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IN THE UNITED STATES DISTRICT COURT

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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

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v.

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

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Defendants.

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The case brought by Plaintiffs Lisa and Mark Hyde is set for a bellwether trial later this month. The parties have filed motions in limine (“MILs”) in advance of trial. The Court previously ruled on Plaintiffs’ MILs 4 and 5. Doc. 12507. This order will rule on the remaining MILs except Defendants’ MIL 5.¹

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¹ Defendants have withdrawn MIL 2, which sought to exclude marketing materials. Docs. 12089, 12496. Defendants’ MIL 5 seeks to exclude opinion testimony of Dr. Kandarpa. Doc. 12092. The parties agreed at today’s final pretrial conference that the Court should review the deposition designations for Dr. Kandarpa and make rulings on a question-by-question basis. The Court will issue a separate order addressing Defendants’ objections to Dr. Kandarpa’s testimony.

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1 **I. Background.**

2 Plaintiff Lisa Hyde received a Bard IVC filter implant in 2011. In 2014, she
3 learned that the filter had tilted, perforated the IVC wall, and fractured. The filter and
4 fractured limbs were removed three months later.²

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

10 **II. Plaintiffs' Motions in Limine.**

11 **A. MIL 1 – FDA Evidence.**

12 In the Booker case, the Court denied a motion in limine to exclude evidence of the
13 FDA's 510(k) clearance process and lack of enforcement action against Bard. Doc. 9881.
14 Plaintiffs state that they are neither re-urging nor seeking reconsideration of that order,
15 but instead seek to exclude evidence beyond the scope of the order. Doc. 12095 at 1 n.1.
16 Plaintiffs assert that the FDA evidence admitted in the Booker and Jones bellwether trials
17 created an impression that the FDA made safety and efficacy determinations by implying
18 that Bard "worked hand-in-hand with the FDA" and "conducted a design process with the
19 FDA." *Id.* at 2. Plaintiffs seek to exclude evidence regarding (1) Bard's post-market
20 surveillance communications with the FDA, (2) the FDA's reclassification of IVC filters
21 from class III to class II devices, and (3) "gratuitously offered" testimony about FDA
22 communications unrelated to the 510(k) process. *Id.* at 2-4.

23 Bard's post-market surveillance communications with the FDA are relevant to the
24 question of whether Bard acted reasonably for purposes of the negligent design claim,
25 particularly since Plaintiffs claim that the G2 line of filters constituted an ongoing design
26 and iteration of the original G2 filter. *See Stevens v. Stryker Corp.*, No. 12-CV-63-BBC,

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28 ² The parties dispute whether Mrs. Hyde's filter was a G2X or an Eclipse. The Court has concluded that the issue should be presented to the jury. Doc. 12157.

1 2013 WL 4758948, at *4 (W.D. Wis. Sept. 4, 2013) (noting that the reasonableness of the
2 manufacturer’s conduct is informed by FDA regulations). Post-market communications
3 are also relevant to Plaintiff’s punitive damages claim that Bard acted maliciously and
4 with intentional disregard for the rights of others. *See* Wis. Stat. § 895.043(3) (to recover
5 punitive damages the plaintiffs must show that the defendants “acted maliciously” or in
6 an “intentional disregard of the rights” of the plaintiffs). Additionally, Plaintiffs have
7 stated that their punitive damages case will be based in part on Bard’s failure to take post-
8 sale remedial actions. *See* Doc. 12400 at 17-19. Bard’s post-market surveillance of its
9 products, and its and communications with the FDEA about that surveillance, are directly
10 relevant to this issue. Finally, evidence regarding Bard’s post-market communications
11 with the FDA and the agency’s lack of enforcement action with respect to Bard filters are
12 relevant to Plaintiffs’ claim that Bard failed to disclose relevant evidence to and misled
13 the FDA. *See* Docs. 11011 at 4, 10323 at 2-3.

