IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WISCONSIN

NATALIE JOHNSON,

Plaintiff,

v.

C.R. BARD INC. and
BARD PERIPHERAL VASCULAR INC.,

Defendants.

OPINION AND ORDER

19-cv-760-wmc

In 2013, plaintiff Natalie Johnson was implanted with a Bard "Meridian Filter," a prescription medical device that is placed in a patient's inferior vena cava ("IVC") and is designed to prevent pulmonary embolisms. In Johnson's case, however, once implanted, the device tilted, migrated, and fractured. Even after a procedure to remove the filter, broken parts of the device still remain in Johnson's body. Now, Johnson has brought suit against defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., claiming that they should be held liable for strict liability and negligence because of the Meridian Filter's allegedly defective design and warnings. Johnson also claims negligence *per se*. She seeks damages for risk of future injury and punitive damages.[1]

This case previously proceeded as part of a multidistrict litigation ("MDL") conducted in the District of Arizona, consisting of plaintiffs who received implants of Bard IVC filters, which they claimed were defective and caused serious injury or death. During the course of those MDL proceedings, six plaintiffs were selected for bellwether trials. (*See*

[1] Plaintiff originally brought warranty-based claims, misrepresentation-based claims, and manufacturing-based claims (*see* Compl. (dkt. #1)), but now seeks to withdrawn them (*see* Pl.'s Opp'n (dkt. #38) 19).

Remand & Transfer Order (dkt. #3).) Three of those cases proceeded to trial. *See Booker v. C. R. Bard, Inc.*, No. CV-16-00474 (D. Ariz.); *Jones v. C. R. Bard, Inc.*, No. CV-16-00782 (D. Ariz.); *Hyde v. C. R. Bard, Inc.*, No. CV-16-00893 (D. Ariz.).[2] The court granted summary judgment in one of the cases, concluding it was barred by the applicable statute of limitations. *Kruse v. C. R. Bard, Inc.*, No. CV-15-01634 (D. Ariz.). As for the remaining two, one was removed from the bellwether trial schedule, and one settled shortly before trial. *See Mulkey v. C. R. Bard, Inc.*, No. CV-16-00853 (D. Ariz.); *Tinlin v. C. R. Bard, Inc.*, No. CV-16- 00263 (D. Ariz.). In 2019, Johnson's claim was transferred to this court.

Presently before the court is defendants' motion for summary judgment (dkt. #24), which the court will deny in part and grant in part. In addition to plaintiff's withdrawn claims for breach of warranty, misrepresentation, and manufacturing, the court will dismiss plaintiff's negligence *per se* claim as preempted. However, disputed issues of material fact remain as to plaintiff's other claims, which must proceed to trial.

## UNDISPUTED FACTS

### A. IVC Filters and the Meridian Filter

The Meridian Filter (sometimes also referred to in this opinion as the "Filter") is a prescription medical device designed to prevent pulmonary embolisms. It is conical in shape and consists of a main shaft to which twelve struts (six arms and six legs) are attached. The device is implanted in the inferior vena cava ("IVC") -- the largest vein in the human body -- where its arms and legs open to anchor the filter in the vein's walls.

[2] As here, the *Hyde* bellwether case was governed by Wisconsin law. *See Hyde*, No. CV-16-00893.

Once implanted, the filter is designed to prevent blood clots from traveling to the heart, lungs, or brain. The Meridian Filter was designed to be a "retrievable" filter that could be implanted, then percutaneously removed at a later time, although defendants also represented that it was safe for permanent use.[3]

Other IVC filters had been in use before the Meridian Filter. In particular, the "Simon Nitinol Filter," which is also manufactured by Bard, has been distributed in the United States since at least 1992. However, the Simon Nitinol Filter is considered "permanent-only" because it cannot be easily retrieved from the patient's body once implanted. In the early 2000s, Bard began developing a retrievable IVC filter; and by 2003, the FDA had cleared Bard's "Recovery Filter" as the first IVC filter that could be implanted and then percutaneously removed at a later time. By 2004, however, defendants became aware of certain problems with the Recovery Filter. For example, a Health Hazard Evaluation from December 17, 2004, noted that data from the U.S. Food and Drug Administration's ("FDA") Manufacturer and User Facility Device Experience ("MAUDE") database revealed significantly higher rates of reported death and complications for the Recovery Filter than for other filters.[4]

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[3] "In surgery, a percutaneous procedure is any medical procedure or method where access to inner organs or other tissue is done via needle-puncture of the skin, rather than by using an 'open' approach where inner organs or tissue are exposed (typically with the use of a scalpel)." *Percutaneous*, Wikipedia (last accessed April 19, 2021), https://en.wikipedia.org/wiki/Percutaneous.

[4] Defendants object to plaintiff's use of this MAUDE data, arguing that "scientific conclusions regarding comparative rates cannot be drawn from MAUDE data because of the many limitations and inherent inaccuracies in the data." (Defs.' Resp. to Pl.'s PFOFs (dkt. #66) ¶ 9.) While this may well affect the weight a trier of fact might assign this data, and perhaps even its admissibility at trial, defendants have not provided a sufficient basis for the court to preclude consideration of the MAUDE data for the purposes of summary judgment. Given the amount of litigation that has

Defendants then developed a "next generation" Recovery Filter, called the "G2 Filter," with the goals of potentially reducing complications such as migration and fracture. However, initial MAUDE data showed that the reported perforation failure rate for the G2 Filter was approximately 14 times that of the Simon Nitinol Filter. The next retrievable filter to be developed by Bard was the "Eclipse Filter" in 2010, and the following year, Bard developed and began marketing the Meridian Filter. However, the Meridian Filter was only on the market from 2011 until 2013, when Bard launched the "Denali Filter."

