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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. MDL 15-02641-PHX-DGC
Lisa Hyde and Mark E. Hyde, a married couple, Plaintiffs, v. C. R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation, Defendants.	No. CV-16-00893-PHX-DGC **ORDER**

This multidistrict litigation proceeding ("MDL") involves thousands of personal injury cases brought against Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard"). Bard manufactures and markets medical devices, including inferior vena cava ("IVC") filters. The MDL Plaintiffs received implants of Bard IVC filters and claim that they are defective and have caused serious injury or death.

One of the MDL cases is brought by Plaintiffs Lisa and Mark Hyde. Mrs. Hyde received a Bard filter seven years ago. Her case has been selected as one of several bellwether cases and is set for trial in September 2018. Defendants have filed a motion

for partial summary judgment. Doc. 7359. The motion is fully briefed, and the parties agree that oral argument is not necessary. The Court will grant the motion in part and deny it in part.

I. Background.

The IVC is a large vein that returns blood to the heart from the lower body. An IVC filter is a device implanted in the IVC to catch blood clots before they reach the heart and lungs. This MDL involves multiple versions of Bard IVC filters – the Recovery, G2, G2X, Eclipse, Meridian, and Denali. They are spider-shaped devices that have multiple limbs fanning out from a cone-shaped head. The limbs consist of legs with elastic hooks that attach to the IVC wall and curved arms to catch or break up blood clots. Each of these filters is a variation of its predecessor.

The MDL Plaintiffs allege that Bard filters are more dangerous than other IVC filters because they have higher risks of tilting, perforating the IVC, or fracturing and migrating to vital organs. Plaintiffs further allege that Bard failed to warn patients and physicians about these higher risks. Defendants dispute these allegations, contending that Bard filters are safe and effective, that their complication rates are low and comparable to those of other IVC filters, and that the medical community is aware of the risks associated with IVC filters.

II. The Hyde Plaintiffs.

The following facts are not disputed for summary judgment purposes. Plaintiff Lisa Hyde has a history of deep vein thrombosis and pulmonary emboli. On February 25, 2011, she received a Bard G2X filter while living in Wisconsin.[1] Dr. David Henry

[1] The parties disagree on whether Mrs. Hyde's filter was a G2X or Eclipse. Defendants stated that Mrs. Hyde received a G2X filter when she was proposed as a bellwether plaintiff (Doc. 5652 at 6), but they now assert that the device likely was an Eclipse based on hospital sales records, copies of which have not been provided to the Court. Doc. 7359 at 2 n.2. Plaintiffs present medical records and physician testimony suggesting the filter was a G2X, but their cited documents are incomplete. Doc. 7952 at 1-2 n.1 (citing Doc. 7950 ¶¶ 150, 153, 162-63). The parties agree that the filter type has no bearing on this motion (*id.*; Doc. 7359 at 2 n.20), and, for ease of reference, this order will assume the filter was a G2X. By August 10, 2018, the parties shall confer and report to the Court on whether there is a means for determining the filter type prior to trial, or whether this will be an issue for the jury.

implanted the filter without incident. In May 2014, after Mrs. Hyde and her husband had moved to Nevada, a CT scan showed that the filter had tilted, perforated the IVC wall, and fractured, with one strut lodged in the right ventricle of her heart. The filter and fractured strut were removed in August 2014.

Mrs. Hyde and her husband assert various claims against Bard: failure to warn (Counts II and VII), design defects (Counts III and IV), failure to recall (Count VI), misrepresentation and concealment (Counts VIII, XII, and XIII), negligence per se (Count IX), breach of implied warranty (Count XI), fraudulent trade practices (Count XIV), loss of consortium (Count XV), and punitive damages. *See* Doc. 364 (master complaint); Doc. 1, Case No. CV-16-00893 (short-form complaint).[2]

Defendants seek summary judgment on the claims for strict liability design defect, failure to warn, failure to recall, misrepresentation and fraud, and breach of implied warranty. Doc. 7359 at 2-4. Plaintiffs concede that summary judgment is proper on the failure to recall and implied warranty claims. Doc. 7952 at 2 n.2. The Court will deny summary judgment on the strict liability design defect claim, but otherwise will grant Defendants' motion. Defendants do not seek summary judgment on claims for negligent design (Counts IV), negligence per se (Count IX), loss of consortium (Count XV), or punitive damages. These claims, plus strict liability design defect, remain in the case.

