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. C.R. Bard, Inc., et al.
Case No. 2:18-cv-1022

DISPOSITIVE MOTIONS ORDER No. 7

Defendants C.R. Bard, Inc. and Davol, Inc. seek summary judgment on each of Plaintiff Aaron Stinson's claims. For the reasons that follow, Defendants' motion (ECF No. 89) is **GRANTED IN PART**, **DENIED IN PART**, **DENIED AS MOOT IN PART**, and **RESERVED IN PART**.

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.) Plaintiff raises Maine law claims against Defendants based on the implantation

[1] Docket citations are to the docket in the instant case, Case No. 18-cv-1022, unless otherwise noted.

of Defendants' PerFix Plug mesh.[2] (ECF No. 17.)

The PerFix Plug is "a pre-formed, three-dimensional device constructed of a fluted outer layer of Bard mesh and multiple inner layers of mesh attached at the tip" with a separate flat onlay mesh patch, and is used for the repair of inguinal, or groin, hernia defects. (ECF No. 89-1 at PageID #619.) The PerFix Plug is cone-shaped with eight pleats. (ECF No. 89 at PageID #563.) The cone is filled with "two propeller-shaped pieces of polypropylene mesh, with a total of eight triangular petals" to keep the plug from collapsing, and looks similar to a badminton shuttlecock. (*Id.*) The flat onlay mesh has an incision and hole to "allow the spermatic cord to be threaded through the mesh." (*Id.*) The PerFix Plug is deployed using a "plug and patch" technique, which is the most common method of inguinal hernia repair in the United States. (ECF No. 89-3 at PageID #643.) Essentially, the plug is placed into an incision in the hernia defect and sutured in place, and the onlay mesh is placed over the incision to act as a reinforcement. (ECF No. 89-2.)

When it was first introduced, the PerFix Plug was available in three sizes: small, medium, and large. (ECF No. 89 at PageID #564.) An extra-large version was introduced in 1996. (*Id.*) The PerFix Plug was developed as a line extension of the Marlex Mesh Dart, which was cleared by the FDA via a 510(k) submission in August 1992.[3] (ECF No. 89-6 at PageID #872.) The small, medium, and large sizes were introduced in April 1993 using a "no-510(k) rationale." (ECF No. 89 at PageID #564; ECF No. 89-6.) A no-510(k) rationale is when a 510(k) application does not need to be submitted because the manufacturer has made changes that do not "significantly affect the safety or effectiveness of the device." (*See* Case No. 18-cv-1320, ECF No. 167,

[2] At the time his PerFix Plug was explanted Plaintiff's surgeon implanted another of Defendants' products, a Bard Marlex Mesh. Due to Plaintiff's recent health issues, the parties have reserved briefing on any damages or injuries allegedly caused by the Bard Mesh.

[3] The 510(k) process has been described previously in this MDL in Motions *in Limine* ("MIL") Order No. 4 (18-cv-01509, ECF No. 355 at PageID #18767–69).

Dispositive Motions Order ("DMO") No. 3 at PageID #13611.) In 1996, the line was expanded to add an extra-large PerFix Plug, also using a no-510(k) rationale. (ECF No. 89 at PageID #564; ECF No. 89-7.) At the FDA's request, Defendants submitted an "add-to-file" for the Marlex Mesh Dart documenting Defendants' decision not to submit a 510(k) application for the PerFix Plug, which included details about the PerFix Plug's design and construction and a summary of clinical data regarding the PerFix Plug's outcomes. (ECF No. 89-8.) After reviewing the submission, the FDA determined that it "d[id] not appear that [Defendants] ha[d] significantly changed or modified the design, components, method of manufacture, or intended use of the [PerFix Plug]." (ECF No. 89-9.) The FDA also stated that it is "[Defendants'] responsibility to determine if the change or modification to the device or its labeling could significantly affect the device's safety or effectiveness and thus require submission of a new 510(k)." (*Id.*)

The parties disagree as to the relevance of Plaintiff's medical history. In addition to information about his 2015 hernia surgery ("implant surgery") and subsequent complications (ECF No. 89 at PageID #568–75), Defendants describe Plaintiff's pre-implant medical history going back to the early 1990s (ECF No. 89 at PageID #565–68).[4] According to Defendants, these details show that Plaintiff has a longstanding history of chronic pain, difficulty urinating, sexual dysfunction, mental health issues, and weight gain that predate his 2015 implant surgery. (*Id.* at PageID #565.) Plaintiff's response instead includes his medical history starting with the 2015 implant surgery. (ECF No. 124 at PageID #4821–24.) The following is a chronological summary of Plaintiff's medical history as offered by the parties.

[4] Plaintiff does not dispute the accuracy of Defendants' description of his medical history. However, he has filed a separate motion *in limine* to exclude evidence regarding the relevance much of his pre-implant medical history (ECF No. 177), which the Court will address in a later order.

In 1993 or 1994, Plaintiff was involved in an altercation and suffered what he described as "horrific[]" injuries to his teeth, jaw, cheekbone, ribs, and eyes. (ECF No. 89-12 at PageID #1005.) In September of 1995, Plaintiff suffered an accident at work in which he had an open fracture in his left foot, "the plantar aspect of [his left] foot was severely lacerated and later required skin grafting," and he experienced a "large buck[et] handle tear of the medial meniscus" in his left knee that required surgical repair. (ECF No. 89-13; ECF No. 89-12 at PageID #1006.) Beginning in 1999, Plaintiff sought treatment for back pain and pain that radiated into both thighs which worsened when moving from lying down to standing. (ECF No. 89-3 at PageID #655.) In August of 2000, Plaintiff sought treatment for right L5 nerve compression that radiated to his thigh and foot, and he reported trouble sleeping. (*Id.*) A diagnostic study indicated bulging discs, stenosis, L5 radiculopathy, and disc disease. (*Id.*) In December of 2000, Plaintiff sought treatment for weakness in his right foot and radicular discomfort pain which responded to epidural steroid injections. (*Id.*) He showed signs of a nerve injury and contemplated, but ultimately did not undergo, back surgery. (*Id.*) In January of 2001, he reported discomfort over his right hip and pain in his right leg. (*Id.*)

In late January 2001, Plaintiff sought treatment for abdominal pressure with difficulty urinating and was found to have an enlarged prostate, and the doctor noted that he could not rule out the possibility of cauda equina syndrome in light of Plaintiff's spinal cord issues; upon examination, Plaintiff walked slightly stooped and also reported tenderness in the suprapubic area and back pain. (*Id.* at PageID #656.) From March of 2001 through April of 2003 Plaintiff continued to report lower back pain and right leg pain and weakness which did not respond to conservative treatment, and Plaintiff mentioned wanting to avoid back surgery. (*Id.*)

In January of 2004, Plaintiff sustained a lower back injury while at work which prevented

him from working. (ECF No. 89-14 at PageID #1028.) X-rays were negative for a compression fracture but revealed mild degenerative changes. (*Id.*) Plaintiff reported that his pain gradually improved, but described a burning and throbbing sensation localized to the left lower back which worsened when attempting to sit or stand, with a pain level of 6 out of 10. (*Id.*) Plaintiff also reported pain along his right inner thigh associated with movement, and difficulty lying on his side. (*Id.*) Plaintiff attended physical therapy for this injury. (*Id.*)

Plaintiff testified that a doctor told him he had a small inguinal hernia on the right side in the early 2000s and that it did not require treatment at that point, but the doctor instructed Plaintiff to "keep an eye on it." (ECF No. 89-12 at PageID #1008.) However, the notes from his July 30, 2015 visit with the surgeon who performed his initial hernia repair indicate that he had had the hernia for approximately five years. (ECF No. 19-16 at PageID #1037.)

