THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF MISSISSIPPI
OXFORD DIVISION

TONYA MUNSON **PLAINTIFF**

V. **CIVIL ACTION NO: 3:14cv279-MPM-RP**

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

ORDER

This cause comes before the court on the motion of defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard"), to dismiss and/or for summary judgment, pursuant to Fed. R. Civ. P. Rules 12 and 56. Plaintiff Tonya Munson has responded in opposition to the motion, and the court, having considered the memoranda and submissions of the parties, is prepared to rule.

On April 18, 2006, Munson had a medical device known as a G2 Filter System ("G2 Filter") surgically implanted into her inferior vena cava ("IVC") [*See* Complaint at 3]. The G2 Filter is a device designed to filter or "catch" blood clots called "thrombi" that travel from the lower portions of the body to the heart and lungs [*See id*. at 4]. Thrombi that reach the lungs are considered "pulmonary emboli" and can be fatal [*See id*.] IVC filters can be inserted either on a permanent or temporary basis. [*See id*.]. Munson alleges that on January 4, 2012 the G2 Filter "migrated in her body and is perforating her aorta and L4 vertebrae causing serious and ongoing physical, emotional, and economic damages." [*Id*. at 2; *see id*. at 24]. Due to the alleged failure of the G2 Filter, Munson alleges that she suffered very significant injuries, including the amputation of her lower leg, and that she incurred significant medical expenses and endured extreme pain and suffering. [*See id*. at 24].

On December 31, 2014 Munson filed a Complaint based on diversity jurisdiction [1]. Plaintiff alleges that, as early as 2005, Bard was aware and had knowledge of the fact that the G2 Filter was defective and unreasonably dangerous and was causing injury and death to patients. [*See* 1 at p. 13]. Plaintiff further alleges that despite Bard's knowledge of the dangers of the G2 Filter, it continued to market and offer the device for sale [*See* 1 at p. 14]. Due to plaintiff's reported experience with the G2 Filter, she seeks compensatory and punitive damages [*See* 1 at p. 35].

This case was part of the coordinated/consolidated pretrial proceedings in *In re: Bard IVC Filters Products Liability Litigation*, Multidistrict Litigation ("MDL") 2641, in the District Court of Arizona [39]. General expert discovery was conducted in the MDL. In September 2019, this case was remanded for further proceedings before this court [40]. Bard has presently moved to dismiss and/or for summary judgment, arguing that there exists no genuine issue of material fact regarding its liability and that it is entitled to judgment as a matter of law.

Discussion

For the reasons discussed below, this court concludes that this case presents material issues of fact regarding Bard's liability for at least some of the products liability claims raised by plaintiff in this case and that it would be improper to dismiss it before trial. In reaching this conclusion, this court is influenced both by generalized factors relating to Bard's conduct in releasing and marketing retrievable IVC filters such as the one in this case and also by this court's interpretation of Mississippi law as it relates to the specific legal arguments raised by Bard in its motion for summary judgment. This court will first discuss the generalized factors which lead it to conclude that triable jury issues exist in this case before proceeding to a more legalistic discussion of specific issues of Mississippi law raised by Bard in its motion.

In discussing the products liability claims in this case, this court begins by noting its agreement with Bard that these claims must be analyzed under the provisions of the Mississippi Products Liability Act ("MPLA"), and not Mississippi common law. Indeed, this court has long expressed its view that the MPLA was intended by the Mississippi Legislature to supplant the common law products liability jurisprudence of this state, and it sees no reason to deviate from this view in this case.

In a 2012 order in *Tucker v. Yamaha Motor Corp., U.S.A.,* No. 3:07CV143, 2012 U.S. Dist. LEXIS 191576 (N.D. Miss. Dec. 3, 2012), this court agreed with a manufacturer defendant that, even prior to 2012 amendments to the MPLA, common law negligence and implied warranty claims were properly considered to be subsumed into the provisions of the MPLA. In so holding, this court wrote that:

> While the Supreme Court in *Lawson v. Honeywell Intern*., Inc., 75 So.3d 1024, (Miss. 2011) did not specifically hold that a common-law negligence claim could not be asserted against a designer of a product who was also its manufacturer, this appears to be the implication of the Court's decision. This court submits that this is the most reasonable interpretation of § 11-1-63, since the statute is, by its terms, applicable to "any action for damages caused by a product except for commercial damage to the product itself." It would make little sense for the Legislature to so provide, only to permit plaintiffs to bypass its provisions by asserting a common-law negligence claim. This would render the enactment of the MPLA an exercise in legislative futility, since few, if any, plaintiffs would choose to proceed under the stricter provisions of the MPLA if they could simply assert a common-law negligence claim instead.
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> The court has similar concerns regarding the ability of plaintiffs to assert implied warranty claims in products cases. Indeed, the court finds even greater concerns in the implied warranty context, since negligence claims at least have their origin in tort law and are not far removed conceptually from MPLA claims (which itself incorporates a negligence analysis in its provisions). The implied warranty cause of action, by contrast, has long occupied a rather unclear status on the fringes of Mississippi products liability law, which is unsurprising considering its origins in commercial law.

Tucker, 2012 U.S. Dist. LEXIS 191576, at *16.

As this court noted in *Tucker,* it seems clear that if plaintiffs could side-step the rigorous provisions of the MPLA simply by asserting a common law negligence or implied warranty claim, then this would serve to render the enactment of that statute an exercise in legislative futility. Moreover, while the Legislature made it abundantly clear in its 2014 amendment to the MPLA that such was not its intent, this court was, as quoted above, already operating under the assumption that this was the case before this amendment. In light of the foregoing, this court agrees with Bard that plaintiff improperly asserts common law negligence and implied warranty claims in this case and that these claims should be dismissed. This court intends to try this case under the provisions of the MPLA, and any liability faced by defendant will be based upon the provisions of that Act.

Having said that, this court has long viewed products liability cases as being a form of litigation which tend to produce triable issues for a jury's consideration, since, in its experience, these cases often come down to a "battle of the experts" regarding rather technical matters as to which this court itself is most assuredly not an expert. This is certainly true in this case, which includes highly complex issues relating to liability and causation relating to the failure of a medical device. Unsurprisingly, each side has been able to offer expert testimony supporting their respective positions in this case, and, while a jury may find Bard's expert testimony in this context more reliable, this court believes that plaintiff has a legitimate case to make before the jury.

This court notes that, aside from the complexity of the expert testimony in this case, there are additional considerations which render it disinclined to take it from a jury's consideration. The seriousness of the liability issues in this case is underscored by the severity of the injuries suffered by plaintiff, which she describes in her brief as follows:

> This is a products-liability action in which Plaintiff seeks to recover damages for personal injuries caused by a Bard G2 inferior vena cava (IVC) filter implanted in her body, ostensibly to filter blood clots (thrombi) from her IVC and to thus prevent those clots from traveling from the lower portions of the body to her heart or lungs. As a result of Defendants' defective design and failure to warn, instead of filtering blood clots as intended, Plaintiff's filter migrated, perforated her IVC, and penetrated her aorta causing clots that migrated to her lower extremities and required the amputation of her right lower leg. A strut from the filter broke off and remains lodged in her right lung to this day.

[Plaintiff's brief at 4].

Clearly, these are very serious injuries, which required the amputation of plaintiff's lower leg, and, more importantly, her brief makes what this court regards as strong allegations that Bard's decision to rush its retrievable IVC filters to market in spite of clear safety warnings may have contributed to her injuries. Specifically, plaintiff writes in her brief that:

> Despite owning and selling an IVC filter that had a low incidence of complications and had never been associated with a patient death (the SNF), Bard recognized a financial opportunity to create a market for a "retrievable" filter by "aggressive marketing even in the absence of solid clinical history and in spite of documented negative clinical experiences." Thus, Bard developed the "Recovery" filter.
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> In its rush to get Recovery on the market, Bard cut significant corners. First, it never properly understood the environment of use for the IVC filters. Bard's Vice President of Research & Development admitted as much. And, internally, long before this lawsuit, Bard admitted as much: "After a year of commercialization, there are still many questions that need to be answered." The Recovery failed internal tests and performed worse than the SNF. And, just a month before full market release, its Special Design Review team raised serious questions and asked for "objective evidence" to support the safety and efficacy of the Recovery, including that certain criteria be supported and tests be done. Regardless, Bard never did any of those things before releasing the Recovery to the market.
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> Bard also never did repeatable, long-term clinical trials regarding the safety or efficacy of its devices. And the one study it held raised serious concerns about the safety and efficacy of its product. Of the first 32 patients evaluated, there were two fractures in one device, one migration, two tilts, one perforation, and 19 deployment problems. As a result of the fractures, the Canadian Institutional Review Board suspended the study. Bard promised the physician who ran the study, Dr. Murray Asch, that it would conduct additional safety studies before the filter was marketed.
>
> But it never did. Contrary to Dr. Asch's testimony that his study should never have been used as a basis for market clearance of the Recovery, Bard used it for just that. Further,

even before the Recovery went to full market release, Bard was already receiving reports of adverse events from the field. Despite these events, never identifying the root cause of the failures in the study (let alone an understanding of how the anatomy of the IVC actually performed in patients), and not conducting studies requested by Bard design review team members, Bard pushed ahead to get the Recovery on the American market.