III. Choice of Law.

Because Wisconsin is the forum where venue would be proper absent this MDL, the parties agree that Wisconsin's conflict-of-law rules should be used to determine the governing law in this case. Docs. 7359 at 5, 7952 at 3; *see* Doc. 1 at 2, Case No. CV-16-00893 (identifying the Eastern District of Wisconsin as the forum court); *see Love v. Blue*

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[2] The master complaint is the operative pleading in this MDL. Doc. 364. It serves as a long-form complaint giving notice, pursuant to Rule 8, of the allegations that Plaintiffs assert generally. Plaintiff-specific allegations are contained in individual short-form complaints and fact sheets. Doc. 249 at 6. The master complaint asserts 17 claims and seeks both compensatory and punitive damages. Doc. 364 ¶¶ 166-349. The Hydes are not pursuing claims for manufacturing defect (Counts I and V), breach of express warranty (Count X), wrongful death (Count XVI), and survival (Count XVII). Doc. 7359 at 2 n.1; Doc. 1 at 4, Case No. CV-16-00893.

Cross & Blue Shield of Ga., Inc., 439 F. Supp. 2d 891, 892 (E.D. Wis. 2006) (federal courts "apply the choice-of-law rules of the forum state to determine the applicable substantive law"). Defendants argue that Wisconsin law applies. Doc. 7359 at 6. Plaintiffs argue that Nevada law applies. Doc. 7952 at 3.[3]

Wisconsin employs a two-step choice-of-law analysis. Step one considers whether "'the contacts of one state to the facts of the case are so obviously limited and minimal that application of that state's law constitutes officious intermeddling.'" *NCR Corp. v. Transp. Ins. Co.*, 823 N.W.2d 532, 535 (Wis. Ct. App. 2012) (quoting *Beloit Liquidating Trust v. Grade*, 677 N.W.2d 298, 307 (Wis. 2004)). If neither state's contacts are insignificant, step two considers several "choice-influencing" factors. *Id.* at 536 (citing *Drinkwater v. Am. Fam. Mut. Ins. Co.*, 714 N.W.2d 568, 576 (Wis. 2006); *Heath v. Zellmer*, 151 N.W.2d 664, 672 (Wis. 1967)).

A. Step One – State Contacts.

In evaluating the contacts with each state, the Court must consider the place of contracting, if any, the place of negotiation of any contract, the place of performance, the location of the subject matter, and the domicile, residence, nationality, place of incorporation, and place of business of the parties. *See NCR Corp.*, 823 N.W.2d at 535 (citing *Haines v. Mid-Century Ins. Co.*, 177 N.W.2d 328 (Wis. 1970)); Restatement (Second) of Conflicts § 188. Where tort claims are made, courts also consider the locations of the tortious conduct and the injury. *See id.* at 535-36 & n.2 (citing *Drinkwater*, 714 N.W.2d at 576; *Beloit*, 677 N.W.2d at 307; Restatement § 145).

In this case, the places of contracting, negotiation, and performance are not relevant because the parties never entered into a contract. Other factors are relevant. Plaintiffs were residents of Wisconsin when Mrs. Hyde received her Bard filter (Docs. 7950 ¶ 151, 7953 ¶¶ 1-2), her medical conditions leading to the filter implant occurred in Wisconsin (*id.*), and the filter was sold in Wisconsin and implanted by a

[3] The filter was removed in California, but neither side contends that California law applies.

Wisconsin doctor (Doc. 7953 ¶¶ 4, 17). On the other hand, Plaintiffs moved to Nevada after Mrs. Hyde received her filter, the filter's failure and resulting injuries were discovered in Nevada, and Plaintiffs still reside there. Doc. 7950 ¶ 156. Considering all of these facts, the Court finds that both Wisconsin and Nevada have significant contacts with this case.

"Because there is a weak presumption in favor of applying the forum law, the nonforum state's contacts must be clearly more significant for that state to prevail under this first step." *NCR Corp.*, 823 N.W.2d at 535 (citing *Drinkwater*, 714 N.W.2d at 576); *see State Farm Mut. Auto. Ins. Co. v. Gillette*, 641 N.W.2d 662, 676 (Wis. 2002); *In re Jafari*, 569 F.3d 644, 649 (7th Cir. 2009). Nevada's contacts with this case are not clearly more significant than Wisconsin's, but neither are they "so obviously limited and minimal" that application of Nevada law would constitute officious intermeddling. *Beloit*, 677 N.W.2d at 307; *see Drinkwater*, 714 N.W.2d at 576-77 (finding Iowa's contacts to be significant but not greater than Wisconsin's where the accident and injuries occurred in Wisconsin and the insurance contract was formed in Iowa); *Love*, 439 F. Supp. 2d at 892 (application of the foreign state's law "only constitutes 'officious intermeddling' if the other state is truly of remote connection to the issues in the case"). As a result, the Court must proceed to step two of the choice-of-law inquiry. *See In re Jafari*, 569 F.3d at 649 ("[I]f it is not clear that the nonforum contacts are of greater significance, then the court typically analyzes as a tie-breaker the five choice-influencing factors developed in *Heath*[.]").

