UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: DAVOL, INC./C.R. BARD, INC., POLYPROPYLENE HERNIA MESH PRODUCTS LIABILITY LITIGATION

Case No. 2:18-md-2846

JUDGE EDMUND A. SARGUS, JR.
Magistrate Judge Kimberly A. Jolson

This document relates to:
Stinson v. Davol, Inc., et al.
Case No. 2:18-cv-1022

EVIDENTIARY MOTIONS OPINION & ORDER No. 26

Before the Court is Defendants' Motion to Exclude the Opinions and Testimony of Plaintiff's Expert Dr. David Grischkan, M.D., F.A.C.S. (ECF No. 93.) For the reasons that follow, Defendants' Motion is **GRANTED IN PART**, **DENIED IN PART**, and **DENIED IN PART AS MOOT**.

I. Background[1]

Plaintiff's case is the third bellwether trial selected from thousands of cases in this multidistrict litigation ("MDL") against Defendants. The Judicial Panel on Multidistrict Litigation described the cases in this MDL as "shar[ing] common factual questions arising out of allegations that defects in defendants' polypropylene hernia mesh products can lead to complications when implanted in patients, including adhesions, damage to organs, inflammatory and allergic responses, foreign body rejection, migration of the mesh, and infections." (No. 2:18-md-02846, ECF No. 1 at PageID #1–2.)

[1] For a more complete factual background, the reader is directed to the Court's summary judgment opinion and order in this case. (Dispositive Motions Order ("DMO") No. 7, ECF No. 225.) All docket citations are to the *Stinson* case, 2:18-cv-1022, unless otherwise noted.

The relevant facts here are that in 2015 Plaintiff underwent a right inguinal hernia repair with an Extra-Large PerFix Plug mesh, a product manufactured by Defendants. In 2017, Plaintiff underwent exploratory surgery to determine if he had a recurrent hernia or nerve entrapment because of chronic pain in his right groin area. The explanting surgeon, Dr. Radke, noted extensive scarring and found "a large ball approximately 2.5 cm in diameter of rolled up mesh next to the pubic tubercle." (ECF No. 89-22 at PageID #1134.) Dr. Radke removed the mesh, which he described as "slow going and extremely difficult" because of the significant scarring. (*Id.*) Dr. Radke then repaired the hernia with another of Defendants' products, Bard Marlex Mesh. (*Id.*) After the explant surgery, Plaintiff claims to have continuing chronic pain and other complications.

The crux of Plaintiff's claims is that Defendants knew of certain risks presented by the PerFix Plug device but marketed and sold the device despite these risks and without appropriate warnings, causing Plaintiff's injuries. Plaintiff alleges that the polypropylene in the PerFix Plug degrades after implantation, which enhances the chronic inflammatory response in the body. (ECF No. 124 at PageID #4826.) Plaintiff also claims that the inflammation and resulting fibrosis are exacerbated by the PerFix Plug's shape, weight, and pore size. Plaintiff also claims that the PerFix Plug is susceptible to migration and has a high incidence of chronic pain. (*Id.*) According to Plaintiff, Defendants downplayed the rate and severity of complications caused by the PerFix Plug, even when faced with reports of negative outcomes, which created an unreasonable risk of significant and permanent harm to patients. (*Id.*)

Plaintiff brings this action to recover for injuries sustained as a result of the implantation of the PerFix Plug, alleging that Defendants knew of the risks presented by the device but marketed and sold it despite these risks and without appropriate warnings. After summary judgment, the following claims remain for trial: design defect, failure to warn, negligence, breach of express

warranty, and breach of implied warranty; the Court has reserved judgment on Plaintiff's claims for manufacturing defect, certain damages, and claims related to his current Bard Mesh implant.

II. Legal Standard

Evidentiary rulings are made subject to the district court's sound discretion, *Frye v. CSX Trans., Inc.*, 933 F.3d 591, 598 (6th Cir. 2019), including the admissibility of expert testimony, *United States v. Dunnican*, 961 F.3d 859, 875 (6th Cir. 2020). This role, however, is not intended to supplant the adversary system or the role of the jury. *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 531–32 (6th Cir. 2008). Arguments regarding the weight to be given to any testimony or opinions of an expert witness are properly left to the jury. *Id.* "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." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 596 (1993).

The burden is on the party offering the expert opinions and testimony to demonstrate "by a preponderance of proof" that the expert evidence is admissible. *Nelson v. Tenn. Gas Pipeline Co.*, 243 F.3d 244, 251 (6th Cir. 2001). Any doubts regarding the admissibility of an expert's testimony should be resolved in favor of admissibility. *See Jahn v. Equine Servs., PSC*, 233 F.3d 382, 388 (6th Cir. 2000) ("The Court [in *Daubert*] explained that Rule 702 displays a 'liberal thrust' with the 'general approach of relaxing the traditional barriers to "opinion" testimony.'" (quoting *Daubert*, 509 U.S. at 588)); Fed. R. Evid. 702 advisory committee's note to 2000 amendment ("A review of the case law after *Daubert* shows that the rejection of expert testimony is the exception rather than the rule.").

The district court's role in assessing expert testimony is a "gatekeeping" one, ensuring that only admissible expert testimony is submitted to the jury; its role is not to weigh the expert

testimony or determine its truth. *United States v. Gissantaner*, 990 F.3d 457, 463 (6th Cir. 2021) (quoting *Daubert*, 509 U.S. at 597). Expert testimony, *i.e.*, testimony given by "[a] witness who is qualified as an expert by knowledge, skill, experience, training, or education," is admissible if:

> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. In this circuit, "[t]he Rule 702 analysis proceeds in three stages." *United States v. Rios*, 830 F.3d 403, 413 (6th Cir. 2016). "First, the witness must be qualified by 'knowledge, skill, experience, training, or education.' Second, the testimony must be relevant, meaning that it 'will assist the trier of fact to understand the evidence or to determine a fact in issue.' Third, the testimony must be reliable." *In re Scrap Metal Antitrust Litig.*, 527 F.3d at 529 (quoting Fed. R. Evid. 702.).

First, an expert witness must be qualified by "knowledge, skill, experience, training, or education." Fed. R. Evid. 702. "[T]he issue with regard to expert testimony is not the qualifications of a witness in the abstract, but whether those qualifications provide a foundation for a witness to answer a specific question." *Madej v. Maiden*, 951 F.3d 364, 370 (6th Cir. 2020) (quoting *Berry v. City of Detroit*, 25 F.3d 1342, 1351 (6th Cir. 1994)). "[T]he only thing a court should be concerned with in determining the qualifications of an expert is whether the expert's knowledge of the subject matter is such that his opinion will likely assist the trier of fact in arriving at the truth. The weight of the expert's testimony must be for the trier of fact." *Mannino v. Int'l Mfg. Co.*, 650 F.2d 846, 851 (6th Cir. 1981). A party's expert need only meet the "'minimal qualifications' requirement—not one who could teach a graduate seminar on the subject." *Burgett v. Troy-Bilt LLC*, 579 F. App'x 372, 377 (6th Cir. 2014) (quoting *Mannino*, 650 F.2d at 851); *see*

also Dilts v. United Grp. Servs., LLC, 500 F. App'x 440, 446 (6th Cir. 2012) ("An expert's lack of experience in a particular subject matter does not render him unqualified so long as his general knowledge in the field can assist the trier of fact.").

