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6 **IN THE UNITED STATES DISTRICT COURT**  
7 **FOR THE DISTRICT OF ARIZONA**  
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9 IN RE: Bard IVC Filters Products Liability  
10 Litigation,

No. MDL 15-02641-PHX-DGC

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12 Lisa Hyde and Mark E. Hyde, a married  
13 couple,

No. CV-16-00893-PHX-DGC

14 Plaintiffs,

**ORDER**

15 v.

16 C. R. Bard, Inc., a New Jersey corporation;  
17 and Bard Peripheral Vascular, Inc., an  
18 Arizona corporation,

19 Defendants.  
20

21 The case brought by Plaintiffs Lisa and Mark Hyde is set for a bellwether trial  
22 later this month. The parties have filed motions in limine (“MILs”) in advance of trial.  
23 This order will rule on Plaintiffs’ MILs Nos. 4 and 5, which seek to exclude evidence  
24 regarding the Bard IVC filter’s instructions for use (“IFU”) and certain guidelines  
25 published by the Society of Interventional Radiologists (“SIR”). Docs. 12100, 12101.

26 **I. Background.**

27 Plaintiff Lisa Hyde received a Bard IVC filter implant in 2011. In 2014, she  
28 learned that the filter had tilted, perforated the IVC wall, and fractured. The filter and

1 fractured limbs were removed three months later.<sup>1</sup>

2 Mrs. Hyde and her husband assert various claims. Doc. 364; Doc. 1, Case No.  
3 CV-16-00893. Applying Wisconsin law, the Court granted summary judgment on their  
4 failure to warn claims (Counts II and VII). Doc. 12007. Plaintiffs continue to assert  
5 claims for strict liability design defect (Count III), negligent design (Count IV),  
6 negligence per se (Count IX), loss of consortium (Count XV), and punitive damages.  
7 *Id.* at 19.

## 8 **II. Discussion.**

### 9 **A. Parties' Arguments.**

10 Under Wisconsin's product liability statute, Wis. Stat. § 895.047, a product is  
11 defective in design if its foreseeable risks of harm could have been reduced or avoided by  
12 the adoption of a reasonable alternative design, and the omission of the alternative design  
13 renders the product not reasonably safe. § 895.047(1)(a). Plaintiffs argue that, consistent  
14 with the statute, the focus of their case will be on the design of the Bard filter and  
15 alternative designs that would have made the filter safe. Doc. 12100 at 2. Plaintiffs  
16 argue that because the IFU says nothing about the filter's design, and because the failure  
17 to warn claims have been dismissed, the instructions and warnings set forth in the IFU are  
18 no longer relevant to any issue in the case and should be excluded under Rules 401 and  
19 402 of the Federal Rules of Evidence. *Id.* at 2-3. Plaintiffs further argue that evidence  
20 regarding the IFU should be excluded under Rule 403 because it would only confuse the  
21 jury. *Id.* at 3.

22 Plaintiffs seek exclusion of the SIR guidelines for similar reasons. Doc. 12101.  
23 They argue that the purpose for which the SIR guidelines were previously admitted – to  
24 show knowledge of IVC filter complications in the medical community – is no longer  
25 relevant now that the failure to warn claims have been dismissed. *Id.* at 2. Plaintiffs  
26 contend that any defense based on the learned intermediary doctrine is moot without a

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28 <sup>1</sup> The parties dispute whether Mrs. Hyde's filter was a G2X or an Eclipse, but the  
filter type has no bearing on these MILs.

1 failure to warn claim, and that the defense otherwise does not apply because Mrs. Hyde,  
 2 not the implanting physician, is the “ultimate consumer” under Wisconsin product  
 3 liability law. *Id.*; Doc. 12100 at 3 (citing *Green v. Smith & Nephew AHP, Inc.*, 629  
 4 N.W.2d 727, 752 (Wis. 2001) (holding that a product is defective if it is in a condition  
 5 “not contemplated by the ultimate consumer”).<sup>2</sup>