Plaintiffs cite *NRC Corp.* and argue that great weight should be given to the location of the tortious conduct and the location of the injury. Doc. 7952 at 5. But the court in *NRC Corp.* did not find these two factors to be "qualitatively stronger" on their own; it found them stronger on the facts of the case before it because they were "the only factors that conclusively weigh[ed] in favor of either [state's] law[.]" 823 N.W.2d at 538. Here, there are several significant contacts with Nevada and Wisconsin. Moreover, Plaintiffs do not contend that the tortious conduct in this case occurred in Nevada.

Plaintiffs' reliance on *Drinkwater* fares no better. Doc. 7952 at 5. The accident and injury in that case occurred in Wisconsin, but the court nonetheless declined to resolve the choice-of-law issue at step one because, as here, the contacts with each state were significant. 714 N.W.2d at 577 ("Iowa's contacts are more than minimal and limited. We therefore turn to apply the five choice-influencing factors." (citation omitted)).

Plaintiffs claim that the district court in *Johnson v. Mylan Inc.*, 107 F. Supp. 3d 967 (E.D. Wis. 2015), applied the state-contacts analysis and determined that Wisconsin law should apply because the illness, treatment, and death occurred in that state. Doc. 7952 at 5. To the contrary, no choice-of-law analysis was needed in *Johnson* because the parties agreed that Wisconsin law applied. 107 F. Supp. 3d at 970. Moreover, the court made clear that "the law of the forum state governs a tort case unless it is clear that nonforum contacts are more significant." *Id.* (citing *Gillette*, 641 N.W.2d at 675-76); *see Schultz*, 2013 WL 4959007, at *4 (applying the law of Wisconsin where the tortious conduct occurred even though the decedent died in Florida and his widow lived there).

B. Step Two – Choice-Influencing Factors.

Step two considers five factors: (1) predictability of results, (2) maintenance of interstate and international order, (3) simplification of the judicial task, (4) advancement of the forum state's interests, and (5) application of the better rule of law. *See NCR Corp.*, 823 N.W.2d at 536 (citing *Drinkwater*, 714 N.W.2d at 576; *Heath*, 151 N.W.2d at 672). "The appropriate law, unless the above factors clearly displace it, is the law of the forum." *Sentry Ins. v. Novelty, Inc.*, No. 09-CV-355-SLC, 2009 WL 5087688, at *5 (W.D. Wis. Dec. 17, 2009).

1. Predictability of Results.

This factor concerns the parties' expectations as to the legal consequences of the conduct that led them to court. *See Drinkwater*, 714 N.W.2d at 577. Bard's interactions with the physician who implanted Mrs. Hyde's filter occurred in Wisconsin, Bard sold

the filter to a Wisconsin hospital, and the filter was implanted while Mrs. Hyde lived in Wisconsin. Doc. 7953 ¶¶ 1-2, 4-5, 17. It was thus reasonable for Bard to expect that Wisconsin law would apply to any product liability claims arising from the filter's use. *See Beloit*, 677 N.W.2d at 308 (corporations are "on notice that, if they choose to transact business in this state, they will be subject to Wisconsin law"); *Schultz v. Glidden Co.*, No. 08-C-919, 2013 WL 4959007, at *4 (E.D. Wis. Sept. 13, 2013) ("[Defendant] purposefully marketed and sold its products to a company doing business in Wisconsin, so the application of Wisconsin law could not have been unexpected."); *Brooks v. Gen. Cas. Co. of Wis.*, No. 06-C-0996, 2007 WL 4305577, at *4 (E.D. Wis. Dec. 7, 2007) ("[D]efendants, in the course of doing business in Wisconsin, had no reason to expect that the legal consequence of conduct undertaken there would be wrongful death damages that exceed the limitations set by Wisconsin law."). Conversely, the parties could not reasonably have expected Nevada law to apply to filter-related claims because Plaintiffs' move to Nevada for employment reasons was a "fortuitous happenstance, not a predictable result." *Schultz*, 2013 WL 4959007, at *4. This factor favors application of Wisconsin law.

2. Maintenance of Interstate Order.

This factor is a variation of the "officious intermeddling" test applied at step one. *See Extrusion Dies Indus., LLC v. Cloeren Inc.*, No. 08-CV-323-SLC, 2008 WL 4401219, at *4 (W.D. Wis. Sept. 24, 2008). It requires that "a jurisdiction which is minimally concerned defer to a jurisdiction that is substantially concerned." *Drinkwater*, 714 N.W.2d at 577; *see Heath*, 151 N.W.2d at 672. Here, as explained above, "both jurisdictions are more than minimally concerned." *Drinkwater*, 714 N.W.2d at 577; *see also Love*, 439 F. Supp. 2d at 895 (application of one state's law over another's would not upset interstate order where neither jurisdiction is minimally concerned nor is there an indication of forum shopping). This factor is neutral.