In October of 2013, Plaintiff reported radiating left knee pain with intermittent numbness and tingling in his left foot, which had been a recurring issue since his 1995 injury and surgeries. (ECF No. 89-3 at PageID #657.) The record from that visit also noted that Plaintiff "had little interest in things, was feeling down, depressed, and hopeless." (*Id.*) Beginning in January of 2015, pharmacy records show prescriptions for Gabapentin, Hydrocodone, and Ketorolac. (*Id.* at PageID #658.)

In July of 2015 Plaintiff sustained an injury while working on a sailboat and testified that he felt a tear at the location of his right inguinal hernia. (ECF No. 89-12 at PageID #1008.) Plaintiff went to the emergency room and was referred to Dr. Amy Tan, a general surgeon. (*Id.* at PageID #1009.) On July 30, 2015, Plaintiff saw Dr. Tan regarding the hernia, and she prescribed hydrocodone-acetaminophen as needed for pain and discussed hernia repair with Plaintiff. (ECF No. 89-16 at PageID #1039.) Dr. Tan gave Plaintiff illustrated literature on hernia repair, which

discussed expectations, a hernia repair overview, recovery and discharge, and risks and possible complications. (ECF No. 89-18.) This pamphlet detailed risks and complications including, among other things, chronic pain, urinary problems, nerve pain, and testicular pain or swelling. (*Id.* at PageID #1081.) Dr. Tan discussed with Plaintiff the risks of the operation, including "infection, bleeding, poor wound healing, scarring, and damage to adjacent structures." (ECF No. 89-16 at PageID #1039.) She "also discussed the risks of damage to nerves and cord structures that could result in pain, numbness, testicular damage or infertility." (*Id.*) Dr. Tan explained the risk of hernia recurrence, and that the risk is higher with any factors that increase abdominal pressure including "coughing, straining, and heavy labor." (*Id.*) Dr. Tan also discussed expected postoperative course and recovery and answered Plaintiff's questions, and Plaintiff ultimately decided that "he would like to proceed with right inguinal hernia repair with mesh." (*Id.*) Plaintiff did not tell Dr. Tan about his prior spinal issues, which she testified that she "would have considered if [she]'d known about the injury." (ECF No. 89-17 at PageID #1063.)

Dr. Tan performed the hernia repair operation on August 5, 2015. (ECF No. 89-19.) She repaired the hernia using an Extra-Large PerFix Plug. (*Id.*) In her operative report she described mobilizing the ilioinguinal nerve and taking care not to entrap it. (*Id.* at PageID #1088.) On August 12, 2015, Plaintiff indicated a 6.5 out of 10 pain level and requested pain medication, and received a prescription for Hydrocodone-Acetaminophen. (ECF No. 89-3 at PageID #661.) At a visit on August 18, 2015, Plaintiff was noted to have lost 16 pounds but to be in no acute distress and recovering as expected without signs of early complications. (*Id.*) On August 24, 2015, Plaintiff was given Toradol for pain. (*Id.*) On September 4, 2015, Plaintiff reported pain while putting on pants. (*Id.*) Dr. Tan asked Plaintiff to return for a visit so she could "examine him and evaluate for any potential problems because it is unusual to have leg pain from a hernia." (ECF

No. 89-17 at PageID #1051.) At a follow-up visit on September 8, 2015, Plaintiff reported shooting pain in his right leg that was worse with certain movements and positions. (*Id.* at PageID #1052.) Dr. Tan noted that the hernia "looked like it was well healed" and that there was "nothing that was tender in the area of the hernia." (*Id.*) Dr. Tan saw no sign of a hernia recurrence at this appointment. (*Id.*) Dr. Tan believed some of Plaintiff's reported pain was "related to nerve root pain from [Plaintiff's] back" and suggested rest and anti-inflammatory medications. (*Id.*)

At another visit with Dr. Tan on September 21, 2015, Plaintiff reported that his shooting leg pain had improved but was still present. (*Id.*) Dr. Tan examined Plaintiff and noted that the hernia repair had healed well but that there was "a spot where pressure relieved the pain," which she testified was more indicative of a nerve issue. (*Id.*) Dr. Tan gave Plaintiff a nerve block injection, and Plaintiff reported that the pain relief only lasted for about 24 hours. (*Id.* at PageID #1052–53.) Dr. Tan testified that although it was brief, the pain relief from the nerve block convinced her that Plaintiff was suffering from nerve pain. (*Id.* at PageID #1053.)

At another visit with Dr. Tan on October 15, 2015, Plaintiff reported that a prescription anti-inflammatory medication did not provide much relief. (*Id.* at PageID #1054.) However, he was prescribed Neurontin, a medication often used for nerve pain, by his family doctor and he felt the Neurontin was helping the pain. (*Id.*) Dr. Tan recommended continued use of the Neurontin. (*Id.*) At a later visit on December 21, 2015, Plaintiff reported to Dr. Tan that he felt the Neurontin "controlled [his pain] reasonably well, but he was still having some limitation." (*Id.*)

On January 27, 2016, Plaintiff saw Dr. Frederick Littlejohn at Northeast Pain Management for complaints of right groin pain which was aggravated by certain positions and by coughing, and rated his pain as ranging from 7 to 10 out of 10. (ECF No. 89-3 at PageID #664.) Dr. Littlejohn noted that Plaintiff's leg pain had dissipated, and most of his pain was in the inguinal and inner

thigh regions. (*Id.*) Based on the evaluation, Dr. Littlejohn concluded that Plaintiff "likely ha[d] some impingement of the ilioinguinal or genitofemoral nerves in association with the spermatic cord, possibly related to the surgery or scar tissue which may have developed after" his hernia repair. (*Id.*) Dr. Littlejohn's diagnosis was ilioinguinal neuritis and myofascial pain syndrome. (*Id.*) On February 24, 2016, a left ilioinguinal nerve block was performed, and Plaintiff continued to receive ilioinguinal nerve blocks. (*Id.*)

Plaintiff again saw Dr. Tan on March 21, 2016, and she recommended he continue the nerve blocks. (ECF No. 89-17 at PageID #1054.) Dr. Tan discussed with Plaintiff the possibility of a neurectomy operation, but she encouraged him to "exhaust treatment options through [the] pain clinic before consideration of a neurectomy." (*Id.*) Plaintiff continued regular nerve block injections in March and April 2016 with an improvement in his symptoms. (ECF No. 89-3 at PageID #665.) On April 22, 2016, Plaintiff and Dr. Littlejohn discussed the possibility that his symptoms may be related to the problems with his lumbar spine. (*Id.*) At a follow-up visit with Dr. Tan on June 23, 2016, Plaintiff reported pain that interfered with his driving, and also reported pain with urination and trouble emptying his bladder. (ECF No. 89-17 at PageID #1055.) Dr. Tan did not believe that "any bladder problems were from the nerves [related to] his hernia repair." (*Id.*) Dr. Tan did not find evidence of hernia recurrence. (*Id.*) Dr. Tan recommended a neurectomy. (*Id.*)

