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 **CASE MANAGEMENT ORDER NO. 30**

The Court held a fourteenth case management conference on January 19, 2018. The conference occurred after oral argument on various expert motions and addressed ongoing matters identified in the parties' joint report. Doc. 9645.

A. Motion Hearings.

The Court heard oral argument on motions relating to experts Muehrcke, Hurst, Eisenberg, and Betensky. The parties and the Court agreed that oral argument is not needed on motions related to experts McMeeking, Morris, Grassi, Garcia/Streiff, criminal law standards, and Ritchie. The Court will rule on these motions during the month of February. The Court will also rule on the motion in limine recently filed by Plaintiffs on the use of FDA-related evidence at trial.

B. Other Matters.

Plaintiffs may use up to five pages for a motion in limine on the issue of non-parties at fault. Defendants may file a five-page response.

Defendants may file a motion in limine of up to ten pages on when evidence regarding the Recovery filter may be introduced. Plaintiffs may file a ten-page response, and Defendants may file a five-page reply, if needed.

The parties will confer about bifurcating the Booker trial under Georgia law. If such bifurcation occurs, evidence regarding Defendants' net worth, as possibly relevant to the issue of punitive damages, will be postponed until after the jury rules on whether punitive damages should be awarded. If the punitive damages phase is needed, the parties agreed that it will be short and will occur immediately after the jury's general verdict. The Court reminded the parties that any time devoted to this punitive damages portion of the trial must be counted against the hours allotted to each side in Case Management No. 29.

Plaintiffs requested permission to conduct limited punitive damages discovery. The Court concludes that the parties should confer to see if they can agree on an exchange of information, in admissible form, that will eliminate the need for additional discovery. If the parties are unable to reach agreement, Plaintiffs may take one deposition under Rule 30(b)(6) for up to two hours. The deposition will be completed before the final pretrial conference on March 2, 2018.

The final pretrial conference will begin at 10:00 a.m. on March 2, 2018. The Court will reserve the balance of the day to address any and all pretrial matters.

The parties asked that the Court rule on the Jones summary judgment motion as soon as possible, but agreed that the expert motions and the motions in limine to be filed on January 26, 2018, take priority. The Court will use its best effort to rule on the Jones motion before the end of February.

The parties and the Court did not set another status conference. If issues arise that require the Court's attention, the parties should place a joint telephone call to the Court so that such a conference can be scheduled. The next scheduled hearing in this case will be the final pretrial conference.

Dated this 23rd day of January, 2018.

David G. Campbell
United States District Judge

Ramon Rossi Lopez - rlopez@lopezmchugh.com
(California Bar Number 86361; admitted *pro hac vice*)
Lopez McHugh LLP
100 Bayview Circle, Suite 5600
Newport Beach, California 92660
949-812-5771

Mark S. O'Connor (011029) – mark.oconnor@gknet.com
Gallagher & Kennedy, P.A.
2575 East Camelback Road
Phoenix, Arizona 85016-9225
602-530-8000

Co-Lead/Liaison Counsel for Plaintiffs

UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

In Re Bard IVC Filters Products Liability Litigation	No. MD-15-02641-PHX-DGC **JOINT STIPULATION ON MOTION *IN LIMINE*** (Assigned to the Honorable David G. Campbell) (Oral Argument Requested)

JOINT STIPULATION ON MOTIONS IN *LIMINE*

The parties have reached a stipulation and agreement regarding several issues that would otherwise be the subject of a motion *in limine*. The parties stipulate that they are prohibited from making any reference or argument, or adducing any evidence or attempting to elicit any evidence in front of the jury suggesting and/or concerning the following topics, unless the issue is first raised with the Court outside the presence of the jury:

1. Domestic violence charges, allegations or evidence related to the domestic violence incident;

2. Abortions or healthcare services related to Plaintiff's pregnancies;

3. Plaintiff conceiving child out of wedlock;

4. Whether a venereal disease was the cause of Plaintiff's cervical cancer;

5. A misdemeanor charge against Plaintiff for leaving her children in a car;

6. Plaintiff's prior claims from a 1996 auto accident involving a fractured foot and back/neck injuries;

7. Termination of Plaintiff's employment prior to her open chest surgery;

8. Plaintiff's relationship with the father of second child while married;

9. Plaintiff's receipt of compensation from some source other than the damages sought against Defendant. (collateral source);

10. Advertising by Plaintiff's counsel, Plaintiff's counsel specializing in personal injury and/or products liability litigation, contingency fee agreements, and/or advertising by any counsel nationally for Bard IVC Filter cases and/or any other IVC filter cases;

11. Other lawsuits or claims against Defendants;

12. Plaintiff could not pay her medical bills or reference to medical liens due to lack of health insurance/financial resources;

13. C.R. Bard's 1994 criminal conviction.

Nothing in this stipulation prohibits any party from raising these issues with the Court outside the presence of the jury, in the event they believe that evidence or events at trial render the topics relevant and admissible.

RESPECTFULLY SUBMITED this 26th day of January 2018.

GALLAGHER & KENNEDY, P.A.

By: s/Mark S. O'Connor

Mark S. O'Connor
2575 East Camelback Road
Phoenix, Arizona 85016-9225

LOPEZ McHUGH LLP
Ramon Rossi Lopez (CA Bar No. 86361)
(admitted *pro hac vice*)
100 Bayview Circle, Suite 5600
Newport Beach, California 92660

Co-Lead/Liaison Counsel for Plaintiffs

By: s/Richard B. North, Jr.___
Richard B. North, Jr.
Georgia Bar No. 545599
Matthew B. Lerner
Georgia Bar No. 446986
NELSON MULLINS RILEY & SCARBOROUGH, LLP
Atlantic Station
201 17th Street, NW / Suite 1700
Atlanta, GA 30363
PH: (404) 322-6000
FX: (404) 322-6050
richard.north@nelsonmullins.com
matthew.lerner@nelsonmullins.com

James R. Condo (#005867)
Amanda Sheridan (#027360)
SNELL & WILMER L.L.P.
One Arizona Center
400 E. Van Buren
Phoenix, AZ 85004-2204
PH: (602) 382-6000
jcondo@swlaw.com
asheridan@swlaw.com

Attorneys for Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on this 26th day of January 2018, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

s/Richard B. North, Jr.
Richard B. North, Jr.

WO

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
Sherr-Una Booker, an individual, Plaintiff, v. C. R. Bard, Inc., et al. Defendants.	No. CV-16-00474-PHX-DGC **ORDER**

This multidistrict litigation proceeding ("MDL") involves thousands of personal injury cases related to inferior vena cava ("IVC") filters manufactured and marketed by Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard"). Plaintiff Sherr-Una Booker, who had a Bard filter implanted ten years ago, brought one of the MDL cases. Plaintiff Booker's case has been selected as one of several bellwether cases and is set for trial in March 2018.

Plaintiffs have filed a motion in limine based on Federal Rules of Evidence 402 and 403 to preclude evidence of (1) the premarket clearance of Bard IVC filters by the Food and Drug Administration ("FDA"), and (2) the lack of FDA enforcement action against Bard. Doc. 9529. The motion is fully briefed, and the parties agree that oral argument is not necessary. The Court will deny the motion.

I. Background.

The IVC is a large vein that returns blood to the heart from the lower body. IVC filters are small metal devices implanted in the IVC to catch blood clots before they reach the heart and lungs. Seven different versions of Bard IVC filters are at issue in this MDL – the Recovery, G2, G2 Express, G2X, Eclipse, Meridian, and Denali.

IVC filters and other medical devices must be approved or cleared for market by the FDA. The FDA may approve a medical device that is shown to be safe and effective through a process known as "premarket approval[.]" 21 U.S.C. § 360e(a). Such approval is not required, however, for most medical devices. Through a less rigorous process known as section "510(k)" review, a manufacturer can obtain "clearance" to market a device by showing that it is substantially equivalent to a device already on the market. 21 U.S.C. § 360c(f)(1)(A). Each Bard IVC filter at issue in this MDL received FDA clearance through 510(k) review.[1]

Plaintiffs allege that Bard filters are more dangerous than other IVC filters because they have a higher risk of tilting, perforating the IVC, or fracturing and migrating to neighboring organs. Plaintiffs further allege that Bard failed to warn physicians and patients about these higher risks. Doc. 303-1. Bard disputes Plaintiffs' allegations, contending that overall complication rates for Bard filters are comparable to those of other IVC filters and that the medical community is aware of IVC filter risks.

Plaintiff Booker was implanted with a G2 filter in June 2007 and suffered injuries from the filter's failure. She asserts various claims against Defendants under Georgia law. Doc. 1, CV-16-00474-PHX-DGC. The following claims remain for trial: design defect, failure to warn, and punitive damages. *See* Doc. 8874 at 22.

II. Federal Rules of Evidence 401, 402, and 403.

The relevance and admissibility of evidence at trial is governed in part by Rules 401, 402, and 403. Evidence is relevant under Rule 401 if it has any tendency to

[1] For further discussion of IVC filters and the FDA regulatory process, see the Court's order regarding preemption. Doc. 8872 at 2-5.

make a material fact more or less probable. Fed. R. Evid. 401(a)-(b). Rule 402 provides that relevant evidence is admissible unless otherwise excluded by the rules, a federal statute, or the Constitution; irrelevant evidence is not admissible. Fed. R. Evid. 402. Under Rule 403, relevant evidence may be excluded if its probative value is substantially outweighed by the danger of "unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403. Trial courts have discretion to limit or exclude evidence under Rules 402 and 403. *United States v. Scholl*, 166 F.3d 964, 971 (9th Cir. 1999).

III. Discussion.

A. The FDA's Clearance of the G2 Filter Under 501(k) Review.

Plaintiffs argue that Defendants intend to assert an "FDA defense" at trial by implying that the 510(k) clearance process demonstrates filter "safety and effectiveness" and the reasonableness of Bard's conduct. Plaintiffs contend that such evidence is not relevant to any issue in the case and should be excluded under Rule 402. Doc. 9529 at 1-2. The Court does not agree.

Georgia courts have adopted a risk-utility analysis for design defect claims like those asserted by Plaintiff Booker. This analysis incorporates negligence principles and the "concept of 'reasonableness,' i.e., whether the manufacturer acted reasonably in choosing a particular product design[.]" *Banks v. ICI Ams., Inc.*, 450 S.E.2d 671, 673 (Ga. 1994). One of the many factors a jury may consider in its reasonableness determination is the manufacturer's compliance with federal regulations. *Id.* at 675 & n.6. Compliance with the regulations may not render a manufacturer's design choice immune from liability, but it can be a "piece of the evidentiary puzzle." *Doyle v. Volkswagenwerk Aktiengesellschaft*, 481 S.E.2d 518, 521 (Ga. 1997); *see Duran v. Paccar, Inc.*, 549 S.E.2d 755, 762 (Ga. Ct. App. 2001) ("[C]ompliance with federal standards or regulations is probative of Paccar's reasonableness under the risk-utility analysis."). Given these principles of Georgia law, the Court finds that evidence of Bard's compliance with the 510(k) process, while certainly not dispositive, is nonetheless

relevant to the reasonableness of Bard's conduct and whether the company defectively designed the G2 filter.

The evidence is also relevant to Plaintiff's punitive damages claim. Under Georgia law, punitive damages may be awarded only where the defendant's actions showed "willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which would raise the presumption of conscious indifference to consequences." Ga. Code Ann. § 51-12-5.1(b). Compliance with federal regulations is not sufficient to preclude an award of punitive damages, *see* Doc. 8874 at 18, but it is probative of whether the manufacturer acted with conscious indifference to the dangers posed by its device. *See Stone Man, Inc. v. Green*, 435 S.E.2d 205, 206 (Ga. 1993) (noting that generally "compliance with county, state, and federal regulations is not the type of behavior which supports an award of punitive damages"); *Barger v. Garden Way, Inc.*, 499 S.E.2d 737, 743 (Ga. Ct. App. 1998) (same).

Plaintiffs note, correctly, that the 510(k) process focuses on device equivalence, not device safety. Doc. 9529 at 2 (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493 (1996)). But this does not render evidence of the 510(k) process irrelevant to the reasonableness of Bard's conduct. The FDA grants 510(k) clearance only where the device "is as safe and effective as a [predicate device] and does not raise different questions of safety and efficacy than the predicate device." Safe Medical Devices Act of 1990, Pub. L. No. 101-629, § 12(a)(1)(A)(ii). The 510(k) process may not speak directly to the applicable standard of care under Georgia law, but it does have probative value in the determination of this action. *See Winebarger v. Boston Sci. Corp.*, No. 3:15CV211-RLV, 2015 WL 5567578, at *7 (W.D.N.C. Sept. 22, 2015) ("The fact that BSC followed the requisite 510(k) protocol – limited as it is – prior to marketing its [medical] device has minimal probative value regarding BSC's efforts to adhere to FDA processes and procedure generally.").

The Court, according to Plaintiffs, already "found that 510(k) clearance is irrelevant to Plaintiffs' state law claims." Doc. 9529 at 2. The Court made no such

finding, and has not previously addressed the question now before it – whether evidence of the 510(k) process is relevant to the claims and defenses in the Booker case.[2]

In their reply brief, Plaintiffs cite a suggested Georgia jury instruction for the proposition that juries are limited to considering only those regulations related to "safety." Doc. 9824 at 2. Plaintiffs note that the cases cited in support of the instruction are the very cases Defendants cite in arguing that a jury may consider federal standards. *Id.*; *see* Doc. 9842-1 at 3 (citing *Banks* and *Doyle*). But in *Banks*, the Georgia Supreme Court made clear that in determining the reasonableness of a manufacturer's conduct, "no finite set of factors can be considered comprehensive or applicable under every factual circumstance, since such matters must necessarily vary according to the unique facts of each case." *Banks*, 450 S.E.2d at 675. And nothing in *Doyle* suggests that only safety regulations may be relevant in design defect cases. *See Doyle*, 481 S.E.2d at 521.

Plaintiffs contend that 510(k) evidence should be excluded under Rule 403 because any probative value it may have is substantially outweighed by the risk of confusion as to whether Bard filters were found by the FDA to be safe and effective. Doc. 9526 at 3-6. Plaintiffs further contend that admission of such evidence would cause the case to devolve into a series of mini-trials regarding the 510(k) process and Bard's compliance with it. *Id.* Plaintiffs note that other courts, including the district court in *Cisson*, have excluded 510(k) evidence under Rule 403. *Id.* at 3-5 & n.2.

In *Cisson*, the court was concerned that allowing 510(k) evidence would create a "substantial risk of misleading the jury to believe that FDA 510(k) clearance might be

---

[2] In its ruling on Defendants' preemption motion, the Court noted that "[m]any cases interpret *Riegel* and *Lohr* to mean that PMA approval preempts different or additional requirements imposed by state tort law, while 510(k) clearance does not." Doc. 8872 at 11. The Court then provided a string cite of these cases that included *Cisson v. C. R. Bard, Inc.*, No. 2:11-cv-00195, 2013 WL 5700513, at *12 (S.D. W. Va. Oct. 18, 2013), with this parenthetical quote from *Cisson*: "[T]he 510(k) process does not address product safety and efficacy and therefore is not relevant to Bard's obligations under Georgia state tort law." *Id.* Plaintiffs cite this citation as support for their claim that the Court has resolved the issue in this motion in limine, but that is a real stretch. Not only was the Court not addressing any evidentiary issue in the preemption discussion, it was not even approving the cases included in the string cite. To the contrary, two pages later the Court held that the 510(k) process can in some circumstances preempt state law claims. *Id.* at 13-14.

dispositive of the plaintiffs' state law claims" and would result in a "mini-trial on the 510(k) process and enforcement[.]" *In re C.R. Bard, Inc., Pelvic Repair Sys. Prod. Liab. Litig. (Cisson)*, No. 2:10-CV-01224, 2013 WL 3282926, at *2 (S.D.W. Va. June 27, 2013). The Court understands these concerns, but believes they can be adequately addressed without excluding relevant evidence to the detriment of Defendants.

Both sides, through appropriate expert testimony or other admissible evidence, will be permitted to tell the jury about the role of the FDA in its oversight of medical device manufacturers, the regulatory clearance process for devices such as IVC filters, and Bard's participation in the 510(k) process and its compliance (or lack thereof) with that process. *See* Doc. 9433 at 8-9, 16; *Block v. Woo Young Med. Co.*, 937 F. Supp. 2d 1028, 1047 (D. Minn. 2013) (allowing expert witness to testify to "the general nature of the FDA's approval and regulatory process, the FDA's general expectations with respect to testing and marketing of new products, and [the defendant's] actions in that respect"); *Musgrave v. Breg, Inc.*, No. 2:09-CV-01029, 2011 WL 4620767, at *3 (S.D. Ohio Oct. 3, 2011) (denying Rule 403 challenge to 510(k) evidence and noting that the plaintiffs "may argue about what it means, but they cannot keep the jury from hearing the fact that the FDA cleared . . . the [device]"). Defendants will not, however, be permitted to present evidence or argument that the FDA "approved" the G2 filter for market, or that clearance of the device under 510(k) review constitutes a finding by the FDA that the filter is "safe and effective." As relevant FDA regulations explain: "Any representation that creates an impression of official approval of a device because of complying with the [510(k)] premarket notification regulations is misleading[.]" 21 C.F.R. § 807.97. Plaintiffs certainly will be free to present evidence and argument that the 510(k) process is a comparative one that requires only substantial equivalence to a predicate device, that 510(k) regulations are not safety regulations, and – as Plaintiffs claim – that Bard withheld information from the FDA and otherwise failed to fully comply with the 510(k) regulations.

Moreover, any potential confusion can be cured, if necessary, by a limiting instruction regarding the nature of the 510(k) process. *See Winebarger*, 2015 WL 5567578, at *7 (finding 510(k) evidence admissible with "a limiting instruction that 510(k) clearance is not to be considered as evidence that the FDA authorized the [device] as safe and approved its intended use as such," or that the defendant "satisfied any standard of care in designing the . . . device").

It is worth noting that the absence of any evidence regarding the 510(k) process would run the risk of confusing the jury as well. Many of the relevant events in this case occurred in the context of FDA 510(k) review, and much of the evidence is best understood in that context. Attempting to remove any references to the FDA from the trial would risk creating a misleading, incomplete, and confusing picture for the jury. Additionally, the Court is not convinced that all FDA-references could be removed, given that much of the evidence – such as the MAUDE database – comes from the FDA. And if the evidence was half-baked, containing some references to the FDA but not explaining what role the FDA played with respect to the Bard filters, the jury would be left to speculate about the FDA's involvement and conclusions.

The Court is also convinced that efficient management of the evidence and adherence to the Court's time limits will avoid any risk of unnecessary or time-consuming mini-trials. Plaintiffs argue that the parties' regulatory experts likely will take a day each for direct and cross-examination, and that the time limitations set by the Court will prove prohibitive. Doc. 9529 at 6 & n.4. The Court does not agree. The Court is confident that counsel for each side will be able to adequately and efficiently try this case in the time allotted by the Court. *See* Doc. 9415 at 2.

B. The Lack of FDA Enforcement.

Plaintiffs argue that evidence of the lack of FDA enforcement action against Bard is irrelevant, and that it would be misleading and prejudicial for Bard to suggest to the jury that the lack of enforcement signifies product safety. Doc. 9529 at 6-8. Whether evidence that the FDA took no enforcement action against Bard is relevant and otherwise

admissible will depend heavily on the context in which the evidence is offered, including evidence presented by Plaintiffs (such as the FDA warning letter). The Court will make this ruling during trial.

IT IS ORDERED that Plaintiffs' Motion in Limine #1 to exclude evidence of FDA 510(k) clearance and lack of FDA enforcement (Doc. 9529) is **denied**.

Dated this 29th day of January, 2018.

David G. Campbell
United States District Judge

WO

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
Sherr-Una Booker, an individual, Plaintiff, v. C. R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation, Defendants.	No. CV-16-00474-PHX-DGC **ORDER**

The parties have filed various motions in limine ("MIL") in advance of the Booker bellwether trial. This order will rule on some of those motions.

A. Defendants' MIL No. 4 (Photograph of Michael Randall).

Plaintiffs wish to introduce a photograph of Michael Randall, Bard's G2 Platinum project leader, flipping off the camera. Plaintiffs contend that the photograph is relevant because it was included in an internal Bard Powerpoint on the G2 Platinum. Bard asserts that the photograph was included in the Powerpoint presentation as an internal joke. Plaintiffs admit that "we don't know to whom this gesture was directed" (Doc. 9911 at 3), but they argue that it nonetheless is relevant as an indication of Bard's cavalier corporate culture.

Because even Plaintiffs don't know to whom the gesture was directed, the Court cannot conclude that it is relevant to any claims or defenses in this case. And even if the photograph were to have some marginal relevancy, such relevancy is substantially outweighed by the danger of unfair prejudice. Fed. R. Evid. 403. Even Plaintiffs admit that "the middle finger picture is indeed inflammatory." The motion in limine (Doc. 9865) is **granted**. The photograph will not be admitted.

B. Defendants' MIL No. 5 (Dr. Kinney's work for Bard).

Defendants seek to exclude evidence that Plaintiffs' expert witness, Dr. Thomas Kinney, was an expert witness for Bard in two prior IVC filter cases and was a paid consultant to Bard for several years. Doc. 9868. Plaintiffs argue that this prior work is relevant because it "provides context for his opinions and his motivation to become an expert witness for the Plaintiffs," shows Bard's "lack of transparency with doctors and consultants, and the seriousness of the problems with its IVC filters," and shows a "corporate culture within Bard that disregarded concerns of consultants and patient safety." Doc. 9914 at 2-3.

The Court is not persuaded by Plaintiffs' arguments. In opposing Defendants' motion to disqualify Dr. Kinney on the basis of his prior work for Bard, Plaintiffs argued vigorously that the prior work had nothing to do with this lawsuit. Plaintiffs asserted that "[n]one of [Dr. Kinney's consulting] work related to the issues discussed, subject matter, or bases of the opinions rendered in his report in this MDL." Doc. 5803 at 6, n.2. Plaintiffs argued that his work for Bard from 2005 to 2008 had "absolutely nothing to do with the issues and causes of action in this MDL." *Id*. at 9. And they claimed that his work as an expert witness for Bard did not "even remotely relate[] to the issues and subject matter of Dr. Kinney's expert report in this MDL." *Id*. at 3. Given these strenuous assertions, the Court cannot accept Plaintiffs current argument that Dr. Kinney's work for Bard provides "context for his opinions," shows "a lack of transparency" with respect to the issues in this case, or shows a corporate culture of

disregard for patient safety. Doc. 9914 at 2-3. By Plaintiffs' own declaration, his prior work for Bard is simply not relevant to the issues in this case. The Court will **grant** Defendants' motion in limine. Doc. 9868. Plaintiffs may not question Dr. Kinney about his prior work for Bard, and should instruct him not to mention it in his testimony. If Plaintiffs believe Defendants make the prior work relevant by the nature of their cross examination at trial, they can raise that issue with the Court outside the hearing of the jury.

C. Plaintiffs' MIL No. 2 (benevolent activities).

Plaintiffs seek to exclude evidence and argument relating to (1) any alleged benevolent activities such as charitable acts or services Bard provides to patients or society, (2) Bard's "good character" in general, and (3) the quality and intent of its workforce as a whole. Doc. 9866. In response, Defendants state that they will not present evidence that they "engaged in benevolent activities such as providing scholarships or making charitable contributions." Doc. 10053 at 1 n.1. Defendants do intend, however, to present evidence regarding the nature, quality, and usefulness of their products, the conscientiousness of their employees, references to their mission statement, and the fact that their products are designed to promote health and save lives. *Id.* at 2-3. Defendants assert that such evidence is relevant background information and is also necessary to rebut Plaintiffs' punitive damages claim that Defendants acted in a willful, malicious, and reckless manner.