Second, expert testimony must be relevant. Expert testimony is relevant if it will "help the trier of fact to understand the evidence or to determine a fact in issue." *Bradley v. Ameristep, Inc.*, 800 F.3d 205, 208 (6th Cir. 2015) (quoting *United States v. Freeman*, 730 F.3d 590, 599–600 (6th Cir. 2013)); Fed. R. Evid. 702(a). "Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." *Daubert*, 509 U.S. at 591 (quoting 3 J. Weinstein & M. Berger, Weinstein's Evidence ¶ 702[02], p. 702–18 (1988)). "This requirement has been interpreted to mean that scientific testimony must 'fit' the facts of the case, that is, there must be a connection between the scientific research or test result being offered and the disputed factual issues in the case in which the expert will testify." *Pride v. BIC Corp.*, 218 F.3d 566, 578 (6th Cir. 2000) (citing *Daubert*, 509 U.S. at 592). This is a case-specific inquiry. *Madej*, 951 F.3d at 370 ("Whether an opinion 'relates to an issue in the case' or helps a jury answer a 'specific question' depends on the claims before the court.").

Third, expert testimony must be reliable. Rule 702 provides the following general standards to assess reliability: whether "the testimony is based on sufficient facts or data," whether "the testimony is the product of reliable principles and methods," and whether "the expert has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702(b)–(d). To evaluate reliability of principles and methods, courts consider "'testing, peer review, publication, error rates, the existence and maintenance of standards controlling the technique's operation, and general acceptance in the relevant scientific community,'" though these "factors 'are not dispositive in every case' and should be applied only 'where they are reasonable measures of the

reliability of expert testimony.'" *In re Scrap Metal Antitrust Litig.*, 527 F.3d at 529 (citations omitted); *see Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 150 (1999) (describing these factors as "flexible" (quoting *Daubert*, 509 U.S. at 594)). The objective of the reliability requirement is to "make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire*, 526 U.S. at 152.

III. Analysis

Defendants challenge the opinions of Plaintiff's expert Dr. David Grischkan, M.D., F.A.C.S. Defendants argue the following: 1) Dr. Grischkan's overall methodology in forming his defect and causation opinions is unreliable because he only took into account studies that conform to his experience; 2) Dr. Grischkan's opinion that the PerFix Plug is defectively designed because of the excessive polypropylene content is unreliable and not helpful; 3) Dr. Grischkan's alternative design opinions improperly focus on medical device manufacturers' marketing practices and the effect those practices allegedly had on surgeons' decisions to use polypropylene mesh in hernia repairs; 4) Dr. Grischkan's opinions that the PerFix Plug can cause complications such as chronic pain, nerve entrapment, bowel obstruction, organ fistulization and penetration, mesh tissue stiffening, mesh contracture, and migration are unreliable and/or irrelevant; 5) Dr. Grischkan's opinion that the PerFix Plug caused Plaintiff's chronic pain is unhelpful because under Maine law the Plaintiff must prove that a specific defect in the PerFix Plug caused his injury, but chronic pain is a risk of any inguinal hernia mesh device; 6) Dr. Grischkan's warning opinions related to mesh migration and loss of tensile strength are irrelevant and lack fit because there is no evidence showing that Plaintiff experienced those complications, and Dr. Grischkan's warning opinion regarding chronic pain is a "dead end;" 7) Dr. Grischkan's polypropylene degradation opinions

should be excluded because there is no evidence that Plaintiff's PerFix Plug degraded; and 8) Dr. Grischkan should be precluded from offering state of mind opinions or disclaimed opinions.

Plaintiff points out that Defendants do not challenge Dr. Grischkan's qualifications as an expert generally. (ECF No. 122 at PageID #4627.) The Court detailed Dr. Grischkan's qualifications as a surgeon in Evidentiary Motions Order ("EMO") No. 5 in the first bellwether case, *Johns v. C.R. Bard, Inc., et al.* (Case No. 18-cv-1509, ECF No. 310 at PageID #16774.)

A. Reliability of Literature Review

Defendants first argue that Dr. Grischkan's defect and causation opinions are unreliable because he "relied only on studies that conformed to his opinions and ferreted out anything to the contrary." (ECF No. 93 at PageID #1735.) They point to Dr. Grischkan's deposition, during which he testified that studies referenced by Defendants did not conform to his opinions or experience as a hernia surgeon. (*See* ECF No. 93-1 at PageID #1779–80, 1789, & 1822.) Defendants claim that Dr. Grischkan's failure to account for any of the literature that does not conform to his experience with self-reported patient complications renders his methodology unreliable. (ECF No. 93 at PageID #1737–38.)

Plaintiff responds that Dr. Grischkan did review studies contrary to his experience, but his expert report only cited to literature that was consistent with his 35 years of experience, related to the topics at issue in this case, and not duplicative of a study he had already cited. (ECF No. 122 at PageID #4658.) Accordingly, Defendants' arguments go to the weight of Dr. Grischkan's opinions, not their admissibility. (*Id.* at PageID #4659.)

Defendants rely on *Tyree v. Boston Scientific Corp.* in support of their argument. In *Tyree* the court adopted the reasoning from a prior decision, *Sanchez v. Boston Scientific Corp.*, regarding an expert who did not consider contrary literature. *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501,

521 (S.D.W. Va. 2014), *as amended* (Oct. 29, 2014). In *Sanchez*, the court found the expert's methodology unreliable when he refused to explain in his deposition why he did not consider contrary authority, testifying: "I don't have to tell you why I don't consider something to be authoritative." *Sanchez v. Bos. Sci. Corp.*, No. 2:12-CV-05762, 2014 WL 4851989, at *12 (S.D.W. Va. Sept. 29, 2014). Here, Dr. Grischkan explained that he did not rely on the studies referenced by Defendants because they were contrary to his personal experience as a hernia surgeon and what he knows of the scientific literature. (ECF No. 93-2 at PageID #1938.) Although Defendants may disagree with his reasoning, unlike the expert in *Tyree* and *Sanchez*, Dr. Grischkan did offer an explanation as to why he did not rely on the studies. As the Court reasoned in the second bellwether case, *Milanesi, et al. v. C.R. Bard, Inc., et al.*, "[t]his is fertile grounds for cross-examination, but it does not show that Dr. [Grischkan's] opinion[s are] unreliable." (Case No. 18-cv-1320, ECF No. 166 at PageID #13589.) "The question of whether [Dr. Grischkan's] opinion is accurate in light of [contrary] data goes to the weight of the evidence, not to its admissibility, and [it is up to] the jury to make this determination." *In re Scrap Metal Antitrust Litig.*, 527 F.3d at 531–32. Accordingly, Defendants' motion as to the reliability of Dr. Grischkan's literature review is **DENIED**.

B. Design Defect Opinions

1. Reliability

According to Defendants, in opining that the PerFix Plug is defectively designed because of its "excessive polypropylene content," Dr. Grischkan does not rely on "any scientific publication that actually evaluates the polypropylene content of the PerFix Plug or the potential complication caused by it." (ECF No. 93 at PageID #1738.) Instead, Dr. Grischkan relies on literature that evaluates the human body's response to polypropylene generally. (*Id.*) Defendants

argue that this is insufficient, because Dr. Grischkan does not opine that the PerFix Plug is defective because it was made with polypropylene but because it has an "*excessive* amount of polypropylene . . . that results in *a more intense* inflammatory reaction than found with other inguinal hernia mesh devices." (*Id.* (emphasis in original).) According to Defendants, the studies Dr. Grischkan relies on do not involve the PerFix Plug specifically and merely show that "implanting polypropylene in the human body results in a foreign body reaction—a well-known and desired outcome for a strong hernia repair." (*Id.* at PageID #1740.)

