No. 21-60689

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

Dennis Nelson; Kathy Nelson,

Plaintiffs – Appellants,

v.

C. R. Bard, Incorporated; Bard Peripheral Vascular, Incorporated,

Defendants – Appellees.

Appeal from the United States District Court
for the Southern District of Mississippi
No. 2:19-CV-135

BRIEF OF DEFENDANTS – APPELLEES

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ORAL ARGUMENT REQUESTED

CERTIFICATE OF INTERESTED PERSONS

The undersigned Counsel of Record certifies that the following listed persons and entities as described in the fourth sentence of Rule 28.2.1 have an interest in the outcome of this case. These representations are made in order that the Judges of this Court may evaluate possible disqualification or recusal.

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b. Kathy Nelson (Plaintiff/Appellant).

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3. Defendants/Appellees:

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Respectfully submitted,

s/ Jesse Wadell Wainwright
Jesse Wadell Wainwright

STATEMENT REGARDING ORAL ARGUMENT

Appellees believe that oral argument will assist the Court in determining whether to alter Mississippi law as Appellants advocate.

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STATEMENT OF ISSUES PRESENTED FOR REVIEW

Should the district court's grant of Bard's summary judgment be upheld under the Mississippi Products Liability Act on the following grounds[1]:

1. Bard's Recovery IVC Filter warning was adequate as a matter of law because it warned of the precise complications Nelson purportedly experienced?

2. Nelson failed to provide evidence the warning proximately caused his injuries because there was no evidence his doctor read the warning?

3. Nelson failed to provide evidence that the Recovery IVC Filter suffered from an unreasonably dangerous design defect that proximately caused Nelson's injuries?

4. Nelson failed to provide evidence that an alternative design for the Recovery IVC Filter would have prevented Nelson's injuries without impairing the Filter's utility, usefulness, practicality or desirability?

[1] This Court may also affirm the district court's order granting Bard's motion for summary judgment on any ground raised in Bard's motion and preserved here, even if rejected or not considered by the district court. *See Castellano v. Fragozo*, 352 F.3d 939, 960 (5th Cir. 2003).

INTRODUCTION

Bard's Recovery IVC Filter ("Recovery Filter" or "Filter") saves lives. The Filter intercepts blood clots traveling toward the lungs and other vital organs to prevent them from causing potentially life-threatening injury. The Food and Drug Administration (FDA) cleared the Filter for that purpose based on its finding that the Filter was as safe and effective as a previously-approved Bard filter. The Filter provided that protection to Appellant Dennis Nelson when he was at high risk of blood clots. The Filter was accompanied by a warning cleared by the FDA. Unfortunately, Nelson suffered from complications that are inherent to all filters of that type. Those complications were included in Bard's adequate warnings. The FDA has never revoked its clearance.

The Mississippi Products Liability Act (MPLA) specifies the burdens a plaintiff must carry to impose liability on a product manufacturer, like Bard, and the Mississippi Supreme Court confirmed that a failure-to-warn claim cannot succeed if the manufacturer warned of the alleged complications. Nelson submitted no evidence to carry his statutory burdens, and he does not, indeed cannot, deny that Bard warned of the complications he suffered.

Instead, Nelson asks this Court to alter Mississippi law. Under his proposed revision to the statute, if a product carries a higher risk of any

injury than any of its competitors, the manufacturer is liable for a purported design defect. Nelson's new law would also hold a manufacturer liable if it fails to provide additional warning details held unnecessary by the Mississippi Supreme Court. This Court should decline Nelson's invitation to rewrite state products liability law and create an infeasible standard that would threaten the supply of life-saving medical devices.

STATEMENT OF THE CASE

I. Bard's Recovery IVC Filter

Bard manufactured the Recovery IVC[2] Filter, which is a life-saving device designed to catch blood clots in the inferior vena cava to prevent them from traveling to the heart, lungs, or brain. ROA.4054. The FDA cleared the Recovery Filter for use as either a permanent or retrievable filter through the 510(k) process outlined in the federal Food, Drug, and Cosmetic Act. 21 U.S.C.A. § 301 et seq.; ROA.4048–4049 (clearance for permanent use); Recovery 510(k) Clearance Letter, July 25, 2003, *available at* https://www.accessdata.fda.gov/cdrh_docs/pdf3/K031328.pdf (last accessed Dec. 13, 2021) (clearance for retrievable use).[3]

[2] "IVC" is the acronym for inferior vena cava. The IVC is a large vein that carries deoxygenated blood from the lower part of the body back to the heart and lungs.

[3] This Court may take judicial notice of information contained in an official government web site under Federal Rule of Evidence 201. *See Hawk Aircargo, Inc. v. Chao*, 418 F.3d 453, 457 (5th Cir. 2005) (taking judicial notice of information published

Bard sold the Recovery Filter to hospitals as a prescription-only medical device for use by physicians. ROA.4054. Physicians use IVC filters like the Recovery Filter to prevent patients from experiencing potentially deadly pulmonary emboli where drug therapy alone has been unsuccessful or is contraindicated. ROA.4049, 4058. Each Recovery Filter was accompanied by an Information for Use. ROA.4054. The Information for Use contains specific warnings regarding the risks of filter migration, fracture, perforation, and embolization of vena cava fragments. ROA.4054. It states, in relevant part:

> **E. Warnings**
> . . .
>
> 8. Filter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in retrieval of the fragment using endovascular and/or surgical techniques.
>
> 9. Movement or migration of the filter is a known complication of vena cava filters. . . . Migration of filters to the heart or lungs have been reported in association with improper deployment, deployment into clots and/or dislodgment due to large clot burdens.
> . . .
>
> **G. Potential Complications**

in the National Mediation Board's agency report that was available on the agency website).

> . . . Complications may occur at any time during or after the procedure. Possible complications include, but are not limited to, the following:
>
> - Movement or migration of the filter is a known complication of vena cava filters . . . . Migration of filters to the heart or lungs have also been reported in association with improper deployment, deployment into clots and/or dislodgment due to large clot burdens.
> - Filter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in retrieval of the fragment using endovascular and/or surgical techniques.
> - Perforation or other acute or chronic damage of the IVC wall.
>
> . . .
>
> **All of these above complications have been associated with serious adverse events such as medical intervention and/or death. The risk/benefit ratio of any of these complications should be weighed against the inherent risk/benefit ratio for a patient who is at risk of pulmonary embolism without intervention.**

ROA.4054 (underline added). Bard's Recovery Filters are implanted by physicians to substantially reduce the risk of serious injury or death from pulmonary emboli in prescribed patients. ROA.4049, 4054, 4058.

On May 16, 2005, Dr. Daniel A. DeVun, Jr., implanted a Recovery Filter in Appellant Dennis Nelson[4] as a prophylactic measure to decrease

[4] For the purpose of this appeal, "Nelson" refers to Mr. Dennis Nelson and "the Nelsons" refers collectively to both Dennis Nelson and Kathy Nelson. Mrs. Nelson separately brought a claim for loss of consortium. ROA.38. The court's order granting summary judgment in favor of Bard on the MPLA claim likewise disposed of Mrs. Nelson's loss of consortium claim because the loss of consortium claim is derivative of Mr. Nelson's MPLA claim. *Rylee v. Progressive Gulf Ins. Co.*, 224 So. 3d 535, 538 (Miss. 2017) (holding

Nelson's risk of fatal pulmonary embolus during his temporary cessation of anticoagulation medication before a scheduled liver transplant surgery. ROA.6431–6432, 6446, 6449–6450. There is no evidence that Dr. DeVun intended that the Filter remain permanently. Following implantation of the Filter, there is no evidence Nelson suffered a pulmonary embolus. The Nelsons alleged that the Recovery Filter fractured, causing Nelson injuries.

There is no evidence that Dr. DeVun read the Information for Use prior to implanting the Filter. When asked if he read it, Dr. DeVun testified: "Maybe, but not definitely." ROA.8614. When pressed further if he would typically read instructions for use from manufacturers, Dr. DeVun responded: "Certainly not every one." ROA.8614. Dr. DeVun acknowledged that when he implanted the Filter, he was aware of the same generally known complications of IVC filters listed in the Information for Use, including migration, fracture, and perforation. ROA.11047–11048.

II. The District Court Proceedings and The Nelsons' Claims

This case is part of multi-district litigation relating to several models of Bard IVC filters (MDL), *In re: Bard IVC Filters Products Liability Litigation*,

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a loss of consortium claim is derivative). Although Mrs. Nelson joined this appeal, she abandoned her loss of consortium claim because Nelson's brief fails to address it. *Crose v. Humana Ins. Co.*, 823 F.3d 344, 351 n.5 (5th Cir. 2016) (holding failure to address an issue in briefing waived appeal, even though it was "intertwined" or "related" to the issues addressed on appeal). Therefore, this brief refers to the arguments in Appellants' Brief as "Nelson's" arguments.

MDL No. 2641. ROA.42. The United States Judicial Panel for Multi District Litigation transferred the MDL to the United States District Court for the District of Arizona in August 2015 for pretrial proceedings. ROA.42. On September 18, 2017, the Nelsons filed this action directly in the MDL using the Second Amended Master Short Form Complaint for Damages (Complaint). ROA.36–38. The Complaint used a check-the-box feature to plead claims, and the Nelsons brought claims for strict products liability, negligence, negligent misrepresentation, breach of express and implied warranties, fraudulent misrepresentation, fraudulent concealment, and a Mississippi Consumer Protection Act (MCPA) claim. ROA.37–38, 10201. The Nelsons alleged that the Filter tilted, migrated, fractured into fragments that embolized, and perforated Nelson's vascular system. ROA.2555, 2538, 10214.