On August 15, 2016, Plaintiff saw Dr. Frederick Radke, a general surgeon, for a possible hernia recurrence. (ECF No. 89-3 at PageID #665.) Dr. Radke diagnosed right inguinodynia and noted no signs of a recurrent hernia, but opined that inguinal nerve entrapment was the most likely possibility for Plaintiff's ongoing pain. (*Id.*) Dr. Radke administered ilioinguinal nerve blocks and concluded, based on Plaintiff's continuing pain, that Plaintiff may benefit from a right

paravertebral block. (*Id.* at PageID #667.) On February 14, 2017, Plaintiff received a lumbosacral transforaminal epidural steroid injection and immediately experienced relief of his groin pain. (*Id.*)

In April of 2017, Plaintiff's family doctor discussed with Dr. Radke the possibility of an exploratory surgery to try to find a way to relieve Plaintiff's pain. (*Id.*; ECF No. 89-21 at PageID #1126.) On June 20, 2017, Dr. Radke performed an exploratory surgery to look for hernia recurrence or nerve entrapment. (ECF No. 89-22 at PageID #1135.) Dr. Radke noted "[a] great deal of scarring in the subcutaneous tissue" and found "a large ball approximately 2.5 cm in diameter of rolled up mesh next to the pubic tubercle." (*Id.* at PageID #1134.) Dr. Radke removed the mesh, which was "slow going and extremely difficult" as the mesh was "very significantly scarred." (*Id.*) Dr. Radke then found Plaintiff's hernia and noted that it was "not large and it was unclear whether this was responsible for any of [Plaintiff's] symptoms." (*Id.*) Dr. Radke then repaired the hernia with a flat piece of Bard Marlex Mesh, another of Defendants' products. (*Id.*; ECF No. 89-21 at PageID #1128.) At the end of Plaintiff's surgery Dr. Radke opined that "the large ball of mesh [was] likely . . . responsible" for Plaintiff's pain. (ECF No. 89-22 at PageID #1134–35.)

Dr. Radke testified that at the time of Plaintiff's surgery, he did not know that the device he removed was a PerFix Plug and instead thought it was a "sheet [of flat mesh] that had pulled loose or something of that sort." (ECF No. 89-21 at PageID #1130.) According to Dr. Radke, the fact that it was a plug device and not a piece of flat mesh "explains the fact that [Plaintiff] had a big ball of scar tissue because . . . part of the way [plug devices] work is by forming scar tissue and healing the area." (*Id.*) Dr. Radke also noted that the location where the mesh was found was "a reasonable place for it to be" because "that's where hernias occur," and that he could not tell if it was exactly where it should have been or not, but "it was at least close to where it was supposed

to be." (*Id.* at PageID #1127–28.)

On June 28, 2017, Plaintiff reported to his family doctor that his neuropathic pain had improved but was still present. (ECF No. 89-3 at PageID #669.) On July 26, 2017, Plaintiff returned to his family doctor and complained of trouble urinating. (*Id.*) Plaintiff still had right testicular and scrotal swelling and some right inguinal pain, but reported that it was much improved from before. (*Id.*)

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 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.*)

On June 10, 2019, Plaintiff filed his third amended complaint. (ECF No. 17.) In the third amended complaint, Plaintiff raises claims for (1) defective design (strict liability), (2) failure to warn (strict liability), (3) manufacturing defect (strict liability), (4) negligence, (5) negligence per se, (6) gross negligence, (7) state consumer protection laws[5], (8) breach of implied warranty, (9) breach of express warranty, (10) negligent infliction of emotional distress, (11) intentional infliction of emotional distress, (12) negligent misrepresentation, (13) fraud and fraudulent

[5] Prior to the filing of the Motion for Summary Judgment, the parties filed a stipulated dismissal of Plaintiff's claim under Maine consumer protection laws. (ECF No. 88.)

misrepresentation, (14) fraudulent concealment, and (15) punitive damages. (ECF No. 17.) Defendants seek summary judgment on all claims. (ECF No. 89.) The motion is fully briefed, and Defendants have filed evidentiary objections in response to Plaintiff's brief. (ECF Nos. 89, 124, 144.)

II. Governing Law and Legal Standard

In federal diversity actions, "state substantive law and federal procedural law apply to state claims." *Range v. Douglas*, 763 F.3d 573, 580 (6th Cir. 2014). Generally, the state law of the transferor court applies in MDLs. *See Wahl v. Gen. Elec. Co.*, 786 F.3d 491, 497–98 (6th Cir. 2015). In cases filed directly with the MDL court, MDL courts will apply the substantive state law of the "originating jurisdiction," including choice-of-law rules. *Sanchez v. Bos. Sci. Corp.*, No. 2:12-cv-05762, 2014 WL 202787, at *4 (S.D. W. Va. Jan. 17, 2014) (quoting *In re Watson Fentanyl Patch Prods. Liab. Litig.*, MDL No. 2732, 2013 WL 4564927, at *2 (N.D. Ill. Aug. 27, 2013)). The originating jurisdiction is where the case would have been filed if the case management order permitting direct filing did not exist. *Wahl v. Gen. Elec. Co.*, 983 F. Supp. 2d 937, 943 (M.D. Tenn. 2013). In a medical device case, this is where the device was purchased, prescribed, and implanted. *E.g.*, *Sanchez*, 2014 WL 202787, at *4. There is no dispute that the action would have been filed in Maine absent Case Management Order No. 2 permitting direct filing with this Court. (ECF No. 17 at PageID #108; ECF No. 89 at PageID #577–78.) Thus, Maine choice-of-law rules apply.

Under Maine choice-of-law rules, Maine law applies to this case. Maine applies the Restatement (Second) of Conflict of Laws approach, the most significant relationship analysis, to tort law claims. *Collins v. Trius, Inc.*, 663 A.2d 570, 572–73 (Me. 1995). Here, all pertinent events took place in Maine. Plaintiff lives there, the surgeries occurred there, and his alleged injuries

occurred there. *See* Restatement (Second) of Conflict of Laws § 145(2) (1971). The parties do not dispute the application of Maine law.

Under the Federal Rules of Civil Procedure, summary judgment is appropriate when "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). "The moving party bears the burden of showing that no genuine issues of material fact exist." *RJ Control Consultants, Inc. v. Multiject, LLC*, 981 F.3d 446, 452 (6th Cir. 2020) (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986)). The burden then shifts to the nonmoving party, who "must set forth specific facts showing that there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986). "In order for the non-movant to defeat a summary-judgment motion, there must be evidence on which the jury could reasonably find for the [non-movant]." *Clabo v. Johnson & Johnson Health Care Sys., Inc.*, 982 F.3d 989, 992 (6th Cir. 2020) (alteration in original) (quoting *Bard v. Brown County*, 970 F.3d 738, 748 (6th Cir. 2020)). The court must "consider the evidence in the light most favorable to the nonmoving party and draw all reasonable inferences in that party's favor." *Johnson v. City of Saginaw*, 980 F.3d 497, 506 (6th Cir. 2020) (quoting *Quigley v. Tuong Vinh Thai*, 707 F.3d 675, 679 (6th Cir. 2013)). The ultimate question is "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Anderson*, 477 U.S. at 251–52.

