IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MISSOURI
WESTERN DIVISION

MELVIN LAMPTON, Plaintiff, v. C. R. Bard, INC. and BARD PERIPHERAL VASCULAR, INC., Defendants.	)	No. 4:19-cv-00734-NKL

ORDER

Pending before the Court is Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc.'s (collectively "Bard") motion to exclude or limit the opinions and testimony of Dr. John F. LaDisa, Jr. Doc. 84. For the reasons described, Bard's motion is granted in part and denied in part.

I. Background

Plaintiff Melvin Lampton brings this product liability action for injuries he suffered as a result of complications allegedly caused by a Bard Meridian inferior vena cava (IVC) Filter. The Filter is a medical device consisting of two tiers of struts that make up its arms and legs. When the Filter is properly placed within the IVC, the arms and legs and anchor onto the walls of the vein. The struts catch or break up blood clots that are traveling up from the legs and prevent them from reaching the heart and lungs.

On October 29, 2012, Lampton's doctor implanted the Filter after Lampton presented to the hospital with pulmonary embolism and deep vein thrombosis (DVT) in his lower right extremity. DVT occurs when blood clots form in a deep vein, usually in the legs, causing pain

and swelling. About seven months after the implantation, on June 30, 2013, Lampton returned to the hospital with leg and back pain. Deposition of Melvin Lampton, 181:21-23. A CT scan revealed that the Filter was well-positioned in his IVC, but also showed extensive iliocaval thrombosis with clot extension above the renal veins. Doc. 107-1, p. 4; Expert Report of Dr. Gurvan Blackman, p. 12.[1] Lampton contends the Meridian Filter caused his thrombosis, and he brought suit against Bard, the maker of the Meridian Filter, alleging design defect, failure to warn, and other claims. Doc. 1.

Lampton's case was transferred to the Court after proceedings in a Multi-District Litigation (MDL). Doc. 3. During the MDL, the plaintiffs designated numerous general experts. After transfer, Lampton designated Dr. John F. LaDisa, Jr., a biomedical engineer, as a case specific expert. Doc. 54-4. Dr. LaDisa is a postdoctoral researcher and Associate Professor within the Department of Biomedical Engineering at Marquette University and the Medical College of Wisconsin. Expert Report of Dr. John F. LaDisa, Jr., p. 1 (hereinafter LaDisa Rep.). He worked as a cooperative education student in Quality Assurance and Research & Development at Boston Scientific Corporation, and took courses in Biodesign and Innovation while studying medical device design innovation at Stanford University. *Id.* His current work involves developing and testing next-generation medical devices, performing computational modeling of these devices, analyzing the impact of medical devices on local vasculature through histology, and teaching students about the methods and best practices applied for these purposes. *Id.* In his report, Dr. LaDisa states:

> In my opinion, the Meridian filter implanted in Mr. Lampton was the source of the thrombotic event which occurred in July 2013 by exposing Mr. Lampton's IVC to a combination of heightened injury due to a smaller caliber IVC and filter-induced adverse blood flow patterns. . .. The Meridian IVC filter is designed for use in IVCs

[1] Lampton designated Dr. Gurvan Blackman as a case specific expert.

> with diameters ≤28 mm, but smaller IVC diameters such as that noted in Mr. Lampton (i.e. 21-22 mm according to his imaging data) are clearly associated with more contact area between filter linkages and the wall. Smaller IVC dimensions also increase the likelihood for damage from arm anchors coming in contact with the IVC wall. These sources of injury, when coupled with local filter-induced changes in blood flow patterns and any imbalance in coagulation factors, are known to cause thrombus formation according to Virchow's Triad.

LaDisa Rep., p. 14. Bard challenges the reliability of Dr. LaDisa's opinions, and Dr. LaDisa's qualifications. Doc. 85. Specifically, Bard seeks to exclude the following five opinions: (1) specific medical causation, including Lampton's alleged injuries and complications that occurred were "caused by the Filter; (2) whether the Filter was "unreasonably dangerous;" (3) whether Bard conducted the required testing prior to taking the device to market; (4) any opinions that are irrelevant to the injuries and complications alleged by Lampton; and (5) any legal conclusions or opinions that rely on documents not previously disclosed. *Id.* at 7-8.