Plaintiff responds that Defendants mischaracterize Dr. Grischkan's design defect opinions, and that he offers many more design defect opinions other than criticisms of the amount of polypropylene in the PerFix Plug. (ECF No. 122 at PageID #4657.) For example, Plaintiff points to Dr. Grischkan's opinions that the PerFix Plug "is unreasonably dangerous because it is comprised of heavyweight polypropylene, has small pores and multiple layers, is prone to migration, is subject to contraction after implantation, is extremely difficult and risky to remove, increases the incidence of chronic pain while it is implanted, is subject to oxidative degradation *in vivo*, and leads to excessive scarring and an intense chronic inflammatory reaction, among others." (*Id.* at PageID #4646 (citing ECF No. 97-11).) Plaintiff also notes several studies cited by Dr. Grischkan that discuss complications specifically related to the PerFix Plug. (*Id.* at PageID #4660.) He further claims that Defendants misrepresent the literature, which does not simply show a foreign body reaction to polypropylene, but shows an "intense inflammatory response" and "significantly higher oxidative stress with heavyweight [polypropylene] mesh," which is not a desirable outcome. (*Id.* at PageID #4661.)

As Plaintiff points out, Dr. Grischkan does rely on studies specific to the PerFix Plug. The fact that he also relies on studies of heavyweight polypropylene mesh, a characteristic of the PerFix

Plug, does not make his opinions unreliable. Not every source referenced by Dr. Grischkan must relate specifically to the PerFix Plug, and as the Court discussed in Section III.B.2.a of DMO No. 7 (ECF No. 225, PageID #9117–19), the fact that some sources relate to other polypropylene mesh products or polypropylene generally is not fatal. The PerFix Plug may have characteristics in common with other mesh products, or some alleged defects may relate to the properties of polypropylene mesh generally. If Defendants believe that Dr. Grischkan's reliance on studies unrelated to the PerFix Plug means his opinions should be afforded less weight, they may raise that issue on cross-examination.

2. Assist the Jury

Defendants also argue that because Dr. Grischkan's defect opinions "constitute nothing more than a list of potential complications inherent in any hernia mesh repair," these opinions will not aid the jury in evaluating the PerFix Plug specifically. (ECF No. 93 at PageID #1740.) Defendants claim that Dr. Grischkan does not offer any meaningful analysis as to the PerFix Plug's risks and benefits, and cannot identify any scientific study that describes any increased risks with the PerFix Plug compared to "another permanent synthetic mesh for inguinal hernia repair." (*Id.* at PageID #1741.) Therefore, because Dr. Grischkan's criticisms are not specific to the PerFix Plug and relate to all inguinal hernia mesh repairs, his opinions will not help the jury weigh the risks and utilities of the PerFix Plug and decide Plaintiff's design defect claim. (*Id.*)

Plaintiff responds that Dr. Grischkan's detailed opinions regarding the design of the PerFix Plug will help the jury to weigh the risks and benefits, "as well as differentiate the risks and complications associated with every hernia repair from those attributed to the PerFix Plug." (ECF No. 122 at PageID #4648.) In his report, Dr. Grischkan identifies potential benefits of mesh hernia repair, such as the relative ease of the procedure for surgeons compared to primary repair and

lower hernia recurrence rates. (*Id.* at PageID #4647–48 (citing ECF No. 97-11).) According to Plaintiff, Dr. Grischkan offers "detailed opinions describing the various defects with the specific design of the PerFix Plug," which will assist the jury in weighing the risks and benefits of the product's design. (*Id.* at PageID #4648.) The Court agrees. To the extent Defendants disagree with Dr. Grischkan's conclusions as to the risks and benefits of the PerFix Plug, they may cross-examine him to that effect.

3. Alternative Design Opinions

Defendants next assert that Dr. Grischkan's alternative design opinions are inadmissible. According to Defendants, his alternative design opinions rely on medical device manufacturers' marketing practices and their impact on surgeons' approaches to hernia repair. (ECF No. 93 at PageID #1742.) Defendants claim that Dr. Grischkan is unqualified to opine on the subject and that these opinions on marking practices and their impact are "irrelevant to the alternative design inquiry, prejudicial, and confusing." (*Id.*) First, Defendants argue that Dr. Grischkan is not qualified to opine on "the marketing of prescription medical devices or the impact such marketing has on surgeons' choice in hernia repair technique." (*Id.*) Next, Defendants claim that opinions regarding marketing practices of manufacturers other than Defendants are irrelevant, confusing, and unduly prejudicial. (*Id.*) Defendants further argue that these opinions improperly go to surgeons' state of mind and motivations in choosing particular surgical techniques. (*Id.*) In response, Plaintiff claims that Dr. Grischkan's opinions as to "why surgeons do not report mesh complications are not state of mind or motive testimony," but are "based on his experience in the industry for over thirty-five years, review of literature discussing these topics, and discussions with colleagues as well as participation at conferences." (ECF No. 122 at PageID #4634.)

In *Johns* and *Milanesi*, the Court stated that it would "not let a witness get on the stand and talk about what all doctors know." (Case No. 18-cv-1509, ECF No. 311 at PageID #16855; Case No. 18-cv-1320, ECF No. 296, Motions *in Limine* ("MIL") Order No. 26 at PageID #17090.) As the plaintiffs argued in *Milanesi*, and the Court agreed, no one "ha[s] sufficient personal knowledge to make blanket statements purporting to speak for all doctors or everyone in the medical community." (*Id.*) The same reasoning applies here, and Dr. Grischkan may not purport to speak on behalf of all doctors or the entire medical community, but may only speak to matters of which he has personal knowledge. Plaintiff does not respond to Defendants' argument that Dr. Grischkan may not opine on the marketing practices of other manufacturers; however, the Court agrees with Defendants that Dr. Grischkan may not opine on the marketing practices of hernia mesh device manufacturers other than Defendants.

Defendants also ask the Court to exclude any of Dr. Grischkan's opinions "that primary tissue repairs, ePTFE, and/or a biologic constitute feasible safer alternative designs for the PerFix Plug." (ECF No. 93 at PageID #1743.) Plaintiff contends that Maine law does not require evidence of a feasible alternative design at all. (ECF No. 122 at PageID #4649.) The Court addressed this argument in Section III.B.2.b of DMO No. 7. (ECF No. 225 at PageID #9119–22.) By the caselaw's plain language, proof of a design defect under Maine law involves an examination of the feasibility of safer alternative designs. *See St. Germain v. Husqvarna Corp.*, 544 A.2d 1283, 1285 (Me. 1988) (quoting *Stanley v. Schiavi Mobile Homes, Inc.*, 462 A.2d 1144, 1148 (Me. 1983)). However, Plaintiff claims that even if proof of feasibility is required, Dr. Grischkan has opined as to several feasible safer alternative designs in his report and deposition. Dr. Grischkan offered opinions as to other materials like ePTFE (ECF No. 93-4 at PageID #2062) and larger pore, lighter weight polypropylene mesh (*id.* at PageID #2065). Dr. Grischkan elaborated in his

deposition and gave examples of specific mesh products that fall into those categories. (ECF No. 122-2 at PageID #4709, 4715.) If Defendants dispute the feasibility of the proffered alternatives, they may raise those arguments on cross-examination. As for Defendants' argument that non-mesh procedures and alternative devices using materials other than polypropylene are not permissible feasible alternatives, the Court addressed this argument in Section III.B.2.b of DMO No. 7 (ECF No. 225 at PageID #9119–22), and the same conclusion applies here. Dr. Grischkan may opine as to alternative product designs using different materials, but not about entirely different non-mesh procedures.

