UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

JUSTIN WAYNE HEATH,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**Case No. 3:19-cv-803**
	)	**Judge Aleta A. Trauger**
C.R. BARD INCORPORATED and BARD PERIPHERAL VASCULAR INCORPORATED,	)	
	)	
Defendants.	)	
	)	

MEMORANDUM

C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard") have filed a Motion for Summary Judgment (Doc. No. 44), to which Justin Wayne Heath has filed a Response (Doc. No. 84), and Bard has filed a Reply (Doc. No. 99). Heath has filed a Motion for Partial Summary Judgment (Doc. No. 61), to which Bard has filed a Response (Doc. No. 75). For the reasons set out herein, each motion will be granted in part and denied in part.

I. BACKGROUND

Bard is a company that designs and manufactures medical devices. Heath is a Tennessean who was implanted with a Bard device, the G2 inferior vena cava ("IVC") filter. In short, the G2 Filter is a small device placed in the IVC for the intended purpose of intercepting blood clots before they can enter into the lungs and cause a pulmonary embolism ("PE"). (*See* Doc. No. 76 ¶ 21; Doc. No. 86 ¶¶ 1, 4.) The G2 Filter and a number of other Bard IVC filters have been the subject of a great deal of litigation, including multidistrict litigation ("MDL"), of which this case was formerly a part.

A. Heath's Experience with the G2 Filter

On February 21, 2008, Heath, then age 34 and being treated for morbid obesity, underwent laparoscopic gastric banding surgery at a Nashville hospital. (Doc. No. 76 ¶ 1; Doc. No. 86 ¶ 34.) A week later, he suffered deep vein thrombosis ("DVT") in his left leg and bilateral PE. In response to the DVT and PE, on February 27, 2008, Dr. Mark Freeman implanted a Bard G2 Filter into Heath's IVC. (Doc. No. 76 ¶¶ 2–3.) Dr. Freeman has testified that he was concerned that another PE could be fatal for Heath and that alternative treatments for patients at a high risk of PE would not have been sufficient to prevent such a reoccurrence in Heath's case. (Doc. No. 86 ¶ 36.) According to Dr. Freeman, he has performed over a thousand IVC filter implantations, and the G2 was his "main go-to filter." (Doc. No. 86 ¶¶ 42–43.) According to Dr. Glenn Barnhart, an expert proffered by Bard, the decision to place the filter "met the standard of care given all the circumstances." (Doc. No. 76 ¶ 6.) Heath's medical records state that a "follow-up radiograph showed good orientation of the filter and good positioning of the struts" and that Heath "tolerated the procedure without incident." (*Id.* ¶ 7.)

During his deposition, Dr. Freeman was asked about the discussions he had with Heath before installing the filter. Dr. Freeman testified that he informed Heath of various potential adverse effects of filter placement, including the risk of the filter's migrating or "embolizing"—that is, the filter's becoming unmoored and traveling to a portion of the circulatory system other than the one in which it had been placed. (Doc. No. 86-9 at 60–63.) According to Dr. Freeman, he and Heath fully discussed the risks to Heath's satisfaction, and Heath elected to go forward with the procedure. (*Id.* at 63–64.) The record includes a two-page informed consent form signed by Heath, Dr. Freeman, and a witness, in which Heath confirms that his "physician(s) . . . fully explained to me the nature and purpose of the operation or procedure, the risks involved, the

prospects for success, and possible alternative methods of treatment." (Doc. No. 47-14 at 2.) Dr. Freeman's section of the form similarly attests to the fact that Heath was given full warnings about the risk of the procedure prior to his consent. (*Id.* at 3.)

Dr. Freeman agreed, when asked during his deposition, that the risks of the G2 Filter, as he discussed them with Heath and understood them at the time, "were essentially common to all types of IVC filters." (Doc. No. 86-9 at 63.) Specifically, Dr. Freeman agreed that he had believed that the risk of the G2 filter migrating to Heath's atrium was "[n]ot any more than [with regard to] any other filter." (*Id.* at 72.) He testified that he had reviewed the filter's official Instructions for Use—typically referred to as a device's "IFU"—which acknowledged such risks, but only in the context of a "class discussion about filters," meaning, as far as the court can tell, a discussion about the risks of IVC filters generally, not of the risks specific to the G2 Filter. (*Id.* at 73.)

Dr. Freeman was asked, "[I]f you had known that the G2 filter had a much higher rate of fracture than other filters, would you have brought that information into your [risk/benefit] analysis?" He replied, "Yes." (*Id.* at 74.) He also testified that, if he had known that a particular filter had a higher risk of migration, he would not have been inclined to use such a filter. He testified that, although the patient has the final say about consent to any particular procedure, Dr. Freeman "wouldn't advocate using a filter that [he] thought was inferior to other filters" and therefore "wouldn't be sharing" that filter with the patient as a desirable option. (*Id.* at 76.) When questioned further, he confirmed that he "[a]bsolutely" "would not have used" the G2 Filter if he had "known that it had a big problem with migration." (*Id.* at 80.)

As the court will discuss in greater detail below, Heath's filter did, in fact, ultimately migrate. One issue that the parties have explored in their attempts to determine why that happened is whether Heath's IVC was (or became) too wide for the filter he received to remain reliably fixed

in place. According to the G2 Filter's IFU, the filter is not indicated for "[p]atients with an IVC diameter larger than 28 mm," and the filter "must not be inserted" if the IVC exceeds that measurement. (Doc. No. 61-8 at 1.) Heath's medical records state that, at the time of implantation, "the cavagram[1] show[ed] that the inferior vena cava [was] normal in caliber." (Doc. No. 76 ¶ 5.) Dr. Freeman, however, has acknowledged that he did not specifically measure the IVC and instead relied on his perception and experience to conclude that the diameter, as he saw it, was within the normal range. (*Id.*) He explained that, although he used to specifically measure the IVC for each implantation, he had come to believe that doing so in every case was "kind of a waste of time," because it was possible to make an adequate determination of the size through a simple visual assessment. (Doc. No. 86-9 at 32.) The G2's IFU, however, instruct a physician not to "deploy the filter unless IVC has been properly measured." (Doc. No. 68-1 at 1.)

On August 12, 2016, an x-ray evaluation of Heath's IVC filter was performed at Premier Radiology. The report of the evaluation states that the filter appeared to be in place. However, according to Dr. Lincoln Patel, an expert proffered by Heath, the x-ray showed that the filter had, in fact, begun to migrate slightly. (Doc. No. 76 ¶ 8.) Dr. Patel also concluded that the August 12, 2016 imaging showed that the diameter of Heath's IVC wall was 15.37 mm. (*Id.* ¶ 9.)

On February 19, 2017, Heath began to experience pain, nausea, and a feeling of general unwellness. He went to the emergency department of Horizon Medical Center–Tristar, where a computed tomography ("CT") scan revealed that his G2 Filter had migrated to his heart. (*Id.* ¶¶ 10–11.) The CT also showed that the diameter of the IVC measured 28.6 mm where the legs of the filter had engaged the walls of the IVC—a bit over half a millimeter wider than the upward

[1] A cavagram is a form of imaging that allows the physician to observe conditions within the IVC. *See In re Cook Med., Inc., IVC Filters Mktg., Sales Pracs. & Prod. Liab. Litig.*, No. 1:14-ml-02570-RLY-TAB, 2018 WL 5885539, at *2 (S.D. Ind. Nov. 9, 2018).

boundary indicated by the IFU. (*Id.* ¶ 12.) Heath was transferred to Centennial Medical Center for a higher level of care. (*Id.* ¶ 13.) There, angiography showed that the filter was at "the orifice of the tricuspid valve." (*Id.* ¶ 14.) During Heath's evaluation, his treating healthcare providers also found that he suffered from "severe coronary artery disease in his proximal left anterior descending ('LAD') coronary artery."[2] (Doc. No. 86 ¶ 55.)

Physicians performed a coronary artery bypass graft to address the LAD coronary artery disease, a right atriotomy to remove the filter, a repair of punctures in the right atrium, and an evacuation—that is, a draining—of a hemorrhagic pericardial effusion. (Doc. No. 76 ¶ 15; Doc No. 86 ¶ 55.) The Operative Report from the procedures shows that, during the atriotomy, physicians found an "embolized . . . filter" and a "copious adherent thrombus" that had to be "bluntly separated from the right atrial surface." (Doc. No. 47-20 at 3.) In other words, Heath's heart contained not only the migrated filter but blood clots. Heath maintains that he also sustained kidney damage during the operation, and the defendants concede that his later medical records do show kidney disease, whatever the cause. (Doc. No. 76 ¶¶ 17–19.)

