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

NATALIE JOHNSON,

Plaintiff,

v.

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

Defendants.

OPINION AND ORDER

19-cv-760-wmc

Before being remanded for trial, this product liability action case was consolidated into a multidistrict litigation ("MDL") proceeding conducted in the District of Arizona against defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc.[1] The specific product at issue in the present case is the "Meridian Filter," a prescription medical device designed to prevent pulmonary embolisms. In advance of the final pretrial conference ("FPTC"), the parties have filed numerous motions in limine, which the court addresses in this opinion.

I. Stipulated Motions in Limine (Dkt. #86, 91)

The parties have stipulated to a variety of evidentiary limits in their "Joint Stipulation on Motions in Limine and Certain Subjects Relating to Trial and Stipulation on Medical Records" (dkt. #86) and "Joint Stipulation Regarding Evidence of Dr. Thomas

[1] The MDL plaintiffs all received implants of Bard IVC filters, which they claimed were defective and caused serious injury or death. During the course of those MDL proceedings, six cases were selected for bellwether trials. (*See* Remand & Transfer Order (dkt. #3).) Of relevance to this opinion and order, three of these cases proceeded to trial, *Booker v. C. R. Bard, Inc.*, No. CV-16-00474; *Jones v. C. R. Bard, Inc.*, No. CV-16-00782; *Hyde v. C. R. Bard, Inc.*, No. CV-16-00893, while a fourth settled shortly before trial but after some pretrial motions were decided, *Tinlin v. C. R. Bard, Inc.*, No. CV-16-00263.

Kinney As a Prior Expert Witness and Paid Consultant for Bard" (dkt. #91). Despite many being unnecessary (and some disturbingly so), the court will grant both in the hopes of streamlining presentations to the jury. The court will also take up the following four issues reserved by the parties:

A. Certain Anecdotal Testimony:

The parties noted that they disputed whether evidence of plaintiff's family history of blood clots and deep vein thrombosis should be admitted (dkt. #86 at 3), however neither party submitted a motion in limine on this specific point.

The parties also dispute whether testimony by medical witnesses or medical experts about their experience with patients who have died of pulmonary embolism should be allowed. (Dkt. #86-3.) This is addressed in plaintiff's motion in limine number 1.5 below.

B. The July 13, 2015, FDA Warning Letter issued to Bard ("Warning Letter"):

Whether plaintiff should be permitted to make any reference to or introduce evidence concerning Topic 3 of the Warning Letter (dkt. #86 at 4), which the court also discusses in defendants' fifth motion in limine below.

C. Dr. Krishan Kandarpa's Deposition Designations regarding Exhibit 7:

The parties dispute whether page/lines 138:23-140:17 relate to Exhibit 7 and whether they should be admitted. (Dkt. #86 at 4.) This dispute is addressed in defendants' fourth motion in limine below.

D. Demonstrative Exhibits:

Each party may use drawings, anatomical representations, and basic stock type models and depictions of the human body provided notice is given to opposing counsel on the morning of jury selection. However, the other party specifically reserves its right to raise evidentiary objections to the same during trial.

The parties are required to provide copies of any power point presentations to the court and opposing counsel *before* they are shown to the jury and in sufficient time to allow objection to its use.

II. Defendants' Motions in Limine (dkts. #92-95, 97, 101-03)

1. Exclude Testimony and Evidence of Recovery Filter Migration Deaths (dkt. #92)

Defendants seek to exclude any reference, evidence, or argument concerning reports of the so-called "Recovery Filter" (Bard's first-generation retrievable filter) allegedly migrating to a patient's heart and resulting in death. Specifically, defendants point out that Johnson was implanted with the "Meridian Filter" -- Bard's fifth-generation retrievable filter -- and also that the filter did not migrate to her heart or any other organ, making any reference to it both irrelevant and highly prejudicial. Plaintiff objects to this motion, arguing that the Recovery was the first of a series of Bard filters that failed in "substantially similar" migrations in patients under Wisconsin law.

For the last few decades, defendants have marketed and sold a line of IVC filter devices, which are placed in a patient's inferior vena cava ("IVC"), the largest vein in the human body, with the goal of preventing blood clots from traveling to the heart, lungs, or

brain. The Recovery Filter was defendants' first "retrievable" filter, meaning it was designed to permit percutaneous removal at a later time.[2] The Recovery was marketed from 2003 until 2005, and during that time, defendants received a number of reports of migration of the entire filter to a patient's heart, resulting in death. As noted, defendants subsequently developed and marketed "next-generation" retrievable IVC filters, although all were based on the Recovery Filter, including the Meridian Filter at issue in this case.

Under Wisconsin product liability, the parties agree that any evidence of other accidents may be relevant "to show notice to the defendant of the danger, to show existence of the danger, and to show the cause of the accident," but only if the other accidents occurred "under *substantially similar circumstances*." *Weir v. Crown Equip. Corp.*, 217 F.3d 453, 457 (7th Cir. 2000) (quoting *Nachtsheim v. Beech Aircraft Corp.*, 847 F.2d 1261, 1268 (7th Cir. 1988)) (emphasis in original). However, "[e]ven when substantial identity of the circumstances is proven, the admissibility of such evidence lies within the discretion of the trial judge who must weigh the dangers of unfairness, confusion, and undue expenditure of time in the trial of collateral issues against the factors favoring admissibility." *Nachtsheim*, 847 F.2d at 1269 (quoting *McKinnon v. Skil Corp.*, 638 F.2d 270, 277 (1st Cir. 1981)).

Similar motions in limine were raised in the *Jones* and *Hyde* bellwether cases. In both cases, the court concluded that evidence of death by migration of the Recovery Filter was not "substantially similar," and thus, not relevant to the plaintiff's claims of non-fatal

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

fracture of later-generation Bard IVC filters. *Jones v. C. R. Bard, Inc.*, No. CV-16-00782-PHX-DGC, 2018 WL 1993767, at *3 (D. Ariz. Apr. 27, 2018), *aff'd* 816 F. App'x 218, 219 (9th Cir. 2020); *Hyde v. C. R. Bard, Inc.*, No. CV-16-00893-PHX-DGC, 2018 WL 4279833, at *3 (D. Ariz. Sept. 7, 2018). In another IVC filter product liability case, the Southern District of Indiana considered on a motion for a new trial whether the court had erred in not excluding evidence of deaths associated with a number of defendant's IVC filters. *In re Cook Med., Inc., IVC Filters Mktg., Sales Pracs. & Prod. Liab. Litig.*, 431 F. Supp. 3d 1033, 1051 (S.D. Ind. 2020). There, the court noted that "[a]lthough the [filter] perforated her IVC, [the plaintiff] did not suffer a retroperitoneal hemorrhage or a hemorrhage of any kind, and she did not die. Instead, the [filter] fractured and the struts migrated to her thigh, psoas muscle, and to an area near her spine." *Id.* at 1051. The court held that the plaintiff's experience was not "substantially similar" to the experience of the patients who had died, and because of that, concluded that the court had erred in admitting the evidence of the patient deaths. *Id.*

This court likewise concludes that the evidence of deaths resulting from migration of the Recovery Filter into the heart did not occur under "substantially similar circumstances" as the non-fatal fracture of the Meridian Filter implanted in Johnson, and moreover, any marginal relevance would be substantially outweighed by the danger of unfair prejudice to defendants. Accordingly, the court will GRANT this motion in limine, unless defendants open the door by disputing notice of the potential for a Meridan Filter to move, perforate, migrate, or fracture and, in exceedingly rare cases, result in death as disclosed in its Instructions for Use.

