendants' motion to dismiss the amended complaint, finding that it lacked personal jurisdiction over ALN Implants and that Gomez failed to state a claim with respect to his manufacturing defect, negligent manufacturing, negligent failure to recall, breach of warranty, and fraud claims. (Docket Entry No. 38 at 18). The court denied Gomez leave to amend those claims. (*Id.*).

B. The Summary Judgment Record

ALN International appends the following evidence to the declaration of John E. Spalding, done in support of its motion for summary judgment:

1. Deposition Transcript of Rana O. Afifi, M.D., dated December 6, 2021 (excerpts). (Docket Entry No. 49-1).

2. Deposition Transcript of Alan M. Cohen, M.D., dated May 12, 2022 (excerpts). (Docket Entry No. 49-2).

3. Certain of Gomez's medical records (filed under seal). (Docket Entry Nos. 50-1).

4. Gomez's informed consent forms and the protocol for the study in which he participated (filed under seal). (Docket Entry No. 50-2).

5. Instructions for Use of the ALN Vena Cava Filter with Hook (Femoral Route). (Docket Entry No. 49-5).

ALN also submits a demonstrative comparing allegations in the complaint to various documentary evidence. (Docket Entry No. 49-6).

In opposition, Gomez submits the following:

1. Deposition Transcript of Rana O. Afifi, M.D., dated December 6, 2021 (complete). (Docket Entry No. 55-1).

2. The discharge summary for Gomez following the removal of the filter, prepared by Dr. Jacqueline Okere. (Docket Entry No. 55-2).

3. Tina R. Desai et al., *Complications of Indwelling Receivable versus Permanent Inferior Vena Cava Filters*, 2 J. OF VASCULAR SURGERY 166 (2014). (Docket Entry No. 55-3).

4. Simer Grewal et al., *Complications of Inferior Vena Cava Filters*, 6 CARDIOVASCULAR DIAGNOSIS & THERAPY 632 (2016). (Docket Entry No. 55-4).

5. U.S. Food & Drug Admin., Removing Retrievable Inferior Vena Cava Filters: FDA Safety Communication (May 6, 2014). (Docket Entry No. 55-5).

6. Deposition Transcript of Esperanza Gomez Gutierrez, dated May 2, 2022 (complete). (Docket Entry No. 55-6).

II. The Legal Standard for Summary Judgment

"Summary judgment is appropriate only if there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." *Vann v. City of Southaven*, 884

F.3d 307, 309 (5th Cir. 2018) (per curiam) (quotation marks omitted); FED. R. CIV. P. 56(a). "A genuine dispute of material fact exists if a reasonable jury could enter a verdict for the non-moving party." *Doe v. Edgewood Indep. Sch. Dist.*, 964 F.3d 351, 358 (5th Cir. 2020). The moving party "bears the initial responsibility of . . . demonstrat[ing] the absence of a genuine issue of material fact," *Jones v. United States*, 936 F.3d 318, 321 (5th Cir. 2019) (citation and quotation marks omitted), and "identifying those portions of [the record] which it believes demonstrate the absence of a genuine issue of material fact," *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986).

"Where the nonmovant 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." *Lyons v. Katy Indep. Sch. Dist.*, 964 F.3d 298, 301–302 (5th Cir. 2020) (citation and quotation marks omitted). While the party moving for summary judgment must demonstrate the absence of a genuine and material factual dispute, it does not need to negate the elements of the nonmovant's case. *Austin v. Kroger Tex., L.P.*, 864 F.3d 326, 335 (5th Cir. 2017) (per curiam) (quoting *Little v. Liquid Air Corp.*, 37 F.3d 1069, 1076 n.16 (5th Cir. 1994) (per curiam)). "A fact is material if its resolution could affect the outcome of the action." *Dyer v. Houston*, 964 F.3d 374, 379 (5th Cir. 2020) (citation and quotation marks omitted). "If the moving party fails to meet [its] initial burden, the motion [for summary judgment] must be denied, regardless of the nonmovant's response." *Pioneer Expl., L.L.C. v. Steadfast Ins. Co.*, 767 F.3d 503, 511 (5th Cir. 2014) (citation and quotation marks omitted).