II. Discussion

To be admissible under Federal Rule of Evidence 702, expert testimony must be both reliable and relevant. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 589 (1993); *Barrett v. Rhodia, Inc.*, 606 F.3d 975, 980 (8th Cir. 2010). To satisfy the reliability requirement, the party offering the expert testimony "must show by a preponderance of the evidence both that the expert is qualified to render the opinion and that the methodology underlying his conclusions is scientifically valid." *Marmo v. Tyson Fresh Meats, Inc.*, 457 F.3d 748, 757 (8th Cir. 2006); *Daubert*, 509 U.S. at 589-90. To satisfy the relevancy requirement, the proponent must show that the expert's reasoning or methodology was relevant to the actual facts at issue. *Barrett*, 606 F.3d at 980.

Rule 702 is a rule of admissibility rather than exclusion. *Lauzon v. Senco Prods., Inc.*, 270 F.3d 681, 686 (8th Cir. 2001); *Robinson v. GEICO Gen. Ins. Co.*, 447 F.3d 1096, 1100 (8th

Cir. 2006) ("A review of the caselaw after *Daubert* shows that the rejection of expert testimony is the exception rather than the rule.") (citations and quotations omitted). "As long as the expert's scientific testimony rests upon good grounds, based on what is known, it should be tested by the adversary process with competing expert testimony and cross-examination, rather than excluded by the court at the outset." *Johnson v. Mead Johnson & Co.*, 754 F.3d 557, 563 (8th Cir. 2014). "As a general rule, the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility…. Only if the expert's opinion is so fundamentally unsupported that it can offer no assistance to the jury must such testimony be excluded." *U.S. v. Coutentos*, 651 F.3d 809, 820 (8th Cir. 2011) (citing *Hartley v. Dillard's Inc.*, 310 F.3d 1054, 1061 (8th Cir. 2002); *Bonner v. ISP Techs, Inc.*, 259 F.3d 924, 929-30 (8th Cir. 2001).

A. Whether Dr. LaDisa's Opinions are Unreliable

i. Medical Causation

Bard argues that Dr. LaDisa is not qualified to opine about medical causation because he is an engineer and does not have any medical training. Doc. 85, pp. 10-11. Specifically, Bard seeks to exclude Dr. LaDisa's opinion that the Filter "implanted in Lampton was the source of the thrombotic event which occurred in July 2013 by exposing Lampton's IVC to a combination of heightened injury due to a smaller caliber IVC and filter-induced adverse blood flow patterns." LaDisa Rep., p. 14. Lampton counters that Dr. LaDisa is not offering an opinion regarding medical causation, and that he may "opine that the specific biomechanical design defects of the Meridian filter implanted into Mr. Lampton's IVC was the source of the thrombotic event." Doc. 134, pp. 7-8.

Many district courts preclude engineers from testifying to specific medical causation, reasoning that engineers do not have the requisite medical training to offer medical opinions.

See, e.g., *Braxton v. DKMZ Trucking, Inc.*, 2015 WL 630297, at *4 (E.D. Mo. Feb. 13, 2015). Some of these courts rely on *Smelser*, a Sixth Circuit case. *Smelser v. Norfolk Southern Railway Co.*, 105 F.3d 299, 305 (6th Cir. 1997). In *Smelser*, the Sixth Circuit considered whether a biomechanical engineer could opine that the forces generated during a rear-end collision caused the plaintiff's injuries. *Id.* abrogated on other grounds by *Morales v. Am. Honda Motor Co.*, 151 F.3d 500, 515 & n.4 (6th Cir. 1998). In holding he could not, the Sixth Circuit stated:

> [The biomechanical engineer's] testimony goes beyond [his] expertise in biomechanics. As he previously admitted, he was qualified to render an opinion that made use of his discipline's general principles, described the forces generated in the August 19, 1989, rear-end collision and spoke in general about the types of injuries those forces would generate. [He] is not a medical doctor who has reviewed [the plaintiff's] complete medical history, and his expertise in biomechanics did not qualify him to testify about the cause of [the plaintiff's] specific injuries. As this court observed. . . '[t]he issue with regard to expert testimony is not the qualifications of the witness in the abstract, but whether those qualifications provide a foundation for a witness to answer a specific question.'

Id. (internal citations omitted). Here, by contrast, Dr. LaDisa's testimony about the thrombotic event does not go beyond his training and expertise in biomedical engineering. Dr. LaDisa has experience evaluating fluid dynamics and implantable medical devices, and reviewed Lamtpon's medical records and imaging data before drawing his conclusion. In his report, Dr. LaDisa utilizes Virchow's Triad to discuss the "cumulative impact of vessel damage, imbalance in coagulation factors and abnormal local blood flow patterns." LaDisa Rep., p. 10. His analysis pertains to how forces may affect or injure an individual, and specifically how the contact between a Filter and an IVC wall has the potential to interrupt blood flow and cause thrombosis, particularly in individuals such as Lampton who have relatively smaller IVC dimensions. *Id.* This technical evaluation is reliable because it uses an acceptable method, Virchow's Triad,[2] and

[2] Bard does not posit that Virchow's Triad is unreliable. Doc. 85. Dr. LaDisa's report cites to relevant literature discussing this method, which has also been used by experts in other litigation.