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3. Simplification of the Judicial Task.

This factor is also neutral. A federal court managing an MDL proceeding, like courts sitting in diversity, "can apply one state's law as easily as another's." *Extrusion*, 2008 WL 4401219, at *4; *see also Love*, 439 F. Supp. 2d at 895.

4. Advancement of the Forum State's Interests.

Where "application of forum law will advance the governmental interest of the forum state, this fact becomes a major, though not in itself a determining, factor in the ultimate choice of law." *Heath*, 151 N.W.2d at 663. Plaintiffs assert that Wisconsin and Nevada have an equal interest in regulating a corporation that has sold a defective product. Doc. 7952 at 7. But this factor focuses on the *forum state's interests*, not the interests of the foreign jurisdiction. Wisconsin has a strong interest in having its laws applied to corporations transacting business within the state. *See Beloit*, 677 N.W.2d at 308. This factor favors application of Wisconsin law.

5. Application of the Better Rule of Law.

This factor asks which state provides "the 'better law' under the circumstances." *Heath*, 151 N.W.2d at 673. Plaintiffs assert that the interests of justice favor applying the law of the state where Mrs. Hyde was injured and resides, but do not explain why Nevada provides the better rule of law. Doc. 7952 at 7. Defendants contend that Wisconsin's adoption of a product liability statute in 2011 indicates that the state considers its legal standards the better rule of law, but do not explain why the views of the state legislature control. Doc. 7359 at 9.

The Court has difficulty with the task of identifying the "better" law. As one court has noted: "Better for whom? Better in what way?" *Extrusion*, 2008 WL 4401219, at *4. Furthermore, "when the question undoubtedly involves compromises between numerous interested groups, such judgments are best preserved for elected legislators." *Love*, 439 F. Supp. 2d at 897. The Court need not wrestle long with this difficulty, however, because it appears this factor seeks only to identify laws that are obsolete. *See Heath*, 151 N.W.2d at 673 (asking whether law is "outmoded, an unrepealed remnant of a

bygone age, [or] 'a drag on the coattails of civilization'" (citation omitted)). Neither Wisconsin's nor Nevada's product liability law can accurately be characterized as "obsolete or senseless[.]" *Id.* The Court therefore concludes that the fifth factor is neutral. *See Gillette*, 641 N.W.2d at 678 (finding this factor neutral where it could not be said that the foreign state's law "is anachronistic or fails to reflect modern trends"); *Schultz*, 2013 WL 4959007, at *4 (Florida did not provide the better rule of law where Wisconsin's rule was not "anachronistic, or the vestige of a 'creed outworn'" (citation omitted)); *Clorox Co. v. S.C. Johnson & Son, Inc.*, 627 F. Supp. 2d 954, 968 (E.D. Wis. 2009) ("The court has no basis on which to conclude that California law is somehow anachronistic on this point of law. Therefore, the court finds that the fifth factor does not favor the application of either Wisconsin or California law.").

C. Conclusion.

The contacts with each state are more than minimal, precluding a decision at step one; none of the step-two factors favors application of Nevada law; and two of the factors favor application of Wisconsin law. The Court therefore will apply Wisconsin law in this case. *See Drinkwater*, 714 N.W.2d at 579-80 (applying Wisconsin law where "[a]ll of the factors either point to the application of Wisconsin law or are neutral"); *Brooks*, 2007 WL 4305577, at *6 (applying Wisconsin law where none of the factors favored application of the foreign state's law).

IV. Summary Judgment.

A party seeking summary judgment "bears the initial responsibility of informing the court of the basis for its motion 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). Summary judgment is appropriate if the moving party 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). Only disputes over facts that might affect the outcome of the suit will preclude summary judgment, and the disputed evidence must be "such that a reasonable jury could return a verdict for the nonmoving

party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The evidence must be viewed in the light most favorable to the nonmoving party, *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986), and all justifiable inferences are drawn in that party's favor because "[c]redibility determinations, the weighing of evidence, and the drawing of inferences from the facts are jury functions," *Anderson*, 477 U.S. at 255.

A. Strict Liability Claims (Counts II and III).

Plaintiffs assert strict liability failure to warn and design defect claims. Doc. 1 at 3, Case No. CV-16-00893. Under Wisconsin's product liability statute, Wis. Stat. § 895.047, a manufacturer is liable where the plaintiff shows the product is "defective in design, or is defective because of inadequate instructions or warnings." § 895.047(1)(a). A product is defective if its foreseeable risks of harm could have been reduced or avoided by the adoption of a reasonable alternative design or warning, and the omission of such alternative renders the product not reasonably safe. *Id.*; *see Lexington Ins. Co. v. Whesco Grp., Inc.*, No. 11-CV-598-BBC, 2013 WL 4454959, at *8 (W.D. Wis. Aug. 16, 2013).

