IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

RANDY J. AFRICANO,

Plaintiff,

v.

ATRIUM MEDICAL CORPORATION,

Defendant.

Case No. 17-cv-7238

Judge Mary M. Rowland

MEMORANDUM OPINION AND ORDER

Plaintiff Randy Africano ("Africano") alleges that during hernia surgery he was injured by the use of mesh manufactured by Atrium. Africano brings product liability claims based on strict liability and negligence against Defendant Atrium Medical Corporation ("Atrium"). Atrium has moved for summary judgment on all of Africano's claims and has moved to exclude Africano's two experts. For the reasons stated below, Atrium's *Daubert* motion as to Dr. Pamela Sylvestre [244] is denied. The *Daubert* motion as to Dr. Duane Priddy [242] is denied as moot. Atrium's summary judgment motion [246] is granted in part and denied in part. Summary judgment is granted in Atrium's favor on Africano's design defect claim, but Africano's manufacturing defect and failure to warn claims survive.

LEGAL STANDARD

I. Rule 702 and *Daubert*

Under *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993), the requirements of Federal Rule of Evidence 702 must be met

before an expert can testify. The court evaluates the expert's qualifications, reliability of the methodology, and relevance of the testimony: "In performing its gatekeeper role under Rule 702 and *Daubert*, the district court must engage in a three-step analysis before admitting expert testimony. It must determine whether the witness is qualified; whether the expert's methodology is scientifically reliable; and whether the testimony will assist the trier of fact to understand the evidence or to determine a fact in issue." *Gopalratnam v. Hewlett-Packard Co.*, 877 F.3d 771, 779 (7th Cir. 2017) (internal citations and quotations omitted). District courts have "significant discretion under the flexible *Daubert* inquiry." *Lapsley v. Xtek, Inc.*, 689 F.3d 802, 818 (7th Cir. 2012). The burden is on the party seeking to admit the expert to show by a preponderance of the evidence that the expert meets the requirements of Rule 702 and *Daubert*. *Gopalratnam*, 877 F.3d at 782.

Because "there are many different kinds of experts, and many different kinds of expertise, . . .the gatekeeping inquiry must be 'tied to the facts' of a particular case." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150, 119 S. Ct. 1167, 1175 (1999) (quoting *Daubert*, 509 U.S. at 591). With regard to reliability, "the key to the gate is not the ultimate correctness of the expert's conclusions. Instead, it is the soundness and care with which the expert arrived at her opinion." *C.W. v. Textron, Inc.*, 807 F.3d 827, 834 (7th Cir. 2015) (internal citations and quotations omitted). While the *Daubert* inquiry focuses on principles and methodology, the "soundness of the factual underpinnings of the expert's analysis and the correctness of the expert's conclusions based on that analysis are factual matters to be determined by the trier of fact, or,

where appropriate, on summary judgment." *Smith v. Ford Motor Co.*, 215 F.3d 713, 718 (7th Cir. 2000).

II. Summary Judgment

Summary judgment is proper where "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); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). A genuine dispute as to any material fact exists if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The substantive law controls which facts are material. *Id*. After a "properly supported motion for summary judgment is made, the adverse party must set forth specific facts showing that there is a genuine issue for trial." *Id*. at 250 (internal quotations omitted).

The Court "consider[s] all of the evidence in the record in the light most favorable to the non-moving party, and [] draw[s] all reasonable inferences from that evidence in favor of the party opposing summary judgment." *Skiba v. Ill. Cent. R.R. Co.*, 884 F.3d 708, 717 (7th Cir. 2018) (internal citation and quotations omitted). The Court "must refrain from making credibility determinations or weighing evidence." *Viamedia, Inc. v. Comcast Corp.*, 951 F.3d 429, 467 (7th Cir. 2020) (*citing Anderson*, 477 U.S. at 255). In ruling on summary judgment, the Court gives the non-moving party "the benefit of reasonable inferences from the evidence, but not speculative inferences in [its] favor." *White v. City of Chi.*, 829 F.3d 837, 841 (7th Cir. 2016) (internal citations omitted). "The controlling question is whether a reasonable trier

of fact could find in favor of the non-moving party on the evidence submitted in support of and opposition to the motion for summary judgment." *Id.* (citation omitted).

BACKGROUND[1]

Africano alleges that he was injured as a result of the use of Atrium mesh during the surgical repair of a hernia. (DSOF ¶15). On March 26, 2013, Atrium manufactured ProLite mesh in Lot 10883365. (*Id.* ¶18). That ProLite mesh was shipped to the Marshfield Clinic at Minocqua, Wisconsin. (*Id.* ¶20). On December 10, 2013, Africano underwent right-side inguinal hernia repair at the Marshfield Clinic. (*Id.* ¶21). ProLite mesh from Lot Number 10883365 was used in Africano's procedure. (*Id.* ¶22). The ProLite mesh implanted in Africano was accompanied by Instructions for Use ("IFU"). (*Id.* ¶23). Before implanting mesh in Africano's December 2013 surgery, Dr. Timothy Phillips did not read the IFU provided with that mesh. (*Id.* ¶25). He typically does not read instructions for use with any mesh product. (*Id.* ¶26). Dr. Phillips obtained the mesh used in Africano's December 2013 surgery from "Central sterile from ambulatory surgery," which obtains the mesh. (*Id.* ¶29). Atrium represents on its IFU that "Atrium Polypropylene Monofilament Surgical Mesh is a sterile, non-absorbable, knitted polypropylene mesh material for tissue reinforcement." (PSOF ¶10).