Dr. LaDisa performed the same evaluation utilizing Lampton's medical records and imaging data that he "routinely" does in his scholastic practice. LaDisa Dep., 35:6; 82:8-24. In sum, Dr. LaDisa's "qualifications provide a foundation for [him] to answer a specific question" about whether the Filter's design caused Lampton's thrombotic event. *Smelser*, 105 F.3d at 305; *Laski v. Bellwood, et al.*, 2000 WL 712502, at *4 (6th Cir. 2000) ("Under both *Daubert* and *Smelser*, the inquiry as to the appropriateness of a given expert's testimony is fact specific."). At trial, Dr. LaDisa will be permitted to offer his opinions, rooted in biomedical engineering analysis, about the cause of Lampton's thrombotic event. *Pennsylvania Trust Co. v. Dorel Juvenile Group, Inc.*, 851 F.Supp.2d 831, 838 (E.D. Penn. 2011) (permitting a biomechanical engineer to "analyze[] the causes of [the plaintiff's] injuries based on the forces involved in the car accident").

ii. Design Defect

Bard takes issue with Dr. LaDisa's statement that "the design of the [Filter] is unreasonably dangerous particularly with regard to the increased thrombogenic effect presented by the filter's unstable conical design that includes the use of sharp leg hooks and traumatic anchors on the arms of the filter." Doc. 85, p. 12. Bard argues this opinion should be excluded because Dr. LaDisa is not qualified to opine on this topic and his opinion lacks a scientific foundation and thus only constitutes a personal opinion. Bard claims Dr. LaDisa has not conducted any testing on IVC filters, been involved with premarket approval or clearance of any IVC Filters, or written any publications or books concerning IVC filters. Doc. 85, pp. 12-13. Finally, Bard states that Dr. LaDisa's testimony is flawed because he does not offer any opinions

In re Testosterone Replacement Therapy, 2017 WL 1833173, at *2 (N.D. Ill. May 8, 2017) (explaining that "[t]he relevant medical literature recognizes three factors, sometimes referred to as Virchow's [T]riad,' that cause or contribute to the formation of problematic clotting in the veins").

regarding safer alternative designs for IVC Filters, but, under Missouri law, testimony of safer alternative designs is not required for a design defect claim. *See, e.g.*, *Pritchett v. Cottrell, Inc.*, 512 F.3d 1057, 1065 (8th Cir. 2008); *McDowell v. Kawasaki Motors Corp. USA*, 799 S.W.2d 854, 866 (Mo.App. 1990).

Further, Dr. LaDisa's medical device design experience included working at Boston Scientific Corporation, and training at Stanford in biodesign and innovation. LaDisa Rep., p. 1. Dr. LaDisa's also has extensive experience with fluid dynamics and implantable medical devices that are similar to IVC filters in composition and purpose. During his deposition, Dr. LaDisa stated, "my familiarity with IVC filters is well covered by my familiarity in publications and, you know, extensive experience in coronary stents. It would be remiss to separate those two out because of the similarity in the materials, behaviors, and guidance documents, as well as the fluid mechanics probably [sic] impact flow patterns to the vasculature." LaDisa Dep., 69:3-9. Further, Dr. LaDisa conducted a visual inspection of the Meridian Filter, and compared the Meridian Filter with other Bard Filters. Paired with his biomedical engineering background, Dr. LaDisa's experience with fluid dynamics and coronary stents provide ample technical, specialized knowledge to be of assistance to the jury in explaining purported design defects of implantable devices, and their impact on vasculature and blood flow. *See, e.g.*, *Am. Auto. Ins. Co. v. Omega Flex, Inc.*, 783 F.3d 720, 723 (8th Cir. 2015) (holding that an expert's qualifications must be sufficiently related to the particular subjects at issue); *Lauzon*, 270 F.3d at 685 (permitting expert engineer to testify about design defect).

iii. Additional Testing

Bard argues that Dr. LaDisa's opinion, given during his deposition, that if Bard had conducted additional testing Bard would have altered the design is speculative because he fails to

offer any opinions regarding safer alternative designs, including whether there are safer alternative designs. Doc. 85, p. 13.