III. Analysis

Defendants argue that Plaintiff fails to demonstrate genuine disputes of material fact exist for trial. Defendants raise arguments for each of Plaintiff's claims: manufacturing defect; design defect; failure to warn; negligence; negligence per se; gross negligence; negligent misrepresentation, fraud, fraudulent misrepresentation, and fraudulent concealment; breach of

express warranty; breach of implied warranty; intentional infliction of emotional distress and negligent infliction of emotional distress; certain damages; and any claims regarding Plaintiff's current Bard mesh. (ECF No. 89.)

A. Manufacturing Defect Claim

Defendants first argue that Plaintiff has "proffered no evidence, expert or otherwise, that the PerFix Plug implanted in him was defectively manufactured in that it departed from its intended design." (ECF No. 89 at PageID #578.) However, the parties proposed, and the Court agreed, that summary judgment briefing on Plaintiff's manufacturing defect claim would be deferred pending further discovery. Therefore, the Court **RESERVES JUDGMENT** on Plaintiff's manufacturing defect claim.

B. Strict Liability Design Defect Claim

Defendants next argue that Plaintiff's strict liability design defect claim fails for three reasons: that comment k to the Restatement (Second) of Torts § 402A applies here and precludes Plaintiff's claim; that Plaintiff cannot carry his burden on this claim because he fails to show that the risks of the PerFix Plug outweighed its benefits nor has he presented a feasible alternative design; and that the design of the PerFix Plug did not cause Plaintiff's injuries. The Court will address each argument in turn.

1. Comment K

Comment k to the Restatement (Second) of Torts § 402A pertains to "unavoidably unsafe products," and states:

> There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably

> leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Restatement (Second) of Torts § 402A (1965). According to Defendants, although the Supreme Judicial Court of Maine has not formally adopted comment k, the Court should apply it in this case. (ECF No. 89 at PageID #579–81.) Defendants point to *Doe v. Solvay Pharmaceuticals, Inc.*, in which the United States District Court for the District of Maine noted that the Supreme Judicial Court "has not directly faced the application of strict liability principles to prescriptive drugs; however, because the Maine Legislature modeled its strict liability statute on § 402A of the Restatement (Second) of Torts, Maine courts have looked to the Restatement for interpretive guidance." *Doe v. Solvay Pharms., Inc.*, 350 F. Supp. 2d 257, 267 (D. Me. 2004), *aff'd on other grounds,* 153 F. App'x 1 (1st Cir. 2005). Defendants also note that other courts across the country have applied comment k in the context of prescription drugs and medical devices. (ECF No. 89 at PageID #580.) Defendants argue that Plaintiff's alleged injuries "are inherent risks of prescription medical devices such as the PerFix Plug that doctors and patients have accepted for decades given the benefits of polypropylene mesh in the repair of hernias." (*Id.*) Defendants claim that Plaintiff's implanting and explanting physicians agree that "Plaintiff's alleged complications are risks in any hernia surgery, with or without mesh, and are not particular to the PerFix Plug." (*Id.* at PageID

#580–81.)

Plaintiff argues that Defendants' comment k argument fails because Maine has not adopted comment k, and because comment k "anticipates that it will apply primarily to new and experimental prescription drugs, not medical devices that have been on the market for decades." (ECF No. 124 at PageID #4830.) Even if comment k applies, Plaintiff contends that Defendants' arguments still fail because Defendants could have made the PerFix Plug safer, the risks of the PerFix Plug are not reasonable, and the PerFix Plug was not accompanied by proper warnings. (*Id.* at PageID #4831.)

"Even if comment k accurately reflects Maine common law," evidence of a safer alternative defeats a claim that a product is unavoidably unsafe under comment k. *Violette v. Smith & Nephew Dyonics, Inc.*, 62 F.3d 8, n.3 (1st Cir. 1995). As the Court addresses below in Section III.B.2.b, there is a genuine issue of material fact as to whether Plaintiff has presented evidence of a safer alternative. Further, the language of comment k itself states that it only applies if a product is "properly prepared and marketed, and proper warning is given." Restatement (Second) of Torts § 402A (1965). As the Court addresses below in Section III.C, there is a genuine issue of material fact as to whether the PerFix Plug was accompanied by adequate warnings. Therefore, the Court declines to apply comment k in this case.

2. Burden to Establish Design Defect

a. Risk-Utility Test

In design defect claims, whether under a theory of negligence or strict liability, Maine law requires a plaintiff to prove that "the product was defectively designed thereby exposing the user to an unreasonable risk of harm." *Stanley v. Schiavi Mobile Homes, Inc.*, 462 A.2d 1144, 1148 (Me. 1983) (internal citations omitted). Such proof involves "an examination of the utility of its

design, the risk of the design and the feasibility of safer alternatives." *Id.* Defendants claim that Plaintiff cannot meet his burden to prove that the PerFix Plug's risks outweighed its utility. Defendants note that the PerFix Plug was developed in collaboration with surgeons to address a need for a plug-shaped device so that surgeons would not have to "hand-shap[e] plug devices using [flat] Bard Marlex Mesh." (ECF No. 89 at PageID #582.) Defendants point to Dr. Tan's testimony that she used the PerFix Plug as her "standard first-line product," and "[t]he only time [she] used others was when there was a specific issue that required it." (*Id.*; ECF No. 89-17 at PageID #1045.) Dr. Tan testified that she used the PerFix Plug in at least 90 percent of the estimated 275 inguinal hernia repairs she has done using mesh. (*Id.* at PageID #1058–59.)

Defendants argue that Plaintiff's medical expert Dr. David Grischkan opines that certain problems are caused by the PerFix Plug, but "offers no opinion that the PerFix Plug performs worse than other plug and patch devices on the market," and that his opinions amount to a criticism of polypropylene mesh generally. (ECF No. 89 at PageID #583.) Defendants assert that these problems, such as chronic inflammation and chronic pain, are "well-known risks of hernia repair with mesh, regardless of the mesh product or design." (*Id.*) Therefore, "Plaintiff has no competent expert evidence supporting any increased risk for the PerFix Plug compared to other synthetic hernia mesh devices indicated for an inguinal hernia like Plaintiff had in 2015." (*Id.* at PageID #584.) According to Defendants, although another surgeon such as Dr. Grischkan may have chosen a different technique or device to repair Plaintiff's hernia, "that is not the same thing as proof that the design of the PerFix Plug increased its risks such that they exceeded the device's benefits." (*Id.*)

In response, Plaintiff agrees that part of the theory of his case relies on the argument that polypropylene is unsafe generally and is not biocompatible. (ECF No. 124 at PageID #4832–33;

4836–37.) Additionally, Plaintiff alleges that the PerFix Plug is unsafe because it is prone to migration, it tends to contract after implantation, it involves a high incidence of chronic pain, and re-operating or explanting the PerFix Plug is difficult and risky. (*Id.* at PageID #4833–35.)