[1] The facts cited are undisputed unless otherwise noted. Atrium's Rule 56.1 Statement of Facts in support of its motion for summary judgment (Dkt. 248) is abbreviated as "DSOF." Africano Rule 56.1 Statement of Additional Facts (Dkt. 256) is abbreviated as "PSOF." Atrium responded to those statements of fact at Dkt. 280. Africano responded to Atrium's statement of facts at Dkt. 256.

On July 29, 2016, Dr. Alexander Nagle performed a partial explantation of the ProLite mesh on Africano. (DSOF ¶41). Dr. Nagle described Africano's symptoms as possibly consistent with an infection from mesh that was contaminated when it was implanted, but that such a contamination would be rare because mesh is supposed to be sterile. (PSOF ¶30). Dr. Nagle considered removal of the mesh to be an urgent matter. (*Id.* ¶32).

ANALYSIS

Africano brings claims for Strict Liability (Count I), Strict Liability Failure to Warn (Count II), Negligence (Count III), and Negligent Failure to Warn (Count IV) (Dkt. 66 (Third Amended Complaint)).[2] Atrium argues that summary judgment is warranted because (1) Africano cannot show that the mesh implanted in him deviated from its intended design and thus cannot prove that the mesh was defective in manufacture; (2) Africano does not have an expert who will testify that the warnings that accompanied the Atrium mesh were inadequate; (3) Africano's failure to warn claims should be dismissed also because he cannot show that a different warning would have caused his physician to choose a different mesh; and (4) Africano's experts should be excluded and thus he cannot meet his burden as to defectiveness and

[2] Count V is labeled "Punitive Damages." As Atrium points out, "a prayer for punitive damages is not, itself, a cause of action. Punitive damages are merely a type of remedy." *Vincent v. Alden-Park Strathmoor, Inc.*, 241 Ill. 2d 495, 504, 948 N.E.2d 610, 615 (2011). The Court strikes Count V. However this ruling does not impact Africano's ability to pursue punitive damages as a remedy if appropriate.

medical causation. Atrium has filed two *Daubert* motions and Africano has filed three *Daubert* motions.[3]

I. Experts

Africano offers expert opinions from Dr. Pamela Sylvestre and Dr. Duane Priddy. ("Sylvestre Rep." (Dkt. 245-3); "Sylvestre Rebut." (Dkt. 255, Exh. 27)). ("Priddy Rep." (Dkt. 243-1; "Priddy Rebut.", Dkt. 267, Exh. B). The Court rules as follows on Atrium's motions to exclude.

A. Dr. Sylvestre

Atrium moves to exclude certain opinions of Dr. Sylvestre. Dr. Sylvestre opined that "to a reasonable degree of medical certainty, the source of [Africano's] infection is bacteria on the mesh." (Sylvestre Rep.). She further opined that the "mesh was contaminated prepackaging, not in the operating room." (Sylvestre May 2019 Dep. (Dkt. 266-1), p. 106). Atrium argues that Dr. Sylvestre (1) is not an expert on the design or manufacture of hernia mesh; (2) is unqualified to provide opinions on hernias and hernia repair; (3) employed unreliable methodology and ignored facts that contradicted her opinions; and (4) offered opinions that are speculative and without any basis in fact or evidence.

Under Federal Rule of Evidence 702, an expert may be qualified "by knowledge, skill, experience, training or education." Fed. R. Evid. 702. "Whether a witness is qualified as an expert can only be determined by comparing the area in which the

[3] Africano's *Daubert* motions (Dkts. 236, 238) are not germane to resolving Atrium's summary judgment motion. For the reasons discussed below the Court denies as moot Africano's motion to exclude Dr. Spiegelberg [240]. The Court will rule on Africano's two remaining *Daubert* motions pre-trial.

witness has superior knowledge, skill, experience, or education with the subject matter of the witness's testimony." *Gayton v. McCoy*, 593 F.3d 610, 616 (7th Cir. 2010) (citation omitted). The question is whether the expert's qualifications "provide a foundation for [him] to answer a specific question." *Id.* at 617 (cleaned up).

The Court finds Dr. Sylvestre qualified to opine on the cause of Africano's infection. Dr. Sylvestre is a pathologist. (Dkt. 239-1). She is Medical Director and Chief Staff Pathologist at Gastro One, an Anatomic Pathology Laboratory. *Id.* She received her M.D. from the University of Southern California in 1995. *Id.* She has been Board Certified since 1999 in Combined Anatomic Pathology and Clinical Pathology. *Id.* Her undergraduate degree is a Bachelor of Science in Mechanical Engineering and she did post graduate work in biomedical engineering. *Id.* She has published two books, has a number of publications in refereed journals, and is a member of a number of medical professional societies. *Id.*

Atrium first argues that Dr. Sylvestre is not an expert on the design or manufacture of hernia mesh. Africano responds that she is not offered as an expert on mesh design. (Dkt. 264 at 4). Atrium does not identify specific opinions by Dr. Sylvestre about the design or manufacture of the mesh in her report or rebuttal report. She testified that the "mesh was contaminated prepackaging, not in the operating room." (Sylvestre May 2019 Dep., p. 106). This was her causation opinion, ruling out other causes of Africano's infection, not an opinion on the design or manufacture of Atrium's mesh. To the extent Atrium seeks to test her opinion that the mesh was contaminated prepackaging it may do so before the jury. *See Lapsley*,

689 F.3d at 805 (once *Daubert* threshold met, "the accuracy of the actual evidence is to be tested before the jury with the familiar tools of 'vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'").