2. Exclude Testimony and Evidence of Recovery Filter Marking, Communications, and other Purported "Bad Acts" (dkt. #93)

Relatedly, defendants seek to exclude "any reference, evidence, or argument concerning certain irrelevant and unfairly prejudicial evidence of marketing, communications, and other purported 'bad acts,' relating to the Recovery Filter." (Dkt. #93.) In particular, defendants seek to exclude: (1) a 2004 crisis communication plan ("CCP") and its subsequent revisions and related materials, (2) two sales communiques in 2004, (3) a 2004 email, and (4) a 2006 email. Because all of these communications relate *only* to the Recovery Filter, defendants argue that they are not relevant or, to the extent relevant, are outweighed by the danger of prejudice to defendants, including to suggest that defendants had a propensity to act in the same manner regarding the development of the Meridian as they allegedly did with the Recovery.

As discussed above, evidence of other accidents may be excluded if they did not occur under substantially similar circumstances. *Weir*, 217 F.3d at 457. Additionally, evidence of prior acts is inadmissible if offered solely to prove bad character or propensity. Fed. R. Evid. 404(b). The Seventh Circuit has explained that a district court "should not just ask *whether* the proposed other-act evidence is relevant to a non-propensity purpose but *how* exactly the evidence is relevant to that purpose -- or more specifically, how the evidence is relevant without relying on a propensity inference." *United States v. Gomez*, 763 F.3d 845, 856 (7th Cir. 2014).

A review of the CCP and the 2004 sales communiques show that they were created in response to deaths from migration of the Recovery Filter. Having decided that those deaths are not substantially similar to the incident in the present case, the court will not

admit efforts to explain them away, however ham-handed the attempt, given the prejudicial confusion that would likely engender.[3]

Even worse in terms of prejudice, the 2004 email involves a question regarding complications after bariatric surgery, to which a Bard employee callously responded, "I think you should stay away from the buffet line!" (Dkt. #93-6.) Similarly, the 2006 email involves communications between two Bard employees, in which one commented that the "filter problem[]" was "held together with scotch tape, smoke, mirrors, crying, etc." (Dkt. #93-8.) Given the potential for unfair prejudice from these remarks, absent as yet unpresented evidence of these specific roles of the author and recipients in the design, manufacture, sale or investigation of accidents involving a Meridian Filter or an immediate generational product, these emails will be excluded for all purposes.[4] Thus, this motion is also GRANTED.

3. Exclude Evidence and References to Other Lawsuits and Trials (dkt. #94)

Defendants next request an order to "exclude evidence, testimony, or argument referring to other lawsuits or testimony in other lawsuits or trials involving Bard IVC filters, other than referring to 'previous testimony' if it is appropriate when questioning a witness,

[3] In *Tinlin*, the court considered a similar motion in limine seeking to exclude evidence of the CCP on similar grounds to the ones advanced by defendants here. *See Tinlin v. C.R. Bard, Inc.*¸ No. CV-16-00263, Doc. 17401 (D. Ariz. April 26, 2019). The court denied defendants motion in limine, finding that the CCP was relevant and admissible. However, unlike the present case, the plaintiff in that case had been implanted with the Recovery Filter and the judge did not exclude evidence of deaths from the Recovery Filter.

[4] Although unlikely even then, proof that those Bard employees were substantially involved with the Meridian filters *might* allow admission of these internal communications, but even then only in a punitive damage phase of trial.

without reference to when the testimony was given, that the testimony was part of a previous case or trial, or that a witness has given testimony on multiple occasions." (Dkt. #94 at 4.) Plaintiff objects to this motion, arguing that such evidence would be relevant to show that defendants knew or should have known about the risks of harm from the Meridian Filter and to explore the credibility of witnesses by using their prior statements.

Plaintiff's argument is not just disingenuous but bolsters defendants' motion. Defendants' requested order is similar to one entered by Judge Campbell in the *Jones* bellwether case, and the *Hyde* parties stipulated to a similar restriction. Further, a similar order was recently entered in *Peterson v. C.R. Bard, Inc.*, Case No. 3:19-cv-01701-MO (D. Or. Apr. 20, 2021), Pretrial Conference Transcript 9:10–14 (dkt. #94-5). As a general matter, evidence regarding the existence of other lawsuits or claims against a party is not admissible. *Hodgson v. Wis. Cent. Ltd.*, No. 19-cv-15-jdp, 2020 U.S. Dist. LEXIS 105952, at *14 (W.D. Wis. June 16, 2020). The mere existence of other related lawsuits, including ones in which no judgment was entered against defendants, has minimal if any probative value as to the foreseeable risk of harm posed by the Meridian Filter, although the risk of unfair prejudice is great. *See Ross v. Am. Red Cross*, 567 F. App'x 296, 308 (6th Cir. 2014) (affirming district court order to withhold evidence of other lawsuits involving the defendant in negligence action).

Although a witness's prior testimony may be relevant to explore his or her credibility, permitting the parties to reference his or her "prior testimony" or "past testimony under oath" without referencing a specific lawsuit will accomplish this goal. *See Newman v. McNeil Consumer Healthcare*, No. 10 C 1541, 2013 U.S. Dist. LEXIS 113439, at

*57-58 (N.D. Ill. Mar. 29, 2013) (excluding evidence of or references to other lawsuits involving the product at issue under Rule 403, noting that "counsel can refer to prior deposition or trial testimony in other Motrin cases without identifying the particular case in which the testimony derives"). Accordingly, the court finds that defendants' motion in limine strikes the proper balance between excluding generally irrelevant evidence while still permitting the parties to explore the credibility of witnesses, and the court will GRANT it as well.