All of these Bard retrievable filters were cleared for marketing to the public under the FDA's § 510(k) process based on each device's "substantial equivalence" to a predicate device. In this case, both the Meridian and the Eclipse were predicated on the G2, which was predicated on the Recovery; and the Recovery was predicated on the Simon Nitinol Filter, Bard's long-standing, permanent-only filter.

Both of plaintiff's experts -- Dr. Darren Hurst and Robert McMeeking[5] -- opine that the Meridian Filter is subject to the same complications experienced with Bard's earlier retrievable filters. As a result, at the time the Meridian Filter was placed in Johnson, Dr. Hurst opines that the risks associated with that filter exceeded the alleged benefits. Dr. Hurst further opines that the Simon Nitinol Filter was a safer alternative filter for Johnson than the Meridian Filter. Similarly, McMeeking opines that the Simon Nitinol Filter is a

already taken place as part of the MDL bellwether cases, this absence is particularly telling. Accordingly, the court relied in part on this data.

[5] McMeeking's expert report was also submitted to all of the MDL cases.

safer IVC Filter than any of defendants' retrievable filters.[6]

Nevertheless, as defendants point out, there have been reported complications linked to all IVC filters, including the Simon Nitinol Filter, and at least one medical article shows a comparable rate of migration for the Simon Nitinol Filter as compared to certain other IVC filters. Defendants also argue that because no comparative studies have been done between IVC filters, definitive comparison rates do not exist.

**B. The Meridian Filter's Warnings**

The "Instructions for Use" ("IFU") that accompanied the Meridian Filter instructed physicians to "[p]osition the retrieval hook 1 cm below the lowest renal vein." (Ex. B, Meridian IFU at 2-4). Those instructions also warned that "[t]he safety and efficacy of this device has not been established for pregnancy, nor in suprarenal placement position." (*Id.*) Additionally, the instructions warned that:

> Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment using endovascular and/or surgical techniques. . . . Movement, migration or tilt of the filter is a known complication of vena cava filters. Migration of filters to the heart or lungs has been reported. There have also been reports of caudal migration of the filter. Migration may be

[6] Plaintiff points to other evidence to support her experts' opinions. In particular, she notes that early clinical studies suggest migration of the Simon Nitinol Filter was rare, with only 2 of 258 (0.8%) migrations reported for patients receiving the filter between February 1988 and November 1990. These studies also make no mention of any filter fractures. As of May of 2011, there had also been no deaths associated with migration of the Simon Nitinol Filter, and a significantly lower number of migrations compared to Bard's Recovery, G2, and Eclipse filters. Moreover, MAUDE data shows that out of 80,187 sales between launch and May of 2011, the Simon Nitinol Filter had only eight fractures. And David Ciavarella, Bard's Corporate Clinical Affairs Director, explained in an email in 2005 that Bard had received "virtually no complaints" regarding the Simon Nitinol Filter. (Ex. 14 (dkt. #50-6).)

> caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots, and/or dislodgement due to large clot burdens.

(*Id.*) More generally, the instructions similarly warned of: "Filter Tilt"; "Filter malposition"; "Perforation or other acute or chronic damage of the IVC wall"; and "Vessel injury." (*Id.* at 3.) Finally, the instructions state that these possible complications "may affect the recoverability of the device and result in the clinician's decision to have the device remain permanently implanted." (*Id.* at 2.)

Defendants further emphasize that the risks associated with all IVC filters have been noted in medical literature as early as 1996. In particular, defendants point to various articles and publications discussing the rate and types of complications associated with such filters.

**C. Johnson's Filter**

On August 6, 2013, Dr. Irina Goncharova placed a retrievable Meridian Filter in Johnson's IVC because she was determined to be at risk of developing a pulmonary embolism, having previously developed a blood clot in her leg. Based on his analysis of a vena cavagram taken the day the Filter was implanted in Johnson, Dr. Hurst testified that the Filter was "at the level of the left renal vein origin and maybe slightly above the right renal vein origin." (Hurst Dep. (dkt. #32) 35:21-:22.) According to Dr. Hurst, this placement was "higher than what you would normally expect," as "[i]deally, you would want it approximately one centimeter below the left -- below the renal veins." (*Id.* at 35:25-36:5.) He also observed that the Filter was slightly tilted (7 degrees) at the time of implant,

although Dr. Hurst acknowledges that a vena cavagram -- the imaging he used to draw conclusions about the placement of Johnson's filter -- is an "indirect visualization of the renal vein," and as such, it is "not exact." (*Id.* at 38:23-:25.)

Consistent with Bard's IFU to physicians accompanying each Meridian Filter and Dr. Hurst's description, medical literature similarly notes that the ideal placement for an IVC filter is at or immediately below the renal veins. According to Dr. Hurst, suprarenal filter placement can lead to tilt of the filter, perforation, or can end up with struts of the filter in the renal walls.