It was successful. Predicated on the claim that the Recovery was substantially equivalent to the SNF in terms of safety and efficacy, Bard obtained clearance from the FDA to market the Recovery filter through the 510(k) process as a permanent device on November 2002, and for optional retrieval on July 25, 2003. As detailed in Section II.C., supra, Bard quickly obtained additional information of what it already knew but did not tell the public, including physicians—that the Recovery and subsequent filters were not the substantial equivalent of the SNF. Full market release of the Recovery was followed by significant migrations and fractures, including seven deaths the first year.

Based on reporting and internal analysis, Bard was fully aware that both the G2 and its predicate (the Recovery) were dramatically inferior to Bard's SNF and most competitor devices in terms of migration, tilt, perforation, and fracture. In early 2004, it learned that its products' design did not account for how the IVC actually performed and that its devices were causing injury and death at alarming rates. In the face of mounting reports of injury and death, and increasing physician and patient complaints, instead of taking its product off the market or warning the medical community of the dangers of its retrievable line of IVC filters, Bard actively sought to keep the medical community in the dark and protect its products' reputation. It hired outside spin doctors to help Bard develop a Crisis Communication Plan to control messaging to physicians and media (e.g., "downplay[ing]" "comparison with other filters [because it was] problematic in many ways"). It misled its own internal employees and sales representatives concerning dangers and failure rates.

Rather than pull its devices off the market, Bard engaged in a campaign of offering newer but equally defective designs to maintain its position in the market. In 2005, after the Recovery's mounting number of fractures, migrations, and deaths, Bard redesigned the filter to the G2 but never adequately tested the device to determine whether it actually fixed the problems. Indeed, it actively avoided certain tests for fracture resistance because it knew the results "would still fall outside of the acceptable range" and its engineers "didn't think the answer would support our design change as a viable option." Nonetheless, Bard pressed forward. Even when its internal analysis and the EVEREST study demonstrated significant complications with the G2 (even greater than the Recovery for several of them) and that the caudal migrations (which can cause perforation and fracture) presented an "unacceptable risk" of harm, Bard continued its marketing and sale of the product. Indeed, even when, in 2008, it identified significant design changes to the G2 that were essential to the safety of the device, it did not notify doctors or remove the product from the market. It kept selling.

Thus, despite the fact that Bard knew that its retrievable IVC filters: (1) had never been adequately tested clinically for safety and efficacy; (2) were vastly less safe and

> efficacious as the SNF; (2) were failing at a rate substantially higher than its competitors; and (3) were injuring and killing patients, Bard never: (a) identified the root cause of its filters' many failures; (b) provided the medical community or regulators with adequate, let alone complete, disclosure of the damning information described above; (c) recalled its filters (instead, allowing stock of prior devices to simply run out); (d) suspended sales of its retrievable IVC filters; or (e) implemented known design improvements to address alarming rates of filter migration and perforation. On this record, it would be "premature" to grant judgment in Bard's favor on Ms. Munson's claim of punitive damages.

[Plaintiff's brief at 52-54, record citations omitted].

In its reply brief, Bard chose not to substantively respond to most of plaintiff's allegations quoted above, writing that:

> As part of her Opposition, Plaintiff included a counterstatement of facts, much of which is argumentative mischaracterizations of the record, inadmissible, irrelevant, or immaterial as a matter of law. For example, the Opposition relies heavily on evidence pertaining to the Recovery filter, which is not at issue in this case. Even assuming that Plaintiff's claims are not time barred, Plaintiff's purported facts about the Recovery filter are not relevant, and hence inadmissible, to resolving claims premised on any of the MPLA's exclusive theories of liability. Furthermore, Bard controverts that statements about what Bard "knew" or Bard's motives are admissible evidence. On the contrary, the documents to which Plaintiff cites in support of these statements: (1) show very low rates of complication for the G2 Filter; (2) consist of out-of-context e-mail or business documents; or (3) consist of internal or external studies that long post-date Plaintiff's implant date. In sum, Plaintiff's counterstatement of facts does not raise any genuine issue of material fact as to any viable theory of recovery under the MPLA, or for punitive damages.

[Reply brief at 2].

This is Bard's reply to several pages of allegations in plaintiff's brief, supported by specific record citations. Bard's responses are rather conclusory and underwhelming. In light of Bard's limited engagement on this issue, this court believes that there are genuine issues of material fact as to whether it rushed its retrievable filters to the market, in spite of clear safety concerns that they were less safe than its permanent SNF filter already on the market. Of course, at the summary judgment stage, this court is required to interpret these disputed facts in the light most favorable to plaintiff, as the non-moving party. Having done so, this court, unlike Bard,

does not regard its conduct relating to the Recovery filter as irrelevant in this case, since, if it was willing to rush that filter to the market, then this raises fact issues as to whether it might have done the same thing with the G2 filter. Moreover, plaintiff makes specific allegations that Bard acted irresponsibly with regard to the G2 filter as well, and, as discussed below, a number of district judges have noted studies which suggest that this filter had a very high risk of fracturing and migrating in the body, compared to the SNF filter. These findings of other federal judges stand in contrast to Bard's conclusory assertion, stated above, that there are "very low rates of complication for the G2 Filter."

This court's overriding impression of Bard's summary judgment briefing is that it is long on technical legal defenses and short on factual defenses of the manner it went about designing, manufacturing and selling its retrievable IVC filters, including the G2 filter. To be certain, Bard is entitled to rely upon such technical legal defenses since, at the end of the day, they are the law. As the trial court, however, this court has the discretion to first ensure itself that it has the relevant facts at its disposal before it makes a ruling of law on these defenses. Ideally, this clarification of the facts would have been provided in summary judgment briefing, but that did not take place here. Therefore, this court finds it necessary to seek this clarification at trial, after which it will make a formal ruling on any directed verdict motions filed by Bard.[1]

Bard seeks dismissal now, but, in cases where, as here, this court is unable to conclude that a defendant acted as a responsible manufacturer, it is strongly inclined to resolve any legal

[1] In concluding that it should take this approach, this court is influenced by the fact that, in light of conflicting rulings in the Bard cases by Mississippi district judges, the governing law as it relates to some of the legal defenses raised by Bard is currently in the process of being determined. It is unclear how the Fifth Circuit will resolve these issues, and waiting until trial to rule on them ensures that this court will have the greatest possible clarification of the governing law.

issues following a full factual development at trial. In so stating, this court is very much aware that Mississippi products liability law places additional hurdles for a plaintiff to surmount, above and beyond demonstrating that a defendant manufacturer demonstrated a lack of due care. Nevertheless, this court places great weight on the question of whether a manufacturer acted responsibly in deciding whether any legal defenses it raises are best resolved before, or after, the presentation of evidence at trial. As discussed below, this court has grave doubts as it relates to Bard's conduct *vis a vis* its retrievable IVC filters, and, since these doubts were not assuaged in the summary judgment briefing, it concludes that further exploration of these issues is needed at trial.

Another factor which makes this court more likely to submit this case to a jury relates to the fact that the very first Bard "bellwether" trial, which appeared to involve allegations similar to those here, resulted in a large plaintiff's verdict which was upheld on appeal. *See In re Bard IVC Filters Prods. Liab. Litig.,* 969 F.3d 1067 (9th Cir. 2020). An Arizona district court recently described this litigation as follows:

> The first bellwether trial concerned Plaintiff Sherr-Una Booker and involved a Bard G2 filter. The filter had tilted, migrated, and fractured. . . . The jury found for Plaintiff Booker on her negligent failure-to-warn claim, and in favor of Defendants on the design defect and strict liability failure-to-warn claims. The jury returned a verdict of $2 million in compensatory damages (of which $1.6 million was attributed to Defendants after apportionment of fault) and $2 million in punitive damages. . . . Defendants appealed, arguing that the Court erred by denying summary judgment on their preemption defense, that a failure-to-warn claim was unavailable, and that the award of punitive damages was not supported by the evidence. The Ninth Circuit affirmed.

In re Bard IVC Filters Prod. Liab. Litig., 2021 WL 1616101, at *8 (D. Ariz. Apr. 26, 2021).

This court is well aware that each case is unique and should stand or fall on its own merits. At the same time, in deciding whether a plaintiff should even be allowed to present her case to a jury, this court is not required to ignore the existence of a similar case which resulted in

a large verdict which was upheld on appeal. In supplemental briefing submitted to this court, Bard notes that, since the adverse jury verdict in *Booker*, it has been able to secure defense verdicts in a number of other bellwether trials nationwide. While this fact suggests that retrievable IVC filter claims may well have significant weaknesses in the eyes of certain jurors, the fact that the cases in question did, in fact, go to trial constitutes helpful authority for the plaintiff in the summary judgment context.

In so stating, this court wishes to emphasize that it is completely open to the possibility that the ultimate "correct answer" in this case is that Bard neither manufactured a defective product nor failed to provide adequate warnings. Nothing in this court's opinion today should be construed otherwise. The question at this juncture is simply whether it is prepared to proclaim, based solely upon the summary judgment briefing, that Bard faces no potential liability in this case. It is not. Nevertheless, this court notes that it, along with the jury, will be educated regarding the highly technical issues in this case at trial, and it is certainly possible that it will view these matters more favorably to Bard after presentation of evidence at trial.

Given that this court concludes that this case should go to trial, it is not essential that it conclusively and irrevocably establish, at this juncture, which specific products liability claims should be decided by a jury here. To the contrary, this court believes that it makes more sense to first observe the evidence presented at trial and then to consider that evidence in light of the current state of the still-evolving law in this context. At this juncture, however, this court is tentatively inclined to submit two claims to the jury in this case, namely plaintiff's failure to warn and design defect claims under the MPLA. This court will discuss these claims, and its reasons for (tentatively) concluding that triable fact issues exist regarding them, in greater detail below.