B. Medical and Regulatory Background Regarding the G2 Filter

The G2 Filter consists of two tiers of struts—often referred to as its "arms" and "legs"—that emanate from a small central structure. It can be introduced into the IVC by puncturing the jugular or femoral vein and inserting a catheter, through which the filter passes. (*Id.* ¶ 23.) Once the filter is in its intended place, the arms and legs open to anchor it against the walls of the IVC. (Doc. No. 86 ¶ 9.) The G2 is a permanent filter—meaning that it is capable of being left in the patient's IVC indefinitely—but it is also designed to be retrievable, meaning "capable of removal."

[2] The LAD coronary artery is "colloquially called the 'widowmaker,'" due to the dire consequences of a loss of its function. *Gougeon v. Parks*, No. E061939, 2016 WL 7406428, at *2 (Cal. Ct. App. Dec. 22, 2016).

(Doc. No. 76 ¶ 24.) It was cleared by the Food and Drug Administration ("FDA") for marketing within the United States through what is widely referred to as the "§ 510(k) process," a procedure through which some medical devices can be cleared for sale without undergoing the rigorous "'premarket approval,' or 'PMA' process" reserved for Class III medical devices. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996). The G2 Filter, which the FDA accepted as a Class II medical device, was cleared based on its "substantial equivalence" to a preexisting "predicate device" that was already on the market—namely, Bard's own Recovery Filter. (Doc. No. 76 ¶ 25.)

The parties agree that "treatment for the prevention of PE is usually anticoagulation therapy (colloquially known as blood thinners)," not the implantation of an IVC filter. (Doc. No. 86 ¶ 4.) Indeed, no one in this case suggests that IVC filters are always appropriate or that implanting one is a risk-free proposition. Bard itself takes the position that "IVC filters present inherent risks of various complications, such as penetration of the IVC by the device, migration or embolization of the device, and fracturing of the device." (*Id.* ¶ 10.) Nevertheless, Bard identifies a number of situations in which filter implantation has been considered indicated, typically because blood thinners have shown themselves to be, or are expected to be, inadequate to prevent future PE. (*Id.* ¶ 4.)

The parties agree that "Bard did not conduct any direct-to-consumer marketing of its G2 Filter devices." (*Id.* ¶ 25.) Bard did, however, provide information to physicians. For example, Bard distributed its G2 Filters with their official IFU. (*Id.* ¶ 20.) The G2 IFU contains a list of "Potential Complications," including "[f]ilter fracture" and "[p]erforation or other acute or chronic damage of the IVC wall." (Doc. No. 48-1 at 2.) Regarding the possibility of filter migration, the IFU states:

> Movement or migration of the filter is a known complication of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate

> labeled dimensions specified in the IFU. 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.

(*Id.*) The list of potential complications is followed by the following text, in bold:

> All of the above complications have been associated with serious adverse events such as medical intervention and/or death. There have been reports of complications, including death, associated with the use of vena cava filters in morbidly obese patients. 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.

(*Id.*) Some of the potential complications are also mentioned in another section of the IFU, under the heading "Warnings." (*Id.*) The IFU, however, does not discuss the risks of adverse events relative to the risks associated with other, non-G2 IVC filters, despite what Heath and numerous other plaintiffs have identified as evidence that the G2 Filter was significantly more prone to adverse events, such as migration, than at least some other filters.[3] (*Id.*)

C. This Litigation

On November 16, 2017, Heath filed a form Complaint directly in the preexisting MDL being overseen by Judge David G. Campbell in the District of Arizona. (Doc. No. 1.) On November 12, 2019, the case was transferred to this court. (Doc. No. 5.)

Heath originally pleaded twelve causes of action against Bard, as well as a request for punitive damages. In his briefing, Heath conceded that he is abandoning seven of those theories of liability, leaving five remaining—namely, Counts II, III, IV, VII, and IX. Count II is a claim for

[3] The contention that the G2 Filter was unusually dangerous, compared to other filters, is central to this case, but it has played a relatively small role in the contested issues covered by the summary judgment motions. For the purposes of this Memorandum, it is sufficient to note that Bard has not demonstrated that a reasonable jury would be compelled to conclude that the G2 Filter was as safe as alternative filters—meaning that, for the purposes of the summary judgment issues that have been raised, Heath can proceed under the theory that a reasonable jury could conclude that the G2 was a riskier product, including with regard to the particular adverse events he suffered.

strict product liability based on a failure to warn; Count III is a claim for strict product liability based on a design defect; Count IV is a claim for negligent design; Count VII is a claim for negligent failure to warn; and Count IX is a claim for negligence *per se*. Heath continues to seek punitive damages. (Doc. No. 1 at 3; Doc. No. 84 at 1 n.1 (stating that Heath "withdraws" the other claims).)[4]

II. LEGAL STANDARD

Rule 56 requires the court to grant a motion for summary judgment if "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). If a moving defendant shows that there is no genuine issue of material fact as to at least one essential element of the plaintiff's claim, the burden shifts to the plaintiff to provide evidence beyond the pleadings, "set[ting] forth specific facts showing that there is a genuine issue for trial." *Moldowan v. City of Warren*, 578 F.3d 351, 374 (6th Cir. 2009); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986). Conversely, to win summary judgment as to its own claims, a moving plaintiff must demonstrate that no genuine issue of material fact exists as to all essential elements of her claims. "In evaluating the evidence, the court must draw all inferences in the light most favorable to the non-moving party." *Moldowan*, 578 F.3d at 374 (citing *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986)).

[4] The parties address the question of which claims remain pending in Bard's Statement of Undisputed Material Facts and Heath's Response to that filing, but the statements they make in those documents do not appear to be entirely consistent with the record. For example, Bard states that Heath originally filed a claim, Count VI, for negligent failure to recall/retrofit, and Heath agrees. (Doc. No. 86 ¶ 31.) But his Complaint, which is a filled-out form complaint common in the MDL, very clearly does not opt into Count VI. (Doc. No. 1 at 3.) Rather than attempting to unpack any misunderstanding underlying those filings, the court will rely on the characterizations of which claims were raised and which were abandoned that can be found in the Complaint and briefing—which would ultimately control anyway, as Heath is not entitled to pursue any claim that he either (1) did not bring or (2) expressly withdrew.

At this stage, "'the judge's function is not . . . to weigh the evidence and determine the truth of the matter, but to determine whether there is a genuine issue for trial.'" *Id.* (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986)). But "[t]he mere existence of a scintilla of evidence in support of the [non-moving party's] position will be insufficient," and the party's proof must be more than "merely colorable." *Anderson*, 477 U.S. at 249, 252. An issue of fact is "genuine" only if a reasonable jury could find for the non-moving party. *Moldowan*, 578 F.3d at 374 (citing *Anderson*, 477 U.S. at 252).

III. ANALYSIS

A. Bard's Motion for Summary Judgment

1. Failure-to-Warn Claims (Counts II and VII)

Bard argues that it is entitled to summary judgment with regard to Heath's failure-to-warn claims on the grounds that (1) Heath cannot make the required threshold showing that the G2 Filter was defective or unreasonably dangerous, (2) the warnings that Bard provided were adequate as a matter of law, and (3) there is no evidence that any flaw in the warnings or other failure to warn was a proximate cause of Heath's injuries. Heath responds that the G2 Filter was, in fact, unreasonably dangerous, that Bard should have warned physicians that, among other things, the G2 Filter had a higher risk of migration than alternative filters, and that, if Dr. Freeman had been adequately warned, he would have recommended an alternative course of treatment that likely would have avoided the migration.

a. "Defective condition or unreasonably dangerous" requirement.

In Tennessee, "actions for or on account of personal injury . . . from the manufacture, construction, design, formula, preparation, assembly, testing, service, warning, instruction, marketing, packaging or labeling of any product" are "product liability actions" subject to the

Tennessee Products Liability Act ("TPLA" or "Act"). *See* Tenn. Code Ann. § 29-28-102(6). Under the TPLA, "[a] manufacturer or seller of a product shall not be liable for any injury to a person or property caused by the product"—under any theory of liability governed by the Act—"unless the product is determined to be in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller." Tenn. Code Ann. § 29-28-105(a). "'Defective condition' means a condition of a product that renders it unsafe for normal or anticipatable handling and consumption." Tenn. Code Ann. § 29-28-102(1). Alternatively,

> "[u]nreasonably dangerous" means that a product is dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics, or that the product because of its dangerous condition would not be put on the market by a reasonably prudent manufacturer or seller, assuming that the manufacturer or seller knew of its dangerous condition.

