COMMONWEALTH OF MASSACHUSETTS

MIDDLESEX, ss. **SUPERIOR COURT**
CIVIL ACTION
NO. 2019-02348

JOHN FUSS

vs.

BOSTON SCIENTIFIC CORPORATION

MEMORANDUM OF DECISION AND ORDER ON DEFENDANT'S MOTION TO EXCLUDE OPINION TESTIMONY OF DR. DAVID SMOGER AND MOTION FOR SUMMARY JUDGMENT

This products liability action arises from Plaintiff John Fuss's ("Fuss" or the "plaintiff") 2007 implantation with the Greenfield Filter, an interior vena cava ("IVC") filter medical device designed and manufactured by Defendant Boston Scientific Corporation ("Boston Scientific"). Fuss seeks damages for alleged injuries he purportedly sustained due to the Greenfield Filter, namely perforation of his IVC wall. He asserts that the Greenfield Filters are defective and unreasonably dangerous, and advances three products liability causes of action against Boston Scientific under the Ohio Product Liability Act ("OPLA")[1]: (1) failure to warn, O.R.C. § 2307.75 (Count I); (2) design defect, O.R.C. § 2307.75 (Count II); and (3) misrepresentation, O.R.C. § 2307.77 (Count III). He also asserts a claim against Boston Scientific under the Ohio Consumer Sales Practices Act ("OCSPA") for allegedly unfair or deceptive acts (Count IV).

Now before the Court are Boston Scientific's two motions: (1) a motion to exclude the opinions of the plaintiff's proposed expert, Dr. David Smoger (Paper No. 17), and (2) a motion for summary judgment on all of the plaintiff's claims (Paper No. 18). This case raises the question whether an asymptomatic alleged injury that has not altered the plaintiff's life qualifies as a compensable injury under Ohio law such that plaintiff's claim may proceed to trial; I

[1] The OPLA is codified in the Ohio Revised Code ("O.R.C.") §§ 2307.71 through 2307.81.

conclude that it does not. After hearing and careful consideration of the parties' written submissions and oral arguments, for the reasons set forth below, both motions are **ALLOWED**.

BACKGROUND

The record presented in connection with the present motions contains the following undisputed facts. The Court reserves certain facts for discussion below.

I. History of the Greenfield Filter[2]

Pulmonary emboli are caused by blood clots that typically originate in the legs and travel through the IVC to the heart and lungs. A pulmonary embolism is a serious and often life-threatening event. Once an individual has experienced a pulmonary embolism, he or she is at an increased risk of experiencing another one. The earliest treatment against recurrent pulmonary emboli was ligation or interruption of the IVC. But in the 1970s, the Greenfield Filter was introduced—a conical filter implanted in the IVC to catch blood clots and stop them from traveling to the lungs, while also maintaining IVC patency and blood flow.

Boston Scientific redesigned the Greenfield Filter several times over the years to come. The filter at issue in the instant case is the 12 French stainless-steel filter with the alternating-hook design, which was cleared by the Food and Drug Administration ("FDA") in 1997. To ensure fixation in the IVC, the Greenfield Filter is designed to penetrate the vena cava wall to a limited extent. In fact, in order for the device to fixate so that it does not move, there must be some penetration. However, in the medical community, industry guidelines define filter penetration (i.e., perforation) as filter struts extending more than 3 millimeters outside the wall of the IVC measured by CT, ultrasound, venography, or autopsy. Perforation is almost always asymptomatic.

[2] The facts in this section and the next are drawn from the parties' Joint Statement of Undisputed Material Facts in Support of Motion for Summary Judgment and Plaintiff's Responses (Paper No. 18.4) and the exhibits cited therein.

II. Fuss's Filter Implantation

In 2007, Fuss developed a pulmonary embolism. He received treatment from Dr. David Vincente, a surgeon with board certifications in general and vascular surgery. Dr. Vincente recommended implantation of an IVC filter. By the time of Fuss's implantation, Dr. Vincente had placed at least hundreds—perhaps a thousand or more—Greenfield Filters. He testified that he chose the Greenfield Filter for Fuss because he believed it had "a really good track record" and was the best filter to use. Prior to implanting Fuss's filter, Dr. Vincente did not review the Instructions for Use; he had "looked at" them in the past but considered himself "independently aware of the risks, and benefits, and complications related to the Greenfield Filter." In the fifteen years since Dr. Vincente implanted the Greenfield Filter, Fuss has not had any pulmonary emboli.

In 2017 or 2018, Fuss saw a commercial about IVC filters—stating that such filters are prone to fracture and migration—which made him nervous. After Fuss saw the commercial, attorneys contacted him. Attorneys later directed Fuss to go for a CT scan. At the time, Fuss had no medical concerns about his filter, and the scan was ordered by a doctor Fuss has never met and had not even heard of until his deposition. Fuss's treating surgeon, Dr. Vincente, testified to his opinion that this CT scan was "100 percent" litigation-driven and was someone "looking for a problem, essentially." The parties dispute whether Fuss discussed the results of the scan with any medical professionals, and whether Fuss's proposed expert, Dr. Smoger, measured the alleged penetration in the CT scan.

In 2020, Fuss saw Dr. Vincente for consultation about his IVC filter. Dr. Vincente ordered an x-ray and concluded that Fuss's filter was still in position as originally implanted.

Since his 2020 visit with Dr. Vincente, Fuss has not been treated for his alleged filter perforation. Dr. Vincente testified that he does not anticipate Fuss will need any follow-up moving forward.