6 Defendants assert that the language of § 895.047(a)(1) reflects Wisconsin’s  
 7 adoption of § 2(b) of the Restatement (Third) of Torts (1998) (“§ 2(b)”). Docs. 12384  
 8 at 2, 12385 at 2. The IFU and SIR guidelines are relevant to the design defect claim,  
 9 Defendants argue, because § 2(b) involves a risk-utility balancing test and consideration  
 10 of a broad range of factors, including the instructions and warnings accompanying the  
 11 product. *Id.* (citing § 2, cmts. d & f). Defendants further argue that Plaintiffs’ reliance on  
 12 *Green* and the “consumer contemplation” test is misplaced because the test has been  
 13 abrogated by Wisconsin’s adoption of § 895.047 and § 2(b). Doc. 12385 at 2 n.2.<sup>3</sup>

#### 14 **B. Wisconsin’s Product Liability Law.**

15 In 1967, Wisconsin adopted the rule of strict product liability set forth in  
 16 the Restatement (Second) of Torts § 402A (1965) (“§ 402A”). *See Dippel v. Sciano*, 155  
 17 N.W.2d 55, 63-65 (1967). Eight years later, the state explicitly adopted a “consumer  
 18 contemplation” test. *See Vincer v. Esther Williams All-Aluminum Swimming Pool Co.*,  
 19 230 N.W.2d 794, 797 (Wis. 1975) (adopting § 402A, cmts. g & i); *Green*, 629 N.W.2d  
 20 at 738-39. Under this test, a product “is defective and unreasonably dangerous when it is  
 21 in a condition not contemplated by the ultimate consumer and unreasonably dangerous to  
 22 that consumer.” *Beacon Bowl, Inc. v. Wis. Elec. Power Co.*, 501 N.W.2d 788, 809 (Wis.  
 23 1993) (citing *Vincer*).

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 25 <sup>2</sup> It is not clear under Wisconsin law whether Mrs. Hyde or the implanting  
 26 physician was the “ultimate consumer” of the Bard filter for purposes of the design defect  
 27 claim. 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.  
*See* Doc. 12007 at 14 n. 6 (citing cases).

28 <sup>3</sup> These arguments, and Wisconsin product liability law, are discussed by the  
 parties more fully in their trial briefs and proposed pretrial order and jury instructions.  
 Docs. 12358 at 2-15, 12400 at 8-13; Doc. 12388 at 19-22; Doc. 12438 at 34, 45-51.

1           The consumer contemplation test was challenged in *Green*. The defendant argued  
2 that a pure consumer contemplation test, without consideration of the risks and benefits  
3 of the product, would unnecessarily cause many useful products to be taken off the  
4 market. *Green*, 629 N.W.2d at 742. The defendant further argued that foreseeability of  
5 the risk of harm should be an element of product liability claims in order to avoid  
6 imposing absolute liability on manufacturers. *Id.* at 744. The defendant urged the court  
7 to adopt Restatement § 2(b), which includes an element of foreseeability:

8           [A product] is defective in design when the foreseeable risks of harm posed  
9 by the product could have been reduced or avoided by the adoption of a  
10 reasonable alternative design[,] . . . and the omission of the alternative  
design renders the product not reasonably safe[.]

11 *See id.* at 751.

12           *Green* rejected these arguments. *Id.* at 737-52. The court declined the “invitation  
13 to abandon or qualify [Wisconsin’s] exclusive reliance on the consumer-contemplation  
14 test.” *Id.* at 743. The court also declined to adopt § 2(b) because its incorporation of  
15 “an element of foreseeability of risk of harm and a risk-benefit test . . . departs from the  
16 consumer-contemplation test set forth in [§ 402A], and blurs the distinction between  
17 strict products liability claims and negligence claims.” *Id.* at 751 (noting that a risk-  
18 benefit test is included in § 2, comment a). The court was “troubled by the fact that  
19 § 2(b) sets the bar higher for recovery in strict products liability design defect cases than  
20 in comparable negligence cases” by adding the requirement that “there was a ‘reasonable  
21 alternative design’ available to the product’s manufacturer.” *Id.* The court concluded:

22           Where a manufacturer places a defective and unreasonably dangerous  
23 product into the stream of commerce, the manufacturer, not the injured  
24 consumer, should bear the costs of the risks posed by the product. Because  
25 2(b) unduly obstructs this equitable principle, we refuse to adopt 2(b) into  
Wisconsin law.