Tenn. Code Ann. § 29-28-102(8). The TPLA further provides, with regard to products that are regulated by statutes and regulations other than the TPLA, that

> [c]ompliance by a manufacturer or seller with any federal or state statute or administrative regulation existing at the time a product was manufactured and prescribing standards for design, inspection, testing, manufacture, labeling, warning or instructions for use of a product, shall raise a rebuttable presumption that the product is not in an unreasonably dangerous condition

Tenn. Code Ann. § 29-28-104(a). Bard argues that it is entitled to that rebuttable presumption because the G2 Filter received § 510(k) clearance and that Heath cannot overcome the rebuttable presumption. (Doc. No. 45 at 6.)

Bard may be able to establish that it is entitled to a presumption in its favor, but it has not demonstrated that it is entitled to summary judgment on the ultimate question of whether the G2 Filter was defective or unreasonably dangerous. Heath has produced a substantial amount of evidence that, if credited by the jury, would show that the G2 Filter was more dangerous than other filters, including, in particular, with regard to the specific risk of filter migration. A reasonable

jury could conclude that, given that other filter models were available that were less prone to migration but could provide an equivalent level of protection from PE, the risks of the G2 Filter were unreasonable and/or the filter was in a defective condition, regardless of any presumption.

b. Adequacy of warnings as a matter of law.

For the purposes of a failure-to-warn claim under the TPLA, "[a]n adequate warning is one calculated to bring home to a reasonably prudent user of the product the nature and the extent of the danger involved in using the product," and "[t]he adequacy of the warning is a question for the jury unless reasonable minds [would] agree on the outcome." *Evridge v. Am. Honda Motor Co.*, 685 S.W.2d 632, 636–37 (Tenn. 1985) (internal quotation marks and citations omitted). An extra layer of complexity arises under that standard with regard to products, such as prescription drugs and medical devices, that are dispensed to laypeople under the supervision of licensed experts, such as physicians. Under the "learned intermediary" doctrine, a medical device manufacturer is required to "reasonably disclose[] to the medical profession all risks inherent in the use of the [device] which the manufacturer knew or should have known to exist." *Harwell v. Am. Med. Sys.*, 803 F. Supp. 1287, 1300 (M.D. Tenn. 1992) (internal quotation omitted); *Nye v. Bayer Cropscience*, 2009 WL 3295137, *12 (Tenn. Ct. App. Oct.14, 2009). If adequate and reasonable disclosures are made, the learned intermediary is typically considered responsible for treatment decisions—in consultation with and subject to the consent of the patient, of course. The learned intermediary doctrine, however, does not remove the requirement that the disclosures be adequate in the first place; the presence of a learned intermediary does not excuse the manufacturer from the obligation to give that intermediary sufficient information to make an informed assessment of risk. *See Pittman v. Upjohn Co.*, 890 S.W.2d 425, 429 (Tenn. 1994).

The Tennessee Supreme Court has provided a non-exclusive list of criteria to be considered in assessing the adequacy of a warning in the medical product liability context:

> 1. the warning must adequately indicate the scope of the danger; 2. the warning must reasonably communicate the extent or seriousness of the harm that could result from misuse of the drug [or device]; 3. the physical aspects of the warning must be adequate to alert a reasonably prudent person to the danger; 4. a simple directive warning may be inadequate when it fails to indicate the consequences that might result from failure to follow it and, . . . 5. the means to convey the warning must be adequate.

Id. (*quoting Serna v. Roche Lab'ys, Div. of Hoffman-LaRoche, Inc.*, 684 P.2d 1187, 1189 (N.M. Ct. App. 1984)). As Bard points out, the G2's IFU disclosed a number of serious risks, including the risk of migration that could lead to potentially catastrophic results. Bard argues that this warning was adequate, as a matter of law, to relieve it from liability for the decision, made by Heath and Dr. Freeman, to install the filter.

Heath responds that he is not arguing that Bard failed to acknowledge that migration was possible; he is arguing that Bard failed to adequately communicate that migration, fracture, and other adverse events were more likely with the G2 than with alternative filters and that, therefore, a physician and his patient could reduce the risk of unwanted outcomes by choosing a different product. Based on the evidence before the court, a reasonable juror could agree. An appropriately comprehensive medical decision-making process looks at risk not merely in yes-or-no terms, but in comparative ones; otherwise, the decisionmaker would have no way to reliably select the best path in the face of a situation in which *some* risk is inherent. For example, it may be that, once a particular patient faces a high risk of a catastrophic PE, there is no course of action that would be totally free of risk. That, though, is why it is so important to know which options are riskier than others; a mere disclosure that some risk will exist no matter what is not enough to guide the ultimate decision. A reasonable jury could conclude that, by disclosing only the risks of IVC filters

generally, without informing the physician that other filters would be less risky, Bard did not provide an adequate warning. The court, accordingly, will not grant Bard summary judgment on the basis that the warnings were adequate.

c. Causation.

Even if a plaintiff shows that a product was unreasonably dangerous and that the warnings that accompanied the product were deficient, the plaintiff must also produce "evidence that [the omitted] warning would have altered the doctor's actions and that the change in the doctor's actions would have averted the patient's injury. 'The key inquiry is whether, had additional warnings been given, the plaintiff would not have sustained [his] injuries.'" *Payne v. Novartis Pharm. Corp.*, 767 F.3d 526, 531–32 (6th Cir. 2014) (quoting *Smith v. Pfizer Inc.*, 688 F. Supp. 2d 735, 746 (M.D. Tenn. 2010)). Bard, based on a few snippets of Dr. Freeman's testimony, argues that the undisputed facts show that his treatment decisions would have been unaffected by any more detailed warning regarding relative risk.

Bard's position on this issue is without merit. Dr. Freeman clearly testified that, if he had been credibly informed that the G2 Filter was riskier than other filters, he would have recommended the other filters instead. While Bard may be able to pick out other portions of his testimony for impeachment purposes, Heath has identified evidence sufficient to allow a reasonable juror to find causation. Similarly, Bard's argument that Heath cannot show causation because another filter *could have* migrated—even if it would have been less likely to—is not a sufficient ground for summary judgment. If the manufacturer of a product could defeat a showing of causation merely by establishing that alternative competitor products were not 100% risk-free, it would effectively give immunity to the manufacturer of any product type that carries some inherent risk, even if that manufacturer made the risk significantly greater than necessary. As the

court will discuss later in this Memorandum, the TPLA contains provisions that account for inherently dangerous products, and those provisions strike a significantly more nuanced and reasonable balance than a *de facto* categorical immunization from liability. Heath will be permitted to argue that, although no filter would have been entirely without risk of migration, his particular migration and injuries were caused by the heightened risks of the G2 Filter.

2. Design-Based Claims (Counts III and IV)

Bard argues that Heath's claims based on the design of the G2 Filter must fail because they are barred by Tennessee's exception to liability for design-based claims if the product at issue is useful but unavoidably dangerous and accompanied by appropriate warnings. While strict liability usually attaches to manufacturers of defective or unreasonably dangerous products for the injuries caused thereby, Tennessee courts have generally adopted Comment k to the Restatement (Second) of Torts § 402A, which creates an exception for "unavoidably unsafe products," if certain conditions are met. *Harwell*, 803 F. Supp. at 1300; *Pittman*, 890 S.W.2d at 428–29. Pursuant to Comment k, an action does not lie against the manufacturer of such a product if the product was "properly prepared and accompanied by proper directions and warning." *Pittman*, 890 S.W.2d at 428–29; Restatement (Second) of Torts, Section 402A, cmt. k.

"Where comment k applies, a prescription drug [or device] manufacturer 'is not subject to strict liability for design defects. Instead, the manufacturer's liability is limited to manufacturing defects, for those cases in which the [drug or device] had been improperly prepared, and warning defects, where a manufacturer's failure to market a drug [or device]. . . [with] adequate warnings of its dangers renders the product defective.'" *House v. Bristol-Myers Squibb Co.*, No. 3:15-CV-00894-JHM, 2017 WL 55876, at *2 (W.D. Ky. Jan. 4, 2017) (quoting *Snawder v. Cohen*, 749 F. Supp. 1473, 1476 (W.D. Ky. 1990)). That limitation on liability is intended to "acknowledge[] that

'some products . . . are so beneficial and necessary that the manufacturer of these products should not, in all instances, be held strictly liable" for harm caused by the product's inherent, unavoidable risks. *Prather v. Abbott Lab'ys*, 960 F. Supp. 2d 700, 706 (W.D. Ky. 2013) (quoting *Graham by Graham v. Wyeth Lab'ys*, 666 F. Supp. 1483, 1496 (D. Kan. 1987)).