14 Plaintiffs seek exclusion of the FDA’s 1996 reclassification memo because it does
15 not directly relate to the 510(k) process or any Bard retrievable filter. Doc. 12095 at 3;
16 *see* Doc. 12095-8. But as Defendants note, the memo explains why IVC filters are
17 subject to 510(k) review instead of the premarket approval process, and tends to rebut
18 Plaintiffs’ argument that Bard strategically chose the easier path of clearance instead of
19 approval. Doc. 12381 at 3 & n.3. Plaintiffs claim that the memo “sends the message that
20 [the] FDA deemed Bard’s devices safe and effective.” Doc. 12095 at 4. But Plaintiffs
21 have ample evidence to contest any such implication. *See* Doc. 10323 at 3. The Court
22 cannot conclude that admission of the reclassification memo will unfairly prejudice
23 Plaintiffs.

24 Similarly, the probative value of testimony from Bard witnesses that they regularly
25 communicated and shared information with the FDA, and that they personally believe
26 Bard filters are safe and effective, is not outweighed by the danger of unfair prejudice.
27 Doc. 12095 at 4. Plaintiffs can make appropriate objections if they feel that gratuitous
28 and irrelevant comments are being made during testimony.

1 Consistent with the Court’s earlier ruling, Defendants will be precluded from
2 presenting evidence or argument that the FDA “approved” Bard retrievable filters for
3 market, or that clearance of the devices under 510(k) review constitutes a finding by the
4 FDA that the filters are “safe and effective.” Doc. 9881 at 6. But Defendants will not be
5 precluded from presenting evidence of the FDA’s 510(k) clearance process and lack of
6 enforcement action against Bard. *See id.* at 3-6. The motion in limine (Doc. 12095) is
7 **denied.**

8 **B. MIL 2 – Surgeon General’s Call to Action.**

9 Plaintiffs seek to exclude evidence and argument regarding a 2008 report issued
10 by the U.S. Department of Health and Human Services titled “The Surgeon General’s
11 Call to Action to Prevent Deep Vein Thrombosis and Pulmonary Embolism” (the “Call to
12 Action report”). Doc. 12097; *see* Doc. 12382-1. Plaintiffs contend that the report is
13 irrelevant and confusing, and any probative value is substantially outweighed by the
14 danger of unfair prejudice. Doc. 12097 at 1-3. Plaintiffs further contend that the report
15 constitutes inadmissible hearsay. *Id.* at 3-4. Defendants argue that the report is
16 admissible under the public records hearsay exception, is relevant, not prejudicial, and
17 will not confuse the jury. Doc. 12382. The Court agrees with Defendants.

18 The Call to Action report is relevant to the design defect and negligence claims.
19 With respect to the design defect claim, the jury must consider not only whether there
20 was a reasonable alternative design for the Bard filter, but also whether Bard’s failure to
21 adopt that design rendered the filter “not reasonably safe.” Wis. Stat. § 895.047(1)(a).
22 The jury thus will be required to make a reasonableness determination with respect to the
23 filter’s safety. Similarly, in deciding Plaintiff’s negligence claim, the jury will be
24 required to decide whether Defendants acted reasonably in designing and releasing the
25 filter. In making this determination, the jury may employ a risk-benefit analysis. *See*
26 *Meyer v. Val Lo Will Farms, Inc.*, 111 N.W.2d 500, 503 (Wis. 1961) (explaining that
27 negligence claims require a risk-benefit analysis); *Green v. Smith & Nephew AHP, Inc.*,
28 629 N.W.2d 727, 751 (Wis. 2001) (same); *see also* Restatement (Third) of Torts, § 2 cmt.