The Court concludes that some evidence regarding the nature of Defendants' business is relevant to the jury's understanding of the issues in this case. The Court also concludes that Defendants' must be permitted to rebut Plaintiffs' themes, stated repeatedly throughout briefing on the expert motions, that Defendants knowingly disregarded patient safety, used patients for experimentation, and placed profits over safety.

Countering Plaintiffs' punitive damages arguments does not mean, however, that Defendants can present irrelevant evidence or try this case on the basis of corporate character. *See* Fed. R. Evid. 404(a). The Court will draw appropriate lines on the basis of objections made during trial. Plaintiffs' motion in limine (Doc. 9866) is **denied**.

D. Plaintiffs' MIL No. 5 (evidence not produced in complaint files).

Plaintiffs ask the Court to exclude evidence and argument relating to failure rates, complication rates, percentages, or comparative analysis of any injuries that were not produced to Plaintiffs during discovery. Doc. 9870. Defendants assert that all such information was produced. Doc. 10060. Plaintiffs' motion in limine (Doc. 9870) is **denied as moot**. If Plaintiffs believe Defendants are using undisclosed evidence at any time during trial, they may object.

E. Plaintiffs' MIL No. 7 (prior judicial opinions).

Plaintiffs seek to exclude evidence and argument relating to prior judicial opinions about Plaintiffs' experts, including the number of times their testimony has been precluded in other cases. Doc. 9872. Defendants state that they do not intend to mention such evidence during opening statements, but it may become relevant during trial. The Court concludes that the rulings of other judges in other cases addressing other claims are not relevant to this case, and will **grant** the motion in limine. Doc. 9872. If Defendants believe such rulings become relevant in light of an expert's testimony, they may raise the issue with the Court outside the hearing of the jury.

F. Plaintiffs' MIL No. 8 (adverse impact of a plaintiff's verdict).

Plaintiffs assert that Defendants must be precluded from arguing at trial that a verdict against them will have an adverse impact on the medical community, future medical device research or costs, and the availability of medical care. Doc. 9873. Plaintiffs also argue that Defendants must be precluded from mentioning tort reform or any perceived "litigation crisis." *Id.* Defendants state that they do not intend to mention such matters during opening statements, but they may become relevant during trial. The Court concludes that the matters identified in Plaintiffs' motion are not relevant to this

case, and will **grant** the motion in limine. Doc. 9873. If Defendants believe such matters become relevant during trial, they may raise the issue with the Court outside the hearing of the jury.

G. Plaintiffs' MIL No. 11 (informed consent form).

Plaintiffs seek to exclude evidence and argument relating to the "Permission For Operation And/Or Procedure" form Ms. Booker signed prior to insertion of her IVC filter. Doc. 9876. Plaintiffs argue that the form is not specific to IVC filters or Bard filters, and therefore is irrelevant and likely to confuse the jury. *Id.*

Defendants state that they have "no intention of arguing that the Consent Form warned the Plaintiff about the potential risks of the G2® Filter." Doc. 10061 at 2. But Defendants argue that the consent form "is still relevant and material to establish that the Plaintiff and her implanting physician, Marcus D'Ayala, M.D. . . . discussed a course of treatment that included implanting a G2® Filter, and that the Plaintiff agreed to this course of treatment." *Id.*

Plaintiffs' failure to warn claim alleges that Bard "knew or reasonably should have known that the users of Bard IVC Filters, including Plaintiffs, would not realize or discover on their own the dangers presented by Bard IVC Filters." Doc. 364, ¶ 213. The complaint further alleges that "Bard breached [its] duties by failing to provide adequate warnings to Plaintiffs communicating the information and dangers described above and/or providing instruction for safe use of Bard IVC Filters." *Id.*, ¶ 216. Georgia law, which will apply in Ms. Booker's case, includes the "learned intermediary" doctrine. Under this doctrine, a medical device manufacturer has no "duty to warn the patient of the dangers involved with the product, but instead has a duty to warn the patient's doctor, who acts as a learned intermediary between the patient and manufacturer." *McCombs v. Synthes (U.S.A.)*, 587 S.E.2d 594, 595 (Ga. 2003) (citing *Ellis v. C. R. Bard, Inc.*, 311 F.3d 1272, 1279-80 (11th Cir. 2002)). Thus, what Dr. D'Ayala knew about the risks of IVC filters, and what he told Ms. Booker, are relevant to the failure to warn claim.

The consent form signed by Ms. Booker states that Dr. D'Ayala "has fully explained to me the nature and purpose of the operation/procedure and has also informed me of expected benefits and complications, attendant discomforts and risks that may arise, as well as possible alternatives to the proposed treatment[.]" Doc. 9876-2, ¶ 2. This document is plainly relevant to Plaintiffs' failure to warn claim. The arguments made in Plaintiffs' motion – that the form is not specific to IVC filters or Bard filters, and therefore does not show what Ms. Booker knew about risks of Bard filters – can be made to the jury. The Court does not find that the jury will be confused by admission of the form, assuming it satisfies other evidentiary rules. Plaintiffs' motion in limine (Doc. 9876) is **denied**.

H. Plaintiffs' MIL No. 12 (Dr. Kang's social media posts).

Plaintiffs seek to exclude evidence and argument related to Dr. Brandon Kang's Twitter and Facebook accounts and his use of the terms "lasso," cowboy," "GTFO" (Get The Filter Out), "#filterout," "#IRad," and a cowboy emoji, as well as comments, posts, photos, or videos that Dr. Kang posted on his social media accounts. Doc. 9877. Plaintiffs assert that the posts were not made until 2017, years after Dr. Kang's treatment of Ms. Booker, and are irrelevant and unfairly prejudicial. *Id.*

Defendants argue that Dr. Kang's social media posts "reflect his approach and attitude about filter removal." Doc. 10063 at 2. Defendants argue that "[a] disputed issue in this case is whether Dr. Kang's failed retrieval attempt, which admittedly damaged Ms. Booker's tricuspid valve, was unduly aggressive. Plaintiffs claim Dr. Kang acted appropriately. Bard, however, will present expert and other evidence that Dr. Kang should have followed a more conservative approach." *Id.*

Although Dr. Kang's attempt to retrieve Ms. Booker's filter is plainly relevant to whether Defendants or Dr. Kang caused some of her injuries, the Court cannot conclude that his subsequent social media posts – which were not about Ms. Booker's case and which were made approximately three years after the attempted removal – are relevant. Even if it could be argued that they reflect Dr. Kang's reckless character, the Court

concludes that such marginally probative character evidence would not be admissible under Rule 403. Any relevancy would be substantially outweighed by the danger of unfair prejudice. The Court will **grant** Plaintiffs' motion in limine. Doc. 9877.

I. Plaintiffs MIL No. 14 (personal traits of employees and witnesses).

Plaintiffs seek to exclude argument or evidence relating to the religion, religious beliefs, religious activities, church membership, church affiliation, socioeconomic status, marital status, parental relationships, family health status, and children of Defendants' current and former employees and other witnesses." Doc. 9879. Plaintiffs contend that Defendants may seek to elicit such information to cause jury sympathy. *Id.*

Defendants agree that "*no party* should elicit information from any witness regarding their religion, religious beliefs, religious activities, church membership or affiliation." Doc. 10064 at 2 (emphasis added). Defendants argue, however, that some background information will be needed to introduce witnesses to the jury and to help them become comfortable in the courtroom. Defendants also note that at least one of its witnesses has a heavy foreign accent, and a brief explanation may be needed for the jury.

The Court agrees that neither side should elicit evidence barred by Rule 610 ("Evidence of a witness's religious beliefs or opinions is not admissible to attach or support the witness's credibility."). Some background information will be necessary to introduce witnesses to the jury, but questions designed to prompt sympathy or empathy are not proper. The Court will rule on objections during trial. In light of this general guidance, the Court will **deny** Plaintiffs' motion in limine as moot. Doc. 9879.

Dated this 15th day of February, 2018.

David G. Campbell
United States District Judge

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation	No. MDL15-2641-PHX DGC
Sherr-Una Booker, an individual, Plaintiff, v. C.R. Bard, Inc., a New Jersey Corporation, et al., Defendants	**ORDER**

Upon consideration of the parties' joint stipulation on motions in limine. Doc. 9861.

IT IS ORDERED that the parties' joint stipulation on motions in limine (Doc. 9861) is **granted**. The parties are prohibited from making any reference or argument, or adducing any evidence or attempting to elicit any evidence in front of the jury suggesting and/or concerning the following topics, unless the issue is first raised with the Court outside the presence of the jury:

1. Domestic violence charges, allegations or evidence related to the domestic violence incident;

2. Abortions or healthcare services related to Plaintiff's pregnancies;

3. Plaintiff conceiving a child out of wedlock;

4. Whether a venereal disease was the cause of Plaintiff's cervical cancer;

5. A misdemeanor charge against Plaintiff for leaving her children in a car;

6. Plaintiff's prior claims from a 1996 auto accident involving a fractured foot and back/neck injuries;

7. Termination of Plaintiff's employment prior to her open chest surgery;

8. Plaintiff's relationship with the father of second child while married;

9. Plaintiff's receipt of compensation from some source other than the damages sought against Defendant. (collateral source);

10. Advertising by Plaintiff's counsel, Plaintiff's counsel specializing in personal injury and/or products liability litigation, contingency fee agreements, and/or advertising by any counsel nationally for Bard IVC Filter cases and/or any other IVC filter cases;

11. Other lawsuit or claims against Defendants;

12. Plaintiff could not pay her medical bills or reference to medical liens due to lack of health insurance/financial resources;

13. C.R. Bard, Inc.'s 1994 criminal conviction.

Nothing in this stipulation prohibits any party from raising these issues with the Court outside the presence of the jury, in the event they believe that evidence or events at trial render the topics relevant and admissible.

Dated this 22nd day of February, 2018.

David G. Campbell
United States District Judge

WO

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
Sherr-Una Booker, an individual, Plaintiff, v. C. R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation, Defendants.	No. CV-16-00474-PHX-DGC **ORDER**

The parties have filed various motions in limine ("MIL") in advance of the Booker bellwether trial. The Court ruled on some of the motions in an earlier order. Doc. 10075. This order will rule on the remaining motions.

A. Defendants' MIL No. 1 (Recovery filter complications).

Plaintiff Booker was implanted with a Bard G2 filter in June 2007. The filter later tilted, migrated, and fractured. Ms. Booker had surgeries to remove the filter and several fractured struts, but one strut remains embedded in the wall of her inferior vena cava ("IVC"). Defendants seek to exclude evidence of complications with an earlier version of the Bard IVC filter – the Recovery filter – arguing that those complications are not "substantially similar" to the issues with Ms. Booker's G2 filter. Doc. 9862 at 5-7.

The Recovery was Bard's first generation of retrievable IVC filters, and was on the market from the beginning of 2003 to the fall of 2005. The Recovery was followed by the G2. As Defendants explain in their motion: "Based on clinical experience with the Recovery Filter, Bard made several significant changes to the G2 Filter: the filter hook wire diameter was increased, the filter arm tips were curved, the curvature radius of the filter arms at the sleeve were increased, and the spline was modified to accommodate the other dimensional changes." *Id.* at 4. Because Ms. Booker received a G2 filter, and that filter had been changed significantly from the Recovery filter, Defendants argue that problems with the Recovery have "absolutely no relevance to the issues in this case." *Id.* The Court does not agree.

Plaintiffs claim that Bard negligently and defectively designed the G2 filter, failed to warn of its risks, and did so with a mindset worthy of punitive damages. In response, Defendants will argue, among other points, that the FDA cleared the G2 filter for market. Defendants vigorously opposed Plaintiffs' motion to exclude evidence of the FDA's 510(k) clearance process, arguing that the steps a manufacturer must take before a product is cleared by the FDA are "highly relevant to a case . . . like this one," and that compliance with the 510(k) process "is certainly probative under Georgia law on the issues of reasonableness of the design, manufacture, and warnings of the G2 Filter, as well as whether Bard's conduct rises to the level justifying punitive damages[.]" Doc. 9690 at 3. The Court agreed with Defendants, noting that the FDA grants 510(k) clearance "only where the device 'is as safe and effective as a [predicate device] and does not raise different questions of safety and efficacy than the predicate device.'" Doc. 9529 at 4 (citation omitted).

Bard identified the Recovery filter as the predicate device for the G2, and avowed to the FDA that the "design, material, components, fundamental technology (mode of device function/operation) and intended use featured with the [G2]" are "substantially equivalent to those featured with the predecessor Recovery Filter System[.]" Doc. 10068-1 at 25. Defendants assert that "one of Bard's goals in developing the G2

Filter was to reduce the number of incidents of filter fracture and migration that Bard had observed with the Recovery Filter." Doc. 9862 at 4.

Given these facts, the Court concludes that Bard's knowledge of problems with the Recovery filter is relevant to central issues in this case – whether Bard properly designed the G2 to correct those problems, whether Bard failed to warn physicians and patients about problems shared by the Recovery and G2, and whether Bard's alleged failure to correct or warn about known problems justifies an award of punitive damages. The Court also concludes that it would be difficult to try this case without evidence of the Recovery filter and the problems it encountered. Defendants' evidence regarding FDA clearance will necessarily include the fact that the Recovery filter was the predicate device for the G2 and was substantially equivalent to the G2. In showing Bard's care in designing the G2, Defendants almost certainly will argue that Bard carefully tracked problems encountered by the Recovery, dutifully reported those problems to the FDA, and took specific steps to correct those problems in the G2. Defendants will use this evidence to show that Bard did not negligently or defectively design the G2 and did not fail to warn of its risks. It is only fair that Plaintiffs be permitted to present evidence to support their claim that the Recovery was known to be more hazardous than Bard admitted publicly or to the FDA, and that it involved problems that were not corrected in the G2 and Bard failed to warn physician and patients of those known problems.

Defendants cite a number of cases for the proposition that other instances of product failure are admissible only if the instances are substantially similar to the product failure at issue in this case. *Id.* at 5. For example, the Ninth Circuit has held that "[a] showing of substantial similarity is required when a plaintiff attempts to introduce evidence of other accidents as direct proof of negligence, a design defect, or notice of the defect." *Cooper v. Firestone Tire & Rubber Co.*, 945 F.2d 1103, 1105 (9th Cir. 1991). For three separate reasons, the Court does not find this case law controlling.

First, Ms. Booker alleges that her G2 filter tilted, perforated her IVC, fractured, and migrated. Doc. 10068 at 7. These methods of failure include virtually all of the

known methods of failure for the Recovery filter.

Second, the facts of this case distinguish it from many of the cases cited by Defendants. This is not simply a product defect case in which Plaintiffs seek to introduce evidence of other potentially unrelated product failures. As already noted, the Recovery was the predicate for the G2 and Bard sought FDA clearance on the basis that the G2 was substantially equivalent to the Recovery. Bard intends to present evidence of that FDA clearance during trial. Defendants surely will note that the clearance required an FDA determination that the G2 was as safe and effective as the Recovery. In this context, evidence regarding the safety and effectiveness of the Recovery filter is plainly relevant, particularly where Plaintiffs claim that the Recovery was not as safe and effective as Bard represented to the FDA. Further, Defendants claim to have designed the G2 to overcome known defects in the Recovery, making the extent and severity of those defects relevant to the adequacy of Bard's design of the G2.

Third, although substantial similarity is required by the Ninth Circuit for direct evidence of negligence, design defect, or notice, it is not required when other examples of product failure are used to impeach an expert's testimony that a product is safe. *Cooper*, 945 F.2d at 1105. The parties do not address whether the evidence in this case would be used for impeachment or direct evidence.

Defendants also seek to exclude evidence of complications involving cephalad migration (toward the heart), asserting that such evidence is irrelevant because Ms. Booker's filter migrated in a caudal direction (away from the heart). Doc. 9862 at 7-8. Plaintiffs respond that Bard combined caudal and cephalad migration in tracking adverse events internally and in reporting migration rates to the FDA. Doc. 10068 at 9 (citing Doc. 10068-9 at 2-4). On this record, however, the Court cannot determine whether evidence of cephalad migration is relevant to Ms. Booker's claims. The parties should be prepared to address this issue at the final pretrial conference – specifically, what instances of cephalad migration Plaintiffs intend to present at trial, and why those instances are relevant.

Finally, Defendants contend that the probative value of the Recovery filter evidence is substantially outweighed by the risks of unfair prejudice, misleading and confusing the jury, and wasting time. Doc. 9862 at 8-9; Fed. R. Evid. 403. Defendants claim that admission of such evidence will require Bard to introduce its own evidence regarding the design of the Recovery, the technology available at the time, and Bard's investigation of adverse event reports. *Id.* at 9. This may be true, but that often is the result of admitting relevant evidence. With the possible exception of cephalad migration, the Court concludes that known complications with the Recovery filter are plainly relevant to this case. It will not, in the Court's view, mislead or confuse the jury, waste time, or result in unfair prejudice. The motion in limine (Doc. 9862) is **denied**, subject to the Court's consideration of cephalad migration at the final pretrial conference.

B. Defendants' MIL No. 2 (development of the Recovery).

Defendants seek to exclude specific evidence relating to the development of the Recovery device: (1) migration resistance tests, (2) testimony from Dr. Asch regarding his clinical trial of the Recovery, and (3) testimony from Bard employee Kay Fuller regarding the 510(k) submission to the FDA. Doc. 9863 at 2-3. Defendants claim that this "bad act" evidence is irrelevant and inadmissible under Rules 404 and 403. *Id.* at 3-4.

The Court cannot conclude that development of the Recovery filter is irrelevant to the G2 filter claims in this case. Bard based its request for FDA clearance of the G2 on the claim that it was substantially equivalent to, and as safe and effective as, the Recovery. Defendants intend to argue at trial that the resulting FDA approval shows that Bard acted responsibly and produced a safe and effective filter. In this context, evidence that the Recovery filter was itself the result of inadequate and incomplete testing, that a doctor involved in the testing concluded that it was inadequate and incomplete, and that a Bard employee reached the same conclusion, is plainly relevant. After considering the Ninth Circuit's four-part test, *see Duran v. City of Maywood*, 221 F.3d 1127, 1132-33 (9th Cir. 2000), the Court concludes that such evidence is admissible under Rule 404(b) as probative of Bard's knowledge, intent, and lack of mistake, and that its probative value

is not substantially outweighed by the potential dangers set forth in Rule 403. Defendants' motion in limine (Doc. 9863) is **denied**.

C. Defendants' MIL No. 3 (FDA warning letter).

Defendants seek to exclude a 2015 FDA warning letter, contending that it is irrelevant because it constitutes an informal advisory statement by the FDA issued more than seven years after Ms. Booker received her G2 filter. Doc. 9864 at 2-3. Defendants also contend that specific topics in the warning letter are not related to the G2 filter or any other issues in this case. Plaintiffs counter that the letter is an essential piece of evidence to rebut Bard's suggestion that the FDA took no action against Bard and expressed no concerns about Bard filters. Doc. 9927 at 2. Other than one sentence, however, Plaintiffs do not address Defendants' argument that topics in the letter are not related to issues in this case. That sentence argues only that deficiencies in Bard's handling and reporting of filter failures are relevant to this case. *Id.*

Many topics in the warning letter lack probative value. Topics 1 and 2 concern the Recovery Cone retrieval system, which is not at issue in this case. *See* Doc. 9864-1. Topic 4(a) concerns the filter cleaning process, which does not appear to be at issue here. Topics 4(b), 5, and 6 concern the Denali filter, a generation of filter developed after the G2 received by Ms. Booker. Topics 3, 7, and 8 concern Bard's complaint handling and reporting processes, but Plaintiffs have not shown why the specific issues raised in those three topics are relevant to this case.

The Court concludes that topics 1, 2, 4(a), 4(b), 5, and 6 are not relevant to this case, and will grant the motion in limine with respect to them. The Court cannot tell on the present record whether topics 3, 7, and 8 are relevant; that decision must be made at trial. To avoid the potential prejudice that will result if the warning letter is mentioned but irrelevant, the Court directs Plaintiffs to raise the potential admissibility of topics 3, 7, and 8 outside the hearing of the jury before mentioning the warning letter to the jury.

A few other comments are warranted. Plaintiffs argue that Defendants intend to present evidence of the lack of FDA enforcement actions, and to argue that the "FDA's

decision not to take any enforcement actions against Bard is probative as to whether Bard acted reasonably in its design and manufacture of the G2 line of filters." Doc. 9690 at 9. In response, Plaintiffs argue, they should be allowed to show that the FDA did issue a warning letter to Bard. But Plaintiffs' statement of Defendants' position is too broad. Defendants argue that they should be permitted to present evidence of "FDA's lack of enforcement action *regarding Bard's G2 line of filters*." Doc. 9690 at 8 (emphasis added). The warning letter did not concern the G2 line of filters, and was issued in 2015, long after Ms. Booker received her G2 filter in 2007. If Defendants open the door at trial by arguing generally that the FDA has never taken enforcement action of any kind, the Court will entertain a request to admit some or all of the FDA warning letter. But on the present record, the Court concludes that the warning letter does not concern issues in this case, with the possible exception of topics 3, 7, and 8, as noted above.

If the warning letter becomes relevant, the Court concludes that it should not be barred as hearsay. The public records exception applies to documents that describe "a matter observed while under a legal duty to report" or contain "factual findings from a legally authorized investigation[.]" Fed. R. Evid. 803(8)(A)(ii)-(iii). The warning letter reports the FDA's factual findings and matters observed under the agency's investigatory authority, and Defendants have not shown that the letter lacks trustworthiness. Fed. R. Evid. 803(8)(B). The Court will not exclude the letter on hearsay grounds. *See Guthrie v. Ball*, No. 1:11-cv-333-SKL, 2014 WL 5314576, at *4 (E.D. Tenn. Oct. 17, 2014) ("Courts have held that FDA warnings . . . are admissible under the public records hearsay exception in Rule 803(8).") (citations omitted); *Sadler v. Advanced Bionics, Inc.*, No. 3:11-CV-00450-H, 2013 WL 1311148, at *2 (W.D. Ky. Mar. 26, 2013) (finding FDA warning letter admissible under the public records exception where "FDA officials conducted the investigation themselves as a neutral party with motivations to protect public health and safety"); *Sabel v. Mead Johnson & Co.*, 737 F. Supp. 135, 140-41 (D. Mass. May 14, 1990) (finding FDA letter recommending a warning label admissible

as a public record where it was based on an investigation pursuant to the FDA's regulation of the safe marketing of prescription drugs).

Defendants' motion in limine (Doc. 9864) is **granted**, subject to Plaintiffs' ability to show that topics 3, 7, and 8 are relevant to issues in this case.

D. Plaintiffs' MIL No. 3 (IVC filters as "lifesaving" devices).

Plaintiffs seek to preclude Defendants from putting on a "filters saves lives" defense, or from describing Bard filters as "lifesaving" or "life-extending." Doc. 9867. Plaintiffs state that IVC filters are designed to prevent blood clots from reaching the heart and lungs and any other presumed benefit is "speculative." *Id.* at 2. But preventing blood clots from reaching the heart and lungs saves lives. Defendants cite statistics showing that some 300,000 people die each year from pulmonary embolisms. Doc. 10059 at 2 n.1. Plaintiffs' own expert has testified that the purpose of IVC filters is to prevent pulmonary embolisms, and in this sense the filters can be lifesaving devices. Doc. 10059-3 at 3-4 (Kinney Dep. Tr. 111:17-112:2).