When the moving party has met its burden, "the nonmoving party cannot survive a summary judgment motion by resting on the mere allegations of its pleadings." *Duffie v. United*

States, 600 F.3d 362, 371 (5th Cir. 2010). The nonmovant must identify specific evidence in the record and articulate how that evidence supports that party's claim. *Willis v. Cleco Corp.*, 749 F.3d 314, 317 (5th Cir. 2014). "This burden will not be satisfied by some metaphysical doubt as to the material facts, by conclusory allegations, by unsubstantiated assertions, or by only a scintilla of evidence." *Boudreaux v. Swift Transp. Co., Inc.*, 402 F.3d 536, 540 (5th Cir. 2005) (citation and quotation marks omitted). In deciding a summary judgment motion, the court draws all reasonable inferences in the light most favorable to the nonmoving party. *Darden v. City of Fort Worth*, 880 F.3d 722, 727 (5th Cir. 2018).

III. Analysis

A. All Counts: Proximate Cause

ALN argues that all of Gomez's remaining claims fail because Gomez is unable to show a dispute of material fact as to whether the ALN filter caused his injuries.

Proof of causation is required for all of Gomez's claims. *See Guijarro v. Enter. Holdings, Inc*., 39 F.4th 309, 318 (5th Cir. 2022) (A plaintiff must show with "'competent expert testimony and objective proof' that the alleged product defect caused their injuries." (quoting *Nissan Motor Co. Ltd. v. Armstrong*, 145 S.W.3d 131, 137 (Tex. 2004)); *Hale v. Metrex Research Corp*., 963 F.3d 424, 428 (5th Cir. 2020) ("[T]he plaintiff must show . . . th[e] failure to warn was the producing cause of the plaintiff's injury."); *Meador v. Apple, Inc.*, 911 F.3d 260, 264 (5th Cir. 2018) (causation in the products liability context required as in a claim for negligence); ("in a design-defect context, holding that the court "we have consistently required competent expert testimony and objective proof that a defect caused the [alleged defect]"); *Smith v. Robin America, Inc.*, 484 F. App'x 908, 912 (5th Cir. 2012) (citations omitted) (finding that a "plaintiff bears the burden of proving" causality as an element to a products liability claim); *Doe v. Boys Clubs of Greater Dallas, Inc*., 907 S.W.2d 472, 477 (Tex. 1995) ("[S]ummary judgment

on the plaintiffs' negligence and DTPA claims was proper for want of evidence on the common element of actual causation.").

A plaintiff must show causation as cause in fact and foreseeability. A plaintiff shows cause in fact by demonstrating that the instrument of injury was a substantial factor in producing the injury, and by demonstrating that the instrument was the but-for cause of the injury. *Boys Club of Greater Dallas*, 907 S.W.2d at 477.

Under Texas law, a plaintiff must come forward with sufficient expert testimony to establish causation when the common understanding of a layperson would be insufficient to determine the causal relationship between the source of the injury and the injury itself, including in medical contexts. *Smith v. Chrysler Group, LLC*, 909 F.3d 744, 751 (5th Cir. 2018) ("Under Texas law, expert testimony is 'required when an issue involves matters beyond jurors' common understanding.'" (quoting *Mack Trucks, Inc. v. Tamez*, 206 S.W.3d 572, 583 (Tex. 2006))); *see also Guevara v. Ferrer*, 247 S.W.3d 662, 665 (Tex. 2007) ("The general rule has long been that expert testimony is necessary to establish causation as to medical conditions outside the common knowledge and experience of jurors."); *Emerson v. Johnson & Johnson*, No. 17-cv-2708, 2019 WL 764660, at *3 (S.D. Tex. Jan. 22, 2019) (requiring expert testimony on causation in the medical products-liability context). ALN argues that establishing a relationship between any failure of the filter—a prescription, surgically implanted medical device—and Gomez's injury requires such testimony (Docket Entry No. 49 at 9), which Gomez does not dispute.

In support of its argument that there is no expert testimony available to establish causation, ALN points to the testimony of Dr. Cohen, who reviewed Gomez's medical records and supervised the study in which he took part, and Dr. Afifi, who surgically removed the ALN

filter.[2] (Docket Entry No. 49 at 9–10). Both doctors stated that they believed the filter was medically indicated to treat Gomez's condition. (Docket Entry No. 49-2 at 27:10–23, 74:8–11; Docket Entry No. 55-1 at 46:12–19, 52:1–14). Dr. Afifi's testified that there were no complications after she removed the filter, (Docket Entry No. 55-1 at 47:9–14), and Gomez's medical records do not indicate any issues with removal. (Docket Entry No. 50-1 at 37).