Dr. Hurst also examined a CT scan taken on August 9, 2013, three days after Johnson's Filter was implanted,[7] and found that the Filter had significantly tilted (22 degrees), migrated down 3 mm, and perforated the IVC, with one strut extending into the right renal vein. In light of these changes, Dr. Hurst opined that, had he been Johnson's treating physician at that time, he would have recommended either (1) Johnson have her filter retrieved or (2) she have follow-up imaging done within three months. Nevertheless, the filter was apparently not retrieved, and Johnson did not have further imaging done on the filter until July 21, 2014. Dr. Hurst further opines that this imaging shows the filter had tilted further and two struts had fractured, with one remaining in the IVC, while the

[7] By way of context, plaintiff also proposes the following fact: "On August 9, 2013 (three days after implantation), Ms. Johnson presented to the Mercy Janesville Hospital for evaluation of abdominal pain that was intermittent but worsening since the placement of the Meridian filter." (Pl.'s PFOFs (dkt. #66) ¶ 41.) However, as defendants point out, the specific page cited by plaintiff to support this fact -- "Ex. 44, Selected Medical Records at JOHNSONN_MHTC_MDR00572" -- does not appear to have been filed with the court. Thus, for the purposes of the present motion, the court finds this proposed fact unsupported by the current record. Of course, supporting evidence may still be offered at trial.

other had migrated to Johnson's right ventricle and penetrated through the wall of the ventricle into the pericardium.

On July 23, 2014, Dr. Goncharova tried to remove the Filter percutaneously, but was unsuccessful. Almost four years later, on March 1, 2018, Johnson had subsequent imaging done to assess the position of the filter. That imaging showed the filter and one of the fractured struts were still in the IVC, while the other fractured strut was still in the right ventricle. At that time, the physician interpreting the imaging, Dr. Bart J. Schmidt, described the filter as "malpositioned . . . with mechanical failure." (Selected Medical records of Natalie Johnson (dkt. #50-36) MDR00227.) According to Dr. Hurst, the imaging also showed that the filter had gone from a significant tilt to a "[s]table 1 degree tilt." (Hurst Rep. (dkt. #61) 6.)

Another attempt to remove the filter was then made on April 17, 2018. This time, Dr. Kyla Bennett was able to retrieve the filter and one of the fractured struts in the IVC. However, she did not retrieve the fractured strut embedded in the right ventricle; plus, another strut fractured during the procedure and remains embedded in the IVC. Dr. Bennett referred Johnson to a cardiothoracic surgeon to evaluate the strut embedded in the right ventricle, but thought that it would be unlikely a surgeon would want to intervene, as she believed the tines had been in the same place since 2014.

In October of 2018, Johnson's cardiothoracic surgeon agreed that the strut was likely embedded and would not move. Accordingly, as predicted, the surgeon recommended against attempting removal. Imaging taken in 2018 and 2019 show that the retained struts are in the same, stable position.

Dr. Hurst opines that the Meridian Filter implanted in plaintiff Johnson failed to perform as a reasonable physician or patient would expect, having penetrated the IVC, with two of the filter's arms fracturing and remaining in Johnson's body. According to Dr. Hurst, the failure of Johnson's filter has also put her at an increased risk of future complications. In particular, he explains that one of the fractured arms has penetrated her right ventricular wall, and it poses a risk of future complications, including hemorrhage, pericardial tamponade, arrhythmia, and cardiac damage. He further opines that there is a fragment of the Filter still within the wall of the IVC, creating a future risk of infection, chronic pain or irritation, and hemorrhage. Finally, Dr. Hurst opines that these fragments would require open surgical procedures to remove if complications do occur, and any complications or surgery could result in serious morbidity or death.

As a result of the fractured struts which remain in her body, Johnson testified that she suffers from anxiety about this possible, future harm. Nevertheless, she has not experienced any physical symptoms related to her filter or the fractured struts. Additionally, she has not been prevented from doing anything that she could do before receiving the filter and has faced no limits on her daily activities due to the filter.

## OPINION

In this case, plaintiff claims that defendants are liable for allegedly defective design of and insufficient warnings on the Meridian Filter, as a matter of strict liability, negligence and negligence *per se*. She also seeks damages for risk of future injury and punitive

damages.[8] Defendants seek summary judgment on all of plaintiff's claims.

Summary judgment is appropriate if the moving party "shows that there is no genuine dispute as to any material facts and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The court must view all facts and draw all inferences in the light most favorable to the non-moving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986).

Although "distinguishing between strict liability claims and negligence claims in the products liability context can be confusing," Wisconsin law does offer a "separate avenue[] of recovery" for such claims via a negligence theory. *See Burton v. E.I. du Pont de Nemours & Co., Inc.*, __ F.3d __ , 2021 WL 1422814, at *15 (7th Cir. Apr. 15, 2021) (quoting *Godoy ex rel. Gramling v. E.I. du Pont de Nemours & Co.*, 2009 WI 78, ¶ 16 n.7, 319 Wis. 2d 91, 768 N.W.2d 674). In their briefing, the parties largely do not distinguish between the different theories of liability. (*See* Def.'s Br. (dkt. #24) 11-23 (addressing plaintiff's failure to warn and defective design claims together); Pl.'s Opp'n (dkt. #38) 10-19 (same).) As the claims share many similarities, this is both understandable and generally appropriate. Accordingly, the court will largely follow suit by addressing directly the issues identified by the parties at summary judgment, while distinguishing between plaintiff's strict liability/negligence theories as appropriate.

[8] As noted, plaintiff originally brought warranty-based claims, misrepresentation-based claims, and manufacturing-based claims (Am. Compl. (dkt. #1)), but she has since withdrawn them (*see* Pl.'s Opp'n (dkt. #38) 19), and those claims will be dismissed.