4. Exclude Certain Evidence and Testimony of Krishna Kandarpa, M.D. (dkt. #95)

By stipulated motion, the parties already agreed to exclude Dr. Kandarpa's deposition testimony regarding "Exhibit 7," as well as that exhibit itself. However, defendant additionally seeks to exclude lines 138:23-140:17 from Kandarpa's deposition, asserting that the MDL plaintiff counsel misused the same exhibit during the deposition to mislead Kandarpa "into believing that a higher number of adverse events occurred during the G2 Filter Clinical Trial than actually occurred, and that Bard failed to disclose these extra adverse events in the clinical trial data section in the Filter's Instructions for Use." (Dkt. #95.) While plaintiff refuses to concede that any exhibit was misused by the MDL plaintiff's counsel, at least for this dispute, she primarily argues that the disputed testimony does not reference or cite to Exhibit 7, and thus, defendants' motion should be denied.

As an initial matter, the court agrees that the MDL counsel's omission of 13 out of 16 pages of the full Exhibit 7 potentially misled Dr. Kandarpa, as well as prevented

defendants' counsel from effectively questioning him about that exhibit. Moreover, having considered the deposition testimony in context, including the video of the deposition which appears to show Dr. Kanpara looking at Exhibit 7 during the disputed testimony, the court agrees with defendants that lines 138:23-140:17 of Dr. Kanpara's testimony are tainted by MDL counsel's misuse of the exhibit. Accordingly, the court will GRANT defendants' motion in limine and exclude lines 138:23-140:17 of Dr. Kandarpa's deposition testimony from use at trial. *See Peterson*, Case No. 3:19-cv-01701-MO, Pretrial Conference Transcript 9:10–14 (dkt. #94-5) (excluding the same lines of Dr. Kandarpa's deposition testimony).

5. Exclude Testimony and Evidence of FDA Warning Letter (dkt. #97)

Having already stipulated that Topics 1-2 and 4-8 are to be excluded, defendants also seek to exclude evidence of Topic 3 of an FDA Warning Letter issued to Bard in 2015, at least until the relevancy of the topic can be considered in light of all the evidence presented at trial. Topic 3 concerns Bard's handling and reporting of complaints and adverse events with respect to the G2 and Eclipse filters, as well as the adequacy of Bard's evaluation of the root cause of the violations. Plaintiff objects to defendants' requested order, arguing that Topic 3 is relevant not only to rebut any false appearance of compliance by the FDA, but also that the evidence is relevant to core questions of punitive damages.

In the *Booker*, *Jones*, *Hyde*, and *Tinlin* bellwether cases, the court deferred ruling on the relevance of Topic 3 until trial, concluding that it *might* be relevant to rebut any implication at trial that the FDA took no action with respect to the IVC filters. *Booker*, 2018 WL 1109554, at *4; *Jones*, MD-15-02641-PHX-DGC, Doc. 11256 (D. Ariz. May 29,

2018); *Hyde*, MD-15-02641-PHX-DGC, Doc. 12736 (D. Ariz. Sept. 25, 2018). Indeed, while *Tinlin* settled before trial, the letter was ultimately admitted in redacted form at trial in *Booker*, *Jones*, and *Hyde*. Trial Tr. Day 9, at 1888:21 to 1892:25, *Booker v. C. R. Bard, Inc.*, CV16-00474-PHX-DGC (D. Ariz. Mar. 27, 2018); Docket Order, *Jones v. C. R. Bard, Inc.*, MD-15-02641-PHX-DGC, Doc. 11256 (D. Ariz. May 29, 2018); Minute Entry, *Hyde v. C. R. Bard, Inc.,* MD-15-02641-PHX-DGC, Doc. 12736 (D. Ariz. Sept. 25, 2018). Accordingly, the court will RESERVE as to the admissibility as to either phase of the trial.

6. Exclude General Expert Opinions in Dr. Garcia's Post-MDL Report Titled "Expert Report Regarding Matters Relating to Bard IVC Filters and Clot Formation and Marie Wright" (dkt. #101)

Defendants' sixth motion in limine further seeks to exclude Dr. Garcia's June 2020 expert report titled "Expert Report Regarding Matters Relating to Bard IVC Filters and Clot Formation and Marie Wright."[5] Notably, Dr. Garcia also produced an earlier report in 2017 while this case was still pending in the MDL, over which there is no admissibility challenge.

Defendants point out that the MDL Court's order remanding this case, as well as the parties' joint status report regarding issues remaining to be resolved, state that all general expert discovery was completed while the case was pending in MDL. (Dkt. #3 at 11, 31-31; dkt. #12 at 2.) According to defendants, plaintiff is now attempting to use a new expert report proffered by Dr. Garcia *after* this case was remanded from the MDL in 2019 and contrary to the MDL court's order and the parties' joint report.

[5] As indicated by the title of the report, this was a case-specific report concerning plaintiff Marie Wright. *Wright v. C. R. Bard, Inc.*, 3:19-cv-2176 (N.D. Tex.).

Plaintiff does not appear to dispute that Dr. Garcia's 2020 report offers new, general opinions, rather than case-specific ones. However, she argues that this late disclosure was harmless and should be permitted. Federal Rule of Civil Procedure 37(c)(1) provides that "[i]f a party fails to provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless." Factors that guide the district court's discretion consist of: (1) the prejudice or surprise to the party against whom the evidence is offered; (2) the ability of the party to cure the prejudice; (3) the likelihood of disruption to the trial; and (4) the bad faith or willfulness involved in not disclosing the evidence at an earlier date. *Bronk v. Ineichen*, 54 F.3d 425, 428 (7th Cir. 1995) (citing *Spray-Rite Serv. Corp. v. Monsanto Co.*, 684 F.2d 1226, 1245 (7th Cir. 1982)).

In related cases, courts considering similar objections to Dr. Garcia's 2020 report appear to have arrived at different conclusions about its admissibility. In *Peterson v. C. R. Bard Inc.*, Case No. 3:19-cv-01701, Doc. 64 (D. Or. Dec. 17, 2020), Judge Mosman granted defendants' motion to strike Dr. Garcia's report in a text order on the grounds that new general opinions were not allowed under the parties' status report and MDL scheduling order. In contrast, courts in four other, related cases have denied defendants' objections to the introduction of Dr. Garcia's 2020 report. *Mattle v. C.R. Bard, Inc., et al*,, Case No. 2:19- cv-07795-SAB (C.D. Cal. Mar. 22, 2021); *Compton v. C.R. Bard, Inc., et al.*, Case No. 4:19-cv-00729 (W.D. Mo. Mar. 1, 2021); *Taylor v. C.R. Bard, Inc.*, et al., No. 2:19-cv-01172- MCJ (W.D. Pa. April 15, 2021); *Munson v. C. R. Bard, Inc.,* Case No. 3:14-cv-279

(N.D. Miss. April 13, 2021). These cases all concluded that the late-disclosure of the report was harmless as defendants were aware of Dr. Garcia's opinions included in the 2020 report well before the transfer order, and that defendants also had the opportunity to challenge those opinions. The court agrees with the reasoning in these latter cases, and concludes that the late filing of Dr. Garcia's 2020 report is harmless, and thus his testimony on these subjects will not be excluded.[6] Accordingly, this motion is DENIED.