Atrium next argues that Dr. Sylvestre is not "qualified to opine on Mr. Africano's hernia or hernia repair or make an assessment about whether he experienced an abscess or hematoma in July 2016." (Dkt. 245 at 10). Again Atrium does not identify specific opinions by her about Africano's hernia or hernia repair. The Court finds Dr. Sylvestre qualified to opine about whether Africano had an abscess or hematoma. Atrium relies on the fact that Dr. Sylvestre does not treat patients in a clinical setting. But a pathologist gathers information from clinical laboratory tests and makes diagnoses. The American Medical Association (AMA) defines pathologist as follows:

> A pathologist deals with the causes and nature of disease and contributes to diagnosis, prognosis, and treatment through knowledge gained by the laboratory application of the biologic, chemical, and physical sciences. This specialist uses information gathered from the microscopic examination of tissue specimens, cells and body fluids, and from clinical laboratory tests on body fluids and secretions for the diagnosis, exclusion, and monitoring of disease.[4]

According to the AMA, a pathologist "incorporates the latest laboratory medicine technology to provide information that serves as the foundation for medical diagnosis, patient treatment and research." Dr. Sylvestre is Board Certified in Combined Anatomic Pathology and Clinical Pathology and is the Medical Director and Chief Staff Pathologist at an anatomic pathology laboratory. She has been practicing as a

[4] AMA Specialty Description, available at https://freida.ama-assn.org/specialty/pathology-anatomic-and-clinical.

pathologist for more than twenty years. To conclude that Africano did not have a hematoma, Dr. Sylvestre relied on her experience and training and her review of the medical records and doctors' deposition testimony in this case. *See Kumho Tire Co*., 526 U.S. at 156 ("no one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience.").

Atrium next contends that Dr. Sylvestre's methodology was flawed, and she ignored facts that contradicted her opinions. An expert's conclusions should be based on "sufficient facts or data." Fed. R. Evid. 702(b). Reliability "is determined on a case-by-case basis." *C.W. ex rel. Wood*, 807 F.3d at 835. It is a "flexible" test. *Kumho Tire Co*., 526 U.S. at 141. *See also Smith*, 215 F.3d at 720 ("the reliability test under Rule 702 is an individualized test whose relevant factors will depend on the type of expertise at issue in a given case.").[5]

Atrium objects to Dr. Sylvestre's differential diagnosis. Differential diagnosis "generally provides a framework in which all reasonable hypotheses are 'ruled in' as possible causes of a medical problem and some of these possible causes are then 'ruled out' to the extent scientific evidence makes it appropriate to do so." *Ervin v. Johnson & Johnson, Inc*., 492 F.3d 901, 903 (7th Cir. 2007). "A differential diagnosis satisfies a *Daubert* analysis if the expert uses reliable methods." *Id*. at 904.

Dr. Sylvestre opined that Africano's injuries were caused by an infection from the mesh, which was contaminated before his procedure. She ruled out contamination

[5] "We give the court great latitude in determining not only *how* to measure the reliability of the proposed expert testimony but also whether the testimony is, in fact, reliable." *United States v. Pansier*, 576 F.3d 726, 737 (7th Cir. 2009) (emphasis in original).

during the procedure or other causes of his injuries such as a hematoma. In assessing Dr. Sylvestre's causation opinion the Court looks at whether the "hypothesis was reliably supported and applied to the known facts, such that it rises above speculation and becomes a presentable probability." *Lapsley*, 689 F.3d at 814. *See also Smith*, 215 F.3d at 719 ("It is not the trial court's role to decide whether an expert's opinion is correct. The trial court is limited to determining whether expert testimony is pertinent to an issue in the case and whether the methodology underlying that testimony is sound.").

Dr. Sylvestre's methodology is sound. To reach her opinions, she relied on her experience and training and her review of the medical records and treating doctors' testimony. She reviewed the radiologist's notes of the CT scan, which the radiologist summarized as "suspicious for infection and abscess." (Sylvestre Rep.). The Court does not find any fault in her reliance on other doctors' notes and opinions. *See Walker v. Soo Line R. Co.*, 208 F.3d 581, 588 (7th Cir. 2000). And she concluded, to a reasonable degree of medical certainty, based on her experience and her review of the medical records which showed no evidence of breach of sterility technique, that the contamination occurred before packaging. (Sylvestre May 2019 Dep. at pp. 99-102).

Dr. Sylvestre also explained how she came to her conclusion that Africano did not have a hematoma:

> a seroma is a collection of fluid in an uncomplicated state. It's serous fluid that's collected. It is not what the surgeon described in 2016. [T]he surgeon also,…raised up a third possibility of -- besides a seroma. He also mentioned a hematoma. But the -- what is described radiographically in 2016 is not a simple seroma because you do not get the fat stranding from a simple seroma. That is why the radiologists

> used both the term abscess and infection when they put down their impressions. And also the surgeon in his notes does not describe a seroma, because a seroma -- an uncomplicated seroma does not contain necrotic tissue…. Dr. Nagle said… this could be a hematoma… If you understand the way the body responds to a hematoma -- hematoma is a collection of blood. Now if you get a larger collection, it's going to take longer. But the body will respond to -- to a blood collection. And it will break it down. And it's not a static environment. So if you get a hematoma in 2013, you're not going to have a hematoma in 2016. In fact, blood is a nice media for bacteria to grow. In fact, there are blood cultures or we call blood augers where we use sheep blood to encourage the growth of certain bacteria. So, this in 2016 is certainly not a hematoma. And as I pointed out to you, it's not -- it's not a seroma because seromas don't contain necrotic. Uncomplicated seroma does not contain necrotic tissue.

(Sylvestre May 2019 Dep., pp. 124-26).