On September 10, 2019, this case was remanded to the United States District Court for the Southern District of Mississippi. ROA.6, 89.

On March 12, 2021, the Nelsons moved for partial summary judgment on their failure to warn claim, ROA.1554–1555, 2538–2562, and Bard moved for summary judgment on all claims, ROA.3904–3905, 3935–3979. The district court held a hearing on the motions on June 30, 2021. ROA.10303–10409.

On August 6, 2021, the district court entered an order granting Bard's motion for summary judgment and denying the Nelsons' motion for partial summary judgment. ROA.10196–10220. It entered final judgment in favor of Bard the same day. ROA.10221.

First, the district court held that the Mississippi Products Liability Act is the exclusive remedy for plaintiffs in any action for damages caused by a product. ROA.10201–10202. Additionally, the court denied the Nelsons' request to amend the complaint to comply with the MCPA in order to advance that claim. ROA.10201. The court held that the MPLA barred the MPCA claims and that "this case is well beyond the amendment stage." *Id.* As such, the district court only addressed the failure to warn and design defect claims under the MPLA. ROA.10202.

Second, the district court considered the competing motions on the failure to warn claim. The Nelsons argued that the Information for Use warning was inadequate as a matter of law because it "did not list the comparative rates of occurrence of complications relative to a predecessor Bard device and other IVC filters." ROA.10206. Conversely, Bard argued the warning was adequate as a matter of law because the Information for Use warned of the same complications purportedly experienced by Nelson: migration, fracture, perforation, and embolization. ROA.10212, 10214. The

district court agreed with Bard, explaining Mississippi law holds that a warning is adequate as a matter of law where "the adverse effect was one that the manufacturer specifically warned against." ROA.10205 (quotations omitted) (citing cases); *accord* ROA.10212–10214. Because the Information for Use specifically warned of the precise complications Nelson allegedly experienced, the district court concluded it was adequate as a matter of law. ROA.10209–10210, 10212–10214.

Relying on the Mississippi Supreme Court's decision in *Johnson & Johnson, Inc. v. Fortenberry*, 234 So. 3d 381 (Miss. 2017), the district court rejected the Nelsons' comparative rate theory. ROA.10207–10209. The Nelsons' argument was inaccurately based on Bard's internal documentation, but the district court found the internal documents wholly irrelevant:

> 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. The inquiry is relegated to the label itself.

ROA.10209. Because the court found that the warning was adequate as a matter of law, it did not reach the issue of proximate causation. ROA.10203 n.5.

Third, the district court held the Nelsons failed to create a genuine issue of material fact as to every element of the design defect claim under the MPLA. ROA.10214–10220. While the district court found that testimony of the Nelsons' expert established the existence of a design feature that caused the Filter to tilt, ROA.10216–10217, the district court concluded there was no necessary expert testimony explaining how the alleged defect caused the Filter to fracture and migrate, ROA.10218. Accordingly, the Nelsons could not prove a defect was the cause of Nelson's injuries.

The district court found that the Nelsons also failed to produce evidence showing that a feasible design alternative existed. ROA.10218. The Nelsons speculated that a permanent filter, the Simon Nitinol Filter (SNF), was "safer" because it allegedly had lower rates of fracture, migration, and perforation. ROA.10218. But the Nelsons failed to produce expert testimony showing "to a reasonable probability" that the SNF would have prevented Nelson's specific injuries. ROA.10218–10220. Because the Nelsons failed to create a genuine issue of material fact on essential elements of the design defect claim, the district court found it unnecessary to address Bard's argument that Mississippi would apply Comment k to Section 402A of the Restatement (Second) of Torts. ROA.10220.

Nelson timely appealed the district court's judgment granting summary judgment on the failure to warn claim and design defect claim. He does not appeal the court's holdings that the MPLA was the exclusive remedy for his claims, he was not entitled to leave to amend his complaint to support his MCPA claim, or the denial of his motion for partial summary judgment.[5]

SUMMARY OF THE ARGUMENT

The district court properly granted summary judgment dismissing the Nelsons' claims for inadequate warning and design defect.

The Nelsons failed to carry their burden to show that Bard provided an inadequate warning that proximately caused Nelson's complications. Bard warned of all of the complications that Nelson allegedly suffered, which is sufficient warning as a matter of law. Nelson's attempt to expand Mississippi law to include rate of complication information in a medical device warning runs contrary to Mississippi precedent rejecting a similar argument in the context of prescription drugs. Rather than address this law head-on, Nelson relies on extra-jurisdictional cases and hyperbole regarding the alleged

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5 Nelson's Summary of the Argument states that the district court "erred in denying the Nelson's [sic] motion for partial summary judgment," which could be read in isolation to suggest he is appealing the order in so far as it denied his motion for summary judgment. Appellants' Brief at 8. But the same Summary of the Argument continues that a "genuine issue of material fact exists whether the Recovery filter's IFU provided an adequate warning[.]" *Id.* Nelson repeats this in the Statement of the Case. *Id.* at 7 ("[a] genuine material fact exists as to the adequacy of the warning"). Nelson has abandoned an appeal of the judgment's denial of his motion for partial summary judgment.

dangers of the Recovery Filter. This approach is untethered to the text of the MPLA and case law interpreting the MPLA.

Further, the Nelsons' warning theory suffers from insurmountable feasibility challenges that fail the objectively reasonable standard for warnings. His rates rely on data from a website of the U.S. Food and Drug Administration that expressly warns against using the data in this manner because it suffers from scientific reliability problems and inaccuracies. The combined effect is that Nelson has asked this Court to create a novel, unsubstantiated exception to Mississippi law to require a unique, unreliable warning absent from all filters of this type. The FDA has never approved such a requirement.

Nelson cannot show that an inadequate warning was the proximate cause of his complications. Nelson's physician cannot remember if he read the warning at issue, and he admitted that he does not always read such warnings. By extension, even if the warning contained comparative rate information, Nelson's physician would not have seen the information, and such information could not have impacted his decision making. This Court and others frequently dismiss failure-to-warn claims that are unsupported by evidence that the learned intermediary, the implanting physician here, read the warning. Additionally, breaking the chain of causation is the fact

that Nelson's physician was undisputedly aware that notwithstanding the Filter's benefits, it carried risks of the alleged complications, and he knew how to weigh those benefits and risks and knew of the publicly-available information that Nelson argues Bard should have provided to him.

The Nelsons provided no evidence of essential elements of his design defect claim.

First, the Nelsons failed to submit evidence that a design defect caused Nelson's complications. The Nelsons provided evidence that the Filter, like all filters of that type, could cause the type of complications Nelson suffered, but not evidence that the Filter did cause the specific complications that he suffered.

Second, the Nelsons failed to identify a design alternative for the Filter that would not have impaired its usefulness or desirability. The Nelsons provided no evidence that an alternative design would have had the same usefulness and would preserve the Filter's desirable features, such as its retrievability, which was valuable for a temporary clot risk like Nelson's.

Lastly, the Nelsons failed to provide evidence that the Filter was "designed in a defective manner" that rendered it "unreasonably dangerous." The Nelsons' experts did not opine that the Filter was unreasonably dangerous in light of all risks and benefits. In addition, the Nelsons identified

only risks inherent to all filters of this type, which as a matter of law cannot render the Filter unreasonably dangerous.

ARGUMENT

I. Standard of Review.

This Court reviews a district court's grant of summary judgment de novo applying the same standard as the district court. *Onoh v. Northwest Airlines, Inc.*, 613 F.3d 596, 599 (5th Cir. 2010). The court grants summary judgment if there is no genuine issue of material fact and the movant is entitled to judgment as a matter of law. *Lofton v. McNeil Consumer & Specialty Pharm.*, 672 F.3d 372, 375 (5th Cir. 2012).

II. Bard's Warnings of the Risks of Migration, Fracture, Perforation, and Embolization Were Adequate As a Matter of Law to Warn Dr. DeVun of the Risks of Migration, Fracture, Perforation, and Embolization.

A failure to warn claim fails under Mississippi law if the plaintiff does not show that the warning was inadequate. Miss. Code Ann. § 11-1-63(a)(i)(2); *Johnson & Johnson, Inc. v. Fortenberry*, 234 So. 3d 381, 390 (Miss. 2017) (reversing jury verdict and holding pharmaceutical label provided an adequate warning as a matter of law where the label warned of the plaintiff's alleged injury). The Recovery Filter indisputably warns of the precise complications Nelson experienced, which renders the warning

adequate as a matter of law in Mississippi.[6] Nelson's attack on the district court's order is fundamentally flawed because he ignores controlling precedent, relies on inapplicable cases applying Georgia and Louisiana law, misrepresents the holding of the one Mississippi case he does cite, and ignores the practical difficulties and inaccuracies inherent in comparative rates. More data does not always mean it's better, and more is certainly not the legal standard.

This Court should affirm dismissal of the failure to warn claim. The warning was adequate as a matter of law.

A. *A Warning Is Adequate as a Matter of Law When It Warns of the Complications at Issue*

Under the MPLA, an adequate warning is a warning 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, taking into account the characteristics of, and the ordinary knowledge common to . . . a physician or other licensed professional who prescribes the drug, device or other product.