## I. Applicability of Presumption under Wis. Stat. § 895.047(3)(b)

Plaintiff's strict liability claims are brought under Wis. Stat. § 895.047, which provides in relevant part that:

> In an action for damages caused by a manufactured product based on a claim of strict liability, a manufacturer is liable to a claimant if the claimant establishes all of the following by a preponderance of the evidence:
> (a) That the product is defective because it contains a manufacturing defect, is defective in design, or is defective because of inadequate instructions or warnings. A product contains a manufacturing defect if the product departs from its intended design even though all possible care was exercised in the manufacture of the product. A product is defective in design if the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the manufacturer and the omission of the alternative design renders the product not reasonably safe. A product is defective because of inadequate instructions or warnings only if the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the manufacturer and the omission of the instructions or warnings renders the product not reasonably safe.
> (b) That the defective condition rendered the product unreasonably dangerous to persons or property.
> (c) That the defective condition existed at the time the product left the control of the manufacturer.
> (d) That the product reached the user or consumer without substantial change in the condition in which it was sold.
> (e) That the defective condition was a cause of the claimant's damages.

Wis. Stat. § 895.047(1). The statute further enumerates a number of statutory defenses to liability. Wis. Stat. § 895.047(3).

Specifically, as a defense to plaintiff's strict liability claims, defendants argue at summary judgment that they are entitled to a rebuttable presumption that their product is not defective because they complied with the FDA's § 510(k) process and conditions.

Under Wisconsin law, "[e]vidence that the product, at the time of sale, complied in material respects with relevant standards, conditions, or specifications adopted or approved by a federal or state law or agency shall create a rebuttable presumption that the product is not defective." Wis. Stat. § 895.047(3)(b). However, as this court recently held, a product that has complied with the FDA's § 510(k) review process is *not* entitled to Wisconsin's statutory presumption. *MacPherran v. Bos. Sci. Corp.*, No. 20-CV-766-JDP, 2020 WL 7061044, at *3-4 (W.D. Wis. Dec. 2, 2020). Indeed, Judge Peterson explained that

> the FDA 510(k) review process is not the same as full FDA approval or other safety reviews. Wisconsin courts have yet to decide whether a product with 510(k) clearance is entitled to the statutory presumption. The weight of federal cases involving medical devices and Wisconsin's statute or similar state statutes suggests that the 510(k) process does not give rise to § 895.047(3)(b)'s rebuttable presumption.

*Id.* at *3.

Even more on point, in another case concerning alleged defects of Bard's IVC filters under Wisconsin law, the District Court of Arizona specifically held that Wisconsin's statutory presumption did not apply:

> 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). . . . 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.

*Hyde v. C.R. Bard*, No. CV-16-00893-PHX-DGC, 2018 WL 3586404, at *6-7 (D. Ariz. July 26, 2018). The court finds the reasoning in these cases to be persuasive, particularly

when the equivalency finding by the FDA here apparently and almost inexplicably rests at bottom on the long-standing approval and use of a permanent-only filter, which by its very definition was *not* equivalent to Bard's IVC filters that followed. Accordingly, defendants are not entitled to a presumption that the Meridian Filter is not defective simply because it went through the FDA's § 510(k) review process.

**II. Failure to Warn Claims**

Defendants next argue that plaintiff's failure to warn claims fall short for a number of reasons. *First*, defendants argue that they had no *duty* to warn *plaintiff*, and so she cannot prevail on these claims under Wisconsin law. In particular, according to defendants, Wisconsin courts are likely to adopt the "learned intermediary doctrine," under which defendants' duty to warn about risks ran to Johnson's doctor, not to Johnson herself. Moreover, because there is no duty to warn about risks generally known within a trade, and the risks of IVC filters are generally known to doctors, defendants further argue they had no duty to warn even Johnson's doctor. *Second*, defendants argue that even if they had a duty to warn, the warnings provided were adequate as a matter of law, having (1) warned of the precise risks of complications that came to pass with Johnson's filter, and (2) no duty to warn of the relative complication rates of Bard's IVC filters compared to other filters. *Third*, defendants argue no reasonable jury could find that any alleged failure to warn was the *proximate* cause of Johnson's alleged injuries, since she has failed to proffer any evidence at summary judgment to prove that a proper warning would have caused her doctor to use a different, safer product. Each of these arguments are addressed in turn below.

### A. Learned Intermediary Doctrine and Bard's Duty to Warn

The learned intermediary doctrine "holds that the manufacturer of a prescription drug or medical device fulfills its duty to warn of the product's risks by informing the prescribing physician of those risks." *In re Zimmer, NexGen Knee Implant Prod. Liab. Litig.*, 884 F.3d 746, 751 (7th Cir. 2018). Both parties agree that Wisconsin courts have yet to consider the applicability of this doctrine. However, the Seventh Circuit has recently predicted that, "given the opportunity, the Wisconsin Supreme Court would join the vast majority of state supreme courts and adopt the learned-intermediary doctrine," at least in defective-warning cases involving a surgical implant. *Id.* at 751.