Atrium argues that Dr. Sylvestre improperly relied on Dr. Nagle's preliminary diagnosis of abscess and infected mesh, and ignored his later testimony that Africano did not experience an infection. It also argues she did not fully account for notes in the pathology report. These are subjects of cross-examination. "So long as the principles and methodology reflect reliable scientific practice, vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Schultz v. Akzo Nobel Paints, LLC*, 721 F.3d 426, 431 (7th Cir. 2013) (cleaned up); *see also Walker*, 208 F.3d at 589 ("To the degree that [the expert] might have relied on faulty information, the matter certainly could be explored on cross-examination.").

Finally, Atrium argues that Dr. Sylvestre's opinions are speculative and without any basis in fact or evidence. It argues that her opinion that mesh was contaminated

prepackaging is speculative because she is not familiar with Atrium's manufacturing process and she could not exclude Staphylococcus lugdunensis as causing the infection. Again Dr. Sylvestre does not offer an opinion about Atrium's manufacturing process and Atrium does not explain why she would need expertise in that topic to offer her opinions here. Further, although an expert should consider other causes, she is not required to rule out every alternative cause. *Schultz*, 721 F.3d at 434; *see also Wilda v. JLG Indus., Inc.*, 2021 WL 392705, at *3 (N.D. Ill. Feb. 3, 2021) ("a failure to look at this or that is not a reason to keep an expert out of a case"). Dr. Sylvestre did consider some if not every other possible cause. A review of her reports and two deposition testimonies shows that this is not a case of an expert offering merely a bottom-line conclusion. Although Atrium does not specifically raise a relevance argument; the Court nevertheless finds Dr. Sylvestre's opinions relevant to this case. *See Daubert*, 509 U.S. at 589; *Smith*, 215 F.3d at 718–19 ("Where an expert's hypothetical explanation of the possible or probable causes of an event would aid the [trier of fact], that testimony satisfies *Daubert*'s relevancy requirement.).

Atrium's motion to exclude Dr. Sylvestre [244] is denied.

B. Dr. Priddy and Dr. Spiegelberg

Dr. Duane Priddy opines that "[t]he PP [polypropylene] Atrium ProLite hernia mesh is unreasonably dangerous and defective for its intended use." (Priddy Rep., p. 9). Dr. Priddy's expert reports and testimony focus on his opinion that polypropylene is dangerous. In light of the Court's ruling below granting summary judgment on Africano's design defect claim, Atrium's *Daubert* motion [242] is denied as moot.

Similarly Atrium's expert Dr. Stephen Spiegelberg's report is about the use of polypropylene. (Dkt. 241-3). Because there is no longer a design defect claim in the case, the Court also denies as moot Africano's motion to exclude Dr. Spiegelberg [240].

II. Africano's Claims

"An injured plaintiff may allege one of two types of products liability claims: a strict liability claim or a negligence claim." *Salerno v. Innovative Surveillance Tech.*, Inc., 402 Ill. App. 3d 490, 497, 932 N.E.2d 101, 108 (1st Dist. 2010). "The key distinction between the two types of claims lies in the concept of fault. In a strict liability claim, the focus of the inquiry is on the condition of the product itself. A negligence claim accounts for a defendant's fault as well as the product's condition." *Id.* (citations omitted). Manufacturing defect, design defect, and failure to warn are three different strict liability theories. *Id.*

A. Manufacturing defect based on failure to sterilize

"A manufacturing defect occurs when one unit in a product line is defective, whereas a design defect occurs when the specific unit conforms to the intended design but the intended design itself renders the product unreasonably dangerous." *Salerno,* 402 Ill. App. 3d at 497. A manufacturing defect claim requires: "(1) a condition of the product that results from manufacturing or design; (2) the condition made the product unreasonably dangerous; (3) the condition existed at the time the product left the defendant's control; (4) the plaintiff suffered an injury; and (5) the injury was proximately caused by the condition." *Id.* at 498 (citation omitted).

Africano's manufacturing defect claim is based on evidence that the mesh implanted in him was not sterile when it left Atrium's manufacturing facility and that condition caused his injuries. Africano relies on: (1) evidence of Atrium's knowledge about the risk that the mesh was unsterile and the link to serious or fatal infection, (2) Dr. Sylvestre's expert opinion about the source of his infection, (3) implant surgeon Dr. Phillips' testimony that he used procedures to ensure the implanted mesh was not contaminated in the operating room, and (4) explant surgeon Dr. Nagle's medical notations of "abscess" and "infected mesh". The Court finds that there is a genuine issue of material fact about whether there was a manufacturing defect in the mesh that caused Africano's injuries.

First there is a factual issue about whether the mesh used in Africano's surgery was sterile when it left Atrium's control. Atrium does not dispute that unsterile mesh is unreasonably dangerous. Africano cites evidence that Atrium knew about the risk that the mesh was not sterile when it left its facility and that lack of sterility could lead to infection.

Atrium does not dispute that it received a Warning Letter from the U.S. Food and Drug Administration (FDA) on October 11, 2012 identifying six separate violations at Atrium's Hudson, New Hampshire facility. (PSOF ¶1; FDA Warning Letter, Dkt. 255, Exh. 3). The letter stated that the FDA completed an inspection of the facility from July 31 to September 7, 2012 and the inspection revealed that Atrium's medical devices are "adulterated" as the term is defined in Section 501(h) of the Federal Food, Drug, and Cosmetic Act. (*Id.*). The first violation was:

> Failure to validate with a high degree of assurance, a process whose results cannot be fully verified by subsequent inspection and test, as required by 21 CFR 820.75(a). For example, you have not adequately validated your current Ethylene Oxide (ETO) sterilization process that is used to sterilize all thirty nine (39) of your medical devices…We have reviewed your response dated September 28, 2012 and find it inadequate…You will need to provide us with documentation of successful validation once completed…You should also be aware that results of sterility testing of finished product alone, does not ensure that your products are sterile. You are required to conduct a successful validation of your sterilization operations to demonstrate product sterility.