Miss. Code Ann. § 11-1-63(c)(ii) (emphasis added). The MPLA's definition of adequacy codifies the learned intermediary doctrine, such that the

[6] In diversity actions in federal court, the substantive law in which the district court sits—here Mississippi—controls. *Erie R.R. v. Tompkins*, 304 U.S. 64, 78 (1938); *Capital City Ins. Co. v. Hurst*, 632 F.3d 898, 902 (5th Cir. 2011); ROA.10202. Under Mississippi law, the Mississippi Products Liability Act applies "in any action for damages caused by a product," including actions asserting failure to warn and design defect. *Elliott v. El Paso Corp.*, 181 So.3d 263, 268 (Miss. 2015).

"manufacturer's duty to warn runs only to the prescribing physician[.]" *Smith v. Johnson & Johnson, Inc.*, 483 F. App'x 909, 913–14 (5th Cir. 2012) (per curiam) (applying Mississippi law); Miss. Code Ann. § 11-1-63(c)(ii); *Fortenberry*, 234 So. 3d at 391 (manufacturer need only adequately warn the learned intermediary).[7]

Construing the MPLA, the Mississippi Supreme Court held: "To be reasonable, the warning should neither understate nor overstate the known risks associated with the use of a particular product." *Janssen Pharmaceutica, Inc. v. Bailey*, 878 So. 2d 31, 58 (Miss. 2004) (internal quotation marks and citation omitted).

> In Mississippi, a warning may be held adequate as a matter of law where the adverse effect was one that the manufacturer specifically warned against.

Austin v. Will-Burt Co., 361 F.3d 862, 868 (5th Cir. 2004) (applying Mississippi law) (emphasis added) (affirming summary judgment and holding warnings on a telescoping news truck mast warned that contact with power lines could cause death and was therefore adequate as a matter of

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[7] Nelson erroneously suggests that the learned intermediary doctrine is an affirmative defense on which Bard bears the burden of proof. Appellants' Brief at 12 ("For a medical product manufacturer to invoke the learned intermediary doctrine as a defense from liability. . . ."). "The learned-intermediary doctrine is not an affirmative defense." *Ackermann v. Wyeth Pharm.*, 526 F.3d 203, 207 (5th Cir. 2008). The MPLA has expressly adopted it as part of its definition of adequate warning. Miss. Code Ann. § 11-1-63(c)(ii). Moreover, Nelson does not dispute the application of the learned intermediary doctrine in this case, which involves a complex medical device and procedure unfamiliar to laypeople, so it is unclear why he argues for burden shifting.

law); *accord Adah v. Bayer Corp.*, No. 3:12-cv-785, 2016 WL 5173512 (S.D. Miss. April 4, 2016) (applying Mississippi law) (granting summary judgment in favor of drug manufacturer because package inserts warned prescribing physician of harms at issue and was therefore adequate as a matter of law); *McSwain v. Sunrise Med., Inc.*, 689 F. Supp. 2d 835, 842–43 (S.D. Miss. 2010) (applying Mississippi law) (holding that warnings in user manual for a wheel chair were adequate warnings as a matter of law, and rejecting plaintiff's contention that the warnings needed to be located on the wheel chair itself); *Cather v. Catheter Technology Corp.*, 753 F. Supp. 634, 640 (S.D. Miss. 1991) (applying Mississippi law) (holding manufacturer's warnings adequate as a matter of law because venous thrombosis and embolism were specifically mentioned in the manufacturer's physician warning as possible side effects). A package insert, such as an information for use, "may be sufficient for the warning to be adequate as a matter of law[.]" *Fortenberry*, 234 So. 3d at 391; *accord Wyeth Labs., Inc. v. Fortenberry*, 530 So. 2d 688 (Miss. 1988) (vaccine warning adequate as a matter of law where it warned of potential, closely related, adverse outcome).[8]

[8] There are two relevant cases with a party named Fortenberry. *Fortenberry* refers to *Johnson & Johnson, Inc. v. Fortenberry*, 234 So. 3d 381 (Miss. 2017), and *Wyeth* refers to *Wyeth Labs., Inc. v. Fortenberry*, 530 So. 2d 688 (Miss. 1988).

An adequate warning under Mississippi law need not be overly detailed or even specific. In *Wyeth*, 530 So. 2d 688, the Mississippi Supreme Court held that a vaccine manufacturer's warning of potential adverse outcomes was adequate as a matter of law even though it did not list the specific outcome suffered by the plaintiff. The vaccine manufacturer warned the vaccine was: (1) "NOT recommended for healthy adults;" and (2) associated with Guillen-Barre Syndrome. *Id.* at 689 n.1, 692–93. The court found that these two warnings adequately warned the treating physician of the risks that a healthy adult might contract "transverse myelitis which 'is closely related, in etiology and pathology, to GBS.'" *Id.* at 689.

Although *Wyeth* pre-dates the MPLA, the Mississippi Supreme Court reaffirmed *Wyeth* in 2017 in *Fortenberry*, 234 So. 3d at 391. The *Fortenberry* court overturned a jury verdict and held a drug company adequately warned of the risk of tardive dyskinesia (TD) where the drug insert listed TD as a potential complication. 234 So. 3d at 386–88. The plaintiff unsuccessfully argued the label was inadequate because it was "cookie cutter" and contained the "same information" on the label as appeared "on every anti-psychotic[,]" which incorrectly gave the impression the drug was "as likely to cause tardive dyskinesia as any of the other [medications]." *Id.* at 392–93.

The plaintiff in *Fortenberry* made the same kind of arguments that Nelson advances. Attempting to create a fact issue regarding the adequacy of the warning for TD, the plaintiff relied on the manufacturer's "promotional materials, internal documents, and expert testimony." *Id.* at 392. Additionally, the plaintiff's expert testified he would have prescribed different, "safer" anti-psychotic medications to plaintiff, where the risk of TD would have been "very unlikely." *Id.* at 390. Although plaintiff did not phrase her arguments as one of comparative rates, the overall thrust of the failure to warn argument was the same: warning of TD was not enough when the likelihood of developing TD was higher when taking the defendant's drug compared to other, similar drugs.

The Mississippi Supreme Court flatly rejected this argument. *Fortenberry* explained, "[the plaintiff's] attempt to prove her failure to warn claim through Janssen's marketing materials and internal documents expanded the claim beyond the statutory scope of the Products Liability Act." *Id.* at 394. Instead, the Court held the proper analysis starts and ends with a review of the label. *Id.* The label warned of the risk of TD; therefore, it was legally adequate. *Id.*

B. *Bard's Warnings Were Adequate as a Matter of Law Because They Explicitly Warn of the Complications Experienced by Nelson*

The complications Nelson experienced were migration, fracture, perforation, and embolization of vena cava filter fragments. ROA.5471, 5481, 10214. Those risks are all identified in the Information for Use, as it warns, in relevant part:

> **E. Warnings**
> . . .
>
> 8. Filter fracture is a known complication of vena cava filters. . . .
>
> 9. Movement or migration of the filter is a known complication of vena cava filters. . . .
> . . .
>
> **G. Potential Complications**
> . . . Complications may occur at any time during or after the procedure. Possible complications include, but are not limited to, the following:
> - Movement or migration of the filter is a known complication of vena cava filters . . . .
> - Filter fracture is a known complication of vena cava filters..
> - Perforation or other acute or chronic damage of the IVC wall.
>
> . . .
>
> **All of these above complications have been associated with serious adverse events such as medical intervention and/or death. . . .**

ROA.4054 (warning set forth in more detail, *supra* pp. 3–4). Under *Fortenberry* and *Wyeth Labs*, the warning is adequate as a matter of law,

and Bard is entitled to summary judgment on the Nelsons' failure to warn claim. ROA.10210, 10213–10214.

Appellants' Brief does not address the Information for Use, or even attempt to argue that the Information for Use fails to warn Dr. DeVun of the risk of migration, fracture, perforation, or embolization. *See generally* Appellants' Brief.[9] While he claims in passing that "Bard concealed its knowledge of the filter's *actual* lethality" (Appellants' Brief at 7 (emphasis in original)), this is both incorrect and irrelevant. The Information for Use does warn of the risk of lethality or "death." ROA.4054, 10198. But the potential risk of death has no bearing on this case as Nelson did not die. *See Austin v. Bayer Pharms.*, No. 5:13-CV-28-KS-MTP, 2013 WL 5406589, at *7–8 (S.D. Miss. Sep. 25, 2013) (dismissing plaintiff's claim for failure to warn of side

[9] The district court noted that Nelson's experts testified the Information for Use did not warn of the risk of a retained, irretrievable foreign body. ROA.10206 n. 6. However, Nelson did not argue in his briefing that the warning was defective because it failed to warn of the risk of an irretrievable foreign body. *See generally* ROA.5467–86. Nonetheless, the district court still addressed this argument and held because Nelson provided no evidence that Bard "knew" or in light of reasonably available knowledge "should have known about" the risk of an irretrievable foreign body, Bard had no duty to warn of this alleged risk. ROA.1026 n. 6. Nelson has not argued on appeal that the district court erred in finding no duty to warn of the risk of irretrievable foreign bodies; similarly, he has not identified any evidence that Bard was aware of this alleged risk. Nelson has waived this issue. Lastly, an irretrievable foreign body "is closely related" to, and thus adequately warned of, by the disclosed complications of fracture and embolization. *Wyeth*, 530 So. 2d at 689.

effects plaintiff did not experience because drug maker's alleged failure to warn of them did not cause any injury).