Dr. Cohen testified that Gomez was "extremely sick" and presented with an extensive medical history and various conditions, including a previous aorta repair, Marfan syndrome, esophageal perforation, hepatitis B, asthma, pulmonary embolism, subdural hematoma, intra-abdominal abscesses, and pancreatitis. (Docket Entry No. 49-2 at 50:10–20). Gomez's sister, Esperanza Gutierrez, testified that, during the relevant period, her brother was either in the hospital or living at her home "because he had no . . . ability . . . to tak[e] care of himself." (Docket Entry No. 55-6 at 19:13–25). The filter addressed only "one potential problem"—albeit a potentially fatal one—the pulmonary embolism. (Docket Entry No. 49-2 at 50:6–8). Dr. Cohen testified that some of the other conditions could have cause the abdominal pain of which Gomez complained. (*Id.* 50:17–18). Gomez does not argue, and there is no evidence to support, a relationship between the implementation of the filter and the presence or absence of Gomez's other medical conditions.

Gomez learned that the filter was penetrating the vena-cava wall in June 2017 and was again hospitalized in October that same year. (Docket Entry No. 49-2 at 63:11–63, 140:15–24). Although the filter's penetration was noted upon Gomez's admission to the hospital, Dr. Cohen testified that he believed the condition of the filter was unrelated to the hospitalization. (*Id.* at

[2] The parties have not provided any testimony from Dr. Kyriakides, who implanted the filter.

141:4–8). With respect to this hospitalization, counsel for Gomez asked Dr. Afifi whether the filter caused Gomez's pain, to which she responded:

> It's hard to tell but . . . usually the vomiting, nausea and . . . the fact that [the pain] was specifically to the left flank pain, which is the furthest away from where the IVC filter which is usually IVC on the right, again, I would . . . have a higher suspicion with his background for a different reason, but I can't rule out that it wasn't related to it.

(Docket Entry 55-1 at 47:17—24).

Gomez contends that the doctors' testimony does not preclude, as a matter of law, the finding that the ALN filter caused Gomez's injury. The filter, acknowledged Dr. Afifi, was removed after a CT scan revealed penetration by its struts. (*Id.* at 47:10–14). Gomez contends that, because the evidence establishes that the filter was penetrating the vena cava when Gomez complained of the pain for which he seeks recovery, a jury could find that the penetration and erosion of the filter—not any preexisting condition—caused Gomez's injury. (Docket Entry No. 55 at 5).

Evaluating the evidence in the light most favorable to Gomez, the court finds that there is no genuine dispute of material fact over whether the ALN filter caused Gomez's injury. The question before the court is not whether the filter's performance was without issue, or whether there is any possibility that the filter's condition caused Gomez pain. The relevant question is whether a reasonable juror could conclude that there is a preponderance of evidence that the ALN filter caused the injuries for which Gomez seeks recovery. *In re Taxotere (Docetaxel) Products Liab. Litig.*, 994 F.3d 704, 710 (5th Cir. 2021) ("The 'judge's inquiry, [at the summary judgment stage] . . . unavoidably asks whether reasonable jurors could find by a preponderance of the evidence that the plaintiff is entitled to a verdict." (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252 (1986))).

The testimony offered by Dr. Afifi, on whom Gomez principally relies, is too equivocal to create a genuine factual dispute regarding causation. Gomez points to her testimony detailing the complications that might have resulted from an IVC filter "ero[ding] and perforat[ing]" adjacent structures in the body, had the filter not been removed.

> Q: [W]hat would have been the risks to Mr. Gomez if he had not undergone removal?
>
> A: It's hard to tell. It's hard to tell if it would have increased or go further in *or cause bleeding or cause infection* or if it would have stayed the same. It's very difficult to say. It might have fractured. But usually I would just even for the smallest risk, I wouldn't recommend to leave it so we don't take a risk for any further complication.

(Docket Entry No. 55 at 6 (quoting Docket Entry No. 55-1 at 29:14–22)). Gomez argues that this testimony indicates that he "was experiencing complications because of the IVC filter which necessitated in the removal of the device." (*Id.* at 7). This is a mistaken reading of Dr. Afifi's testimony. Dr. Afifi identifies potential "further complication[s]" caused by the filter that did not, in fact, come to pass, because the filter was removed. Dr. Afifi also pointed to potential complications that might occur if a filter could not be removed but through "open surgery," (Docket Entry No. 55-1 at 25:21–26:5), but Gomez's filter was removed through expected, less invasive, means. There is no evidence creating a fact dispute as to whether the removal itself injured Gomez; it went as planned. Dr. Afifi was unable to determine with any level of certainty whether the filter caused the injury complained of while it was implanted in Gomez. In short, that Dr. Afifi "can't rule out" the filter as a cause of pain to Gomez is an insufficient basis on which a jury could find ALN liable.

