UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

CHRISTOPHER A. SHAFER, Plaintiff, v. C.R. BARD, INC. and BARD PERIPHERAL VASCULAR, INC., Defendants.	Case No. C20-1056RSM ORDER GRANTING MOTION FOR SUMMARY JUDGMENT

I. INTRODUCTION

This matter comes before the Court on Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc.'s Motion for Summary Judgment. Dkt. #27. Defendants move to dismiss certain causes of action that Plaintiff has agreed to withdraw: Count I (Negligence), Count IV (Strict Products Liability – Manufacturing Defect), Count V (Breach of Express Warranty), Count VI (Breach of Implied Warranty), Count VII (Fraudulent Misrepresentation), Count VIII (Negligent Misrepresentation), and Punitive Damages. *See* Dkt. #27. Defendants attach evidence of Plaintiff's agreement to withdraw these claims, *see* Dkt. #29-23, and Plaintiff does not oppose. These claims will be dismissed. Next, Defendants move to dismiss the remaining two causes of action: Count II (Strict Products Liability – Failure to Warn) and Count III (Strict

Products Liability - Design Defects). Plaintiff opposes. Dkt. #49. For the reasons stated below, the Court finds that these claims are properly dismissed for lack of causation evidence.

II. BACKGROUND

On December 29, 2004, then 17-year-old Christopher Shafer was involved in a serious car accident. Dkt. #49-29. Plaintiff Shafer sustained injuries to his chest and abdomen and had to be airlifted to Harborview Medical Center in Seattle. *Id*., *see also* Dkt. #49-31. Although successfully treated for his immediate injuries, he was subsequently diagnosed with a pulmonary embolism ("PE") in his lower right lung.

On January 14, 2005, Dr. Sandeep Vaidya implanted a Bard Recovery filter ("Recovery Filter") into Mr. Shafer's inferior vena cava ("IVC") to mitigate or prevent the PE problem. Dkt. #29-11; *see also* Dkt. #49-31. Dr. Vaidya described the procedure as a "successful deployment" and noted that "this type of IVC filter is made to be retrievable, if clinically desired." Dkt. #29-11 at 2. Mr. Shafer was discharged from Harborview on January 20 to continue to heal at home.

The Information For Use ("IFU") pamphlet, presumably sent to hospitals along with the Recovery Filter, states many warnings, including, "filter fracture is a known complication of vena cava filters…. Most cases of filter fracture, however, have been reported without any adverse clinical sequelae." Dkt. #28-1 at 2. Under "Potential Complications," the Recovery IFU warns that "[p]ossible complications include, but are not limited to. . . Perforation or other acute or chronic damage of the IVC wall." *Id.* This section ends with the following, in bold: "All these above complications have been associated with serious adverse events such as medical intervention and/or death. The risk/benefit ratio of any of these complications should be

weighed against the inherent risk/benefit ratio for a patient who is at risk of pulmonary embolism without intervention." *Id*.

On April 4, 2019, Mr. Shafer had an x-ray revealing a "[s]mall part of IVC filter found to be fractured off inferiorly to main part." Dkt. #29-17 at 5. Mr. Shafer was referred to the University of Washington Medical Center. Dkt. #29-19. A CT scan on August 2, 2019, showed "one broken limb seen extending posterior to the IVC likely into a small lumbar vein… some limbs are seen extending beyond the wall of the IVC…" Dkt. #29-20.

Mr. Shafer discussed this with his doctor, who agreed to remove the filter. Dkt. #29-19. On August 20, 2019, Dr. Christopher Ingraham successfully removed the Recovery Filter with eleven of its twelve limbs. Dkt. #29-21. No attempt was made to retrieve the limb "left behind . . . in the iliac arterial region." *Id*. at 3.

In the coming weeks, Mr. Shafer complained of chest pain and subsequent imaging revealed hyperdensities in his lungs. Mr. Shafer's physician opined that these "may reflect broken off pieces of the IVC filter rather than calcifications." Dkt. #29-22. His physician noted that he was merely "speculating whether this . . . material or calcifications could be due to his history of pulmonary thromboembolism and past history of having a IVC filter." *Id*. His physician ultimately concluded that Mr. Shafer was asymptomatic and did not order any further workup beyond regular monitoring. *Id.*

Mr. Shafer has testified in deposition that he experienced anxiety and stress thinking about the fact that he had a defective filter, starting from the day that he became aware of the situation in April of 2019. *See* Dkt. #29-24 ("Plaintiff Dep.") at 29:13-30:1. However, he has not sought any medical treatment for these symptoms. *Id.* at 14:17-21.