III. Fuss's Lawsuit and Proposed Expert

Fuss claims that his Greenfield Filter perforated his IVC wall. As indicated above, he claims the Greenfield Filters are defective and unreasonably dangerous, and asserts three products liability causes of action under Ohio law: design defect, failure to warn, and failure to conform to representations. He also asserts a claim under the OCSPA. In support of his lawsuit, Fuss retained Dr. Smoger, an interventional radiologist, to support virtually all of the elements for each of his claims. Dr. Smoger is a practicing interventional radiologist who holds a dual certificate from the American Board of Radiology in Interventional Radiology and Diagnostic Radiology. He is Chairman of the Department of Radiology at Holy Redeemer Hospital and Medical Center in Meadowbrook, Pennsylvania, and Clinical Assistant Professor of Radiology at the Sidney Kimmel Medical College of Thomas Jefferson University.

Dr. Smoger has implanted hundreds of filters throughout his training and career, namely the VenaTech Filter, Celect Filter, and Option Filter. He has implanted only two Greenfield Filters—one in a pig and one in a person—during his residency approximately fifteen years ago. Dr. Smoger developed and currently acts as director of a complex filter retrieval program focusing on the removal of IVC filters. He has removed hundreds of IVC filters throughout his training and career. Dr. Smoger offers opinions on a wide range of topics, including design, alternative design, warnings, injury, causation, testing, and alleged misrepresentations.

DISCUSSION

I. Motion to Exclude Opinions of Dr. Smoger

A. Standard of Review

"The judge serves as a gatekeeper on the admission of expert opinion testimony." *Hicks's Case*, 62 Mass. App. Ct. 755, 760 (2005). For expert testimony to be admissible, the proposed witness must be qualified as an expert to testify to a specific subject matter. See *Commonwealth* v. *Rintala*, 488 Mass. 421, 426 (2021); Mass. G. Evid. § 702 (2021). "'The crucial issue,' in determining whether a witness is qualified to give an expert opinion, 'is whether the witness has sufficient "education, training, experience and familiarity" with the subject matter of the testimony.'" *Commonwealth* v. *Frangipane*, 433 Mass. 527, 533 (2001), quoting *Commonwealth* v. *Richardson*, 423 Mass. 180, 183 (1996). "Testimony '*on matters within the witness's field of expertise* is admissible' when the testimony concerns matters beyond the common knowledge of the jurors and will aid the jurors in reaching a decision" (emphasis in original). *Frangipane*, 433 Mass. at 533, quoting *Commonwealth* v. *Dockham*, 405 Mass. 618, 628 (1989). At the same time, however, "a judge's discretion can be abused when an expert witness is permitted to testify to matters beyond an area of expertise or competence." *Frangipane*, 433 Mass. at 533.

In addition to determining whether the proposed expert is qualified, the judge must also determine that the expert testimony is sufficiently reliable to reach the jury. As the proponent of the expert testimony at issue, the plaintiff "bears the burden of establishing . . . that the methodology or theory underlying the expert testimony is sufficiently reliable." *Commonwealth* v. *Shanley*, 455 Mass. 752, 761 (2010). See *Commonwealth* v. *Davis*, 487 Mass. 448, 453 (2021) ("proponent must establish a sufficient foundation for a judge to determine whether the expert's opinion satisfies gatekeeper reliability"); *Commonwealth* v. *Hinds*, 487 Mass. 212, 220 (2021), quoting *Commonwealth* v. *DiCicco*, 470 Mass. 720, 729 (2015) ("Under the *Daubert-Lanigan* standard, 'the touchstone of admissibility is reliability'"). See also *Daubert* v. *Merrell Dow*

Pharms., Inc., 509 U.S. 579, 585-595 (1993); *Commonwealth* v. *Lanigan*, 419 Mass. 15, 25-26 (1994).

B. Design Defect Opinions

Boston Scientific first argues that Dr. Smoger's design defect opinions are inadmissible because he is not qualified to opine about filter design and his opinions lack reliability. Because the Court, for the reasons set forth below, agrees with Boston Scientific that Dr. Smoger is not qualified to give opinions about filter design, it need not reach the reliability of those opinions.

Dr. Smoger is an interventional radiologist—a "clinical doctor," as he describes himself. Exhibit 2, Smoger Dep. at 269:23. Per his own deposition testimony, he is not an engineer, has never worked for a medical-device company, and has never designed a marketed medical device or any other product. *Id*. at 269:21-24, 56:17-58:11. Dr. Smoger also admittedly has not done any bench testing of any medical device or conducted a clinical study for a medical device. *Id.* at 58:16-59:5.

In his report, Dr. Smoger puts forth an analysis of the Greenfield Filter's design, stating as follows:

> "Because of the design of the struts of the Greenfield filters, the base of the filter expands outward and all the radical force and pressure resulting from that expansion is focused on only six points of contact, the hooks, rather than being distributed around the surface of the vena cava wall. This focused force creates significant problems related to perforation of the hooks beyond the vena cava wall and fails to provide a mechanism to prevent tilting of the filter." Exhibit 14, Smoger Report at p. 4.

Likewise, as to a proposed alternative design, the Vena Tech LP Filter, Dr. Smoger opines that the Vena Tech LP Filter is "designed to disperse the outward pressure of the filter over a larger surface area" and that the filter's "stabilizing legs and alternating hooks . . . further ensures self-centering and optimal positioning." *Id.* at p. 15. He asserts that "[t]hese advances significantly reduce, or completely eliminate, the risks associated with perforation" and other issues. *Id.*

There is no question that Dr. Smoger is, as Fuss observes, a well-qualified interventional radiologist. However, as noted above, to be sufficiently qualified to testify as an expert, a witness needs to have knowledge, skill, experience, training, or education in the specific subject for which his testimony is offered. See *Rintala*, 488 Mass. at 426; *Commonwealth* v. *Neverson*, 35 Mass. App. Ct. 913, 915 (1993). See also *Berry* v. *Detroit*, 25 F.3d 1342, 1351 (6th Cir. 1994) (noting that what matters for purposes of Fed. R. Evid. 702 are not "the qualifications of a witness in the abstract, but whether those qualifications provide a foundation for a witness to answer a specific question"). As discussed in the ensuing paragraphs, courts have consistently held that while clinical doctors may testify to medical opinions about medical devices, they lack qualifications to offer engineering opinions about those devices. Such is the case here.