26 *Id.*

27           In early 2011, the Wisconsin legislature changed this law by enacting § 895.047.  
28 *See Gopalratnam v. Hewlett-Packard Co.*, No. 13-CV-618-PP, 2016 WL 8193573, at \*1

1 (E.D. Wis. Mar. 11, 2016) (citing Wis. Senate Bill 1, 2011 Wis. Act 2 (Jan. 27, 2011));  
 2 *In re Zimmer Nexgen Knee Implant Prods. Liab. Litig.*, 218 F. Supp. 3d 700, 723 (N.D.  
 3 Ill. 2016) (discussing § 895.047 and noting that it was “enacted as a part of a ‘tort reform’  
 4 initiative in 2011”), *aff’d* 884 F.3d 746 (7th Cir. 2018). The new statute adopted § 2 of  
 5 the Restatement (Third). Doc. 12400 at 11. The statute reads:

6           **(1) Liability of manufacturer.** In an action for damages caused by  
 7 a manufactured product based on a claim of strict liability, a manufacturer  
 8 is liable to a claimant if the claimant establishes all of the following by a  
 9 preponderance of the evidence:

10           (a) That the product is defective because it . . . is defective in design  
 11 . . . . A product is defective in design if the foreseeable risks of harm posed  
 12 by the product could have been reduced or avoided by the adoption of a  
 13 reasonable alternative design by the manufacturer and the omission of the  
 14 alternative design renders the product not reasonably safe.

15 § 895.047(1)(a); *see Lexington Ins. Co. v. Whesco Grp., Inc.*, No. 11-CV-598-BBC, 2013  
 16 WL 4454959, at \*8 (W.D. Wis. Aug. 16, 2013); WIS JI-CIVIL § 3260.1 (2014). Thus, a  
 17 plaintiff claiming strict product liability under Wisconsin law must now show that the  
 18 product’s foreseeable risk of harm could have been reduced or avoided by a reasonable  
 19 alternative design, and that the failure to adopt the alternative design rendered the product  
 20 “not reasonably safe.” § 895.047(1)(a).

21           **C. Analysis.**

22           Plaintiffs rely on *Green* in arguing that the IFU and the SIR guidelines have no  
 23 relevance to the design defect claim because “a product is not reasonably safe under  
 24 Wisconsin law if it is ‘in a condition not contemplated by the ultimate consumer.’”  
 25 Doc. 12101 at 2 (quoting *Green*, 245 Wis. 2d at 825-26); *see* Doc. 12100 at 3. But *Green*  
 26 was effectively overruled by the adoption of § 895.047, and the consumer contemplation  
 27 test is now only one factor in determining whether the Bard filter was unsafe. The statute  
 28 adopts § 2 of the Restatement, and, under § 2, “consumer expectations do not constitute  
 an independent standard for judging the defectiveness of product designs” because they  
 do not take into account “whether an alternative design would provide greater overall

1 safety.” *See* Restatement (Third) § 2, cmt. g; *see also* WIS JI-CIVIL § 3260.1 (noting  
2 that § 895.047(1)(a) introduced the “reasonable alternative design” test for design defect  
3 cases “apparently discarding the consumer contemplation test”). Thus, the Court cannot  
4 exclude the IFU and SIR guidelines on the basis urged by Plaintiff – that they are not  
5 relevant to consumer expectations.<sup>4</sup>

6 Plaintiffs further argue that the IFU and SIR guidelines are no longer needed to  
7 support a learned intermediary defense because the failure to warn claims have been  
8 dismissed. Docs. 12100 at 1-2, 12101 at 2. Those claims have been dismissed, but the  
9 IFU and SIR guidelines are also relevant to the design defect claim. As noted above, the  
10 jury must consider not only whether there was a reasonable alternative design, but also  
11 whether Bard’s failure to adopt that design rendered the filter “not reasonably safe.” Wis.  
12 Stat. § 895.047(1)(a). The SIR guidelines – created by the Society of Interventional  
13 Radiologists to inform the medical community regarding acceptable rates of risk in IVC  
14 filters – are relevant to the jury’s determination of whether Bard’s filter was reasonably  
15 safe. Bard’s IFU, including what it tells physicians about risks of the Bard filters and  
16 how to mitigate them, is also relevant in determining whether the filter was reasonably  
17 safe. Nothing in § 895.047 precludes Defendants from arguing to the jury that the  
18 warnings provided with the Bard filter disclosed the risks of complications, that the  
19 medical community was aware of those risks and found them to be acceptable, and that  
20 the omission of an alternative design therefore did not render the filter “not reasonably  
21 safe.”<sup>5</sup>