"Jurisdictions are split on whether" medical devices automatically qualify as unavoidably unsafe for the purposes of Comment k, "with the majority of courts favoring [a] case-by-case methodology" that looks at the details of the particular device. *In re DePuy Orthopaedics, Inc., Pinnacle Hip Implant Prod. Liab. Litig.*, 888 F.3d 753, 772 (5th Cir. 2018). Even if medical devices do not inherently qualify as unavoidably unsafe, however, the evidence before the court strongly supports the conclusion that IVC filters are, as a general matter, at least *somewhat* unavoidably unsafe, even if they may not need to be *as* unsafe as the G2 Filter was. IVC filters treat a dangerous condition in an aggressive, invasive way that entails inserting a foreign object into the circulatory system of a living person; there is no reason to think that such a process can be done entirely safely. Whether Comment k applies, therefore, is unlikely to hinge on the question of whether IVC filters, as a product type, carry enough inherent risk to at least invoke the possibility of the Comment's applying.

That said, however, Bard has not identified any ground for concluding that, simply because a particular product category is unavoidably unsafe to a certain degree, an individual product within that category will also be treated as unavoidably unsafe, for Comment k purposes, even to the extent that it is vastly more unsafe than the product unavoidably needs to be. This court, therefore, concludes that a case-by-case approach is appropriate, to determine not only whether the relevant broad product category is unavoidably unsafe, but also whether the risks of the particular product at issue were unavoidable or whether, instead, the product suffers from an

additional, avoidable level of risk. *See Adams v. G.D. Searle & Co.*, 576 So. 2d 728, 732 (Fla. Dist. Ct. App. 1991) (stating that, under Comment k, "a product which is as safe as current testing and research permits should be protected," but that "[t]he reverse is also true; a product which is not as safe as current technology can make it should not be protected") (collecting cases from multiple states). In other words, the mere fact that a product is unavoidably unsafe *up to a point* is not license, under Comment k, to make it vastly *less* safe while still avoiding liability. The evidence in this case is sufficient to allow a jury to conclude that the G2 filter was not only unsafe, but avoidably unsafe beyond the unavoidable risks inherent in the product category.

Moreover, as Heath notes, the availability of protection under Comment k is dependent on whether Bard adequately warned physicians regarding the heightened risks associated with the G2 Filter. As the court has already held, there are reasonably disputed issues regarding the adequacy of Bard's warnings. Without an adequate warning, there is no protection from Comment k. Granting summary judgment with regard to Counts III and IV would therefore be premature.[5]

3. Negligence *Per Se* (Count IX)

Tennessee courts have historically recognized that "violation of [certain] statute[s] may be deemed to be negligence *per se*. " *Whaley v. Perkins*, 197 S.W.3d 665, 672 (Tenn. 2006) (quoting

[5] Moreover, as Heath points out, Comment k is, by its own terms, an exception to *strict liability* for products that are *unavoidably* dangerous—not a defense to *negligent* design of a product that is *unnecessarily* dangerous. *See Toner v. Lederle Lab'ys, a Div. of Am. Cyanamid Co.*, 732 P.2d 297, 305 (Idaho 1987) ("Courts and commentators universally agree to [the] limitation on comment k's grant of immunity [to claims for] strict liability.") (collecting cases); *but see Cooper v. Bristol-Myers Squibb Co.*, No. CIV.A. 07-885 FLW, 2013 WL 85291, at *10 (D.N.J. Jan. 7, 2013) (seemingly applying Alabama's version of Comment k to negligence claims). Indeed, even if one disregarded the textual limitation of Comment k to strict liability claims, there would be difficulties in trying to extend it to cases involving negligence. For example, if a product is negligently designed to be more dangerous than alternative versions of the same product, then the product is, under the ordinary meaning of the language used in Comment k, not covered by the Comment because the increased risks at issue were not "unavoidable." Similarly, a court could just as easily reason that the product would not be covered by Comment k because a warning that failed to disclose that heightened risk was not "proper."

Cook ex rel. Uithoven v. Spinnaker's of Rivergate, Inc., 878 S.W.2d 934, 937 (Tenn. 1994)) (italics added). In order for a plaintiff to prevail on such a claim, "it must be shown that the statute violated was designed to impose a duty or prohibit an act for the benefit of a person or the public," and it must "also be established that the injured party was within the class of persons that the statute was meant to protect." *Cook*, 878 S.W.2d at 937 (citations omitted). Bard acknowledges that Heath "lists a litany of federal statutes and regulations that Bard allegedly violated." (Doc. No. 45 at 17.) Bard argues, however, that none of the alleged violations is sufficient to support a negligence *per se* claim, at least in this instance. In support of that argument, Bard relies in significant part on the Tennessee Court of Appeals' opinions regarding medical device liability in *Bish v. Smith & Nephew Richards, Inc.*, No. W1998-00373-COA-R9-CV, 2000 WL 1294324 (Tenn. Ct. App. Aug. 23, 2000), and *King v. Danek Med., Inc.*, 37 S.W.3d 429, 459 (Tenn. Ct. App. 2000), which addressed the boundaries of negligence *per se* in Tennessee with regard to statutory violations that could be considered administrative in nature.[6]

In *King*, the plaintiff had accused the manufacturer of a medical device of "promoting a medical device for . . . a use which has not received premarket approval or 510(k) clearance from the FDA," thereby "violat[ing] the express statutory prohibition against the sale of unapproved or non-cleared devices as well as adulterating and misbranding the devices in violation of the provisions of the Federal Food, Drug, and Cosmetic Act . . . and the Medical Device Amendments

[6] Bard refers to these cases as "binding" and "dispositive." (Doc. No. 99 at 7.) For reasons that the court will explain in this section, the court would not find the cases dispositive, even if they were binding. It should be noted, however, that opinions from Tennessee's intermediate appellate courts on issues of state law are not binding on this court, but are, rather, merely persuasive evidence of how the Tennessee Supreme Court—which does have the authority to bind federal courts on issues of state law—would resolve the same issue. *See Meridian Mut. Ins. Co. v. Kellman*, 197 F.3d 1178, 1181 (6th Cir. 1999) (noting that a federal court may "disregard the decisions of intermediate appellate state courts" if "it is convinced by other persuasive data that the highest court of the state would decide otherwise") (citing *Comm'r v. Bosch's Est.*, 387 U.S. 456, 465 (1967)).

to that Act." *King*, 37 S.W.3d at 455 (citations omitted). The court rejected potential negligence *per se* claims based on those violations, however, writing that "it is not sufficient for a plaintiff to assume . . . that the alleged violation of a statute automatically supports a claim of negligence *per se*," because, "[e]ven if the plaintiffs are within the class to be protected by the statute [violated], a statutory negligence *per se* claim cannot stand unless the statute establishes a standard of care." *Id.* at 460. The court explained:

> Where a statutory provision does not define a standard of care but merely imposes an administrative requirement, such as the requirement to obtain a license or to file a report to support a regulatory scheme, violation of such requirement will not support a negligence *per se* claim[, e]ven if the regulatory scheme as a whole is designed to protect the public or to promote safety . . . .

Id. (quoting *Talley v. Danek Med., Inc.*, 179 F.3d 154, 159 (4th Cir. 1999)). The court concluded that the plaintiffs' claims failed to satisfy that requirement because the plaintiffs had "not even attempted to show that the statutes upon which they base their negligence *per se* claim set out [anything] other than administrative requirements." *Id.* at 457. The court in *Bish* applied the same rule to dismiss similar claims. *Bish*, 2000 WL 1294324, at *1–3.