The case of *In re Bard IVC Filters Prods. Liab. Litig.*, 2017 WL 6554163 (D. Ariz. Dec. 22, 2017) ("*In re Bard*") is closely analogous to the present circumstances. *In re Bard* was a multidistrict litigation that involved thousands of personal injury cases related to IVC filters defendant Bard manufactured. *Id.* at *1. There, each plaintiff received an implant of a Bard IVC filter and claimed that the filter was defective and caused serious injury or death. *Id.* The plaintiffs identified three interventional radiologists as expert witnesses on various issues in the case.[3] *Id.* Bard filed a motion to exclude four categories of opinions from these radiologists, one of which concerned IVC filter engineering and the suitability of Bard's bench testing of its

[3] One of the doctors, Dr. Kinney, received a master's degree in mechanical engineering in 1979 and accepted a job with a physician designing angioplasty balloons, vascular clams, and a cardioplagia jacket for use during open heart surgery. *Id.* at *5. In 1983, Dr. Kinney entered medical school and continued to work with the cardioplagia jackets as part of his independent study. *Id.* Since graduating from medical school, Dr. Kinney had not done any medical device design work, and had never designed bench top testing. *Id.* Dr. Kinney had served as chair of data safety monitoring boards for clinical trials involving other IVC filters, and had published studies and review articles on IVC filters, including IVC design function. *Id.*

The other two doctors, Drs. Roberts and Kalva, were clinical physicians with no background in engineering or actual bench testing of medical devices. *Id.* The doctors had studied IVC filters and had seen filter failures in their medical practices. *Id.* Dr. Kalva published studies on the function, use, and complications of IVC filters, and was involved in developing an undisclosed patent for an IVC filter design. *Id.*

filters, asserting that the radiologists were not qualified to opine on several matters in their expert report. *Id.* at *1, 5. One such matter was the radiologists' opinion about how changing the size of the diameter of the Bard filter impacted the radical force for the hook to engage the cava wall. *Id.* at *5. Ultimately, the Court held that the radiologists were not qualified to testify on technical matters such as engineering and design implications of the IVC filters, reasoning that Drs. Roberts and Kalva, despite their significant clinical experience with the device, "ha[d] no training or experience on such matters" and "Dr. Kinney's training and experience in this field [was] more than 30 years old."[4] *Id*. at *6.

Morritt v. *Stryker Corp.*, 973 F. Supp. 2d 177 (E.D.N.Y. 2013) is similarly instructive. There, the patient (later substituted by her estate), filed a products liability action against the defendant manufacturer for injuries caused by an allegedly defective polyethylene tibial insert, a component of the knee prosthesis implanted in the patient. *Id.* at 184. The plaintiffs sought to offer the testimony of an orthopedic surgeon that a manufacturing, material, or design defect caused the tibial insert in the patient's knee to fail. *Id.* at 186. The defendant moved to preclude the physician from opining on issues related to biomedical engineering and medical device manufacturing. *Id.* The Court, while appreciating the physician's extensive clinical experience using the defendant knee systems, held that the physician's opinions about design and manufacturing defects went "well beyond the reasonable confines of his clinical expertise." *Id.* at 188. Indeed, it explained that the "[p]laintiffs have failed to show that [the physician's] expertise in orthopedic medicine and surgical principles and concepts qualifies him to testify as to the mechanical functioning of a medical device."[5] *Id.*

[4] The *In re Bard* court added one final note to its conclusion that the radiologists were not experts in mechanical design and therefore unqualified to opine on such topics, stating that "[o]ther somewhat technical opinions may be within the expertise of these doctors" to the extent that they are "reasonably based on expertise and experience in implanting, monitoring, and removing IVC filters." *Id.* at *6.

Equally instructive is *Conn* v. *C.R. Bard, Inc.*, 2021 WL 2346036 (S.D. Tex. June 8, 2021), a products liability action involving an IVC filter called the G2 Filter, a medical device Bard manufactured and distributed. There, the plaintiff was implanted with the filter and claimed it "fractured and a strut migrated to the right ventricle causing [ ] significant injuries." *Id.* at *1. The plaintiff sued the defendant manufacturer alleging, among other things, design defects. *Id.* The plaintiff identified an interventional radiologist as a case specific expert witness, who sought to offer several opinions regarding the filter's design. *Id.* at *1, 5. The defendant moved to exclude the radiologist's opinions as to design defects, including that the "defective design of the G2 filter caused [the plaintiff's] injuries, including tilt and apex embedment, multiple strut fractures, fragment embolization to the patient's heart, caval perforation into the retroperitoneum, liver, uncinate process of pancreas and direct impingement on the crossing right renal artery" and that the "strut perforations and fractures associated with [the plaintiff's] G2 filter were and are the result of the filter design itself." *Id.* at *5. The defendant argued that the radiologist lacked the qualifications to opine on the design of the filter, and that such an opinion was an impermissible legal conclusion. *Id.* The Court held that the radiologist was unqualified to offer design defect opinions as to the filter, explaining that:

> "[The radiologist] is not an engineer of any kind. He has never successfully designed or made a medical device to be implanted in a human. He is not a metallurgist or any other kind of specialist in designing, selecting, or crafting materials to be used in human implantation. He has never consulted with a medical device manufacturing company on product development. As a result, [the radiologist] lacks the specialized knowledge, skill, experience, and training to opine as to whether the filter suffers from a 'defective design' or has a 'design defect.'"[6] *Id.*

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[5] The Court specified that the physician, as an orthopedic surgeon with ample experience using the knee systems and as the plaintiff's treating physician, was qualified to testify as to matters based on his first-hand observations and professional clinical experience. *Id.* at 187.