Defendants' criticisms of Dr. Grischkan's opinions as condemnations of polypropylene mesh generally are not well taken. In MIL Order No. 30, the Court noted that the history and safety of polypropylene mesh generally is directly relevant to the claims in this MDL and is part of the case's "story." (Case No. 18-cv-1320, ECF No. 303 at PageID #17326.) The same holds true here. The safety of polypropylene mesh is a central issue in this case, and in this MDL generally, and Dr. Grischkan's opinions demonstrate a genuine issue of material fact as to whether the PerFix Plug's risks outweighed its utility because of, among other things, its use of polypropylene mesh.

In addition to Plaintiff's claims regarding the safety and biocompatibility of polypropylene generally, Plaintiff presents evidence regarding contraction (ECF No. 97-11 at PageID #2757–58), mesh pore size (*id.* at PageID #2758), and chronic pain (*id.* at PageID #2758–59). Although the PerFix Plug may have some of these characteristics in common with other mesh devices, that does not mean that Plaintiff has not shown a genuine issue of material fact exists regarding the risks of the PerFix Plug. Defendants' contention that any evidence of the risks of the PerFix Plug must relate to a design unique to only the PerFix Plug is not well taken. Defendants present no compelling authority nor argument that Plaintiff must show that the risks of the PerFix Plug outweigh the risks of all other plug and patch hernia mesh devices on the market.

b. Feasible Alternative Design

Defendants claim that Plaintiff also cannot carry his burden to show that a feasible alternative design would have prevented his injuries, or that "the alternative design was

1) reasonably available to the manufacturer at the time; and 2) its cost, any impairments on the design's utility, and any new dangers posed by the alternative design were outweighed by its utility." (ECF No. 89 at PageID #585.) Defendants point to "the widespread consensus among courts" that in the medical device context, "the existence of an altogether different product or a different surgical technique does not satisfy the burden to identify a feasible alternative design." (*Id.* at PageID #586.) *See Barnes v. Medtronic, PLC*, No. 2:17-CV-14194, 2019 WL 1353880 (E.D. Mich. Mar. 26, 2019) (Rejecting the plaintiff's proposed alternative treatment methods or alternative types of hernia mesh, instead of an alternative production practice for the defendant's product, as insufficient as a matter of law.); *Mullins v. Johnson & Johnson*, 236 F. Supp. 3d 940 (S.D.W. Va. 2017) (Rejecting evidence of an alternative surgical procedure and an entirely different product, and finding that the plaintiffs "must provide evidence of an alternative, feasible design for the *product* at issue.") (emphasis in original); *Schmidt v. C.R. Bard, Inc.*, No. 2:11-CV-00978-PMP, 2013 WL 3802804 (D. Nev. July 22, 2013) (Finding that a non-mesh inguinal hernia repair was not an alternative design to the mesh device at issue and did not meet the plaintiff's burden to support a design defect claim.); *Linsley v. C.R. Bard, Inc.*, No. CIV.A.98-2007, 2000 WL 343358 (E.D. La. Mar. 30, 2000) (Finding that alternative techniques for hernia repair, as opposed to an alternative design for hernia mesh device, were not sufficient evidence to create an issue of material fact to support a design defect claim.). Defendants claim that Dr. Grischkan has not offered any feasible alternative designs for the PerFix Plug, and instead simply opined that Dr. Tan should have performed a primary tissue repair without a mesh device. (ECF No. 89 at PageID #586.) A primary repair is an entirely different procedure and therefore, according to Defendants, it does not qualify as a feasible alternative design. (*Id.* at PageID #586–87.)

Similarly, Defendants claim that Dr. Grischkan's other suggestions such as using ePTFE

or biologic devices are not feasible alternative designs, because they are completely different devices that entail completely different repair procedures. (*Id.* at PageID #587.) Defendants also argue that Dr. Julia Babensee's opinions on possible alternative features of hernia mesh devices in general "do not include any opinions on how the risks of the PerFix Plug would be reduced with any design change." (*Id.*)

In Plaintiff's response, he argues that there is no requirement under Maine law to present evidence of the feasibility of safer alternative designs. However, in so arguing, Plaintiff quotes language from *St. Germain v. Husqvarna Corp.* and *Stanley v. Schiavi Mobile Homes* which states that "[s]uch proof [of defective design] will involve an examination of the utility of its design, the risk of the design and *the feasibility of safer alternatives*." *St. Germain v. Husqvarna Corp.*, 544 A.2d 1283, 1285 (Me. 1988) (quoting *Stanley,* 462 A.2d at 1148) (emphasis added). Therefore, in explicit plain language, proof of design defect under Maine law clearly involves an examination of the feasibility of safer alternative designs. *See also Espeaignnette v. Gene Tierney Co.*, 43 F.3d 1 (1st Cir. 1994) (quoting *Stanley* and analyzing the evidence of the possibility and practicality of the plaintiff's proposed alternative design); *Walker v. Gen. Elec. Co.*, 968 F.2d 116, 119 (1st Cir. 1992); *Canning v. Broan-Nutone, LLC*, 480 F. Supp. 2d 392, 404 (D. Me. 2007), *as amended* (Mar. 27, 2007); *Taylor v. Ford Motor Co.*, No. CIV. 06-69-B-W, 2008 WL 879411, at *12 (D. Me. Mar. 28, 2008), *report and recommendation adopted,* No. CV-06-69-B-W, 2008 WL 2224887 (D. Me. May 27, 2008); *Moores v. Sunbeam Prod., Inc.*, 425 F. Supp. 2d 151, 156 (D. Me. 2006); *Elwell v. Conair, Inc.*, 145 F. Supp. 2d 79, 91 (D. Me. 2001).

Plaintiff's expert Dr. Babensee identifies features such as a larger pore size or lighter mesh weight that could increase the PerFix Plug's safety. (ECF No. 91-3 at PageID #1310–11.) Dr. Babensee also identifies specific products, including some of Defendants' own products, as safer

alternatives. (*Id.* at PageID #1311–13.) Defendants claim that the different devices or designs suggested by Dr. Babensee and Dr. Grischkan involve different procedures than those required for polypropylene devices. (ECF No. 144 at PageID #5926.) However, an alternative design would, by its nature, be different from the PerFix Plug. If the procedure and device were exactly the same, it would not be an alternative design. Defendants also claim that proposing the use of alternative materials does not constitute a proper alternative design for the PerFix Plug. However, as the Court discussed previously in Section III.B.2.a, a central theory of Plaintiff's case is the danger of heavyweight, small-pore polypropylene mesh. Therefore, the fact that some of Plaintiff's proposed alternatives feature different materials does not defeat his claim. Additionally, whether the products, materials, or designs at issue were feasible or available is a question of fact for the jury. Plaintiff has made a sufficient showing regarding safer alternative designs to survive summary judgment on this element of his design defect claim. Similarly, whether Plaintiff's proposed alternative designs would have prevented his injuries is a question for the jury. However, the Court does find persuasive Defendants' arguments and the caselaw holding that the availability of entirely different non-mesh procedures does not support Plaintiff's design defect claim as an alternative design. *See Mullins*, 236 F. Supp. 3d at 944; *Barnes*, 2019 WL 1353880 at *2; *Schmidt*, 2013 WL 3802804 at *2; *Linsley*, 2000 WL 343358 at *3.