Heath ultimately does not dispute that some statutory violations are "administrative requirements" insufficient for supporting a negligence *per se* claim. (Doc. No. 84 at 19.) Heath argues, however, that at least one particular requirement that he has identified—the ban on mislabeling embodied in 21 U.S.C. § 352 and 21 C.F.R. § 801.6—establishes a standard of care sufficiently definite to support a negligence *per se* claim in this case. As Heath points out, 21 C.F.R. § 801.6 expressly forbids labeling of a medical device that includes any "false or misleading representation with respect to another device." 21 C.F.R. § 801.6. Such language clearly establishes a particular standard of care intended to protect patients such as Heath. Although the rule set out in *King* and applied in *Bish* involved somewhat similar allegations, the court in *King*

expressly based that rule on the plaintiffs' failure to identify and explain the particular standard of care at issue—a flaw not present here. As the court has already discussed, moreover, a reasonable jury could conclude that Bard's IFU, by discussing the risks of the G2 Filter exclusively in terms of the risks of IVC filters generally, gave the misleading and potentially dangerous impression that the filter was equivalent to alternative devices in terms of risk.

Bard, however, identifies an additional hurdle for a negligence *per se* claim under Tennessee law. As Bard points out, 21 U.S.C. § 337 provides that "all . . . proceedings for the enforcement, or to restrain violations, of [the Food, Drugs, and Cosmetics Act ("FDCA")] shall be by and in the name of the United States." A number of courts, including the District Court for the Western District of Tennessee, have held that that provision impliedly preempts state-law negligence *per se* claims based on FDCA violations. *Hafer v. Medtronic, Inc.*, 99 F. Supp. 3d 844, 862 (W.D. Tenn. 2015) (collecting cases). Similarly, the MDL court has already held, in bellwether cases, that "allowing [a negligence *per se*] claim to go forward would authorize an impermissible action to enforce provisions of the FDCA and its implementing regulations" and that such claims should therefore be dismissed as preempted. *In re Bard IVC Filters Prod. Liab. Litig.*, No. CV-16-00474-PHX-DGC, 2017 WL 5625548, at *9 (D. Ariz. Nov. 22, 2017); *see also In re Bard IVC Filters Prod. Liab. Litig.*, No. CV-16-00893-PHX-DGC, 2018 WL 4356638, at *3 (D. Ariz. Sept. 12, 2018); *In re Bard IVC Filters Prod. Liab. Litig.*, No. CV-16-00782-PHX-DGC, 2018 WL 1256768, at *9 (D. Ariz. Mar. 12, 2018). This court agrees. It is one thing for the State of Tennessee to impose liability related to medical devices that functions alongside federal statutes and regulations. It would be another for Tennessee to appoint itself an independent enforcer of federal laws that Congress has expressly precluded it from enforcing. The court, accordingly, will dismiss

Count IX on the ground that a claim based solely on a federal statutory or regulatory violation would be preempted.

4. Punitive Damages

Bard asks the court to dismiss Heath's request for punitive damages based on Tenn. Code Ann. § 29-39-104(d)(1), which forbids the award of such damages for an injury caused by a drug or device that

> [w]as manufactured and labeled in relevant and material respects in accordance with the terms of an approval or license issued by the federal food and drug administration under the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040, compiled in 21 U.S.C. §§ 301-392, as amended, or the Public Health Service Act, 53 Stat. 682, compiled in 42 U.S.C. §§ 201-300cc-15.

Tenn. Code Ann. § 29-39-104(d)(1)(A). Heath argues first that that provision does not apply to the G2 Filter because § 510(k) clearance does not constitute an "approval or license" issued by the FDA and that the G2 Filter was not "manufactured and labeled . . . in accordance with" any FDA requirements associated with that clearance.

"When resolving an issue of state law," a federal court must "look to the final decisions of that state's highest court, and if there is no decision directly on point, then [it] must make an *Erie* guess[7] to determine how that court, if presented with the issue, would resolve it." *In re Fair Fin. Co.*, 834 F.3d 651, 671 (6th Cir. 2016) (quoting *Conlin v. Mortg. Elec. Registration Sys., Inc.*, 714 F.3d 355, 358–59 (6th Cir. 2013)). Neither party has identified any Tennessee Supreme Court case resolving whether § 510(k) clearance qualifies as "approval" under Tenn. Code Ann. § 29-39-104(d)(1)(A). The court, therefore, must turn to the language of the statute and attempt to construe it in the manner that the Tennessee Supreme Court would. Neither "approval" nor "license" has a statutory definition for the purposes of Tennessee's statutes limiting noneconomic

[7] "*Erie* guess" refers to *Erie R.R. Co. v. Tompkins*, 304 U.S. 64 (1938).

damages. *See* Tenn. Code Ann. § 29-39-101. If one limits those terms to their use in ordinary speech, however, it seems clear that authorization to market a product pursuant to the § 510(k) process is, in fact, a form of "approval." Indeed, as Bard points out, the U.S. Supreme Court itself has referred to "§ 510(k) approval" in its opinions. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 322 (2008); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001).

Heath's argument, therefore, hinges on the premise that, when the Tennessee General Assembly used the term "approval" in Tenn. Code Ann. § 29-39-104(d)(1), it was using a term of art specific to the pharmaceutical and medical device fields, pursuant to which "approval" would refer only to a product's satisfying the "rigorous" standards of the "'PMA' process." *Lohr*, 518 U.S. at 477; *see* 21 C.F.R. § 807.97 ("Any representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding."); *N. Am. Med. Corp. v. Axiom Worldwide, Inc.*, 522 F.3d 1211, 1225 (11th Cir. 2008) ("The DRX 9000 is a Class II medical device, which is only eligible for FDA 'clearance' rather than FDA 'approval;' FDA approval is a separate process that applies only to Class III devices."); *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 762 (S.D.W. Va. 2014) (holding, in the context of a Texas tort statute, that "[c]learance through [§] 510(k) notification . . . does not constitute FDA 'approval' of the device"). The distinction between PMA and § 510(k) clearance is significant and could substantially affect the scope of Tennessee's punitive damages bar; "[i]n 2005, for example, the FDA authorized the marketing of 3,148 devices under § 510(k) and granted premarket approval to just 32 devices." *Riegel*, 552 U.S. at 317 (citing P. Hutt, R. Merrill, & L. Grossman, Food and Drug Law 992 (3d ed. 2007)).

Heath is correct that § 510(k) clearance is decidedly different, in both substance and procedures, from the full premarket approval that is required of Class III devices. "[A]lthough the

[§ 510(k)] process is . . . not a rubber stamp program . . . , it does operate to exempt devices from rigorous safety review procedures." *In re C.R. Bard, Inc., MDL. No. 2187, Pelvic Repair Sys. Prod. Liab. Litig.*, 810 F.3d 913, 920 (4th Cir. 2016). As one circuit court of appeals explained:

> [T]he PMA and 510(k) processes have distinct requirements and different goals. PMA "*is* federal safety review," *Riegel*, 552 U.S. at 323, whereas "the 510(k) process is focused on *equivalence*, not safety," *Lohr*, 518 U.S. at 493 (quotation omitted and alteration adopted). Indeed, "devices that enter the market through § 510(k) have never been formally reviewed . . . for safety or efficacy." *Riegel*, 552 U.S. at 323 (quotation omitted). Rather, the 510(k) exemption is "intended merely to give manufacturers the freedom to compete, to a limited degree, with and on the same terms as manufacturers of medical devices that [previously] existed . . . ." *Lohr*, 518 U.S. at 494.

Eghnayem v. Bos. Sci. Corp., 873 F.3d 1304, 1317 (11th Cir. 2017) (formatting of citations altered). The court, therefore, must determine whether the Tennessee General Assembly's reference to "approval or license" by the FDA includes clearance through § 510(k), a process by which the FDA does, in fact, authorize devices for sale and use but which is distinct from the rigorous safety review that forms the bedrock of the FDA's approval of new Class III medical devices.

Although the question is certainly debatable, the court's best guess is that the Tennessee Supreme Court would be more likely to adopt the more expansive interpretation of "approval or license" that would include § 510(k) clearance. First, it is persuasive that Tenn. Code Ann. § 29-39-104(d)(1) uses only the generic word "approval," rather than the more specific and specialized term "premarket approval." The use of the more general term suggests that the General Assembly was using language in its ordinary sense, not in the more specialized parlance found in federal medical device statutes and regulations. Moreover, there is a plausible argument that the key word in "premarket approval" is not "approval," but "premarket." In that light, § 510(k) clearance is, in fact, a form of "approval"—just not approval that is "premarket," because the § 510(k) process

assumes that a substantially equivalent device is *already* on the market. The court is also persuaded by the fact that the broader statutory scheme in which Tenn. Code Ann. § 29-39-104(d)(1) appears is not primarily a scheme for regulating drugs and medical devices, but for defining the substance and procedures of tort law more generally. The fact that the relevant statutes are ones of broad, general applicability makes it less likely that the General Assembly would have intended to use "approval" in a specialized sense.