Defendants also ask the Court to exclude Dr. Grischkan's opinion, offered for the first time at the end of his deposition, that the ProLite Ultra, another polypropylene device, would be a safer alternative design for the PerFix Plug. (ECF No. 93 at PageID #1745.) Defendants claim that Dr. Grischkan's reference to the ProLite Ultra is an undisclosed opinion offered for the first time in his deposition, but his report references the alleged benefits of lighter weight, larger pore polypropylene mesh. (*See* ECF No. 93-4 at PageID #2065 ("The greater the surface presented by the mesh, as in particular with a PerFix Plug, the more intense the inflammatory reaction and consequential scarring and shrinkage of the mesh. This concept led to the development of lighter weight, larger pore polypropylene meshes, which are less dense and therefore result in a reduced foreign body reaction.").) The fact that in his deposition Dr. Grischkan provided a specific product as an example of a lighter weight, larger pore polypropylene mesh is not an inadmissible undisclosed opinion, but simply an elaboration on the opinions in his report. As the Court has previously explained in this MDL, there is a difference between new opinions and further developments of core opinions stated in an expert's report. (Case No. 18-cv-1320, ECF No. 342, "EMO" No. 25 at PageID #18785.) "'Rule 26 contemplates that [an] expert will supplement,

elaborate upon, explain and subject himself to cross-examination upon his report,' exactly as Dr. [Grischkan] did in his deposition." (*Id.* at PageID #18784 (citing Case No. 18-cv-1509, ECF No. 157, EMO No. 3 at PageID #9512).)

Next, Defendants argue that under Maine law, "a feasible safer alternative design is one that would have prevented the plaintiff's injuries." (ECF No. 93 at PageID #1744.) According to Defendants, Dr. Grischkan "offered no information about the risk of chronic pain with his proposed alternatives," and the ePTFE device identified as an alternative by Dr. Grischkan has also been linked to reports of chronic pain. (*Id.* at PageID #1745.) Plaintiff disputes Defendants' characterization of Maine law and argues that Dr. Grischkan is not required to show that feasible safer alternative designs would have prevented his injuries. (ECF No. 122 at PageID #4652.) Plaintiff points out that Defendants cite no caselaw to support this argument and refer only to Maine Jury Instruction § 7-25, which is not a substitute for caselaw. (*Id.* at PageID #4653.) He also relies on *Guiggey v. Bombardier* to support his argument that no product comparison is required under Maine law, citing to the following language: "The testimony of plaintiff's expert would support a conclusion that cutting the throttle springs presented a risk of injury to the user of the snowmobile, and that the risk of the throttle sticking would have been reduced if the springs were not cut." *Guiggey v. Bombardier*, 615 A.2d 1169, 1172 (Me. 1992). This language does not reference a product comparison, and it is not clear how the cited language is relevant to or supports Plaintiff's argument. However, the Court agrees with Plaintiff that Defendants cite no persuasive authority to show that Plaintiff is required to present a comparison of the risks of the PerFix Plug and proposed alternatives. Defendants only cite to the Maine Jury Instructions, and offer nothing to show that jury instructions are a proper legal authority in this context. If

Defendants disagree as to the feasibility of the proposed alternatives, they may cross-examine Dr. Grischkan to that effect.

Therefore, excepting alternative procedures, the Court finds that Dr. Grischkan's alternative design opinions are admissible. Accordingly, Defendants' motion to exclude Dr. Grischkan's design defect opinions is **DENIED**, but the motion is **GRANTED** as to opinions that propose entirely different surgical procedures as a feasible alternative design.

C. General Causation Opinions

1. Chronic Pain Opinions

According to Defendants, chronic pain is "a well-known potential complication of any inguinal repair using synthetic mesh." (ECF No. 93 at PageID #1747.) Defendants claim that "nothing in Dr. Grischkan's report or any of his deposition testimony supports that the PerFix Plug poses a higher risk of this complication than any other hernia mesh device available for inguinal hernia repairs." (*Id.* at PageID #1747–48.) Defendants allege that Dr. Grischkan cannot identify any scientific studies at all that show a higher rate of pain with the PerFix Plug compared to any other inguinal hernia mesh device. (*Id.* at PageID #1748.)

Plaintiff responds that, although he did not recall the name of the study at his deposition, Dr. Grischkan did rely on a study comparing the PerFix Plug with a Lichtenstein patch and evaluating quality of life of patients one year after implantation. (ECF No. 122 at PageID #4663.) Although Dr. Grischkan testified that he "could not give [Defendants] an answer right off the bat" as to studies that compare rates of chronic pain with the PerFix Plug with other devices, he did in fact cite to the study in the Chronic Pain section of his report (ECF No. 93-4 at PageID #2066) and in his deposition, without referencing the study by name, he mentioned studies that compared the PerFix Plug and the Lichtenstein patch (ECF No. 93-2 at PageID #1916). Dr. Grischkan also

testified that his own experience has informed his conclusions as to chronic pain and the PerFix Plug. (*Id.* at PageID #1918.) Defendants claim that Plaintiff is pointing to a study after the fact on Dr. Grischkan's behalf, but Dr. Grischkan's report shows that, in addition to his own experience, he did rely on the study in informing his opinions. The Court therefore finds that the referenced study, along with Dr. Grischkan's experience, form a reliable basis for his chronic pain opinions.

2. Nerve Entrapment, Bowel Obstruction, Organ Fistulization, and Mesh Stiffening Opinions

Defendants next argue that Dr. Grischkan's opinions regarding nerve entrapment, bowel obstruction, organ fistulization, and mesh tissue stiffening should be excluded because they are not at issue in this case. According to Defendants, Plaintiff's sole alleged injury is chronic pain and Dr. Grischkan's opinions regarding unrelated complications are irrelevant, lack fit, and would cause undue prejudice. (ECF No. 93 at PageID #1749–50.) Defendants ask the Court to exclude opinions about potential complications that have no connection to Plaintiff's theory of injury or the injury itself. Plaintiff briefly notes but does not respond to Defendants' arguments regarding nerve entrapment, bowel obstruction, organ fistulization, and mesh tissue stiffening. (ECF No. 122 at PageID #4663.)

Plaintiff has not claimed that he suffered from bowel obstruction or organ fistulization as a result of the PerFix Plug. As the Court held in *Johns*, an expert's opinions are irrelevant if they lack a connection to the plaintiff's theory of injury or the injuries themselves. (*See* Case No. 18-cv-1320, ECF No. 271, EMO No. 21 at PageID #16766 ("Dr. Rudo opines that PFOA causes a litany of issues, spanning from adverse reproductive and developmental effects to cancer. Mr. Milanesi claims none of these issues as injuries.").) Therefore, Dr. Grischkan may not testify as to organ fistulization and bowel obstruction. Additionally, in his report, Dr. Grischkan claims that

he "rule[d] out a neuroma or nerve entrapment as the cause of [Plaintiff's chronic pain]." (ECF No. 93-4 at 2071.) Because Dr. Grischkan explicitly opined that neuroma and nerve entrapment did not cause Plaintiff's injuries, his opinions regarding neuromas and nerve entrapment are irrelevant and inadmissible.