(*Id.*). Atrium's FDA Sterilization Response Quality Plan ("Sterilization Plan") was not effective until May 2013. (PSOF ¶4).[6]

Further, according to Atrium President Trevor Carlton, the contractor responsible for Atrium's sterilization process at all times relevant to the issues of sterilization in this case, Steris, made "countless careless mistakes during [Atrium's] critical testing." (*Id.* ¶¶17-18).[7] And Frank Casamassina, who was responsible for quality and regulatory matters at Atrium from August 2012 until November 2013, had "several concerns" about the cleanroom at Atrium, including a lack of contamination control in entering the cleanroom. (*Id.* ¶19). Casamassina testified that he did not think Atrium employees "really underst[ood] the whole concept of contamination

[6] Atrium argues that "[t]he Warning Letter did not relate specifically to the mesh implanted in Plaintiff." (Dkt. 274 at 6). Atrium does not cite any support for this argument. The FDA issued the warning letter in October 2012 and Atrium's FDA response plan was not effective until May 2013. Atrium manufactured the ProLite mesh that was implanted in Africano during that timeframe, in March 2013. Drawing reasonable inferences from the evidence in favor of Africano as the Court must at this stage, the Court can infer that the mesh implanted in Africano was among the products covered by the FDA Warning Letter.

[7] Atrium objects to the "admissibility of Frank Casamassina's interpretation of Trevor Carlton's email." (Dkt. 280, ¶18). But Africano also cites Carlton's March 2013 email itself (PSOF ¶18; Ex. 20) and Atrium does not object to the admissibility of the email.

control." (*Id.* ¶20). Atrium admits that it understood that "if the sterilization of the product is not properly validated then it is potentially not sterile. This could lead to serious even fatal infection." (*Id.* ¶2).

Second there is an issue of fact about causation. A plaintiff bringing a product liability action in Illinois must "demonstrate a causal relationship between the injury and the manufacturer's product." *Schaefer v. Universal Scaffolding & Equip., LLC*, 839 F.3d 599, 604 (7th Cir. 2016) (cleaned up). "The causal relationship can be proven by circumstantial evidence. But in order to get to the jury, the plaintiff must demonstrate more than a mere possibility that the product caused the injury. Rather, the plaintiff must come forward with evidence justifying an inference of probability." *Thornton v. M7 Aerospace LP*, 796 F.3d 757, 770 (7th Cir. 2015) (citations omitted); *see also Blood v. VH-1 Music First*, 668 F.3d 543, 546 (7th Cir. 2012) ("Ordinarily, proximate cause is a question for the trier of fact").

It is undisputed that Dr. Phillips testified that when he implanted the mesh, he ensured the mesh was not contaminated in the operating room. (PSOF ¶36). Explant surgeon Dr. Nagle's July 2016 note, under "postoperative diagnoses" noted "abscess" and "infected mesh." (*Id.* ¶24). Dr. Nagle testified that Africano's symptoms were possibly consistent with an infection from mesh that was contaminated when it was implanted, but that such a contamination would be rare because mesh is supposed to be sterile. (*Id.* ¶30). Atrium argues that Dr. Nagle's initial notation of "infected mesh" should be disregarded in favor of his later deposition testimony explaining he believed Africano had developed a hematoma. Africano contends that the Court should

disregard Dr. Nagle's "flip flop" testimony. Neither of these arguments is persuasive on summary judgment. *See Viamedia*, 951 F.3d at 467 (the court "must refrain from making credibility determinations or weighing evidence."). Instead Dr. Nagle's notes and testimony underscore that there is an issue of fact for a jury about whether unsterile mesh caused Africano's injuries.

Africano also relies on expert Dr. Sylvestre's causation opinion. Generally expert testimony is needed to show causation in product liability cases. *See Baltus v. Weaver Div. of Kidde & Co.*, 199 Ill. App. 3d 821, 834, 557 N.E.2d 580, 588 (1st Dist. 1990) ("Products liability actions [] often involve specialized knowledge or expertise outside the layman's knowledge."). Other evidence may create an issue of fact making summary judgment inappropriate as well. *See DiCosolo v. Janssen Pharms., Inc.,* 2011 IL App (1st) 093562, ¶ 28, 951 N.E.2d 1238, 1247 (for manufacturing defect claim, "plaintiff may rely on direct or circumstantial evidence to establish his case or on expert testimony") (citation omitted); *Greybill v. Zimmer, Inc.*, 2013 WL 593460, at *6 (N.D. Ill. Feb. 14, 2013) (noting the need for expert testimony will depend on the facts of the case and "expert testimony is itself a form of circumstantial evidence.") (citations omitted).

In any event, as discussed, the Court has found Dr. Sylvestre's opinions admissible. Dr. Sylvestre's causation opinion in combination with other evidence discussed above give rise to the inference of probability that unsterile mesh caused Africano's injuries. Thus Africano's manufacturing defect claims in Counts I and III survive summary judgment.

B. Design defect based on use of polypropylene

Atrium argues that Africano did not allege a design defect claim and his attempt to add one now should be rejected. Africano's design defect claim is based on the use of polypropylene in the ProLite mesh. It is well-settled that "although a plaintiff generally can alter the legal theories asserted in its complaint, it cannot alter the factual basis of [its] complaint at summary judgment. Such an alteration would be an unacceptable attempt to amend the pleadings through summary judgment argument." *BRC Rubber & Plastics, Inc. v. Cont'l Carbon Co.*, 900 F.3d 529, 541 (7th Cir. 2018) (cleaned up); *see also Anderson v. Donahoe*, 699 F.3d 989, 997 (7th Cir. 2012). The Court agrees that Africano belatedly sought to add a design defect claim based on the use of polypropylene but in any event, the lack of evidence linking the alleged design defect to Africano's injuries dooms his claim.