3. Causation

Next, Defendants argue that Plaintiff's design defect claim fails because the design of the PerFix Plug did not cause Plaintiff's injuries. Under Maine law, "to prevent a summary judgment, [a] plaintiff [is] required to present evidence . . . that the defect caused the harm." *Guiggey v. Bombardier*, 615 A.2d 1169, 1172 (Me. 1992). Defendants argue that Plaintiff's claim fails unless Dr. Grischkan identifies a specific design defect in the PerFix Plug that allegedly caused Plaintiff's

injuries. Defendants further argue that "Plaintiff cannot establish proximate cause if the same injury would have occurred regardless of a change in the product design." (ECF No. 89 at PageID #588.) According to Defendants, Dr. Grischkan has not identified any defects specific to the PerFix Plug, as opposed to three-dimensional mesh products or polypropylene mesh generally.

Defendants also argue that Plaintiff and his experts ignore other plausible explanations for his post-implant pain. Defendants point to Plaintiff's medical history, which includes "longstanding complaints of pain in addition to pain directly related to his preexisting hernia." (*Id.* at PageID #590.) The inguinal hernia brochure that Dr. Tan gave to Plaintiff before his implant surgery explains that "80% of patients with severe groin pain [after inguinal hernia repair] had pain before the operation." (ECF No. 89-18 at PageID #1085.) Additionally, prior to his explant surgery, the explanting surgeon said that "it [wa]s [his] opinion that [Plaintiff] is suffering from a nerve entrapment," and that "everyone has had this suspicion [all] along." (ECF No. 89-28 at PageID #1197.) According to Defendants, Plaintiff's alleged injuries are "simply a risk of any hernia repair surgery and not the result of some alleged defect in the design of the PerFix Plug." (ECF No. 89 at PageID #591.)

Plaintiff responds that Dr. Grischkan's differential diagnosis is evidence of causation. (ECF No. 124 at PageID #4842–43.) Plaintiff also again argues that there is no requirement under Maine law to prove that a safer alternative design would have prevented Plaintiff's injuries.

As to Defendants' argument that Dr. Grischkan ignored other potential causes for Plaintiff's pain, Plaintiff points to Dr. Grischkan's differential diagnosis, in which he considered other potential causes of Plaintiff's injuries such as hernia recurrence, neuroma/nerve entrapment, and Plaintiff's previous spinal issues. (ECF No. 97-11 at PageID #2763–65.) Based on his "education, training, experience, and review of the medical records and depositions, as well as the

relevant medical literature," Dr. Grischkan concluded that "[t]he design of the [PerFix Plug] caused an excessive inflammatory response with massive scarring, chronic inflammation and severe pain." (*Id.* at PageID #2765.) As to Defendants' argument that Plaintiff "has not identified a single defect specific to the PerFix Plug that proximately caused Plaintiff's injuries" (ECF No. 89 at PageID #590), Dr. Grischkan's report points to the "dense segment of polypropylene that constitutes the PerFix Plug" as the cause for "anatomical distortion in the right groin as well as the severe consequential pain suffered by [Plaintiff]." (ECF No. 97-11 at PageID #2764.) Dr. Grischkan also discusses issues with the weight and pore size of the polypropylene in the PerFix Plug. The Court addressed Defendants' contention that any alleged defects must be exclusive to the PerFix Plug, and not present in other mesh products or polypropylene mesh generally, in Section III.B.2.a. Defendants certainly may challenge Dr. Grischkan's causation opinions on cross-examination, but the fact that Defendants disagree with his conclusions is not grounds for summary judgment.

Accordingly, Defendants' motion for summary judgment on Plaintiff's design defect claim is **GRANTED** as it relates to alternative procedures as feasible alternative designs, but is otherwise **DENIED**.

C. Failure to Warn Claim

Defendants argue that Plaintiff's failure to warn claim fails because 1) the learned intermediary doctrine applies and therefore its duty to warn applied to the implanting physician, not to Plaintiff directly, 2) the PerFix Plug Instructions for Use ("IFU") was adequate as a matter of law, and 3) Plaintiff cannot establish that an inadequate warning proximately caused his injuries.

1. Learned Intermediary Doctrine

Defendants argue that "although Maine has not expressly addressed the applicability of the

learned intermediary doctrine," this Court should apply the learned intermediary doctrine in this case. (ECF No. 89 at PageID #592.) Defendants claim that "for more than fifteen years, the First Circuit has predicted that Maine courts would adopt the doctrine if given the opportunity." (*Id.* (citing *Doe v. Solvay Pharms., Inc.*, 153 F. App'x 1, 3 (1st Cir. 2005); *Novak v. Mentor Worldwide LLC*, 287 F. Supp. 3d 85, 95 (D. Me. 2018); *Doe v. Solvay Pharms.*, 350 F. Supp. 2d at 270; *Herzog v. Arthrocare Corp.*, No. CIV. 02-76-P-C, 2003 WL 1785795, at *8 (D. Me. Mar. 21, 2003)).) Defendants also point to the fact that a Maine Superior Court adopted the learned intermediary doctrine in a case involving a prescription drug. (ECF No. 89 at PageID #592 (citing *Tardy v. Eli Lily & Co.*, No. CV-03-538, 2004 WL 1925536 (Me. Super. Aug. 3, 2004)).)

Plaintiff correctly notes that federal courts should be reluctant to "speculate on any trends of state law," especially to "a plaintiff in a diversity case, like this one, who has chosen to litigate his state law claim in federal court." *Combs v. Int'l Ins. Co.*, 354 F.3d 568, 577 (6th Cir. 2004). However, the fact that Maine's highest court has not had a chance to adopt the learned intermediary doctrine is not dispositive. In determining whether to apply the learned intermediary doctrine, this Court may look at "the decisional law of . . . [Maine] trial courts, although a federal court is not bound by lower court determinations if convinced by other data that the state's highest court would determine otherwise. . . . In addition, consideration may be given to . . . decisions from other jurisdictions or the 'majority' rule." *Bailey v. V & O Press Co.*, 770 F.2d 601, 604 (6th Cir. 1985). As the court pointed out in *Tardy*, "Maine has not explicitly adopted the learned intermediary doctrine. However, the 'overwhelming majority' of jurisdictions nationwide" apply the doctrine. *Tardy*, 2004 WL 1925536 at *2. The District Court for the District of Maine and the First Circuit Court of Appeals have also "applied the learned intermediary rule to [] medical device case[s] on the assumption that Maine would adopt the rule." *Doe v. Solvay Pharms.*, 350 F. Supp. 2d at 271

(citing *Violette*, 62 F.3d at 13). This Court finds the reasoning in *Tardy* and in the numerous federal trial and appellate court decisions applying Maine law to be persuasive. Therefore, the Court finds that the learned intermediary doctrine should apply in this case.