Although, as plaintiff points out, some courts interpreting Wisconsin law *had* previously declined to apply the doctrine, these decisions all predate *Zimmer*. *See Rodenkirch-Kleindl v. C. R. Bard, Inc.*, No. 2:13-CV-26026, 2016 WL 7116144, at *3 (S.D.W. Va. Dec. 6, 2016) (collecting Wisconsin and Seventh Circuit cases regarding the learned intermediary doctrine). Since *Zimmer*, district courts in this circuit applying Wisconsin law have consistently applied the learned intermediary doctrine to product liability cases involving surgical implants. *See Karnes v. C. R. Bard, Inc.*, No. 18-CV-931-WMC, 2019 WL 1639807, at *7 (W.D. Wis. Apr. 16, 2019) ("With no basis under Wisconsin case law to hold otherwise, this court would appear bound by the Seventh Circuit's holding in *Zimmer*. Regardless, the reasoning in *Zimmer* is sound, especially in the case of surgical implants."); *Tzakis v. Wright Med. Tech., Inc.*, No. 19-CV-545-WMC, 2020 WL 955016, at *5 (W.D. Wis. Feb. 27, 2020) (applying the learned intermediary doctrine to a product liability case involving a surgical hip implant); *Zember v. Ethicon, Inc.*, No. 20-

CV-369-JPS, 2021 WL 1087041, at *4 n.4 (E.D. Wis. Mar. 22, 2021) (applying the learned intermediary doctrine to a product liability case involving surgical mesh).

Even if this court has the temerity, much less the authority, to depart now from the Seventh Circuit's prediction in *Zimmer*, there still appears no reason to do so, and this court will accordingly apply the learned intermediary doctrine to this case. Thus, as the manufacturer of the medical device at issue, defendants had only a duty to warn Johnson's physician of the product's risks, not Johnson herself. *See Zimmer*, 884 F.3d at 751.

Defendants next argues that they had no duty to warn Johnson's physician of the risks of an IVC filter under the "sophisticated user doctrine." (Def.'s Br. (dkt. #24) 13.) This doctrine generally provides that a supplier of a product does not have a duty to warn if the supplier knows or has reason to believe that the user would realize the dangerous condition of the product. *See Mohr v. St. Paul Fire & Marine Ins. Co.*, 2004 WI App 5, ¶ 16, 269 Wis. 2d 302, 674 N.W.2d 576. Wisconsin courts have not only applied this doctrine in the negligence context, *id.,* but it has been codified as a statutory defense to a strict product liability claim. *See* Wis. Stat. § 895.047(3)(d) ("The court shall dismiss the claimant's action under this section if the damage 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.").

Here, defendants argue that since the risks inherent to IVC filters were generally known to physicians (the community that uses the product), they owed no duty to warn Johnson's physician of the risks of using the Meridian Filter. To prove this "community knowledge," defendants point to various articles and publications in the medical literature

discussing the overall risks of IVC filters. Defendants' essential argument appears to be that because medical literature discusses the general risks associated with a *category* of product, then they are absolved of any duty to warn physicians about the risks of their *specific* product. As a general proposition, such a rule, though broad, does not strike the court as unreasonable on its face, provided the known risks are reasonably associated with a category of product clearly including the subject product, but even that would seem to require a trier of fact to weigh the evidence, likely to include expert testimony, at least absent a strong consensus, which is lacking on the current record. In particular, the court is not convinced that defendants had *no* duty to warn Johnson's physician as a matter of law, particularly based solely on the existence of the publications. Regardless, the publications do not appear to address the main defect identified by plaintiff -- namely, that the Meridian Filter had comparatively higher rates of complications even in comparison to other IVC filters. Therefore, defendants have yet to prove that the specific defect claimed was generally known to physicians. Accordingly, the sophisticated user defense either does not apply at all here *or* at minimum, defendants will have to prove its application to the satisfaction of the trier of fact at trial.

**B. Adequacy of Warnings**

Defendants next argue that they are entitled to summary judgment on plaintiff's failure to warn claims because the warnings accompanying the Meridian Filter were adequate as a matter of law. In particular, defendants point to the warnings given to physicians through the IFUs that accompanied each IVC filter, noting that these IFUs warned of migration, tilt, fracture, and perforation, and that complications may affect the

recoverability of the device. According to defendants, "[b]ecause the IFU warned Dr. Goncharova about the precise risks of complications that came to pass with Mrs. Johnson's IVC filter, Bard's warnings were legally adequate." (Def.'s Br. (dkt. #24) 15.) For her part, plaintiff argues that the IFU "[did] not contain any clear information on the likelihood or potential severity of the risks of complications, lack[ed] any recommendations for imaging follow-up, and provide[d] insufficient warnings of the incidence and seriousness of the cascade of events of tilt, migration, fracture, and especially fractured component embolization to the heart and lungs that was characteristic of these devices and occurred with a higher frequency and more serious complications than the prior permanent SNF device and other permanent filters available at the time." (Pl.'s Opp'n (dkt. #38) 14-15.)