Mr. Shafer filed this action on January 8, 2020. Dkt. #1.

In the course of this litigation, Mr. Shafer's expert, Dr. Allen, reviewed the medical records and concluded that it was not possible with any medical certainty to say that the filter caused Mr. Shafer's chest pain or subclinical pulmonary embolisms, and that "it's just one of those things that we just don't have objective evidence [for]." *See* Dkt. #29-16 ("Allen Dep.") at 54:10–55:21. Claims of abdominal pain likewise lack medical certainty from Dr. Allen. *See id*. at 22:8–12 and 48:4–5.

III. DISCUSSION

A. Legal Standard for Summary Judgment

Summary judgment is appropriate where "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986). Material facts are those which might affect the outcome of the suit under governing law. *Anderson*, 477 U.S. at 248. In ruling on summary judgment, a court does not weigh evidence to determine the truth of the matter, but "only determine[s] whether there is a genuine issue for trial." *Crane v. Conoco, Inc.*, 41 F.3d 547, 549 (9th Cir. 1994) (citing *Federal Deposit Ins. Corp. v. O'Melveny & Meyers*, 969 F.2d 744, 747 (9th Cir. 1992)).

On a motion for summary judgment, the court views the evidence and draws inferences in the light most favorable to the non-moving party. *Anderson*, 477 U.S. at 255; *Sullivan v. U.S. Dep't of the Navy*, 365 F.3d 827, 832 (9th Cir. 2004). The Court must draw all reasonable inferences in favor of the non-moving party. *See O'Melveny & Meyers*, 969 F.2d at 747, *rev'd on other grounds*, 512 U.S. 79 (1994). However, the nonmoving party must make a "sufficient showing on an essential element of her case with respect to which she has the burden of proof" to survive summary judgment. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986).

B. Failure to Warn Claim

The only remaining claims are product liability failure to warn and defective design claims. In Washington, these claims are governed by the Washington Product Liability Act, RCW 7.72 *et seq.* RCW 7.72.030(1) provides that a manufacturer is "subject to liability to a claimant if the claimant's harm was proximately caused by the negligence of the manufacturer in that the product was . . . not reasonably safe because adequate warnings or instructions were not provided." Under the WPLA, warnings are inadequate:

> if, at the time of manufacture, the likelihood that the product would cause the claimant's harm or similar harms, and the seriousness of those harms, rendered the warnings or instructions of the manufacturer inadequate and the manufacturer could have provided the warnings or instructions which the claimant alleges would have been adequate.

RCW 7.72.030(1)(b). Mr. Shafer cites this subsection, but also cites RCW 7.72.030(1)(c):

> A product is not reasonably safe because adequate warnings or instructions were not provided after the product was manufactured where a manufacturer learned or where a reasonably prudent manufacturer should have learned about a danger connected with the product after it was manufactured. In such a case, the manufacturer is under a duty to act with regard to issuing warnings or instructions concerning the danger in the manner that a reasonably prudent manufacturer would act in the same or similar circumstances. This duty is satisfied if the manufacturer exercises reasonable care to inform product users.

See Dkt. #49 at 12; *see also Thongchoom v. Graco*, 117 Wash. App. 299, 306-07, 71 P.3d 214, 219 (2003) ("A postsale duty to warn arises after a manufacturer has sufficient notice about a specific danger associated with the product."). Defendants argue that a claim brought under (1)(c) is not a strict liability claim but a negligence claim, and that therefore it was withdrawn by Mr. Shafer. *See* Dkt. #61 at 2 (citing *Guerrero Apodaca v. Eaton Corp.*, No. C20-1064-JCC, 2020 WL 6799007, at *4 (W.D. Wash. Nov. 19, 2020). Examining the evidence submitted by

Defendants, as well as the difference between claims brought in the original Complaint, the Court concludes that Mr. Shafer has withdrawn all claims other than strict liability failure to warn and defective design, and that a claim under RCW 7.72.030(1)(c) is a negligence claim that lines up with Mr. Shafer's First and possibly Eighth Causes of Action, which were withdrawn.