Failure to Warn

In order for plaintiff to prevail on a failure-to-warn theory of recovery under the MPLA, she must prove by a preponderance of the evidence that at the time the G2 Filter left Bard's control: (1) it was defective because it failed to contain adequate warnings or instructions; (2) the defective condition rendered the product unreasonably dangerous to plaintiff; and (3) the defective and unreasonably dangerous condition of the Filter proximately caused plaintiff's damages. Miss. Code Ann. § 11-1-63(a)(i)(2), (ii), (iii). Plaintiff must also prove by a preponderance of the evidence that at the time the Filter left Bard's control, it knew or in light of reasonably available knowledge should have known about the danger that caused the damage for which plaintiff seeks recovery, and that her implanting physician (the ordinary user) would not have realized the Filter's dangerous condition. Miss. Code Ann. § 11-1-63(c)(i).

The Fifth Circuit has stated, in interpreting Mississippi law, that:

> Under the learned intermediary doctrine, which is codified in the Mississippi Products Liability Act, a manufacturer of a prescription drug has no duty to warn the end user of the drug's possible adverse effects. The manufacturer's duty to warn runs only to the prescribing physician, who acts as an intermediary between the manufacturer and the patient. The learned intermediary doctrine applies to medical devices as well as prescription drugs.

Smith v. Johnson & Johnson, Inc., 483 F. App'x 909, 913-14 (5th Cir. 2012) (per curiam) (internal citations and quotations omitted). "In order to make out a case for failure to warn under the learned intermediary doctrine, the plaintiff must establish that the treating physician, or a reasonable physician in the treating physician's position, would not have used the product had he received an adequate warning." *Id.* at 914.

In seeking dismissal of plaintiff's failure to warn claim under the MPLA, Bard relies heavily upon *Nelson v. C.R. Bard, Inc.,* 2021 WL 3578874, at *1 (S.D. Miss. Aug. 6, 2021), in which Judge Starrett recently dismissed failure to warn (and design defect) claims against Bard similar to the ones here. In rejecting plaintiff's failure to warn theory, Judge Starrett wrote in *Nelson* that:

> Plaintiffs only legal support for the theory that the warnings were inadequate because they did not include comparative failure rates is a Ninth Circuit case interpreting Georgia law wherein the Court stated, "A warning may be inadequate when a manufacturer knows its product carries a higher risk of injury than its competitor's similar product, and does not share that information with physicians." [89] at p. 14 (*citing In re Bard IVC Filters Product Liability Litigation,* 969 F.3d 1067, 1076 (9th Cir. 2020)). While courts in other states and circuits may have allowed claims to proceed under the theory that comparative risk information should be included in warnings, none of those rulings involved Mississippi law, and Plaintiffs have failed to establish why this Court should rule in their favor on this issue of first impression under Mississippi law, and to the contrary, the Court finds that it cannot.

Nelson, Slip op. at 12.

Judge Starrett thus rejected the "comparative risk" failure to warn theory advanced by the plaintiff in this case and in a large number of other Bard cases nationwide. Under this theory, the plaintiff contends that a manufacturer should be held liable not for failing to warn of a particular risk at all, such as the possibility that an IVC filter will fracture and migrate in the body, but for failing to warn that a particular filter had a *much higher risk* of such a complication occurring, relative to similar products.

In explaining his conclusion that Mississippi law required a rejection of this theory, Judge Starrett wrote that:

> Not only is there no Mississippi law expressly supporting Plaintiffs' theory, the Court finds that the 2017 Mississippi Supreme Court case of *Johnson & Johnson v. Fortenberry*, *supra*, in light of the facts in this case expressly does not. Fortenberry was a case involving the antipsychotic medication Risperdal from which the plaintiff allegedly developed a motion disorder called tardive dyskinesia. 234 F. 3d at 386. The case went to trial and the jury found in favor of the plaintiff on a failure to warn claim. Id. To prove that the warning for Risperdal was inadequate, Plaintiff had introduced the Defendants' promotional materials, internal

> documentation, and expert testimony. *Id.* at 392. On appeal from a denial of a motion for judgment notwithstanding the verdict, the Mississippi Supreme Court reversed and rendered the verdict, holding that the warning for Risperdal was adequate as a matter of law despite testimony from an expert neurologist who testified that the safest antipsychotic medications were two other brands and had the plaintiff been prescribed either of those, rather than Risperdal, it would be very unlikely she would have developed tardive dyskinesia. *Id.* at 390, 392.
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> The court also held that the plaintiff's attempt to prove her failure to warn claim through the Defendants' marketing materials and internal documentation expanded the claim beyond the statutory scope of the MPLA. Id. at 393. The high court relied on its prior case of *Janssen Pharmaceutica, Inc. v. Bailey*, 878 So. 2d 31 (Miss. 2004) and found that, because the Bailey court had focused only on the actual drug label, it would not consider the Defendants' marketing materials or internal documents as support for a failure to warn claim under the MPLA in determining the adequacy of the label. Id. Further of note for this case, the court held that the warning was adequate as a matter of law even though there was also testimony that the warning provided was cookie cutter and meaningless because the same information was on every antipsychotic medication. *Id.* at 392. Here, Plaintiffs rely on Bard's HHE and other of Bard's internal documentation in an effort to show that the Recovery Filter had higher rates of complications compared to other Bard filters and other brands of IVC filters. This Court, like the court in *Fortenberry*, finds that Plaintiffs' theory of liability utilizing Defendants' internal documentation to argue that the warning was inadequate goes beyond the statutory scope and takes us far afield from a manufacturer's duty under Mississippi law.

Id. at 12-13.

This court regards Judge Starrett's opinion in *Nelson* as very well-written, and, if the Fifth Circuit agrees with Judge Starrett, then it will, of course, follow its ruling without hesitation. At this juncture, however, this court does not believe that there should be a hard-and-fast rule barring claims based on a failure to warn of the relative risk of a particular product, particularly since the MPLA specifically *requires* manufacturers to disclose the "dangers" of their products. *See* Miss. Code Ann. § 11-1-63(c)(ii)(providing that "an adequate product warning or instruction is one that . . . communicates sufficient information on the dangers . . . of the product.") As discussed below, this court regards the term "comparative risk" as simply another way of saying "more dangerous," and it can discern no reason why an MPLA which specifically *requires* the disclosure of product dangers should be interpreted as *barring* claims based on a failure to do so. In the court's view, the law would not be well served by a "one size fits all" rule relating to all product information which

can be regarded as falling under the category of "comparative risk," and it submits that courts should, instead, focus on whether the information in question is of a nature that is likely to be important to patients and their physicians.

This court believes that the MDL court made a strong case for such a case-specific approach, writing in *Booker* that:

> The Court is not holding, as a matter of Georgia law, that manufacturers must always disclose how the risks of their product compare to the risks of other products. But presumably there is a point where the risks of a product so depart from the norm that a failure to disclose them constitutes an inadequate warning. Whether that point was reached in this case will be for the jury to decide."

In re Bard IVC Filters Prods. Liab. Litig., 2017 WL 5625548, at *5 (D. Ariz. Nov. 22, 2017). The MDL court in *Booker* thus rejected a blanket, categorical approach to comparative risk claims, finding that, at some point, the risks associated with a particular treatment may become so strikingly out of line with other similar products that a warning is necessary. This court agrees.

Very recently, a Georgia district court approvingly cited the MDL court's observations in *Booker*, writing that:

> Like the MDL Court and the Northern District of Georgia, the Court finds that because Milton presents evidence that his G2X Filter had higher risks of complication than IVC filters generally, it is a jury question whether the warning was adequate. As explained above, Milton places facts in the record that purport to show that the G2X Filter has a complication rate 14 times higher than the SNF—another of Bard's filters. While Bard is of course free to challenge this assertion at trial, the Court has no trouble finding that a jury should have a chance to decide whether Bard should have had to warn of the higher risk associated with the G2X.

Milton v. C.R. Bard, Inc., 2021 WL 2483143, at *4 (M.D. Ga. June 17, 2021). The Georgia district court thus had "no trouble" finding that a jury should decide the failure to warn issue, based partly upon its finding that "the G2X Filter has a complication rate 14 times higher than the SNF —another of Bard's filters." *Milton* involved the Bard G2X filter, which the Georgia

court noted "is essentially the same as the G2 filter" at issue in this case, "but with an added snare hook that is meant to improve the retrievability of the filter." *Id.* at fn. 1.

In a May 2021 decision, a Wisconsin district court similarly concluded that it should allow a jury to consider the plaintiff's failure to warn theory under a "comparative risk" theory, writing that:

> [A]lthough defendants did warn of the specific complications that happened to Johnson, a reasonable jury *could* conclude that those warnings were inadequate because they did not sufficiently communicate the degree and likelihood of the risk associated with placing a Meridian Filter in a patient's IVC, especially in light of purported, lower-risk options on the market and the seriousness of the potential complications. Accordingly, the court cannot conclude that the warning was adequate as a matter of law.

Johnson v. C.R. Bard Inc., 2021 WL 1784661, at *8 (W.D. Wis. May 5, 2021). This court notes that the Wisconsin court made note of the high relative risk of the G2 filter at issue in this case, writing that:

> Defendants then developed a "next generation" Recovery Filter, called the "G2 Filter," with the goals of potentially reducing complications such as migration and fracture. However, initial MAUDE data showed that the reported perforation failure rate for the G2 Filter was approximately 14 times that of the Simon Nitinol Filter.