Plaintiff briefly states that Dr. Grischkan's opinions as to mesh stiffening are relevant because Dr. Grischkan does opine that mesh stiffening related to Plaintiff's case and contributed to the failure of the mesh and Plaintiff's injuries. (ECF No. 122 at PageID #4630.) However, Plaintiff does not point to anything in Dr. Grischkan's report to support that contention, and it does not appear that Dr. Grischkan opined that Plaintiff's injuries were related to or caused by mesh tissue stiffening. (*See generally* ECF No. 93-4.) Therefore, Dr. Grischkan's opinions regarding mesh stiffening are also irrelevant and therefore excluded.

3. Mesh Shrinkage, Pore Size, Degradation, and Migration Opinions

Defendants seek to exclude Dr. Grischkan's opinions regarding mesh shrinkage, mesh pore size, migration of the PerFix Plug, and polypropylene degradation. (ECF No. 93 at PageID #1751–55, 1761–62.) Plaintiff responds that the complications he allegedly suffered, "chronic pain, mesh migration, excessive fibrosis and scarring, shrinking and wadding up of the mesh," are all a result of mesh shrinkage, pore size, migration, and degradation, and therefore Dr. Grischkan's opinions are relevant to this case. (ECF No. 122 at PageID #4665–68.)

a. Mesh Shrinkage and Pore Size Opinions

Defendants ask the Court to exclude Dr. Grischkan's opinions that heavyweight polypropylene mesh with a small pore size results in contraction, or shrinkage, and deformation of the mesh. (ECF No. 93 at PageID #1751.) According to Defendants, any such opinion is irrelevant because there is no evidence of contracture here, and there is nothing that would tie any contracture

to Plaintiff's alleged injury because the only clinical outcome Dr. Grischkan associates with mesh contracture is hernia recurrence, which Plaintiff did not experience. (*Id.*) Defendants also claim that Dr. Grischkan's contracture and pore size opinions lack a reliable methodology because Dr. Grischkan does not rely on any study involving the PerFix Plug, but only on studies involving different devices with different polypropylene mesh configurations. (*Id.* at PageID #1752.) Additionally, Defendants claim that Dr. Grischkan's methodology for determining whether a mesh is small or large pore is unreliable. (*Id.* at PageID #1753.)

Defendants' argument that the only condition Dr. Grischkan links to contracture is hernia recurrence is not well taken. Dr. Grischkan's report references a study which found that mesh with a smaller pore size caused "formation of a thick scar plate that can contract and deform the mesh," and lighter weight mesh with a larger pore size "demonstrated minimal, if any scar plate." (ECF No. 93-4 at PageID #2066.) Additionally, Dr. Grischkan's report links mesh shrinkage to scarring and foreign body reaction, which is "further amplified by the heavy weight and bulkiness of the PerFix Plug." (ECF No. 93-4 at PageID #2064.) Plaintiff does claim that he experienced excessive scarring or fibrosis.

Defendants next argue that Dr. Grischkan's contracture opinions are not reliable because he relies on studies involving polypropylene mesh devices other than the PerFix Plug. (ECF No. 93 at PageID #1752–53.) As the Court addressed above in Section III.B.1 and in DMO No. 7, the fact that Dr. Grischkan bases his opinions on studies involving different polypropylene mesh devices does not make his opinions unreliable. If Defendants believe that his reliance on these studies makes his opinions less persuasive, they may raise the issue on cross-examination.

Defendants further claim that Dr. Grischkan's pore size opinions are unreliable because of his methods of measuring pore size. (*Id.* at PageID #1753.) Plaintiff recites the complications that

Dr. Grischkan alleges are due to the small pore size of the PerFix Plug, but does not offer any response to Defendants' arguments regarding Dr. Grischkan's methodology or the reliability of his pore size opinions. (ECF No. 122 at PageID #4666.) In his deposition, Dr. Grischkan stated that he did not have a specific measurement for what he considered "large pore" versus "small pore" mesh, but that it "would be a clinical determination." (ECF No. 93-2 at PageID #1887.) As an example, Dr. Grischkan explained that if the pores were wide enough that he could read newsprint through them, he would consider that a large pore mesh. (*Id.*) Defendants claim that Dr. Grischkan's "newspaper" methodology is an unreliable basis for his pore size opinions, and they should therefore be excluded. (ECF No. 93 at PageID #1753.) However, in explaining the basis for his opinions on mesh pore size in his report, Dr. Grischkan cited to multiple studies related to mesh pore size and its potential effects, and explained the results of one study that described a small pore size as 0.8 mm or less, as contrasted with a large pore size of 4 mm. (ECF No. 93-4 at PageID #2065.) Dr. Grischkan does not mention a "newspaper methodology" anywhere in his report, but only offered it as an example in his deposition. Dr. Grischkan's "report tips the scales in favor of admission of his opinions at this time, although some of his testimony may be an appropriate topic for cross examination." (Case No. 18-cv-1509, ECF No. 459, EMO No. 11 at PageID #23426.)

b. Degradation Opinions

Defendants seek to exclude Dr. Grischkan's opinion that the PerFix Plug is defectively designed because of alleged degradation of polypropylene in the body. Defendants claim that there is no evidence that Plaintiff's PerFix Plug degraded, or that any such degradation could or did cause Plaintiff's chronic pain. (ECF No. 93 at PageID #1761.) As with Dr. Grischkan's contracture opinions, Defendants also claim that the only clinical outcome that Dr. Grischkan links

to polypropylene degradation is hernia recurrence, which did not occur in this case. (*Id.* at PageID #1761–62.) Therefore, because there is no connection between degradation and Plaintiff's injuries, Dr. Grischkan's degradation opinions are irrelevant and lack fit. (*Id.* at PageID #1762.) Defendants also argue that the degradation opinions are not based on a reliable methodology, and the opinions should be excluded under Rule 403. (*Id.*)

Plaintiff responds that Dr. Grischkan's degradation opinions are relevant, and that Dr. Grischkan connects the oxidative degradation of polypropylene *in vivo* to the excessive fibrosis/scarring and mesh shrinkage that occurred in this case. (ECF No. 122 at PageID #4668.) Dr. Grischkan's report cites to Dr. Radke's observations of "the difficulties with the dissection through the scar tissue" during Plaintiff's explant surgery. (ECF No. 93-4 at PageID #2069.) Plaintiff also points to this Court's prior ruling that evidence of polypropylene degradation was relevant and admissible (Case No. 18-cv-1320, ECF No. 286, MIL Order No. 19 at PageID #16902) and argues that the result should be the same here. (ECF No. 122 at PageID #4633.) Plaintiff notes that in *Johns* and *Milanesi* the Court permitted the plaintiffs' biomaterials expert, Dr. Ahmed El-Ghannam, to offer opinions on polypropylene degradation, and argues that "a two-step mechanism of injury (one explained by the clinician and the other by the biomaterials engineer) is admissible." (ECF No. 122 at PageID #4668.)