The statute provides several defenses. Wis. Stat. § 895.047(3)(a)-(e). Defendants assert three in this motion. Defendants first contend that the G2X filter is presumed to be non-defective under § 895.047(3)(b) because the device was cleared by the Food and Drug Administration ("FDA"). Doc. 7359 at 10-13. Defendants further contend that the strict liability claims are barred under § 895.047(3)(d) because the risks associated with IVC filters are well known and inherent characteristics of the product. *Id.* Finally, Defendants claim that Plaintiffs provide no alternative design or warning as required by § 895.047(1)(a). *Id.*

1. Section 895.047(3)(b): Compliance with Government Standards.

Section 895.047(3)(b) creates a rebuttable presumption that a product is not defective if, at the time of sale, it complied with "relevant standards, conditions, or specifications adopted or approved by a federal or state law or agency[.]" The design of the G2X filter and the warnings provided with the device are presumed to be non-

defective, Defendants contend, because Bard complied with the FDA's 510(k) process. Docs. 7359 at 12. Defendants claim that Plaintiffs cannot rebut the presumption. *Id.*

Cases have held that § 895.047(3)(b) creates no rebuttable presumption for medical devices cleared under 510(k) review because that review does not concern the safety of the product. *See Hall v. Boston Sci. Corp.*, No. 2:12-CV-08186, 2015 WL 874888, at *2 (S.D. W. Va. Feb. 27, 2015) ("510(k) is not a 'relevant standard' here. Section 895.047 concerns whether a defect rendered the product 'unreasonably dangerous,' § 895.047(1), and, as the Supreme Court has held, 510(k) compliance does not go to the safety of a product."); *Williams v. Boston Sci. Corp.*, No. 2:12-CV-02052, 2016 WL 1448860, at *3 (S.D. W. Va. Apr. 12, 2016) (same). Defendants argue that these cases were wrongly decided. Doc. 8392 at 5. The Court does not agree.

Under Wisconsin's statute, a product is defective only if it is "not reasonably safe." Wis. Stat. § 895.047(1)(a). The 510(k) clearance process, however, "is focused on *equivalence*, not safety." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493 (1996) (emphasis in original). The FDA does not approve the product or make a determination that the device is safe and effective; it finds only that the product is substantially equivalent to a predicate device. *See* 21 U.S.C. § 360c(f)(1)(A); 21 C.F.R § 807.97 (510(k) clearance "does not in any way denote official approval of the device"); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323 (2008) (citing *Lohr* and noting that "products entering the market through 510(k) may be marketed only so long as they remain substantial equivalents of the relevant [predicate] devices as a qualification for an exemption [from federal safety review] rather than a requirement"); *Hovey v. Cook Inc.*, 97 F. Supp. 3d 836, 845 (S.D. W. Va. Apr. 1, 2015) (510(k) review "is predominantly relative, and the FDA does not engage in an independent investigation of the medical device's safety and effectiveness").

Because the 510(k) clearance process focuses on equivalence, not safety, the presumption of non-defectiveness afforded by § 895.047(3)(b) is not applicable. Given

this ruling, the Court need not determine whether Plaintiffs' have presented sufficient evidence to rebut the presumption. *See* Doc. 7952 at 9.[4]

2. Section 895.047(3)(d): Known and Inherent Characteristics.

Section 895.047(3)(d) requires dismissal of strict liability claims where the harm was caused by "an inherent characteristic of the product that would be recognized by an ordinary person with ordinary knowledge common to the community that uses or consumes the product." Defendants contend that the complications associated with IVC filters – migration, tilt, perforation, and fracture – are inherent characteristics of the device and are well known in the medical community. Doc. 7359 at 10-13. Defendants rely on guidelines published by the Society of Interventional Radiology, a 2010 FDA safety alert, and testimony from the implanting physician and one of Plaintiffs' experts to show that the types of complications experienced by Mrs. Hyde were widely known before the implant procedure. *Id.* at 10-11.

Plaintiffs acknowledge that IVC filters experience adverse events, but contend that Bard's own analysis shows that the G2-line of filters experienced adverse events at rates higher than other IVC filters. Doc. 7952 at 10. Plaintiffs argue that these increased risks were not known and inherent characteristics of the product. *Id.* at 11.