2. Adequacy of IFU

Defendants argue that "Plaintiff cannot carry his burden to establish that the PerFix Plug IFU was inadequate in terms of its presentation of the risk of the alleged injuries at issue in this case." (ECF No. 89 at PageID #593.) According to Defendants, the IFU described all relevant risks in a way that was consistent with Dr. Tan's understanding, and that Dr. Tan believed the IFU was reasonable and adequate. (*Id.*) In her deposition, Dr. Tan stated that from a practitioner's point of view, she found the risks listed in the IFU to be satisfactory. (ECF No. 89-17 at PageID #1071.) Dr. Tan also testified that she was aware of, and warned Plaintiff of, the complications that he allegedly experienced. (*Id.*) Defendants acknowledge that Dr. Grischkan criticized the "lack of definitions in terms of the potential serious complications" in the PerFix Plug IFU. (ECF No. 89 at PageID #594; ECF No. 89-20 at PageID #1094.) However, Defendants point to Dr. Grischkan's later testimony in which he was asked if he knew what the standard was for which descriptors were included and answered that he "wouldn't know what the standards are." (ECF No. 89 at PageID #594; ECF No. 89-20 at PageID #1095.) According to Defendants, Dr. Grischkan's general criticisms do not outweigh the fact that Plaintiff's implanting physician found the warnings in the IFU to be adequate. (ECF No. 89 at PageID #594.) Therefore, Defendants argue, there can be no dispute of material fact that the warnings for the PerFix Plug were adequate.

Plaintiff argues that the PerFix Plug's IFU is inadequate because it fails to warn about certain risks associated with its use, such as chronic inflammation and chronic pain. (ECF No. 124 at PageID #4847.) Plaintiff points to reports received by Defendants regarding chronic pain

(Case No. 18-md-2846, ECF No. 337-2 at PageID #3868–70) and the fact that Defendants considered adding "pain" to the list of adverse reactions associated with the PerFix Plug but did not do so (*Id.* at PageID #3873). Plaintiff also presents evidence that degradation of polypropylene in the body can cause excessive scarring and fibrosis which can lead to pain (ECF No. 97-15 at PageID #2969), and evidence that the PerFix Plug is susceptible to contracture (ECF No. 97-11 at PageID #2757–58), which was not warned about in the IFU. Plaintiff contends that this evidence shows that the PerFix Plug's IFU was inadequate. The Court agrees that Plaintiff has demonstrated that there is a genuine issue of material fact as to whether the PerFix Plug's IFU was inadequate.

3. Causation

Next, Defendants argue that Plaintiff cannot meet his burden to prove that any inadequate warnings caused his injuries. Defendants claim that "if the treating physician is aware of the risks [a] plaintiff claims to have suffered—regardless of the source of this knowledge—then any failure to warn in the product labeling cannot be the proximate cause of [a] plaintiff's injury as a matter of law." (ECF No. 89 at PageID #595.) As previously noted, Dr. Tan testified that she was aware of the risks of hernia repair with the PerFix Plug, including the risk of the specific injuries Plaintiff claims to have suffered. (*See* ECF No. 89-17 at PageID #1064–65, 1068, 1071, 1073.) Defendants also note that the IFU was not Dr. Tan's only source of information about the PerFix Plug. Defendants emphasize Dr. Tan's "decades of experience with the PerFix Plug [and] the inguinal hernia repair pamphlet from the American College of Surgeons that Dr. Tan gave Plaintiff" that discussed the risks and rates of complications following a hernia repair using mesh. (ECF No. 89 at PageID #597.) According to Defendants, "the record is clear that Dr. Tan knew every relevant risk, negating any chance of Plaintiff carrying his burden on proximate cause for alleged failure to warn." (*Id.*) Defendants further argue that just because Dr. Tan testified that she would have

"*considered* additional hypothetical information if it were somehow available to her, she did not testify that she would have changed her course of treatment in response." (ECF No. 89 at PageID #598 (emphasis in original).)

Plaintiff shows a genuine issue of material fact as to whether the PerFix Plug had inadequate warnings that proximately caused Plaintiff's injuries. During her deposition, Dr. Tan testified that she would have expected the device's IFU to include warnings of any increased risk specific to the PerFix Plug of chronic pain, mesh contraction, and increased fibrotic reaction. (ECF No. 124-1 at PageID #4895–96.) Dr. Tan also testified that any such warnings would have factored into her decision to use the PerFix Plug for Plaintiff's surgery, and she would have discussed those risks with Plaintiff before his surgery. (*Id.* at PageID #4896.) Defendants claim that because Dr. Tan knew that inguinal hernia surgeries carry a risk of chronic pain, any failure to mention chronic pain in the PerFix Plug's IFU could not be the proximate cause of Plaintiff's injuries. But according to Plaintiff, the risks created by certain properties of the PerFix Plug carry a risk of chronic pain above and beyond other types of inguinal hernia repair devices. Dr. Tan testified that if she had known about any increased risk, it would have affected her decisions regarding Plaintiff's course of treatment. There is a genuine issue of material fact as to whether any deficient warnings were the cause of Plaintiff's injuries.

Accordingly, Defendants' motion for summary judgment as to Plaintiff's failure to warn claim is **DENIED**.

D. Negligence Claim

To succeed on a claim of negligence, a plaintiff must prove that the defendant owed the plaintiff a duty of care, that the defendant breached that duty, and that the breach was the actual and legal cause of the injury suffered by the plaintiff. *Adams v. Buffalo Forge Co.*, 443 A.2d 932,

938 (Me. 1982). Under Maine law, actions "predicated upon negligence in the manufacture or design of a product" are not distinguished from other types of negligence actions. *Id.* Defendants claim that Plaintiff's negligence claim relies on the same evidence as his strict liability claims and must fail for the same reasons, reasons which the Court has already addressed. Defendants also reiterate their argument that any alleged defects must be specific to the PerFix Plug, which the Court has also addressed above. Additionally, Defendants argue that "Plaintiff cannot establish the key additional element of a negligence claim that any defect in the PerFix Plug's design, manufacture, or warnings was a result of [Defendants'] negligence." (ECF No. 89 at PageID #599.)

As to Defendants' argument that Plaintiff cannot show that any defect was a result of Defendants' negligence, Plaintiff has presented expert opinions that polypropylene is unsafe for use in the human body, and that the risks of polypropylene, and therefore of the PerFix Plug's design, have been "known by the medical research community and discussed in the scientific literature for years before [Plaintiff] was implanted with the PerFix Plug." (ECF No. 124 at PageID #4853; *see* Case No. 18-cv-1320, ECF No. 71-1.) According to Plaintiff, "[t]his evidence shows intention, recklessness and, at bare minimum, negligence, and creates a genuine dispute of material fact for trial on [Plaintiff's] negligence claim." (ECF No. 124 at PageID #4854.) The Court agrees that Plaintiff has shown that a genuine issue of material fact exists as to his negligence claim. Accordingly, Defendants' motion for summary judgment as to Plaintiff's negligence claim is **DENIED**.

E. Negligence Per Se Claim

Defendants argue that Plaintiff's negligence per se claim must fail because Maine does not recognize an independent cause of action for negligence per se. (ECF No. 89 at PageID #600.)

Plaintiff responds that he does not intend to pursue a standalone negligence per se claim and Defendants' arguments on that point are moot. (ECF No. 124 at PageID #4854.) Therefore, Defendants' Motion for Summary Judgment as to Plaintiff's negligence per se claim is **DENIED AS MOOT**.

