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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,

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[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