A warning need not be detailed or expound on risk rates—it need only warn in clear language that there is a risk of a complication. *See Fortenberry*, 234 So. 3d at 393–94. Here, the Information for Use provides that warning. As such, the warning is adequate as a matter of Mississippi law, and this Court should affirm the district court's order dismissing the failure to warn claim.

C. *Nelson Ignores Controlling Law and Advocates for Comparative Rates Based on Inapposite Law and Irrelevant Allegations.*

Nelson's analysis is limited to insisting that Bard was obligated to disclose comparative complication rates of various filters in addition to warning that the complications could occur.[10] He provides this Court with no Mississippi law to justify this novel interpretation of adequacy.

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[10] Nelson asserts for the first time on appeal that the warning should have contained information about the comparative rates of adverse events when the IVC filter is removed at six months versus left in permanently. Appellants' Brief at 13 ("[t]he 'when should it have been removed' issues has been lost amidst the discussion about tilt, fracture, etc."). Nelson never raised this issue in the district court. *See* ROA.1554–1555, 2538–2562, 5467–5485, 10303–10409. "A party forfeits an argument by failing to raise it in the first instance in the district court—thus raising it for the first time on appeal—or by failing to adequately brief the argument on appeal." *Rollins v. Home Depot USA, Inc.*, 8 F.4th 393, 397 (5th Cir. 2021). A plaintiff forfeits an argument "that a fact dispute precluded summary judgment by failing to raise it first before the district court." *Id.* at 397–98. Nelson failed to argue in the district court that rates of complications after six months were lower than when the filter remained permanently, and that this created a fact issue as to adequacy. Nelson has forfeited this argument.

Bard's warnings were adequate as a matter of law, and Bard's alleged knowledge that the Recovery Filter purportedly experiences higher complication rates than other devices cannot create a fact dispute, as explained in the five sections below. First, *Fortenberry* affirms that comparative-rate information is irrelevant to the adequacy analysis under Mississippi law. Second, Mississippi is by no means an outlier, as numerous jurisdictions have reached the same conclusion. Nelson avoids these cases entirely and relies on a single case applying Georgia products liability law, which is fundamentally different than Mississippi law. Third, Nelson argues that a duty to warn of "dangerous propensities" requires warning of rates of adverse outcomes, but the linguistic argument falls flat. Fourth, Nelson argues that adequacy should be determined based on "how it influences the learned medical intermediary," which essentially attempts to transform the objective standard in the MPLA into a subjective inquiry. Fifth, Nelson never articulates how manufacturers should provide comparative rates and overlooks the practical problems with this approach.

1. Under *Fortenberry*, Comparison With Competing Products Is Not Relevant to the Adequacy of a Warning.

Mississippi has flatly rejected the notion that internal documents regarding the safety of a medical product and comparisons to competing

products are relevant to an adequacy inquiry where the manufacturer has warned of the complications at issue. *Fortenberry*, 234 So. 3d 381. This is binding precedent. Nelson offers no explanation as to how his suggested warning comports with *Fortenberry*.

As previously discussed, *supra* pp. 18–19, *Fortenberry*, 234 So. 3d at 386–88, took the dramatic measure of reversing a jury verdict and held that a drug warning was adequate as a matter of law where it warned of the complications at issue. Plaintiff conceded that the label warned of TD, but presented the manufacturer's internal documents, marketing materials, and expert testimony attempting to show that the risk of TD was higher than in other similar medications. Had the Mississippi Supreme Court wished to expand the definition of adequacy to encompass additional information regarding complication rates under such circumstances, this case would have presented a prime opportunity to do so.

The dissenting opinion indicates that the *Fortenberry* Court certainly considered this argument. The dissent argued that the adequacy of the warning should be a question of fact because "[r]easonable and fair-minded jurors in the exercise of impartial judgment could have heard [the expert's] testimony and concluded that the Risperdal warnings, which Dr. Fann described as 'meaningless,' 'cookie-cutter information' which appeared on

every antipsychotic drug, were inadequate to warn [the treating physician] of the severity of the risk of tardive dyskinesia associated with Risperdal." *See id.* at 410-11 (Kitchen, J. dissenting). Instead, *Fortenberry* not only held the label was adequate, but also concluded that considering internal documents "expanded the claim beyond the statutory scope of the [Mississippi] Products Liability Act." *Id.* at 393.

From *Wyeth* to *Fortenberry*, decades of Mississippi law consistently hold that a warning is adequate as a matter of law where the manufacturer expressly warns of the risks at issue; additional information about that risk is not required.

2. Numerous Jurisdictions With Similar Legal Frameworks Have Rejected Comparative Rates.

Mississippi is not an outlier. Courts across the country have similarly held that a manufacturer has no duty to warn of rates of adverse events generally or comparative rates related to other similar products. *See Yates v. Ortho-McNeil-Janssen Pharm., Inc.*, 808 F.3d 281, 291–92 (6th Cir. 2015) (applying New York law) (affirming summary judgment on failure-to-warn claim where manufacturer warned of risk of stroke, but did not warn risk was higher than in other birth control methods, and explaining "[w]arnings can always be made 'better,' . . . 'better' is not the standard New York law requires—adequacy is"); *Ackley v. Wyeth Labs., Inc.*, 919 F.2d 397, 405 (6th

Cir. 1990) (applying Ohio law) ("The manufacturer is obligated to make a reasonable disclosure of all the risks inherent in its own drug. It is not obligated to provide a comparison of its drug with others." (citation omitted)); *Adamson v. Ortho-McNeil Pharm., Inc.*, 463 F. Supp. 2d 496, 504 (D.N.J. 2006) (applying New Jersey law) ("Plaintiff does not cite a single case to suggest the existence of such a duty [to provide information comparing their product to another] and courts have routinely held that competitors have no duty to advertise or sell a competitor's products."); *McDowell v. Eli Lilly & Co.*, 58 F. Supp. 3d 391, 405 (S.D.N.Y. Nov. 7, 2014) (applying New York law) ("courts have refused to graft onto the adequacy standard a requirement that a package insert must include specific adverse event frequencies."); *Hurley v. Lederle Labs.*, 651 F. Supp. 993, 1002 (E.D. Tex. 1986), rev'd on other grounds, 863 F.2d 1173 (5th Cir. 1988) (applying Texas law) ("The plaintiff cites no authority for the proposition that a drug manufacturer has a duty to warn prescribing physicians of the rate of adverse reaction."); *Pluto v. Searle Lab.*, 690 N.E.2d 619, 621 (Ill. App. 1997) (holding warning adequate as a matter of law where label warned of risks and explaining manufacturer "is under no duty to provide information on other products in the marketplace.").

Rather than grapple with these authorities, Nelson cites *Booker v. C. R. Bard, Inc.* (*In re Bard IVC Filters Prod. Liab. Litig.*), 969 F.3d 1067, 1076 (9th Cir. 2020), for the incorrect proposition that "a Bard IFU warning was found to be inadequate[.]" Appellants' Brief at 16 n. 11. The Ninth Circuit did not hold that the warning was inadequate—it held that under Georgia law, adequacy was a fact question for the jury. *See Booker*, 969 F.3d at 1076. Conversely, Mississippi does not require that the adequacy of a written warning always go to a jury. *See Austin*, 361 F.3d at 868; *Fortenberry*, 234 So. 3d at 391; *Wyeth Labs.,* 530 So. 2d at 692. Also unlike here, two other courts had considered the comparative rates issue under Georgia law, and both courts had also concluded it was an issue of fact for the jury. *See Booker*, 969 F.3d at 1076–77.[11]

[11] Bard notes a recent anomaly concerning Mississippi jurisprudence in *Munson v. C. R. Bard, Inc.*, No. 3:14-cv-279-MPM-RP, 2021 WL 4261595 (N.D. Miss. Sep. 20, 2021), a decision from the Northern District of Mississippi. *Munson* is at odds with binding precedent from the Mississippi Supreme Court, as the opinion creates an unsupportable exception to *Fortenberry*. *Munson* held that the issue of comparative rates created a fact issue as to the adequacy of an IVC filter warning under the MPLA. Under this exception, the adequacy of a warning that properly advises of the complications at issue is nevertheless a fact issue for the jury because the plaintiff's injuries are serious, a paid expert testifies that the label is not adequate, and a different plaintiff governed by different state laws prevailed in a different trial. *Id.* *2–4, *6. The opinion does not reconcile its exception with Mississippi precedent and erroneously comments that *Fortenberry* had "no clear holding either way on this issue." *Id.* at *11. Further, the opinion ventures into public health policy, and supplants the work of the FDA with independent medical research on the purported "dangers" of IVC filters. *See id.* *11–13. This opinion dramatically departs from controlling Mississippi law and should not be followed. This opinion also departs from the consensus in other jurisdictions. *See supra* Section II.C.2.