Similar to their arguments regarding shrinkage and pore size, Defendants' assertion that Dr. Grischkan's degradation opinions are not relevant because the only condition he links to degradation is hernia recurrence is not well taken. In his report, Dr. Grischkan does note the link between degradation and hernia recurrence. (ECF No. 93-4 at PageID #2062.) However, he also describes the link between polypropylene degradation generally and chronic inflammation, scarring, and mesh shrinkage. (*Id.* at PageID #2068.) Additionally, Plaintiff presents opinions

from other experts that the polypropylene in Plaintiff's PerFix Plug degraded. For example, in Dr. El-Ghannam's report, he noted that "deformation and significant degradation were repeatedly observed during SEM analyses of the PerFix Plug gross specimen removed from [Plaintiff]." (Case No. 18-cv-1509, ECF No. 33-1 at PageID #1385.) He also observed "inflammation of the tissue around the surface of the degraded polypropylene" in Plaintiff's explanted PerFix Plug. (*Id.* at PageID #1400.) Dr. El-Ghannam opined that Plaintiff "suffered a chronic inflammatory response as a result of the degradation of the [PerFix Plug] implanted in his body." (*Id.*)

In *Milanesi* the plaintiffs' medical expert, Dr. David Krpata, addressed "the first step" of the plaintiffs' theory of injury, buckling and contracture, while other experts offered opinions on polypropylene degradation and its effects. (Case No. 18-cv-1320, ECF No. 166, EMO No. 17 at PageID #13590.) Dr. Krpata detailed the "buckling" phenomenon at issue in that case and explained that the resulting exposure of bare polypropylene to the viscera could cause adhesions, fistula, and erosion. (*Id.*) The Court found this testimony to be relevant in conjunction with Dr. El-Ghannam's opinions, which explained the second step of the theory of injury. (*Id.*) The same reasoning applies here. Dr. Grischkan "need not supply every link in the chain of Plaintiff['s] theory of the case for his opinion to be relevant. (*Id.* (citing *In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4536456, at *3 (S.D.W. Va. Aug. 30, 2016)).)

Defendants also offer a brief conclusory statement that Dr. Grischkan's degradation opinions should be excluded because they are not based on a reliable methodology. Dr. Grischkan cites to studies in stating that "[u]ncontrolled chronic inflammation and oxidative degradation of the polypropylene fibrils *in vivo* had been known to lead to excessive scarring and shrinkage of the mesh." (ECF No. 93-4 at PageID #2068.) Dr. Grischkan also cites to sources in support of his opinion that chronic pain following implantation of polypropylene mesh is due to many factors,

including inflammation, nerve entrapment due to excessive scarring, erosion, and migration. (*Id.* at PageID #2065–66.) Dr. Grischkan linked excessive scarring to difficulties during reoperation and a significant incidence of chronic pain. (*Id.* at PageID #2066–67.) Dr. Grischkan testified regarding a paper he had co-authored, which found that "patients who had mesh removal for chronic pain had a much higher influx of scar tissue." (ECF No. 93-1 at PageID #1853.) He also relied on his personal experience and testified that based on "probably thousands of cases" that he had seen in his years as a hernia surgeon, there is "a direct relationship" between the degree of scarring and a patient's pain levels. (*Id.* at PageID #1859.) Dr. Grischkan relied on scientific research and his own experience as a hernia surgeon forming his opinion on the link between polypropylene degradation, shrinkage, and excessive scarring, and the link between excessive scarring, shrinkage, and chronic pain.

As to their Rule 403 argument, Defendants claim that evidence of defects or complications not alleged to have occurred in this case should be excluded. (ECF No. 93 at PageID #1762.) However, as the Court discussed above, Dr. Grischkan linked polypropylene degradation to excessive fibrosis, which Plaintiff does allege happened in this case. The Court therefore finds that Dr. Grischkan has a reliable basis for his degradation opinions.

c. Migration Opinions

In his report, Dr. Grischkan opines that mesh plugs can migrate within the body and cause serious complications, including death. (ECF No. 93-4 at PageID #2063.) Defendants claim that Dr. Grischkan's migration opinions are unreliable because they are based solely on case reports, which "courts have routinely held do not form a reliable methodology to establish general causation." (ECF No. 93 at PageID #1754.) In addition to being unreliable, Defendants argue that Dr. Grischkan's migration opinions are irrelevant because Plaintiff's PerFix Plug did not migrate.

(ECF No. 93 at PageID #1754.) Plaintiff does not address Defendants' argument that Dr. Grischkan's migration opinions are unreliable because they are based solely on case reports, but instead focuses on Defendants' arguments as to relevance.

"Case reports are 'reports in medical journals describing clinical events in one or more individuals. They report unusual or new disease presentations, treatments, manifestations, or suspected associations between two diseases, effects of medication, or external causes.'" *Caraker v. Sandoz Pharms. Corp.*, 188 F. Supp. 2d 1026, 1034 (S.D. Ill. 2001) (quoting *Reference Manual on Scientific Evidence* at 374 (Fed. Judicial Center 2000)). Although experts may use case reports together with other reliable evidence to support their opinions, Defendants are correct that many courts have found that case studies alone are not a reliable basis for an expert's opinions. *See, e.g., Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194, 1199 (11th Cir. 2002); *DeGidio v. Centocor Ortho Biotech, Inc.*, 3 F. Supp. 3d 674, 684–86 (N.D. Ohio 2014); *Caraker*, 188 F. Supp. 2d at 1035; *Cloud v. Pfizer Inc.*, 198 F. Supp. 2d 1118, 1133–34 (D. Ariz. 2001); *Lennon v. Norfolk & W. Ry. Co.*, 123 F. Supp. 2d 1143, 1152–53 (N.D. Ind. 2000); *Casey v. Ohio Medical Products,* 877 F. Supp. 1380, 1385–1386 (N.D.Cal.1995); *Davis v. McKesson Corp.*, No. CV-18-1157-PHX-DGC, 2019 WL 3532179, at *14–15 (D. Ariz. Aug. 2, 2019); *In re: Tylenol (Acetaminophen) Mktg., Sales Pracs., & Prod. Liab. Litig.*, No. 2:12-CV-07263, 2016 WL 3997046, at *9 (E.D. Pa. July 26, 2016); *In re Accutane Prod. Liab.*, No. 804MD2523T30TBM, 2007 WL 2340496, at *1 (M.D. Fla. Aug. 15, 2007). As one court explained:

> As a foundation for a causation opinion, case reports have many shortcomings. First, "[c]ase reports make little attempt to screen out alternative causes for a patient's condition." *Glastetter v. Novartis Pharms. Corp.,* 252 F.3d 986, 989–990 (8th Cir.2001).
>
> Second, case reports "simply describe[ ] reported phenomena without comparison to the rate at which the phenomena occur in the general population or in a defined control group; do not isolate and exclude potentially alternative causes; and do not investigate or explain the mechanism of causation." *Casey v. Ohio Med.*

> *Prods.,* 877 F.Supp. 1380, 1385 (N.D.Cal.1995); *see also Reference Manual on Scientific Evidence* 475 (Fed. Judicial Ctr.2000) ("[c]ausal attribution based on case studies must be regarded with caution"). As the Eleventh Circuit aptly noted, "case reports raise questions; they do not answer them." *McClain v. Metabolife Int'l, Inc.,* 401 F.3d 1233, 1254 (11th Cir.2005).
>
> Third, case reports "often omit relevant facts about the patient's condition," *Glastetter, supra,* 252 F.3d at 989, thereby hampering one's ability to apply any conclusions made in a given report to other cases.

DeGidio, 3 F. Supp. 3d at 684. Case reports, which "record nothing more than a temporal association between an exposure and a particular occurrence," are considered less reliable than epidemiological studies, which "eliminate [] chance associations and confounding factors . . . to determine whether a statistically significant positive association exists." *Lennon*, 123 F. Supp. 2d at 1153 (citing *Glastetter v. Novartis Pharmaceuticals Corp.,* 107 F.Supp.2d 1015, 1029 (E.D.Mo.2000)).