Absent proof of a more definitive consensus among doctors, the court is inclined to agree with plaintiff that just because Bard's IFU generally warned of possible complications ultimately experienced by Johnson does *not* render the warning adequate as a matter of law. Rather, "*[t]he jury* is to consider *all* pertinent factors" in determining the adequacy of a product warning. *Mohr v. St. Paul Fire & Marine Ins. Co.*, 2004 WI App 5, ¶ 32, 269 Wis. 2d 302, 674 N.W.2d 576 (citing *Tanner v. Shoupe*, 228 Wis.2d 357, 367, 596 N.W.2d 805 (Ct. App. 1999)) (emphasis added). In particular, under Wisconsin law factors other than just the *type* of injury have been found to be relevant, including the "likelihood of a particular accident taking place" and the "seriousness of the consequences." *Id.*

Here, although defendants did warn of the specific complications that happened to Johnson, a reasonable jury *could* conclude that those warnings were inadequate because

they did not sufficiently communicate the degree and likelihood of the risk associated with placing a Meridian Filter in a patient's IVC, especially in light of purported, lower-risk options on the market and the seriousness of the potential complications. Accordingly, the court cannot conclude that the warning was adequate as a matter of law. *See In re Bard IVC Filters Prod. Liab. Litig.*, 969 F.3d 1067, 1076-77 (9th Cir. 2020) (applying Georgia law in concluding that the adequacy of Bard's warnings regarding its G2 Filter was a question properly posed to the jury).

**C. Causation**

Defendants finally argue that plaintiff's failure to warn claims are doomed by a lack of evidence on which a reasonable jury could find causation. Whether based on strict liability or negligence, an essential element of any failure to warn claim is causation. *See* Wis. Stat. § 895.047 (1)(e) (requiring a plaintiff to prove that "the defective condition was a cause" of her injuries); *Kessel ex rel. Swenson v. Stansfield Vending, Inc.*, 2006 WI App 68, ¶ 15, 291 Wis. 2d 504, 714 N.W.2d 206 (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"). "Cause" is established by showing that the defendants' actions were a "substantial factor" in producing plaintiff's injury. *Werner v. Pittway Corp.*, 90 F. Supp. 2d 1018, 1027 (W.D. Wis. 2000) (citing *Clark v. Leisure Vehicles, Inc.*, 96 Wis.2d 607, 617, 292 N.W.2d 630, 635 (1980)). More specifically, in a failure to warn case, a plaintiff must show that the relevant actor would have altered his or her behavior and avoided injury if properly warned. *Zimmer*, 884 F.3d at 754.

Defendants point out that there is *no* direct testimony from Dr. Goncharova explaining that she would have changed her decision to use the Meridian Filter had she received a different warning. While testimony from Dr. Goncharova would certainly have been the most straightforward way to prove causation, however, defendant cites to no Wisconsin case law holding that such testimony is the *only* way that a plaintiff may establish this element.[9] Not only is this failure not fatal, the evidence that plaintiff *has* produced is sufficient for a reasonable jury to conclude Dr. Goncharova would have altered her behavior had she been properly warned. In particular, plaintiff has proffered an expert report from Dr. Hurst opining that had he been Johnson's treating physician at the time *and* aware of the safety issues regarding the Meridian Filter known to Bard at the time, he would not have used the Filter for the prevention of a pulmonary embolism in his patients, nor would any other reasonable implanting physician. Accordingly, defendants have not shown that plaintiff cannot prove causation as to her failure to warn claims.[10]

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[9] In fairness, defendants do cite to a number of cases from *outside of Wisconsin* to attempt to support its position, but the court does not find any to be persuasive. In all of the cases, there was no indication that the plaintiff had produced *any* evidence of causation, and so the courts did not have the opportunity to consider fully whether evidence other than the physician's testimony itself would have been adequate to establish causation. *See May v. Ethicon, Inc.*, No. 1:20-CV-322-TWT, 2020 WL 674357, at *4 (N.D. Ga. Feb. 11, 2020); *Higgins v. Ethicon, Inc.*, No. 2:12-CV-01365, 2017 WL 2813144, at *2-3 (S.D.W. Va. Mar. 30, 2017); *Contreras v. Bos. Sci. Corp.*, No. 2:12-CV-03745, 2016 WL 1436682, at *4 (S.D.W. Va. Apr. 11, 2016); *Sowder v. Bos. Sci. Corp.*, No. 2:13-CV-05149, 2015 WL 5838507, at *5 (S.D.W. Va. Oct. 5, 2015). To the extent that any of the cases cited by defendants suggest that testimony from plaintiff's physician is the *only* way to establish causation, again this court finds no support for this restriction in Wisconsin law.

[10] Defendants also argue that because Dr. Goncharova "ignored" the instructions on how to properly place the filter, no reasonable jury could find that she would have heeded a different warning about the risks of the filter. (Def.'s Br. (dkt. #24) 18.) First, this is not a reasonable interpretation of the facts. Although imaging taken the day the filter was implanted suggests that the filter was placed higher than was ideal, there is some question as to the accuracy of this imaging. Second, it is not reasonable to infer from this imaging that Dr. Goncharova "ignored" the placement

**III. Defective Design**

Under Wisconsin law, "[a] product is defective in design if the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the manufacturer and the omission of the alternative design renders the product not reasonably safe." Wis. Stat. § 895.047(1)(a).[11] Defendants contend that plaintiff's claims fail because she has produced no evidence of a reasonable alternative design. However, plaintiff counters that she *has* produced evidence of a reasonable alternative design -- namely, the Simon Nitinol Filter.

To support her argument that the Simon Nitinol Filter was a reasonable alternative design, plaintiff has proffered the opinions of two experts who both agree it was a safer alternative to the Meridian Filter. She also cites to other evidence showing the Simon Nitinol Filter has lower rates of complications than Bard's retrievable filters, including the Meridian Filter. From this evidence, a reasonable jury could certainly conclude that the foreseeable risks of harm posed by the Meridian Filter could have been reduced by the adoption of a reasonable alternative design, as embodied by Bard's own Simon Nitinol Filter.