Johnson, 2021 WL 1784661, at *2.

It is unclear to this court whether the study indicating such a high failure rate for the G2 refers to the entire G2 product line (as the *Johnson* court indicated) or merely the G2X, but, at any rate, the district judge in *Milton* found that the G2 and G2X are "essentially the same." *Id.* Even assuming that this is incorrect, and that Bard has a legitimate jury argument that the G2 at issue in this case is somehow safer than the retrievable filters released before and after it, that is irrelevant for the purposes of the legal ruling which it would have this court make. That is, a blanket bar on "comparative risk" claims would cover even the most egregious cases in which the manufacturer had specific notice beforehand that the product it was releasing was

dramatically more dangerous than comparable products, and this court must assess Bard's argument in light of its actual effects, in *all* cases.[2]

There is, as discussed above, very substantial authority for the proposition that this court should not automatically bar a failure to warn theory based on undisclosed information which falls under the category of "comparative risk," and it seems likely that policy concerns figured prominently in those decisions. This court regards the MDL court's opinion in *Booker* as being particularly instructive in this regard, given that court's extensive experience in dealing with IVC litigation and considering also that it was dealing with the very same G2 filter at issue in this case. In its brief, defendant seeks to dismiss *Booker* as being based on Georgia law, but, as noted above, the *Johnson* court reached the same result under Wisconsin law. Moreover, the MDL court's observation that "presumably there is a point where the risks of a product so depart from the norm that a failure to disclose them constitutes an inadequate warning" strikes this court as being a rather common-sensical observation that is not dependent upon the peculiarities of one state's law.

A fundamental problem with a blanket bar on "comparative risk" claims is that it seems to presuppose that the *relative degree* of risk is irrelevant information for the consumer. This court does not believe that most consumers would view things that way. In the court's view, it is

[2] Once again, Bard chose to provide only limited and vague arguments in its summary judgment briefing regarding the specifics of the studies relating to retrievable filters, and their impact upon this case. This is likely in recognition of the fact that, at the summary judgment stage, this court is required to view the facts in the light most favorable to the plaintiff, and, that being the case, it is highly unlikely that Bard could have removed any jury issues in this regard simply by disputing the applicability of studies relating to its retrievable filters. This court's ruling regarding the merits of a bar on "comparative risk" claims is not based upon the specifics of the rather bewildering array of models of retrievable Bard filters, and the studies relating to them, and any incorrect perceptions it may have developed in this regard are not material to its analysis.

one thing for consumers to read in a package insert that, say, having batteries in their cell phone explode is a known risk of the product. In any event, the consumer still needs to make phone calls, and it is unlikely that many individuals would refrain from buying a cell phone based on a remote risk that its battery might explode. It seems far from unlikely, however, that a consumer would be less likely to choose a *particular* cell phone if he were told that the battery in it was fourteen times more likely to explode than the battery in another model of cell phone.

Under Bard's understanding of the law, the manufacturer of a phone with a one in ten thousand risk of catching fire would be required to give exactly the same warning as one who built a phone with a one in ten risk of doing so, namely, that catching fire was "a" risk of the product. While such a rule of law would, no doubt, give comfort to the latter manufacturer, this court would find it very difficult to justify. A blanket bar on "comparative risk" claims would tend to encourage manufacturers to withhold information which most consumers would regard as important in making an informed product choice and in protecting their own personal safety, and it is therefore disinclined to recognize such a bar.

That brings this court to perhaps the most important basis for rejecting Bard's position, namely that a bar on "comparative risk" claims would run contrary to the basic inquiry mandated by the MPLA. *See* Miss. Code Ann. § 11-1-63. In so stating, this court emphasizes that the failure to warn provisions of the MPLA are based heavily on negligence principles, indeed, they are a statutory codification of the negligence standard in a products liability context. For example, the MPLA requires that the plaintiff demonstrate that "the manufacturer or seller knew or in light of reasonably available knowledge should have known about the danger that caused the damage for which recovery is sought and that the ordinary user or consumer would not realize its dangerous condition" and it provides that "an adequate product warning or instruction

is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates sufficient information on the dangers and safe use of the product." *See* Miss. Code Ann. § 11-1-63(c)(ii).

The negligence origins of the failure to warn standard in the MPLA are thus clear and obvious, and (as any first year law student knows) in negligence cases, a defendant's conduct is judged in *comparison* to the "reasonably prudent defendant." That being the case, barring evidence that a particular manufacturer made a product which was dangerous in *comparison* to similar products would run contrary to the basic inquiry mandated by the MPLA. In the court's view, when a plaintiff presents proof that some other manufacturer, or the same manufacturer, was able to make a product which performs a similar function, but at a much lower risk to the consumer, that is evidence which falls squarely in the wheelhouse of the analysis mandated by the MPLA, and it can discern no reason why it should be regarded as inadmissible.

In the court's view, the language in the MPLA which most squarely defeats Bard's argument is its provision that "an adequate product warning or instruction is one that . . . communicates sufficient information on the dangers . . . of the product." *Id.* This court regards this language as fatal to Bard's position since, at the end of the day, "comparative risk" is simply another way of saying "more dangerous." Indeed, if evidence that the G2 Filter had a fourteen times greater risk of fracturing and migrating in the body than the SNF filter is not evidence regarding its "dangers" then exactly what is it? On what possible basis would an MPLA which specifically *requires* information regarding product dangers be interpreted as *barring* claims based on the failure to disclose such dangers? So considered, it strikes this court that Bard's entire argument regarding "comparative risk" is simply a clever legal straw man which finds no support in the MPLA and which this court has little difficulty in rejecting.

This court fears that recognizing an artificial and arbitrary island of immunity for "comparative risk" would open a gaping hole in this state's products liability jurisprudence which would tend to discourage manufacturers from taking full care to ensure that their products are built as safely as possible, relative to comparable products. Indeed, it is not difficult for this court to imagine a scenario, virtually identical to the one alleged in this case, in which a manufacturer learns that an eagerly-awaited and, potentially, hugely profitable product is being found by studies to have a much higher risk of causing injury to consumers than existing products. The public policy question, as this court sees it, is what incentives the law wishes to provide in this context. Does the law really wish to allow the legal advisers for such a manufacturer to re-assure their employer that, so long as they disclose that there is *some* risk of a particular injury occurring, they need not disclose that this risk is actually *much higher* than that of comparable products? It is submitted that the answer to this question should be "no." In so stating, this court is well aware that it goes against all business instincts for a manufacturer to disclose that its product is more dangerous than comparable products. In this context, however, this court comes down on the side of the old newspaperman's adage that "if you don't want it reported, don't let it happen." Or, in this case, "build a better product."

This court has before it a plaintiff who suffered serious injuries which, it believes, a jury might conclude would not have occurred if Bard had simply continued to sell its SNF filter and waited for the safety concerns relating to its retrievable filters to be resolved before putting them on the market. That being the case, this court is unwilling to interpret Mississippi law in a manner which would provide an island of immunity for Bard in this case and provide comfort for manufacturers in similar cases that may keep uncomfortable truths about the risks of their product to themselves. As discussed above, courts have found that no such island of immunity

exists for "comparative risk" claims under Georgia and Wisconsin law, and it is unclear to this court why Mississippi law would be well served by inferring a different result. Defendant interprets the Mississippi Supreme Court's decision in *Fortenberry* as having rejected such a "comparative risk" theory in failure to warn cases, but this court reads *Fortenberry* as being based on the facts of that case which made no clear holding either way on this issue. In the absence of such a clear decision, this court will instead follow the reasoning of the previously-discussed decisions which have found such a comparative risk theory to be potentially valid in products liability cases.

This court will take this opportunity to note certain factual questions which it has developed in researching this case, so that the parties may, if they so choose, address them at trial. This court does not base its summary judgment ruling upon these questions, but it does regard them as worthy of exploration. Once again, Bard argues in this case that having disclosed that fracturing and migrating in the body is a known risk of IVC filters absolves it of all liability for failure to warn. However, this court believes that, in deciding *which* IVC filter to choose, the average consumer might also like to know that the G2 retrievable filter was shown in one study to have a risk of failure which was fourteen times greater than Bard's permanent SNF filter. In so stating, this court notes that it is unaware of any benefit of retrievable, as opposed to permanent, IVC filters which would necessarily, and as a matter of law, justify such an increased risk. Indeed, one study found that "retrievable" IVCs are rarely removed, noting in its abstract that:

> There has been an increasing nationwide trend of inferior vena cava (IVC) filter placement over the past 3 years. Most of these have been the newer, removable variety. Although these are marketed as retrievable, few are removed. The purpose of this study was to examine the practice pattern of IVC filter placement at Huntington Hospital. This study is a retrospective chart review of all IVC filter placements and removals between January 1, 2004, and December 31, 2006. . . . Three hundred ten patients received IVC

> filters at our institution during this period. Eighty-four were placed in 2004, 95 in 2005, and 131 in 2006. Of those, only 12 (3.9%) were documented permanent filters, whereas the remainder (298) were removable. Of the retrievable filters placed, only 11 (3.7%) underwent successful removal.

Gaspard S F, Gaspard D J. Retrievable inferior vena cava filters are rarely removed. Am Surg. 2009;75(5).