1 d (1998) (noting that “[s]ubsection (b) adopts a reasonableness (‘risk-utility balancing’)
2 test as the standard for judging the defectiveness of product design”).³

3 The Call to Action report is relevant to the risk-benefit analysis because it explains
4 the benefits of IVC filters. It notes that deep vein thrombosis and pulmonary emboli are
5 major public health problems, contributing to at least 100,000 deaths per year.
6 Doc. 12382-1 at 8. The report calls for actions to reduce the risk of these diseases, and
7 notes that IVC filters are one option for the prevention of pulmonary emboli. *Id.*
8 at 26-28. The report plainly is probative of whether the benefits of Bard filters, when
9 weighed against their risks, render Bard’s actions unreasonable or the filter “not
10 reasonably safe.” *See* Doc. 10258 at 8 (denying motion to exclude evidence that IVC
11 filters are “lifesaving” devices because the benefits of IVC filters are relevant to a risk-
12 utility analysis).

13 The record does not support Plaintiffs’ assertion that Defendants argued during the
14 first two bellwether trials that “Bard acted at the direction of the Surgeon General” and
15 “the Surgeon General considers Bard’s IVC filters necessary” to treat pulmonary emboli.
16 Doc. 12097 at 2. If Plaintiffs believe that Defendants are improperly implying the
17 imprimatur of the Surgeon General, they may object at trial. *See id.* But the Court
18 cannot conclude that admission of the Call to Action report will confuse the jury or
19 unfairly prejudice Plaintiffs.

20 Nor can the Court conclude that the report constitutes inadmissible hearsay. The
21 report falls within the public records hearsay exception. Fed. R. Evid. 803(8). Plaintiffs’
22 citation of *Philip Morris USA, Inc. v. Pollari*, 228 So. 3d 115, 123 (Fla. Dist. Ct. App.
23 2017), does not help their position. *Pollari* found that Surgeon General reports satisfy
24 Federal Rule of Evidence 803(8)(A)(iii) as records of factual findings from authorized
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26 ³ Plaintiffs contend that the Call to Action report has no relevance because
27 Wisconsin law employs a “consumer contemplation” test for design defect claims, not a
28 risk-benefit analysis. Doc. 12097 at 4 (citing *Green*, 629 N.W.2d at 752). As explained
in the Court’s order denying Plaintiffs’ MILs 4 and 5, this contention is incorrect.
Doc. 12507. In addition, the risk-benefit analysis is relevant to Plaintiffs’ negligence
claim, as noted above. *Green*, 629 N.W.2d at 751; *Meyer*, 111 N.W.2d at 503.

1 investigations, but excluded the reports because Florida law did not follow the federal
2 rule. *Id.* Other cases have admitted Surgeon General reports under Rule 803(8). *See*
3 *Boerner v. Brown & Williamson Tobacco Co.*, 394 F.3d 594, 600 (8th Cir. 2005) (finding
4 Surgeon General reports “properly admitted under the public records exception,
5 inasmuch as they were prepared pursuant to a legal obligation”). The motion in limine
6 (Doc. 12097) is **denied**.

7 **C. MIL 3 – November 2012 and May 2013 Falling Incidents.**

8 Plaintiffs seek to exclude evidence and argument that Mrs. Hyde’s falls in
9 November 2012 and May 2013 caused or contributed to the Bard filter’s failures.
10 Doc. 12099. Defendants state that they will not argue or suggest that the falls contributed
11 to the filter’s failures or otherwise impacted Mrs. Hyde’s filter-related complications.
12 Doc. 12383 at 2. The motion in limine is **granted** in this regard.⁴