A jury could likewise not conclude by a preponderance of the evidence that Gomez suffered a surgical procedure that would not have occurred but-for the filter's condition. Gomez's best evidence is testimony from Dr. Afifi stating that the cause of the removal "was the

penetration and erosion." (*Id.* at 65:14–18). The court considers that statement in light of Dr. Afifi's other testimony establishing that, once the filter is no longer required, "that by itself is also an indication to recommend removing it." (Docket Entry No. 51-1 at 27:8–18). Gomez presents no evidence to contradict Dr. Cohen's testimony that, when the filter was removed, he no longer suffered from the condition that the filter was implanted to treat. Once the condition is gone, Dr. Cohen testified that "you pull [the filter] out so it doesn't break." (Docket Entry No. 49-2 at 72:1–3). There is no dispute of material fact from which a jury could conclude by a preponderance of the evidence that the condition of the filter, rather than the absence of that condition, caused the filter to be removed and thereby caused injury in the form of a procedure that Gomez would not have otherwise endured.

The court grants the motion for summary judgment on all remaining counts because Gomez cannot demonstrate a dispute of material fact regarding the cause of his alleged injuries.

B. Count II, VII, VIII, and XIII: Failure to Warn

Besides the lack of a fact dispute regarding proximate causation, there are additional reasons to grant the motion with respect to the Counts II, VII, VIII, and XIII: failure to warn (as such), negligent failure to warn, negligent misrepresentation, and violations of the Texas Deceptive Trade Practices Act involving representations made by ALN. As the court previously concluded, these counts are all analyzed under a failure-to-warn framework, because they all involve ALN's alleged misrepresentations or omissions regarding the risks inherent in the IVC filter at issue. (Docket Entry No. 38 at 12–13 (citing *Ebel v. Eli Lilly & Co.*, 536 F. Supp. 2d 767, 733 (S.D. Tex. 2008), *aff'd*, 321 F. App'x 350 (5th Cir. 2009); *In re Norplant Contraceptive Prods. Liab. Litig.*, 955 F. Supp. 700, 710 (E.D. Tex. 1997), *aff'd*, 165 F.3d 374 (5th Cir. 1999))).

Under Texas law, to establish liability under a failure-to-warn theory, "the plaintiff must [1] show that the warning was defective and that [2] this failure to warn was the producing cause of the plaintiff's injury." *Hale v. Metrex Research Corp*., 963 F.3d 424, 428 (5th Cir. 2020). "Generally, the adequacy of a warning is a question of fact." *Id.* (alterations, quotation marks, and citation omitted). "However, if a warning specifically mentions the circumstances complained of, then the warning is adequate as a matter of law." *Id.* (quoting *Seifried v. Hygenic Corp*., 410 S.W.3d 427, 433 (Tex. App.—Houston [1st Dist.] 2013, no pet.) (citing *Rolen v. Burroughs Wellcome Co*., 856 S.W.2d 607, 609 (Tex. App.—Waco 1993, writ denied)).

Medical products-liability actions are subject to the "learned intermediary" doctrine, in which "the manufacturer . . . satisfies its duty to warn the end user of its product's potential risks by providing an adequate warning to a 'learned intermediary,' who then assumes the duty to pass on the necessary warnings to the end user." *In re DePuy Orthopaedics, Inc., Pinnacle Hip Implant Prod. Liab. Litig*., 888 F.3d 753, 774 (5th Cir. 2018) (quoting *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 142 (Tex. 2012)). The parties agree that the doctrine applies. (Docket Entry No. 49 at 11–12; Docket Entry No. 55 at 7–11). The consequence for Gomez is that he must show that, "but for the inadequate warning, [his] doctors would have recommended different treatment or provided additional warnings that would have led [him] to withhold consent." *In re DePuy Orthopaedics*, 888 F.3d at 774 (citations omitted). If ALN's warnings were adequate, Gomez's claims fail. If the warnings were inadequate, Gomez must still then show that adequate warnings would have led to a recommendation for different treatment or that he would have withheld consent on the basis of further warnings from his doctors.

ALN argues that the warnings in the device's IFU were adequate because they "would have accurately informed a reasonable prudent physician of the risks associated with the Filter."