The only way that the General Assembly could have intended to use "approval" narrowly here would have been if that legislative body had specifically had the distinction between PMA and lesser forms of FDA review in mind. But if the General Assembly was that deep into the details of federal pharmaceutical law, why did it not more clearly indicate that it was drawing such a distinction? Why did it not just say "premarket approval" or cite the relevant subsections, as opposed to merely saying "approval" and citing generally to the Food, Drug, and Cosmetics Act as a whole? Heath's argument requires the court to assume that the General Assembly was cognizant of, and intended to invoke, a counterintuitive, formal distinction used only in federal medical device law, while, at the same time, being unusually casual and imprecise about the way it referred to that distinction. That reading strikes this court as implausible, and the court's best prediction, based on the currently available clues, is that the Tennessee Supreme Court would agree and hold that "approval" is used in an ordinary sense to encompass § 510(k) clearance. The court accordingly construes Tenn. Code Ann. § 29-39-104(d)(1) to set forth a defense to punitive damages that can be satisfied by establishing that the device at issue was "approved" by the FDA through the § 510(k) process and sold in accordance with that approval.

Heath argues next that, regardless of the definition of "approved," Bard is not entitled to rely on Tenn. Code Ann. § 29-39-104(d)(1) because the G2 Filter was not "manufactured and

labeled in relevant and material respects in accordance with the terms of [its] approval." Tenn. Code Ann. § 29-39-104(d)(1). Specifically, Heath argues that the FDA's conclusion that Bard had satisfied the "substantial equivalence" requirement of § 510(k) clearance "did not impose any requirements on the G2 filter that were 'material and relevant' to the product failures and risks that resulted in harm to Heath." (Doc. No. 84 at 23.) That argument, however, is premised on the assumption that the § 510(k) process is, in effect, wholly unrelated to the questions of product safety and efficacy, which is not the case. Although § 510(k) clearance focuses on equivalence rather than safety or efficacy in and of themselves, it does so because equivalence is defined in relation to a preexisting device that has itself proven to be safe and effective. Moreover, as Bard points out, the G2 Filter's § 510(k) clearance necessarily meant that the FDA concluded that the filter had been appropriately categorized as a Class II, not Class III, medical device, which is only permissible if the FDA concludes that the agency has "sufficient information to establish special controls" related to the device that will "provide reasonable assurance of the safety and effectiveness of the device." 21 U.S.C. § 360c(b). Clearance pursuant to § 510(k), therefore, does, in fact, entail FDA review of facts intended to resolve issues of safety—simply through a different and less arduous process than PMA. The terms of the clearance, therefore, bore directly on the issues of safety and risk allegedly underlying Heath's injury, and selling the device in accordance with that clearance was selling it in accordance with the terms of the relevant approval.

Heath argues next that Tenn. Code Ann. § 29-39-104(d)(1) should not apply here because it includes an exception stating that the defense

> shall not apply in an action against a manufacturer of a drug or device, if, at any time before the event alleged to have caused the harm, the manufacturer, in violation of applicable regulations of the food and drug administration:
>
> (A) Withheld from the food and drug administration information known to be material and relevant to the harm that the claimant allegedly suffered; or

(B) Misrepresented to the food and drug administration information of that type.

Tenn. Code Ann. § 29-39-104(d)(2). As Bard points out, however, that exception raises yet another difficult question about the interplay between state and federal law. The U.S. Supreme Court and the Sixth Circuit have both held that a state's laws will be preempted if they veer too far into the realm of policing a party's actions during the FDA review process, which those courts recognize as particularly within the domain of the FDA itself and, more generally, the federal government and federal law. *See Buckman*, 531 U.S. at 350 ("State-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Agency's judgment and objectives."); *Garcia v. Wyeth-Ayerst Lab'ys*, 385 F.3d 961, 967 (6th Cir. 2004) (holding that exception to Michigan liability shield for FDA-approved products was preempted because it was based on the defendant's alleged wrongdoing before the FDA). There is little doubt that Tennessee's statute, as written, at least risks running afoul of that rule; indeed, Tennessee's statute appears to fall squarely within the Sixth Circuit's holding in *Garcia v. Wyeth-Ayerst*, which, like this case, involved an exception to a statutory safe harbor based on FDA approval. The Sixth Circuit held that a state statute that creates a defense based on FDA approval cannot include an exception to that defense that calls on the court to independently evaluate the propriety of a party's actions before the FDA, because doing so would invade an area that federal law has reserved to itself. *Garcia*, 385 F.3d at 967. Applying Tenn. Code Ann. § 29-39-104(d)(2) wholly as written would violate the same principle.

In *Garcia*, however, the Sixth Circuit stressed that not every application of such a statute would be preempted and that a court, rather than disregarding the relevant provision entirely, can limit its application to those situations in which preemption would not occur. Specifically, the Sixth Circuit held that federal law preempts only a state-law distinction that depends on a *court's*

finding of wrongdoing before the FDA, which "would raise . . . inter-branch-meddling concerns." *Garcia*, 385 F.3d at 966. In contrast, however, the Sixth Circuit held that a state statute could include a distinction based on wrongdoing before the FDA as long as it relied solely on the FDA's *own* finding of wrongdoing to determine whether that provision should apply. *Id.* Accordingly, for example, a provision like Tenn. Code Ann. § 29-39-104(d)(2) could permit punitive damages in a case arising out of an FDA-approved device based on the fact that "the *FDA itself*" made a determination that the manufacturer withheld information, but the same provision could not allow punitive damages based solely on the court's independent finding that such withholding had occurred. *Id.*

In support of its argument that the exception based on withholding evidence from the FDA should apply, Heath points to evidence that, "[i]n 2015, [the] FDA found that Bard's adverse event reporting practices . . . resulted in the failure to properly report to [the] FDA serious injuries resulting from the use of its retrievable filter line," and Heath asserts that those same faulty practices extended back to before his injury. (Doc. No. 100 ¶ 39.) None of the FDA's actual findings, however, expressly identifies a discrete instance of wrongdoing "before the event alleged to have caused the harm" in this case—the implantation of the filter—as required by Tenn. Code Ann. § 29-39-104(d)(2). Heath, rather, asks the court to permit a factfinder to extrapolate the FDA's 2015 findings backwards to conclude that Bard withheld relevant information prior to the 2008 implantation of Heath's filter. Such an inference, however reasonable as it might be from a purely factual perspective, would run afoul of the rule set forth in *Garcia* that, in order to avoid preemption, a state law that draws the line between liability and non-liability based on wrongdoing before the FDA must rely exclusively on the FDA's own finding of wrongdoing to do so. Heath, therefore, has not identified a disputed issue of material fact with regard to the applicability of

Tenn. Code Ann. § 29-39-104(d)(1) and (2), as modified by federal preemption. The court will grant Bard summary judgment with regard to punitive damages.

D. Heath's Motion for Summary Judgment

Heath has identified nine ostensible "affirmative defenses"[8] raised by Bard in its Answer to Master Complaint,[9] on which Heath argues he is entitled to summary judgment: (1) sole proximate cause; (2) assumption of risk; (3) failure to mitigate; (4) comparative fault of Heath; (5) third-party liability, including comparative fault of non-parties, superseding cause, or misuse of the product; (6) sophisticated user; (7) preemption; (8) no injury/damages; and (9) preexisting conditions. (Doc. No. 61 at 1–2.) Bard responds that Heath is not entitled to summary judgment in any respect. The court will address each defense, with the understanding that many of the underlying legal issues have already been explained or even resolved, at least in part, in prior portions of this opinion.

1. Sole Proximate Cause/Fault of Non-Parties (Defenses 1 and 5)

Bard argues that it "has presented sufficient facts to support the affirmative defense that the sole proximate cause of Plaintiff's injuries[,] if any, was the conduct of persons other than Bard and for which Bard is . . . not liable" and that, therefore, summary judgment in Heath's favor on

[8] It may be questionable whether some of these defenses are actually affirmative defenses, as opposed to merely means for negating portions of Heath's case-in-chief. At least for the limited purposes of Heath's motion for summary judgment, that distinction is mostly not significant, because, except where indicated, the court does not conclude that any of the issues raised should be resolved in a way that depends on the allocation of burdens between the parties, other than the ordinary burdens imposed on movants by Rule 56. The court, therefore, will use the nomenclature adopted by the parties, without prejudice to determining whether any particular defense is an affirmative defense for any other purposes.