7. Exclude Testimony Related to Damages During the Liability Phase of Trial (dkt. #102)

Under the Federal Rules of Civil Procedure, bifurcation is governed by Rule 42(b), which allows federal courts discretion to order bifurcation of issues "[f]or convenience, to avoid prejudice, or to expedite and economize[.]" Fed. R. Civ. P. 42(b). In keeping with this court's normal practice, Magistrate Judge Crocker bifurcated the trial into liability and damages phases. (Dkt. #18 at 5.) Defendants apparently simply seek to confirm this order (although the phrasing of defendants' motion could be read to exclude relevant evidence as to liability), and ask that plaintiff be precluded from submitting any evidence or testimony regarding her alleged damages during the liability phase. Although seemingly unnecessary given Judge Crocker's earlier ruling, defendants' motion is perhaps wise, as plaintiff's opposition indicates that she believes that the bifurcation extends only to the issue of punitive damages.

[6] Unlike some other federal courts, this court deems expert reports as the hearsay they are, and under ordinary circumstances does not admit these reports, although the court will restrict expert's testimony to the scope of those reports and may admit certain attachments to the extent separately admissible or appropriate as demonstratives.

Therefore, the court clarifies that the trial will be divided into at least two phases: liability and damages. As a result, unless the parties can convince the court otherwise, "the fact of *injury* belongs in the first trial and the *quantification of the injury* by means of an assessment of damages in the second." *Hydrite Chem. Co. v. Calumet Lubricants Co.*, 47 F.3d 887, 890-91 (7th Cir. 1995) (emphasis added). Accordingly, this motion in limine will also be GRANTED except to the extent it could be misconstrued to exclude evidence relevant to issues of liability.

8. Exclude Plaintiff's Hearsay Testimony (dkt. #103)

Defendants' final motion in limine seeks to exclude hearsay testimony from plaintiff Johnson regarding an alleged statement made by her physician -- Irina Goncharova, M.D. -- and an alleged statement by her co-worker, Charlotte Vietch. In particular, plaintiff testified that after the unsuccessful attempt to remove the filter, Dr. Goncharova told Johnson that, "she could not retrieve it. She attempted and that I would be -- I said -- Well, I don't exactly recall what my exact words were, but a quote I remember very vividly was she told me that I would just be filtered for life." (4/15/2020 Johnson Dep. (Dkt. # 31) 35:16-23.) Plaintiff also testified that several years after Dr. Goncharova attempted unsuccessfully to remove the filter, and before the filter was later removed (at least in substantial part), Johnson had a conversation with Vietch -- a former co-worker of plaintiff's at Mercy Hospital & Trauma Center -- where Vietch asked her, "Nat, do you still have that filter?" (*Id.* at 41:14-15.) Plaintiff described the conversation as one "with a co-worker who had been a participant in a procedure where a patient's IVC filter had migrated and perforated the large vessel and the patient died, bled out." (*Id.* at 38:8-11.)

Plaintiff testified that she did not know any of the particulars of the alleged patient's case, including what brand filter was implanted in the patient. (*Id.* at 38:18-23.)

Plaintiff objects to the exclusion of these statements on two grounds. First, she argues that the statements are not being offered for the truth of the matter asserted, and therefore are not hearsay at all. In particular, she intends to offer these statements to "show her state of mind in delaying a second retrieval attempt and to counter Bard's anticipated narrative that her retrieval attempts were 'lawyer-driven.'" (Dkt. #144.) While both statements may be admitted for this narrow purpose, they would be excluded as to liability if defendants will agree not to challenge plaintiff's decision to delay a second attempt at renewal.

Second, plaintiff contends that these statements fall under the residual exception to the hearsay rule, which provides that a hearsay statement may be admissible to prove the truth of the matter asserted if "the statement is supported by sufficient guarantees of trustworthiness -- after considering the totality of circumstances under which it was made and evidence, if any, corroborating the statement," and "it is more probative on the point for which it is offered than any other evidence that the proponent can obtain through reasonable efforts." Fed. R. Evid. 807(a)(1)-(2). However, this rule is inapplicable here, as neither of the statements have any additional corroboration in the record and are not otherwise supported by guarantees of trustworthiness, especially as reported by an interested party. Accordingly, the court will GRANT IN PART defendants' final motion in limine and RESERVE as to the remainder. Thus, the statements may not be admitted to show the truth of the matter asserted, although they may be relevant if used only for

some, narrower and relevant purpose.

III. Plaintiff's Motions in Limine (dkts. #110, 112, 115, 117, 119, 121)

1. "Omnibus" Motions (dkt. #110)

Plaintiff advances a series of motions in limine in what she styles as an "omnibus motion to preclude reference to, argument, or evidence of certain subjects." (Dkt. #110.) The court addresses the sub-parts as follows:

1.1. Preclude certain references to attorney advertising

Plaintiff seeks to preclude: (a) "[a]ny reference to advertising by Plaintiff's counsel (including members of Martin Baughman, PLLC, Waters & Kraus, LLP, or Branstetter, Stranch & Jennings, PLLC) or any other plaintiffs' attorneys";[7] (b) "[a]ny reference to IVC Filter Litigation as 'lawyer driven litigation' or any similar description"; and (c) "[a]ny reference to the manner, or circumstances under which Plaintiff retained counsel." Defendants oppose this requested order, but only in part.

The court agrees that this material is largely irrelevant. However, the court will consider asking a general question about attorney advertising during *voir dire* to assess a potential juror's exposure to related advertising. Defendants additionally contend that evidence of attorney advertising is necessary to put into context evidence that plaintiff may present of an internal Bard email stating that a change in filter names was necessary to

[7] The court notes that the parties have stipulated to exclude "any reference to advertising by counsel for this Plaintiff (including members of Martin Baughman, LLP and Dalimonte, Rueb, Stoller, LLP)." (Dkt. #86.)

"break with the baggage" associated with previous versions. According to defendants, the "baggage" referred to in the email is the attorney advertising website "filterlaw.com," although this seems a stretch.[8] Defendants also contend that plaintiff could introduce other evidence that may require reference to attorney advertising to properly contextualize the evidence. Again, given the inherent prejudice and general lack of relevance of this subject matter, the court will GRANT the motion, while allowing defendants to proffer evidence as to attorney advertising outside the jury presence if they contend plaintiff has opened the door.