3. Nelson's Fixation on Warnings of a "Dangerous Propensity" Fails to Explain Why Rate Information is Required Under the Law

Nelson's singular attempt to find a Mississippi hook for his argument is based exclusively on an erroneous citation. Nelson cites *Mississippi Valley Silica Co. v. Eastman*, 92 So. 3d 666, 672 (Miss. 2012), for the proposition that there is a duty to warn of a product's "dangerous propensities." Appellants' Brief at 13, 20. *Mississippi Valley Silica* does not contain the phrase "dangerous propensities," or even the words "dangerous" or "propensities,"[12] and it contains no such holding. Instead, the case relates to jury instructions concerning the sophisticated user doctrine. 92 So. 3d. at 672. Furthermore, Mississippi does not use the phrase "dangerous propensities" in formulating its test for the adequacy of a warning. *See, e.g.*, Miss. Code. Ann § 11-1-63(c)(ii) (defining adequate warning by using reasonably prudent physician standard); *Fortenberry*, 234 So. 3d at 391 ("An adequate warning is one reasonable under the circumstances."); *Wyeth Labs., Inc.*, 530 So. 2d at 692 (same).

Nonetheless, Nelson engages in a linguistic analysis that achieves nothing. According to Nelson, a "dangerous propensity":

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[12] The district court admonished counsel on this point: "this quoted language cannot be found anywhere in *Windham*, nor any other decision. Counsel [for Nelson] is strongly reminded to exercise extreme caution in quoting the law/holdings to this Court or any other court for that matter." ROA.10207.

> means a tendency to behave in a particular *harmful* way . . . . If "risk" means the possibility of something harmful happening, then "substantially significant"[13] risk means an unreasonably high possibility of something harmful happening (i.e., a likelihood).

Appellants' Brief at 14. The suggestion is that the manufacturer must issue a warning where there is a "high possibility of something harmful happening." Bard provided this very warning, although there is no high probability of harmful occurrence with the Recovery Filter. ROA.6289, 6314. The Information for Use clearly warns of the potential risk of migration, perforation, fracture, and embolization (and death). ROA.4054. Missing from Nelson's analysis is how "dangerous propensities" translates into metrics regarding number of complications, as opposed to a clear warning that there is a risk of such complications. No Mississippi court has interpreted this phase to require rates, comparative information, odds ratios, or any other metric.

Nelson's dangerous propensities argument metamorphosizes into an assertion that the district court erred because "isn't there a bright red line

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[13] Nelson does not state what he is quoting by referring to a "substantially significant risk." Appellants' Brief at 14. Further, he later references "statistically significant" information. Appellants' Brief at 21. Whether a result from a study is "statistically significant" refers to the likelihood a particular result is likely due to chance rather than some factor of interest. *See* Federal Judicial Center, Reference Manual on Scientific Evidence, 116, 121, 123–25. (2000 2d ed.) It does not mean, in the colloquial sense, that the probability of the complication occurring is "significant."

where the information concealed is so egregious that the IFU is *per se* inadequate? Isn't this a question best resolved by a jury?" Appellants' Brief at 20. Contradiction aside (as it is either legally inadequate or a jury question—it cannot be both), the thrust of the argument appears to be that the adequacy of an otherwise adequate warning becomes a jury question when the medical device is "egregious[ly]" more dangerous than its competitors' devices.

At the outset, it is crucial to address a serious flaw with the premise—nothing has been concealed. The rates upon which Nelson relies are from publicly available Manufacturer and User Facility Device Experience (MAUDE) data on the FDA's website. This information is accessible and is reported to and maintained by the very federal agency tasked with regulating medical devices in order to protect patients. It is inaccurate to claim that information is "concealed."

Nelson's proposed exception also ignores that the Recovery Filter is an FDA-cleared medical device. In addition to receiving MAUDE reports regarding potential adverse outcomes, the FDA has expansive investigative authority. Yet, the FDA did not recall the Recovery Filter, require Bard to issue a "Dear Doctor" letter advising of the risks Nelson alleges, or otherwise express any concern about the rates of adverse events associated with the

Recovery Filter.[14] To be clear, these facts do not matter to the analysis under Mississippi law and cannot now be used to manufacture a fact dispute to reverse summary judgment. Mississippi law focuses on the actual warning. But, if the basis for Nelson's appeal is to use the federal court to create a novel exception to Mississippi law based on "egregious" risks, his own rule certainly does not apply. The FDA's inaction undermines any assertion that the risks are "egregious."

4. The Subjective and Unreasonable Expectation of the Implanting Physician Is Irrelevant Under Mississippi Law

Nelson incorrectly argues that "[t]he adequacy of the warning is determined by how it influences the learned medical intermediary, and the mere mention of possible injury or failure modes is not necessarily adequate." Appellants' Brief at 16 (citing *Stahl v. Novartis Pharms. Corp.*, 283 F.3d 254, 266–67 (5th Cir. 2002) (applying Louisiana law)). That is the totality of the argument. The suggestion is that because Dr. DeVun purportedly testified that had he known of the complication rates, as represented by Nelson, he would not have implanted the Filter (*id.* at 2), there is an issue of fact as to the adequacy of the warning. Stated another

[14] When Bard later replaced the Recovery Filter with its newer generations of filters, this decision was based on additional design benefits presented by the new generations, not on any action of the FDA.

way, Nelson's self-serving claim is that the adequacy of a warning is based not on the language of the warning, but on the subjective testimony of a single doctor, with the benefit of hindsight, who could have potential liability. Such a proposition fails for three reasons.

First, as previously discussed, Mississippi law has intentionally narrowed its adequacy inquiry to the language in the label alone. *Fortenberry*, 234 So. 3d at 394. If the testimony of a retained expert physician (with no potential medical malpractice liability) is not enough to create a fact issue as to the adequacy of a warning in *Fortenberry*, then the testimony of a physician who could conceivably face medical malpractice liability, who has the benefit of hindsight, is not sufficient either.

Second, the district court properly disposed of a similar argument in its Order:

> Plaintiffs rely on several portions of testimony stating that physicians and patients expect that kind of information to be put into the IFU. However, subjective expectations are not the standard for liability in Mississippi. To find that Bard may potentially be found liable for failing to include comparative risk information in warnings based on the expectations of physicians and patients, regardless of the reasonableness of such expectations, would create new law in Mississippi, which this federal district court is not willing to do. Also, [Nelson's expert] testified that he has never seen comparative risk information included in any IFU for an IVC filer.

ROA.10210 (emphasis added).

The district court is correct: The "reasonably prudent person" standard is an objective standard under Mississippi law. *See Reikes v. Martin*, 471 So. 2d 385, 392 (Miss. 1985). Here, the evidence shows that complication rate warnings do not appear in *any* information for use for *any* filter. ROA.10210, 11029–11030. Just as it is objectively unreasonable for a physician to expect to receive information that he or she never receives, it would be unreasonable to define "sufficient information," Miss. Code Ann. § 11-1-63(c)(ii), to include information that is never provided.

Third, Nelson's citation to *Stahl* is misplaced. Appellants' Brief at 16. In *Stahl,* the Fifth Circuit held that under distinct Louisiana law a drug warning was not adequate as a matter of law "simply because the warning label contains a clear and unambiguous reference to the adverse reaction suffered by the plaintiff. . . . the plaintiff's prescribing physician must also unequivocally testify that the warning was adequate to inform him or her of the risks involved in prescribing the drug." 283 F.3d at 267. Thus, unlike Mississippi law, Louisiana law has both subjective and objective components in determining adequacy. *Stahl* has no persuasive value to this Court. [15]

[15] The district court also distinguished *Stahl* by noting that the Information for Use did not contain a "mere mention of possible injury" as the warning did in *Stahl*; rather, the Information for Use clearly articulated the risk of known complications. ROA.10212. "These warnings are clear and explicit and were sufficient to warn Dr. DeVun of these possible complications." ROA.10214.

5. There Is No Feasible Method for a Medical Device Manufacturer to Adequately Report Complication Rates.

One factor relevant to the objectively reasonable standard is that Nelson asks for something that is simply not feasible as a general practice. Unsurprisingly, Nelson never describes what his proposed warning should look like, or the nature, type, and source of complication rates that should be included to cross the adequacy threshold. The district court observed the inherent difficulties in Nelson's proposed duty:

> The Court agrees with Defendants that Plaintiffs' "failure to disclose comparative risk" theory effectively charges manufacturers and sellers with having to know their competitors' products' failure rates, ignores informational biases associated with the latency with which manufacturers or sellers receive complaints for new products as compared to established products, and creates new liability in every instance where one product is alleged to have a higher risk of complications than another—regardless of whether any such difference has clinical significance.
>
> For this Court to deem that the warnings were inadequate because they did not include information on the *likelihood* of occurrence would be to embark on a slippery slope. At present, a manufacturer's duty is to adequately warn of known adverse effects. To go beyond that and find that, even though a manufacturer warned of a known danger, it can be liable because it failed to give the frequency of the danger or the percentages of danger compared with other products makes legal compliance nearly impossible and potential liability wholly unpredictable. As defense counsel pointed out during oral argument, rate of failure statistics would change on a regular basis. How often would such information need to be disseminated? Would the percentage of

> failure rate be tied to finding the product is unreasonably dangerous?

ROA.10210–10211.

Similarly, in *Hurley,* 651 F. Supp. at 1002, the Eastern District of Texas held a drug manufacturer has no duty to warn prescribing physicians of the rate of adverse reactions, commenting, "[a]s a practical matter, this would be extremely difficult, perhaps impossible." (quotation marks and citation omitted). Even *Booker*, the comparative rate case upon which Nelson relies, prefaced its holding that adequacy was a fact question under Georgia law by acknowledging practical difficulties in comparative rates: "manufacturers generally do not have special access to information about their competitors' products, and such information might be difficult for consumers to evaluate meaningfully." 969 F.3d at 1076–77; *see also Pluto*, 690 N.E.2d at 621.