The Court will thus stick to RCW 7.72.030(1)(b). Under the "learned intermediary" doctrine, a medical device manufacturer satisfies its duty to warn of dangers involved in using its product if the manufacturer "gives adequate warning to the physician who prescribes it." *Terhune v. A.H. Robins Co.*, 577 P.2d 975, 977 (Wash. 1978); *see also Adams v. Synthes Spine Co., LP.*, 298 F.3d 1114, 1117 (9th Cir. 2002) (citing *Terhune* and explaining that, "[u]nder Washington law, the 'consumer' of a prescription-only medical device such as this is the physician, not the patient"). The adequacy of the warning provided to the prescribing physician may be assessed within either the risk-utility or consumer expectation test. As to the former, "the trier of fact must balance the likelihood that the product would cause the harm complained of, and the seriousness of that harm, against the burden on the manufacturer of providing an adequate warning." *Ayers v. Johnson & Johnson Baby Products Co.*, 818 P.2d 1337, 1346 (Wash. 1991). As to the latter, "the trier of fact shall consider whether the product was unsafe to an extent beyond that which would be contemplated by the ordinary user"—the prescribing physician. RCW 7.72.030(3); *O'Connell v. MacNeil Wash Systems Ltd.*, 409 P.3d 1107, 1115 (Wash. Ct. App. 2017) ("The consumer expectation test is more direct. Under this test, the plaintiff must show the product was more dangerous than the ordinary consumer would expect.").

Here, Defendants argue that the Instructions For Use ("IFU") sent to hospitals with the Recovery Filter warned about the very risks that Mr. Shafer experienced: perforation and fracture. The Recovery IFU contains two relevant sections: "E. Warnings" and "G. Potential Complications." Dkt. #28-1. Under "Potential Complications," the Recovery IFU warns that "[p]ossible complications include, but are not limited to . . . Perforation or other acute or chronic damage of the IVC wall." *Id.* at 2. Both the "Warnings" and "Potential Complications" sections warn that, "Filter fracture is a known complication of vena cava filters." *Id*. Defendants argue that "[n]o reasonable prescribing physician apprised of the label's contents would be unaware of the risk[s]" of perforation or fracture. Dkt. #27 at 12 (citing *Falsberg v. GlaxoSmithKline, PLC*, 176 Wn. App. 1019, 2013 WL 4822205, *4 (Sept. 9, 2013)).

The Court disagrees with Bard that this issue can be ruled on as a matter of law. Mr. Shafer has pointed to genuine disputes of material fact related to the adequacy of these warnings and the question of whether no reasonable physician could be unaware of the risks associated with *this* filter based on one or two sentences contained in the IFU. Mr. Shafer presents at least some evidence as to what Defendants could have provided in the warnings or instructions that would have been adequate. *See* Dkt. #49 at 14. This Court finds that it is a question of fact whether such warnings would have been reasonable or adequate.

C. Design Defect Claim

Defendants point to Comment k to the Restatement (Second) of Torts § 402A, arguing it applies to medical product WPLA cases:

> There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. . . . The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate

> consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Defendants argue that, in the absence of a manufacturing defect (improper preparation) or inadequate warnings (improper marketing or warnings), manufacturers of medical devices are not to be held liable for injuries attending the use of such products. Dkt. #27 at 15 (citing *Taylor*, 389 P.3d at 527). However, as the Court has found that inadequate warnings remain an issue for the jury, the Court cannot conclude as a matter of law that Comment k precludes a design defect claim.