1.2. Preclude evidence of good character or acts

Plaintiff next seeks to preclude evidence that "Bard is a 'good company' or has 'nice employees,' the conscientiousness of its employees, usefulness of its products, or that Bard has a mission statement, core values, and/or a vision statement to help people or save lives, or similar gratuitous complementary testimony or comments." (Dkt. #110.) Defendants object to this motion on the grounds that it is impermissibly vague and seeks to exclude relevant background information.

Some of the evidence that plaintiff apparently seeks to exclude would be relevant to the issues in this case, including the nature and usefulness of Bard's products, as well as the conscientiousness of its employees, particularly to rebut plaintiff's evidence that

[8] In *Jones*, the court granted plaintiff's motions in limine to exclude evidence of (1) contingency fee agreements, (2) plaintiff's counsel specializing in personal injury and products liability litigation, and (3) evidence that plaintiff's husband IVC filter advertising on facebook. *Jones v. C.R. Bard, Inc.*, No. MDL 15-02641-PHX-DGC, Doc. 10947 (D. Ariz. May 3, 2018). However, the *Jones* court deferred on whether defendants could present evidence of attorney advertising to rebut the "break the baggage" evidence. *Id.* Accordingly, plaintiff may be playing with fire if she chooses to offer this evidence at trial.

defendants knowingly disregarded patient safety. Accordingly, this motion in limine will be GRANTED IN PART AND DENIED IN PART as overly broad. On appropriate objection at trial, plaintiff may seek to exclude evidence that is principally offered to prove the "corporate character" of defendants. *See* Fed. R. Evid. 404(a) ("Evidence of a person's character or character trait is not admissible to prove that on a particular occasion the person acted in accordance with the character or trait."); *see also Booker v. C.R. Bard Inc.*, MDL 15-02641-PHX-DGC, Doc. 10075 (D. Ariz. Feb. 15, 2018) (denying similar motion in limine). Similarly, to the extent relevant, the court will entertain cumulative objections if defendants abuse this ruling.

1.3. Preclude Any Suggestion that the Filter Caught or Stopped a Clot and Saved Plaintiff's Life

Plaintiff argues that: (a) the Meridian Filter was implanted in Johnson as a precaution; (b) there is no evidence that it ever actually caught any clot; and (c) the only way to know if a filter stops a clot is to monitor with a scan in real time. Defendants counter that they should be able to reference the Meridian Filter's general ability to save lives to contextualize the product and to establish the medical benefits of the filter, as well as to introduce evidence regarding Johnson's medical history and the reason that the filter was implanted. The court agrees that defendants' proposed evidence is probative and is not outweighed by unfair prejudice or other considerations. As the District Court for the Eastern District of Pennsylvania observed in denying a similar motion in limine in a Bard IVC filter case, "[e]vidence is not irrelevant and unduly prejudicial merely because it conflicts with one party's side of the story." *Keen v. C.R. Bard, Inc.*, No. CV 13-5361, 2020

WL 4818801 (E.D. Pa. Aug. 19, 2020). Accordingly, this motion will be DENIED.

1.4. Preclude Refences to Any Other Bard Non-Filter Products

Plaintiff next argues generally that defendants should be prohibited from introducing evidence of Bard's non-filter products, as "[t]he only purpose that Bard might want to reference other Bard products is to curry favor and create good will with the jury because a juror might like or have been treated with that other product or to imply that an adverse verdict against Bard would affect the availability of the other product." (Dkt. #110 at 5.) Defendants argue that plaintiff's motion is vague and overly broad, and urges that the court "not deny the motion outright," and address objections "at trial on a case-by-case basis." (Dkt. #126 at 5 n.5.) As with its ruling in 1.2 above, the court will GRANT IN PART AND DENY IN PART, agreeing that evidence of non-filter products would generally appear to be irrelevant, but that given the vagueness of plaintiff's requested motion, the admissibility of *some* evidence addressing the nature of Bard's business generally is appropriate, but again, less will be more with respect to any related cumulative objection once relevant, unchallenged general evidence has been admitted on this subject. The court further RESERVES as to the possible relevance of any evidence of this kind as to the punitive damages phase of trial.

1.5 Preclude Certain Anecdotal Testimony

In another vague motion, plaintiff requests that the court exclude "[a]necdotal testimony by medical witnesses or medical experts about their experience with patients who have died of pulmonary embolism." (Dkt. #110 at 5-6.) Since an issue in this case

is whether the Meridian Filter was "unreasonably dangerous," Wis. Stat. § 895.047(1)(a), the benefit of the filter is relevant and so this motion will be DENIED. Specifically, the clinical experience of physicians or experts of patients dying of pulmonary embolisms is directly relevant to this issue.

1.6.A. Preclude Refences to Experts Not Called to Testify

According to plaintiff, "Bard should be precluded from referring to any individual not called as an expert for Plaintiff in this case as a 'Plaintiff's expert,' including Dr. Michael Streiff[.] Such would only harm Plaintiff with no underlying merit." (Dkt. #110 at 6.) Plaintiff has offered no further argument or support for this vague request. Defendants further note that Drs. Streiff and Garcia proffered joint opinions, but only Dr. Garcia will appear as an expert, and that given the joint nature of the report defendants seek to be allowed to ask questions regarding the non-testifying doctors' statements. The court agrees, and it will DENY this motion barring greater specificity.

1.6.B. Preclude References to Plaintiff's Experts' Testimony in Cases Against Other Manufacturers

Plaintiff argues that any reference to the number of times an expert has testified in cases against other medical device manufacturers is irrelevant and should be precluded. However, this evidence may be relevant to the bias of an expert. *See United States v. Hunter*, 932 F.3d 610, 620-21 (7th Cir. 2019) (explaining that "exposing witness bias [is] an acceptable means of impeachment under the Federal Rules of Evidence"). Accordingly, this motion will also be DENIED.

1.7.A. Preclude Any Reference Implying That Numbers of Complaints Shows the Safety of IVC Filters or that the Complaint Rate Equals the Complication Rate

In the *Booker* bellwether trial, evidence of defendants' internally calculated reporting rates was admitted over the MDL plaintiff's hearsay and Rule 403 objections. Trial Tr. 2349:16–2351:2, *Booker v. C. R. Bard, Inc.*, MD-15-02641-PHX-DGC (D. Ariz. Mar. 2018). Moreover, the District Court for the District of Oregon recently considered and rejected a similar motion. *See* Pretrial Conf. Tr. 18:11–19:21, *Peterson v. C. R. Bard, Inc.*, No. 3:19- cv-01701-MO, Doc. 161 (D. Or. April 20, 2021). Nevertheless, plaintiff here argues that defendants should be precluded from introducing evidence of reporting rates, arguing that it is "inaccurate" and "misleading." (Dkt. #110 at 6-7.) However, this evidence appears central to the dispute in this case -- namely, whether the Meridian Filter was unreasonably dangerous, whether its warnings were adequate, and whether the benefits of the device outweigh its risks. If anything, plaintiff's objection goes to the weight, not the admissibility, of this evidence, and her motion will be DENIED.