[9] As its full title would suggest, Bard's Answer in this case was drafted and filed in response to the MDL Master Complaint, not a more detailed complaint regarding Heath's own case. As a result, much of the Answer's language is somewhat general in nature, and it appears to have been designed to account for possible variations between individual cases, including variation in the law and legal terminology of different states. The court will attempt to reconstruct the substance of the alleged defenses at issue from the Answer and the briefing.

any such defenses would be inappropriate. (Doc. No. 75 at 5.) Specifically, Bard argues that it has produced evidence sufficient for a reasonable jury to conclude that Heath was, by no fault of Bard's, either originally implanted with a filter too small for his IVC, which led to or contributed to the migration, or suffered an unusual and unforeseen ballooning of his IVC which caused the filter, which was working as designed, to migrate under the strain of its clot burden. These issues are relevant to the defenses pleaded in the Answer to Master Complaint in two primary ways: first, Bard asserts that it was not the cause of Heath's injuries, which would negate the causation portion of Heath's case-in-chief; and, second, Bard requests that, if Bard is found to be liable, the court should apply comparative fault to assess a portion of Heath's damages to third parties. (Doc. No. 77-3 (Defenses) ¶¶ 5–6, 25–26.) Although these defenses are based on the same basic facts, they differ in key regards, including the fact that the first defense is focused solely on *causation*, whereas the latter defense incorporates the additional concept of *fault*.

Although the evidence on the issue of alternative causation is mixed, Bard is correct that it is reasonably disputable. Specifically, there is evidence that Heath's IVC was, by the time of the migration, too large and that IVCs do not typically change significantly in size over time, meaning either that Heath's physiological predicament was unusual or that his IVC had been mismeasured prior to the migration. As Heath points out, weighing against the possibility that Heath had an unusually distended IVC when the filter was placed in 2008 is that, according to Dr. Patel, 2016 imaging did not show the extreme circumference that had arisen by the time of his 2017 emergency surgery.

While that evidence suggesting that the distension occurred in late 2016 or early 2017 might be sufficient to support summary judgment in a case involving Dr. Freeman's potential liability in placing the filter without doing a precise measurement, the issue with regard to Defense

1 is not necessarily whether Dr. Freeman violated any standard of care, but whether the confluence of all the relevant events meant that the migration of Heath's filter was caused by something *other than* errors by Bard. Based on the evidence available, the court cannot rule out the possibility that a reasonable juror could conclude that issues related to the uncertain and possibly changing circumference of Heath's IVC caused the migration in a way that better behavior by Bard (or even the implantation of a different brand's filter) would not have averted. The court, accordingly, will not grant Heath summary judgment with regard to the first defense identified, the possibility of a non-Bard cause of Heath's injuries that would prevent Heath from establishing causation.

The evidence in support of actual comparative *fault*, however, is decidedly more limited. The purpose of Tennessee's comparative liability regime "is to assess liability in proportion to *fault*," not merely in proportion to causation. *Sherer v. Linginfelter*, 29 S.W.3d 451, 455 (Tenn. 2000) (emphasis added); *see McIntyre v. Balentine*, 833 S.W.2d 52, 57 (Tenn. 1992) (explaining, in case adopting comparative fault in Tennessee, that comparative fault is assessed in proportion to the "percentage *negligence* attributed to" a person (emphasis added)). Accordingly, assessment of comparative fault against an individual "requires proof of the elements" sufficient to establish his negligence and legal responsibility for the injury. *George v. Alexander*, 931 S.W.2d 517, 520 (Tenn. 1996); *see Ridings v. Ralph M. Parsons Co.*, 914 S.W.2d 79, 81 (Tenn. 1996) (recognizing that the foundation for comparative fault is the existence of an applicable "cause of action in tort"); *Comparative Fault, Theory and Effect,* 8 Tenn. Prac. Pattern Jury Instr. T.P.I.-Civil 3.50 (2020 ed.) ("A party is at fault if you find that the party was negligent and that the negligence was a cause in fact and legal cause of the injury or damage for which a claim is made."). To establish that a healthcare provider's role in an injury was wrongful—as opposed to merely unfortunate—a Tennessee plaintiff must establish that the provider violated "the recognized standard of acceptable

professional practice in the profession and the specialty thereof, if any, that the defendant practices." *Kidd v. Dickerson*, No. M2018-01133-COA-R3-CV, 2020 WL 5912808, at *4 (Tenn. Ct. App. Oct. 5, 2020) (quoting *Mitchell v. Jackson Clinic, P.A.*, 420 S.W.3d 1, 6 (Tenn. Ct. App. 2013)); *see* Tenn. Code Ann. § 29-26-115(a)(1), (3) (stating that the plaintiff in a healthcare liability action must establish a deviation from the standard of care and that the injuries at issue were caused by negligence). Bard, however, concedes that its "experts have not opined that [Heath's] physicians violated a standard of care." (Doc. No. 75 at 11.) Instead, it merely points to the fact that Dr. Freeman did not strictly follow the IFU in his assessment of the IVC size and placement of the filter, while nevertheless conceding that "a deviation from the IFU . . . is not necessarily a deviation from the standard of care." (*Id.* at 3 n.2.)

Bard takes the position that "whether Dr. Freeman deviated from the standard of care [by failing to measure the IVC and by selecting the location of the IVC placement] is immaterial," because Bard is offering the underlying facts as "probative of the core issue of whether an alleged defect in Bard's G2 Filter did or did not cause [Heath's] injuries." (*Id.* at 2–3.) Although Bard maintains that it is not conceding the (partial) defense of comparative fault, the court does not know how to construe that portion of its briefing as anything other than an admission that it has not produced evidence sufficient to support such a holding. By raising the issue of comparative fault in an authorized motion for partial summary judgment, Heath created a burden on Bard to identify the evidence and argument that would justify sending the issue of comparative fault to a jury. Insofar as Bard wished for comparative fault to be assessed to a physician, it needed to present evidence that the physician violated a standard of care. It did not do so and admits that it did not do so, and it has identified no caselaw suggesting that establishing a deviation from the IFU is an adequate substitute. The court, accordingly, will grant Heath summary judgment as to the issue of

comparative fault of non-parties, without prejudice to Bard's arguing that actions of those parties were part of the chain of events that was the cause of Heath's injuries.

2. Assumption of Risk (Defense 2)

Generally speaking, Tennessee law recognizes that "[a] person who knows the danger, appreciates the danger, and voluntarily exposes himself or herself to the danger is deemed to have assumed the risk of the injury he or she incurs." *Bielfeldt v. Templeton*, No. M2008-01093-COA-R3-CV, 2009 WL 416002, at *4 (Tenn. Ct. App. Feb. 18, 2009) (citation omitted). Based on the undisputed facts and, in particular, Heath's signing of the surgical consent form, it is clear that Heath—like any competent adult who consents to surgery—did assume *some* risk, and he does not suggest otherwise. However, Heath argues that he cannot reasonably be found to have assumed the full, relevant risk of the implantation of the G2 Filter because he "was not aware, and had no reasonable opportunity to be aware, of the risks associated with" the G2, particularly in comparison to other filters. (Doc. No. 61-1 at 7.)

Although Heath may prevail on such an argument at trial, the viability of this defense will ultimately hinge on facts regarding the adequacy of Bard's warnings—an issue that, as the court has already explained, is reasonably contestable in this case. It will be up to a jury to determine whether the risks of the G2 Filter exceeded those disclosed to Heath and his physicians and whether Heath could therefore be found to have knowingly and voluntarily assumed those risks. The court, accordingly, will not resolve this defense in either party's favor on summary judgment.

3. Failure to Mitigate (Defense 3)

"Under . . . Tennessee . . . law, the failure to mitigate damages is an affirmative defense, and the burden of proving a failure to mitigate falls on the defendant." *B.W. Byrd Metal Fabricators, Inc. v. Alcoa, Inc.*, No. E2018-01750-COA-R3-CV, 2019 WL 3889798, at *6 (Tenn.

Ct. App. Aug. 19, 2019). Heath argues that Bard has not identified evidence sufficient to establish that he failed to mitigate his damages. Bard responds that Heath first experienced chest pain in August of 2016, at which point an x-ray allegedly showed that the filter has begun to migrate slightly. Heath did not suffer the potentially far more dangerous complications until early 2017. Bard argues that Heath failed to mitigate his damages by failing to have the filter removed prior to that later, more serious migration.