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23 <sup>4</sup> Plaintiffs note in their trial brief that comment g to § 2(b) provides that consumer  
24 expectations, while not dispositive, still play a role in determining defectiveness.  
25 Doc. 12400 at 10-11. A Wisconsin district court has expressed doubt whether this “is an  
26 accurate statement of the law in Wisconsin.” *In re Zimmer*, 218 F. Supp. 3d at 723. The  
Court need not decide this issue for purposes of the MILs because consumer expectations  
are, at most, only one factor to be considered in the ultimate determination of whether the  
omission of a proposed alternative design renders a product not reasonably safe. *See id.*;  
§ 895.047(1)(a).

27 <sup>5</sup> Defendants note that a comment to the Restatement provides that the instructions  
28 and warnings accompanying a product may be considered in determining whether a  
product is defective. Docs. 12384 at 2, 12385 at 2 (citing § 2, cmt. f). Based on this and  
other comments to the Restatement, Defendants propose jury instructions setting forth a

1           The IFU and SIR guidelines also are relevant to Plaintiffs’ negligence and punitive  
2 damages claim. In deciding whether Defendants acted reasonably for purposes of the  
3 negligence claim, the jury may consider rates of risk accepted within the medical  
4 community (the SIR guidelines) and what Defendants told physicians about those risks in  
5 the IFU.

6           To recover punitive damages under Wisconsin law, Plaintiffs must show that  
7 Defendants “acted maliciously” or in an “intentional disregard of the rights” of Plaintiffs.  
8 Wis. Stat. 895.043(3); *see Strenke v. Hogner*, 694 N.W.2d 296, 304-05 (Wis. 2005). The  
9 jury may consider Defendants’ “attitude and conduct” and “the degree of [Defendants’]  
10 awareness of the hazard and of its excessiveness.” Doc. 12438 at 38-39; *see* WIS JI-  
11 CIVIL § 1707.2. Warnings provided in the IFU are relevant to Defendants’ attitude and  
12 conduct toward patients who receive Bard filter implants, and whether Defendants acted  
13 with malice or an intentional disregard for patient safety. The SIR guidelines are relevant  
14 to Defendants’ awareness of filter complication rates and the extent of harm posed by  
15 filter complications, and can also inform the jury of risk levels found acceptable by  
16 interventional radiologists – a relevant fact for deciding whether Defendants’ acted with a  
17 disregard for patient safety.

18           Plaintiffs contend that the IFU should be excluded under Rule 403. Docs. 12100  
19 at 3. But evidence regarding the IFU will not unfairly prejudice Plaintiffs or confuse the  
20 jury. Defendants will not be permitted to assert a learned intermediary defense or  
21 otherwise defend against the dismissed failure to warn claims, and the Court will properly  
22 instruct the jury on the claims at issue and the law that applies to them.

23           Plaintiffs contend that any probative value of the SIR guidelines is substantially  
24 outweighed by the dangers described in Rule 403 because no expert has testified that the  
25 SIR guidelines set forth “acceptable” complication rates. Doc. 12101 at 2-4. But the

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host of factors the jury may consider in deciding whether the Bard filter is defective.  
Doc. 12438 at 46-48. Plaintiff objects to the proposed instructions, arguing that the  
comments to the Restatement have not been incorporated into Wisconsin product liability  
law. *Id.*; Doc. 12400 at 11 (trial brief). The Court need not decide this issue in order to  
resolve the MILs.

1 Court will require an appropriate foundation before admitting the SIR guidelines, and  
2 Plaintiffs' challenge to their veracity will go to their weight, not their admissibility.

3 **IT IS ORDERED** that Plaintiffs' MILs Nos. 4 and 5 (Docs. 12100, 12101) are  
4 **denied.**

5 Dated this 4th day of September, 2018.

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David G. Campbell  
9 Senior United States District Judge

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