Africano argues that whether his claim is characterized as a manufacturing or design defect claim is not important. (Dkt. 254 at 23-24). The Court disagrees. A manufacturing defect and design defect are "*different* theories of liability." *Salerno*, 402 Ill. App. 3d at 497 (emphasis added). "A manufacturing defect differs from a design defect in that the former occurs in only a small percentage of units in a product line, whereas the latter arises when the specific unit conforms to the intended design but the intended design itself, or its sale without adequate instructions or warnings, renders the product not reasonably safe." *Blue v. Env't Eng'g, Inc.*, 215 Ill. 2d 78, 89–90, 828 N.E.2d 1128, 1137 (2005). *See also Mech. Rubber & Supply Co. v. Caterpillar Tractor Co.*, 80 Ill. App. 3d 262, 264, 399 N.E.2d 722, 723 (3d Dist. 1980)

("[M]anufacturing defects result from qualities of a product not intended by the manufacturer while design defects refer to characteristics of a product intended by the manufacturer which render the product not reasonably safe."). Africano's manufacturing defect claim, based on allegedly unsterile mesh, is different from his claim that Atrium's use of polypropylene in its mesh caused his injuries—a design defect claim.[8]

Africano does not indicate whether his design defect claim is based in strict liability or negligence. If based on strict liability, Africano fails to discuss the applicable tests in Illinois. "In Illinois, two tests are employed when determining whether a product is unreasonably dangerous under a strict liability design-defect theory—the consumer-expectation test and the risk-utility test." *Calles v. Scripto-Tokai Corp.*, 224 Ill. 2d 247, 250, 864 N.E.2d 249, 252 (2007). The consumer-expectation test assesses whether "a product meet[s] ordinary consumer expectations as to safety," and the risk-utility test assesses whether "the risk of danger inherent in the challenged design outweighs the benefits of such design." *Id.* at 255-56 (citations omitted).

Furthermore, whether based on strict liability or negligence, Africano fails to provide evidence that polypropylene caused his injuries. *See Salerno*, 402 Ill. App. 3d at 498, 501 (both strict liability and negligent design claims require showing of causal link to injury); *Baltus*, 199 Ill. App. 3d at 831 ("[plaintiff] must [] establish an

[8] If construed as a manufacturing defect claim, Africano does not provide *any* evidence that polypropylene was *not* an intended part of Atrium's ProLite mesh product or that only a small percentage of the mesh contained polypropylene.

evidentiary base for the proximate cause element of his claim in order to survive the motion for summary judgment. We will not presume a causal link between the alleged design defect…and [plaintiff's] injury."); *Thornton*, 796 F.3d at 770 (in products liability action based on either strict liability or negligence, "plaintiff must demonstrate a causal relationship between the injury and the manufacturer's product.").[9]

Africano offered Dr. Priddy as an expert on polypropylene. Dr. Priddy opines that polypropylene "is unstable and readily oxidizes", "all polypropylene meshes are defective" and Atrium's "ProLite hernia mesh is unreasonably dangerous and defective for its intended use." (Priddy Rep. at pp. 3, 9; Priddy Dep. (Dkt. 255, Exh. 31) at 184:7-9). But Dr. Priddy does not provide any causation opinion linking polypropylene to Africano's injuries.

Relying on Dr. Priddy's testimony, Africano asserts that "the polypropylene from which the mesh is made provides an environment that will promote the return of the infection" and because not all the mesh was removed, Africano's infection could return. (PSOF ¶¶ 39, 41). But that is not evidence that polypropylene caused the injuries Africano claims to have suffered in this case. And while Africano used the phrase "the infection" to seemingly reference *his* infection, nothing in the cited deposition testimony or cited expert report refers to *Africano's* infection. *See Salerno,* 402 Ill. App. 3d at 498, 502 (explaining that summary judgment would have been

[9] As Atrium points out (Dkt. 274 at 6), Africano's causation theory is unclear. First, Africano asserts that unsterile mesh caused his injuries, then polypropylene "degraded" over time in his body, causing his injuries. In any event, Africano does not provide any evidence of a causal link between his injuries and polypropylene.

proper on negligent design claim where plaintiff did not provide expert testimony about standard of care and deviation from that standard that proximately caused *his* injury) (emphasis added). Dr. Priddy's opinion that polypropylene meshes are defective does not lead to the conclusion that Africano's mesh caused his injuries.

In short, Africano has not offered any evidence of a causal link between his injuries and the use of polypropylene. *See Baltus*, 199 Ill. App. 3d at 833 (requiring "affirmative factual base from which to infer [] proximate cause"); *Thornton*, 796 F.3d at 771 (rejecting as speculation plaintiffs' argument that because they can "establish that the charts were flawed, [the court] can infer that the charts probably contributed to the crash.").

The Court grants summary judgment in favor of Atrium on Counts I and III to the extent they are based on an alleged design defect.

C. Failure to Warn

In Illinois, "[a] duty to warn exists only when there is unequal knowledge and the defendant, possessed of such knowledge, knows or should know that harm might occur if no warning is given." *Proctor v. Davis*, 291 Ill. App. 3d 265, 277, 682 N.E.2d 1203, 1211 (1st Dist. 1997) (cleaned up). A manufacturer's duty to warn is a "*continuous*" one. *Id.* at 278 (emphasis in original). "The adequacy of the warning is usually a jury question." *Collins v. Sunnyside Corp.*, 146 Ill. App. 3d 78, 80, 496 N.E.2d 1155, 1157 (1st Dist. 1986).