A plaintiff's duty to mitigate his damages is not absolute. Rather, "[t]he standard for mitigation of damages is reasonable care . . . ." *Id.* (quoting *Cummins v. Brodie*, 667 S.W.2d 759, 766 (Tenn. Ct. App. 1983)). Bard has not identified any basis for concluding that reasonable care *on Heath's part* would have entailed his making a decision to have the filter removed after the August 2016 x-ray. At most, Bard has identified some limited evidence that Bard's physicians should have identified a potentially loose filter at that time and moved swiftly to address it—although, as the court has discussed, Bard has not actually established (or attempted to establish) that Heath's physicians violated any relevant standard of care. Any argument about potential errors by Heath's physicians, moreover, is immaterial to Heath's own duty to mitigate. The court, accordingly, will grant Heath summary judgment as to the affirmative defense of failure to mitigate damages.

4. Heath's Comparative Fault/Preexisting Conditions (Defenses 4 and 9)

Like the mitigation-based defense to *damages*, two of Bard's defenses to *liability* also focus on Heath's own health and conduct: first, that Heath is comparatively at fault and, second, that his injuries were the result of preexisting conditions beyond Bard's control. On the issue of fault, Bard identifies three ways in which a reasonable juror could allegedly find Heath to be at least partially at fault in his injuries: (1) Heath was a heavy smoker, increasing his risk of PE and of a heavy clot

burden that, Bard argues, led to the migration; (2) Heath failed to undergo testing for hypercoagulation disorder, as had been recommended, which might have resulted in treatment and monitoring that would have reduced his likelihood of developing a large clot burden; and (3) Heath failed to have the filter removed sooner. With regard to the topic of preexisting conditions, Bard, in its Answer, preserved the defense that "[t]he injuries and damages sustained by [Heath] may be due to operation of nature or idiosyncratic reaction(s) and/or pre-existing conditions . . . over which [Bard] had no control." (Doc No. 77-3 (Defenses) ¶ 29.)

The question of comparative fault by a plaintiff poses unique issues in the medical context, because a major purpose of medical treatment is to care for individuals who are already injured and/or at identifiable risk of injury, and those injuries and risks frequently are, as a factual matter, attributable, at least in part, to the actions of patients themselves. In other words, it is often technically true that any injuries that were ultimately caused by medical errors could nevertheless have been prevented if the patient had avoided the actions that brought him to the hospital or doctor's office in the first place. Nevertheless, "a health care provider is required to meet a uniform standard of care in its delivery of medical services to all patients," regardless of the cause for any patient's condition, and "a patient's negligent conduct that occurs prior to a health care provider's negligent treatment and provides only the occasion for the health care provider's subsequent negligence may not be compared to the negligence of the health care provider." *Mercer v. Vanderbilt Univ., Inc.*, 134 S.W.3d 121, 129–30 (Tenn. 2004) (*Harvey ex rel. Harvey v. Mid-Coast Hosp.*, 36 F. Supp. 2d 32, 38 (D. Me. 1999)). Although this is, of course, not a medical malpractice case, similar concerns might arise if Bard sought to rely on Heath's pre-implantation actions to reduce Bard's liability. The G2 Filter was *made for* patients with high-risk, preexisting conditions;

it would make little sense to excuse Bard from liability because Heath did things, prior to the implantation of the filter, that made him high-risk.

Bard, however, does not rely solely on Heath's pre-implantation actions here, but, rather, on his post-procedure actions, to argue that he contributed to the filter's eventual migration, which poses a more difficult problem. Neither party, frankly, has briefed the issue of whether Heath's post-implantation actions are sufficient to constitute comparative fault in much detail. It is Heath, though, who seeks summary judgment on the matter, so the court must consider the adequacy of his briefing as a threshold matter. Heath's discussion of this issue in his initial Memorandum in support of his Motion is less than a page long and includes only a single, very general case citation. (Doc. No. 61-1 at 8–9.) That briefing is not sufficient to demonstrate his entitlement to summary judgment in this instance. The court, accordingly, will deny Heath's motion with regard to his own comparative fault.

With regard to a defense based on preexisting conditions but *not* comparative fault, Bard points to the size of Heath's IVC, his body's generation of a "massive clot burden," and the coronary artery disease that, Bard argues, would have necessitated *some* major surgical intervention, even if there had been no filter migration. Heath's discussion of this issue is even briefer than his discussion of comparative fault. There likely are both legitimate and improper reasons for which Bard might wish to raise issues related to Heath's health in its own defense, and Heath, as the movant, bore the burden of setting out what precisely the court should allow or disallow, if he wished the issue resolved prior to trial. Moreover, as the court has held, the issue of causation is reasonably debatable in this case, and Heath's preexisting health is certainly at least relevant to that inquiry. Because Heath's briefing does not go into the level of detail necessary for

the court to set out what will be permissible as an argument at trial on this issue and what will not, the court will not grant him partial summary judgment.

5. Sophisticated User (Defense 6)

The "sophisticated user" doctrine is sometimes contrasted with the learned intermediary doctrine, because, although they touch on similar principles, "[t]he sophisticated user doctrine focuses on the ultimate user or consumer of the product, whereas the learned intermediary or sophisticated purchaser doctrine focuses on the knowledgeable intermediary who intercedes between the supplier or manufacturer and the ultimate user." *Nye v. Bayer Cropscience, Inc.*, 347 S.W.3d 686, 691 n.4 (Tenn. 2011). In its Response to Heath's Motion for Partial Summary Judgment, Bard writes that it did not plead and does not intend to pursue a "sophisticated user" defense, but rather to proceed under the sophisticated purchaser/learned intermediary theories that the court has already discussed. (Doc. No. 75 at 14.) A review of Bard's Answer confirms that this is correct; Bard uses the phrase "sophisticated *purchaser*," not "user," meaning that there is no distinct sophisticated purchaser defense at issue on which Heath could be entitled to partial summary judgment. (*See* Doc. No. 77-3 (Defenses) ¶ 18 (emphasis added).)

With regard to whether Bard can escape liability based on the theory that Dr. Freeman was a sophisticated purchaser/learned intermediary, that issue is inextricably tied to the adequacy of Bard's warnings, which, as the court has concluded, is reasonably contested and inappropriate for summary judgment. The court, accordingly, will not grant Heath summary judgment with regard to any such defense.

6. Preemption (Defense 7)

The court has already discussed preemption in this Memorandum. Preemption is a legal doctrine that dictates how state and federal law will interact—in particular, when the former must yield to the latter. As the court has held, there are, in fact, legitimate issues of preemption in this case. Specifically, (1) express statutory preemption forbids Heath from pursuing a theory of negligence *per se* because Congress has reserved enforcement of federal pharmaceutical and medical device laws to the federal government, and (2) at least a portion of Tennessee's misconduct-before-the-FDA exception to its punitive damages cap is preempted under Sixth Circuit precedent. Insofar as preemption is a defense in this case, it is Bard, not Heath, that is entitled to partial summary judgment.

7. No Injury/Damages (Defense 8)

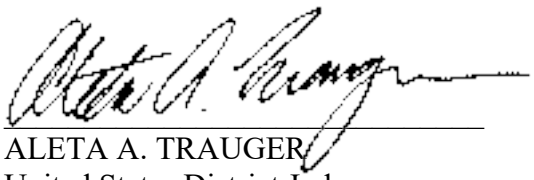
Heath asserts that Bard has preserved a defense that Heath suffered "no injury," which is, of course, belied by the undisputed fact that Heath did suffer a migration of his filter to his heart, for which he required medical intervention. (Doc. No. 61-1 at 11.) Bard responds that Heath has misapprehended this purported defense and that Bard will merely argue that Heath "suffered no injury or damages as a result of the alleged conduct" of Bard; in other words, this defense is just another gloss on the contested issue of causation. (Doc. No. 75 at 17.) The court has already addressed that aspect of Bard's anticipated defense, and there is no separate "no injury" defense on which to grant summary judgment.

IV. CONCLUSION

For the foregoing reasons, Bard's Motion for Summary Judgment (Doc. No. 44) and Heath's Motion for Partial Summary Judgment (Doc. No. 61) will each be granted in part and denied in part. The court will grant Bard summary judgment as to Counts I, V, VIII, IX, X, XI,

XII, and XIII and as to punitive damages. The court will grant Heath summary judgment as to the assessment of comparative fault to third parties and as to the mitigation of damages.

An appropriate Order will enter.



ALETA A. TRAUGER
United States District Judge