Nelson's brief includes multiple references to the FDA's MAUDE[16] database. Appellants' Brief at 4, 5, 14, 15. But the FDA expressly disclaims the use of that data for comparative purposes on the FDA's MAUDE database homepage:

- Although MDRs are a valuable source of information, this passive surveillance system has limitations, including the potential submission of incomplete, inaccurate, untimely, unverified, or biased data. In

[16] Nelson refers to MAUDE/IMS data, but offers no explanation of what IMS data is, how it is used, or the source for such data. Nelson does not cite to the record for any explanation. Because the phrase is used in conjunction with MAUDE data, Bard addresses the propriety of MAUDE data only.

addition, the incidence or prevalence of an event cannot be determined from this reporting system alone due to under-reporting of events, inaccuracies in reports, lack of verification that the device caused the reported event, and lack of information about frequency of device use.

- MDR data alone cannot be used to establish rates of events, evaluate a change in event rates over time or compare event rates between devices. The number of reports cannot be interpreted or used in isolation to reach conclusions about the existence, severity, or frequency of problems associated with devices.

- Confirming whether a device actually caused a specific event can be difficult based solely on information provided in a given report. Establishing a cause-and-effect relationship is especially difficult if circumstances surrounding the event have not been verified or if the device in question has not been directly evaluated.

Food & Drug Admin, MAUDE—Manufacturer and User Facility Device Experience, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/textsearch.cfm (accessed Dec. 15, 2021) (emphasis added) (hereafter "MAUDE" webpage).[17]

MAUDE data is anecdotal, requires self-reporting, does not verify causation, and is anonymous. In fact, Nelson's own expert criticized reliance on MAUDE as a source of comparative rates for these reasons. Appellants' Brief at 15 (citing ROA.6591–6592). It is, in essence, not reliable for the

[17] This Court may take judicial notice of information contained in an official government web site under Federal Rule of Evidence 201. *See Hawk Aircargo, Inc. v. Chao*, 418 F.3d 453, 457 (5th Cir. 2005) (taking judicial notice of information published in the National Mediation Board's agency report that was available on the agency website).

proposed purpose.[18] *See, e.g.*, *Keen v. C. R. Bard, Inc.*, 480 F. Supp. 3d 624, 632–33 (E.D. Penn. 2020) (refraining from relying on MAUDE data as a basis for evaluation of complication rates for purposes of ruling on summary judgment). Complication rate information is inherently nuanced, and, frankly, is counterproductive on an Information for Use.

The district court's legal analysis of Mississippi law alone justifies affirming its order granting Bard summary judgment on the failure to warn claim. But the district court's observations on the feasibility, or lack thereof, of Nelson's proposal reinforces that the Law makes good common sense.

III. Nelson Failed to Provide Evidence That an Inadequate Warning Caused His Injuries.

A. *The Court Can Reach This Issue.*

This Court need not reach this issue because the adequacy of Bard's warning is fatal to the Nelsons' claim for failure to warn. However, the Court can hold that the Nelsons failed to create a genuine issue of material fact as to proximate cause, even though the district court did not reach it.

[18] To be certain, MAUDE has it uses and is a valuable tool for the FDA oversight process. It can be thought of as a proverbial canary in the coal mine, and reports can put the FDA and manufacture on notice of potential issues. To that end, the FDA is aware of the MAUDE reports regarding the Recovery Filter, and has taken no adverse action, indicating that the FDA does not share Nelson's opinions regarding the risks associated with the Recovery Filter.

"It is settled that an appellee may urge any ground available in support of a judgment even if that ground was earlier and erroneously rejected by the trial court." *Castellano*, 352 F.3d at 960.

The final judgment in this case orders that "Plaintiffs take nothing from this action, and all claims are dismissed with prejudice." ROA.10221. Therefore, this Court can uphold dismissal of the Nelsons' claims on any preserved basis supported by the record. *See* ROA.3966–3967 (Bard argues to the district court that one basis to dismiss the Nelsons' failure-to-warn claim is their failure to provide evidence of causation).

B. *The Nelsons' Claims Fail to Meet the MPLA's Proximate Cause Requirements, Which Require the Nelsons to Show That the Implanting Physician Would Have Read the Alternative Warning, Learned Something That He Did Not Already Know, and Acted on That Warning to Prevent the Injuries.*

The Nelsons have the burden to prove by a preponderance of the evidence that an inadequate warning "proximately caused the damages for which recovery is sought." Miss. Code Ann. § 11-1-63(a)(iii). To prove proximate causation under the MPLA, the Nelsons must produce evidence showing that "an adequate warning would have altered [Dr. DeVun's] conduct." *Wyeth Labs*, 530 So. 2d at 691; *accord Deserie Lim v. Ethicon, Inc.*, 519 F. Supp. 3d 380, 387 (S.D. Miss. 2021) (applying Mississippi law and holding summary judgment is appropriate where there is no evidence

that a different warning would have prevented the treating physician from implanting the medical device at issue).

Due to the proximate cause requirement, "[w]hen a physician does not recall ever reading the label at issue, the learned intermediary doctrine requires summary judgment for the manufacturer" facing a failure-to-warn claim. *In re Taxotere (Docetaxel) Prods. Liab. Litig. (Stewart)*, No. MDL 16-2740, 2021 WL 1534481, at *3 (E.D. La. Apr. 19, 2021) (applying Louisiana law).[19] Accordingly, the Fifth Circuit has dismissed failure-to-warn claims on several occasions when the treating physician "did not recall ever reading the" warning. *Pustejovsky v. PLIVA, Inc.*, 623 F. 3d 271, 277 (5th Cir. 2010); *see also Hall v. Elkins Sinn, Inc.*, 102 F. App'x 846, 849–50 (5th Cir. 2004) (dismissing failure to warn claim on summary judgment where treating physician "never read the warning" and "was aware of the risks . . . independently of [the] labels"); *Porterfield v. Ethicon, Inc.*, 183 F.3d 464, 468 (5th Cir. 1999) (holding the plaintiff could not prove causation because "the surgeon who performed Porterfield's hernia surgery using the mesh, testified that at no time prior to Porterfield's surgery had he read Ethicon's package insert or any other Ethicon literature"); *Lim*, 519 F. Supp. 3d at 387

[19] Although Mississippi and Louisiana law differ on issues of adequacy, they apply the same proximate cause standard. *Compare In re Taxotere*, 2021 WL 1534481, at *3, *with Lim v. Ethicon, Inc.*, 519 F. Supp. 3d at 387.

(granting summary judgment in favor of Defendants because implanting physician's testimony that he did not consult Defendants' accompanying documentation meant that Defendants' warnings would not have altered his decision to implant the device); *Blackwell v. C. R. Bard, Inc.*, 2:19-CV-180-Z, 2021 WL 2355393, at *5 (N.D. Tex. June 9, 2021) (dismissing failure-to-warn claim because the plaintiff "presented no record evidence that [the learned intermediary] read or encountered any warning from Bard"). This rule makes practical sense—a warning has no impact if it is not read.

C. *The Implanting Physician, Dr. DeVun, Could Not Say Whether He Read the Information for Use.*

Dr. DeVun "never read the warning, and thus the warning played no role in the events leading to plaintiff's injury." *See Dykes v. Johnson & Johnson*, No. 09-5909, 2011 WL 2003407, at *5 (E.D. La. May 20, 2011). The Nelsons provided no evidence that Dr. DeVun read the Information for Use or any other warning from Bard. Appellants' Brief does not assert otherwise. Therefore, "even assuming that the warnings were inadequate, more detailed warnings, such as comparative failure rates, would have made no difference." *Ebert v. C. R. Bard, Inc.*, 459 F. Supp. 3d 637, 648 (E.D. Pa. 2020).

When asked if he had read the Information for Use prior to placing the Filter, Dr. DeVun testified: "Maybe, but not definitely." ROA.8614. A learned intermediary's "lack of memory" cannot "sustain [a plaintiff's] burden."

Pustejovsky v. PLIVA, Inc., 623 F. 3d 271, 277 (5th Cir. 2010). Dr. DeVun could not even speculate from his general habits because, when asked if he would typically read information-for-use documents, he responded: "Certainly not every one." ROA.8614.

Since the Nelsons cannot show that Dr. DeVun read the Information for Use, "even if the Court were to assume, *arguendo*, that the warning was inadequate, plaintiff would be unable to show that a proper warning would have changed [plaintiff's] doctor's decision" about the device discussed in the Information for Use. *Dykes v. Johnson & Johnson*, No. 09-5909, 2011 WL 2003407, at *5 (E.D. La. May 20, 2011).

D. *Nelson's Choice Not to Look at MAUDE Data on a Publicly Available Website Demonstrates That Omission of Such Data From the Information for Use Cannot Be the Proximate Cause of Dr. DeVun Choosing the Filter.*

Nelson identifies no method, besides checking publicly available databases, that Bard could have feasibly learned the complication rate information that Nelson alleges should have been included in the Information for Use. However, any member of the public can search the MAUDE database with a simple keyword search for a device name. *See generally* MAUDE Webpage. Dr. DeVun testified that he understood the MAUDE complication data. ROA.1046. Accordingly, if Dr. DeVun had

believed that complication rates were significant for his choice of filter and that MAUDE accurately revealed complication rates, he could have easily learned that information. Therefore, omitting MAUDE information from the Information for Use cannot be the proximate cause of Dr. DeVun's decision to use the Filter.