Georgia law, which applies in this case, includes a risk-utility analysis for design defect claims. This analysis involves balancing "the risks inherent in a product design" against "the utility or benefit derived from the product." *Banks v. ICI Ams., Inc.*, 450 S.E.2d 671, 673 (Ga. 1994). Evidence concerning the benefits of IVC filters is directly relevant to this analysis. Plaintiffs' motion in limine (Doc. 9867) is **denied**.

E. Plaintiffs' MIL No. 4 (IVC filters are the "gold standard").

Plaintiffs seek to exclude evidence and argument that IVC filters are the "gold standard" or the "standard of care" for the treatment of pulmonary embolisms. Doc. 9869. In response, Defendants state that they will not characterize IVC filters as the "gold standard." Doc. 10054 at 2, n.1. The Court need not address this issue further.

Defendants do intend to present evidence that IVC filters, including the G2, are within the standard of care for the medical treatment of pulmonary embolisms. *Id.* Defendants assert that such evidence is relevant to the risk-utility analysis for the design defect and negligence claims, and that admission of the evidence will not confuse the jury

or result in a mini-trial. *Id.* at 2-4. The Court agrees. Evidence regarding the use and benefits of IVC filters, and when they are called for, will be relevant to the jury's risk-utility analysis, as well as evaluation of the failure to warn claims and Dr. D'Ayla's decision to implant the G2 in Ms. Booker.

Plaintiffs express concern that reference to the "standard of care" will confuse the jury concerning the standard of care to be applied in this case. But the standard of care for Bard's design and marketing of IVC filters is entirely distinct from the medical standard of care for when filters should be used to treat patients. To avoid confusion, the parties should refer to the "medical standard of care" when referring to the standard for implanting filters. The parties may also seek a clarifying jury instruction if warranted. Plaintiffs' motion in limine (Doc. 9869) is **denied**.

F. Plaintiffs' MIL No. 6 (nonparties at fault).

Georgia's nonparty at fault statute provides that the "[n]egligence or fault of a nonparty shall be considered if . . . the defending party gives notice not later than 120 days prior to the date of trial that a nonparty was wholly or partially at fault." O.C.G.A. § 51-12-33(d)(1). When such notice is given, evidence of the nonparty's fault may be presented to the jury and the jury may apportion fault and damages between the plaintiff, the defendant or defendants, and the nonparty. *Id.*, § 51-12-33(b)-(c).

Defendants filed a timely notice identifying Dr. Sarwat Amer as a nonparty at fault. Doc. 8844. The notice states that "Dr. Amer was the diagnostic radiologist who read [Ms. Booker's] lumbosacral spine x-ray on March 26, 2009, which showed her G2® Filter had fractured but with all struts adjacent to the filter in the IVC. Dr. Amer reported only: 'IVC Filter is noted.'" *Id.* at 2. Defendants contend that Dr. Amer failed to properly report the condition of the G2 filter to Ms. Booker's treating physicians, and therefore prevented the physicians from fully evaluating her medical condition and treatment options. *Id.* Defendants further contend that this alleged failure "constituted the sole proximate cause and/or contributing cause to [Ms. Booker's] injuries." *Id.*

Plaintiffs seek to exclude evidence and argument related to (1) the fault or negligence of nonparties not included in Defendants' notice, and (2) the "standard of care" of Ms. Booker's healthcare providers not identified in the notice. Doc. 9871 at 1. Plaintiffs argue that the notice identifies only Dr. Amer as a nonparty at fault, and evidence and argument relating to the negligence or fault of any others is improper under § 51-12-33. *Id.* at 2. For the same reason, Plaintiffs argue that it would be improper for Defendants to present evidence or argument that treatment by other healthcare providers fell below the medical standard of care. *Id.*

Defendants state that they will not seek to have the jury apportion fault or damages under the Georgia statute for any healthcare provider other than Dr. Amer. Doc. 10055 at 3. Defendants argue, however, that they should be permitted to present evidence of intervening causes of Ms. Booker's injuries. *Id.* Specifically, Defendants contend that "the jury is entitled to hear evidence that Dr. Brandon Kang tore Ms. Booker's tricuspid valve during his attempt to retrieve a fractured strut in her right ventricle," necessitating open heart surgery to repair the valve. *Id.* Defendants intend to argue that Dr. Kang's "medical treatment relates to [Ms. Booker's] damages claim and constitutes an intervening act that severed Bard's liability." *Id.*

The parties' arguments require the Court to examine Georgia law related to nonparties at fault and intervening causation.

The nonparty at fault statute provides that the "[n]egligence or fault of a nonparty" may be considered by the jury when appropriate notice is given. § 51-12-33(d)(1). The meaning of "negligence" is clear, and the Georgia Supreme Court has defined "fault" to mean "any breach of a legal duty that sounds in tort for the protection of the plaintiff, the breach of which is a proximate cause of the injury about which he complains[.]" *Zaldivar v. Prickett*, 774 S.E.2d 688, 694 (Ga. 2015). Thus, notice is required before a defendant can argue that a nonparty's negligence or other breach of duty proximately caused the plaintiff's injuries, and that some portion of liability and damages should therefore be allocated to the nonparty.

A defendant in Georgia can also escape liability by showing that an intervening cause broke the chain of causation between the defendant and the plaintiff. The Georgia Supreme Court has held that the intervening cause need not be "wrongful or negligent." *Jordan v. Everson*, 806 S.E.2d 533, 534 (Ga. 2017). That court has also held that "[f]or an intervening act 'to become the sole proximate cause of a plaintiff's injuries, the intervening act must not have been foreseeable by [the] defendant, must not have been triggered by [the] defendant's act, and must have been sufficient by itself to cause the injury.'" *Zaldivar*, 774 S.E.2d at 698 (quoting *Ontario Sewing Machine Co. v. Smith*, 572 S.E.2d 533 (Ga. 2002)). "[I]f the character of the intervening act . . . was such that its probable or natural consequences could reasonably have been anticipated, apprehended, or foreseen by the original wrong-doer, the causal connection is not broken." *Id*. (quotation marks and citation omitted).

From these authorities, the Court reaches four conclusions:

First, with the exception of Dr. Amer, Defendants may not assert at trial that other medical providers, including Dr. Kang, should be apportioned fault under § 51-12-33. For the jury to apportion fault to a nonparty under the statute, Defendants must have given notice regarding the nonparty. *See Monitronics Int'l, Inc. v. Veasley*, 746 S.E.2d 793, 804 (Ga. Ct. App. 2013) (noting that Georgia's nonparty at fault statute "mandates *strict* compliance") (emphasis in original). The instructions and verdict form will not permit the jury to apportion fault to any nonparty other than Dr. Amer.

Second, Defendants may assert the separate legal doctrine of intervening cause with respect to Dr. Kang or other nonparties not named in the notice. The Court cannot conclude that failure to identify Dr. Kang in the notice forecloses the defense of intervening cause. The nonparty at fault statute specifically provides that "nothing in in this Code section shall eliminate or diminish any defenses or immunities which currently exist, except as expressly stated in this Code section." O.C.G.A. § 51-12-33(e). The Code section says nothing about the intervening cause defense.[1]

[1] The statute does state that negligence or fault of a nonparty "shall be considered"

Third, to prevail on their intervening cause defense, Defendants must show that Dr. Kang's intervening act, or the intervening act of any other nonparty, (1) was not foreseeable by Bard, (2) was not triggered by Bard's act, and (3) was sufficient by itself to cause Ms. Booker's injury. *See Zaldivar*, 774 S.E.2d at 698. The jury will be so instructed.

Fourth, although Defendants will be precluded from arguing that Dr. Kang or others (besides Dr. Amer) were negligent or at fault for purposes of apportioning liability, the Court cannot conclude that they should be precluded from asserting the fault of these nonparties as an intervening cause of Ms. Booker's damages. Georgia law states that an intervening cause need not be negligent or wrongful, but it also recognizes that such a cause can be negligent or wrongful. *See Jordan*, 806 S.E.2d at 534; *Vega*, 670 S.E.2d at 122. It appears that Defendants intend to suggest to the jury that Dr. Kang was at fault. In a separate motion in limine, Plaintiffs sought to exclude evidence related to Dr. Kang's social media accounts. Doc. 9877. Defendants opposed the motion, asserting that a central issue is "whether Dr. Kang's retrieval was unduly aggressive in this case." Doc. 10063 at 2. Defendants stated that they "will present expert and other evidence that Dr. Kang should have followed a more conservative approach." *Id.* Defendants may make this argument as part of their intervening cause defense. The Court will instruct the jury carefully, making clear that the fault or actions of Dr. Kang (or similarly situated nonparties) may be considered only if the three requirements for intervening cause set forth above are satisfied, while the fault of Dr. Amer may be considered by the jury in

---

only if proper notice is given. § 51-12-33(d)(1). Arguably, this phrase could be read broadly to suggest that the jury may consider evidence of a nonparty's negligence or fault – for any purpose – only if notice is given. The Court reads the phrase more narrowly. Section 51-12-33 specifically focuses on apportionment of damages, and the Court concludes that "shall be considered" means "considered" in apportioning damages. This reading is reinforced by the statute's express statement that it does not eliminate other defenses, and seems to comport with Georgia case law. *See Vega v. La Movida, Inc.*, 670 S.E.2d 116, 122 (Ga. Ct. App. 2008) (finding that the defendant was entitled to argue that a nonparty's act was an intervening cause of the plaintiffs' injuries and noting that § 51-12-33 concerns apportionment of damages and therefore was inapposite).

apportioning fault. Whether the intervening cause defense must apply to all of Ms. Booker's injuries or may be applied to only a discrete part of them is an issue the parties should be prepared to address when jury instructions and the verdict form are finalized.[2]

Plaintiffs' motion in limine (Doc. 9871) is **granted in part and denied in part**. The Court will limit Defendants' nonparty-at-fault and apportionment arguments to Dr. Amer, but deny the motion to the extent Plaintiffs seek to preclude Defendants from asserting that the conduct of Dr. Kang or others constituted an intervening cause.

G. Plaintiffs' MIL No. 13 (the alleged fault of Dr. Amer).

In a related motion, Plaintiffs seek to exclude evidence regarding the alleged fault of Dr. Amer on the ground that Defendants have no expert testimony to support a causation finding by the jury. Doc. 9878. In their notice of nonparty at fault, Defendants state that they rely on the expert reports and deposition testimony of Drs. Daniel Cousin and Piotr Sobieszczyk. Doc. 8844 at 2. Defendants argue that, under Georgia law, causation may be established by linking the testimony of different expert witnesses, and that in this case Dr. Cousin opines that Dr. Amer fell below the standard of care and Dr. Sobieszczyk provides the causation opinion. Doc. 10066 at 2-5.

Dr. Sobieszczyk's report references several imaging studies Ms. Booker received, including the radiological exam performed by Dr. Amer in March 2009. Doc. 10067 at 9. He notes that Dr. Amer's exam "showed an IVC filter with one short fragment separated from the filter and pointing up above the filter tip," and another fragment "separated from

---

[2] Defendants argue that they can use the intervening cause defense to assert that Dr. Kang "contributed to" Ms. Booker's injuries. Doc. 10055 at 3. This is not correct. Either his conduct became an intervening cause and broke the causal chain between Defendants and Ms. Booker, eliminating Defendants' liability, or it did not. True, if Defendants are able to show that his actions were the intervening cause for some discrete part of her injury (say, her heart surgery), it may have the same effect as if the jury apportioned fault and assigned 100% of the heart surgery responsibility to Dr. Kang. But the jury could reach this result only through the intervening cause analysis and a finding that the three elements set forth above are satisfied. Defendants cannot use the intervening cause defense to essentially argue for equitable apportionment – that the jury should divide the liability between Defendants and Dr. Kang on the basis of their respective degrees of fault.

the filter and moved towards the midline." *Id.* He refers to the imaging studies as "missed opportunities," opining that they "clearly defined progressive tilting and strut movement" and "[r]ecognition of this process would have allowed timely retrieval of the filter." *Id.* at 11, ¶ 2.

The Court finds that this opinion, when combined with Dr. Cousin's opinion regarding the standard of care (Doc. 9878-4 at 4), is sufficient to create a jury issue on whether Dr. Amer is at fault for allegedly failing to report the condition of Ms. Booker's filter to her treating physicians. Georgia courts have made clear that "[q]uestions regarding causation are peculiarly questions for the jury except in clear, plain, palpable and undisputed cases." *Moore v. Singh*, 755 S.E.2d 319, 323-24 (Ga. Ct. App. 2014) (citation omitted). This is not one of those cases. *See id.* at 324 ("Based on the combined expert testimony, we conclude that Moore presented evidence creating a jury issue as to whether Dr. Singh would have discovered the fracture if she had properly complied with the standard of care [and] . . . whether the failure to diagnose the fracture during that time led to further complications[.]"). Plaintiffs' motion in limine (Doc. 9878) is **denied**.

H. Plaintiffs' MIL No. 9 (statements from associations and other groups).

Plaintiffs seek to exclude evidence of "statements from various associations, trade groups, organizations, societies of physicians, [and] medical providers[.]" Doc. 9874 at 1. Plaintiffs first contend that such statements constitute inadmissible hearsay, and possibly hearsay within hearsay. *Id.* at 2. Plaintiffs also contend that admission of such statements through non-experts would evade *Daubert* scrutiny and would violate Rule 403. *Id.* at 2-3. Because Plaintiffs identify no specific statement from any particular association, the Court cannot grant Plaintiffs' motion. But the Court will address some of the parties' arguments.

Defendants argue that statement by medical societies may be relevant even if they are not offered for the truth of the matter asserted. Doc. 10058 at 2. Defendants note, for example, that the risk-utility test of Georgia law permits a jury to consider "the gravity and severity of the danger posed by [a product's] design; the likelihood of that danger;

the avoidability of the danger, i.e., the user's knowledge of the product, publicity surrounding the danger, or the efficacy of warnings, as well as common knowledge and the expectation of danger[.]" *Banks*, 450 S.E.2d at 675 n.6. Defendants argue that statements from the Society of Interventional Radiologists ("SIR") about the risks of IVC filters are relevant to several of these factors – the user's knowledge of the product, publicity surrounding the product's danger, and the common knowledge the danger – regardless of whether the SIR's statements are true. Admission for these non-truth purposes, Defendants assert, would not implicate the hearsay rules. Whether statements should be admitted for these purposes must be decided at trial.

Defendants also contend that statements by medical societies are admissible under Rule 803(18) even if offered for the truth of the matter asserted. Doc. 10058 at 3. Rule 803(18) provides that a statement contained in a treatise or periodical is excluded from the hearsay rule if (1) "the statement is called to the attention of an expert witness on cross-examination or relied on by the expert on direct examination," and (2) "the publication is established as a reliable authority by the expert's admission or testimony, by another expert's testimony, or by judicial notice." Fed. R. Evid. 803(18)(A)-(B).[3] If deemed admissible, "the statement may be read into evidence but not received as an exhibit." *Id*. "This limitation ensures that the jurors will not be unduly impressed by the treatise, and that they will not use the text as a starting point for conclusions untested by expert testimony." 5 *Weinstein's Federal Evidence* § 803.20[1]. Whether Rule 803(18)'s requirements are satisfied requires a statement-by-statement inquiry, which must be determined at trial. The party proposing to use a statement under Rule 803(18) must be prepared to show that both requirements are met.

Plaintiffs further contend that testimony from non-expert witnesses about statements from medical societies such as the SIR would allow Bard to avoid the scrutiny

[3] On the second requirement, Weinstein's explains: "To establish a proper foundation, the proponent must show that the author of the treatise or article in question is an authority." 5 Jack B. Weinstein & Margaret A. Berger, *Weinstein's Federal Evidence* § 803.20[2] (2d. ed. 2018).

of *Daubert*. *Id.* Defendants avow that they will not attempt to offer any expert opinion about such statements through a fact witness. Doc. 10058 at 3. Defendants do state, however, that SIR guidelines were discussed routinely among Bard employees, and that fact witnesses should be permitted to testify about the things they said and the actions they took concerning SIR guidelines. *Id.* at 3-4. If a discussion at Bard that included reference to SIR statements is relevant to an issue in this case and not otherwise objectionable, then a lay witness's recounting of the discussion may be appropriate. The Court will defer ruling on any objections until trial.

Defendants contend that even if SIR guidelines are themselves inadmissible on hearsay or other grounds, their experts may rely on the guidelines under Rule 703. Defendants assert that some of their experts have relied on the guidelines in forming their opinions and were not challenged by Plaintiffs in any *Daubert* motion. Doc. 10058 at 3. But even if an expert is allowed to state an opinion formed in part by reliance on the SIR guidelines, that does not mean that the guidelines themselves may be disclosed to the jury. "Rule 703 is not, itself, an exception to or exclusion from the hearsay rule or any other evidence rule that makes the underlying information inadmissible." 4 *Weinstein's Federal Evidence* § 703.05[2]. Rule 703 generally does not permit an expert to relay inadmissible evidence – as opposed to the expert's own opinion based on such evidence – to the jury. Indeed, there is "a presumption against disclosure to the jury of information used as the basis of an expert's opinion and not admissible for any substantive purpose, when that information is offered by the proponent of the expert." Fed. R. Evid. 703 (2000 Advisory Committee's Note). Thus, if an objection is made, otherwise inadmissible information may be disclosed to the jury under Rule 703 only if the proponent shows that "the probative value of the information in assisting the jury to evaluate the expert's opinion substantially outweighs its prejudicial effect." *Id.*; Fed. R. Evid. 703.

If the Court sustains an objection to the admission of the SIR guidelines through expert testimony, and Defendants' believe that the probative value of the guidelines in

helping the jury evaluate the expert's opinion substantially outweighs any prejudicial effect, Defendants are instructed to raise this issue with the Court outside the hearing of the jury. If the Court concludes that the SIR guideline evidence may be disclosed to the jury under Rule 703, Plaintiffs may request a limiting instruction that the evidence may be used only for evaluating the expert's opinion and not for substantive purposes.

Plaintiffs assert that Bard intends to use the SIR guidelines to establish acceptable failure rates for IVC filter manufacturers, and that use of the SIR guidelines in this way would be misleading and result in unnecessary mini-trials. Doc. 9874 at 3. Plaintiffs further assert that statements from professional organizations with lofty names have limited probative value that is substantially outweighed by the risk of unfair prejudice, confusion, and delay. *Id.* at 3-4. Efficient management of the evidence and adherence to the trial time limits will avoid the risk of mini-trials and delay. Doc. 10058 at 4. The Court cannot conclude on the present record that any probative value the SIR guidelines may have is substantially outweighed by the danger of unfair prejudice. Plaintiffs may object during trial if they believe specific SIR guideline evidence is inadmissible.

Finally, Plaintiffs seek to exclude evidence regarding the lack of statements from the SIR and similar organizations. Doc. 9874 at 1-2. Plaintiffs cite to the testimony of one of Bard's experts that, to her knowledge, no medical society has taken the position that Bard retrievable filters carry more risks than other IVC filters. Doc. 9874-2 at 3 (Roberts Dep. Tr. 78:9-79:6). Defendants counter that what organizations like the SIR do not say about the risks of IVC filters is relevant to the jury's consideration of the design defect and failure to warn claims. Doc. 10058 at 3. Whether such evidence is relevant and otherwise admissible will depend heavily on context. The Court will make rulings as necessary during trial.

Defendants assert that testimony regarding the absence of a statement is not hearsay. Doc. 10058 at 3 n.1 (citing *Llamas v. Seibel*, No. 16-CV-05812-WHO, 2017 WL 3782175, at *8 (N.D. Cal. Aug. 31, 2017)). Although this generally is true, silence can be a "statement" for purposes of the hearsay rules where the person "intended it as an

assertion." Fed. R. Evid. 801(a); *see McGiboney v. CCA W. Props., Inc.*, No. 1:13-cv-00214-REB, 2016 WL 843253, at *7 (D. Idaho Mar. 1, 2016) (Rule 801 "explicitly requires that the declarant must actually intend his statement (even if it consists of silence) as an assertion"); *Weinstein's Federal Evidence* § 801.10[2][b] ("Even silence may be intended as an assertion"). If Plaintiffs believe that testimony regarding the absence of statements from medical societies constitutes inadmissible hearsay, they may object. Plaintiffs' motion in limine (Doc. 9874) is **denied**.

I. Plaintiffs' MIL No. 10 (FDA consent for warnings or recalls).

Plaintiffs seek to exclude evidence or argument that Bard needed the FDA's consent to add warnings to its labels, send warning letters to physicians and consumers, or recall the G2 filter. Doc. 9875. Defendants do not dispute that a medical device manufacturer may send warning letters and voluntarily initiate a recall without FDA consent. Doc. 10062 at 2-4. Defendants will be precluded from presenting evidence or argument to the contrary. Defendants may, however, present evidence and argument explaining the FDA's potential involvement in any recall effort and the reasons why Bard filters were not recalled. *Id.* at 4.

Defendants dispute that manufacturers may add warnings to device labels without FDA consent. Defendants cite 21 C.F.R. § 807.81, but this regulation says nothing about adding warnings to labels. Rather, the significant changes or modifications that may require FDA premarket notification are those affecting the intended use of the device or the "design, material, chemical composition, energy source, or manufacturing process." 21 C.F.R. § 807.81(a)(3)(ii)-(iii). None of these constitutes adding a warning to a label.

Defendants also cite an FDA guidance document that notes that a labeling change "meant to significantly improve clinical outcomes, to mitigate a known risk, or in response to adverse events . . . likely requires submission of a new 510(k)." Doc. 10062 at 2.[4] As the Court previously noted, this document is meant only to provide guidance

[4] *See* FDA, *Deciding When to Submit a 510(k) for a Change to an Existing Device, Guidance for Industry and FDA Staff*, at 19 (Oct. 25, 2017), *available at* https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm

and does not bind the FDA or device manufacturers. Doc. 8872 at 24 n.13. Moreover, the document provides that "manufacturers should monitor device usage and promptly revise the warnings and precautions based on user experience," and that "[s]ubmission of new 510(k)s for such labeling changes are generally not required." Guidance Doc. at 22.

Defendants cite a regulation that requires FDA approval for label changes or product comparisons, but that regulation applies only to prescription drugs. *See* 21 C.F.R. § 201.57(c) ("The requirements in this section apply only to prescription drug products described in § 201.56(b)(1)[.]"). Similarly, the regulation Defendants cite regarding clinical trials concerns the FDA's approval of new drugs, not medical devices. *See* 21 C.F.R. § 314.126.

Plaintiffs' position, according to Defendants, is that "Bard could have added warnings regarding 'the increased risks' of complications 'associated with its products.'" Doc. 10062 at 2. Defendants contend that the concept of "increased risks" necessarily requires a comparison of the G2 and other filters based on medical device reports ("MDRs") and data from the FDA's Manufacture and User Facility Device Experience ("MAUDE") database, and Plaintiffs' proposed warning regarding increased risks runs afoul of FDA regulations governing what content may be used in device instructions for use. *Id.* (citing 21 C.F.R. § 201.57(c)). As noted above, however, the cited regulation applies only to prescription drugs. Moreover, Plaintiffs' motion states that Bard could have warned about increased risks by voluntarily sending letters to physicians and patients. Doc. 9875. Defendants cite no FDA rule or regulation prohibiting such letters.