[6] The court there, like the *Bard* and *Morritt* courts, noted that although the radiologist was not qualified to testify that the filter's alleged failure was caused by its alleged design defect, he was qualified to testify about the resulting problems or consequences from the filter's fragmentation in the plaintiff because he had reviewed the plaintiff's medical records. See *id.* ("In other words, [the physician] can offer the opinion *that* the filter failed but not the

Evidently, courts have considered whether the scope of clinical doctors' qualifications under Rule 702 includes expertise in engineering and mechanical design, and have routinely concluded that it does not. Indeed, while clinical doctors, like interventional radiologists, may testify to their medical opinions about medical devices, they are not qualified to testify to design issues that are in the province of engineers. For this reason, Dr. Smoger's proffered design defect opinions are excluded.

C. Alternative Design Opinion

Relatedly, Boston Scientific argues that Dr. Smoger's alternative design opinion is unreliable and therefore inadmissible. More specifically, Boston Scientific argues that Dr. Smoger's opinion regarding a safter alternative design for the Greenfield Filter should be excluded because he failed to address the risks associated with the alternative design as required by the OPLA. O.R.C. § 2307.75. I agree.

Under Ohio Rev. Code § 2307.75(F), a product is not defective in design or formulation if a "technically feasible alternative design or formulation was not available" at the time the product was manufactured. See *Burris* v. *Ethicon, Inc.*, 2021 WL 3190747 at *5 (N.D. Ohio July 28, 2021) (noting requirement to establish "a practical and technically feasible alternative design" to the product at issue); *McGrath* v. *General Motors Corp.*, 26 Fed. Appx. 506, 510 (6th Cir. 2002) (explaining that, under Ohio law, design defect claim requires a plaintiff to prove that risks exceed benefits and feasible alternative design would have prevented harm without reducing product's usefulness or purpose). The plaintiff must show the nature and seriousness of foreseeable risks of using that alternative, instead of the particular design that is being challenged. O.R.C. § 2307.75(C).

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reason, and that there were subsequent strut fractures, fragment embolization, impingements, and perforations") (emphasis in original).

Here, in his report, Dr. Smoger identifies the Vena Tech LP filter as an alternative design to the Greenfield Filter, opining that it was superior to the Greenfield Filter and would have "significantly reduce[d], or completely eliminate[d]" the risks associated with Fuss's alleged injury.[7] Exhibit 14, Smoger Report at p. 15. However, as the defendant points out, Dr. Smoger never analyzed the risks of the Vena Tech LP filter, as required under Ohio law. See O.R.C. § 2307.75(C). In fact, Dr. Smoger explicitly responded "no" when asked at his deposition whether he thought he "should be talking about the problems with the [Vena Tech LP filter]." Exhibit 2, Smoger Dep. at 382:23-389:9. In his memorandum in opposition to Boston Scientific's motion to exclude, Fuss counters that Dr. Smoger specifically testified about several risks associated with the Vena Tech LP filter, citing excerpts of Dr. Smoger's deposition testimony. The proffered citations are inapposite, however, where they in no way amount to an analysis of the risks of using the Vena Tech LP filter as statutorily required, but rather can be more aptly described as fleeting comments in response to pointed questions.[8]

In sum, Dr. Smoger's opinion that the Vena Tech LP filter is an alternative design to the Greenfield Filter is unreliable and inadmissible because he never analyzed the risks of the Vena Tech LP filter as explicitly required under Ohio law.

D. Warnings Opinion

Boston Scientific next contends that Dr. Smoger's warnings opinion—that the warnings in the Greenfield Filter's Instructions for Use ("IFU") are inadequate because they fail to warn of the injury potential of a perforation—is inadmissible for lack of qualifications and foundational

[7] Dr. Smoger also included retrievable/temporary filters in his report under alternative designs, but later clarified in his deposition that he was not offering them as alternative designs because he did not think it was fair to compare a permanent filter to a retrievable filter. Exhibit 2, Smoger Dep. at 142:5-143:1.

[8] It is also worth noting that Fuss, despite selecting only certain pages of Dr. Smoger's deposition testimony to include in the referenced exhibit (Plaintiff's Exhibit 20), has failed to include the actual pages that contain three out of the four deposition testimony citations.

reliability.[9] As to the latter basis, Boston Scientific avers that Fuss cannot establish the reliability of Dr. Smoger's warnings opinion for several reasons, not least that an express warning was in fact given. Because the Court, for the reasons set forth below, agrees with Boston Scientific that Dr. Smoger is not qualified to opine on warnings, it technically need not reach Boston Scientific's reliability argument. However, because this argument has further-reaching implications, namely for the motion for summary judgment (see Section II(C), infra), the Court addresses it in brief here, and concludes that the exclusion of Dr. Smoger's warnings opinion is also warranted on the basis of reliability.