As a biomedical engineer, Dr. LaDisa is without the requisite corporate experience and knowledge to opine about Bard's hypothetical, internal decisions. *See In re C.R. Bard., Inc.*, 948 F.Supp.2d 589, 611 (S.D. W.Va. 2013) (holding that a corporation's "alleged bad acts, failures to act, or other matters related to corporate conduct" are "not appropriate subjects of expert testimony because opinions on these matters will not assist the jury"); *In re Baycol Products Litigation*, 532 F.Supp.2d 1029, 1069 (D. Minn. 2007) (finding that the question of corporate intent is one for the jury, not for an expert, and that an expert may not testify as to his personal views about a party's business decisions); *In re Rezulin Prods. Liab. Litig.*, 309 F.Supp.2d 531, 547 (S.D.N.Y. 2004). The Court agrees that what Bard would or would not have done if it had conducted additional testing is speculative, and Dr. LaDisa's opinion to that effect is excluded. *See Group Health Plan, Inc. v. Philip Morris USA, Inc.*, 344 F.3d 753, 760 (8th Cir. 2003) (holding that it is within the district court's discretion to determine whether an expert has engaged in "too much" speculation).

B. Whether Dr. LaDisa's Opinions Regarding Specific Causation are Supported and Reliable

Bard next argues that Dr. LaDisa's specific causation opinions are based on assumptions not supported by the factual record and are the product of an unreliable methodology, namely purported differential diagnoses that fail to account for and exclude numerous alternate causes of Lampton's alleged injuries. Doc. 85, p. 15. Lampton responds that because Dr. LaDisa's analysis is mechanical rather than medical, he need not perform a differential diagnosis. Doc. 134, p. 13.

As previously discussed, Dr. LaDisa does not offer a medical opinion; instead he offers a biomedical engineering opinion about the cause of Lampton's thrombotic event based on Virchow's Triad. Differential diagnoses are traditionally performed by doctors who identify "the cause of a medical condition by eliminating the likely causes until the most probable cause is isolated." *Bland v. Verizon Wireless, (VAW) LLC*, 538 F.3d 893, 897 (8th Cir. 2008). Bard does not cite to any cases in which an engineer was required to perform a differential diagnosis, and the Court is unaware of such a rule. *Cf. Berner v. Carnival Corp.*, 632 F.Supp.2d 1208, 1214 (S.D. Fla. 2009) (finding an expert engineer's reliance on Newton's Laws of Physics to perform mathematical equations about the force required to cause injury constituted reliable methodology); *Pennsylvania Trust Co.*, 851 F.Supp.2d at 838. In the absence of such authority, Bard's attacks regarding the completeness of Dr. LaDisa's methodology go to the weight and not the admissibility of his testimony. *See, e.g.*, *Kudabeck v. Kroger Co.*, 338 F.2d 856, 861 (8th Cir. 2003); *Lauzon*, 270 F.3d at 694.

C. Whether Dr. LaDisa's Opinions are Related to the Issues in the Case

Next Bard argues that Dr. LaDisa's opinions pertaining to filter complications Lampton did not experience should be excluded as irrelevant under Federal Rule of Evidence 403. Doc. 85, p. 17. For example, Dr. LaDisa's report includes subsections addressing perforation and tilt, two filter complications that Lampton did not suffer. LaDisa Rep., pp. 9-10. Lampton responds that information and analyses of alternative filter models and failure modes constitute supporting facts, data, and reasoning that form the bases of Dr. LaDisa's conclusions, and are required to be included under Rule 26(a)(2)(B). Doc. 134, p. 14.

Under Rule 702, expert opinions must "assist the trier of fact to understand the evidence or to determine a fact in issue." *Daubert*, 509 U.S. at 591. "Expert testimony which does not

relate to any issue in the case is not relevant and, ergo, non-helpful." *Id.* "[A]n expert's testimony need not relate directly to the ultimate issue that is to be resolved by the trier of fact, it only need be relevant to evaluating a factual matter." *Smith v. BMW North America, Inc.*, 308 F.3d 913, 919 (8th Cir. 2002) (citing *Smith v. Ford Motor Co.*, 215 F.3d 713, 720 (7th Cir. 2000)). Describing the progression of the Bard Filters as well as some of the common complications, and the changes made in response to those purported problems, will be helpful background information for the jury. Moreover, Dr. LaDisa's opinions on these topics are consistent with testimony also given by Lampton's general experts. Docs. 54-4, 72, 109. Based on the current record, the Court cannot say these opinions should be excluded.