Defendants note that MDR and MAUDE data "alone cannot be used to . . . compare event rates between devices" and cannot be "used in isolation to reach conclusions about the existence, severity, or frequency of problems associated with devices." Doc. 10062 at 2.[5] This appears to be correct, but Defendants have not shown

---

514771.pdf (last visited Feb. 21, 2018).

[5] *See FDA MAUDE Database*, *available at* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm (last updated Jan. 31, 2018; last visited Feb. 27, 2018).

that FDA consent would be required to provide a warning about increased risks based on other reliable sources.

Plaintiffs' motion in limine (Doc. 9875) is **granted** in part. Defendants will be precluded from presenting evidence or argument that Bard needed FDA consent to add any warning to its labels, send warning letters to physicians and patients, or recall its filters. Defendants may, however, present evidence and argument explaining the reasons why Bard filters were not recalled, the FDA's potential involvement in any recall effort, and the fact that warnings about failure rates and increased risks could not be based on MDR and MAUDE data alone.

Dated this 1st day of March, 2018.

David G. Campbell
United States District Judge

WO

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
Sherr-Una Booker, an individual, Plaintiff, v. C. R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation, Defendants.	No. CV-16-00474-PHX-DGC **ORDER**

In the parties' proposed pretrial order, Defendants objected to Plaintiffs' use at trial of the depositions of three defense expert witnesses, Drs. Moritz, Rogers, and Stein, who originally were retained by Defendants but have since been withdrawn. Doc. 10255 at 2. Defendants assert that the depositions constitute hearsay and are not admissible as admissions of a party-opponent. *Id.* (citing Fed. R. Evid. 801(d)(2)(C); *Glendale Fed. Bank, FSB v. United States*, 39 Fed. Cl. 422, 425 (1997); *In re Hanford Nuclear Res. Litig.*, 534 F.3d 986, 1016 (9th Cir. 2008)). Plaintiffs counter that once a party has offered opinions through deposition or expert reports, those opinions do not belong to that party alone, but rather are available for all parties to use at trial. *Id.* at 26 (citing *NetAirus Techs., LLC v. Apple, Inc.*, No. LA CV10-03257 JAK, 2013 WL 9570686, at *3

(C.D. Cal. Nov. 11, 2013)).

At the final pretrial conference, the Court directed the parties to file memoranda addressing the issue of whether the depositions are admissible under Federal Rule of Civil Procedure 32(a)(4) and Federal Rule of Evidence 804(b)(1). *See* Doc. 10323 at 3. The parties have now done so. Docs. 10343, 10345.

Plaintiffs contend that depositions of the withdrawn experts are admissible because a party may use "for any purpose" the depositions of unavailable witnesses under Rule 32(a)(4), and the depositions fall within the "former testimony" exception to the hearsay rule set forth in Rule 804(b)(1). *Id*. at 1-2 (citing *Tatman v. Collins*, 938 F.2d 509, 511 (4th Cir. 1991)). Defendants acknowledge that several courts have held that a withdrawn expert's deposition may be used at trial under Rule 32(a)(4). Doc. 10343 at 2-3. Defendants assert that the depositions nonetheless should be excluded under Rule 804 unless Plaintiffs have used reasonable but unsuccessful means to procure live testimony from the experts, and unless Defendants had a "similar motive" to develop the testimony during the deposition. *Id.* at 2. But Defendants do not dispute that the withdrawn experts are unavailable for purposes of Rule 804(a)(5) and that any attempt by Plaintiffs to subpoena them would be futile. Nor do Defendants explain why they did not have a similar motive to develop the experts' testimony during the depositions. Once it was clear that the experts were giving answers helpful to Plaintiffs, Defendants had sufficient incentive to clarify or cross-examine on those answers. Defendants have not shown that the depositions are inadmissible on hearsay grounds.

Defendants argue that even if the depositions can be used at trial, it would be unfairly prejudicial under Rule 403 to disclose to the jury that the experts originally were retained by Defendants. Several courts have recognized "the significant potential prejudice of informing the jury that the expert presently testifying for one party was originally designated, retained, or consulted by the opposing party." *House v. Combined Ins. Co. of Am.*, 168 F.R.D. 236, 243 (N.D. Iowa 1996) (citing *Peterson v. Willie*, 81 F.3d 1033, 1037 (11th Cir. 1996) (collecting cases)); *Healy v. Counts*, 100 F.R.D. 493, 496 (D.

Colo. 1984); *Rubel v. Eli Lilly & Co.*, 160 F.R.D. 458, 460 (S.D.N.Y. 1996) (noting that one leading commentator "aptly has characterized the fact of the prior retention by the adversary as 'explosive'" (quoting 8 Wright, Miller & Marcus, *Federal Practice & Procedure* § 2032, at 447 (1994)). As one court explained:

> The admission of this evidence . . . would only serve to unfairly prejudice the [opposing party]. Jurors unfamiliar with the role of counsel in adversary proceedings might well assume that . . . counsel had suppressed evidence which he had an obligation to offer. Such a reaction could destroy counsel's credibility in the eyes of the jury.

Granger v. Wisner, 656 P.2d 1238, 1242-43 (Ariz. 1982).

Plaintiffs contend that Defendants should not be able to "hide" their experts' unfavorable opinions from the jury. Doc. 10345 at 2. But disclosing the fact that Defendants have withdrawn the experts could be unfairly prejudicial, leading the jury to speculate as to why the experts were withdrawn and, potentially, to conclude that Defendants or their counsel attempted to engage in dishonest or unethical behavior. And such information has little relevance to the substance of the experts' opinions on any claim or defense in this case. *See Granger*, 656 P.2d at 381 (finding the fact of the prior consultation irrelevant to the issue of negligence); *House*, 168 F.R.D. at 243 ("House has asserted as an argument for permitting her to offer [the expert's] testimony the assertion that [the defendant] is trying to hide [the] opinion from House and the jury. However, the court in *Peterson* recognized the prejudice that results from informing the jury that an expert had originally been consulted by the opposing party.").

The Court concludes that Plaintiffs may use portions of the experts' depositions that support Plaintiffs' case, but may not disclose to the jury, through argument or deposition excerpts, that the experts originally were retained by Defendants. The Court concludes that the probative value of such arguments or deposition excerpts would be substantially outweighed by the danger of unfair prejudice. Fed. R. Ev. 403.

The Court is also concerned about the presentation of cumulative evidence. The Court has made clear that it will not permit either side to use multiple experts at trial to

address the same issue. Thus, before the deposition of any withdrawn expert may be used at trial, "there should be some showing . . . that no other expert of similar qualifications is available or that the unavailable expert has some unique testimony to contribute." *Carter-Wallace, Inc. v. Otte*, 474 F.2d 529, 536-37 (2d Cir. 1972). If Plaintiffs make this showing for any of the withdrawn experts, the Court will allow the expert's deposition to be used at trial subject to the Rule 403 decision above and any other evidentiary objections Defendants may assert. *See* Doc. 10343 at 3. Defendants will be permitted to counter-designate other relevant portions of the deposition transcript. *See* Doc. 10255 at 25.

Dated this 9th day of March, 2018.

David G. Campbell
United States District Judge

WO

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
Sherr-Una Booker, an individual, Plaintiff, v. C. R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation, Defendants.	No. CV-16-00474-PHX-DGC **ORDER**

Near the close of trial last week, Plaintiff objected to Defendants presenting evidence of complications associated with Bard's Simon Nitinol Filter ("SNF"). In addition to arguments made in court, the parties have filed memoranda addressing the issue. Docs. 10487, 10488.[1]

In seeking to prove her claim that Defendants defectively designed the G2 filter and failed to warn about its risks, Plaintiff has claimed during trial that the G2, and its

[1] Each party also provided the Court with a USB flash drive containing SNF-related documents. Defendants' documents consist of medical literature about SNF complications, expert reports citing some of those articles, and documents produced to Plaintiff during discovery. Plaintiff's documents consist largely of internal Bard communications about the safety and effectiveness of the SNF.

predicate device, the Recovery filter, were considerably less safe that the SNF. Defendants intend to rebut this evidence by presenting medical literature about SNF failure rates and expert testimony that failures with the SNF, as a permanent filter, are reported less frequently than failures for retrievable filters.

Plaintiff claims that Defendants should be prevented from presenting this evidence because she was barred from conducting relevant discovery, citing Case Management Order No. 10 ("CMO 10"). *See* Doc. 1319. Defendants argue that Plaintiff's reliance on CMO 10 is misplaced because the order afforded Plaintiff significant discovery concerning the SNF, all of Bard's adverse event data concerning the SNF were produced, and the only materials not produced were SNF design and testing documents. Doc. 10487 at 2.

Plaintiff sought production of six categories of documents related to the SNF: (1) design materials, (2) testing information, (3) regulatory communications, (4) sales and marketing materials, (5) information comparing the SNF to other filters, and (6) internal Bard communications related to these subjects. Doc. 1161 at 1-2. The Court permitted discovery regarding topics (4), (5), and (6), and Defendants agreed to produce the documents on topic (3). Doc. 1319 at 4-5. The only discovery not allowed by CMO 10 was on topics (1) and (2) – the design and testing of the SNF. The Court foreclosed this discovery because Plaintiff did not contend then, and does not contend now, that the SNF is defective.

Plaintiff argues that discovery regarding the design and testing of the SNF would somehow have permitted her to challenge Bard's assertion that the SNF has had as many failures as the Recovery and G2. Doc. 1048 at 2. But Plaintiff was not precluded from conducting discovery of SNF failures. CMO 10 specifically permitted Plaintiff to obtain "documents comparing filter performance and failure rates to the SNF." Doc. 1319 at 4. True, Plaintiff was precluded from conducting discovery into the design and testing of the SNF, but that was because she does not claim that the SNF was designed defectively. Rather, she asserts that the SNF is a markedly safer filter than the Recovery and G2. The

Court cannot see, and Plaintiff does not explain, how discovery into the design and testing of the SNF would have produced any information on failure rates the SNF experienced after it was on the market.

Plaintiff argues that the SNF received design changes through 1995 and that she will be unable to contradict the medical literature Defendants intend to present because those articles depend on the precise version of the SNF filter at issue. But Plaintiff never made this argument in connection with CMO 10, and, in arguing that the SNF is a safe and effective filter, Plaintiff has never distinguished between different versions.

Nor has Plaintiff shown that she will be unable to rebut the medical literature Defendants intend to present. To the contrary, Plaintiff has identified multiple internal Bard documents showing that failure rates for the SNF were much lower than Recovery and G2 rates. This information was produced by Defendants during discovery. Plaintiff has already presented much of it during trial, will present more, and will be free to cross-examine witnesses with this evidence.

Plaintiff may make appropriate evidentiary objections to any evidence Defendants seek to present, but the Court will not preclude Defendants from presenting their SNF evidence on the basis of a discovery ruling. The Court does not agree that Plaintiff was foreclosed from obtaining relevant evidence for rebuttal.

Dated this 19th day of March, 2018.

David G. Campbell
United States District Judge

WO

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
Doris Jones, an individual, Plaintiff, v. C. R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation, Defendants.	No. CV-16-00782-PHX-DGC **ORDER**

The Court held a hearing with the parties on April 13, 2018, to discuss matters decided for the Booker trial that the parties wish to have reconsidered for the Jones trial. The Court took two matters under advisement: whether evidence of the complications, testing, and design of the Recovery filter should be admitted in the Jones trial, and whether evidence of deaths caused by cephalad migration of the Recovery filter should be admitted. These matters were the subject of briefing before the hearing and argument during the hearing. *See* Docs. 10677, 10707.

Plaintiff Doris Jones was implanted with a Bard Eclipse filter in August 2010. The filter later fractured, and a strut migrated to Ms. Jones' lung. She asserts claims for defective design, failure to warn, fraudulent concealment, and punitive damages.

A. Evidence of Recovery Filter Complications, Testing, and Design.

Defendants note that the relevant progression of their retrievable filter line is as follows: Recovery, G2, G2X, Eclipse. They argue that the Eclipse filter at issue in this case is three generations removed from the Recovery filter and that complications with the Recovery therefore are not relevant to the alleged design defects or failure to warn related to the Eclipse.

Plaintiff claims that design defects in the Eclipse trace directly back to the Recovery, and that those defects can be understood only in the context of the entire filter-line development. Plaintiff asserts that problems with the Recovery led directly to a poorly-tested set of changes in the G2 filter; that those changes created other problems in the G2, including tilt, fracture, and caudal migration (away from the head); that the G2X and Eclipse filters were essentially the same as the G2, adding only a retrieval hook and electropolishing; and that Bard acted unreasonably in failing to implement effective tests and design changes when developing the G2, and, later, in failing to correct apparent G2 problems, leading directly to the Eclipse defects that caused Ms. Jones' injury. Doc. 10707.

The Court concludes that the Recovery filter's complications, testing, and design are relevant to this case. Those events help explain the testing, development, and design of the G2, and Plaintiff contends that the G2 was essentially the filter she received. The history of the Recovery and how it led to the G2 tends to make a fact in dispute – the allegedly defective design of the Eclipse – more probable. Fed. R. Evid. 401.

The Court cannot conclude that evidence of the Recovery's complications, testing, and design should be precluded under Rule 403. The Court does not find such evidence to be unfairly prejudicial – it is a relevant part of the Eclipse filter's design history. Further, Plaintiff's counsel presented much of the same evidence during the Booker trial. Although the Court felt that Plaintiff's counsel were less efficient in that trial than they could have been, the Court will hold Plaintiff to the established time limits in this case

and concludes that Recovery filter evidence will not result in a waste of time or confusion of the issues. *See* Doc. 10587.

B. Evidence of Deaths Caused by Recovery Filter Cephalad Migration.

Deaths caused by the Recovery filter's cephalad migration (toward the head) present a different question. Such deaths might clear the threshold for relevancy in Rule 401 because, as explained above, they are part of the history of the filter line's development. But for several reasons the Court finds this relevancy to be marginal in Ms. Jones' case.

First, the complication of cephalad migration did not continue in any significant degree beyond the Recovery filter. As Plaintiff's counsel admitted during the April 13 hearing, changes made in response to cephalad migration largely eliminated that direction of migration in the G2 and later filters. The Court's notes from the Booker trial reflect that Plaintiff identified only one instance of cephalad migration by a G2 filter. And Plaintiff's counsel acknowledged during the hearing that they are not aware of any instances of death caused by cephalad migration of G2, G2X, or Eclipse filters.

Second, the cephalad migration deaths all occurred before the Recovery filter was taken off the market in late 2005. Ms. Jones did not receive her Eclipse filter until January of 2010. The passage of more than four years and three filter generations makes the cephalad migration deaths remote in time.

Third, the cephalad migration deaths say nothing about several of Ms. Jones' claims in this case: strict liability design defect, strict liability failure to warn, negligent failure to warn, or fraudulent concealment. Proof of the cephalad migration deaths from the Recovery filter in 2004 and 2005 does not show that the Eclipse filter had a design defect when it left Defendants' control several years later, or that Defendants' later warnings regarding the Eclipse were inadequate or fraudulent.

The cephalad migration deaths arguably are more relevant to Ms. Jones' negligent design defect claim because they help show the extent to which Defendants allegedly failed to exercise reasonable care in designing and testing the G2 filter. But the things

Defendants allegedly failed to do in developing the G2 – perform a viable root cause analysis, test adequately, follow established design principles – can all be shown through Plaintiff's experts and without mention of the cephalad migration deaths. The deaths arguably could make these failures appear even more negligent because Defendants were aware of severe consequences from the Recovery's design, but they do not prove the negligence. Evidence of the deaths remains marginal – it adds some weight to Plaintiff's negligence claim, but it is not central to proof of design negligence.

Fourth, Plaintiff asserts a claim for punitive damages and argues that the cephalad migration deaths are relevant to whether Defendants acted with the state of mind needed for such damages: willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care that would raise the presumption of conscious indifference to consequences. Doc. 10588 at 29. Under Georgia law, which governs Plaintiff's claims, "evidence of other incidents involving the product is admissible, and relevant to the issues of notice of a defect and punitive damages, provided there is a showing of substantial similarity." *Gen. Motors Corp. v. Moseley*, 447 S.E.2d 302, 306 (Ga. Ct. App. 1994) (citing *Mack Trucks v. Conkle*, 436 S.E.2d 635 (Ga. 1993)). "'Without a showing of substantial similarity, the evidence is irrelevant as a matter of law.'" *Id.* (quoting *Carlton Co. v. Poss*, 183 S.E.2d 231 (Ga. Ct. App. 1971)); *see also State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 422 (2003) ("A defendant's dissimilar acts, independent from the acts upon which liability was premised, may not serve as the basis for punitive damages.").

In denying Defendants' request for summary judgment on Plaintiff's punitive damages claim, the Court found generally that Plaintiffs have shown a substantial similarity between filters – between the Eclipse filter and the Recovery and G2 filters. Doc. 10404 at 19. But the Court concludes that instances of cephalad migration resulting in death are not substantially similar to complications experienced by the G2, G2X, or Eclipse. As noted above, cephalad migration was largely eliminated by the design of the G2, and Plaintiff has identified no cephalad migration deaths caused by any of the G2

line of filters, including the Eclipse. The deaths therefore do not meet the substantial similarity requirement of Georgia law.

The deaths would be clearly relevant to punitive damages if they were caused by the Eclipse or its predicate device – if Defendants continued to market the Eclipse in the face of unusually high patient deaths. But Defendants did not do that; the cephalad migration deaths stopped when the Recovery was taken off the market in 2005. Plaintiffs do contend that Defendants continued to market the G2, G2X, and Eclipse with knowledge of other complications, but none of those complications included cephalad migration. The deaths shed little light on Defendants' state of mind when marketing different filters with different complications, years later. *See Gen. Motors*, 447 S.E.2d at 307 (finding reversible error where counsel for plaintiffs referenced deaths and other lawsuits during trial without first making a showing of substantial similarity to the incident at issue); *Ray v. Ford Motor Co.*, 514 S.E.2d 227, 230-31 (Ga. Ct. App. 1999) (affirming decision to exclude evidence about a Ford database listing prior instances of inadvertent vehicle movement where the plaintiff failed to establish that the incidents were substantially similar to his accident).[1]

Thus, when all of the issues in this case are considered, the cephalad migration deaths have, at most, marginal relevancy. Given this level of relevancy, the Court finds that the probative value of the death evidence is substantially outweighed by the danger of unfair prejudice. "Unfair prejudice is an undue tendency to suggest decision on an improper basis, commonly, though not necessarily, an emotional one." *United States v. Haischer*, 780 F.3d 1277, 1281 (9th Cir. 2015) (citation and quotation marks omitted). The fact that several patients died when their Recovery filters migrated in a cephalad

[1] To the extent Plaintiff suggests that Defendants' alleged indifference during the marketing of the Recovery shows that Defendants were also indifferent when marketing the Eclipse, they suggest a propensity use of the evidence that is prohibited by Rule 404(a) and (b). Plaintiff has not argued that cephalad migration deaths should be admitted under one of the permissible purposes in Rule 404(b)(2). But even if Plaintiff made this argument, the Court can see no permitted use of the death evidence in that rule. And, in any event, Rule 404(b) analysis remains subject to Rule 403, and the Court concludes in this order that admission of the death evidence would violate Rule 403.

direction would have an undue tendency to prompt a jury decision based on emotion. The Court concludes that the danger of this emotional reaction substantially outweighs any marginal relevancy of the death evidence in this case, and therefore will exclude the evidence under Rule 403.

The Court reached a different conclusion in Booker, holding that evidence of cephalad migration deaths could be admitted. Doc. 10323 at 4. But Booker concerned a G2 filter for which the Recovery was the predicate device. Defendants represented to the FDA – and, in essence, to the jury – that the G2 was as safe and effective as the Recovery. This put the safety and effectiveness of the Recovery filter squarely at issue. And even with this greater relevancy, the Court in Booker expressed concern that too heavy an emphasis on the cephalad migration deaths would result in unfair prejudice that substantially outweighed the probative value of the evidence. *Id.*

In this case, the Court finds that deaths caused by a non-predicate device, and by a form of migration that was eliminated years earlier, are of sufficiently limited probative value that their relevancy is substantially outweighed by the danger of unfair prejudice.

IT IS ORDERED: At trial, Plaintiff may present evidence of the complications, testing, and design of the Recovery filter, but not of deaths caused by cephalad migration of the Recovery filter.

Dated this 18th day of April, 2018.

David G. Campbell
United States District Judge

WO

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
Doris Jones, an individual, Plaintiff, v. C. R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation, Defendants.	No. CV-16-00782-PHX-DGC **ORDER**

Plaintiff Doris Jones has filed a motion for reconsideration of the Court's order excluding evidence of deaths caused from cephalad migration of the Recovery filter under Rule 403. Doc. 10873. Defendants have filed a response. Doc. 10899. The Court will deny the motion in part as set forth below.

I. Background.

The Court held a hearing with the parties on April 13, 2018, to discuss matters decided for the Booker trial that the parties wish to have reconsidered for the Jones trial. Doc. 10805. The Court took two matters under advisement: whether evidence of the design, testing, and complications of the Recovery filter should be admitted in the Jones trial, and whether evidence of deaths caused by cephalad migration of the Recovery filter

should be admitted. These matters were the subject of briefing before the hearing and argument during the hearing. *See* Docs. 10677, 10707.

Several days later, the Court issued an order finding that evidence of the design, testing, and complications of the Recovery filter is relevant to Ms. Jones' case and should not be excluded under Rule 403. Doc. 10819 at 2-3. The Court further found, however, that evidence of deaths caused by Recovery filters migrating to a patient's heart has only marginal relevance in Ms. Jones' case. *Id.* at 3-5. The Court held that the minimal probative value of the evidence is substantially outweighed by the danger of unfair prejudice because the death evidence may prompt a jury decision based on emotion. *Id.* at 5-6.

II. Discussion.

Plaintiff argues that the Court's decision is based on a false premise because cephalad migration continued to be associated with deaths in later devices, including the Eclipse. Doc. 10874 at 4-5. Plaintiff further argues that cephalad migration is relevant and substantially similar to her claims. *Id.* at 6-7. Finally, Plaintiff contends that the death evidence cannot reasonably be extracted from the overall complication evidence, and its exclusion would unreasonably curtail her proof in this case. *Id.* at 7-10.

Plaintiff's arguments and supporting evidence could have been presented to the Court in earlier briefing and argument. As a result, Plaintiff has not identified a legitimate basis for reconsideration. *See* LRCiv 7.2(g)(1); *Nicole-Pickett v. Wells Fargo Bank, N.A.*, No. CV-16-03262-PHX-DGC, 2016 WL 7187988, at *1 (D. Ariz. Dec. 12, 2016); *Sch. Dist. No. 1J, Multnomah Cty., Or. v. ACandS, Inc.*, 5 F.3d 1255, 1262-63 (9th Cir. 1993). Because of the importance of this issue, however, the Court will address each of Plaintiff's arguments.

A. The Evidentiary Basis for the Court's Ruling.

At the April 13 hearing, counsel for Plaintiff agreed that there has been very little cephalad migration after the Recovery filter, in part because the G2 filter was given a wider design to correct the cephalad migration problem. Doc. 10874-1 at 4. Counsel was

not able to identify any instance of cephalad migration causing death in the G2 or later filters. *Id.* at 3-4. Plaintiff now claims that a review of thousands of complaints in Bard's Trackwise database shows that cephalad migration was not eliminated by later-generation filters, and that deaths caused by cephalad migration continued after the Recovery. Doc. 10874 at 4-6. A careful review of Plaintiff's evidence shows otherwise.