Boston Scientific first argues that Dr. Smoger is not qualified to opine about the adequacy of the warnings in the Greenfield Filter's IFU or what should or should not be included in those warnings. As noted above, to be sufficiently qualified to testify as an expert, a witness needs to have knowledge, skill, experience, training, or education in the specific subject for which his testimony is offered. See *Rintala*, 488 Mass. at 426. By his own admission, Dr. Smoger is neither a warnings nor labeling expert. Exhibit 2, Smoger Dep. at 61:12-14, 131:2-4. He repeatedly reiterated his lack of expertise in this area, and declined to answer questions about warnings. *Id.* at 292:13-18, 294:18-24, 295:1-13. Dr. Smoger has never drafted warning language for a medical device company and acknowledges he is unfamiliar with what should be included in the IFU. *Id.* at 60:16-22, 287:10-15, 300:9-13. Given his lack of knowledge and experience in the adequacy of warnings, Dr. Smoger is unqualified to opine that the Greenfield Filter's warnings are inadequate. See *Rintala*, 488 Mass. at 426*; Conn.*, 2021 WL 2346036 at *4 (ruling that interventional radiologist is unqualified to offer opinions on the adequacy of warnings in an IVC filter case because he "has no expertise or experience related to the requirements for or the

[9] In his report, Dr. Smoger states that Boston Scientific should have made the "potentially injurious results" of perforation "more apparent." Exhibit 14, Smoger Report at 18.

drafting of IFUs or warnings"); *Dorgan* v. *Ethicon, Inc.*, 2020 WL 5367063 at *2 (W.D. Mo. Sept. 8, 2020) (finding expert with similar qualifications unqualified to testify about adequacy of warning); *In re C.R. Bard, Inc.*, 2018 WL 4220618 at *5 (2018) (holding that mere personal knowledge or observation of risks by doctor does not qualify him to opine that IFU adequately and appropriately warned of risks, without a background in the requirements of an IFU).

Boston Scientific further argues that Dr. Smoger's warnings opinion lacks a reliable evidential basis, and should be excluded on this basis as well. As indicated in the above standard of review, the plaintiff, as the proponent of the expert testimony at issue, "bears the burden of establishing . . . that the methodology or theory underlying the expert testimony is sufficiently reliable." *Shanley*, 455 Mass. at 761. For the reasons Boston Scientific proffered, the Court agrees that Fuss has failed to meet the foundational reliability requirement. First, Dr. Smoger fails to explain how the Greenfield Filter's IFU is inadequate given that it *does* warn of perforation. Indeed, under a section entitled "Potential Complications," the IFU explicitly warns about "[p]erforation of the vena cava, adjacent blood vessels or organ by one or more hooks." Exhibit 9, IFU at 8. Boston Scientific further reasons that Dr. Smoger offers no explanation as to why Fuss's implanting physician would have found these perforation warnings incomplete, misleading, or otherwise inaccurate, and that, by Dr. Smoger's own admission, physicians are aware that perforation is a risk for IVC filters. Exhibit 2, Smoger Dep. at 312:8-13. Finally, Boston Scientific avers that to the extent that Dr. Smoger intends to testify that Boston Scientific should have warned about the rate of perforation, he conceded at deposition that this is not required and that he is unaware of any manufacturers who do this for any medical device.[10] *Id.* at

[10] As Boston Scientific points out, courts decline to require manufacturers to go into detail of frequency or severity of warned-about risks. See e.g., *Nelson* v. *C.R. Bard, Inc.*, 2022 U.S. App. LEXIS 22157 at *13-16 (2022) (affirming failure to include rates of injury does not render instructions defective); *Smith ex. Rel. Smith* v. *Wyeth Labs., Inc.*, 1986 WL 720792 at *10 (S.D. W. Va. Aug. 21, 1986) (rejecting complication-rates argument on grounds

307:11-15. In light of the foregoing, exclusion of Dr. Smoger's warnings opinion is also warranted on the basis of reliability.

E. Warnings Causation Opinion

Because Dr. Smoger is not qualified to opine about the adequacy of the warnings in the Greenfield Filter's IFU, he similarly cannot opine that any deficiency in the warnings caused Fuss's alleged injuries. In any event, Boston Scientific additionally argues that Dr. Smoger's opinion that different warnings would have changed the behavior of Fuss's implanting physician, Dr. Vincente, inducing him either to use a different filter or to change his informed-consent practices, is unreliable and inadmissible. More specifically, it contends that Dr. Smoger's causation opinion is pure speculation, lacking any basis in the record. I agree. Critically, Dr. Smoger concedes that he did not read Dr. Vincente's deposition and has never spoken to him. Exhibit 2, Smoger Dep. at 313:15-18, 337:2-6, 338:6-13. On this record, Dr. Smoger is entirely unaware of what Dr. Vincente knew or did not know when he met with Fuss, how Dr. Vincente used or did not use Boston Scientific's IFU, or how Dr. Vincente would have reacted to different or additional warnings. As such, Dr. Smoger lacks a reliable factual basis to comment on whether different warnings would have made a difference. See *In re Rezulin Prod. Liab. Litig.*, 309 F. Supp. 2d 531, 556-557 (S.D.N.Y. 2004) (excluding as "speculative" opinions about "whether physicians would have prescribed [drug]" based on different information*); In re Diet Drugs Prods. Liab. Litig.*, 2001 U.S. Dist. LEXIS 1174 at *58 (E.D. Pa. 2001) (same).

F. Injury Opinion

Further, Boston Scientific seeks to exclude Dr. Smoger's injury opinion for lack of foundational reliability. Dr. Smoger opines that Fuss sustained perforation, is at risk for future

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that the "plaintiff cites no authority for the proposition that a drug manufacturer has a duty to warn prescribing physicians of the rate of adverse reactions" and that as "a practical matter, this would be extremely difficult").

injury, and will need his filter removed in the future.[11] Exhibit 14, Smoger Report at p. 21. The industry guidelines define filter penetration (i.e., perforation) as "filter strut[s] . . . extending more than 3 [millimeters] outside the wall of the IVC demonstrated by CT, US, venography, or autopsy." Exhibit 8, Grassi, Quality Improvement Guidelines for Percutaneous Permanent Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism at p. 2. In other words, a measurement is required. Here, the CT scan on which Dr. Smoger relies does not measure any protrusions, and Dr. Smoger did not say in his report—and could not say at his deposition—whether any of Fuss's filter struts protrude at least three millimeters. Exhibit 2, Smoger Dep. at 414:10-16. Fuss counters that Dr. Smoger advances an alternative definition of perforation that does not require a measurement. However, neither Fuss nor Dr. Smoger have demonstrated that this alternative definition is accepted in the industry or is otherwise reliable. See *Palandjian* v. *Foster*, 446 Mass. 100, 107 (2006) (noting that acceptance in the relevant scientific community remains "most important factor" in determining reliability). Accordingly, the Court agrees with Boston Scientific that Dr. Smoger's injury opinion is unreliable and should be excluded.