In his deposition, Dr. Grischkan testified that he was not aware of any published studies regarding migration of a mesh plug device. (ECF No. 93-1 at PageID #1855.) Instead, the migration opinions in Dr. Grischkan's expert report are based solely on case reports. (ECF No. 93-4 at PageID #2063–64.) A strong majority of courts have found that case reports, without additional supporting evidence, are not reliable scientific evidence to support an opinion on causation, and Plaintiff provides no arguments to the contrary. Therefore, the Court agrees that Dr. Grischkan's migration opinions are not based on a reliable methodology.

4. Fatal Outcomes Opinions

Defendants also seek to exclude Dr. Grischkan's opinions that the PerFix Plug can cause "deadly complications," "fatal outcomes," and "death." (ECF No. 93 at PageID #1755.) According to Defendants, any such opinions are irrelevant because "Plaintiff has not alleged and no expert has opined that Plaintiff suffered from a deadly complication (or death) as a result of the

PerFix Plug." (*Id.* at PageID #1756.) Defendants further argue that these opinions lack a reliable basis because "Dr. Grischkan conceded that he is unaware of any death reported in connection with a mesh plug (including the PerFix Plug)." (*Id.*) Lastly, Defendants argue that because no such complications were alleged here, inflammatory statements regarding "deadly complications," "fatal outcomes," and "death" would unduly prejudice Defendants. (*Id.* at PageID #1756–57.) Plaintiff did not respond to this portion of Defendants' motion. As the Court reasoned above in Section III.C.2, an expert's opinions are irrelevant if they lack a connection to the plaintiff's theory of injury or the injuries themselves.

Accordingly, Defendants' motion to exclude Dr. Grischkan's general causation opinions is **GRANTED** as it relates to nerve entrapment, bowel obstruction, organ fistulization, mesh tissue stiffening, migration, and fatal outcomes opinions, and **DENIED** as it relates to chronic pain, mesh shrinkage and pore size, and degradation opinions.

D. Specific Causation Opinions

Defendants next seek to exclude Dr. Grischkan's opinion that "the body's natural inflammatory response to the polypropylene mesh in the PerFix Plug was the proximate cause of Plaintiff's chronic pain." (ECF No. 93 at PageID #1757.) According to Defendants, a defect in the PerFix Plug's design cannot be the cause of Plaintiff's injuries "when chronic pain is a potential risk of any inguinal hernia mesh device or where the vast majority of devices used for inguinal hernia repair are made of polypropylene mesh." (*Id.*) However, the Court has already addressed Defendants' argument that any alleged defects or complications must be exclusive to the PerFix Plug above, and in Section III.B.2.a of DMO No. 7. (ECF No. 225 at PageID #9117–19.)

Defendants also dispute the sufficiency of Dr. Grischkan's differential diagnosis. According to Defendants, Dr. Grischkan did not properly consider Plaintiff's history of chronic

pain and injuries, nor did he obtain or fully consider the available medical records related to Plaintiff's pre-implant pain. (ECF No. 93 at PageID #1758–59.) Defendants claim that Dr. Grischkan focused exclusively on Plaintiff's back pain and ignored his other prior pain issues. (*Id.* at PageID #1759.) Plaintiff responds that Dr. Grischkan did perform a reliable differential diagnosis to reach the conclusion that the PerFix Plug caused Plaintiff's injuries. (ECF No. 122 at PageID #4669–71.)

Defendants argue that Dr. Grischkan's differential diagnosis is unreliable because he did not fully consider medical records related to Plaintiff's pre-implant pain. However, his report shows that Dr. Grischkan reviewed documentation regarding Plaintiff's back problems going back to 1999. (ECF No. 93-4 at PageID #2072.) Additionally, Dr. Grischkan testified that in his opinion, chronic pain "for other reasons" would not relate to separate chronic pain at the site of the hernia. (ECF No. 93-2 at PageID #1971.) Dr. Grischkan also testified that he reviewed a large volume of Plaintiff's medical records, spoke with Plaintiff, and reviewed the depositions of Plaintiff's treating physicians. (ECF No. 122-2 at PageID #4714–15.) Dr. Grischkan therefore ruled out Plaintiff's prior injuries and pain as unrelated to chronic pain at the site of the hernia. Dr. Grischkan also cited scientific literature in support of his conclusion that the PerFix Plug was the cause of Plaintiff's chronic pain. The Court finds that Dr. Grischkan "reliably rule[d] in the possible causes" and "reliably rule[d] out the rejected causes" of Plaintiff's injuries. *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 674 (6th Cir. 2010). If Defendants disagree with Dr. Grischkan's conclusions regarding the source of Plaintiff's chronic pain, or the role any prior injuries may have played, they may raise the issue on cross-examination. Accordingly, Defendants' motion to exclude Dr. Grischkan's specific causation opinions is **DENIED**.

E. Warnings Opinions

Defendants next argue that Dr. Grischkan's warnings opinions are irrelevant, lack fit, and are not based on a reliable methodology. According to Defendants, Dr. Grischkan's warnings opinions regarding migration and lack of tensile strength should be excluded as irrelevant because there is no proof of migration or loss of tensile strength with Plaintiff's PerFix Plug. (ECF No. 93 at PageID #1759.) Additionally, Dr. Grischkan's report states that "degradation with loss of tensile strength could lead to a hernia recurrence" but Plaintiff does not allege that his hernia recurred. (ECF No. 93-4 at PageID #2062.) Further, Defendants note that even if Plaintiff's hernia had recurred, the PerFix Plug IFU does warn of potential hernia recurrence. (ECF No. 93-11 at PageID #2277.)

As Defendants point out in their reply brief, Plaintiff's response lists several alleged complications caused by the PerFix Plug, such as chronic inflammation, excessive fibrosis and scarring, and mesh contraction, which Dr. Grischkan did in fact detail in his report. (ECF No. 134 at PageID #5645–46.) However, Dr. Grischkan did not opine as to the sufficiency of the *warnings* of those risks in his expert report. (*See generally* ECF No. 93-4.) The only opinion as to the sufficiency of the PerFix Plug's warnings in Dr. Grischkan's report is the following: "Even today, the product insert for the PerFix Plug and Patch and the information contained on the manufacturer's website makes no mention of mesh migration, chronic pain or the loss of tensile strength of the polypropylene fibers." (*Id.* at PageID #2068.) He also states that in the early 2000s "heavyweight polypropylene meshes and in particular, the PerFix Plug, continued to be aggressively marketed without any warning as to many of the potential short and long-term serious consequences of their use, including chronic pain[.]" (*Id.* at PageID #2067–68.) Plaintiff does not claim that Dr. Grischkan did in fact offer warnings opinions on the issues of chronic inflammation,

excessive fibrosis and scarring, and mesh contraction, but instead makes his own argument that the risks should have been included in the IFU. (ECF No. 122 at PageID #4672.)

Dr. Grischkan did offer an opinion as to the lack of warning of the loss of tensile strength in polypropylene fibers. (ECF No. 93-4 at PageID #2068.) However, as Defendants point out in their Motion, "there is no allegation or evidence to support that Plaintiff's PerFix Plug experienced [loss of tensile strength] or that [loss of tensile strength was] the cause of Plaintiff's chronic pain." (ECF No. 93 at PageID #1759.) Dr. Grischkan does not opine that Plaintiff's PerFix Plug suffered a loss of tensile strength, and only mentioned that loss of tensile strength could cause a hernia recurrence, which is not alleged in this case.[2] (ECF No. 93-4 at PageID #2062.) Plaintiff's Response also makes no argument that a loss of tensile strength is relevant to this case.