1. Evidence of cephalad migration deaths.

Plaintiff claims that two cases of cephalad migration by Eclipse filters resulted in patient deaths. Doc. 10874 at 5 (citing Complaint Nos. 313635, 354264); Doc. 10874-2 at 2-3, 33-99. Although both cases involved cephalad migration of an Eclipse filter and a patient's death, the evidence presented by Plaintiff does not show that the migrations caused either of the deaths.

In the first incident, records provided by Plaintiff show that the Eclipse filter did not migrate to the patient's heart; it migrated above the renal veins due to a large clot burden. Doc. 10874-2 at 34. The patient later died due to pulmonary embolism, but the death occurred after the Eclipse filter had been removed and replaced with a competitor's device. According to the records provided by Plaintiff, the treating physician reported that "the Bard filter did its job." *Id.*

In the second incident, the Eclipse filter migrated "within proximity to the right atrium" of the heart due to a "clot burden within the filter extending down into the patient's legs." *Id.* at 73-76. The patient later died, possibly due to pulmonary embolism. *Id.* The record provided by Plaintiff suggests that the cause of death was never determined because the coroner chose not to do an autopsy, and also states that the physician "did not feel that the filter was related to the patient's death." *Id.*

These are the only records provided by Plaintiff to support her claim that G2, G2X, or Eclipse filters caused death by cephalad migration. They do not support the claim. Thus, one of the fundamental grounds for the Court's previous order – that cephalad migration deaths stopped after the Recovery filter – remains intact.

2. Evidence of other cephalad migrations.

Plaintiff cites eight other complaint files purportedly showing cephalad migration by the G2-line of filters. Docs. 10874 at 3, 10874-2 at 2-4. One involved a G2 filter (No. 260851), two involved Eclipse filters (Nos. 291446 and 383261), and five involved G2X filters (Nos. 239963, 248122, 250927, 273135, and 283282). Doc. 10874-2 at 2-4. The last two G2X cases did not involve cephalad migration of a properly deployed filter, but instead resulted from faulty deployment. *Id.* at 4 (Nos. 273135 and 283282).[1]

Thus, out of approximately 180,000 G2 and G2X filters sold (according to Defendants (Doc. 10899 at 3)), Plaintiff provides evidence of cephalad migration by one G2 and three G2X filters. And out of approximately 66,000 Eclipse filters sold (again, according to Defendants (*id.*)), Plaintiff provides evidence of four cephalad migrations. Another premise of the Court's previous order thus remains intact – cephalad migrations largely ceased due to changes made to the G2-line of filters.

3. Plaintiff's other arguments.

Plaintiff argues that ongoing cephalad migration played a role in the contemplated redesign of the Eclipse shortly after it was launched. Doc. 10874 at 4-5. But the documents relied on do not support this assertion. The memo from Bard employee Brett Baird largely addresses whether the introduction of electropolishing was well received by customers, and says nothing about cephalad migration. Doc. 10874-4. The Idea POA Eclipse Anchor Filter document contemplates the addition of anchor hooks to the Eclipse due to the "increased frequency of migration in the *caudal* direction with the G2 and G2X as compared to the Recovery." Doc. 10874-5 at 2 (emphasis added). Although the document noted generally the need for a long-term filter that "[s]tays in the deployed location without migrating cranially or caudally," the addition of caudal anchors was meant to "[r]educe caudal migrations [and] tilt, fracture, and penetration secondary to caudal migrations." *Id.* at 2-3. These documents simply do not show that cephalad

[1] Plaintiff cites one additional complaint of cephalad migration, but it is of a Recovery filter, not a G2, G2X, or Eclipse. *Id.* (No. 257249).

migration continued to be a significant problem after the Recovery.

After considering the evidence cited in Plaintiff's motion for reconsideration, the Court continues to conclude that Recovery filter cephalad migration deaths are only marginally relevant in this Eclipse filter case. The Court also continues to find that the limited relevancy of this evidence is substantially outweighed by the danger of unfair prejudice, and that the death evidence is therefore inadmissible under Rule 403.

B. Substantial Similarity.

In its previous order, the Court cited Georgia case law holding that "evidence of other incidents involving the product is admissible, and relevant to the issue[] of . . . punitive damages, provided there is a showing of substantial similarity." Doc. 10819 at 4 (quoting *Gen. Motors Corp. v. Moseley*, 447 S.E.2d 302, 306 (Ga. Ct. App. 1994)). Plaintiff's Eclipse filter did not migrate in a cephalad direction to her heart or any other organ. Rather, the filter fractured and one of its struts travelled to her lung. Because deaths by cephalad migration of Recovery filters are not substantially similar to Plaintiff's alleged injury from her Eclipse filter, the Court continues to conclude that they are not substantially similar for purposes of punitive damages.

Plaintiff argues in this section of her motion that the Recovery deaths are a "direct cause" of the design change to the G2, asserting that Defendants' efforts to address cephalad migration resulted in a poorly-tested widening of the G2 filter that in turn led to new complications that adversely affected Plaintiff. Doc. 10874-2 at 6. Even if this causal chain were to be accepted, it represents the marginal relevancy the Court recognized in its original order – limited relevancy the Court finds to be substantially outweighed by the danger of unfair prejudice.

C. Impact of Excluding Cephalad Migration Death Evidence.

Plaintiff asserts for the first time in her motion for reconsideration that cephalad migration death evidence cannot reasonably be extracted from the overall Recovery-filter complication evidence, and that eliminating the death evidence would hamstring her ability to prove that the Eclipse lacked the necessary design changes to make a safe and

non-defective filter. Doc. 10874 at 7-10. Plaintiff claims that there is no testimony regarding Defendants' cephalad migration investigation or root cause analysis that is independent of the deaths. *Id.* at 9. Defendants counter that Plaintiff's concerns are overblown, that the parties can work together to review and edit the death evidence as needed, and that Plaintiff has substantial non-death evidence at her disposal. Doc. 10899 at 9.

On this record, the Court cannot determine whether exclusion of all cephalad migration death references would seriously hinder Plaintiff's ability to prove her claims. The Court will address this issue in more detail at the final pretrial conference on **May 4, 2018**. If the Court finds that removing all references to cephalad migration deaths will seriously hinder Plaintiff's presentation of her claims, it will consider allowing some references. The purpose of allowing these references, however, will be to make key evidence understandable, not to allow Plaintiff to rely on the death evidence to support her claims. The purpose of considering this issue on May 4 is *not* to reconsider whether Plaintiff may make the cephalad migration deaths a component of her case – the Court's Rule 403 ruling stands. The purpose will be to consider whether some references to death must remain in the evidence in order for Plaintiff to effectively present evidence of Recovery filter complications, testing, and design.

At the final pretrial conference, Plaintiff may present up to **six key trial exhibits and three depositions** to illustrate how death references cannot be removed without seriously impairing her ability to prove her case. Plaintiff shall provide the selected evidence to Defendants by the close of business on **May 1, 2018**, and the parties shall confer in good faith before the final pretrial conference to identify areas of disagreement. The Court will rule on the admissibility of the exhibits and deposition testimony and, as necessary, draw lines for the parties to apply to other evidence.

IT IS ORDERED:

1. Plaintiff Doris Jones' motion for reconsideration (Doc. 10873) is **denied in part** as set forth above.

2. In light of the issue to be addressed at the final pretrial conference, the April 30 deadline for submitting deposition designations that include cephalad migration is extended to **May 7, 2018**.

Dated this 27th day of April, 2018.

David G. Campbell
United States District Judge

WO

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
Doris Jones, an individual, Plaintiff, v. C. R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation, Defendants.	No. CV-16-00782-PHX-DGC **ORDER**

The case brought by Plaintiff Doris Jones has been selected as one of several bellwether cases and is set for trial this month. The parties have filed various motions in limine ("MIL") in advance of trial. This order will rule on those motions.

I. Background.

In August 2010, before gastrointestinal surgery, Plaintiff was implanted with a Bard Eclipse filter due to recurrent deep vein thrombosis. Five years later, Plaintiff went to the emergency room with complaints of lightheadedness and arm pain. A chest scan revealed a fractured filter limb that had embolized in her right pulmonary artery. The filter was removed, but the fractured filter limb remains in place.

Plaintiff alleges that Bard filters are more dangerous than other IVC filters because they have higher risks of complications, including fracture. Plaintiff further alleges that Bard failed to warn physicians and patients about these higher risks. Plaintiff asserts various state law claims under Georgia law. The following claims remain for trial: design defect, failure to warn, and punitive damages. *See* Docs. 10404, 10732.

II. Discussion.

A. Plaintiff's MILs Nos. 1-3 (Other Medical Issues).

Plaintiff has filed three motions seeking to exclude evidence of purported unrelated medical issues under Rules 402 and 403: (1) her anemia, hypertension, and vitamin B12 deficiency, and her alleged failure to take prescribed medications for those conditions; (2) her use of nonsteroidal anti-inflammatory drugs ("NSAIDs") and failure to follow medical advice against the use of those drugs; and (3) her treatment from Dr. Colleen Taylor for gastric bleeding in March 2016. Docs. 10813-15. Plaintiff contends that this evidence is not relevant to any issue in this case, and that any probative value is substantially outweighed by the danger of unfair prejudice and juror confusion.

1. Anemia, Hypertension, B12 Deficiency, and Prescriptions.

When doctors discovered in April 2015 that Plaintiff's Eclipse filter had fractured, they also found that she was anemic, had a B12 deficiency, and suffered from hypertension. Doc. 10814 at 2. Dr. Kristen Nelson, an interventional radiologist, took charge of Plaintiff's care for the fractured filter, and Dr. David Chodos prescribed medications for Plaintiff's other conditions. *Id.* Plaintiff contends that evidence concerning those other conditions and her inability to obtain the prescriptions due to her limited access to healthcare is irrelevant and unfairly prejudicial. *Id.* at 2-3.

Defendants contend that Plaintiff's anemia is relevant to the issues of causation and damages, but make no such argument with respect her hypertension and B12 deficiency. Doc. 10905 at 1-2. The Court will **grant** the motion in limine on her hypertension and B12 deficiency. Defendants are precluded from presenting evidence or argument about Plaintiff's hypertension and B12 deficiency and her alleged failure to

take prescribed medications for those conditions.

Evidence of Plaintiff's anemia is relevant to causation and damages. Under Georgia law, "evidence concerning a plaintiff's 'other' injuries may be admissible to show that the injuries currently at issue are not the result of the defendant's alleged negligence." *Lindsey v. Turner*, 631 S.E.2d 789, 791 (Ga. Ct. App. 2006) (citing *Wages v. Sibran, Inc.*, 318 S.E.2d 679, 680 (Ga. Ct. App. 1984)); *see Kilday v. Kennestone Physicians Ctr., L.P.*, 676 S.E.2d 271, 273 (Ga. Ct. App. 2009) (same). In this case, Plaintiff claims that her tiredness is related to the Eclipse filter fragment lodged in her pulmonary artery. Doc. 10900-1 at 3. But Dr. Chodos has testified that one of the primary symptoms of anemia is fatigue (Doc. 10905-4 at 3), and Plaintiff complained of fatigue even before she received the filter implant (Doc. 10902-2 at 2). Given this evidence, Plaintiff's anemia is relevant to whether the filter fragment is a proximate cause of her fatigue, and the amount of any damages award based on fatigue. The Court will **deny** the motion in limine with respect to evidence of Plaintiff's anemia. *See Lindsey*, 631 S.E.2d at 791; *Levine v. Choi*, 522 S.E.2d 673, 674 (Ga. Ct. App. 1999) ("Evidence that plaintiff's injuries were pre-existing is sufficient for a jury to find the accident did not proximately cause the injuries."); *Blosfield v. Hall*, 511 S.E.2d 196, 197-99 (Ga. Ct. App. 1999) (affirming judgment for the defendant on a negligence claim where he presented evidence that the plaintiff's injuries were not caused by the accident).

Defendants also assert that evidence of Plaintiff's failure to take prescribed medication for her anemia is relevant to causation. Doc. 10905 at 3. The Court agrees, but, as noted below, will allow evidence of Plaintiff's inability to pay for the medication if Defendants pursue this line of defense.

On a related matter, Defendants do not assert a comparative negligence defense. Docs. 10930, 10932; *see* Ga. Code. Ann. § 51-12-33(a); Ga. Pattern Jury Instruction § 60.141. Defendants do request a jury instruction on the duty to mitigate damages, but they do not raise this as a disputed issue in the proposed pretrial order. Docs. 10930-4 at 13, 10932 at 12-13. The parties should be prepared at the final pretrial conference to

discuss whether failure to mitigate damages will be asserted in this case.

2. Use of NSAIDs and March 2016 Treatment from Dr. Taylor.

Plaintiff suffers from migraine headaches. Doc. 10813 at 2. Against the advice of her doctors, she treats the headaches with NSAIDs such as Ibuprophen and "Goody's" headache powder. *Id.* Plaintiff also suffers from ulcers and gastric bleeding, and the use of NSAIDs exacerbates this condition. *Id.* In March 2016, Plaintiff was treated by Dr. Taylor for gastric bleeding that was caused in part by her use of NSAIDs. *Id.*; Doc. 10815 at 2.

Various medical records and physician testimony designated by Defendants, including testimony from Dr. Taylor, concerns Plaintiff's failure to follow medical advice with respect to the use of NSAIDs. Plaintiff contends that there is no evidence that taking NSAIDs impacted the Eclipse filter or the fragment that remains in her pulmonary artery, and that her use of the drugs is not related to any of her claims or injuries. Doc. 10813 at 2-3. Plaintiff claims that Defendants seek to present the evidence in an attempt to portray her as irresponsible and somehow at fault for her condition. *Id.*; *see* Doc. 10815 at 3.

Defendants counter that Plaintiff's medical conditions are interrelated and she placed the conditions at issue when she filed suit. Doc. 10902 at 1-2. Defendants claim that the gastric bleeding caused by Plaintiff's use of NSAIDs is one of the reasons she cannot take anticoagulants, thereby increasing the risk of future clotting. Doc. 10908 at 2. Defendants claim that they should be allowed to cross-examine Plaintiff's expert witnesses about whether she can take anticoagulants if she stops using NSAIDs, and that it is for the jury to decide whether her use of the drugs contributed to her current condition. *Id.* at 3; 10902 at 3.

As noted above, however, Defendants do not assert the defense of comparative negligence. Thus, whether Plaintiff contributed to her need for the filter is not relevant. And Plaintiff has made clear that her injuries related to the filter do not include her gastrointestinal problems or any of the symptoms for which she obtained treatment from

Dr. Taylor. Doc. 10815 at 2. Given this position, it is irrelevant whether Plaintiff failed to mitigate those conditions.

The motions in limine (Docs. 10813, 10815) are **granted**. Defendants are precluded from presenting evidence or argument about Plaintiff's use of NSAIDs and any testimony from Dr. Taylor regarding the same.[1]

B. Plaintiff's MIL No. 4 (Tobacco Use).

Plaintiff seeks to exclude evidence that she smokes cigarettes. Doc. 10816. Plaintiff admits to smoking about a half-pack a day for the past 20-30 years, but claims that evidence of this habit is irrelevant and carries the risk of unfair prejudice. *Id.* at 1-3; Doc. 10905-2 at 2. Defendants argue that the jury should be entitled to consider whether smoking is a cause of Plaintiff's shortness of breath. Doc. 10911 at 2. Defendants further argue that they should be allowed to cross-examine Plaintiff's experts on whether smoking is an independent risk factor for pulmonary embolism, and whether smoking was accounted for in determining Plaintiff's normal life expectancy. *Id.* at 2-3. The Court agrees with Defendants in part.

Plaintiff claims her shortness of breath is related to the Eclipse filter fragment in her pulmonary artery. Doc. 10909-1 at 3. But Dr. Taylor prescribed an Albuterol bronchodilator inhaler for Plaintiff's shortness of breath in part because of her "long history of smoking." Doc. 10911-2 at 3-4. This evidence is directly relevant to Plaintiff's claim that the filter fragment is the cause of her shortness of breath.

Plaintiff contends that Defendants should be barred from presenting evidence that she smokes because they have no expert to opine that smoking has caused any of her symptoms. Doc. 10816 at 3. Under Georgia law, issues of causation generally "are for the jury to resolve . . . except in plain and undisputed cases." *Ogletree v. Navistar Int'l Transp. Corp.*, 535 S.E.2d 545, 548 (Ga. Ct. App. 2000). Expert testimony is required

---

[1] Plaintiffs contend that any failure on her part to seek follow-up care from Dr. Taylor's treatment is irrelevant. Doc. 10815 at 3. This issue is moot because Defendants do not intend to present Dr. Taylor's testimony on this topic. Doc. 10908 at 1 n.1.

to establish causation only where medical questions are involved and the causal link "cannot be determined from common knowledge and experience." *Nixon v. Pierce Cty. Sch. Dist.*, 746 S.E.2d 225, 228 (Ga. Ct. App. 2013) (citation omitted).

It is common knowledge that long-term smoking can cause shortness of breath and shorten a person's life expectancy. *See FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 138 (2000) (finding that "the adverse health consequences of tobacco use [are] well known," including that "cigarette smoking causes . . . chronic bronchitis and emphysema"); *Spain v. Brown & Williamson Tobacco Corp.*, 363 F.3d 1183, 1194 (11th Cir. 2004) (ordinary consumers "with access to knowledge common to the community, could not be unaware of the dangers of smoking"); *Guilbeault v. R.J. Reynolds Tobacco Co.*, 84 F. Supp. 2d 263, 273 (D.R.I. 2000) (taking judicial notice of "the community's common knowledge of the general disease-related health risks of smoking"); *Johnson v. Brown & Williamson Tobacco Corp.*, 122 F. Supp. 2d 194, 204 (D. Mass. 2000) ("[T]his Court is firmly convinced that the risks of smoking were quite clear to the population at large before 1969."); *Paugh v. R.J. Reynolds Tobacco Co.*, 834 F. Supp. 228, 231 (N.D. Ohio 1993) ("[T]he risks of smoking are an inherent characteristic of cigarettes, and . . . knowledge of these risks has been common to the community since well before 1966.").

The same cannot be said, however, with respect to pulmonary embolism. Defendants cite a medical article published in late 2013 for the proposition that smoking is a risk factor for pulmonary embolism, but the article makes clear that this theory "remains controversial."[2] Defendants have not shown that the causal link between smoking and pulmonary embolism can be "determined from common knowledge and experience." *Nixon*, 746 S.E.2d at 228. Nor have Defendants identified an expert who will testify to this causal link.

The motion in limine (Doc. 10816) is **granted in part and denied in part**. Defendants will not be permitted to present evidence or cross-examine Plaintiff's experts

[2] *See Current and Former Smoking and Risk for Venous Thromboembolism: A Systematic Review and Meta-Analysis*, http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001515 (last visited May 2, 2018).

on whether smoking contributes to the risk for pulmonary embolism. Defendants may, however, present evidence to show that smoking is a cause of Plaintiff's shortness of breath. Defendants also may cross-examine Plaintiff's experts on whether smoking was accounted for in determining her life expectancy.

Plaintiff's reliance on *Seymour Electric & Air Conditioning Service, Inc. v. Statom*, 710 S.E.2d 874 (Ga. Ct. App. 2011), is misplaced. That case involved the potential exposure to carbon monoxide from a negligently installed furnace. The plaintiffs "failed to come forward with any evidence that a physician ever tested them for carbon monoxide poisoning or diagnosed them as having that condition." 710 S.E.2d at 877. In this case, by contrast, Plaintiff admits to a long-term smoking habit. A jury reasonably could find, without the need for expert testimony, that smoking contributes to her shortness of breath and may shorten her life expectancy.

Plaintiff notes that other courts have excluded evidence of smoking under Rule 403. Doc. 10816 at 2-3. Those cases are inapposite. *See Nolte v. AbbVie, Inc.*, No. 14 C 1748, 2018 U.S. Dist. LEXIS 2547, at *205-06 (N.D. Ill. Jan. 6, 2018) (finding that the evidence had limited probative value where the doctor did not address whether it was significant that the plaintiff had quit smoking three years prior to his pulmonary embolism); *Allegro Ventures, Inc. v. Almquist*, No. 11-cv-2009-L (WVG), 2014 WL 1871628, at *4 (S.D. Cal. May 8, 2014) ("[I]t is clear that evidence of Almquist's smoking and drinking do not bear on the threshold issue of Almquist's status as an employee or as a seaman."); *In re Prempro Prods. Liab. Litig.*, No. 4:03CV1507-WRW, 2006 WL 3806391, at *4 (E.D. Ark. Dec. 27, 2006) (issuing summary ruling excluding evidence of smoking unless the defendant could show "heavier evidence than they presented during the hearing").

C. Plaintiff's MIL No. 5 (Other Bard Filter Implants).

Two Bard employees testified in the Booker trial that their relatives had received Bard filter implants. Doc. 10817 at 2. Plaintiff seeks to exclude similar testimony in her case as irrelevant and otherwise inadmissible under Rule 403. *Id.* Defendants counter

that such evidence is highly relevant to the claims in this case, particularly punitive damages, and that the evidence is necessary to rebut any attacks by Plaintiff on the credibility of Bard witnesses. Doc. 10896 at 2-3.

The Court generally agrees with Plaintiff that any probative value of this evidence is outweighed by the dangers set forth in Rule 403, at least to the extent that a Bard witness offers gratuitous testimony that a relative received a Bard filter implant. *See* Doc. 10567 at 108. But such testimony may be appropriate if the line of questioning suggests that the Bard witness viewed adverse event data only in terms of "numbers" and "rates" rather than "people with names." Doc. 10584 at 80-81.

The motion in limine (Doc. 10817) is **granted**. Defendants shall not elicit testimony on direct examination that Bard employees or their relatives have received Bard filter implants. If Defendants believe such testimony becomes appropriate during trial, they can raise that issue with the Court outside the hearing of the jury.[3]

D. Plaintiff's MIL No. 6 (Experts Retained in Other Litigation).

In the Booker trial, counsel for Defendants asked Dr. Robert McMeeking whether he was retained in the Cook IVC filter litigation by some of the same attorneys that had retained him in this litigation. He answered, "Yes, some of them are the same attorneys." Doc. 10818 at 1-2.

Plaintiff seeks to exclude similar testimony in her trial, claiming that the "implicit message is that Plaintiff's attorneys are driving the litigation, hiring experts to sue multiple manufacturers in lawsuits all over the country." *Id.* at 2. The Court does not agree. As Plaintiff concedes, it is entirely appropriate to ask an expert how many times he has been retained by the same attorneys. *Id.* at 3; *see* Doc. 10895 at 2-3 (citing cases).

---

[3] In the Booker trial, the Court sought to strike a balance by allowing some evidence regarding the nature of Bard's business and the conscientiousness of Bard employees without having the case tried on the basis of specific employee conduct. Doc. 10075 at 3-4. The Court excluded a photograph of a Bard employee flipping off the camera and the "better stay away from the buffet line" comment by a Bard executive. The Court found this evidence unfairly prejudicial to Bard and not highly probative to any issue in the case. Similarly, evidence that relatives of Bard employees have received Bard filters has, at most, only marginal relevancy and may prove unfairly prejudicial to Plaintiff.