The Gaspard study thus found that "[o]f the retrievable filters placed, only 11 (3.7%) underwent successful removal," which raises questions in this court's mind whether the retrievable nature of the G2 and similar filters is a benefit which would lead the average consumer to accept a much high risk of them fracturing and migrating in her body. At the very least, this evidence tends to make this court wonder whether the consumer should have been provided with this information, so that she might reach an informed decision on the matter for himself. In the court's view, the 2004 to 2006 time period of the Gaspard study arguably renders it a particularly relevant indication of doctor and patient preferences, since it preceded the widespread publicity surrounding the high failure rate of retrievable IVC filters and thus arguably provides a better indication of the true patient need (or lack thereof) for a retrievable IVC filter. This court notes that a more recent study cited a "a meta-analysis of 37 studies" as finding that retrievable IVC filters are "removed only a third of the time."[3] This one-third removal rate is considerably higher than that found in the Gaspard study, but this court believes that there are real questions as to whether publicity regarding the dangers of retrievable filters might have provided an incentive to have them removed. If so, then this fact could hardly be regarded as helpful evidence for Bard regarding the inherent need for removable filters, in

[3] See https://pulmccm.org/cardiovascular-disease-review/inferior-vena-cava-filters-placement-often-misguided-unhelpful-rarely-removed-jama-int-med.

comparison to a permanent filter with a much smaller propensity to break apart and migrate in the body.

This court recognizes that it has taken some liberties in conducting its own research into this topic, which was based on its own confusion as to why a patient would want a retrievable filter in the first place. In citing the above studies, this court is not taking formal judicial notice of them, within the meaning of Federal Rule of Evidence 201. Such a taking of judicial notice would require this court to "instruct the jury to accept the noticed fact as conclusive," *see* FRE 201(f) and it simply notes the studies in the context of explaining that it believes there are important unanswered questions in this case which should be delved into at trial. The contents of that trial will consist of the evidence developed by the parties during discovery and during the presentation of expert testimony, and this court's eventual directed verdict ruling will be based on the contents of the trial. At the same time, this court's research revealed an enormous amount of data suggesting that most retrievable filter patients utilize them as permanent filters, and it does not believe that it is going out on a limb, factually speaking, in stating this to be the case.

Given that most patients seem content to allow retrievable IVC filters to, in effect, serve as permanent IVC filters, this court believes that further exploration at trial would be helpful to determine whether Bard should have disclosed the much higher failure rate of the G2 filter as opposed to the SNF filter. Given this conclusion, this court does not find persuasive Bard's argument that it should infer a blanket bar on "comparative risk" claims and evidence, since this would tend to unduly limit the function of the trial as a search for truth, in this case and other cases as well. In so stating, this court further notes that, if a blanket bar on failure to warn claims based on "comparative risk" were adopted, then it would seemingly absolve manufacturers of any responsibility to disclose that a particular product had not only a fourteen-times greater risk

of failure, but a thousand-fold greater risk as well. This court can discern no public policy or legal reason justifying this sort of blanket immunity. Though justice is blind, she must never be found in league with those who may knowingly hide the truth.

As a final point on this issue, this court wishes to emphasize its belief that not every study demonstrating any sort of greater risk of a particular product, relative to its competition, need be disclosed by a manufacturer. At the same time, this court very much agrees with the MDL court's observation that "presumably there is a point where the risks of a product so depart from the norm that a failure to disclose them constitutes an inadequate warning" and that "[w]hether that point was reached in this case will be for the jury to decide." *Booker*, 2017 WL 5625548, at *5. Once again, *Booker* involved the very same G2 filter at issue in this case, and it therefore constitutes very strong persuasive authority, from the court most experienced in dealing with these matters, that this case should go to trial. This court does not doubt that there may be some difficulties in ascertaining whether "the risks of a product so depart[ed] from the norm that a failure to disclose them constitute[d] an inadequate warning" in a particular case, but juries exist in order to make difficult judgment calls such as this. Moreover, this court strongly believes that any difficulties in establishing standards for liability in this context constitutes an insufficient reason to recognize the blanket immunity which is urged by Bard.

This court therefore concludes that plaintiff's failure to warn claims should go to trial, and since the MPLA includes a version of the "learned intermediary" defense, the testimony of her treating physician regarding the importance of any warnings to him will be of great importance. To the full extent that Mississippi substantive law and the Federal Rules of Evidence permits this court to do so, it intends to allow the jury to evaluate the credibility of such testimony. Bard appears to regard the representations of treating physicians regarding

matters such as what they "would have done" if provided with certain information as unimpeachable, but this court does not believe that this comports with the practical realities in this context. In so stating, this court trusts that it will not come as a shocking revelation when it observes that, sometimes, witnesses fail to tell the truth. Moreover, when a witness testifies as to what he "would have done" in a particular situation, he generally has nothing other than his own credibility and honesty to back up this assertion.

In its brief, Bard cites the 1992 district court decision of *Windham v. Wyeth Laboratories, Inc.*, 786 F. Supp. 607, 612 (S.D. Miss. 1992) for the proposition that "[i]f a plaintiff's treating physician testifies that he or she was fully apprised of the potential risks of using a medical device and it would not have altered their conduct, an inadequate warning claim must fail as a matter of law." [Brief at 25]. *Windham* preceded the enactment of the MPLA, and, at any rate, it was simply the interpretation by one district judge of the evidence regarding failure to warn in the case before him. The decision is thus not binding authority upon this court, and, once again, it can discern no reason why the testimony of a physician regarding what he "would have done" in a particular situation should be afforded a conclusive presumption of truthfulness and accuracy by a court, when such credibility assessments have long been the province of a jury. This court notes that, in this case, plaintiff's treating physician Dr. Byars was less than unequivocal regarding what he would have done if fully advised of the risks of the G2 filter, but, even if he had professed certainty that a warning would have made no difference, it would still regard the issue of the credibility and truthfulness of his testimony as being a jury issue.

In the court's view, granting a conclusive presumption of truthfulness and accuracy to a physician's testimony in cases such as this would not comport with the practical realities in this context. In so stating, this court notes that, in its experience, many physicians enjoy close

business relationships with medical suppliers such as Bard, and many of them harbor a strong reluctance to offer helpful testimony to a plaintiff in a case arising out of medical services provided. It strikes this court that, if the law were to provide for any context in which the testimony of a witness were to be regarded as unimpeachable, it would be most justifiable in situations where the witness in question had no possible basis for harboring sympathies for either side to the litigation. That is clearly not the case here, and this court thus concludes that the issue of what plaintiff's treating physician "would have done" if fully advised regarding the G2 filter's risks is one which should be resolved by a jury. This is particularly true in this case, since any testimony by a physician that he would have regarded a fourteen-times greater risk of the G2 filter relative to the SNF filter as irrelevant strikes this court as being a rather eye-opening assertion which should not automatically be granted a presumption of being the gospel truth. This court therefore concludes that defendant's motion to dismiss plaintiff's failure to warn claims under the MPLA should be denied, and it will therefore turn to what it regards as the other central claim in this case: plaintiff's design defect claim under the MPLA.

Design Defect

To survive summary judgment on a design defect claim under the MPLA, Plaintiff must present evidence that "at the time the product left the control of the manufacturer or seller: (1) the product was designed in a defective manner; (2) the defective condition rendered the product unreasonably dangerous to the user or consumer; and (3) the defective and unreasonably dangerous condition of the product was the proximate cause of the plaintiff's damages." *Brown v. Ford Motor Co.,* 121 F. Supp. 3d 606, 611 (S.D. Miss. 2015), *citing 3M Co. v. Johnson*, 895 So. 2d 151, 161 (Miss. 2005); see Miss. Code Ann. § 11-1-63(a)(i). Additionally, Plaintiff must produce evidence demonstrating that: "(i) [t]he manufacturer or seller knew, or in light of

reasonably available knowledge or in the exercise of reasonable care should have known, about the danger that caused the damage for which recovery is sought; and (ii) [t]he product failed to function as expected and there existed a feasible design alternative that would have to a reasonable probability prevented the harm." Miss. Code Ann. § 11-1-63(f)(i)-(ii).

In seeking dismissal of plaintiff's design defect claims under the MPLA, Bard writes that:

> Bard is entitled to judgment on the pleadings on any MPLA design defect theory of recovery because Plaintiff's Complaint (1) fails to identify any specific defect in design, (2) how such defect rendered the Filter unreasonably dangerous, (3) how the defective and unreasonably dangerous condition was the proximate cause of Plaintiff's injuries, and (4) the existence of a feasible design alternative. Alternatively, Bard is entitled to summary because Plaintiff has not put forth any evidence that (1) the Filter was designed in a defective manner; (2) a defective condition rendered the Filter unreasonably dangerous; the defective and unreasonably dangerous condition of the Filter proximately caused Plaintiff's damages; and (4) there existed a feasible alternative design that would have to a reasonable probability prevented the harm.

[Brief at 32].