G. Failure to Test Opinion[12]

Next, Boston Scientific argues that Dr. Smoger's opinion that Boston Scientific failed to adequately test any iteration of the Greenfield Filter is inadmissible for lack of qualifications and foundational reliability. At the outset, the Court is dubious of this opinion given that the Greenfield Filter, introduced in the 1970s, was on the market for over thirty years before Fuss's implantation, and underwent extensive animal and bench-top testing. See Exhibit 4, Greenfield

[11] Dr. Smoger testified to his opinion that there were three of six struts that were perforating here. Exhibit 2, Smoger Dep. at 413:5-13.

[12] Fuss's memorandum in opposition to Boston Scientific's motion to exclude does not address that portion of the motion seeking to exclude the opinion testimony of Dr. Smoger discussed in this section and the subsequent section.

Dep. at 33:7-40:5; Exhibit 3; Exhibit 5. In any event, it is clear from the record that Dr. Smoger is not qualified to render an opinion about the level of testing required prior to marketing a device where he admits he has no experience developing a marketed device, has never taken a device to market, has never worked for a medical device company in any capacity, has never done any bench testing of any medical device, and has never conducted a clinical study for a medical device. See *Rintala*, 488 Mass. at 426. See also, e.g., *Davis* v. *Johnson & Johnson*, 2022 WL 2116323 at *3 (D. Kan. 2022), and cases cited (excluding surgeon's opinion about what testing a device manufacturer must perform). Because the Court concludes that Dr. Smoger is not qualified as an expert to opine on the adequacy of Boston Scientific's testing procedures, it need not address the reliability of his opinion.

H. Misrepresentation Opinion

Finally, Boston Scientific argues that Dr. Smoger should not be permitted to opine that Boston Scientific misrepresented that the Greenfield Filters are "permanent." Exhibit 14, Smoger Report at p. 11. The Court agrees with Boston Scientific that this opinion is nonsensical and overtly contradicted by Dr. Smoger's own testimony. Indeed, Dr. Smoger admits that the Greenfield Filter was cleared by the FDA in its capacity as a permanent device, and that he is not disputing the permanent nature of the device. See Exhibit 2, Smoger Dep. at 117:1-14. As such, insofar as he intends to testify that Boston Scientific misrepresented the permanent nature of the Greenfield Filter, any such testimony is appropriately excluded as unreliable and unhelpful.

II. Motion for Summary Judgment

A. Standard of Review

The court grants summary judgment where there are no genuine issues of material fact and the record entitles the moving party to judgment as a matter of law. See Mass. R. Civ. P. 56(c); *Cassesso* v. *Commissioner of Corr.*, 390 Mass. 419, 422 (1983). The moving party bears the burden of establishing that there is no dispute of material fact on every relevant issue. See *Pederson* v. *Time, Inc.*, 404 Mass. 14, 16-17 (1989). A party moving for summary judgment who does not bear the burden of proof at trial may demonstrate the absence of a genuine dispute of material fact either by submitting affirmative evidence negating an essential element of the nonmoving party's case, or by showing that the nonmoving party has no reasonable expectation of proving an essential element of its case at trial. See *Flesner* v. *Technical Commc'ns Corp.*, 410 Mass. 805, 809 (1991); *Kourouvacilis* v. *General Motors Corp.*, 410 Mass. 706, 716 (1991).

Once the moving party establishes the absence of a triable issue by either of the above methods, the party opposing summary judgment must respond with evidence of specific facts establishing the existence of a genuine dispute. See *Pederson*, 404 Mass. at 17. The opposing party cannot rest on the allegations in the pleadings. See *Key Capital Corp.* v. *M&S Liquidating Corp.*, 27 Mass. App. Ct. 721, 728 (1989). And, mere contradictions of factual allegations, without evidentiary support, are insufficient to raise questions of material fact sufficient to defeat summary judgment. See *Madsen* v. *Erwin*, 395 Mass. 715, 721 (1985).

B. Design Defect Claim

To survive summary judgment in an action brought under the OPLA, a plaintiff must prove: (1) the existence of a defect in the product at issue, (2) that the defect existed at the time the product left the hands of the manufacturer, and (3) the defect was the direct and proximate cause of the plaintiff's injury. See *Great N. Ins. Co.* v. *BMW of N. Am, LLC*, 84 F. Supp. 3d 630,

649 (S.D. Ohio 2015). The parties agree that Ohio law "requires expert testimony where aspects of the defect or the proposed alternative designs are technically complex and outside the understanding of a lay juror," *Newell Rubbermaid, Inc.* v. *Raymond Corp.*, 676 F.3d 521, 529 (6th Cir. 2012) (applying Ohio law), and that expert testimony is required in this case.