Plaintiff states that none of her attorneys were involved in actually preparing Dr. McMeeking for his testimony in the Cook litigation, but he did not testify that the attorneys did so. To the extent Plaintiff believes that any testimony by Dr. McMeeking on this point is not entirely accurate or complete, she may clarify matters on re-direct. The motion in limine (Doc. 10818) is **denied**.

E. Plaintiff's MIL No. 7 (Attorney Advertising).

In the Booker trial, the parties stipulated to the exclusion of evidence regarding contingency fee agreements, Plaintiff's counsel specializing in personal injury and products liability litigation, and advertising by Plaintiff's counsel or any counsel nationally for IVC filter cases. Doc. 10235 at 2. Defendants have refused to enter into a similar stipulation in this case, contending that the growing trend in product liability litigation is to admit evidence of attorney advertising where it is probative of credibility regarding the plaintiff's injuries. Doc. 10914 at 2-3. Defendants, however, provide no basis for the admission of evidence regarding (1) contingency fee agreements or (2) Plaintiff's counsel specializing in personal injury and products liability litigation. The motion in limine (Doc. 10811) will be **granted** on these two subjects.

Defendants claim that the testimony of Plaintiff's husband about how he first contacted counsel is relevant to whether Plaintiff filed suit because of symptoms she was experiencing with her Eclipse filter or in response to attorney advertising. *Id.* The Court does not agree. In response to a question about why he decided to file suit, Mr. Jones explained as follows:

> I never decided to file. I was worried about my wife's health being she had this strut stuck in her and was told that the procedure was supposed to be a permanent procedure. But then that happened, it broke, and she had to go back under and have it removed. And I just was just looking for some answers. . . . I was looking on Facebook and a little pop-up – and when it popped up, that's what took my mind back to thinking about my wife more so. And I was wondering if I could get further any information about filters, not looking to go as far as suing.

Doc. 10811-2 at 4-5. This testimony has, at most, only marginal relevancy to Plaintiff's

claimed injuries. The testimony does not show that Plaintiff and her husband were prompted by attorney advertising to file suit. To the contrary, Mr. Jones testified that he was not looking to sue. *Id.* at 5. Moreover, any probative value of the evidence is substantially outweighed by the danger of unfair prejudice and juror confusion. The motion in limine will be **granted** with respect to evidence that Plaintiff did not report complaints about her Eclipse filter and the fractured strut until after her husband saw information about IVC filters on Facebook.

Defendants contend that evidence of an attorney advertising website, www.filterlaw.com, is necessary to refute Plaintiff's evidence that the change in brand name to Eclipse was to create a "break with the baggage" associated with the G2 line of filters. Doc. 10914 at 3-4. Defendants assert that the "baggage" Bard was referring to was the filter law website. *Id.* at 4 (citing 10914-2 at 3). The Court will defer ruling on this issue until trial. If Plaintiff presents the "break with baggage" evidence at trial and Defendants believe that evidence of the filter law website is relevant, they may raise that issue with the Court outside the hearing of the jury.

F. Defendants' MIL No. 1 (Financial Information).

Defendants seek to exclude evidence of Plaintiff's financial status, including her inability to pay for medical expenses or obtain medical care. Doc. 10808. Defendants contend that such evidence is irrelevant and highly prejudicial because it may garner sympathy from the jury. *Id.* at 2. Plaintiff counters that Defendants have chosen to make this a material issue by seeking to present evidence that Plaintiff failed to take medications and otherwise follow-up on her medical care. Doc. 10916 at 2.

As explained above, the Court finds that evidence of Plaintiff's failure to take prescribed medication for her anemia is relevant to causation. To the extend Defendants argue that this failure has caused her shortness of breath, the Court will allow evidence of Plaintiff's inability to pay for the medication. The Court otherwise finds evidence of Plaintiff's financial status to be irrelevant and potentially prejudicial.

/ / /

G. Defendants' MIL No. 2 (Other Lawsuits).

In the Booker trial, the parties stipulated to the exclusion of evidence of other lawsuits against Defendants. Doc. 10235 at 2. Plaintiffs contend that the other lawsuits will be material in this case if Defendants are allowed to offer evidence that Plaintiff filed suit in response to attorney advertising. Doc. 10915 at 2. The Court has excluded this evidence for reasons set forth above. Defendants' motion in limine (Doc. 10809) is therefore **granted**.

Dated this 3rd day of May, 2018.

David G. Campbell
United States District Judge

WO

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
Doris Jones, an individual, Plaintiff, v. C. R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation, Defendants.	No. CV-16-00782-PHX-DGC **ORDER**

The Court has entered two previous orders finding that evidence of deaths caused by cephalad migration of Recovery filters is marginally relevant to this case, and that the limited relevance is substantially outweighed by the danger of unfair prejudice. Docs. 10819, 10920. As a result, the Court has concluded that the death evidence is inadmissible under Rule 403.

In the second order, which ruled on a motion for reconsideration filed by Plaintiff, the Court addressed a new argument: that cephalad migration death evidence cannot reasonably be extracted from the overall Recovery filter complication evidence, and that eliminating the death evidence would hamstring Plaintiff's ability to prove that the

Eclipse filter lacked the design changes necessary to make it a safe filter. Doc. 10920 at 5. Because the Court could not resolve that issue on the existing record, the Court instructed the parties to address it more fully at the final pretrial conference on May 4, 2018. *Id*. at 6. Plaintiff's counsel presented six exhibits and three deposition excerpts at the conference, and argued extensively. Defense counsel presented four of the same exhibits with death evidence redacted, and also argued.

A. General Observations.

The Court previously held that evidence regarding the complications, testing, and design of the Recovery filter are relevant to Plaintiff's claims in this case. Docs. 10819, 10920. As the Court explained:

> Those events help explain the testing, development, and design of the G2, and Plaintiff contends that the G2 was essentially the filter she received. The history of the Recovery and how it led to the G2 tends to make a fact in dispute – the allegedly defective design of the Eclipse – more probable.

Doc. 10819 at 2 (citing Fed. R. Evid. 401).

The Court also concluded, however, that evidence of deaths from cephalad migration was only marginally relevant. This is because cephalad migration did not continue in any significant degree beyond the Recovery filter; cephalad migration deaths all occurred before the Recovery filter was taken off the market in late 2005; the deaths say nothing about three of Ms. Jones' four claims in this case: strict liability design defect, strict liability failure to warn, or negligent failure to warn; although the evidence may add some weight to her fourth claim – negligent design – it is not central to proof of design negligence; and instances of cephalad migration resulting in death are not substantially similar to complications experienced by Ms. Jones and therefore do not meet the Georgia standard for evidence on punitive damages. *Id.* at 3-4. Given the limited relevancy of the cephalad migration death evidence, the Court found that its probative value was substantially outweighed by the danger of unfair prejudice and therefore was inadmissible under Rule 403. *Id.* at 5-6.

When the Court agreed to hear more of Plaintiff's arguments regarding the

difficulty of excising death evidence from other relevant evidence, it specifically advised the parties that this would not be another opportunity to argue the Rule 403 ruling:

> The purpose of considering this issue on May 4 is *not* to reconsider whether Plaintiff may make the cephalad migration deaths a component of her case – the Court's Rule 403 ruling stands. The purpose will be to consider whether some references to death must remain in the evidence in order for Plaintiff to effectively present evidence of Recovery filter complications, testing, and design.

Doc. 10920 at 6 (emphasis in original). At the final pretrial conference, Plaintiff's counsel nonetheless felt compelled to argue again that the cephalad death evidence is relevant to her claims. The Court will address briefly some of the arguments made.

Plaintiff's counsel argued that the 2004-2005 cephalad migration deaths show that the Recovery filter was not performing as advertised, that is was adulterated and misbranded, that it was therefore being marketed illegally, and that Defendants should have removed it from the market. If the Recovery filter was removed from the market, Plaintiff argues, it could not have served for the predicate device for the G2 filter, and, without the G2, Plaintiff's Eclipse filter never would have been sold by Defendants.

But this case does not include a claim that Defendants negligently failed to recall the Recovery filter. It includes claims that the Eclipse filter was defectively designed and that Defendants failed to warn about the risks of the Eclipse filter. The Court can see no clear connection between the design of and warnings about the Eclipse filter in 2010, and Defendants' alleged failure to remove the Recovery filter from the market in 2004 and 2005. Plaintiff may have an attenuated "but for" argument – that but for Defendants' failure to remove the Recovery filter from the market, the G2 and G2X never would have been marketed, and the Eclipse never would have been available to hurt her – but such a domino-like causal link does not help prove that the Eclipse was designed defectively or that Defendants' 2010 warnings about the Eclipse were inadequate. Thus, the Court cannot conclude that Plaintiff should be permitted to present evidence of Recovery filter cephalad migration deaths in order to convince the jury that Defendants should have

removed the Recovery filter from the market years before Plaintiff received her later-generation filter.

Plaintiff's counsel argued that the medical community should have been warned about the cephalad migration deaths – that Defendants should have described the deaths in the Instruction for Use (IFU) that accompany each Bard IVC filter. Plaintiff's counsel further argued that such a warning should have carried forward into the G2 and Eclipse filters. But as noted in the Court's two prior orders, cephalad migration deaths stopped with the Recovery and did not recur in the G2-line of filters. Docs. 10819 at 3, 10920 at 3. Thus, even if Plaintiff could credibly argue that users of the Recovery filter should have been warned of cephalad migration deaths, that argument has no relevancy with respect a later-generation filter that was not causing cephalad migration or such deaths. Plaintiff cannot plausibly claim that the jury should find Defendants liable to her for failure to warn of deaths that occurred five years earlier, from a filter she did not receive, and by a means of migration she did not experience.

Plaintiff's counsel argued that Defendants' failure to warn Recovery users about the cephalad migration deaths – and failure to warn G2-line users about the Recovery deaths – is a basis for punitive damages. The Court might agree if cephalad migration deaths continued with the G2-line of filters, but they did not. The Court cannot conclude that Defendants should be punished for their sale of an Eclipse filter to Plaintiff because they failed to warn Recovery patients about cephalad migration deaths five years earlier. Nor can the Court conclude that Recovery cephalad migration deaths are "substantially similar" to Plaintiff's injury from embolization of an Eclipse filter fragment, as required by Georgia law with respect to punitive damages. *See Gen. Motors Corp. v. Moseley*, 447 S.E.2d 302, 306 (Ga. Ct. App. 1994).

Plaintiff's counsel argued that they should be able to show the jury "[h]ow incredibly unreasonable it was that they put out another device only having done bench testing, less bench testing and less animal testing than they did with the Recovery filter[.]" Court's Livenote Transcript, 5-4-18. But the Court's ruling does not prevent

Plaintiff from making this showing. The Court's exclusion of cephalad migration death evidence does not limit her ability to show what testing was done or not done on the G2 filter.

Plaintiff's counsel argued that Defendants will assert at trial that IVC filters save lives, and "we're not going to be able to establish that these things could actually cause people to lose their lives." *Id.* Not so. The Court has not ruled that Plaintiff is precluded from asserting that filter migration, tilt, fracture, and perforation can cause serious health effects including death. The Court has not barred Plaintiff from asking her experts what consequences could arise from the complications seen in the G2-line of filters. The Court has held only that Plaintiff cannot present evidence of Recovery filter deaths caused by a complication that did not continue in the G2-line.

Plaintiff's counsel argued that evidence of the cephalad migration deaths shows that Defendants "overreacted" to the deaths and hastily placed a faulty G2 filter on the market. If Plaintiff's argument is that cephalad migration of the Recovery filter caused Defendants to widen the filter's diameter in order to prevent cephalad migration, they can make that showing with the evidence of cephalad migration discussed below. If Plaintiff's argument is that patient deaths caused the company to overreact and seek to correct the problem too quickly, it is hard to see how that argument supports Plaintiff's claim that this was a callous and indifferent company that did not care about patient health.

The Court previously acknowledged that the fact of the deaths could be viewed as making Defendants' conduct in creating the G2 look more negligent:

> The cephalad migration deaths arguably are more relevant to Ms. Jones' negligent design defect claim because they help show the extent to which Defendants allegedly failed to exercise reasonable care in designing and testing the G2 filter. But the things Defendants allegedly failed to do in developing the G2 – perform a viable root cause analysis, test adequately, follow established design principles – can all be shown through Plaintiff's experts and without mention of the cephalad migration deaths. The deaths arguably could make these failures appear even more negligent because Defendants were aware of severe consequences from the Recovery's

> design, but they do not prove the negligence. Evidence of the deaths remains marginal – it adds some weight to Plaintiff's negligence claim, but it is not central to proof of design negligence.

Doc. 10819 at 3-4. The Court found that this marginal benefit was substantially outweighed by the risk of unfair prejudice. *Id.* at 5-6.

What is more, the thrust of Plaintiff's claim, as was apparent in the Booker trial, is that Defendants learned of a variety of new complications with the G2 – established by the Everest study and other events – and yet continued to market the G2 and its later iterations without correcting those new complications. Indeed, Plaintiff claims that these are the complications that caused her injuries, not cephalad migration.

At the end of the day, Plaintiff's counsel seems to be asserting that elimination of the death evidence will impair Plaintiff's ability to present the death evidence. Of course it will. That is the purpose of the Court's ruling. The relevant question is whether elimination of the death evidence will impair Plaintiff's ability to prove the Recovery filter's complications as part of explaining how the G2-line of filters came into existence with the defects that allegedly injured Plaintiff. As explained below, the Court concludes that elimination of the cephalad migration death evidence will not seriously impair Plaintiff's ability to prove Recovery filter complications.

B. Specific Evidence.

The Court will address each of the exhibits and deposition excerpts presented by Plaintiff at the final pretrial conference.

1. Exhibit 280.

This is a June 16, 2005 memorandum written between Defendants' employees. The subject is "IVC Recovery Filter Adverse Events (Migration/Fractures) – Executive Summary." The memo explains that it contains an adverse event summary of Recovery filter migrations and fractures through June 14, 2005. Although the memorandum does mention deaths, each of those references could be eliminated from the memorandum without detracting from the following points: (a) 43 filter migrations in excess of two

centimeters have been reported; (b) 25 of these cases included a filter encased in a large thrombi; (c) in 9 of the cases, the presence of blood clots was unknown; and (d) 12 of the cases involved migration to the heart. Further, a chart at the bottom of the memo indicates that the Recovery filter has a migration rate of 0.099%, which is higher than any of the seven other IVC filters included in the chart, and much higher than Defendants' own Simon Nitinol filter (0.003%).

Thus, with all of the references to deaths redacted, this memo shows that Recovery filters were migrating at a rate higher than any other filter considered, and considerably higher than Defendants' previous version, and in 12 instances the filter had migrated to the heart. It permits Plaintiff to make her point of high rates of Recovery migration.

2. Exhibit 1014.

This is a June 11, 2004 Remedial Action Plan ("RAP") for the "Recovery Filter – Migration." It is reviewed and approved by numerous Bard executives. With all death evidence omitted, this document still enables Plaintiff to make the following points: (a) on April 14, 2004, Defendants received a message than an IVC filter had migrated;[1] (b) as of that date, there had been six previous instances of filters migrating more than two centimeters (with the six instances described); (c) as a result of this report, the Recovery filter was placed on hold pending the completion of the RAP; (d) "There were no design or manufacturing defects found to be associated with the filter";[2] (e) a comparison between the Recovery and all other IVC filters will be completed to ensure that adverse events associated with the Recovery are not occurring with excess frequency; (f) the product was removed from hold status; (g) "There has been no device design or manufacturing problem that was identified"; and (h) no field action is recommended.

Redactions would eliminate the fact that the April 2004 event was a patient death,

---

[1] The Court will permit the memo to include the following language at the end of part III.a: "an IVC filter that migrated. (Complaint Report #5922, attached)."

[2] Plaintiff's counsel emphasized the importance of this sentence during argument.

but it would not change any of the other information about Recovery filter complications – that there had been six previous migrations, the product had been placed on hold, a comparison of filter failure rates would be completed, and, as Plaintiff emphasized, there were no design or manufacturing defects found to be associated with the filter.

3. Exhibit 1020.

This is an internal failure investigation "to determine the cause of the filter migration reported on August 23, 2004." All of the following information would be available if death references were removed from this exhibit: There had been approximately 17,400 Recovery filters distributed. On August 23, 2004, Defendants became aware that a Recovery filter had migrated more than two centimeters in a patient. As of October 12, 2004, there had been 20 instances of filter migration more than two centimeters. As a result, Defendants considered updating the Recovery IFU "with enhanced language regarding filter migrations," and distributing a "Dear Doctor" letter highlighting changes to the IFU. No other remedial action was recommended.

The only essential facts removed through redaction would be that the incident that prompted this investigation was a patient death. Eliminating references to the death will not eliminate any information about the fact that the filter migrated and that there had been 20 instances of filter migration of more than two centimeters. Nor would it change the fact that Defendants considered changing the IFU and contacting doctors, but otherwise recommended no action.

4. Exhibit 1022.

With death evidence redacted, this exhibit includes the following information: This was another failure investigation to determine the cause of a Recovery filter migration reported on December 7, 2004. As of early 2004, there had been approximately 22,471 Recovery filters distributed. In this case, the Recovery filter was found in the patient's right ventricle.[3] From April 2003 to January 20, 2004, there had

[3] The only language the Court requires to be redacted from paragraph 5.1 is the following: "[Redacted] reported that on [redacted] 2004, the patient on the neurological service collapsed and died in the hospital. An autopsy was performed and . . . ".

been 28 instances of Recovery filter migrations in excess of two centimeters. There was insufficient data to determine the root cause of this failure, and no corrective actions were recommended.

Again, the essential information contained in this document remains after redaction of the death evidence – a Recovery filter migrated more than two centimeters, there had been 28 such migrations by this point in time, and no further remedial action was recommended.

5. Exhibit 10322.

This is a December 17, 2004 Health Hazard Evaluation. With all death evidence redacted, this document would demonstrate the following: "An analysis of reporting rates of serious adverse events for all inferior vena cava filters, as determined by analysis of the MAUDE and IMS databases by a consultant, revealed that reporting rates for Recovery are significantly higher than other filters." This warrants further investigation. The frequency of serious injury is 0.153% and the frequency of non-serious injury is 0.21%. "Reports of . . . filter migration (movement), IVC perforation, and filter fracture associated with the Recovery filter were seen in the MAUDE database at reporting rates that were 4.6, 4.4, 4.1, and 5.3 higher, respectively, than reporting rates of all other filters. These differences were all statistically significant. Recovery's reporting rates for all adverse events, filter fracture, filter migration, . . . were found to be significantly higher than those for other removable filters." "These reported adverse event rates were analyzed in conjunction with a bench test performed at BPV. This test measured 'migration resistance' in a simulated IVC. Recovery had the lowest mean migration resistance (50mm Hg), just below that of the removable Tulip filter (55mm Hg)." "Little formal analysis had been completed with respect to potential clinical trials to obtain more definitive risk/benefit information." For the Recovery filter, "there were a total of 32 reported serious injuries, a reporting rate of 0.153%." The total adverse event reporting rate for the Recovery filter, including migration, fractures, and perforation, was 0.365% with a serious injury of 0.153%. "From the analysis of the MAUDE and IMS databases,

Recovery reporting rates are significantly higher than those of other filters." There appears to be a "significant correlation" of the "migration reporting rates with the simulated migration resistance bench test."

Even with death evidence redacted, this document proves the point the Court has deemed relevant – that the Recovery filter was experiencing complication rates higher than that of other filters. Indeed, this is the basis upon which Plaintiff claims that Defendants undertook to create the G2 in a hasty and poorly-tested manner.

6. Exhibit 2243.

This is an email exchange. The first email, dated April 23, 2004, suggests that the data being evaluated was based on deaths. The actual statistical analysis is contained in an email dated May 20, 2004. Natalie Wong concludes that: "[a]t a 95% confidence, there IS a significant difference between Recovery and Gunther Tulip, Birdsnest filter, and SNF." Thus, without any reference to death evidence, this document demonstrates that the Recovery had a statistically higher complication rate than Defendants' previous device, the Simon Nitinol filter.

7. Ganser Deposition.

The Court has reviewed each of the Plaintiff's excerpts in this deposition (highlighted in yellow) in light of the death references that would be redacted (highlighted in green). Many of the death references are in the question, not the answer, and the answer does not encompass the death reference. *See* pages 41, 130, 223, 254, and 296. Other questions and answers continue to convey the essence of the testimony without the death reference. *See* pages 95 (Bard did not share complaint files), 223 (the hold on recovery filters was removed in 2004), and 267 (many of the migration complaints included a large clot burden overwhelming the filter). Some questions and answers would be altered by elimination of the death reference, but the relevancy of the questions and answers is doubtful. *See* 133 (Defendants elected to continue the Recovery – this seems to be related to Plaintiff's "but for" recall argument), 237-238 (customers would want to know if a product was causing serious injury and death – this fact about

patients using the Recovery filter seems irrelevant to patients using the Eclipse filter that did not cause cephalad migration deaths), 244 (although it is not entirely clear, this exchange seems to be the witness describing what he is reading in Exhibit 2243 discussed above, which is not essential to understanding the central point of 2243). Finally, one series of questions and answers concern Natalie Wong's calculations based on death evidence as noted above with respect to Exhibit 2243, but the Court concludes that the death evidence is not essential to understanding the more relevant point that the Recovery had higher complication rates than the SNF and other filters.

Thus, the Court concludes that references to death evidence can be redacted from the Ganser deposition without significantly detracting from Plaintiff's ability to show Recovery complication rates. None of these references concern G2 testing or design.

8. Decant Deposition.

A number of the designated portions of this deposition simply present the death evidence the Court has concluded is inadmissible. *See* 268 (lines 14-17 and 21-24), 269 (lines 1-6), 272 (lines 5-14), 275 (lines 18-21), 312 (lines 9-15), 333 (lines 13, 21), 338 (lines 5-8), 349 (lines 2-5), 350 (lines 7-9), 361 (line 1). Other designations include only marginally relevant evidence. *See* 251, 255. And still other designations communicate the essence of the evidence even if the death reference is removed. *See* 252, 256, 264, 268 (lines 18-20), 269-70, 275 (lines 15-17), 316, 358-59.

9. Orms Deposition.

Some of the designated evidence in this deposition simply concerns death evidence the Court has found inadmissible. *See* 25. Other designations are of marginal relevance. *See* 29-30 (failure to warn related to the Recovery is not relevant to failure to warn related to the Eclipse), 41 (same). And, with respect to other designations, the essence of the evidence is communicated even if death references are omitted. *See* 45.

C. Conclusion.

Having reviewed each of the exhibits and deposition excerpts provided by Plaintiff, the Court concludes that Plaintiff will not be seriously hampered in her ability

to prove Recovery filter complications, testing, and design when references to cephalad migration deaths are removed. As a result, the Court holds that such references should be redacted from evidence to be presented at trial. Including such evidence that would violate Rule 403 in this Eclipse filter case. *See* Docs. 10819, 10920.

The parties shall provide the Court with additional deposition excerpts as soon as reasonable possibly. With trial only a week away, the Court will do its best to rule on the designations promptly.

Dated this 8th day of May, 2018.