1.7.B. and 1.7.C. Preclude Any Refence to the Number of People Allegedly Implanted or Treated with IVC Filters Based on the Number of Units Sold and Preclude Any Refence to the Total Product Sales for IVC Filters

Plaintiff argues that the number of IVC units sold does not reliably indicate the number of people actually receiving IVC filters, and she further seeks to preclude any reference to the total product sales for IVC Filters at trial. Defendants will apparently use the total number of units sold as the "denominator" to calculate its reported complication rates. However, defendants' expert acknowledges that not all IVC filters sold are actually implanted, while further explaining that given the relatively high price of Bard's filters, the

large majority of filters sold are likely implanted. Moreover, defendants' reported complications rates appears relevant to both liability and punitive damages. Thus, although the number is admittedly not perfect as the rate could be artificially lowered by filters sold but not implanted, defendants' evidence is transparent about this fact, and plaintiff is free to present evidence at trial clarifying the meaning of defendant's reported complication rates. Given the relevance of the evidence and seeing no admissibility problems, therefore, the court will DENY this motion as well.

1.7.D. Preclude Any Reference to Any Specific Percentage of Doctors Who Use IVC Filters

Defendants represent that they have no intention of offering evidence of the specific percentage of doctors who use IVC filters. Accordingly, the court will GRANT this motion.

1.7.E. Preclude any Reference as to what "All Physicians Know" Regarding Risks or Benefits of Procedures or Devices, DVT, or Similar Statements

Defendants again represent that they do not intend to offer evidence about what "all" physicians know, and so the court will also GRANT this motion. At the same time, defendants are free to present evidence about what the medical community knows and accepts about IVC filter use, as well as their known risks and benefits, as such evidence appears directly relevant to plaintiff's claims.

1.8. Preclude Evidence of Trade Associations' or Organizations' Opinions for the Purpose of Supporting Legal Theories, Acceptable Rates of Complications, and/or Safety Profiles

Plaintiff next seeks to exclude evidence regarding certain information published by physician trade associations on the subject of IVC filters. Although her motion is phrased

broadly, the only evidence referred to by plaintiff are guidelines published by the Society for Interventional Radiologists ("SIR"), and so the court will limit its discussion to the SIR Guidelines. Should defendants wish to present any other evidence related to opinions of trade associations or organizations, it should make a proffer outside the jury's presence.

Among other things, the SIR Guidelines discuss the complications of fracture, tilt, migration, and penetration of the IVC of certain filters, including the Meridian Filter and other Bard IVC Filters. (Dkts. #110-6, 110-8.) These numbers appear to be based on a review of medical literature regarding reported complication rates. (Dkts. #110-6, 110-8.) Also, the 2016 version of the guidelines specifically state that the document is "an educational tool designed to assist practitioners in providing appropriate radiologic care for patients," and the "Practice Parameters and Technical Standards" included in the guidelines "are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care." (Dkt. #110-8.) Defendants' expert and the lead author of the SIR Guidelines, Dr. Grassi, further testified that "[o]ur SIR guidelines were designed for physicians and practitioners . . . in an educational and instructive fashion and for those who are involved with IVC filter placements," but the Guidelines "did not create safety thresholds with respect to the filters studied that relate to perforation, fracture, migration, tilt, or the inability to remove the filter." (Grassi Dep. (dkt. #110-7) 113:20-24, 770:24-771:7.)

In the *Booker* bellwether case, the court initially denied a similar motion in limine made by the plaintiff, *Booker v. C.R. Bard, Inc.*, MDL 15-02641-PHX-DGC, Doc. 10258 (D. Ariz. Mar. 1, 2018), although the court ultimately admitted the two SIR Guideline

documents at trial for "purposes of notice and knowledge within the medical community . . . instruct[ing] that the jury cannot consider it for the truth of the facts and details included in it." (Dkt. #126-5 at 22.) The *Hyde* court took the same approach, denying plaintiff's initial motion in limine seeking to exclude the SIR Guidelines, 2018 WL 4215028, at *4, but ultimately admitting the evidence to show notice and knowledge within the medical community with a limiting instruction to the jury. (Dkt. #126-8 at 3-8.) *See also* Pretrial Conf. Tr. 18:11–19:21, *Peterson v. C. R. Bard, Inc.*, No. 3:19- cv-01701-MO, Doc. 161 (D. Or. April 20, 2021) (reserving on a similar motion in limine brought by the plaintiff in light of "pretty serious potential FRE problems," pending specific rulings "at trial").

This court also anticipates that the SIR Guidelines will be admitted for the purpose of establishing notice and knowledge, but will entertain a cautionary instruction with respect to its proper use by the jury. Accordingly, the court will DENY plaintiff's motion as to the admissibility of the evidence for purposes other than the truth of the matter asserted, with leave for plaintiff to proffer an appropriate cautionary instruction during or at the end of trial.[9]

[9] In addition, although the statements in the documents would appear to be hearsay generally, a specific statement in the documents could fall under a hearsay exception. For example, Federal Rule of Evidence 803(18) recognizes an exception for "[a] statement contained in a treatise, periodical, or pamphlet if: (A) the statement is called to the attention of an expert witness on cross-examination or relied on by the expert on direct examination; and (B) the publication is established as a reliable authority by the expert's admission or testimony, by another expert's testimony, or by judicial notice." Absent further proffer outside the jury's presence as to the admissibility of the specific statement, however, the court's ruling stands.