Here, Fuss's sole purported evidence of a design defect is Dr. Smoger's testimony that the Greenfield Filter's design is at an increased risk for perforation. Because the Court has determined that Dr. Smoger's design defect opinions should be excluded, it further determines that Boston Scientific is entitled to summary judgment on Fuss's design defect claim; without expert testimony to prove Boston Scientific's filter was designed defectively, Fuss cannot prevail on this claim under the applicable law. See *id.*

C. Failure to Warn Claim

To prevail on a failure to warn claim under Ohio law, "a plaintiff must establish that a duty to warn against reasonably foreseeable risks exists, a breach of that duty occurred, and the plaintiff's injuries were proximately caused by the breach." *Linert* v. *Foutz*, 149 Ohio St. 3d 469, 476-477 (2016). A manufacturer provides "inadequate warnings if it knew or reasonably should have known of the risk in the exercise of ordinary care and failed to take precautions that a reasonable person would take in presenting the product to the public." *Id.*, quoting *Welch Sand & Gravel, Inc.* v. *O & K Trojan, Inc.*, 107 Ohio App. 3d 218, 226 (1st Dist.1995). The parties agree that to contend a warning is inadequate, a plaintiff needs expert testimony. See *Romans* v. *Ford Motor Co.*, 2018 WL 2268133 at *7 (S.D. Ohio Mar. 13, 2018) ("Evaluating a warning directed to medical experts will necessarily require expert testimony"). Because the Court has determined that Dr. Smoger's warnings opinion should be excluded—leaving Fuss with no supporting expert

testimony for his failure to warn claim—it further determines that summary judgment on this claim is proper. See *id*; *Saraney* v. *TAP Pharm. Prods.*, 2007 WL 148845 at *6 n.3 (N.D. Ohio Jan. 16, 2007) (noting that expert medical testimony is required to establish inadequacy of a warning related to drug injection); *Yanovich* v. *Sulzer Orthopedics, Inc.*, 2006 WL 3716812 at *12 (N.D. Ohio Dec. 14, 2006) (granting summary judgment on warning claim regarding artificial knee implant where plaintiffs failed to "designate expert medical testimony on the sufficiency of defendants' warnings").

In any event, the Court determines that the Greenfield Filter's IFU warnings are adequate as a matter of law where the precise harm Fuss alleges to suffer (i.e., perforation of the vena cava) was clearly listed as a potential complication associated with the use of the Greenfield Filter.[13] See *Nelson* v. *C.R. Bard*, 2022 U.S. App. LEXIS 22157 at *11 (5th Cir. 2022) (affirming district court's holding that IFU warnings were adequate as a matter of law where the IFU "expressly warned" the treating physician of the "very complications" that the plaintiff ultimately suffered); *Ziliak* v. *AstraZeneca LP*, 324 F.3d 518, 521 (7th Cir. 2003) (holding inhaler warning adequate as a matter of law because it "warn[ed] doctors [of the] specific adverse side effects" that injured the plaintiff). This determination furnishes an independent legal basis for granting Boston Scientific's motion for summary judgment on Fuss's failure to warn claim.[14]

D. Misrepresentation Claim (OPLA) and Consumer Practices Claim (OCSPA)

As indicated in the above standard of review, once the moving party establishes the absence of a triable issue, the party opposing summary judgment must respond with evidence of

[13] Under the heading "Potential Complications," Boston Scientific explicitly warned about "[p]erforation of the vena cava, adjacent blood vessels or organ by one or more hooks." Exhibit K, IFU at 8.

[14] As summary judgment is properly granted on the issue of the adequacy of the warnings, the Court need not address whether the alleged inadequacy of the warnings was a proximate cause of Fuss's alleged injury.

specific facts establishing the existence of a genuine dispute. See *Pederson*, 404 Mass. at 17. The opposing party cannot rest on the allegations in the pleadings. See *Key Capital Corp.*, 27 Mass. App. Ct. at 728.

Fuss's complaint alleges claims of misrepresentation under the OPLA and unfair or deceptive consumer practices under the OCSPA. Boston Scientific seeks summary judgment on these claims, arguing that Fuss's misrepresentation claim fails without a showing of express representation, nonconformance, or reliance as required under Ohio law, and that his consumer practices claim fails because it is abrogated, untimely, and unsupported. Fuss's opposition to Boston Scientific's motion does not respond to these arguments, and does not address these claims at all. Accordingly, the Court deems these claims waived. See *Pederson*, 404 Mass. at 17; *Key Capital Corp.*, 27 Mass. App. Ct. at 728.

E. Legally Compensable Injury

Boston Scientific also asserts an overarching basis for summary judgment: that Fuss has sustained no injury. More specifically, it contends that Fuss cannot establish he experienced a perforation, and even if he could, his asymptomatic condition cannot, as a matter of law, amount to a compensable injury. In response, Fuss asserts that he has suffered and continues to suffer the injurious effects of the defective Greenfield Filter, reasoning that "[t]he medical evidence, including the CT scan that [he] received in 2018, unequivocally proves that [he] has suffered a perforation where three struts of his [filter] extend beyond the vena cava [wall] [*sic*] and two of those struts have contacted, and threaten damage to adjacent organs and vital structures." Plaintiff's Opposition (Paper No. 18.3) at p. 13. Fuss does not dispute that he is asymptomatic. As such, the question before the Court is whether an asymptomatic alleged injury that requires no treatment and has not altered the plaintiff's life constitutes a compensable injury under Ohio

law such that plaintiff's claim may proceed to trial. I conclude that such an alleged injury does not warrant a trial.

To sustain a products liability claim, OPLA § 2307.71(A)(13) requires a plaintiff to set forth a claim seeking compensatory damages for "death, physical injury to person, emotional distress, or physical damage to property other than the product in question." Here, Fuss is seeking damages related to his alleged physical injury. In so doing, however, he provides no legal authority suggesting that an asymptomatic perforation can constitute a physical injury.