Defendants challenge Plaintiffs' rate calculations as inaccurate, but this dispute simply creates a triable issue of fact. Doc. 8392 at 6-7. Defendants have not shown that they are entitled to summary judgment based on the defense provided by § 895.047(3)(d).

3. Section 895.047(1)(a): Alternative Design and Warning.

Section 895.047(1)(a) requires the plaintiff to show that the harm posed by the product could have been reduced or avoided with a reasonable alternative design or warning. Defendants claim that Plaintiffs provide no such alternatives. Doc. 7359 at 11-13. The Court does not agree.

[4] Defendants assert that the presumption applies even if the government standard is not safety, but cite no legal authority in support. Doc. 8392 at 5.

a. Design Defect.

Plaintiffs' expert, Dr. Robert McMeeking, has testified that Bard could have developed caudal anchors and penetration limiters sooner that it did. Doc. 7973 at 32. These safety features ultimately were incorporated into Bard's Meridian and Denali filters, and Bard knew as early as March 2006 that one of its competitors had designed anchors to reduce caudal (downward) migration by flipping two of the hooks that secured the filter to the IVC wall. Doc. 7950 ¶ 87 (Ex. 80). A jury reasonably could conclude from this evidence that specific and reasonable alternative design changes were available when Defendants developed the G2X filter.

Defendants note in their reply that Dr. McMeeking does not specify all of the changes that should have been made to the G2X and that Plaintiffs themselves claim the Meridian to be defective even with caudal anchors. Doc. 8392 at 8. But Defendants do not explain why this entitles them to summary judgment. A manufacturer may be liable under § 895.047(1)(a) where the alternative design would have "reduced" the harm posed by the product. Plaintiffs present evidence that caudal anchors help reduce filter migration, which can lead to other complications like those experienced by Mrs. Hyde (tilt, perforation, and fracture). Plaintiffs have presented sufficient evidence of a reasonable alternative design to survive summary judgment.[5]

b. Warning Defect.

Defendants contend that the warning defect claim fails because Plaintiffs identify no "alternative warnings that would have rendered Bard's filter 'safe.'" Doc. 7359 at 13. But this is not the standard. The alternative warning need not render the product safe; instead, the plaintiff must show that the warning "could have . . . reduced or avoided" the

[5] The parties dispute whether Bard's Simon Nitinol filter ("SNF") can serve as an alternative design. Defendants contend that the SNF is a purely permanent filter and, therefore, not a reasonable alternative for the retrievable G2X. Docs. 7359 at 12 n.6 (citing *Godoy v. E.I. du Pont de Nemours & Co.*, 743 N.W.2d 159, 162 (Wis. Ct. App. 2009) (the alternative design cannot make the product "something else")). Plaintiffs counter that the SNF is a suitable alternative because the G2X can also serve as a permanent device and its optional retrievability is not a functional element. Doc. 7952 at 16-17. Given the ruling above, the Court need not resolve this issue for purposes of summary judgment.

harm and that the warning's omission "renders the product not reasonably safe." Wis. Stat. § 895.047(1)(a); *see Lexington*, 2013 WL 4454959, at *8.

Plaintiffs assert that the G2X filter's IFU should have disclosed "the ***increased*** risk of adverse events when compared to the SNF and competitor filters." Doc. 7952 at 21 (emphasis in original). Whether this proposed warning could have reduced or avoided the harm caused by the G2X filter, and whether omission of the warning renders the G2X defective, are questions best resolved by the jury. As explained below, however, Plaintiffs' strict liability failure to warn claim (Count II) fails for lack of causation.

B. Failure to Warn Claims (Counts II and VII).

Defendants contend that the negligent failure to warn claim is barred by the learned intermediary and sophisticated user doctrines.[6] Doc. 7359 at 13-15. Defendants further contend that the warnings Bard provided with the G2X were adequate as a matter of law. *Id.* at 15-16. Finally, Defendants argue that Plaintiffs' strict liability and negligent failure to warn claims fail because the alleged inadequate warning was not the proximate cause of Mrs. Hyde's injuries. *Id.* at 17-18 & n.8. Plaintiffs contend that Wisconsin does not apply the learned intermediary doctrine and that Bard's warnings were inadequate, but do not address causation. Doc. 7952 at 18-22.