Defendants seek to exclude Dr. Grischkan's warnings opinions as to the risk of migration. As the Court found above in Section III.C.3.c, Dr. Grischkan has not provided a reliable opinion regarding a risk of migration with the PerFix Plug, therefore he may not offer a warnings opinion as to a risk of migration.

Defendants also ask the Court to exclude Dr. Grischkan's warnings opinions as to the risk of chronic pain. Defendants claim that, because Dr. Tan knew there was a risk of pain with inguinal hernia repair and she warned Plaintiff of that risk, "any additional warning of chronic pain would not and could not have changed the outcome for Plaintiff, and Dr. Grischkan's opinion that such a warning should have been included in the IFU is irrelevant and will not assist the jury in deciding a fact at issue." (ECF No. 93 at PageID #1760.) Plaintiff points to Dr. Tan's testimony that she did not know of the alleged risks specific to the design and construction of the PerFix

[2] The Court notes that the parties have agreed to additional briefing and discovery regarding Plaintiff's ongoing medical issues and potential new injuries.

Plug, and that she would have wanted to be told of such risks. (ECF No. 122-3 at PageID #4729; 4733–36; 4738–39.) The plaintiffs' medical expert in *Milanesi* offered a similar opinion that the IFU at issue "fail[ed] to inform the surgeon that certain adverse reactions are at an increased probability due to the design of the device." (Case No. 18-cv-1320, ECF No. 166, EMO No. 17 at PageID #13605.) The Court found that the opinion was helpful to the jury, and finds the same here.

Therefore, Defendants' motion to exclude Dr. Grischkan's warnings opinions as to migration, chronic inflammation, excessive fibrosis and scarring, mesh contraction, and loss of tensile strength is **GRANTED**. Defendants' motion as it relates to Dr. Grischkan's warnings opinions regarding chronic pain is **DENIED**.

Defendants also challenge Dr. Grischkan's warnings opinions as not being based on any reliable methodology but instead on his own "personal preference for what he would like to see in an IFU for a device he does not even use." (ECF No. 93 at PageID #1760.) Defendants argue that Dr. Grischkan should have taken into account other IFUs from 2015, standards for what medical device manufacturers could and could not include in an IFU in 2015, and the regulatory requirements for IFUs and descriptors used therein. (*Id.* at PageID #1760–61.) Therefore, Defendants claim, Dr. Grischkan's opinion lacks any reliable basis to support that his suggested language could be included in the IFU and that it would have complied with the applicable standards. (*Id.* at PageID #1761.)

The Court has ruled in this MDL that "'experts may offer opinions about whether the warnings sufficiently apprised medical doctors of the risks of the [device at issue] from the vantage point of the end-user' if the expert opining has 'some on-point experience, such as conducting hernia surgeries with mesh devices.'" (Case No. 18-cv-1320, ECF No. 166, EMO No. 17 at

PageID #13604 (quoting Case No. 18-cv-1509, ECF No. 461, EMO No. 13 at PageID #23451).) As Plaintiff points out, Dr. Grischkan has "explant[ed] hundreds of plug and patch devices over the last thirty-five years." (ECF No. 122 at PageID #4672.) As the Court previously ruled, Dr. Grischkan's "significant experience as a hernia surgeon, and his experience with mesh generally" render his warnings opinions reliable. (Case No. 18-cv-1509, ECF No. 310, EMO No. 5 at PageID #16796.) However, Dr. Grischkan may not testify as to the adequacy of the warnings from a regulatory or legal perspective. (*Id.* at PageID #16797.)[3]

F. State of Mind Opinions

Defendants next ask the Court to exclude any of Dr. Grischkan's opinions "regarding [Defendants'] and others' purported knowledge, state of mind, and alleged intent." (ECF No. 93 at PageID #1762–63.) Defendants point to Dr. Grischkan's opinion that "the intent behind hernia device manufacturers' decision to start developing the lightweight mesh devices was to avoid the complications with heavyweight mesh devices" and his opinions on the motivations of surgeons in not using the PerFix Plug and in not reporting certain complications. (*Id.* at PageID #1763.) Plaintiff only briefly addresses this portion of Defendants' Motion in his introduction, and states that "Dr. Grischkan's opinions related to the switch from heavyweight mesh products to lighter weight mesh products and why surgeons do not report mesh complications are not state of mind or motive testimony. These opinions are based on his experience in the industry for over thirty-five years, review of literature discussing these topics, and discussions with colleagues as well as participation at conferences." (ECF No. 122 at PageID #4633.)

[3] The Court will note that Plaintiff's Response to Defendants' challenge to Dr. Grischkan's warnings opinions cuts off mid-paragraph and jumps to what appears to be two pages regarding causation from his response to Defendants' Motion for Summary Judgment, which are not relevant to this Motion. (ECF No. 122 at PageID #4674–76; ECF No. 124 at PageID #4851–53.)

As discussed above in Section III.B.3, the Court reasoned in *Johns* and *Milanesi*:

> I would not let a witness get on the stand and talk about what all doctors know. There are other ways to do that that would be admissible evidence, and that would be what training did you receive, what are the procedures in the hospital where you practice, are you familiar with other hospital practices, et cetera. You know how to do it. But we're not bringing a doctor on to give a survey of other doctors. That's my only concern.

(Case No. 18-cv-1509, ECF No. 311 at PageID #16855; Case No. 18-cv-1320, ECF No. 296, MIL Order 26 at PageID #17090.) In fact, in those cases the plaintiffs argued that doctors should only be permitted to testify regarding their personal knowledge and that blanket statements purporting to speak for all doctors were inherently speculative and prohibited under Federal Rule of Evidence 602. (*Id.*) Consistent with the Court's holdings in *Johns* and *Milanesi*, Dr. Grischkan may not offer blanket statements as to why surgeons do not use the PerFix Plug or do not report complications, nor may he speculate as to hernia mesh manufacturers' state of mind or intent in switching from heavy weight to lighter weight mesh devices. (*See* Case No. 18-cv-1320, ECF No. 302, MIL Order No. 29 at PageID #17320 ("Although witnesses may discuss certain subjects about which they possess specialized knowledge, this does not mean that they may speculate regarding corporate intent, state of mind, and/or motivations.").) Dr. Grischkan may only speak to matters of which he has personal knowledge. Accordingly, Defendants' motion to exclude Dr. Grischkan's state of mind opinions is **GRANTED**.

G. Disclaimed Opinions

Lastly, Defendants ask the Court to preclude Dr. Grischkan from offering any opinions that he has disclaimed. (ECF No. 93 at PageID #1763–64.) Plaintiff has agreed that Dr. Grischkan will not offer opinions that he disclaimed at his deposition. (ECF No. 122 at PageID #4677.) Consistent with its rulings in the prior bellwether cases, this portion of Defendants' motion is **DENIED AS MOOT**. (*See* Case No. 18-cv-1320, ECF No. 273, EMO No. 23 at PageID #16807.)

IV. Conclusion

For the reasons set forth above, Defendants' Motion to Exclude the Opinions and Testimony of Plaintiff's Expert Dr. David Grischkan, M.D., F.A.C.S. (ECF No. 93), is **GRANTED IN PART**, **DENIED IN PART**, and **DENIED IN PART AS MOOT**.

IT IS SO ORDERED.

3/14/2023
DATE

s/Edmund A. Sargus, Jr.
EDMUND A. SARGUS, JR.
UNITED STATES DISTRICT JUDGE