D. Causation Issues

Finally, Defendants assert that "Plaintiff's WPLA claims fail because he has not presented any reliable expert testimony showing that any alleged defects of the Recovery Filter's design or warnings proximately caused his injuries." Dkt. #27 at 17. Under RCW 7.72.030(1), it is Mr. Shafer's burden to prove his "harm was proximately caused by the negligence of the manufacturer in that the product was not reasonably safe as designed or not reasonably safe because adequate warnings or instructions were not provided." "Expert testimony is required to establish causation when," as here, "an injury involves obscure medical factors that would require an ordinary layperson to speculate or conjecture in making a finding." *Bruns v. PACCAR, Inc.*, 890 P.2d 469, 477 (Wash. Ct. App. 1995). Such testimony must establish the defect "more probably than not" caused Plaintiff's injuries, and testimony that an alleged defect "may, might, could or possibly" have caused Plaintiff's injuries "does not provide enough guidance to the jury to remove the decision-making process from speculation and conjecture." *Id*. Additionally, the testimony must be based on a reasonable degree of medical certainty. *McLaughlin v. Cooke*, 774 P.2d 1171, 1176 (Wash. 1989).

Defendants' Motion argues that Plaintiff's expert, Dr. Allen, "cannot say within a reasonable degree of medical certainty, that Plaintiff's chest pain was attributable to an allegedly defective aspect of the Recovery Filter." Dkt. #27 at 18. The transcript of Dr. Allen's deposition contains speculation and conjecture as to the Recovery Filter causing this symptom, as well as abdominal pain. Such cannot serve as a basis for WPLA claims. Dr. Allen appears to admit that he cannot connect the dots for these symptoms for this Plaintiff.

Mr. Shafer is also claiming damages for the anxiety and emotional distress of knowing he had a fractured filter inside his IVC. Defendants argue that "[l]ike Plaintiff's physical symptoms, Dr. Allen offered no opinion reliably tying these psychological symptoms to any particular defect in the design of the Recovery Filter or its warnings." *Id*. at 20.

In Response, Mr. Shafer fails to rebut any of Defendants' arguments on causation. Instead, Mr. Shafer argues he can rely on the opinions of Dr. McMeeking, a general expert from the MDL. However, Dr. McMeeking has not opined on this Plaintiff's individual injuries. The Response brief completely fails to address Mr. Shafer's alleged injury of anxiety or stress.

On Reply, Defendant sums up the situation:

> Bard does not dispute that Plaintiff's Recovery Filter perforated his IVC and fractured. (ECF No. 27 at 6.) Bard's contention, with which Dr. Allen agrees, is that the possibility of these complications occurring is inherent to all filters and would not necessarily have been avoided with a different filter. (ECF No. 29-16 at 134, 150.) Moreover, and wholly unaddressed in Plaintiff's opposition, Dr. Allen fails to make a causal connection stemming from a specific defect of the Recovery Filter to any filter complication and then to a specific injury. (ECF No. 27 at 17-20.) Notwithstanding Dr. Allen's cursory adoption of Dr. McMeeking's design defect opinions, (ECF No. 29-25 at 10), a review of his testimony shows that the record is devoid of any expert testimony raising a genuine issue of material fact as to a causal connection between alleged defects in either the design of or warnings accompanying Plaintiff's Recovery Filter and his injuries.

Dkt. #61 at 11. Without an expert witness able to testify with a reasonable degree of medical certainty that the Recovery Filter more probably than not caused the alleged injuries, the case cannot proceed. Dr. Allen has testified that such causal link cannot be provided for Mr. Shafer's chest pain and abdominal pain. The Court agrees with Defendants that Mr. Shafer's claim of anxiety and distress after learning that his filter had fractured is not supported by adequate expert testimony, or indeed supported with any medical evidence. Faced with this, Plaintiff's opposition brief fails to point to specific testimony or evidence supporting a more-probable-than-not finding that a failure to warn or design defect proximately caused this injury. As such, Mr. Shafer has failed to make a "sufficient showing on an essential element of [his] case with respect to which [he] has the burden of proof," and therefore dismissal on summary judgment is warranted. *See Celotex, supra*.

IV. CONCLUSION

Having reviewed the relevant briefing and the remainder of the record, the Court hereby finds and ORDERS that Defendants' Motion for Summary Judgment, Dkt. #27, is GRANTED. All of Plaintiff Shafer's claims are DISMISSED. The pending Motions in Limine, Dkts. #64 and #66, are STRICKEN AS MOOT. This case is CLOSED.

DATED this 4th day of October, 2021.

RICARDO S. MARTINEZ
CHIEF UNITED STATES DISTRICT JUDGE