The Court can resolve these claims on the element of causation. Regardless of whether Bard's duty to warn extended to Dr. Henry or Mrs. Hyde, Plaintiffs have failed to present any evidence that an inadequate warning caused Mrs. Hyde's injuries, as required under Wisconsin law. *See* Wis. Stat. § 895.047(1)(e) (requiring a plaintiff to

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[6] The Wisconsin Supreme Court has not decided whether to adopt the learned intermediary doctrine, and federal courts applying Wisconsin law are split on the issue. *Compare Maynard v. Abbott Labs.*, No. 12-C-0939, 2013 WL 695817 (E.D. Wis. Feb. 26, 2013) ("Wisconsin does not apply the learned intermediary doctrine"), *and Forst v. SmithKline Beecham Corp.*, 602 F. Supp. 2d 960, 968 (E.D. Wis. 2009) (declining to apply the doctrine absent some indication that the Wisconsin Supreme Court would do so), *with In re Zimmer, NexGen Knee Implant Prods. Liab. Litig.*, 884 F.3d 746, 751-52 (7th Cir. 2018) (concluding that the Wisconsin Supreme Court would adopt the doctrine), *Monson v. Acromed Corp.*, No. 96-C-1336, 1999 WL 1133273, at *20 (E.D. Wis. May 12, 1999) ("manufacturers have a duty to warn only the treating physician"), *and Lukaszewicz v. Ortho Pharm. Corp.*, 510 F. Supp. 961, 963 (E.D. Wis. 1981) (noting that "the provision of proper warnings to a physician will satisfy the manufacturer's duty to warn").

prove that "the defective condition was a cause" of her injuries); *Kessel v. Stansfield Vending, Inc.*, 714 N.W.2d 206, 211-12 (Wis. Ct. App. 2006) (a plaintiff claiming negligent failure to warn must prove "a causal connection between the defendant's breach of the duty of care and the plaintiff's injury"); *Kurer v. Parke, Davis & Co.*, 679 N.W.2d 867, 876 (Wis. Ct. App. 2004) ("A plaintiff who has established both a duty and a failure to warn must also establish causation by showing that, if properly warned, he or she would have altered behavior and avoided injury.").

Plaintiffs argue at length that Bard's warnings for the G2X were inadequate, but present no evidence or argument that an adequate warning would have prevented use of the Bard filter in this case. Doc. 7592 at 19-22; *see* Doc. 8392 at 12. Plaintiffs identify no evidence suggesting that Mrs. Hyde would have chosen not to receive a G2X filter had she been informed the device had an increased risk of adverse events relative to other IVC filters. Nor do Plaintiffs present evidence from which a reasonable inference can be drawn that an adequate warning would have altered Dr. Henry's decision to use a G2X filter. Dr. Henry testified that he did not remember Mrs. Hyde, was not even sure that the filter implanted in her was a G2X, was not certain who made the decision to use a G2X, and had no independent recollection of the procedure, his thought processes, or what may have been explained to Mrs. Hyde regarding potential risks and treatment options. Doc. 7012 at 5, 8, 18-22, 25. Dr. Henry further testified that he tended to trust the FDA more than individual companies and simply did not know whether he would have considered information about complication rates among filters in making the treatment decision for Mrs. Hyde. *Id.* at 10, 13-14. With respect to the Everest clinical study for the G2 filter, Dr. Henry testified that he "may or may not have been swayed by its content" had he read about it. *Id.* at 16.

Plaintiffs argue that there is sufficient evidence that Dr. Henry would have altered his treatment of Mrs. Hyde had he been warned about the risks of Bard filters. Doc. 7953 ¶ 15. But the portion of Dr. Henry's deposition relied on by Plaintiffs (*id.* (citing pages 44, 45, and 47)) do not support Plaintiffs' argument. When asked whether he would have

found "useful" the fact that "Bard determined its Recovery filter migrated three times more than the industry average," Dr. Henry testified: "Right or wrong, I felt that the risks for all of the FDA-approvable devices were – were reasonable and customary, and that I probably wouldn't have deferred or postponed the filter placement in a patient who I felt really needed it." Doc. 7012 at 44-45. The following exchange then occurred:

> Q. As I'm understanding your answer, right or wrong, you assumed that the complication rates among the FDA cleared or approved IVC filters was roughly equivalent?
>
> A. Yes.
>
> Q. If you had learned differently, that would be the type of information that you would have used in your clinical practice, true?
>
> * * *
>
> THE WITNESS: I tend to trust the FDA more than individual companies.

Id. at 45.

Plaintiffs' counsel continued to press:

> Q. Based on your practice of medicine back in 2011, when you're making the decision about which device to implant in a patient's body, you – is it your testimony that you wouldn't be concerned with how frequently those fail?
>
> * * *
>
> THE WITNESS: It was my understanding that the complication rates were low. And, as a physician, you have to look at the big picture. And I think that the – all of the devices were meeting the expectations of the FDA, and I didn't see any deciphering thing to persuade me one way or the other.

Id. at 48.