In addition, the MPLA states that a manufacturer cannot be liable for failure to warn unless the "ordinary user or consumer would not realize its dangerous condition." Miss. Code Ann. § 11-1-63(c)(i). Before Dr. DeVun implanted the Filter, he was already aware that the Filter might cause the injuries that Nelson alleges. ROA.11047–11048. And, as explained above, an ordinary physician would look up the information Nelson identifies if such information was required to detect a dangerous condition.

IV. Nelson Provided No Evidence of Essential Elements of His Design Defect Claim.

To prove a design defect claim, a plaintiff must establish that the manufacturer knew of a defective design that created an unreasonably dangerous condition that proximately caused the plaintiff's injuries. A plaintiff must also establish that the design issue could have been eliminated with a feasible alternative design without sacrificing the usefulness or desirability of the device. MPLA §§ 11-1-63(a), (c)(i), (f). Nelson provided no evidence of these elements.

A. *Nelson Failed to Carry His Burden to Provide Evidence That a Design Defect Caused His Injuries.*

1. **The MPLA standard that Nelson ignored required him to show not only that the Filter had a defect that could cause the type of injury alleged, but also that the defect did cause the specific injuries alleged.**

The MPLA states that a manufacturer cannot be liable for a defect unless that defect "proximately caused the damages for which recovery is sought." Miss. Code Ann. § 11-1-63(a)(iii) (emphasis added).[20] This means that Nelson had to provide evidence that a design defect in the Filter not only had the potential to cause the injuries he alleges, but also actually did cause those injuries. *Id.*

"Causation has two levels, general and specific, and a plaintiff must prove both." *Wells v. SmithKline Beecham Corp.*, 601 F.3d 375, 377 78 (5th Cir. 2010). "General causation is whether a substance is capable of causing a particular injury or condition in the general population, while specific

[20] In order to prove that a design defect proximately caused his injuries, Nelson must provide reliable expert testimony. *See Harris v. Stryker Spine*, 39 F. Supp. 3d 846, 855 (S.D. Miss. 2014) (granting summary judgment in favor of medical device manufacturer where plaintiff's medical expert's causation testimony was excluded). Drs. Hurst's and Muehrcke's opinions are inadmissible under *Daubert* and Federal Rule of Evidence 702 because they are unreliable and speculative and neither are qualified to opine that any specific defect caused Nelson's specific injuries. *See generally* ROA.1478–1493 (motion to exclude Dr. Hurst), 3704–3705 (Motion to exclude Dr. Muehrcke), 3837–3860 (memorandum in support of motion to exclude Dr. Muehrcke), 3961 (motion for summary judgment). Because this testimony is inadmissible, Nelson cannot meet his evidentiary burden on the design defect claim, and the court may affirm the district court's order on this basis.

causation is whether a substance caused a particular individual's injury." Courts in the Fifth Circuit dismiss claims unsupported by evidence of specific causation. *Id. See, e.g.*, *Shelter Ins. Co. v. Ford Motor Co.*, No. 2:03CV150-P-A, 2006 U.S. Dist. LEXIS 15238, at *15–16 (N.D. Miss. Feb 8, 2006) (granting summary judgment because plaintiff had not shown specific causation).

Evidence of specific causation is especially important when the alleged injuries are the same type caused by non-defective devices. That is the case here because all inferior vena cava filters carry the risk of the complications that Nelson alleges. Nelson's expert Dr. Muehrcke explained: "the IFU does talk about problems with, you know, death, fracture, perforation, migration; but they are all generic complications of filters. They can occur with all filters." ROA.6474; *see also* ROA.3520–3521; ROA.3222–3228.

2. Nelson provided no evidence that a defect in the Filter caused the specific injuries that he alleged.

Nelson provided no evidence that a design defect[21] (rather than another potential cause such as surgeon error, delaying fourteen years before

[21] The district court held that testimony from Dr. McMeeking established the existence of a defect. ROA.10215–17. However, Dr. McMeeking is not a case-specific expert, and, as such, he may not be used to establish the existence of a design defect in the device at issue in this case. ROA.3968–3970 (motion for summary judgment), 7126–7128 (reply in support of motion). In the absence of evidence of a design defect the claim fails, *see* Miss. Code Ann. § 11-1-63(a)(i)(3), and the Court may affirm summary judgment.

attempting to retrieve the Filter, or an inherent risk of filters) caused his injuries. Instead, Nelson relies on the testimony of his "generic causation expert Robert McMeeking." Appellants' Brief at 23. Fatally, Nelson presents no case-specific expert opinion that a defect in the Filter caused the injuries alleged in this case. Dr. McMeeking merely opined that a defect is "likely" to cause risks for patients, and that tilt associated with the defect "can" lead to the type of injuries Nelson alleges. ROA.6630–6633.

Nelson's expert Dr. Hurst merely opined that the complications were "a cascade of events that is typical of the Bard Recovery Filter." ROA.6541 (emphasis added). This says nothing about whether a defect caused the complications for Nelson, or whether a filter without that defect would have caused the same complications in a patient with Nelson's specific medical history.

Nelson is reduced to asserting, without citation to the Record on Appeal, that the defect "manifested" because complications occurred that the defect could have caused. Appellants' Brief at 27. Nelson supports this speculative assertion only with the following rhetorical question: "How could he have a retained fragment in his lung absent design-induced fracture and migration?" Appellants' Brief at 27. That is the question that Nelson's experts

should have answered but did not.[22] "Without medical expert testimony, [plaintiffs] cannot meet their burden." *King v. Synthes (U.S.A.)*, 532 F. Supp. 2d 828, 836 (S.D. Miss. 2006). Causation in a complex products liability case requires reliable expert testimony. *See Harris v. Stryker Spine*, 39 F. Supp. 3d 846, 855 (S.D. Miss. 2014); *Cuevas v. E.I. DuPont de Nemours & Co.*, 956 F. Supp. 1306, 1312–1313 (S.D. Miss. 1997); *Vaughn v. Miss. Baptist Med. Ctr.*, 20 So. 3d 645, 653–654 (Miss. 2009).

Nelson is making the equivalent of a *res ipsa loquitur* argument that the injuries speak for themselves. In Mississippi, *res ipsa loquitur* cannot be used to establish medical causation. *See Powell v. Methodist Health Care Jackson Hosps.*, 856 So. 2d 353, 356 (Miss. Ct. App. 2003), aff'd, 876 So. 2d 347 (Miss. 2004) (holding plaintiff could not rely on *res ipsa loquitur* to establish proximate causation in medical malpractice case and affirming summary judgment for defendant). That argument is barred by the MPLA, which requires Nelson to prove causation "by the preponderance of the evidence." Miss. Code Ann. § 11-1-63(a). In addition, *res ipsa loquitur* requires showing that "the accident is such that, according to ordinary human experience, it could not have happened without such negligence."

[22] All filters have these known complications. *See, e.g.*, ROA.6474. Perhaps the reason Nelson did not put this question to his experts is that the answer would be fatal to his case: it is not a defect, it is just inherent in these types of life-saving products.

Yazoo & M. V. R. Co. v. Skaggs, 179 So. 274, 277 (Miss. 1938). Nelson's injuries do not meet those prerequisites because the different causes of inferior vena cava filter complications are not within ordinary human experience, and all the alleged complications can happen with filters that do not have a defect. ROA.3222–3228, 3520–3521, 6474

B. *Nelson Failed to Meet His Burden to Provide Evidence of a Feasible Design Alternative.*

"[M]ere mention of a design alternative by an expert comes well-short of lending evidentiary guidance to a court." *Williams v. Bennett*, 921 So. 2d 1269, 1275 (Miss. 2006). Nelson has the burden to establish that a design alternative "would have to a reasonable probability prevented the harm . . . without impairing the utility, usefulness, practicality or desirability of the product to users or consumers." Miss. Code Ann. § 11-1-63(f)(ii).

Failure to provide evidence supporting all elements of a feasible alternative design requires dismissal of the claim by motion for summary judgment. *See Guy v. Crown Equip. Corp.*, 394 F.3d 320, 331 (5th Cir. 2004) (affirming trial court's judgment when plaintiff failed to provide requisite evidence of a feasible design alternative); *Lim*, 519 F. Supp. 3d at 382–86 (granting summary judgment in MDL transfer case because plaintiff's experts' reports failed to discuss alternative designs); *Estes v. Lanx, Inc.*, No. 1:14-CV-052-SA-DAS, 2015 WL 9462964, at *2 (N.D. Miss. Dec. 23, 2015)

("Plaintiff put forth no evidence as to an alternate design. Accordingly, the Court finds that no genuine issue of material fact has been produced as to Plaintiff's design defect claim and that claim is dismissed"); *Elliott*, 181 So. 3d at 268 (surveying Mississippi Supreme Court decisions affirming summary judgment where plaintiffs' experts failed to put forth evidence of a feasible design alternative).