13 **III. Defendants’ Motions.**

14 **A. MIL 1 – Recovery Filter Cephalad Migration Deaths.**

15 Defendants seek to exclude evidence of deaths caused by cephalad migration of
16 Recovery filters. Doc. 12088. Plaintiffs contend that such evidence is relevant because
17 excluding the deaths associated with the predicate Recovery filter that led to the G2’s
18 design would unduly prejudice Plaintiffs in proving the design defect claim. Doc. 12392
19 at 2. But this case does not involve a Recovery filter. Mrs. Hyde received a filter that
20 was either a G2X or Eclipse, two or three generations after the Recovery filter. *See*
21 Doc. 12157. She was implanted with the filter in early 2011, more than five years after
22 cephalad migration deaths stopped when the Recovery was taken off the market in 2005.
23 The cephalad migration deaths from the Recovery in 2004 and 2005 do not show that
24 G2X or Eclipse filters – which did not cause cephalad migration deaths (*see* Doc. 10920)
25 – had design defects when they left Defendants’ control several years later. Nor do the
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27 ⁴ Defendants state that they intend to introduce evidence of the falls only to rebut
28 the injuries and damages Mrs. Hyde alleges she suffered as a result of her IVC filter. *Id.*
Plaintiffs have not sought to preclude Defendants from using the evidence for this
purpose.

1 cephalad migration deaths, which were eliminated by design changes to the G2, shed
2 light on Defendants’ state of mind when designing and marketing the G2X and Eclipse.

3 The Court will exclude evidence of Recovery filter cephalad migrations deaths
4 under Rule 403, for the reasons it excluded the same evidence in the Jones trial.
5 Docs. 10819, 10920, 11041.⁵ The motion in limine (Doc. 12088) is **granted**.⁶

6 **B. MIL 3 – Simon Nitinol Filter as a Reasonable Alternative Design.**

7 To prove that the Bard filter is defective in design, Plaintiffs must show that the
8 foreseeable risks of harm could have been reduced or avoided by a reasonable alternative
9 design. Wis. Stat. § 895.047(1)(a). Defendants seek to exclude evidence that Bard’s
10 Simon Nitinol filter (“SNF”) is a reasonable alternative design because, unlike the G2X
11 and Eclipse, the SNF is a non-retrievable, permanent filter. Defendants cite no rule of
12 evidence that would make this evidence inadmissible. *See* Doc. 12090.

13 Presumably, Defendants are suggesting that the evidence is irrelevant because a
14 permanent filter cannot be a reasonable alternative to a filter that is both permanent and
15 retrievable. But relevancy is a relatively low standard – evidence having “any” tendency
16 to make a fact in dispute more probable (Fed. R. Evid. 401) – and it is the jury’s task to
17 decide whether a proposed alternative is “reasonable.” Defendants can make a Rule 50
18 motion if they think the evidence would not support a jury verdict on this issue, but the
19 Court cannot conclude that Plaintiffs should be precluded from presenting evidence and
20 argument to support their theory. The motion in limine (Doc. 12090) is **denied**.

21 **C. MIL 4 – Personal Opinions of Dr. Muehrcke.**

22 Defendants seek to exclude testimony from Dr. Muehrcke that he “personally felt
23 betrayed” because Bard had not told physicians about information contained in Bard’s
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25 ⁵ *See In re Bard IVC Filters Prods. Liab. Litig.*, No. CV-16-00782-PHX-DGC,
26 2018 WL 2124146 (May 8, 2018), 2018 WL 1993767 (Apr. 27, 2018), and 2018 WL
1876896, at *2-4 (Apr. 18, 2018).

27 ⁶ Nothing in this ruling precludes Plaintiffs from presenting “crucial” evidence
28 that Defendants were able to modify their filter design quickly – within nine months of
Recovery reaching the market – as part of Plaintiffs’ claim that alternative designs were
possible. Doc. 12392 at 6-7 & n. 6.