D. Whether Dr. LaDisa's Legal Conclusion Opinions Should be Excluded

Bard next argues that Dr. LaDisa's opinion that "the design of the Bard Meridian IVC filter is unreasonably dangerous" constitutes a legal conclusion and should be excluded. Doc. 85, p. 18. Lampton contends that Dr. LaDisa will not offer any legal conclusions, and that testimony utilizing legal terms should not be precluded where the party retaining the expert expressly asserts that the party does not intend to elicit opinions that draw a legal conclusion. Lampton asks the Court to deny Bard's request, and to allow Bard to object to specific testimony at trial. Doc. 134, pp. 14-15. In the alternative, Lampton asks that if the Court prohibits Dr. LaDisa from using the term "unreasonably dangerous" he nonetheless be permitted to offer his opinion that the Meridian Filter increases the risk of thrombotic events. *Id.* at 15.

Under Missouri law, in order to establish liability for defective design, a plaintiff must demonstrate that (1) "the product was defective and dangerous when put to a use reasonably anticipated by the manufacturer and (2) the plaintiff sustained injury or damage as a direct result of the defect." *Stanger v. Smith & Nephew, Inc.*, 401 F.Supp.2d 974, 979 (E.D. Mo. 2005)

(quoting *Lewis v. Envirotech Corp.*, 674 S.W.2d 105, 110 (Mo.Ct.App. 1984)). The Eighth Circuit has repeatedly held that "expert testimony on legal matters is not admissible." *Southern Pine Helicopters, Inc. v. Phoenix Aviation Managers, Inc.*, 320 F.3d 838, 841 (8th Cir. 2003); *United States v. Klaphake*, 64 F.3d 435, 438-39 (8th Cir. 1995). "Unreasonably dangerous" appears to be a legal term. Because it is for the Court to instruct the jury on the law, Dr. LaDisa's use of the term is improper.

Similarly, in *In re C.R. Bard*, the district court held that an expert may not offer an opinion that a product was "not reasonably safe," but may "offer a more general expert opinion, using terms that do not have a separate, distinct, and specialized meaning in the law." *In re C.R. Bard*, 948 F.Supp.2d at 629; *Warren v. C.R. Bard, Inc.*, 2020 WL 1899838, at *3 (M.D. Fla. Apr. 17, 2020) (excluding an expert's testimony that a filter was "unreasonably dangerous"); *Perez v. Townsend Eng'g Co.*, 562 F.Supp.2d 647, 652 (M.D. Pa. 2008) (holding that an expert may not offer testimony using "legal terms of art," such as "unreasonably dangerous"). Accordingly, Dr. LaDisa may not opine that the Filter's design was "unreasonably dangerous" because doing so would impermissibly allow expert testimony on a legal matter. *Southern Pine Helicopters*, 320 F.3d at 841; *In re C.R. Bard*, 948 F.Supp.2d at 629. Dr. LaDisa will be permitted to offer his causation opinions, consistent with this Order.

E. Whether Reliance and Opinions Based on Documents Not Previously Disclosed Should Be Excluded

Lastly, Bard argues that because Dr. LaDisa failed to provide information that he relied on in his expert report, he should not be permitted to use that information to supply evidence at trial. Doc. 85, p. 20. Bard points to four instances during Dr. LaDisa's deposition in which he allegedly relied on documents that he failed to disclose in his report. Doc. 85, p. 20. However,

Bard does not state which specific opinions it asks the Court to exclude due to Dr. LaDisa's failure to properly cite his resources. Lampton responds that, "[r]egardless of what information was and was not discussed at deposition, Dr. LaDisa will not present any opinion or discuss any underlying information not identified and disclosed in [his] report." Doc. 134, pp. 15-16. Accordingly, the parties are in agreement and the Court will limit Dr. LaDisa's opinions to those contained in his report, as required by Federal Rule of Civil Procedure 26. At trial, Dr. LaDisa may "supplement, elaborate upon, explain and subject himself to cross-examination" as all experts are permitted to do. *See, e.g.*, *Thompson v. Doane Pet Care Co.*, 470 F.3d 1201, 1203 (6th Cir. 2006); *Metavante Corp. v. Emigrant Sav. Bank*, 619 F.3d 748, 762 (7th Cir. 2010).

III. Conclusion

For the reasons described, Bard's motion to exclude or limit the opinions and testimony of Dr. LaDisa, Doc. 84, is granted in part and denied in part.

/s/ Nanette K. Laughrey
NANETTE K. LAUGHREY
United States District Judge

Dated: December 3, 2020
Jefferson City, Missouri