"[T]he manufacturer of a prescription medical device has a duty to warn prescribing physicians or other health professionals who may prescribe the device of

the product's known dangerous propensities…Likewise, physicians, using their medical judgment, have a duty to convey the warnings to their patients." *Hansen v. Baxter Healthcare Corp.*, 198 Ill. 2d 420, 430, 764 N.E.2d 35, 42 (2002). The manufacturer's duty to warn the health professional, rather than the patient, is the "learned intermediary doctrine." *Id*. The Court agrees with Africano that the learned intermediary doctrine does not apply here because the evidence shows that Atrium did not warn either Dr. Phillips or Marshfield Clinic that the mesh was potentially not sterile. As one Illinois appellate court recently explained:

> Naturally, when a manufacturer or its representatives withholds crucial information about a drug or medical device, it has breached its duty to warn the medical community because without this information, doctors could not provide appropriate and comprehensive medical advice for their patients…Ultimately, the learned intermediary doctrine is a shield, which protects drug and device manufacturers that adequately warn the medical community of the known dangers of their products… [W]here a manufacturer *never* gives adequate warning to a physician, the learned intermediary doctrine is…inapplicable.

Plass v. DeKalb Eye Consultants, LLC, 2020 IL App (2d) 190403-U, ¶¶ 18-19 (cleaned up) (emphasis in original).

There is an issue of fact for a jury about whether Atrium violated its duty to warn. Atrium represents on its mesh IFU that "Atrium Polypropylene Monofilament Surgical Mesh is a *sterile*, non-absorbable, knitted polypropylene mesh material for tissue reinforcement." (PSOF ¶10) (emphasis added). The FDA Warning Letter explained that the FDA's inspection revealed that Atrium's medical devices were "adulterated", and the FDA found Atrium's sterilization process was not in compliance with the FDA's regulations. *Id*. ¶1. The FDA warned, "You should also be

aware that results of sterility testing of finished product alone, does not ensure that your products are sterile. You are required to conduct a successful validation of your sterilization operations to demonstrate product sterility." *Id*. ¶11. Atrium understood that "if the sterilization of the product is not properly validated then it is potentially not sterile. This could lead to serious even fatal infection." *Id*. ¶2.

The same day that the FDA issued its warning letter, Atrium alerted its "Valued Customers" about the letter. *Id*. ¶ 12. Atrium's letter to its "Valued Customers" stated that it was cooperating with the FDA but the Warning Letter did not "prevent Atrium from continuing to sell any of its products" and all of its products "have [] been properly sterilized." (Dkt. 255, Exh. 8). A similar letter was again sent to "Valued Customers" on November 30, 2012. (PSOF ¶13). Marshfield Clinic, where Africano was implanted with the mesh, did not receive any notice of the FDA Warning Letter. *Id*. ¶15.[10] Dr. Phillips testified that he would not have used the mesh had he known of the sterility issues in the Warning Letter. *Id*. ¶40.[11] Explant surgeon Dr. Nagle testified he would have to investigate further if he knew that the mesh was subject

[10] Atrium admits that the sale to Marshfield Clinic was not accompanied by the Warning Letter. (Dkt. 280, ¶15). But it disputes that "Atrium did not issue any notice from October 11, 2012 to February 2, 2015 regarding the Warning Letter to hospitals, clinics, doctors, or potential users of ProLite mesh." (*Id*.). However, Atrium's response does not specifically address Marshfield Clinic. And Atrium cites no evidence that the letter to its "Valued Customers" was also sent to Marshfield Clinic.

[11] Atrium admits that Dr. Phillips gave this testimony but "disputes that Dr. Phillips would have changed his practice, as he 'universally tell[s] people that infected mesh is a known complication. If a mesh gets infected, it can be terribly difficult to take care of.'" (Dkt. 280, ¶40). Dr. Phillips specifically testified that had he known that Atrium was operating under an FDA warning letter at the time he implanted the mesh, he "wouldn't use the product" because of the increased risk of infection. (Phillips Dep. Dkt. 255, Exh. 5). Atrium's response to PSOF ¶40 does not contradict this evidence.

to a warning letter concerning the product's sterility, potentially because of the increased risk of infection. *Id*. ¶33.

Atrium argues that the ProLite mesh IFU "specifically warned of the risk of inflammation and infection" (Dkt. 247 at 14) and that "infection…is a well-known potential complication of surgery." (Dkt. 274 at 7). But Africano's claim is not that Atrium failed to warn that infection can result from surgery. Africano's claim is that Atrium failed to warn that its mesh was potentially not sterile when it was manufactured. Atrium does not argue that *this* risk was already known to the medical community. *See Hansen,* 198 Ill. 2d at 430 (manufacturer need not provide warning of risks already known to the medical community). The IFU here represented the mesh as being sterile, whereas the FDA Warning Letter stated that Atrium had not validated its sterilization process. (Atrium's argument that the warning letter did not relate to the mesh implanted in Africano is addressed, *supra*.)

Africano points to other evidence of the imbalance of information between Atrium and Africano's doctor and clinic. Steris, Atrium's sterilization contractor, made ""countless careless mistakes during [Atrium's] critical testing," according Atrium's President. (PSOF ¶¶17-18). Frank Casammina had "several concerns" about contamination control in the cleanroom at Atrium. (*Id*. ¶19). He testified that "It's a requirement. It's important," and that "if you don't have a sterility assurance level which is a result of actually producing the data and you can't demonstrate that, then you really don't have a sterilization cycle and you would not proceed – should not proceed to be shipping those products. (*Id*. ¶22).