Plaintiffs argue that Dr. Henry referred to FDA "approval" of a product and obviously did not understand that 510(k) review results only in "clearance." Doc. 7953 at

5-6. This is not entirely correct. As quoted above, counsel posed questions in terms of FDA clearance or approval. Doc. 7012 at 44-45. But even if true, this fact does not provide what is missing in Dr. Henry's testimony – that a warning of greater risks would have affected his decision to use a G2X filter. Plaintiffs also cite the deposition testimony quoted immediately above, focusing particularly on Dr. Henry's statement that "I didn't see any deciphering thing to persuade me one way or the other." *Id*. at 48. But this statement was made right after he said "all of the devices were meeting the expectations of the FDA" (*id.*), and does not constitute evidence that he would have acted differently had he received some different warning from Bard. Finally, Plaintiffs complain that Dr. Henry's counsel instructed him not to answer questions about how he would have reacted to facts found in various Bard internal documents (Doc. 7953 at 6), but the Court previously held that this instruction was proper under Wisconsin law (Doc. 8180).

Because Plaintiffs present no evidence that Mrs. Hyde or Dr. Henry would have acted differently in the face of different warnings by Bard, summary judgment is warranted on the failure to warn claims. *See Kurer*, 679 N.W.2d at 876 ("Absent proof that a more complete or explicit warning would have prevented Kurer's use of Loestrin, she cannot establish that [the] alleged failure to warn was the proximate cause of her injuries."); *Menges*, 61 F. Supp. 2d at 830 ("[A] plaintiff must not only show that the manufacturer's warning was inadequate, but that such inadequacy affected the prescribing physician's use of the product and thereby injured the plaintiff."); *Hanson v. Boston Sci. Corp.*, No. 2:13-CV-10653, 2016 WL 1448868, at *5 (S.D.W. Va. Apr. 12, 2016) (applying Wisconsin law and finding the causation evidence insufficient where it "require[d] a reasonable juror to speculate, based only on mere *possibility*, that [the doctor] would have altered her decision to prescribe the product simply because she would have *considered* an additional factor in her risk/benefit calculus" (emphasis in original)).

/ / /

C. Misrepresentation and Fraud Claims (Counts VIII and XII-XIV).

Plaintiffs assert claims for negligent and fraudulent misrepresentation, fraudulent concealment, and fraudulent trade practices in violation of Wis. Stat. § 100.18. Doc. 364 ¶¶ 218-28, 245-321. The parties agree that an essential element of each of these claims is reliance or causation. Doc. 7592 at 22. Defendants argue that summary judgment is warranted because there is no evidence showing that Mrs. Hyde or Dr. Henry relied on any representations by Bard or that Bard's public statements caused Mrs. Hyde's injuries. Docs. 7359 at 19-20. The Court agrees.

Mrs. Hyde admits that she never spoke to anyone at Bard or received any information from Bard. Doc. 7953 ¶ 27. She presents no evidence that Dr. Henry relied on any information Bard provided about its IVC filters, through its sales force or otherwise. Dr. Henry testified that he tends to trust the FDA more than individual companies and was comfortable using FDA-approved medical devices. Doc. 7950 ¶ 181. Absent some evidence Dr. Henry or Mrs. Hyde relied on representations made by Bard, or that Bard's alleged concealment of information caused Plaintiffs' injuries, the fraud and misrepresentation claims fail as a matter of law. *See Staudt v. Artifex Ltd.*, 16 F. Supp. 2d 1023, 1030 (E.D. Wis. 1998) (misrepresentation and concealment claims require reliance resulting in damage).

Plaintiffs contend that Bard committed fraud on the FDA, and that Dr. Henry's trust in the FDA constitutes reliance on Bard's misrepresentations and concealment. Doc. 7952 at 22-24. But Plaintiffs present no legal authority to support this contention, and any claim based solely on fraud on the FDA is preempted. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001). Plaintiffs' misrepresentation and fraud claims fail for lack of reliance and causation.

IT IS ORDERED:

1. The following claims are **dismissed** based on Plaintiffs' withdrawal of the claims before Defendants moved for summary judgment: manufacturing defect (Counts I and V) and breach of express warranty (Count X).

2. Defendants' motion for partial summary judgment (Doc. 7359) is **granted in part and denied in part**. The motion is granted with respect to Plaintiffs' claims for failure to warn (Counts II and VII), failure to recall (Count VI), misrepresentation, concealment, and fraud (Counts VIII and XII-XIV), and breach of implied warranty (Count XI). The motion is denied with respect to the strict liability design defect claim (Count III). This claim, along with the claims for negligent design (Count IV), negligence per se (Count IX), loss of consortium (Count XV), and punitive damages, remain for trial.

3. By **August 10, 2018**, the parties shall confer and provide a joint report to the Court on whether there is a means for determining Mrs. Hyde's filter type prior to trial, or whether this will be an issue for the jury to decide.

Dated this 26th day of July, 2018.

David G. Campbell
United States District Judge