1.9. Preclude References to IVC Filter Products Being the "Standard of Care"

Plaintiff next argues that defendants should be precluded from admitting evidence which refers to "IVC filters, generally, or the Meridian filter, specifically as the standard of care." (Dkt. #110 at 11.) Defendants respond that they do "not intend to present evidence that its filters are 'the' standard of care." (Dkt. #126 at 15.) However, they *do* intend to present "evidence that placement of IVC filters in response to certain medical situations is within the medical standard of care for patient treatment." (*Id.*) In response to the same motion in limine, Judge Campbell concluded in *Booker* that "[e]vidence 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." 2018 WL 1109554, at *5. Although *Booker* was decided under Georgia law, Wisconsin law also requires consideration of whether the product was "not reasonably safe" by virtue of a defective design or warnings, which likewise can involve a consideration of the relative risks and benefits of the product. Wis. Stat. § 895.047. Under Wisconsin law, plaintiff will further have to prove that if her physician were properly warned, she would have altered her behavior and avoided injury. *See In re Zimmer, NexGen Knee Implant Prod. Liab. Litig.*, 884 F.3d 746, 752 (7th Cir. 2018). Thus, whether implanting an IVC filter in Johnson was within "the medical standard of care" is relevant. Nevertheless, to the extent that references or arguments to IVC filters themselves being "the standard of care" may confuse the jury, the court will follow the lead of the *Booker* court and instruct the parties to refer to the "medical standard of care" when referring to any standard for implanting IVC filters. *Booker*, No. CV-16-00474-PHX-DGC,

2018 WL 1109554, at *5. Accordingly, plaintiff's motion is GRANTED.

1.10 Preclude Any Reference to the Number of Documents that Bard has Produced or the Number of Current and/or Former Employees that Bard has Produced for Deposition

Plaintiff observes that substantial discovery has occurred in the Bard IVC Filter MDL, and she argues that "[t]o refer to the overall discovery would only imply that Plaintiff had somehow harassed Bard, which would be unfairly prejudicial." (Dkt. #110 at 3.) The court agrees that such evidence is irrelevant and will GRANT plaintiff's motion. Defendants' arguments to the contrary are not persuasive. First, references to voluminous discovery is more distracting than relevant should plaintiff claim that defendants withheld information and documents from its sales representatives, and as a result, to physicians implanting its filters. Second, defendants are free to point out that plaintiff's experts did not review certain, relevant documents or portions of depositions, but argument or reference to defendants' producing over eight million documents or to every individual produced by defendants for deposition amounts to irrelevant hyperbole.

1.11.A. and B. Preclude Reference to Fault or Negligence of Non-Parties and Preclude Reference to or Adverse Inference For Not Suing All Potential Parties

Plaintiff next argues that any suggestion that a non-party, such as Johnson's physicians, "had any responsibility for Plaintiff's injuries is improper" and should be excluded. (Dkt. #110 at 14.) This motion is DENIED. The medical treatment that Johnson received is highly relevant to the jury's determination of causation and will not be excluded. *See Westrich v. Mem'l Health Ctr., Inc.*, 2013 WI App 73, ¶ 21, 348 Wis. 2d 262,

831 N.W.2d 824 (trial court erred in excluding evidence of a "potential alternative cause" for plaintiff's injury). Plaintiff additionally argues that defendants should not be permitted to blame an "empty chair." (Dkt. #110 at 15.) However, such an argument *is* permissible under Wisconsin law. *Connar v. W. Shore Equip. of Milwaukee, Inc.*, 68 Wis. 2d 42, 44-45, 227 N.W.2d 660 (1975) ("It is established without 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 tort-feasors either by operation of law or because of a prior release.").

1.12. Preclude Any Reference to Plaintiff Having Filed Bankruptcy

Finally, as to plaintiff's "omnibus motion," plaintiff argues that her having filed bankruptcy in the past is not relevant and should be excluded. In response, defendants agree not to raise this issue, although they seek to reserve the right to raise the issue outside the presence of the jury if they believe that plaintiff has opened the door to its admission during trial. This approach is proper, and the court will GRANT this motion subject to revisiting it should plaintiff "open the door."

2. Preclude References to the Clearance of Bard IVC Filters by the FDA, and Lack of FDA Enforcement Action as Proof of Safety and Efficacy (dkt. #112)

In this separate motion, plaintiff seeks to exclude evidence of the FDA's 510(k) "clearance" of Bard IVC filters, as well as the lack of FDA enforcement action against defendants. As discussed at summary judgment, the 510(k) process is a premarket

submission made to FDA to demonstrate that the device to be marketed is substantially equivalent to a legally marketed device.[10] Plaintiff argues that because the 510(k) process is not a finding of safety or efficacy, any evidence by defendants related as to the clearance of the Meridian Filter under this process is irrelevant or at least has the potential to mislead the jury into thinking that the FDA found it to be safe and effective. Defendants object to this motion, arguing that evidence of the devices clearance of the 510(k) process is relevant and admissible.

There exists legal support for both parties' positions. In *Cisson v. C.R. Bard Inc.*, 810 F.3d 913, 922 (4th Cir. 2016), the Fourth Circuit affirmed the district court's ruling excluding evidence of 510(k) clearance. *Id.* at 922. In that case, the district court was concerned about the "substantial risk of misleading the jury to believe that FDA 510(k) clearance might be dispositive of the plaintiffs' state law claims" and the possibility that such evidence would lead to a "mini-trial on the 510(k) process and enforcement[.]" *Cisson v. C.R. Bard Inc.*, No. 2:10-CV-01224, 2013 WL 3282926, at *2 (S.D.W. Va. June 27, 2013); *see also Kaiser v. Johnson & Johnson*, 947 F.3d 996, 1018 (7th Cir. 2020) (affirming exclusion of evidence related to 510(k) process in product liability action).

On the other hand, in *Booker*, Judge Campbell concluded that: (1) evidence of the 510(k) process was relevant to the plaintiff's claims of design defect and to punitive damages; (2) concerns that such evidence might mislead the jury could be addressed by

[10] At that stage of the case, this court concluded that defendants' compliance with the 510(k) process created no presumption as to that the product is safe or effective. (Dkt. #89.) However, this ruling does not automatically render the 510(k) process irrelevant or inadmissible for all purposes.

efficient management of the evidence and, if necessary, a limiting instruction; and (3) the absence of evidence regarding the 501(k) review process could run the risk of confusing the jury as many relevant events occurred in the context of that review. *Booker v. C.R. Bard Inc.*, 289 F. Supp. 3d 1045, 1047 (D. Ariz. 2018). In considering the concerns raised in *Cisson* to the contrary, Judge Campbell concluded that they could "be adequately addressed without excluding relevant evidence to the detriment of Defendants." *Id.* at 1049. Even in *Booker*, however, defendants were precluded from presenting "evidence or argument that the FDA 'approved' the [Bard IVC] 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.'" *Id.; see also Keen v. C.R. Bard, Inc.,* No. CV 13-5361, 2020 WL 4818801 (E.D. Pa. Aug. 19, 2020) (following Judge Campbell's decision in *Booker* and denying plaintiff's motion to exclude evidence of the FDA's 510(k) clearance of the Bard IVC Filter altogether).

Since a brief explanation of the 510(k) process may help the jury understand the relationship between the Recovery, Meridian, and other filters, provided that defendants understand that introduction of the truncated review and clearance of the Meridian filter will open up relevant review and clearance of other filters, the court will RESERVE on this motion pending further discussion at the FPTC.