In so arguing, Bard writes that:

> Fatally, Plaintiff has not alleged or identified any specific allegations as to **how** the Filter was defectively designed. "[T]he mere fact of an accident or injury is not sufficient to prove a product defect." *Wolf v. Stanley Works*, 757 So. 2d 316, 321 (Miss. Ct. App. 2000) (affirming summary judgment where "[t]here was no effort to show a specific defect in the design of the sensor, but reliance was placed solely on the evidence that the door shut prematurely"); A*ustin v. Bayer Pharms. Corp*., No. 5:13-CV-28-KS-MTP 2013, U.S. Dist. LEXIS 137480, at * 15-16 (S.D. Miss. Sept. 25, 2013) (dismissing design defect claims for failure to state a claim because "[p]laintiff failed to identify Mirena's design defect. She alleged that it is defective in design, but she did not explain — even in the simplest terms — what the defect is"); *Chatman v. Pfizer, Inc.,* 960 F. Supp. 2d 641, 648 (S.D. Miss. 2013) (dismissing design defect claim due to, inter alia, plaintiff's failure "to identify the defect in the design"); *Adams v. Energizer Holdings, Inc.,* 2013 U.S. Dist. LEXIS 56432, at *6-7 (S.D. Miss. Apr. 19, 2013) ("[P]laintiffs necessarily must identify some defect in the design of the product(s), yet plaintiffs herein have alleged in the most conclusory fashion only that the products were defective, without suggesting even generally the nature of any defect."); *McIntosh v. Nissan N. Am., Inc*., 2008 U.S. Dist. LEXIS 91972, at 8-9 (S.D. Miss. Oct. 28, 2008) (granting summary judgment in favor of defendant on design defect claim because plaintiff's expert could not identify any design defect).
> Here, dismissal is warranted because the Complaint is void of the basis for how and why the Filter is defective in design. See Miss. Code Ann. § 11-1-63(a)(i)(3) Instead, the

> Complaint contains only two conclusory allegations: (1) "[t]he G2 Filter implanted in Plaintiff was defective in design because it failed to perform safely as persons who ordinarily use the product would have expected at the time of use;" and (2) "[t]he G2 Filter implanted in Plaintiff was defective in design, in that its risk of harm exceeded its claimed benefits."

[Id. at 33].

> For her part, plaintiff argues that she adequately plead a design defect, writing that:
>
> First, Plaintiff has pled that the G2 "[w]as designed . . . in such a manner so as to present an unreasonable risk of" fracture, migration, tilting, or perforation, and that the G2 "[w]as designed . . . to have unreasonable and insufficient strength or structural integrity to withstand normal placement within the human body." Compl. ¶ 113. Specifically, the G2 implanted into Plaintiff was defectively designed because it "migrated and perforated her aorta and L4 vertebrae." Id. ¶ 100. In short, "[t]he G2 Filter implanted in Plaintiff was defective in design because it failed to perform as safely as persons who ordinarily use the product would have expected at the time of use." Id. ¶ 133. Plaintiff has therefore adequately pled the existence of a design defect. *See, e.g., Little,* 2015 U.S. Dist. LEXIS 75666, at *19 (holding that the plaintiff's allegations of "a defect in the design of the screw, that is, that the screw was discovered to be fractured three months after it was implanted in Plaintiff's humerus" were sufficient to state a MPLA design-defect claim).

[Plaintiff's brief at 30].

While this court tends to agree with Bard that some of the allegations of plaintiff's complaint are rather conclusory and vague, it believes that her expert testimony regarding design defect is far more substantive than defendant suggests. For example, Bard complains in its reply brief that plaintiff's expert testimony is inadequate, writing that:

> The Opposition argues Plaintiff has met her evidentiary burden because Dr. Hurst opined that the SNF would have "significantly reduced" Plaintiff's risk of harm. (Opp. at 42.) But nowhere in his report or his testimony does he opine that it "would have prevented Plaintiff's injuries." See Miss. Code Ann. § 11-1-63(f)(2). Neither does Dr. McMeeking, one of Plaintiff's general experts. He simply opines that the SNF is safer than the G2 because "the design of the SNF is substantially better than the G2 with respect to migration, tilt, arm fracture and arm penetration." (Opp. at 42.)

[Reply brief at 8-9].

This court has reviewed the deposition testimony and expert report of plaintiff's expert Dr. McMeeking, and it believes that his opinions are considerably more specific than Bard would have it believe. Most notably, Dr. McMeeking devotes several pages of his expert report to ways in which, he submits, the G2 filter has design aspects which are not present in the SNF Filter and which make it more likely to fracture and migrate in the body. For example, on page 8 of his report, Dr. McMeeking asserts that "[t]o a reasonable degree of scientific certainty based on my engineering analysis detailed herein, the SNF is substantially less likely to result in complications once implanted as compared to the Bard Recovery and later generation Bard filters." [Exhibit 49 at 8]. Dr. McMeeking then backs that assertion up with highly technical observations, such as that "the bending stiffness of the wire used for the SNF is 1.35 times stiffer in elastic bending than the wire used for the Recovery and G2 filters." [*Id.* at 10]. Later in his report, Dr. McMeeking writes that:

> I note that in my previous reports such as ref. [22] I have drawn attention to the question of the chamfer, or the lack of it, at the opening of the sleeve of the Recovery and G2 filters. In that assessment I noted that the SNF sleeve is specified in the engineering drawings for it to have a chamfer, whereas the Recovery and G2 filters lack such a feature. The presence of a chamfer at the mouth of the upper sleeve of the SNF filter helps to avoid severe strain concentrations at adjacent locations of the wires of the petals. If there are chamfers at the openings of the lower sleeve where the petal wires exit it and where the leg wires exit it, these chamfers will help to avoid severe strain concentrations at adjacent locations of the wires of the petals and the wires of the legs.

[*Id.* at 11]

Having reviewed the expert testimony in this case, this court is not prepared to agree with the basic premise of Bard's motion, namely that nowhere in Dr. McMeeking's extensive and complex testimony does he offer any opinion of an actual defect in the G2 filter. Moreover, in concluding that it should allow plaintiff's design defect claim to go to trial, this court is motivated by the facts that 1) having reviewed the summary judgment evidence in this case, it

believes that there is real cause to suspect that the G2 filter does, in fact, have significant design defects, as evidenced by studies showing a much higher failure rate relative to the SNF filters; 2) a number of other district courts, including the MDL court in *Booker*, have allowed similar design defect claims against Bard to go before a jury; and 3) since it is allowing plaintiff's inadequate warning claims to go before a jury, a trial will be required regardless, and judicial economy considerations favor this court's erring on the side of allowing the jury to consider all potentially valid claims. With regard to the last point, this court notes that, if a jury were to return a verdict for plaintiff on the design defect claim, and the Fifth Circuit concluded that it should not have been submitted, then it could simply strike the jury's verdict. If, on the other hand, this court dismissed the design defect claim now, and the Fifth Circuit held this was in error, then it would have to remand for an entirely new trial. Judicial economy considerations thus favor this court allowing a jury to decide this issue.

Even if this court were to assume, for the sake of argument, that Dr. McMeeking's expert opinions were legally inadequate, it believes that there is reason to doubt that the Mississippi Supreme Court would provide as stringent an interpretation of the plaintiff's duty to establish a "defect" as defendant suggests, in all products liability cases.[4] To explain this belief, this court will begin with a (deliberately) extreme and implausible hypothetical, which it will utilize to make a point. Assume the existence of a model of vacuum cleaner, which, for unexplained reasons, demonstrates a marked propensity to explode with sufficient force to kill the operator. Assume further that, despite the best efforts of engineers hired by plaintiffs, the exact reason for the vacuum cleaner's propensity to explode cannot be ascertained. In that scenario, would it not

[4] In so stating, this court notes that the decisions cited by Bard in its argument quoted above all involved decisions of either the Mississippi Court of Appeals or federal district courts, none of which has the authority to conclusively resolve the issue.

be reasonable to allow the plaintiff to essentially argue that "the defect in the vacuum cleaner is that it explodes and kills the operator, and vacuum cleaners aren't supposed to do that"? This court tends to think so. In that hypothetical, in which the product clearly demonstrates a propensity to do harm to consumers in a manner which is not present in similar products, why should it be left to the plaintiff to essentially do the engineering work for the defendant and explain exactly what engineering, metallurgical, or any other specific reason is causing the product to fail?

It is submitted that, if it can be agreed that the manufacturer in the above hypothetical would not be allowed to escape liability (which seems certain to this court) then it must be agreed that any rule of law suggesting that the plaintiff must point out a specific engineering defect in a product is not an absolute one. Rather, it seems likely to this court that, while demonstrating such a specific defect is ordinarily required, there may be cases where the product in question so clearly deviates from that of other, similar, products in ways which endanger the safety of consumers that a jury should be allowed to infer from the deviation that a design defect exists. If such were not the law, then the law would essentially reward the manufacturer for releasing a product that, while highly dangerous to consumers, is dangerous in ways that it is difficult for plaintiffs to identify and prove at trial.

This court can discern no public policy reason why manufacturers should be rewarded for releasing products which are dangerous in ways which may be difficult to identify and prove. Rather, it believes that the law should provide incentives for manufacturers to err on the side of first ensuring that the product is safe before selling it to the public, even if identifying the specific engineering defect in the product proves difficult. This court would hasten to add that, at any trial in this context, the manufacturer should be given every opportunity to prove to the

jury that some reason other than a design defect, such as shortcomings in the studies in question, explain the data suggesting that the product is unreasonably dangerous. In cases where the manufacturer is unable to provide such an explanation to the jurors' satisfaction, however, this court can discern no reason why they should be unable to conclude that a design defect is the most likely explanation in this regard.