David G. Campbell
United States District Judge

ATTYADD,LEAD,MULTI-DISTRICT,PROTO,REMAND,STD

U.S. District Court
DISTRICT OF ARIZONA (Phoenix Division)
CIVIL DOCKET FOR CASE #: 2:15-md-02641-DGC

IN RE: Bard IVC Filters Products Liability Litigation
Assigned to: Judge David G Campbell
Case in other court: Ninth Circuit, 16-16163
Cause: 28:1332 Diversity-Product Liability

Date Filed: 08/17/2015
Jury Demand: Both
Nature of Suit: 365 Personal Injury: Prod. Liability
Jurisdiction: Diversity

Date Filed	#	Docket Text
05/15/2018	11082	ORDER. At the close of trial today, Plaintiff's counsel again asked the Court to admit evidence of Recovery filter cephalad migration deaths. Plaintiff argued that Defendants' opening statement opened the door to such evidence. (1) Plaintiff noted that Defendants argued that IVC filters are life-saving devices. True, but the Court has not precluded Plaintiff from presenting evidence that IVC filter complications can also cause death. Indeed, Plaintiff's counsel stated in his opening statement that unacceptable risks of Bard filters can include death, severe injury, or permanent disability. The Court does not find that the "life-saving device" argument has opened the door to the cephalad migration death evidence the Court has excluded under Rule 403. (2) Plaintiff argued that Defendants emphasized the disclosures contained in the Eclipse filter IFU, including disclosure of the risk of death, and argued that the Recovery filter IFU should have described deaths from cephalad migration. When asked why Recovery filter warnings (or lack thereof) are relevant in this Eclipse filter failure-to-warn case, Plaintiff asserted that such information would have carried forward into the Eclipse IFU. The Court cannot conclude, however, that IFU warnings for the Eclipse filter should have included deaths caused by a different filter, four-generations and five-years earlier, through a method of migration that largely ended after the Recovery filter. Plaintiff's counsel stated that they have no expert, and can cite no regulation, that would require such warnings. The Court again concludes that the marginal relevancy of this evidence to the Eclipse failure-to-warn claim is substantially outweighed by the danger of unfair prejudice. (3) Defendants did assert in their opening statement that only 16 deaths have been caused by pulmonary emboli (PE) in patients with Bard IVC filters, and they did not limit this assertion to the Eclipse or G2 line of filters. This statistic was also included in a slide shown to the jury. When the Court asked defense counsel what witness would present these statistics to the jury, he said it would be either Mr. Modra or Mr. Carr. The Court is inclined to permit Plaintiff's counsel to cross-examine the witness on the basis for this calculation, including what deaths were included in the calculation and the fact that other deaths have been reported in Bard IVC filter patients, including deaths caused by filter migration. Certainly other filter-related deaths, even if not caused by a PE, are relevant to the risk-benefit analysis on which Defendants placed considerable emphasis in their opening. The Court will make a final decision on this issue after the direct examination of Mr. Modra or Mr. Carr. Plaintiff's counsel should raise this issue before mentioning

		it in front of the jury, and the Court will decide the proper scope of such cross-examination. Signed by Judge David G Campbell on 5-15-18. This is a TEXT ENTRY ONLY. There is no PDF document associated with this entry. (DGC) (Entered: 05/15/2018)

PACER Service Center			
Transaction Receipt			
07/17/2018 10:37:42			
PACER Login:	nmrs0003:4310666:0	**Client Code:**	000389/08373-mb13
Description:	Docket Report	**Search Criteria:**	2:15-md-02641-DGC Starting with document: 11082 Ending with document: 11082
Billable Pages:	2	**Cost:**	0.20

APPEAL,ATTYADD,LEAD,MULTI-DISTRICT,PROTO,REMAND,STD

U.S. District Court
DISTRICT OF ARIZONA (Phoenix Division)
CIVIL DOCKET FOR CASE #: 2:15-md-02641-DGC

IN RE: Bard IVC Filters Products Liability Litigation
Assigned to: Judge David G Campbell
Case in other court: Ninth Circuit, 16-16163
Ninth Circuit, 18-16349
Ninth Circuit, 18-16460
Ninth Circuit, 18-16461
Ninth Circuit, 18-17259
Cause: 28:1332 Diversity-Product Liability

Date Filed: 08/17/2015
Jury Demand: Both
Nature of Suit: 365 Personal Injury: Prod. Liability
Jurisdiction: Diversity

Date Filed	#	Docket Text
05/29/2018	11256	ORDER. After having heard argument on several issues today, the Court enters the following orders: (1) Plaintiff proposes to place four redacted monthly management reports in evidence (Exs. 4504, 4519, 4522, 4528), with filter-related complaints included. These four reports include 83 filter complaints and would greatly expand the 40 complaints the Court previously permitted. Doc. 11157. This number of complaints would raise the concerns addressed in the Schwartz case previously cited by the Court. See Doc. 11122. The Court concludes that one monthly management report, with filter-related complaints included, is sufficient to accomplish Plaintiff's objective of showing that complaints were communicated monthly to senior management. The Court will admit Ex. 4519, including its filter-related complaints, for this purpose. The Court will also admit the Rule 1006 summary of complaints received by Defendants (assuming Defendants have no objection to the chart). (2) The Court concludes that evidence and argument presented during the trial have made section 3 of the FDA warning letter relevant, and that its relevancy is not substantially outweighed by the danger of unfair prejudice. The Court will admit Ex. 1680 as redacted. (3) The Court has two observations concerning the continued arguments regarding Recovery filter cephalad migration deaths. (a) Plaintiff continues to argue that if the Recovery had been recalled there would have been no predicate for the G2 and, therefore, no Eclipse filter to injure her. In fact, today Plaintiff's counsel called this a "key" to the case. But as the Court has noted before, there is no claim in this case for negligent failure to recall the Recovery filter. The only claims are for design defects and failures to warn with respect to the Eclipse filter. Thus, even if it is true that there would have been no Eclipse filter had the Recovery been recalled, that fact does not prove any of Plaintiff's claims. Nor does it prove that design defects or failures to warn with respect to the Eclipse filter proximately caused Plaintiff's injury. The Court is concerned that Plaintiff's counsel will argue in

		closing that the jury should find in her favor because recall of the Recovery would have meant no Eclipse, when that fact has nothing to do with any of her four claims. Plaintiff should be prepared to address this tomorrow morning. (b) The Court has previously noted that Recovery filter problems are a relevant part of the overall filter history in this case, but has found the cephalad migration deaths only marginally relevant in light of the fact that the G2 line of filters largely eliminated this type of complication. However, Defendants presented testimony from Dr. DeFord that the Recovery filter saved many more lives than it put at risk. Given this evidence, why should Plaintiff not be permitted to present at least some evidence that the Recovery filter in fact caused several deaths? Defendants should be prepared to address this tomorrow morning. Signed by Judge David G Campbell on 5-29-18. This is a TEXT ENTRY ONLY. There is no PDF document associated with this entry. (DGC) (Entered: 05/29/2018)

WO

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**

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. This order will rule on Plaintiffs' MILs Nos. 4 and 5, which seek to exclude evidence regarding the Bard IVC filter's instructions for use ("IFU") and certain guidelines published by the Society of Interventional Radiologists ("SIR"). Docs. 12100, 12101.

I. Background.

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

fractured limbs were removed three months later.[1]

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

II. Discussion.

A. Parties' Arguments.

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

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

[1] The parties dispute whether Mrs. Hyde's filter was a G2X or an Eclipse, but the filter type has no bearing on these MILs.

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

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

B. Wisconsin's Product Liability Law.

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

---

[2] It is not clear under Wisconsin law whether Mrs. Hyde or the implanting physician was the "ultimate consumer" of the Bard filter for purposes of the design defect 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).

[3] 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.

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

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

See id. at 751.

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

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

Id.

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

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

> **(1) Liability of manufacturer.** 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 . . . is defective in design . . . . 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.

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

C. Analysis.

Plaintiffs rely on *Green* in arguing that the IFU and the SIR guidelines have no relevance to the design defect claim because "a product is not reasonably safe under Wisconsin law if it is 'in a condition not contemplated by the ultimate consumer.'" Doc. 12101 at 2 (quoting *Green*, 245 Wis. 2d at 825-26); *see* Doc. 12100 at 3. But *Green* was effectively overruled by the adoption of § 895.047, and the consumer contemplation test is now only one factor in determining whether the Bard filter was unsafe. The statute 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

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

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

---

[4] Plaintiffs note in their trial brief that comment g to § 2(b) provides that consumer expectations, while not dispositive, still play a role in determining defectiveness. Doc. 12400 at 10-11. A Wisconsin district court has expressed doubt whether this "is an 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).

[5] Defendants note that a comment to the Restatement provides that the instructions 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

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

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

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

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

---

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.

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

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

Dated this 4th day of September, 2018.

David G. Campbell
Senior United States District Judge

WO

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**

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]

[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.

I. Background.

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

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

II. Plaintiffs' Motions in Limine.

A. MIL 1 – FDA Evidence.

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

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

---

[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.

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

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

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

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

B. MIL 2 – Surgeon General's Call to Action.

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

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

d (1998) (noting that "[s]ubsection (b) adopts a reasonableness ('risk-utility balancing') test as the standard for judging the defectiveness of product design").[3]

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

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

Nor can the Court conclude that the report constitutes inadmissible hearsay. The report falls within the public records hearsay exception. Fed. R. Evid. 803(8). Plaintiffs' citation of *Philip Morris USA, Inc. v. Pollari*, 228 So. 3d 115, 123 (Fla. Dist. Ct. App. 2017), does not help their position. *Pollari* found that Surgeon General reports satisfy Federal Rule of Evidence 803(8)(A)(iii) as records of factual findings from authorized

---

[3] Plaintiffs contend that the Call to Action report has no relevance because Wisconsin law employs a "consumer contemplation" test for design defect claims, not a 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.

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

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

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

III. Defendants' Motions.

A. MIL 1 – Recovery Filter Cephalad Migration Deaths.

Defendants seek to exclude evidence of deaths caused by cephalad migration of Recovery filters. Doc. 12088. Plaintiffs contend that such evidence is relevant because excluding the deaths associated with the predicate Recovery filter that led to the G2's design would unduly prejudice Plaintiffs in proving the design defect claim. Doc. 12392 at 2. But this case does not involve a Recovery filter. Mrs. Hyde received a filter that was either a G2X or Eclipse, two or three generations after the Recovery filter. *See* Doc. 12157. She was implanted with the filter in early 2011, more than five years after cephalad migration deaths stopped when the Recovery was taken off the market in 2005. The cephalad migration deaths from the Recovery in 2004 and 2005 do not show that G2X or Eclipse filters – which did not cause cephalad migration deaths (*see* Doc. 10920) – had design defects when they left Defendants' control several years later. Nor do the

[4] Defendants state that they intend to introduce evidence of the falls only to rebut 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.

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

The Court will exclude evidence of Recovery filter cephalad migrations deaths under Rule 403, for the reasons it excluded the same evidence in the Jones trial. Docs. 10819, 10920, 11041.[5] The motion in limine (Doc. 12088) is **granted**.[6]

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

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

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

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

Defendants seek to exclude testimony from Dr. Muehrcke that he "personally felt betrayed" because Bard had not told physicians about information contained in Bard's

---

[5] *See In re Bard IVC Filters Prods. Liab. Litig.*, No. CV-16-00782-PHX-DGC, 2018 WL 2124146 (May 8, 2018), 2018 WL 1993767 (Apr. 27, 2018), *and* 2018 WL 1876896, at *2-4 (Apr. 18, 2018).

[6] Nothing in this ruling precludes Plaintiffs from presenting "crucial" evidence 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.

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

D. MIL 6 – Informed Consent.

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

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

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

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

Dated this 7th day of September, 2018.

David G. Campbell
Senior United States District Judge

WO

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
Debra and James Tinlin, a married couple, Plaintiffs, v. C. R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation, Defendants.	No. CV-16-00263-PHX-DGC **ORDER**

Plaintiffs move to exclude certain opinions of Dr. Morris and evidence that Ms. Tinlin's medical care was an intervening cause of injury. Docs. 15077, 16576. The motions are fully briefed. Docs. 15661, 16032, 16890. The parties request oral argument, but it will not aid the Court's decision. *See* Fed. R. Civ. P. 78(b); LRCiv 7.2(f). For reasons stated below, the Court will grant the motion to exclude Dr. Morris's opinions and grant in part and deny in part the motion in limine regarding medical care as an intervening cause of injury.

I. Background.

On May 7, 2005, Dr. Riebe implanted a Bard Recovery filter in Plaintiff Debra Tinlin's inferior vena cava ("IVC"). Ms. Tinlin had multiple chest scans after the implantation, including one taken by Dr. Haller on April 15, 2008.

Ms. Tinlin experienced cardiac tamponade on June 10, 2013. A chest scan showed evidence of two fractured Recovery struts in the right ventricle of her heart. Dr. Roitstein performed emergency surgery to drain a large pericardial effusion. The procedure – a subxiphoid pericardial window – involved removing a small piece of the heart sac and inserting a drainage tube through the incision.

On July 31, 2013, Dr. Kress removed a fractured strut through open heart surgery. A subsequent chest scan revealed multiple fractured struts in the pulmonary arteries. These struts and the filter have not been removed.

II. Motion to Exclude Dr. Morris's Opinions About Drs. Roitstein and Kress.

In his case-specific report, Dr. Morris opines that an interventional radiologist could have drained Ms. Tinlin's pericardial effusion through percutaneous placement of a drainage tube. Doc. 15081-2 at 18, ¶ 6. He claims that this procedure "likely would have been performed more expeditiously, with less morbidity and risk than [Dr. Roitstein's] surgical procedure, using moderate sedation rather than general anesthesia." *Id.*

Dr. Morris further opines that the fractured strut Dr. Kress removed potentially could have been retrieved percutaneously by an interventional radiologist, which "might have precluded open heart surgery, with all of its attendant risks and morbidity, including tracheomalacia and epigastric ventral hernia." *Id.* at 18-19, ¶ 7. Dr. Morris notes that a chest scan taken two days before the surgery revealed no strut in the heart. *Id.* He opines that the failure to perform a chest scan immediately before surgery is significant because "it was possible that neither arm fragment was still located in the heart, and therefore, open heart surgery would have been contraindicated." *Id.* at 19, ¶ 7.

Plaintiffs have filed a motion to exclude these opinions, arguing that Dr. Morris is not qualified to opine on the standard of care for cardiothoracic surgeons and his opinions

are unreliable and would be unhelpful and confusing to the jury. Doc. 15081-1 at 3-4. Defendants make clear that they are not offering Dr. Morris to opine on the standard of care for the surgeries performed by Drs. Roitstein and Kress, or any related breach. Doc. 15661 at 6, 11. Defendants assert that they are merely "exercising [their] right under Wisconsin law to present expert testimony that may 'weaken' Plaintiffs' claim of injuries[.]" *Id.* at 11 (citations omitted).

Under Wisconsin law, "when a tortfeasor causes an injury to another person who then undergoes unnecessary medical treatment of those injuries despite having exercised ordinary care in selecting her doctor, the tortfeasor is responsible for all of that person's damages arising from any mistaken or unnecessary surgery." *Hanson v. Am. Family Mut. Ins.*, 716 N.W.2d 866, 871 (Wis. 2006) (citing *Butzow v. Wausau Mem'l Hosp.*, 187 N.W.2d 349, 351-52 (Wis. 1971)). The rule was first announced in *Selleck v. City of Janesville*, 75 N.W. 975, 976 (Wis. 1898):

> The plaintiff is not held responsible for the errors or mistakes of a physician or surgeon in treating an injury received by a defect[,] providing she exercises ordinary care in procuring the services of such physician. Where one is injured by the negligence of another, . . . if her damages have not been increased by her own subsequent want of ordinary care she will be entitled to recover in consequence of the wrong done, and the full extent of damage, although the physician that she employed omitted to employ the remedies most approved in similar cases, and by reason thereof the damage to the injured party was not diminished as much as it otherwise should have been.

The *Selleck* rule remains good law in Wisconsin. *See Fouse v. Persons*, 259 N.W.2d 92, 95 (Wis. 1977) ("The rule for awarding damages for injuries aggravated by subsequent mistaken medical treatment was established in *Selleck* . . . and has been followed since."); *Paddock v. United States*, No. 16-CV-947, 2018 WL 3696618, at *3 (E.D. Wis. Aug. 3, 2018) (discussing the "long-standing principle set forth in *Selleck*"); *see also* Wis Civil-JI 1710 (citing *Selleck* to support the jury instruction for aggravation of injury because of medical negligence).

Defendants do not dispute that the surgeries performed by Drs. Roitstein and Kress were undertaken to treat injuries Ms. Tinlin sustained from the Recovery arm fragment in her heart. *See* Docs. 15081-2 at 6-7, 16952 at 5. Nor do Defendants present any evidence or argument that Ms. Tinlin was negligent in selecting the doctors to perform the surgeries. Thus, even if the surgeries were unnecessary as Dr. Morris suggests, Plaintiffs still can recover resulting damages under the *Selleck* rule if Defendants are found liable at trial.

As a result, Defendants have not shown that Dr. Morris's opinions about the treatment provided by Drs. Roitstein and Kress are relevant to any issue in the case. The opinions would be unhelpful and confusing to the jury. The Court will grant the motion to exclude the opinions. *See* Fed. Rs. Evid. 401-03.[1]

III. Motion in Limine No. 1: Medical Care as an Intervening Cause of Injury.

Plaintiffs argue that under the *Selleck* rule, Defendants should be precluded from offering Dr. Morris's opinions that an interventional radiologist could have drained Ms. Tinlin's pericardial effusion and retrieved the Recovery arm fragment from her heart through percutaneous procedures less intrusive than heart surgeries. Doc. 16576 at 1-2 & n.1 (citing Doc. 15661 at 2). The Court agrees for reasons stated above, and will grant the motion in limine in this regard.

Plaintiffs argue more broadly that Defendants should be precluded from offering any evidence that Ms. Tinlin's medical care was an intervening cause of her injury. *Id.* at 2. But Plaintiffs identify no specific evidence other than Dr. Morris's opinions discussed above.

Defendants make clear that they intend to present evidence that Dr. Riebe's decision to implant a Recovery in Ms. Tinlin after measuring her IVC diameter at larger than 28 mm constitutes negligence that was an intervening cause of her injuries. Doc. 16890 at 3-4. Defendants also intend to present evidence that the April 15, 2008 chest scan showed

---

[1] Given this ruling, the Court need not determine whether the opinions are reliable under Rule 702 and *Daubert*. Nor must the Court decide whether Dr. Morris is qualified to opine on the standard of care for cardiothoracic surgeons given Defendants' avowal that no such opinion will be offered at trial. *See* Doc. 15661 at 6, 11.

foreign metallic bodies in Ms. Tinlin's heart, and Dr. Haller's failure to identify this abnormality prevented Ms. Tinlin's treating physicians from properly evaluating her condition before the Recovery arm fragments became symptomatic and caused her injury five years later. *Id.* at 4. Defendants argue that the *Selleck* rule does not apply because the negligence of Drs. Riebe and Haller preceded Ms. Tinlin's injuries – her cardiac tamponade and pericardial effusion procedure, the open heart surgery to remove a fractured strut, and subsequent medical complications. *Id.*[2]

Defendants also raise this issue in the parties' proposed final pretrial order, asserting that the jury is entitled to consider the negligence of both Dr. Riebe and Dr. Haller, and to allocate a percentage of fault to each of them because their negligence was a cause of Ms. Tinlin's injuries. Doc. 16952 at 18 (citing *Connar v. W. Shore Equip. of Milwaukee, Inc.*, 227 N.W.2d 660, 662 (Wis. 1975) (explaining that "when apportioning negligence, a jury must have the opportunity to consider the negligence of all parties to the transaction")). In response, Plaintiffs reference their motion in limine and contend that under the *Selleck* rule, Defendants are liable for the full amount of damages caused by the aggravation of Ms. Tinlin's injuries. *Id.* at 19; *see also* Doc. 16950 at 45. But Plaintiffs fail to address Defendants' argument that the *Selleck* rule does not apply because the alleged negligence of Drs. Riebe and Haller preceded, rather than aggravated, Ms. Tinlin's injuries.

Plaintiffs have not shown that evidence regarding the medical care provided by Drs. Riebe and Haller should be excluded. The Court will deny the motion in limine in this respect.[3]

---

[2] Defendants contend that an asymptomatic filter complication is not an injury. *Id.*

[3] Plaintiffs contend that a directed verdict is proper on this issue because Defendants lack the requisite expert opinion that the alleged negligence of Drs. Riebe and Haller was a cause of Ms. Tinlin's injuries. Doc. 16952 at 19. Plaintiff will be free to raise this argument at the appropriate time during trial. *See* Fed. R. Civ. P. 50.

IT IS ORDERED:

1. Plaintiffs' motion to exclude certain opinions of Dr. Morris (Doc. 15077) is **granted**. Dr. Morris is precluded from opining that the surgeries performed by Drs. Roitstein and Kress were unnecessary. *See* Doc. 15081-2 at 18-19, ¶¶ 6-7.

2. Plaintiffs' motion in limine regarding medical care as an intervening cause of injury (Doc. 16576) is **granted in part and in denied part**. The motion is **granted** regarding the medical care provided by Drs. Roitstein and Kress and **denied** with respect to the care provided by Drs. Riebe and Haller.

Dated this 23rd day of April, 2019.

David G. Campbell
Senior United States District Judge

WO

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
Debra and James Tinlin, a married couple, Plaintiffs, v. C. R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation, Defendants.	No. CV-16-00263-PHX-DGC **ORDER**

The parties have filed motions in limine ("MIL") in advance of the Tinlin bellwether trial. The Court previously ruled on Plaintiffs' MIL 1. Doc. 17285. This order will rule on the remaining motions.

I. Plaintiffs' MILs.

A. MIL 2 – Ms. Tinlin's IVC Size.

The diameter of Ms. Tinlin's inferior vena cava ("IVC") measured between 28 and 29 mm when she received her Recovery filter. Plaintiffs seek to preclude Defendants from using this evidence to show that Dr. Riebe's decision to implant a Recovery filter

constitutes negligence that was a cause of Ms. Tinlin's injuries. Doc. 16578 at 1-2. Plaintiffs contend that the evidence is irrelevant and unfairly prejudicial because Dr. Riebe is not a defendant in the case and no medical malpractice claim is asserted against him. *Id.* at 2-3.

Wisconsin law has "established without a doubt that, when apportioning negligence, a jury must have the opportunity to consider the negligence of all parties to the transaction, whether or not they be parties to the lawsuit and whether or not they can be liable to the plaintiff or to the other tortfeasors." *Connar v. W. Shore Equip. of Milwaukee, Inc.*, 227 N.W.2d 660, 662 (Wis. 1975); *see Heldt v. Nicholson Mfg. Co.*, 240 N.W.2d 154, 157 (Wis. 1976) (trial court did not err in including the plaintiff's employer in the verdict where the record was replete with evidence of its negligence); *Hauboldt v. Union Carbide Corp.*, 467 N.W.2d 508, 515 (Wis. 1991) ("We have held that in an action for negligence, the jury must be given the opportunity to consider the possible negligence of all persons, whether parties or not, who might have contributed to the total negligence.") (citing *Connar*); *York v. Nat'l Cont'l Ins.*, 463 N.W.2d 364, 367 (Wis. Ct. App. 1990) ("If there is evidence of conduct that, if believed by the jury, would constitute negligence on the part of an actor, then that actor should be included in the special verdict."). The fact that Dr. Riebe is not a party to this case and cannot be found liable does not preclude Defendants from presenting evidence that he was negligent in selecting a Recovery filter for Ms. Tinlin and that this was a cause of her injuries.