(Docket Entry No. 15 at 15). Among other things, the IFU warns that "[c]linical complications may include . . . [p]erforation of the vena cava, vessels, or an adjacent organ by one or more hooks." (Docket Entry No. 49-5 at 10).

Gomez does not dispute that his treating physicians reviewed the IFU but argues that the IFU is misleading and incomplete in light of subsequent medical studies. (Docket Entry No. 55 at 10). Specifically, he points to studies suggesting that retrievable filters like the one at issue have a higher rate of complications than permanent IVC filters. (*Id.*). ALN did not provide adverse event reports in its IFU or to the treating physicians. (*Id.*). And the IFU did not address the 2014 FDA communication stating that "some complications may be avoided if the filter can be removed once the risk of pulmonary embolism has subsided." (Docket Entry No. 55-5 at 2). Gomez points to testimony from Dr. Afifi in which she states that she would "like to know about the devices" and that she would want to know about adverse events related to the ALN filters. (Docket Entry No. 55-1 at 67:15–24).

The parties point to no authorities regarding the relevance of relative complication rates of products or the lack of reportage of adverse events to a duty-to-warn claim involving IVC filters or other medical devices. District-court decisions in other jurisdictions provide some guidance. In *Milton v. C.R. Bard, Inc.*, the court found that testimony from a doctor indicating that, were she to have known that the filter in question "migrate[d] or tilt[ed] at a rate four to five times higher than [other filters], she would not have implanted [the patient] with the [filter.]" No. 14-cv-00351, 2021 WL 2483143, at *5 (M.D. Ga. June 17, 2021). In that case, the plaintiff presented evidence that the filter had "a complication rate 14 times higher" than a comparable filter. *Id.* Gomez has not presented testimony from any doctor claiming that, had they known of the information to which Gomez points, they would not have implanted the filter. And a Florida

district court stated that the absence of comparative failure rates in an IFU would not defeat a motion for summary judgment in the absence of qualified expert testimony stating that the warning was not adequate. *Ocasio v. C.R. Bard, Inc*., No. 13-cv-1962, 2015 WL 3496062, at *5 (M.D. Fla. June 3, 2015).

In the absence of competent testimony regarding the adequacy of the warning, the court agrees with ALN that the warnings provided in the filter's IFU were adequate as a matter of law because they described the "circumstances complained of," *Hale*, 963 F.3d at 428, that is, the perforation of the vena cava wall. The study referenced by Gomez indicating that retrievable filters had higher complication rates than permanent filters does not change the analysis.[3] Dr. Afifi suggested that one article proves little in assessing a particular medical device. (Docket Entry No. 55-1 at 31:11–32:5). The court is not positioned to assess independently the salience to medical professionals of one study regarding the relative rates of failure between retrievable and permanent IVC filters.

Gomez points to authority from West Virginia district courts, ruling on Florida and Mississippi law, suggesting that "qualifying language" in an IFU that "minimizes the presented risks and renders the entire [I]FU inadequate" supports denial of summary judgment. *Eghnayem v. Boston Sci. Corp.*, No. 13-cv-07965, 2014 WL 5460605, at *5 (S.D.W. Va. Oct. 27, 2014); *In re C.R. Bard, Inc*., No. 11-cv-00114, 2013 WL 5591948, at *5 (S.D.W. Va. June 4, 2013) ([T]here is a genuine issue of material fact as to whether the warnings were adequate under the circumstances, given what [the defendant] allegedly knew.").

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[3] The court notes that the study in question compared failure rates of permanent filters with "long-term use" of retrievable filters. (Docket Entry No. 55-3 at 1). The study concluded that "[p]atients with indwelling retrievable filters had significantly more complications than those with permanent filters . . . . after mean follow-up of 20 months," (*id.*), but Gomez's filter was removed after eight months.

Assuming that the warning was inadequate, Gomez has nonetheless not established that the learned intermediary would have made a different decision in the face of a warning containing more information. Dr. Cohen stated that one of the studies,[4] (Docket Entry No. 55-3), cited by Gomez would not have changed Gomez's treatment. (Docket Entry No. 49-2 at 144:20–25). Dr. Afifi stated that she would like to be informed of failure rates and risk of complications involving the filter but did not provide any testimony that the information Gomez presents regarding the filter would have caused her or others to avoid the ALN filter or other retrievable filters to treat Gomez. The best evidence Gomez offers is Dr. Afifi's statement that "if there are papers or documentation that would show that a certain type has a higher rate than others or more complications than others, then that would make my decision different based on any device I use." (Docket Entry No. 55-1 at 36:21–37:6). But this general statement does not speak to Gomez's particular course of treatment and the medical decision-making surrounding it. Dr. Afifi also offered the following testimony:

> Q: The next sentence on your designation says [that you] . . . will further testify that the permanent filters are a safer product for insertion and have a safer alternative design. Do you plan on testifying as an expert to that topic?
>
> A: No. As I discussed, usually permanent filters have stopped being used because of other complications, and I usually prefer the temporary because I prefer removing them when the time comes.