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instructions, nor that this placement somehow means that she would ignore warnings of risks provided. Notably, defendants do *not* argue that the suprarenal placement of the filter itself prevents plaintiff from proving causation, likely because it would have been a losing argument. As noted above, causation only requires that defendants' actions be a "substantial factor" in producing the injury, not the *only* factor. *See Werner*, 90 F. Supp. 2d at 1027. Thus, while the placement of the filter may have *also* been a factor in Johnson's injuries, at the same time, there is still a genuine dispute over whether defendants' actions were a substantial factor in her injuries.

[11] Although Wis. Stat. § 895.047 addresses only strict liability claims, the Seventh Circuit recently explained that a product liability claim brought under a negligence theory also requires the plaintiff to prove that the product causing the injury was "defective." *Burton*, __ F.3d __.

However, defendants argue that the Simon Nitinol Filter is not a reasonable alternative design because it is a permanent filter, whereas the Meridian Filter is retrievable. Other district courts have considered similar arguments with respect to Bard IVC filters, with varying results. In *Oden v. Bos. Sci. Corp.*, 330 F. Supp. 3d 877 (E.D.N.Y. 2018) (applying New York law), the District Court for the Eastern District of New York concluded that the plaintiff failed to plead the existence of a reasonable alternative design because the proposed retrievable filters were not a reasonable alternative to her implanted permanent Bard IVC filter. *Id.* at 889. In the *Hyde* bellwether case (applying Wisconsin law), however, the court concluded that a trier of fact must decide if the Simon Nitinol Filter, a permanent filter, was a reasonable alternative design to the retrievable Bard filter that the plaintiff had received. 2018 WL 4742976, at *3 (D. Ariz. Oct. 2, 2018).

At least on the record before it, this court is inclined to agree with the *Hyde* court. In particular, contrary to what defendants argue, they have offered no *definitive* evidence compelling a finding that a permanent filter would not have been a reasonable alternative for Johnson. In fact, Dr. Hurst opines that if Johnson had been his patient, he would have recommended the Simon Nitinol Filter despite it being permanent. Despite this, defendants argue that plaintiff must demonstrate that there is a safer alternative to the Meridian Filter *specifically for suprarenal placement*. But this, too, appears a disputed issue of fact. First, there is some question as to whether the filter was indeed placed suprarenally. Although Dr. Hurst testified that the imaging taken from the same day that the filter was implanted suggested that it was placed higher than was ideal, he also explained that the type of imaging (a vena cavagram) was not an exact visualization. Moreover, a CT scan

taken on August, 9, 2013, three days after the filter was implanted, showed the filter had moved lower than appeared in the earlier vena cavagram.[12] Second, defendants have not identified, nor could this court find, any case suggesting that a plaintiff must produce a reasonable alternative design that reduces or avoids the risks of harm under a very particular set of circumstances. Rather, Wisconsin law explains that a product manufacturer is to consider the *foreseeable* use -- including abnormal use that is foreseeable -- of its products. *See Schuh v. Fox River Tractor Co.*, 63 Wis. 2d 728, 741-42, 218 N.W.2d 279 (1974).

Finally, defendants assert that a defective product cannot be a reasonable alternative design as a matter of law. Whether or not an accurate statement of law, the evidence at summary judgment does not suggest that the Simon Nitinol Filter was a defective product, and defendants do not try to argue this, pointing instead to the alleged defectiveness of *other* filters. Even if some evidence supported finding the Simon Nitinol Filter defective, it just creates another disputed issue of fact, not a basis for summary judgment.

**IV. Negligence *Per Se***

Under Wisconsin law, "[f]or the violation of a safety statute to constitute negligence *per se*, a plaintiff must show: (1) the harm inflicted was the type the statute was designed to prevent; (2) the person injured was within the class of persons sought to be protected; and (3) there is some expression of legislative intent that the statute become a basis for the

[12] Elsewhere, plaintiff suggests that the filter migrated downwards, which would appear to be inconsistent with her position that the CT scan from August 9 showed the correct initial placement of the filter. Regardless, resolution of these issues is best left to a jury.

imposition of civil liability." *Tatur v. Solsrud*, 174 Wis. 2d 735, 743, 498 N.W.2d 232 (1993). Here, it is unclear what safety statute plaintiff claims was violated.

Plaintiff's form complaint simply checks off "negligence *per se*" without specific reference to *any* statute (*see* Compl. (dkt. #1)), and none of the other materials submitted to this court provide further guidance. Defendants appear to assume that plaintiff asserts violations of FDA requirements. (*See* Defs.' Br. (dkt. #24) 26.) This assumption is perhaps guided by the fact that the plaintiffs in the *Hyde* bellwether case argued defendants' design of the IVC filter at issue in that case violated various provisions of, as well as related federal regulations promulgated under the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.* -- namely, 21 U.S.C. §§ 321, 331, and 352, and 21 C.F.R. §§ 803, 806.1, 820.100, 820.198, and 820.250. *Hyde*, 2018 WL 4356638, at *2. However, the court can find no reference to any of these specific provisions or regulations in plaintiff's submissions. Instead, plaintiff confusingly argues that defendants are not entitled to summary judgment on her negligence *per se* claim because § 510(k) is not a "safety statute," (*see* Pl.'s Opp'n (dkt. #38) 19), which as discussed above is true as far as it goes, since that section merely sets forth the process by which the FDA determines whether a proposed device is substantially equivalent to an already legally marketed device. However, since proving the violation of a safety statute is a required element of *plaintiff's* claim, her response amounts to a non sequitur.