As there is no specific statutory definition of "physical injury," the Court looks to Ohio case law to guide its analysis. In the case of *Day* v. *NLO, Inc.*, 814 F. Supp. 646, 650 n.4 (S.D. Ohio Jan. 11, 1993), the court determined that workers and frequenters of a nuclear weapons manufacturing plant, who alleged that they suffered an increased risk of cancer and cancer itself as a result of exposure to materials used in the weapons-making process, sufficiently claimed "physical injury" as required to sue for emotional distress under Ohio law, in the absence of severe and debilitating emotional distress. In reaching this determination, the *Day* court effectively defined "physical injury" as an affliction with which one cannot lead a normal life, stating in relevant part:

> "The Defendants cite to *Roese* v. *Battelle Mem. Inst.,* Case No. 90 AP-213, 1991 WL 10923 (Ohio Ct. App., Franklin Cty., March 27, 1991), in support of their position. In *Roese,* the court considered the appeal of a husband and his wife against his employer, the Battelle Memorial Institute. The plaintiff-appellants claimed that the employer had knowingly and intentionally exposed them to hazardous materials. Among other causes of action, the plaintiffs sued for their emotional distress. In analyzing this cause of action, the *Roese* court stated that 'the alleged physical injury upon which appellants base their claim is Roese's elevated white blood cell count.' *Id.* at 6.
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> "The *Roese* court held as a matter of law that a change in the plaintiff-employee's white blood cell count did not constitute a physical injury. The court reasoned that 'because people with high white blood cell counts can lead a normal life and never develop an injury . . .' the plaintiff-employee did not have a 'physical injury' for purposes of analyzing the plaintiffs' emotional distress. *Id.* The court then held that the plaintiffs did

> not suffer from severe and debilitating emotional distress as a matter of law. *Id.* We are unsure of the soundness of the holding in *Roese,* as an increase in the white-blood cell count appears to constitute a significant change in the body.
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> "In any event, the case before this Court, however, is distinguishable. The Plaintiffs in *Day v. NLO* are alleging emotional distress, increased risk of cancer, and cancer, itself. We assume that the Plaintiffs are basing their emotional distress claims on the increased risk of cancer and cancer itself. Unlike a high white blood cell count, many people cannot lead normal lives with an increased risk of cancer or cancer itself. Therefore, we conclude that the decision in *Roese* supports this Court's holding that the Plaintiffs in this case may sue for their emotional distress, because they also claim to have suffered a physical injury." *Id.*

Here, there is no evidence to suggest that Fuss cannot lead a normal life—or that his life has been altered at all—because of his alleged injury. Per Fuss's own testimony, he is experiencing no symptoms or pain whatsoever. See Exhibit O, Fuss Dep. at 49:10-13, 94:6-13. Indeed, Fuss testified that outside of having a perforation, he does not have any injuries or physical symptoms.[15] *Id.* None of Fuss's healthcare providers testified that he is at risk of anything, and Fuss's treating surgeon testified that he does not anticipate Fuss will need any follow-up moving forward. *Id.* at 94:18-20; Exhibit A, Vincente Dep. at 57:17-20. In other words, Fuss cannot show that he has suffered a compensable physical injury. See *Day*, 814 F. Supp. 646 at 650 n.4.

In any case, as noted above, Fuss provides no legal authority, and the Court is not aware of any, suggesting that an asymptomatic perforation can constitute a physical injury. As Boston Scientific points out, the most apposite legal authority on this point is the Supreme Court of Ohio's decision in *Ackison* v. *Anchor Packing Co.*,120 Ohio St. 3d 228 (2008). There, the court determined that an asymptomatic medical condition caused by asbestos exposure was not a compensable injury under Ohio's common law. See *id.* at 232. The same result is warranted here.

[15] Fuss admits that he became nervous about his filter only after seeing a commercial about IVC filters. Exhibit O, Fuss Dep., 92:13-24. He was contacted by an attorney and later directed to go for a CT scan by his attorney; at that time, he had no medical concerns about his filter. *Id.* at 51:18-20, 52:10-14.

As a final note, the Court addresses in brief the argument advanced in Boston Scientific's supplemental letter. On September 2, 2022, following the hearing on its motion for summary judgment, Boston Scientific filed a letter of supplemental argument and authorities. Therein, it states that during the motion hearing, Fuss "injected new argument about [his] alleged emotional distress being sufficient on its own to constitute an injury," characterizing this as a "last-ditch effort to stave off summary judgment [that] is untenable under the evidence and Ohio law." To the extent that Fuss is asserting that his alleged emotional distress gives rise to an independent, legally compensable injury, I disagree. Under Ohio law, a plaintiff who has not suffered a physical injury, as is the case here, may only recover for emotional distress that is severe and debilitating. *Paugh* v. *Hanks,* 6 Ohio St. 3d, 72 (1983). In following Ohio law, the Sixth Circuit explained that "where a plaintiff seeks to recover for emotional or psychiatric injury alone, 'plaintiffs [are] limited to only those which are 'severe and debilitating' to a reasonable person.'" *Igo* v. *Coachmen Indus., Inc.,* 938 F.2d 650, 656 (6th Cir. 1991), quoting *Paugh,* 6 Ohio St. 3d at 72. Here, as Boston Scientific avers, there is nothing in the record for a jury to find that Fuss experienced serious emotional distress; he is not receiving any treatment for his alleged fear and stress, there is no evidence of any changes in his emotional condition, and there has not been a diagnosis that these conditions exist.

ORDER

For the foregoing reasons, Boston Scientific's motion to exclude the opinion testimony of Fuss's proposed expert (Paper No. 17) and motion for summary judgment (Paper No. 18) are hereby **ALLOWED**.

Date: October 20, 2022

/s/
Christopher K. Barry-Smith

Associate Justice, Superior Court