Before examining specific useful and desirable features, it is important to note as a threshold matter that Nelson's identification of different products is not sufficient to meet his burden to show that the Filter could be designed differently. "[T]he availability of alternative treatments is not equivalent to a safer alternative design for the underlying product." *Cole v. C. R. Bard, Inc.*, 4:20-CV-01630, 2021 WL 784661, at *3 (S.D. Tex. Feb. 11, 2021), report and recommendation adopted, 4:20-CV-01630, 2021 WL 784136 (S.D. Tex. Feb. 26, 2021). "[C]ourts throughout the country have held that a party may not show a reasonable alternative design by pointing to the availability of a different [product] available for the same purpose." *Young v. Bristol-Myers Squibb Co.*, No. 4:16-cv-00108-DMB-JMV, 2017 WL 706320, at *10–12 (N.D. Miss. Feb. 22, 2017). Nelson's flawed comparison is akin to arguing that since a vehicle could have been designed as a station wagon

instead of a mini-van, any risk of the mini-van design absent from a station wagon design is a "defect."

1. Nelson provided no evidence of an alternative design that does not impair the Filter's usefulness.

"IVC filters are designed to catch blood clots and prevent them from reaching the heart and lungs" and thus "prevent pulmonary embolism." *Ebert*, 459 F. Supp. 3d, at 641. Nelson provided no evidence that an alternative design would have been just as useful for this purpose, let alone just as useful without impairing desirability.

2. Nelson provided no evidence of an alternative design for the Filter that does not impair the Filter's desirability.

None of Nelson's experts testified that an alternative design for the Filter would not have impaired any of its desirable features, such as its retrievability, cost, method of implantation, ease of use, and overall safety. This is dispositive.

This section analyzes two desirable features of the Filter that Nelson's experts overlooked: overall safety and retrievability.[23]

Nelson provided no evidence that an alternative design was safer overall than the Filter. Instead, Nelson argues, with unreliable evidence, that the Filter has higher rates of some complications. Nelson provided no expert

[23] Bard raised the desirability issue in district court briefing. *See, e.g.*, ROA.10219.

testimony that the Filter has higher rates of the majority of potential complications, or that the combined risks of the Filter are significantly higher than the rates for comparison filters, or that the other complications are less life-threatening. IVC filters can cause a wide range of complications that Nelson does not address, including: acute or recurrent pulmonary embolism, caval thrombosis/occlusion, air embolism, hematoma or nerve injury at the puncture site, hemorrhage, restriction of blood flow, occlusion of small vessels, distal embolization, infection, and stenosis at implant site. ROA.4054.

Under Nelson's approach of cherry-picking complications, the safest filter on the market considering all complications would still be "defective" if a less-safe filter had a lower rate of one complication. This could allow plaintiffs to paradoxically show that all filters, which save lives every day, are defective. For example, if there are two filters, one with a 4% risk of fracture and 1% risk of perforation, and one with a 2% risk of fracture and 2% risk of perforation, both filters would be defective under Nelson's approach because both have a complication rate that is higher than another filter's.

Lastly, Nelson provided no evidence that an alternative design does not impair the retrievability of the Filter. Retrievability is a feature enhancing "desirability" under the MPLA because "clinicians wanted a device they could

retrieve." ROA.4883. "[A]n increasing number of physicians choose retrievable over non-retrievable vena cava devices"). ROA.6367. Therefore, "a permanent filter, is not comparable to a retrievable filter, since the design and purpose of these two products is different." *Oden v. Boston Sci. Corp.*, 330 F. Supp. 3d 877, 889 (E.D.N.Y. 2018). "Any suggestion that [the plaintiff's] physician could have . . . implanted a permanent IVC filter rather than a retrievable one . . . says nothing about whether Bard's [retrievable] Filter is defectively designed." *Cole*, 2021 WL 784661, at *3. The alternative designs that Nelson suggests, such as "stronger hooks" and "longer arms," are likely to impair retrievability, and Nelson provided no evidence to the contrary. Appellants' Brief at 27.

Dr. Hurst opines that "if the implanting physician determined that plaintiff needed a permanent filter, the Simon Nitinol filter, which was on the market at the time of the filter implantation, was a safer alternative filter." ROA.4308 (emphasis added). This is irrelevant because the implanting physician determined that Nelson needed a retrievable filter. Dr. Hurst admits that he does not have any criticism of Dr. DeVun's decision to implant a retrievable filter in light of Nelson's age and comorbidities. ROA.11033.

Nelson argues, without citation to the record, that the Filter was "intended to be permanent." Appellants' Brief at 6. This is misleading because there is no evidence that Dr. DeVun intended it to be permanent and because the FDA approved the Filter for use both as a permanent filter and as a retrievable filter. ROA.6780 (Nelson's brief admitting that the FDA approved the Filter for use as a retrievable filter); ROA.6838 (finding the Filter is retrievable); ROA.10126 (explaining the "FDA determined that these data demonstrated that the Recovery filter could be used safety and effectively in the retrievable filter patient population"); ROA.5435 ("it can be retrieved"). The option to retrieve the Filter from Nelson was valuable because the Filter was implanted for a temporary purpose—to prevent clots during the temporary cessation of anticoagulation medication in anticipation of a liver transplant. ROA.6431–6432, 6446, 6449–6450. "The Recovery Filter may be used as a permanent filter or be implanted temporarily to treat the temporary risk of pulmonary embolism." ROA.2386; ROA.4309 ("Bard represented the Recovery® IVC filter as a device that could be safely placed permanently or temporarily.").

If it were sufficient for a plaintiff to merely identify another device with a lower rate of complications, then the only device that could survive litigation would be the device that diverted all resources away from other

features such as effectiveness, expense, comfort, and flexibility. The MPLA wisely bars that result.

3. Nelson failed to provide evidence that the Filter was "designed in a defective manner" that rendered it "unreasonably dangerous."

Nelson had the burden to prove that the Filter was "designed in a defective manner [that] . . . rendered the product unreasonably dangerous." Miss. Code Ann. § 11-1-63(a)(i), (ii). Nelson cannot carry that burden. Dr. DeVun testified that he could not say whether the complication rates mentioned in Bard's internal documents were necessarily high or low and admitted that complication rates can be significantly different, but still acceptable. ROA.11427–11428. Dr. DeVun also acknowledged that he needed to see more data than what Nelson's counsel presented before he could say whether or not he would still have implanted the Filter. ROA.11427–11428. The district court properly excluded any opinion by Dr. Hurst "that Bard filters have higher complication rates than other IVC filters and have unacceptable risks of caudal migration." ROA.6926.

In addition, all IVC filters have risks of the complications Nelson allegedly experienced. *See supra* pp. 2, 6, 13, 44–46. For this reason, the Filter qualifies as an "unavoidably unsafe product[]" under the Restatement of Torts. *See* Restatement (Second) of Torts, § 402, cmt. K. Comment K

specifies that "[s]uch a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous." *Id.*

The Mississippi Supreme Court "adopted the language of the Second Restatement of Torts § 402A," including "Comment k to this section." *Thompson v. Carter*, 518 So. 2d 609, 619 (Miss. 1987). One court has already held that another model of Bard IVC filter is an "unavoidably unsafe product" because "every IVC filter, including Bard's G2 filter, carries risks of fracture, migration, and perforation." *Ebert v. C. R. Bard, Inc.*, 459 F. Supp. 3d 637, 653 (E.D. Pa. 2020).[24]

The MPLA codifies this rule by providing that a "product is not defective in design or formulation if the harm for which the claimant seeks to recover compensatory damages was caused by an inherent characteristic of the product which is a generic aspect of the product that cannot be eliminated without substantially compromising the product's usefulness or desirability." Miss. Code Ann. § 11-1-63(b).

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[24] While Comment K states that its application is "especially common" for drugs, its rules broadly apply to "products," which by its plain meaning includes devices. Accordingly, in a case involving a punch press device, this Court reminded that "Section 402A is a firmly settled principle in Mississippi's jurisprudence." *Gordon v. Niagara Mach. & Tool Works*, 574 F.2d 1182, 1189 (5th Cir. 1978). There is no "meaningful difference between [a] device and a prescription drug," nor a reason to "believe the framers of comment k would exclude" a device. *Prather v. Abbott Labs.*, 960 F. Supp. 2d 700, 707 (W.D. Ky. 2013).

C. *Nelson Failed to Provide Evidence That a Design Alternative Would Have to a Reasonable Probability Prevented the Harm.*

Nelson had the burden to prove that a design alternative "would have to a reasonable probability prevented the harm." Miss. Code Ann. § 11-1-63(f)(ii). Nelson provided no evidence to carry that burden. ROA.10219–10220. Expert testimony that alternative designs would have "improved" the safety and "help to limit" the complications, Appellants' Brief at 28, is not evidence that these designs would to a reasonable probability have prevented the harm to Nelson. That conclusion would require expert testimony about the effect of a different filter in this specific context with a patient with Nelson's specific needs, lifestyle, and comorbidities. Nelson failed to provide that evidence.

CONCLUSION

For the foregoing reasons, Bard respectfully requests affirmance of the District Court's Final Judgment.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that a copy of this brief was served on counsel of record by using the Court's CM/ECF system on the 16th day of December, 2021.

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CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rules of Appellate Procedure 28(a)(10), 28(b), and 32(g)(1), I certify this brief complies with the type-volume limitations set forth in Federal Rule of Appellate Procedure 32(a)(7) because this brief contains 12,791 words, exclusive of the corporate disclosure statement, table of contents, table of authorities, statement of interest, certificates of counsel, and other items exempted by Federal Rule of Appellate Procedure 32(f).

This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type–style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this brief has been prepared in Microsoft Word in a proportionally spaced typeface using a plain, roman-style, 14-point font.

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