As for evidence and argument that the FDA took no enforcement action against defendants, plaintiff argues that any such evidence would be irrelevant, as well as misleading in suggesting that the lack of enforcement amounts to a determination of product safety. Judge Campbell considered a similar issue, and concluded: "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)." *Booker*, 289 F. Supp. 3d at 1050. Not fully understanding the context in which some or any of this evidence would be relevant, the court will also RESERVE on this question pending discussion at the FPTC.

3. Preclude Any Reference to IVC Filters as Lifesaving Devices or to Statistics of Thrombosis and Pulmonary Embolism (dkt. #115)

In her third motion in limine, plaintiff argues that defendants should be prevented from referencing testimony or evidence suggesting that IVC filters save lives or provide a clinical benefit. In particular, plaintiff points to evidence suggesting that IVC filters did not improve the rates of pulmonary embolisms, or at least that no good evidence exists to prove their benefits. Defendants counter that they should be able to reference the Meridian Filter's (alleged) ability to save lives to contextualize the product and to establish the medical benefits of the filter.

The court agrees that defendants' proposed evidence is relevant. Plaintiff's claims require her to establish that the product was not reasonably safe by virtue of its design and/or warnings, Wis. Stat. § 895.047(1)(a), to which defendants may respond with evidence of the medical benefits of the product. This evidence may also be relevant to establish a reasonable alternative design for the filter. Moreover, plaintiff has not demonstrated that the probative value of this evidence is outweighed by unfair prejudice or other considerations. Indeed, plaintiff's principal argument against defendants' medical benefit evidence primarily rests on her assertion that it is weak, but this goes to its weight

rather than its admissibility. As the District Court for the Eastern District of Pennsylvania observed in denying a similar motion in limine in another Bard IVC filter case, "[e]vidence is not irrelevant and unduly prejudicial merely because it conflicts with one party's side of the story." *Keen v. C.R. Bard, Inc.*, No. CV 13-5361, 2020 WL 4818801 (E.D. Pa. Aug. 19, 2020). Accordingly, this motion will be DENIED.

4. Preclude Reference, Argument, or Evidence of the 2008 Surgeon General's Call to Action (dkt. #117)

In 2008, "The Surgeon General's Call to Action to Prevent Deep Vein Thrombosis and Pulmonary Embolism" asked for "stakeholders to come together in a coordinated effort to reverse the projected trends and to dramatically reduce the pain and suffering caused by [deep vein thrombosis] and [pulmonary embolism]." (Dkt. #117-4.) Plaintiff seeks to exclude references to this publication, on the grounds that it is hearsay, irrelevant, and prejudicial. (Dkt. #117 at 3.) Defendants point out that Judge Campbell considered a similar motion in limine in the *Hyde* bellwether case, ultimately concluding that the publication was admissible and should not be excluded. *Hyde v. C.R. Bard Inc.*, No. CV-16-00893-PHX-DGC, 2018 WL 4279833, at *3 (D. Ariz. Sept. 7, 2018).

The court agrees with Judge Campbell's assessment. First, the publication is not hearsay as it falls under the public records exception. Fed. R. Evid. 803(8); *Hyde*, 2018 WL 4279833, at *3; *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"). Second, the publication is relevant to plaintiff's claim that the filter was not reasonably safe, which

necessarily involves a risk-benefit analysis. *See Hyde*, 2018 WL 4279833, at *3 ("The [Surgeon General's] 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.'"). Finally, the report itself does not present any risk of unfair prejudice to plaintiff. To the extent that defendants intend to argue at trial that the Surgeon General "somehow compelled or condoned actions of consequence here" as plaintiff fears (dkt. #117), plaintiff should object and the court will take appropriate action, just as it will for any other misstatement or misrepresentation of the evidence. For the reasons discussed above, therefore, this motion will be DENIED.

5. Preclude Reference to the Surgical Consent Form Signed by Plaintiff (dkt. #119)

Plaintiff next seeks to exclude reference to the surgical consent form signed by plaintiff, arguing that it is irrelevant or that any probative value is outweighed by unfair prejudice. In making this argument, plaintiff refreshingly points to this court's summary judgment opinion and order, which concluded that in applying the learned intermediary doctrine, *defendants'* duty was to warn plaintiff's implanting physician and not plaintiff herself. (Dkt. #89.) However, as defendants point out, the surgical consent form *is* relevant to what plaintiff's physician herself knew about the risks of IVC filters, which at least indirectly, speaks to the sufficiency of the warning provided to the physician and directly to the physician's own understanding of these risks. Moreover, the court does not see how the probative value of this form would be outweighed by any unfair prejudice. Accordingly, this motion will also be DENIED. *See Booker,* 2018 WL 934795, at *3

(holding that the consent form signed by plaintiff prior to the IVC filter procedure was relevant to what plaintiff's physician knew about the risks of IVC filters and what he told the plaintiff, and thus, relevant to plaintiff's failure to warn claim).

6. Lack of FDA Consent and its Effect of Defendants' Failure to Issue Warning Letters, Alter its Instructions for Use, or Effectuate Removal or Recall (dkt. #121)

Plaintiff's final motion in limine seeks to preclude defendants from:

> commenting on, referring to, introducing testimony or evidence, attempting to elicit testimony of, or arguing that in the absence of FDA consent, Bard was precluded from: 1) sending warning letters to physicians or consumers; 2) changing the instructions for use ("IFU") for its Meridian filter to add or strengthen warnings regarding the risk of migration, perforation, fracture and/or death associated with its IVC products that had undergone the 510(k) clearance process; or 3) effectuating a removal or recall, in the presence of the jury, whether directly or indirectly, and whether at voir dire or during trial.

(Dkt. #121.)

Defendants respond by promising "not [to] argue that [they] could never modify the Instructions for Use ('IFU') that accompanied the Meridian Filter, issue warning letters, or voluntarily initiate a recall without FDA consent." (Dkt. #131.) However, defendants also point to the FDA's explanation (and plaintiff's concession) that data from medical device reports ("MDRs") and from the FDA's Manufacture and User Facility Device Experience ("MAUDE") database, alone, cannot be used to establish rates of events, evaluate a change in event rates over time, or compare event rates between devices. (Dkt. #131 at 2.)

Thus, while plaintiff's final motion is GRANTED, defendants will not be precluded

from presenting evidence as to "the fact that warnings about failure rates and increased risks could not be based on MDR and MAUDE data alone." *Booker,* 2018 WL 1109554, at *12. Relatedly, defendants may also "present evidence and argument explaining the reasons why Bard filters were not recalled[and] the FDA's potential involvement in any recall effort." *Id.*

ORDER

IT IS ORDERED that the parties' motions in limine are GRANTED, DENIED, or RESERVED as set forth above.

Entered this 24th day of May, 2021.

BY THE COURT:

/s/

_____

WILLIAM M. CONLEY
District Judge