Unfortunately, *both* parties' briefing largely glosses over this issue; instead, they focus on whether plaintiff's negligence *per se* claim is preempted by federal law. Despite this lack of clarity as to the specific provisions and regulations at issue, the parties do at

least appear to agree that the safety statutes underlying plaintiff's negligence *per se* claim refer to FDA statutes and regulations, although according to defendants, such provisions are only enforceable by the federal government, and any state law private rights of action seeking to enforce those provisions are impliedly preempted.

This latter defense was thoroughly addressed in the *Hyde* bellwether case. *Hyde*, 2018 WL 4356638, at *2. Relying on 21 U.S.C. § 337(a), the court confirmed that violations of the FDA are *only* enforceable by the United States itself. *Id.* According to *Hyde*, the Supreme Court in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001), "held that a state law claim that a defendant made fraudulent statements to the FDA, in violation of the FDCA, was impliedly preempted by § 337(a) because the claim 'exist[ed] solely by virtue' of FDCA requirements and therefore 'would not be relying on traditional state tort law which had predated the [FDCA].'" 2018 WL 4356638, at *2 (quoting *Buckman*, 531 U.S. at 353). Accordingly, the court concluded, the *Hyde* plaintiffs' claim of negligence *per se* was likewise preempted because it would not exist before enactment of the FDCA and is based only on violations of that federal law. *Id.* This reasoning applies with equal force here. While plaintiff's design defect and failure to warn claims based on state tort law are, of course, not preempted by the FDCA, her claims of negligence *per se* based solely on some alleged violation of the FDCA or its implementing

regulations are, like those in *Buckman* and *Hyde*, impliedly preempted by federal law.[13] Accordingly, the court will grant summary judgment in favor of defendants as to this claim.

## V. Future Damages and Punitive Damages

Defendants' final, two arguments relate to plaintiff's request for damages. First, defendants contend that plaintiff has failed to adduce sufficient evidence to support an award of damages for fear of risk of future complications. A plaintiff cannot recover for damages related to future injury, either physical or mental, if she has not proven that such injuries are anything more than "remotely conceivable complications." *Martindale v. Ripp*, 2001 WI 113, ¶ 90, 246 Wis. 2d 67, 629 N.W.2d 698. Instead, she must produce evidence of a "realistic prediction" as to the possibility of those future complications. *Id.* ¶ 89. Here, however, a reasonable fact finder *could* find that plaintiff has met this burden. In particular, Dr. Hurst has testified that the failure of Johnson's filter puts her at an increased risk of future complications, enumerating specific kinds of future complications that may arise (such as hemorrhage and cardiac damage), and he further explains that such complications could require surgical procedures with attendant risks of serious morbidity or death. Although not a specific prediction, this evidence is enough for a reasonable trier of fact to find risks of complications that are more than "remotely conceivable."

[13] The court notes that, in a previous case, this court held that plaintiffs *could* bring a negligence *per se* claim premised on a violation of a federal regulation for prescription drug labeling. *See Marvin v. Zydus Pharms. (USA) Inc.*, 203 F. Supp. 3d 985, 989 (W.D. Wis. 2016) (emphasizing that plaintiffs claim was a "tort law claim based on defendant's alleged failure to warn, rather than fraud on a federal agency," and as such was not impliedly preempted under *Buckman*). However, unlike in *Marvin*, plaintiff's negligence *per se* claim here would appear to have *no* independent basis in state law; rather, it is premised solely on FDA statutes and regulations.

Defendants also contend that Johnson has not presented sufficient evidence to support her claim for punitive damages. Under Wisconsin law, recovery for punitive damages requires a showing that a party "acted maliciously toward the plaintiff or in an intentional disregard of the plaintiff's rights." Wis. Stat. § § 895.043. The Wisconsin Supreme Court has explained that "a person acts in an intentional disregard of the rights of the plaintiff if the person acts with a purpose to disregard the plaintiff's rights, or is aware that his or her acts are substantially certain to result in the plaintiff's rights being disregarded." *Strenke v. Hogner*, 2005 WI 25, ¶ 3, 279 Wis. 2d 52, 694 N.W.2d 296. A defendant's conduct need not be directed at the specific plaintiff seeking punitive damages in order to give rise to recovery. *Id.* Nevertheless, punitive damages may not be awarded based on conduct that did not cause or contribute to the plaintiff's loss. *Henrikson v. Strapon*, 2008 WI App 145, ¶ 19, 314 Wis. 2d 225, 758 N.W.2d 205.

Here, plaintiff has produced evidence for a reasonable jury to find that she is deserving of punitive damages. In particular, she has offered evidence that defendants knew its Meridian Filter had higher risks of complications than other IVC filters on the market, yet chose not to disclose this information in its warnings to physicians or to the public, while continuing to produce and market the Meridian Filter.

Accordingly, the court will not dismiss plaintiff's claim for punitive damages at summary judgment. *See Hyde*, 2018 WL 4742976, at *4 (on similar facts, refusing to grant defendants judgment as a matter of law regarding plaintiffs' claims for punitive damages under Wisconsin law).

ORDER

IT IS ORDERED that defendants' motion for summary judgment (dkt. #24) is DENIED IN PART and GRANTED IN PART, consistent with the opinion above.

Entered this 5th day of May, 2021.

BY THE COURT:

/s/

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WILLIAM M. CONLEY
District Judge