(Docket Entry No. 55-1 at 44:13–22). Viewing Dr. Afifi's testimony in full, it does not create an issue of material fact regarding whether a doctor would avoid use of retrievable filters if they knew of the information cited by Gomez. *Centocor*, 372 S.W.3d at 171 ("Not only did the [plaintiffs] lack subjective evidence, but they presented no objective evidence that a different

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[4] Neither party submitted Dr. Cohen's complete deposition transcript, and the court is unable to know whether he was shown the other study, (Docket Entry No. 55-4), or the FDA communication, (Docket Entry No. 55-5), which Gomez cites in his opposition brief.

warning would have affected the decision of a reasonable doctor to prescribe [the product] for [the plaintiffs'] condition.").

Gomez argues that he—by his medical proxy, Gutierrez—would have refused the ALN filter were he to have been made aware of the information contained in the articles and the FDA bulletin regarding the relative risks of different IVC filters. (Docket Entry No. 55 at 10–11). But is not enough for the patient to argue that he would have refused treatment based on the evidence in the lawsuit. The patient must show that the there is a material dispute of fact regarding whether his treating physician "would have provided additional warnings that would have led [the patient] to withhold consent." *In re DePuy Orthopaedics*, 888 F.3d at 774. In other words, Texas law requires a plaintiff to show that the physician "would have altered his . . . . risk-related disclosures to" the patient, on the basis of which the patient would make his decision whether to accept the treatment. *Id.* (citing *Centocor*, 372 S.W.3d at 170). Gomez has not presented evidence that his treating physicians would have provided him additional warnings even if the IFU accompanying the ALN filter provided the information that Gomez contends it should.

The court grants summary judgment on the failure-to-warn claims, Counts II, VII, VIII, and XIII.

C. Counts III and IV: Design Defect and Negligent Design

A plaintiff alleging a design defect under Texas law must allege that "(1) the product was defectively designed so as to render it unreasonably dangerous; (2) a safer alternative design existed; and (3) the defect was a producing cause of the injury for which the plaintiff seeks recovery." *Timpte Indus., Inc. v. Gish*, 286 S.W.3d 306, 311 (Tex. 2009). Although the Texas statute defining the requirements for a design-defect claim does not apply to medical devices, TEX. CIV. PRAC. & REM. CODE § 82.005(d)(2), courts considering medical-device claims appear

to use the same criteria. *See Labiche v. Johnson & Johnson*, No. 20-cv-4249, 2021 WL 3719554, at *1 & n.5 (S.D. Tex. Aug. 19, 2021) (collecting cases).

The parties focus on the "safer alternative design" portion of the design-defect claims. ALN argues that Gomez presents no evidence suggesting that the ALN filter was defectively designed, or sufficient evidence of a safer alternative design that would have been used for Gomez's treatment. (Docket Entry No. 49 at 20–21). Gomez points to Dr. Afifi's testimony, arguing that "Dr. Afifi testifies that had she been given the information that a permanent filter causes less complications she would factor it into her decision regarding which device to use," and that "a filter with less complications would also impact her decision." (Docket Entry No. 55 at 12).

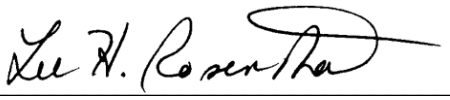
Dr. Afifi's testimony does not speak to the availability of a safer alternative design. Dr. Afifi testified that she would like to know about adverse events involving ALN filters. (Docket Entry No. 55-1 at 35:15–23). The other portion of her testimony cited by Gomez simply addresses how Dr. Afifi reads and considers medical studies. (*See id.* at 31:11–32:5). Neither portion of Dr. Afifi's testimony establishes the existence of a safer alternative design to the ALN filter.

Because Gomez has not offered evidence of a safer alternative design, the court grants summary judgment with respect to counts III and IV.

IV. Conclusion

The court grants the motion for summary judgment. Final judgment is entered by separate order.

SIGNED on October 10, 2022, at Houston, Texas.



Lee H. Rosenthal
Chief United States District Judge