Ms. Tinlin's IVC size also is relevant to the failure to warn claims. The Recovery's instructions for use ("IFU") cautioned that "[i]f the IVC diameter exceeds 28 mm, the filter must not be inserted into the IVC." Doc. 16893-1 at 2. Plaintiff claims that Dr. Riebe would have read an IFU that contained an adequate warning and may have changed his decision to use a Recovery for Ms. Tinlin. *See* Doc. 16893 at 4. Existing warnings in the IFU clearly are relevant.

In his Tinlin report, Dr. Morris opines that a Recovery filter should not be placed in an IVC larger than 28 mm because this can lead to tilt and migration. Doc. 15081-2

at 16-17, ¶ 1. He further opines that Dr. Riebe's decision to implant a Recovery in Ms. Tinlin fell below the standard of care. *Id.* Based on Dr. Morris's recent deposition testimony, Plaintiffs contend that he can only speculate that the IVC size and Dr. Riebe's decision to implant a Recovery caused Ms. Tinlin's injuries. Doc. 16748 at 2-3.

Plaintiff has the burden of proof as to her claimed injuries, and her "medical testimony in meeting such burden cannot be based on mere possibilities." *Hernke v. N. Ins. Co. of N.Y.*, 122 N.W.2d 395, 399 (Wis. 1963). But in challenging Plaintiff's claim, Defendants are "not required to confine [themselves] to reasonable medical probabilities." *Id.* Rather, Defendants "may attempt to weaken the claim of injuries with medical proof which is couched in terms of possibilities." *Id.*; *see Felde v. Kohnke*, 184 N.W.2d 433, 441 (Wis. 1971) ("It is clear that a contrary opinion to that presented by an opposing party may be presented in terms of possibilities[.]"); *Roy v. St. Lukes Med. Ctr.*, 741 N.W.2d 256, 264 (Wis. Ct. App. 2007) (explaining that "a defense expert is allowed to produce evidence of possibilities").

Plaintiff will claim that the filter's defective design caused her injuries, and Defendants can respond with Dr. Morris's testimony that her injuries possibly were caused by placement of the filter in an IVC that exceeded 28 mm. Plaintiffs will be free to argue that this is a mere possibility and Dr. Morris's opinions are nothing more than speculation and conjecture. *See id.* at 3-5. But the fact that Dr. Morris could not "affirmatively state" the cause of Ms. Tinlin's injuries is no basis for excluding his opinions under Wisconsin law. Doc. 16748 at 3; *see Hernke*, 122 N.W.2d at 399; *Roy*, 741 N.W.2d at 264. The motion in limine (Doc. 16578) is **denied**.[1]

[1] Defendants contend that the jury may apportion fault to Dr. Riebe based solely on evidence that he breached the standard of care and therefore was negligent. Docs. 16946 at 8-9, 16893 at 4. This is not correct. To apportion fault to physicians in this case, Defendants must "prove that [they] were *causally* negligent." *Hegarty v. Beauchaine*, 727 N.W.2d 857, 901 (Wis. Ct. App. 2006) (emphasis added). This requires a showing not only of negligence, but also that the negligence was a substantial factor in producing Ms. Tinlin's injuries. *See Fandrey v. Am. Family Mut. Ins.*, 680 N.W.2d 345, 353 (Wis. 2004); *Burton v. Am. Cyanamid*, No. 07-CV-0303, 2019 WL 325318, at *2 (E.D. Wis. Jan. 25, 2019); Wis JI-Civil 1023 (medical negligence standard); *see also Hegarty*, 727 N.W.2d at 903 (rejecting the argument that the jury should have been allowed to apportion fault to other physicians where the defendants failed to show that

B. MIL 3 – Unrelated Medical Conditions.

Plaintiffs seek to exclude evidence concerning certain medical conditions that they claim are unrelated to the injuries caused by the Recovery filter:

- Graves' disease
- Surgical resection of the thyroid gland
- Hypothyroidism
- Sjogren's syndrome
- Hypertension
- Uterine and rectal prolapse
- Fibromyalgia and rheumatoid arthritis
- Pernicious anemia

Doc. 16577 at 1-2. Plaintiffs contend that these conditions are not relevant to any issue in the case and would only mislead the jury, confuse the issues, and waste time. *Id.* at 3.

Defendants counter that the conditions carry symptoms that overlap with some of Ms. Tinlin's claimed injuries – future cardiac complications, shortness of breath, back pain, and a weakened trachea. Doc. 16938 at 3. Defendants cite various medical articles purportedly showing the causal connections (*id.* at 2-5), but it is not clear that the documents will be admissible at trial. Nor do Defendants identify any expert medical testimony they will offer on the issue.

Under Wisconsin law, however, Defendants may cross-examine Plaintiffs' experts as to whether it is possible that Ms. Tinlin's medical conditions are related to her claimed injuries. *See Hernke*, 122 N.W.2d at 399. The Court cannot conclude that Ms. Tinlin's medical conditions are irrelevant or otherwise inadmissible. The motion in limine (Doc. 16577) is **denied**.[2]

"the alleged negligence *caused* [the patient's] injuries") (emphasis in original).

[2] Defendants assert that the Recovery filter protected Ms. Tinlin when she needed to stop anticoagulation treatment for various medical procedures between 2005 and 2015, including procedures for uterine and rectal prolapse. Doc. 16938 at 3. Defendants agree that they need not divulge the specific reasons that Ms. Tinlin temporarily stopped taking anticoagulants as long as they can offer evidence that she needed to do so multiple times over the years for conditions unrelated to this case. *Id.* at 3-4. The parties should confer and agree on how evidence that Ms. Tinlin stopped anticoagulation from time to time will be presented during trial.

C. MIL 4 – Rates of Filter Complications.

Plaintiffs anticipate that Defendants will attempt to use a chart they created from their internal TrackWise database regarding reporting rates of IVC filter complications. Doc. 16579 at 2. Plaintiffs contend that the chart is an untrustworthy hearsay document that fails the requirements of the business records exception provided by Rule 803(6). *Id.* at 2-3. Plaintiffs further contend that the chart is inadmissible under Rule 403 because any probative value it may have is substantially outweighed by the danger of unfair prejudice. *Id.* at 3-4.

Defendants assert that they have been fully candid in explaining what the internally calculated reporting rates represent, and Plaintiffs will be free to challenge the accuracy of the rates through evidence of their own and cross-examination of Defendants' witnesses. Doc. 16896 at 2-4. Defendants note that the chart was admitted in the Booker trial over Plaintiffs' hearsay and Rule 403 objections. *Id.* at 2; *see* Doc. 16896-1 at 13-16.

The Court will not predetermine whether Defendants will be able to lay adequate foundation for admission of the chart in the Tinlin trial, or whether the chart should be precluded under Rule 403. The motion in limine (Doc. 16579) is **denied**.[3]

D. MIL 5 – Retrievable Filter Sales Versus SNF Sales.

Plaintiffs seek to preclude Defendants from using a chart comparing the sales of the permanent Simon Nitinol filter ("SNF") with those of retrievable filters between 2002 and 2016. Doc. 16580 at 1-2. Plaintiffs contend that the chart is not relevant because Ms. Tinlin received her filter in 2005. *Id.* at 2.

Plaintiffs will present evidence that the SNF is a reasonable alternative design to the Recovery filter. The Court concludes that Defendants should be allowed to present evidence of diminished SNF sales to show that the medical community viewed

---

[3] Defendants were precluded in the Hyde trial from using reporting rates to claim that Bard filters are "99.9% effective." *See* Doc. 16579-2. Defendants do not state that they will attempt to make the same claim in this case, but if they decide to do so, they should first raise the issue with the Court outside the presence of the jury.

retrievable filters – including the Recovery – as offering benefits over permanent-only filters. The fact that the chart includes sales after Ms. Tinlin received her filter can be pointed out to the jury and goes to the weight of the evidence, not its admissibility. Plaintiffs have not shown that admission of the rates chart would mislead the jury or result in unfair prejudice. The motion in limine (Doc. 16580) is **denied**.

E. MIL 6 - Social Security Benefits.

Plaintiffs contend that evidence regarding social security disability benefits Ms. Tinlin applied for or received is barred by Wisconsin's collateral source rule. Doc. 16581 at 1-2. "[T]he collateral source rule states that benefits an injured person receives from sources that have nothing to do with the tortfeasor may not be used to reduce the tortfeasor's liability to the injured person." *Leitinger v. DBart, Inc.*, 736 N.W.2d 1, 7 (Wis. 2007). The rule "generally precludes introduction of evidence regarding benefits a plaintiff obtained from sources collateral to the tortfeasor." *Id.* at 9.

Plaintiffs seek to exclude a June 8, 2005 letter Dr. Stanko wrote in support of Ms. Tinlin's application for permanent disability, a phone message regarding a request for the letter, and Dr. Stanko's deposition testimony about the letter. Doc. 16581 at 2; *see* Doc. 16583. Defendants make clear, however, that they will not offer evidence of Ms. Tinlin's disability to show that she received benefits from a collateral source as compensation for her claimed injuries or to offset any potential damages award. Doc. 16897 at 2. Indeed, Defendants acknowledge that "an award of damages cannot be limited or reduced by a collateral source payment." Doc. 16897 at 2. Defendants instead intend to use the evidence to show that Ms. Tinlin's deep vein thrombosis with pulmonary emboli was a serious condition and she was permanently disabled before her Recovery filter failed. Doc. 16897 at 2-3.

Plaintiffs have not shown that the challenged evidence is inadmissible. The motion in limine (Doc. 16581) is **denied**.

/ / /

/ / /

II. Defendants' MILs.

A. MIL 1 – Recovery Death Evidence.

In each of the other bellwether cases tried in this MDL – Booker, Jones, and Hyde – Defendants have moved to exclude evidence of deaths caused by Recovery filter cephalad migration. Docs. 9862, 10677, 10288. The Court denied the motion in the Booker case, which concerned a G2 filter, finding that the evidence concerned the device that was a predicate for the G2 in Defendants' FDA submissions and also would be necessary for the jury to understand what prompted design changes in the G2. Doc. 10323 at 4. The Court reached a different conclusion in the Jones and Hyde cases because the G2 design eliminated cephalad migration, the cases concerned filters that were two or three generations after the Recovery (G2X and Eclipse), the plaintiffs received the filters more than four years after the Recovery was taken off the market, and Recovery filter cephalad migration deaths – which stopped after the G2 was introduced – said little if anything about the plaintiffs' claims regarding the G2X and Eclipse. The Court concluded that Recovery death evidence had only marginal relevance that was substantially outweighed by the danger of unfair prejudice. Docs. 10819 at 3-5, 12533 at 6-7; *see* Docs. 10920, 11041 (orders denying motion for reconsideration in Jones).

Defendants contend that the Court's reasoning in Booker should not apply in this case because the Court did not consider whether cephalad migration was substantially similar to complications Ms. Booker's G2 filter experienced. Doc. 16575 at 2. But this case concerns the Recovery filter. Plaintiffs contend that the Recovery was defectively designed, presented unusually high risks to patients, and continued to be marketed despite Defendants' knowledge of high failure rates and deaths. Plaintiff Tinlin contends that she never would have received a Recovery filter if Defendants' had disclosed these increased risks to her doctor, and that Defendants' continued marketing of this dangerous product warrants punitive damages. The Recovery deaths are directly relevant to these claims.

To establish the strict liability design defect claim, Plaintiffs must show that the Recovery's "foreseeable risks of harm" could have been reduced by an alternative

reasonable design, and that omission of the alternative design rendered the Recovery "not reasonably safe." Wis. Stat. § 897.047(1)(a). Plaintiffs must also show that the alleged defect rendered the Recovery "unreasonably dangerous[.]" § 895.047(b). Recovery filter patient deaths and Defendants' knowledge of those deaths go directly to the Recovery's foreseeable risks of harm and whether it was unreasonably dangerous.

Defendants contend that Plaintiff Tinlin did not experience the kind of whole-filter cephalad migration that resulted in the reported deaths, but Plaintiffs contend that same filter defects and instability that caused cephalad migration led to the kinds of migration, tilting, perforation of the IVC, and fracturing that Ms. Tinlin experienced.

Recovery death evidence also is relevant to Plaintiffs' failure to warn and concealment claims. Ms. Tinlin's implanting physician, Dr. Riebe, testified that he needed complete and accurate information from medical device manufacturers to help him conduct a proper risk-benefit analysis. Doc. 15702-1 at 5. He explained that a manufacturer's concealment of true risks prevents him from conducting such an analysis. *Id.* He further stated that he would have wanted to know that Bard had placed the Recovery on hold due to significant migration problems and internally found the Recovery to have unacceptable risks. *Id.* at 6-8, 14. This information would have been important to him in understanding the Recovery's safety and conducting a proper risk-benefit analysis. *Id.* at 8-9, 19. The fact that patients died from Recovery migration problems is probative on the causation issue – that is, whether Dr. Riebe would have selected a different filter for Ms. Tinlin had he been warned about the Recovery's true risks, as Plaintiffs describe them.

Defendants cite *Cooper v. Firestone Tire & Rubber Co.*, 945 F.2d 1103, 1105 (9th Cir. 1991), for the proposition that a showing of substantial similarity is required when a plaintiff attempts to introduce evidence of other incidents of product failure as direct proof of negligence or defect. Doc. 16575 at 2. But substantial similarity is not required when the other incidents are used to impeach an expert's testimony that a product is safe. *See Cooper*, 945 F.2d at 1105. Indeed, even where other-incident evidence may have

"some prejudicial effect, it [is] also highly probative of the credibility of the assertion of [defense] experts that the [product] was generally safe." *Id.* Defendants clearly will assert in this case that the Recovery filter was safe and effective.

Defendants note that the Court expressed concern in Booker that too heavy an emphasis on deaths could result in unfair prejudice that substantially outweighs the probative value of the cephalad migration evidence. *Id.* at 3 (citing Doc. 10323 at 4). The Court has the same concern in this case, but this is no basis for precluding the evidence before trial. Defendants may object during trial if they believe Plaintiffs are overemphasizing the cephalad migration deaths.

Defendants contend that admitting the death evidence to support an award of punitive damages would violate due process and Wisconsin law. *Id.* at 4. To recover punitive damages, Plaintiffs must show that Defendants "acted maliciously" or in an "intentional disregard of the rights" of Plaintiffs. Wis. Stat. 895.043(3); *see Strenke v. Hogner*, 694 N.W.2d 296, 304-05 (Wis. 2005). The jury may consider Defendants' "attitude and conduct" and "the degree of [Defendants'] awareness of the hazard and of its excessiveness." Wis JI-Civil § 1707.2; *see* Doc. 12438 at 38-39. Evidence that Bard continued to market the Recovery in the face of unusually high patient deaths is relevant to Bard's state of mind.[4] Moreover, the death evidence "can help to show that the conduct that harmed [Ms. Tinlin] also posed a substantial risk of harm to the general public, and so was particularly reprehensible[.]" *Philip Morris USA v. Williams*, 549 U.S. 346, 355 (2007); *see State Farm Mut. Auto. Ins. v. Campbell*, 538 U.S. 408, 419 (2003) (explaining the "most important indicium of the reasonableness of a punitive damages award is the degree of reprehensibility of the defendant's conduct," which includes whether "the tortious conduct evinced an indifference to or a reckless disregard

[4] The Court reached a different conclusion in Jones because cephalad migration deaths stopped when the Recovery was taken off the market in 2005, and the deaths shed little light on Defendants' state of mind when marketing different filters with different complications, years later. Doc. 10819 at 5.

of the health or safety of others") (quoting *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 574 (1996)).

Defendants' reliance on *Henrikson* and *Kehl* is misplaced. Doc. 16575 at 4. Each case involved a separate act of fleeing the scene of the accident that caused the plaintiff no injury. *See Henrikson v. Strapon*, 758 N.W.2d 205, 215 (Wis. Ct. App. 2008) ("[T]here is no evidence that Strapon's fleeing the scene caused an injury to Henrikson or aggravated any injury he received from being hit by Strapon's car[.]"); *Kehl v. Econ. Fire & Cas.*, 433 N.W.2d 279, 281 (Wis. Ct. App. 1988) ("The collision . . . resulted from negligence and was distinct from the fleeing, which was a separate volitional act."). Plaintiffs contend that the Recovery migration problems that caused Ms. Tinlin's injuries and the deaths of other patients resulted from the same flawed design. Doc. 16943 at 2.

Defendants have not shown that Recovery death evidence is inadmissible in this case. The motion in limine (Doc. 16575) is **denied**.

B. MIL 2 – FDA Warning Letter.

Defendants re-urge their motion to exclude the 2015 FDA warning letter. Docs. 9864, 16572; *see* Doc. 9864-1; Ex. 1680. The Court previously found the that the following topics in the letter lack probative value: Topics 1 and 2 (Recovery cone retrieval system), topic 4(a) (filter cleaning process), and topics 4(b), 5, 6, 7 and 8 (Denali filter). Doc. 10258 at 6-8; Booker Trial Tr. at 1890. Plaintiffs have not shown that topics 1, 2, 4 and 6 are relevant to any issue in this case. Plaintiffs contend that topics 7 and 8 show that Bard failed to properly report adverse events, and this evidence demonstrates a pattern of concealment that is relevant to the failure to warn claims and punitive damages. Doc. 16945 at 2. But the adverse events in topics 7 and 8 involved Bard's latest-generation filter – the Denali – which is not at issue in this case. The Court will **grant** the motion (Doc. 16572) with respect to topics 1-2 and 4-8.

Topic 3 concerns Bard's regulatory violations for failure to establish and maintain procedures for receiving, evaluating, and reporting IVC filter complaints, and expressly references the G2 and Eclipse – the filters at issue in the other bellwether trials.

Doc. 9864-1 at 5-6. The Court deferred ruling on the relevance of topic 3 until trial in Booker, and took the same approach in Jones and Hyde. *See* Doc. 10805. The Court ultimately concluded in Booker that topic 3 was relevant because much evidence had been presented about the MAUDE database and adverse event reports to the FDA, the data upon which Bard relied in making reports, and Bard's root cause analysis. Topic 3 was relevant to rebut the implication, if not the express argument, that the FDA never took action against Bard. *See* Booker Trial Tr. at 1888-89. The Court noted that topic 3 included reference to the G2, the filter at issue in Booker. *Id.* at 1889. The Court reached similar conclusions in Jones and Hyde. *See* Docs. 11256, 12736.

Defendants contend that topic 3 should be excluded in this case because it has nothing to do with the Recovery filter and is not otherwise relevant to any issue or claim. Doc. 16572 at 2-4. Defendants further contend that the presentation of evidence about the warning letter would waste important trial time and only confuse the jury about the true issues in the case. *Id.* at 4.

Plaintiffs counter that topic 3 is relevant for the same reasons it was relevant in the other bellwether trials. Doc. 16945 at 2-4. Plaintiffs assert that although topic 3 does not reference the Recovery by name, it covers Bard's processes for the entire IVC filter line, including the Recovery. *Id.* at 3-4. Plaintiffs note that the Court previously rejected Defendants' Rule 403 objections. *Id.* at 4.

The decision on this issue will need to be made at trial once the relevancy of topic 3 can be determined in light of all the facts presented. Plaintiffs shall raise the issue with the Court outside the presence of the jury before seeking to admit the FDA warning letter. The motion (Doc. 16572) is **denied** in this regard.[5]

C. MIL 3 – Crisis Communications Plan.

Defendants seek to exclude the Recovery Filter Crisis Communications Plan ("CCP") that Bard had prepared in 2004 to help manage damaging media coverage about

[5] If topic 3 of the letter is deemed admissible at trial, Plaintiffs shall make appropriate redactions before offering it into evidence. *See* Booker Trial Tr. at 1889-90.

a Recovery migration death. Doc. 16573. Defendants contend that the CCP is irrelevant for three reasons.

First, Plaintiffs cannot show a substantial similarity between the cephalad migration death that prompted the CCP and Ms. Tinlin's filter failures and resulting injuries. *Id.* at 2 (citing *Cooper*, 945 F.2d at 1105; *State Farm*, 538 U.S. at 422). But as explained above, cephalad migration deaths are relevant to Plaintiffs' claims.

Second, the CCP was never put into action and therefore had no causal impact on Plaintiffs' claims or injuries. *Id.* at 2-3. Defendants' causal connection is not the only relevant issue in this case. The CCP is relevant to Defendants' understanding of the risks presented by Recovery, their response to those risks, and, potentially, their state of mind for punitive damages.

Third, the CCP does not support Plaintiffs' punitive damages claim because retaining a public relations firm to help manage negative media coverage of product failures is good corporate policy. *Id.* at 3. This may be a good jury argument, but it does not render the CCP irrelevant. The CCP notes that, as a result of unfavorable press coverage, "stock prices may plummet [and] analysts may downgrade the affected company's rating[.]" Doc. 16573-1 at 3. The CCP goes to Bard's attitude toward Recovery complications and is relevant to Plaintiffs' claim that Bard acted with intentional disregard of Plaintiff's rights. *See* Wis. Stat. 895.043(3); Wis JI-Civil § 1707.2. Defendants will be free to argue that the CCP was never finalized and contains "template language" not specific to or approved by Bard (Doc. 16753 at 4), but this goes to CCP's evidentiary weight, not its admissibility.

The Court cannot conclude that the CCP is irrelevant. Nor does the Court find it inadmissible under Rule 403. The motion in limine (Doc. 16573) is **denied**.

D. MIL 4 – Patient at Dr. Muehrcke's Hospital.

Dr. Muehrcke was a consulting physician for a patient who had a Bard filter and purportedly died from cardiac tamponade. He recently opined in a state-court deposition that the patient's cardiac tamponade was caused by a fractured strut that had embolized to

her heart. Doc. 16574-1 at 8. Defendants seek to preclude Plaintiffs from referencing this opinion during opening statements or eliciting it during Dr. Muehrcke's direct examination because it is not included in Dr. Muehrcke's expert reports and was not offered during his deposition in this case. Doc. 16574 at 2-3 & n.2.

As the Court outlined in Case Management Order No. 8, expert reports under Rule 26(a)(2)(B) must set forth "the testimony the witness is expected to present during direct examination, together with the reasons therefor." Doc. 519 at 3, ¶ 6 (citation omitted). Plaintiffs note that Dr. Muehrcke opines in his Tinlin report that "pulmonary fragments are known to cause . . . death" and "an additional strut can embolize at any time to [Ms. Tinlin's] heart causing her to suffer cardiac tamponade[.]" Doc. 16951 at 2. But this says nothing about his opinion in the state-court case that one of his patients died from cardiac tamponade caused by a fractured strut. Plaintiffs have not timely disclosed that opinion in this case, nor have they shown that the failure to disclose is substantially justified or harmless. Plaintiffs therefore are precluded from eliciting the opinion during opening statements and direct examination of Dr. Muehrcke. *See* Fed. R. Civ. P. 37(c)(1) (a party that fails to disclose information required by Rule 26(a) "is not allowed to use that information . . . at a trial, unless the failure was substantially justified or harmless"); *see also Yeti by Molly Ltd. v. Deckers Outdoor Corp.*, 259 F.3d 1101, 1106 (9th Cir. 2001) ("Rule 37(c)(1) gives teeth to these requirements by forbidding the use at trial of any information required to be disclosed by Rule 26(a) that is not properly disclosed."). The motion in limine (Doc. 16574) is **granted**.[6]

Dated this 26th day of April, 2019.

David G. Campbell
Senior United States District Judge

[6] Given this ruling, the Court need not address whether the opinion should be excluded under Rules 403 and 702. *See* Doc. 16574 at 3-4.