1 internal documents, and that he has a “moral and ethical issue” with how Bard addressed
2 adverse events. Doc. 12091 at 2; *see* Doc. 12091-1 at 3 (testimony in Jones trial).
3 “Personal views on corporate ethics and morality are not appropriate expert opinions.”
4 *In re Baycol Prods. Liab. Litig.*, 532 F. Supp. 2d 1029, 1053 (D. Minn. 2007); *see In re*
5 *Trasylol Prods. Liab. Litig.*, No. 08-MD-1928, 2010 WL 1489793, at *9 (S.D. Fla.
6 Feb. 24, 2010) (finding opinions on Bard’s responsibilities inadmissible under Rule 702
7 because they were based on the doctor’s subjective beliefs rather than any objective
8 standard or specialized knowledge); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp.
9 2d 531, 542-43 (S.D.N.Y. 2004) (“The opinions of plaintiffs’ witnesses, however
10 distinguished these individuals may be as physicians and scientists, concerning the ethical
11 obligations of pharmaceutical companies and whether the defendants’ conduct was
12 ethical are inadmissible[.]”). Dr. Muehrcke will be permitted to explain, if asked at trial,
13 why he does not use Bard’s filters based on his personal experience using the filters and
14 his review of Bard internal documents. But he is precluded from testifying about his
15 personal feelings of betrayal and his moral and ethical issues with Bard’s conduct.
16 Dr. Muehrcke’s personal feelings are not relevant. *See Ollier v. Sweetwater Union High*
17 *Sch. Dist.*, 768 F.3d 843, 861 (9th Cir. 2014) (noting that “personal opinion testimony is
18 inadmissible as a matter of law under Rule 702”); *see also* Doc. 9433 at 17 (holding that
19 no expert, on either side, will be permitted to opine on ethics). The motion in limine
20 (Doc. 12091) is **granted**.

21 **D. MIL 6 – Informed Consent.**

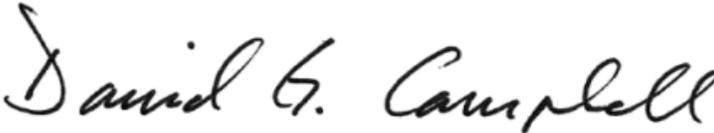
22 Defendants seek to exclude evidence and argument about informed consent.
23 Doc. 12093. Plaintiffs’ medical experts have offered opinions that Bard needed to
24 provide the medical community with additional information about its IVC filters so that
25 physicians could obtain informed consent from patients. *See id.* at 2-3. Defendants argue
26 that the opinions are irrelevant now that the failure to warn claims have been dismissed.
27 *Id.* at 2-4. The Court does not agree.

28 In opposing Plaintiffs’ motion in limine to exclude evidence of the Bard filter’s

1 instructions for use (“IFU”), Defendants argued that warnings provided in the IFU about
2 filter complication risks are relevant to the jury’s determination of whether Bard acted
3 reasonably in designing the filter and whether the filter is “not reasonably safe” under
4 Wisconsin product liability law. Doc. 12384 at 2 (citing Wis. Stat. § 895.047(1)(a);
5 Restatement (Third) of Torts, § 2 cmts. d, f). Defendants similarly argued that certain
6 guidelines published by the Society of Interventional Radiologists (“SIR”) are relevant in
7 evaluating what is “not reasonably safe” because they inform treating physicians about
8 acceptable rates of risk in IVC filters. Doc. 12385 at 2-3. The Court agreed, and held
9 that Defendants are not precluded from arguing to the jury that the warnings provided
10 with the Bard filter disclosed the risks of complications, that the medical community was
11 aware of those risks and found them to be acceptable, and that the omission of
12 an alternative design therefore did not render the filter “not reasonably safe.” Doc. 12507
13 at 6. The Court also found that the IFU and SIR guidelines are relevant to the punitive
14 damages claim because they reflect Bard’s attitude toward patient safety and awareness
15 of filter complication rates. *Id.* at 7.

16 If Defendants are permitted to present evidence about Bard’s warnings to doctors
17 as part of their defense, then Plaintiffs are permitted to present evidence about what
18 warnings Bard did not give. *See* Doc. 12508 at 4. In this regard, Plaintiffs’ experts are
19 not precluded from explaining to the jury that they have an obligation to obtain informed
20 consent from patients and, in order to fulfill this obligation, they need manufacturers to
21 provide honest and complete information about the risks and benefits associated with the
22 medical device. The Court cannot conclude that evidence regarding informed consent is
23 irrelevant. The motion in limine (Doc. 12093) is **denied**.

24 Dated this 7th day of September, 2018.

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David G. Campbell
Senior United States District Judge