The case law cited by Atrium is distinguishable. In *Sosnowski v. Wright Med. Tech., Inc.*, the court concluded that defendant "warned of the precise risk" that plaintiff complained of, and that warning "was not inaccurate or misleading." 2012 WL 1030485 at *8 (N.D. Ill. Mar. 27, 2012). Again, Atrium does not argue or cite any evidence that it warned Marshfield Clinic or Dr. Phillips of the risk that its mesh was not sterile. And Africano has provided evidence from which it can be inferred that the IFU was misleading, because the IFU claimed the mesh was sterile. *See Plass*, 2020 IL App (2d) 190403-U, ¶ 19 (misrepresentation about device's status was deception that "was *worse* than a mere failure to warn.") (emphasis in original).

In *Vaughn v. Ethicon, Inc.,* the court granted summary judgment to defendants on plaintiff's failure to warn claims because defendants "presented uncontroverted evidence" that the doctor did not consult the IFU in deciding whether to recommend the device for plaintiff, so new or different warnings in the IFU could not have changed his advice. 2020 WL 5816740 at *4 (S.D. Ill. Sept. 30, 2020). And assuming the doctor "would have heeded different warnings—had he read them—the evidence clearly shows his recommendation would not have changed [because he] testified that even today he believes the [device] was a safe and appropriate device for [plaintiff]." *Id*. Similarly in *Zimmer*, there was no evidence that "if properly warned, [Dr. Larson] would have altered [his] behavior and avoided injury." *In re Zimmer, NexGen Knee Implant Prod. Liab. Litig*., 884 F.3d 746, 753–54 (7th Cir. 2018).

This case is different. Dr. Phillips specifically testified that he would not have used the mesh product had he known the information in the FDA Warning Letter. PSOF

¶40. And Atrium *did* alert other members of the medical community. *Id*. ¶ 12. This evidence supports Africano's theory that had his doctor received a warning about the risk of unsterile mesh, he would not have been injured. *See In re Depakote*, 2015 WL 4776093, at *7-9 (S.D. Ill. Feb. 14, 2015) (disputed issues of fact about causation precluded summary judgment).[12]

In *Hansen*, a case not discussed by Atrium, the Illinois Supreme Court concluded that Baxter had a duty to warn and "the record contains sufficient conflicting evidence to raise factual questions concerning the comparative knowledge of Baxter and that of the medical community concerning both the danger of using friction-fits in central lines and the need to use only Luer-locks in these applications." 198 Ill. 2d at 431. Similarly here, the record contains conflicting evidence about the comparative knowledge of Atrium and Africano's doctor and clinic about the sterility of the mesh. In fact, Atrium *had* alerted some members of the medical community to the FDA Warning Letter, but not Marshfield Clinic or Dr. Phillips. Doctors who are not sufficiently warned by the manufacturer are not "learned intermediaries" and "the adequacy of warnings is a question of fact, not law, for the jury to determine." *Proctor*, 291 Ill. App. 3d at 283. *See also Hansen,* 198 Ill. 2d at 432 (issue properly submitted to jury where defendant gave "no warning at all" about connector).

Finally, though often needed in product liability case, expert testimony is not always required for a duty to warn claim. *See N. Tr. Co. v. Upjohn Co.*, 213 Ill. App. 3d 390, 399, 572 N.E.2d 1030, 1036 (1st Dist. 1991). Africano argues that Atrium's

[12] Moreover, none of Atrium's cited cases involved a warning letter from the FDA citing specific violations related to the device at issue.

alleged misrepresentation that the mesh was sterile and failure to warn of this risk can be readily understood and does not require expert testimony. The Court agrees. A jury will be able to decide the failure to warn issue without expert testimony. *See Lott v. ITW Food Equip. Grp. LLC*, 2013 WL 3728581, at *28 (N.D. Ill. July 15, 2013) (agreeing with plaintiff "that the warnings at issue are not beyond the comprehension of a layperson.").

Accordingly Atrium's motion is denied as to Africano's failure to warn claim based on the allegedly unsterile mesh, whether based on strict liability or negligence. *McMahon v. Eli Lilly & Co.*, 774 F.2d 830, 838, n. 12 (7th Cir. 1985)) ("The elements of negligent failure to warn are very similar to those of failure to warn in strict liability."). But, the failure to warn claim based on use of polypropylene cannot proceed. The Court is granting summary judgment on Africano's design defect claim and therefore there is no basis for failure to warn based on that alleged design defect. *See Salerno*, 402 Ill. App. 3d at 499, 502.

For these reasons, Counts II and IV survive the summary judgment motion.

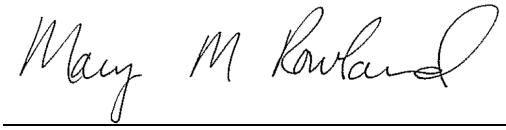
CONCLUSION

For the stated reasons, Atrium Medical Corporation's motion for summary judgment [246] is granted in part and denied in part. The Court grants summary judgment in favor of Atrium on Counts I and III to the extent they are based on an alleged design defect. Randy Africano's manufacturing defect and failure to warn claims survive. Atrium's *Daubert* motion as to Dr. Pamela Sylvestre [244] is denied.

Atrium's *Daubert* motion as to Dr. Duane Priddy [242] is denied as moot. Africano's Motion to Exclude Dr. Stephen Spiegelberg [240] is denied as moot.

E N T E R:

Dated: June 10, 2021



MARY M. ROWLAND
United States District Judge