Once again, this court is not prepared to conclude that Dr. McMeeking offered no evidence of a defect at all in this case; to the contrary, it believes that he did. This court makes the above legal observations merely to illustrate that it would not regard the legal issues in this context as cut-and-dried even if it reached the opposite conclusion regarding that expert's testimony. In so stating, this court's views are informed by facts surrounding this case which, unlike some aspects of Dr. McMeeking's highly technical report, it believes it *does* understand. As discussed previously, this court concludes that there is significant summary judgment evidence that, in designing and selling the Release retrievable filters, Bard ignored specific warnings that it was failing at an unacceptably high rate and that it negligently chose to rush the product to market, rather than doing its due diligence with regard to its safety. This court believes that, particularly in light of this evidence, it would be unjust to dismiss Bard from this lawsuit, based on plaintiff's *alleged* failure to do what its own engineers apparently could not do, namely demonstrate exactly what it is about the retrievable filters that (apparently) caused them to fail at a much higher rate than the permanent SNF filter.[5] In the court's view, a jury could reasonably find that, even if the reason for the Recovery filter's propensity to fail (and that of

[5] Once again, this court's discussion of this issue is based upon its assumption, for the sake of argument, that Bard is correct that Dr. McMeeking offers no proof of defect.

the G2 filter) could never be ascertained by Bard's engineers, the correct and responsible course of action as a manufacturer would have been *not to release the product at all*.

As noted previously, the Gaspard study found that, between 2004 and 2006, only 3.7% of the retrievable filters implanted in the hospital in question were successfully removed, and this arguably suggests that there was no great patient need for retrievable filters in the first place, and certainly not at the cost of a far greater failure rate resulting in many grave injuries. This court must emphasize that this suggestion is merely that, and it does not wish for this opinion to be interpreted as any sort of formal finding that the Bard retrievable filters in question were defective and should not have been released. This court does believe, however, that, considering the summary judgment evidence in the light most favorable to plaintiff, this is one reasonable interpretation of the evidence.

This court makes the above observations in order to explain its ruling that it will wait until the full evidence of design defect has been presented at trial before formally deciding, at the directed verdict stage, whether Mississippi law permits it to make the ruling it believes to be the fair one, namely allowing a jury to decide the issue of design defect under the MPLA. This court does agree with Bard, however, that Dr. McMeeking's opinions were far more specific than the allegations of design defect in the complaint, and it therefore concludes that it should grant plaintiff's request to amend her complaint to make allegations of defect consistent with her expert testimony. If Bard contends that such allegations remain inadequate even after amendment, then it may so argue at the directed verdict stage of trial.

That brings this court to the issue of feasible alternative design, which is, as in most states, a required showing in a design defect claim under Mississippi law. In this case, as in many other Bard cases, the plaintiff seeks to argue that the SNF filter constituted a feasible

alternative design for the purposes of a design defect claim, while Bard essentially argues that this is comparing apples and oranges since the SNF filter was a permanent filter, and not a retrievable filter like the G2 filter at issue in this case. Federal courts have reached differing results in ruling on this argument, but this court concludes that it should, at least at this juncture, follow the lead of the courts which have regarded it as a jury issue. In reaching this conclusion, the Wisconsin district court in *Johnson* wrote that:

> However, defendants argue that the Simon Nitinol Filter is not a reasonable alternative design because it is a permanent filter, whereas the Meridian Filter is retrievable. Other district courts have considered similar arguments with respect to Bard IVC filters, with varying results. In *Oden v. Bos. Sci. Corp.*, 330 F. Supp. 3d 877 (E.D.N.Y. 2018) (applying New York law), the District Court for the Eastern District of New York concluded that the plaintiff failed to plead the existence of a reasonable alternative design because the proposed retrievable filters were not a reasonable alternative to her implanted permanent Bard IVC filter. *Id.* at 889. In the *Hyde* bellwether case (applying Wisconsin law), however, the court concluded that a trier of fact must decide if the Simon Nitinol Filter, a permanent filter, was a reasonable alternative design to the retrievable Bard filter that the plaintiff had received. 2018 WL 4742976, at *3 (D. Ariz. Oct. 2, 2018). At least on the record before it, this court is inclined to agree with the *Hyde* court.

Johnson, 2021 WL 1784661 at *9.

In concluding that it should follow the lead of the *Hyde* and *Johnson* decisions, this court is influenced by its conclusion that plaintiff's reliance upon a real-life product, in the form of the SNF filter, presents, in many respects, a factually more compelling case than if she had relied solely upon expert testimony, no matter how thorough that testimony may have been. This is because, at the end of the day, an expert's opinion is simply that, and if plaintiff wishes to prove that it "could have been done better" than the G2 filter, then this court frankly regards real-life data about the performance of a real-life product such as the SNF filter as being much more persuasive, as a factual matter, than unproven opinions offered by an expert.

In this case, Dr. McMeeking offered his opinions of defect in the context of comparisons with the SNF Filter, but this court finds no basis for stating, as a matter of law, that this was

improper. Rather, this court believes that it is for a jury to decide whether, in so doing, Dr. McMeeking was comparing apples and oranges or whether this is a valid comparison which supports a finding that the G2 Filter was defective. This court therefore concludes that triable jury issues exist regarding plaintiff's design defect claim, and Bard's motion for summary judgment will be denied as to this claim.

This court likewise concludes that it should wait until trial to resolve the issue of whether a punitive damages instruction should be submitted to a jury. In so concluding, this court emphasizes that Mississippi's punitive damages statute provides for mandatory bifurcation of punitive damages issues at trial. Specifically, Miss. Code Ann. § 11–1–65(1)(c) provides that "[i]f, but only if, an award of compensatory damages has been made against a party, the court shall promptly commence an evidentiary hearing to determine whether punitive damages may be considered by the same trier of fact." This court notes that one arguable interpretation of this statute is that the "shall" language requires an evidentiary hearing on punitive damages to be held in the event that such damages are sought and an award of compensatory damages is entered against the defendant at trial. And, indeed, the Mississippi Supreme Court concluded in a 2006 decision that the § 11–1–65 procedure must be "meticulously" followed, writing that:

> Importantly, our punitive damages statute mandates the bifurcation of the issues of liability/compensatory damages and punitive damages. The statute requires that evidence concerning punitive damages be presented separately at a subsequent evidentiary hearing to take place, if and only if, the jury has awarded some measure of compensatory damages. Thus, the detailed procedure which is outlined above must be meticulously followed because, without an evidentiary buffer at trial, juries will ultimately confuse the basic issue of fault or liability and compensatory damages with the contingent issue of wanton and reckless conduct which may or may not ultimately justify an award of punitive damages.

Bradfield v. Schwartz, 936 So.2d 931, 938 (Miss. 2006).

Bradfield has not been overruled, but it is unclear to this court just how stringently the Mississippi Supreme Court would apply it. For example, it is unclear to this court whether the Supreme Court would reverse a trial court's pretrial grant of summary judgment on the punitive damages issue, as being a violation of § 11–1–65 as interpreted in *Bradfield*. This court has some doubts whether *Bradfield* would be enforced as strictly as that, and it is of the view that resolving these issues at the summary judgment stage can be of benefit, in certain cases where the issues are particularly clear. As a general matter, however, this court concludes that the most prudent course of action is to strictly follow the procedure outlined in § 11–1–65(1)(c) and leave the issue of punitive damages for trial, in the event that an award of compensatory damages is entered against the defendant. This court will follow this general approach in this case, particularly since it believes that Bard has failed to adequately respond to plaintiff's argument that it rushed its retrievable filters to the market without sufficiently addressing safety concerns.

This court now turns to a statute of limitations defense raised by Bard which, unlike the products liability issues discussed previously, is specific to this case. Product liability actions are subject to a three-year statute of limitations in Mississippi. Miss. Code Ann. § 15-1-49(1). "In actions . . . which involve latent injury or disease, the cause of action does not accrue until the plaintiff has discovered, or by reasonable diligence should have discovered, the injury." § 15-1-49(2). Bard argues that it is entitled to summary judgment "because the undisputed evidence shows Plaintiff filed her Complaint more than three years after she first learned from the results of [an] August 31, 2011 CT scan that her Filter had migrated and perforated her IVC." (Brief at 14).

While this court believes that Bard has a legitimate argument that plaintiff's claims are time-barred, it concludes that plaintiff likewise has a legitimate argument on this issue and that a jury should resolve this issue. In so stating, this court notes that plaintiff argues that:

> Ms. Munson did not learn that her filter had migrated, much less perforated or fractured, until on or about January 4, 2012—fewer than three years before she filed this suit on December 31, 2014—when she underwent a CT scan performed by Harvey Edward Garrett, M.D., which found:
>
> > Several struts extend beyond the lumen of the inferior vena cava. Two of these terminate within the wall of the distal abdominal aorta. There is miniscule mural thrombus along the right side of the aortic wall near one of these struts. A third strut extends into anterior portion of the L4 vertebral body.
>
> Defendants' contention otherwise is based on an earlier CT scan, which found that her filter "may not be in the correct position." Such a possible finding by no means gave Plaintiff knowledge that her filter had migrated, much less perforated and fractured. In fact, Plaintiff testified that she only underwent her January 2012 CT scan because she had seen television advertisements regarding filter complications and answered affirmatively when asked if she "just wanted to go get it checked out"—not because she was suffering any symptoms or already knew or suspected her filter had migrated. Because there is a reasonable dispute as to the material fact of when Ms. Munson did know or should have known that her filter had migrated, perforated, and fractured, summary judgment is inappropriate on the issue of limitations.

[Plaintiff's brief at 39].

This court agrees with plaintiff that triable jury issues exist regarding Bard's statute of limitations defense, which brings it to a decision it has reached regarding the nature of the trial presently set for January 2022. In a scheduling order issued this past February, this court noted that, in managing its docket in light of the Covid-19 pandemic, it could not justify granting a high priority to litigating products liability issues against Bard which have already been, and continue to be, litigated in courts throughout the country. Specifically, this court wrote that:

> This court's consideration of these issues is heavily influenced by its awareness of a recent federal trial in the Southern District of Texas in which, despite the court's best efforts to ensure a safe trial, there was a large Covid-19 outbreak among trial participants. In light of this fact, this court is very reluctant to conduct any trial while the pandemic remains ongoing, and it must engage in a judicial triage of sorts to decide which of its numerous continued cases should have priority once it is deemed safe for trials to resume.

> This and other inferior vena cava (IVC) filter cases returned from the MDL court are operating at significant disadvantages with respect to any such judicial triage, for multiple reasons. First, these trials are each set to be very lengthy ones, and they are each therefore likely to require judicial resources which this court could use to dispose of multiple shorter trials. Second, the length of the trials involved will serve to increase the risk of a Covid-19 outbreak among trial participants, and it seems unlikely that the virus will be completely eradicated in the foreseeable future. Third, this court is cognizant of the fact that a number of trials in the IVC filter litigation have already occurred and are continuing to be held nationwide. These trials have provided litigants with a basis for estimating the settlement value of each case, and a number of the Bard cases which have been returned to this district from the MDL court have, in fact, settled in recent months.
>
> In light of the foregoing, this court believes that the parties should prioritize using the information gleaned from similar trials which have already occurred in attempting to settle this case, and it can discern no good reason why they would be unable to do so. If the parties are, in fact, unable to settle this matter, then this court will be disinclined to give additional "test trials" in the Bard litigation priority over certain other trials on its docket which involve liability issues which have not already been litigated elsewhere. This court notes that it has not held a single trial since the Covid-19 pandemic began. This extraordinary situation has resulted in serious dislocations in this court's docket, and it will be dealing with its after-effects for many months, if not years, to come. During this difficult time, this court suggests that all parties, in all cases, make good faith efforts to resolve cases without placing undue burdens on local jurors.

[Slip op. at 1-2].

Unfortunately, the pandemic has proved even more difficult to surmount than this court feared, and it has continued to have a severe impact upon the scheduling of trials. Given that the trial in this matter has already been continued once, this court will not continue the entire trial again, but it concludes that the January trial should relate solely to the statute of limitations defense raised by Bard which is specific to this case. Assuming plaintiff prevails on this issue, the parties will be left with products liability issues similar to those which have already been litigated in a number of other courts nationwide, which should give them a good basis for settling this case. To assist the parties in doing so, this court directs that the parties consult with the Magistrate Judge about finding a mutually agreeable time to conduct a settlement conference in this matter.

In the court's view, both sides to this case have good reason to wish to settle, since they must each confront adverse facts and legal developments affecting this action. This court has previously discussed the facts relating to the development and release of Bard's retrievable filters which give it serious concern, and, once again, a jury in *Booker* found similar claims persuasive. At the same time, it is certainly arguable that plaintiff has not provided as strong expert testimony in this case as she might have, and Judge Starrett's decision in *Nelson*, and its pending appeal to the Fifth Circuit, raise the possibility that Mississippi law in this context will be held inconsistent with the claims asserted in this case. This court trusts that the Magistrate Judge will discuss all these factors with the parties during the settlement conference, and this court's decision on how soon this case should be set for a full trial will be informed by the willingness which each side demonstrates to resolve this matter amicably. Bard has earned a certain degree of credibility with this court by demonstrating a willingness to settle similar claims, and, if this attitude continues, and plaintiff fails to reciprocate, then this would tend to support a later trial setting than if the opposite were to occur. At this juncture, however, this court will be focused on the upcoming trial on statute of limitations issues, and it directs the parties to limit their pretrial motions accordingly.

As a final point, this court notes that Bard has filed a motion to strike [237-1] evidence relied upon by plaintiff relating to the Recovery Filter which preceded the G2 filter and evidence regarding studies which occurred after the implantation of the device at issue in this case. This court has previously stated its view that Bard's conduct relating to the Recovery Filter may, in fact, be deemed by a jury to be relevant in this case and it reiterates this view here. As noted previously, plaintiff alleges that:

> Predicated on the claim that the Recovery was substantially equivalent to the SNF in terms of safety and efficacy, Bard obtained clearance from the FDA to market the Recovery filter through the 510(k) process as a permanent device on November 2002, and for optional

> retrieval on July 25, 2003. As detailed in Section II.C., *supra*, Bard quickly obtained additional information of what it already knew but did not tell the public, including physicians—that the Recovery and subsequent filters were not the substantial equivalent of the SNF. Full market release of the Recovery was followed by significant migrations and fractures, including seven deaths the first year.
>
> Rather than pull its devices off the market, Bard engaged in a campaign of offering newer but equally defective designs to maintain its position in the market. In 2005, after the Recovery's mounting number of fractures, migrations, and deaths, Bard redesigned the filter to the G2 but never adequately tested the device to determine whether it actually fixed the problems. Indeed, it actively avoided certain tests for fracture resistance because it knew the results "would still fall outside of the acceptable range" and its engineers "didn't think the answer would support our design change as a viable option."

[Brief at 49].

Plaintiff thus alleges that there was a consistent pattern of negligence by Bard in releasing both the Recovery Filter and the successor G2 filter without adequate testing and without adequate attention given to indications that the retrievable filters were more dangerous than Bard's permanent SNF filter. In its briefing, Bard simply dismisses this proof based on the difference in the exact models of retrievable filters, but this court is unable to dismiss plaintiff's evidence so easily. Indeed, in her response to the motion to strike, plaintiff offers what this court regards as very strong evidence for the relevance of Bard's conduct relating to the Recovery Filter in this case, noting that it represented to the FDA that it was substantially identical to the G2 filter in obtaining government approval for latter filter. Specifically, plaintiff argues that:

> Bard obtained clearance from the United States Food and Drug Administration to market the G2 Filter at issue for permanent implantation on August 2, 2005, less than a year before Ms. Munson's implant. (Doc. 226-2). To obtain clearance, Bard represented to the FDA that the G2's design was materially "identical" to the Bard Recovery IVC Filter, upon which it was predicated:
>
> > The G2 Filter System (subject) description is identical to the Recovery Filter System (predicate) description and indications for use. The modifications made to the predicate filter device and delivery system are primarily dimensional. No material changes. Or additional components have been incorporated.

[Brief in response to motion to strike at 2]. In support of this assertion, plaintiff offers a letter from the FDA dated August 29, 2005, in which it agreed with Bard that the Recovery Filter was "substantially equivalent … to legally marketed predicate devices" so as not to require further agency approval. [Docket entry 226-2].

In the court's view, evidence such as this calls Bard's basic good faith into question, given that it does appear to have made evolving arguments of convenience regarding the similarities (or lack thereof) between the G2 and Recovery Filter. Indeed, this court concludes that the evidence regarding the Recovery Filter, standing alone, is sufficient to create fact issues regarding the extent of Bard's knowledge and liability in this case, and it makes it even less inclined to accept its summary judgment arguments. This court notes that, in its reply brief, Bard partially concedes and withdraws its motion to strike, writing that:

> Plaintiff's Response argues that the Court should deny Bard's request to strike those exhibits related to the Bard Recovery filter and its development under the "law of the case" doctrine. With the expectation that the principles of the law of the case doctrine will apply with equal force to Plaintiff, Bard withdraws its request to strike Exhibits 2-19, 21-26, 28, 31, 52-54, 56, 59-60, 62-66 from consideration as summary judgment evidence.

[Reply brief at 2]. Bard's partial withdrawal of its motion to strike appears to reflect rulings by the MDL court which found its conduct relating to the Recovery Filter to be quite relevant, and this court certainly agrees with the MDL judge's rulings in this regard.

This court admits to some confusion regarding exactly which arguments have, and have not, been conceded by Bard, and it concludes that, since its summary judgment ruling does not depend on the admissibility of any of the proof in question, it should wait until trial to make a formal ruling on these issues. This court does tentatively agree with Bard, in principle, that it can not, for the purposes of a failure to warn claim, be imputed with knowledge of studies which occurred *after* the relevant conduct for which it is being sought to be held liable, and it directs

plaintiff not to use any such studies for this purpose at trial without seeking prior approval from this court.[6] However, Bard asserted many of its arguments in this regard in its reply brief (thereby depriving plaintiff of the opportunity to respond), and this court concludes that, since trial will be required regardless, it should wait for trial to make more specific rulings regarding which evidence and studies are or are not relevant, and for what purpose. This court will therefore deny the motion to strike as it relates to the Recovery Filter and reserve ruling on the remaining portions of the motion until trial.

With regard to the motion for summary judgment, this court concludes, for the reasons stated previously, that triable fact issues exist regarding at least some of the claims raised by plaintiff in this case, and that motion will be granted in part and denied in part.

This, the 20th day of September, 2021.

/s/ Michael P. Mills
U.S. DISTRICT COURT JUDGE

[6] This court reiterates that one of Bard's primary summary judgment arguments is that Mississippi law bars any and all claims based on failure to warn of the "comparative risk" of products. As discussed previously, this ruling of law would apply equally in cases where a defendant had full knowledge of the fact that its product was far more dangerous than existing products, and this court has used proof of Bard's knowledge of dangers of its retrievable filters to illustrate the public policy concerns in this context. Thus, even assuming that some of the studies cited in this order were released after the implantation of the device in this case, they would still be relevant in discussing the public policy implications of accepting Bard's legal argument in this case.