F. Gross Negligence Claim

Defendants argue that Maine does not recognize an independent cause of action for gross negligence. (ECF No. 89 at PageID #600.) Additionally, Defendants contend, even if a claim for gross negligence did exist under Maine law, because Plaintiff's argument sounds in failure to warn, a gross negligence claim would fail for the same reasons. (*Id.*) Plaintiff disputes Defendants' interpretation of Maine law, and points to *Goucher v. Dineen* and *Leadbetter v. Family Fun Management, Inc.* In *Goucher*, the Supreme Judicial Court of Maine denied an appeal from a verdict in favor of the plaintiff where the "[p]laintiff's complaint included claims of abuse of process and gross negligence." *Goucher v. Dineen*, 471 A.2d 688, 688 (Me. 1984). In *Leadbetter*, the court denied a motion for summary judgment as to the plaintiff's claims for recklessness, negligence, and gross negligence. *Leadbetter v. Family Fun Management, Inc.*, No. CV-17-173, 2018 WL 1881962 (Me.Super. Feb. 06, 2018).

"In Maine 'gross negligence' has no specific legal meaning in civil proceedings." *Flewelling-Rafford v. Com. Union-York Ins. Co.*, No. CIV.A. CV-00-67, 2001 WL 1715955, at *1 (Me. Super. June 5, 2001) (citing *Beaulieu v. Beaulieu,* 265 A.2d 610, 611-12 (Me.1970)). Maine law does not recognize differing degrees of negligence, and "[t]he concept of 'gross negligence' is 'a synonym for willful and wanton injury' and has been described as 'the equivalent of wanton or reckless misconduct.'" *Leadbetter*, 2018 WL 1881962 at *7 (citing *Bouchard v. Dirigo Fire Ins. Co.*, 114 Me. 361, 365, 96 A. 244, 246 (1916); *Blanchard v. Bass*, 153 Me 354, 361, 139 A.2d

359, 363 (1958)).

Plaintiff's arguments as to the existence of a gross negligence claim are not persuasive. In *Goucher*, the court mentioned the plaintiff's claim of gross negligence a single time. The opinion contains no analysis of a gross negligence claim, but does reject the defendant's challenge to an award of punitive damages. *Goucher*, 471 A.2d at 689. At the time *Goucher* was decided, an award of punitive damages under Maine law was determined by weighing aggravating and mitigating factors, including whether the defendant's conduct was "intentional, wanton, malicious, reckless, or grossly negligent." *Hanover Ins. Co. v. Hayward*, 464 A.2d 156, 158 (Me. 1983) (internal citations omitted). This leads the Court to believe that the "gross negligence" mentioned in *Goucher* was a factor in the award of punitive damages rather than a standalone claim. In *Leadbetter*, the court likewise offered no analysis of gross negligence as a claim in its own right. As Defendants point out, the court recharacterized the plaintiff's claim for gross negligence as "the equivalent of wanton or reckless misconduct" and allowed the claim to proceed. *Leadbetter*, 2018 WL 1881962 at *7. Accordingly, Defendants' motion for summary judgment as to Plaintiff's gross negligence claim is **GRANTED**.

G. Negligent Misrepresentation, Fraud, Fraudulent Misrepresentation, and Fraudulent Concealment Claims

Defendants argue that 1) Plaintiff's fraud and misrepresentation claims collapse into his failure to warn claims, 2) Plaintiff's claim for fraud and fraudulent misrepresentation independently fail, 3) Plaintiff's fraudulent concealment claim fails, and 4) Plaintiff's negligent misrepresentation claim fails. The Court will address each argument in turn.

1. Fraud and Misrepresentation Claims as "Repackaged" Failure to Warn Claims

Defendants claim that Plaintiff's claims related to fraud and misrepresentation are simply a

"repackaging" of his failure to warn claims. Defendants made this argument and relied on the same caselaw in *Milanesi* (*see* Case No. 18-cv-1320, ECF No. 57 at PageID #411–12), and the Court rejected Defendants' argument (Case No. 18-cv-1320, ECF No. 167 at PageID #13631–32). The Court adopts the same reasoning here. The cases cited by Defendants "do[] not stand for the proposition that all fraud-based claims are 'repackaged' failure-to-warn claims if they address the same conduct; the operative issue is whether Plaintiff[is] attempting to do an end-run around the learned intermediary doctrine by focusing on Defendants' statements to [Plaintiff], not [Dr. Tan]." (*Id.* at PageID #13632.)

2. Fraud and Fraudulent Misrepresentation Claims

Defendants next argue that even if Plaintiff's fraud claims do not collapse into his failure to warn claims, Plaintiff cannot establish the elements of a fraud claim. (ECF No. 89 at PageID #602.) According to Maine law:

> To sustain a fraud claim, a party must show: (1) that the other party made a false representation (2) of a material fact (3) with knowledge of its falsity or in reckless disregard of whether it is true or false (4) for the purpose of inducing him to act in reliance upon it, and (5) he justifiably relied upon the representation as true and acted upon it to his damage.

Guiggey, 615 A.2d at 1173. According to Defendants, Plaintiff has not identified any false representations made by Defendants and has in fact admitted that he did not communicate with Defendants whatsoever, nor rely on any alleged misrepresentations. (ECF No. 89 at PageID #602.) Additionally, Defendants claim that Plaintiff has not identified any misrepresentation that Defendants made to Dr. Tan, that she relied on any misrepresentation in deciding how to treat Plaintiff, or how Plaintiff was injured by any such misrepresentation and reliance. (*Id.*) Defendants also argue that Plaintiff cannot bring suit based on an alleged misrepresentation to Dr. Tan. (*Id.* at PageID #603.) In support of this argument, Defendants cite to *Herzog v. Arthrocare*

Corp. which reasoned that surgical tools are not marketed to the general public, but "manufacturers and sellers of surgical products make their representations directly to surgeons and other medical personnel. Thus, the standard patient would not be able to show that he or she had received false statements of fact, let alone that he or she had relied on such statements when deciding to undergo a surgical procedure." *Herzog*, 2003 WL 1785795 at *9. Further, the court disagreed with "the [plaintiffs'] suggestion that a misrepresentation to a surgeon about a surgical tool would support a misrepresentation claim by the patient." *Id.* at *10.

Plaintiff responds that Defendants' arguments are mistaken, and that Defendants made a false representation in the IFU when they failed to disclose the risks discussed in Section III.C.2 of this opinion. (ECF No. 124 at PageID #4856.) Plaintiff argues that "[t]he presence in the scientific literature of the PerFix Plug's risks, the knowledge of those risks by the medical research community, and Defendants' refusal, despite this information, to change the design or marketing of the PerFix Plug create a genuine dispute of material fact as to whether Defendants knew or recklessly disregarded the falsity of their representation in the IFU." (*Id.*) As to Defendants' argument that Plaintiff cannot bring a suit based on an alleged misrepresentation to Dr. Tan, Plaintiff points to *In re Neurontin* to show that "a consumer injured by a fraudulent misrepresentation to his doctor has a claim based on third party reliance." *In re Neurontin Mktg., Sales Pracs. & Prod. Liab. Litig.*, 618 F. Supp. 2d 96, 110 (D. Mass. 2009). Plaintiff claims that Defendants' reliance on *Herzog* is misplaced because that case involved unique claims based on a surgical tool not marketed to the general public. (ECF No. 124 at PageID #4858.) Plaintiff instead likens this case to the scenario discussed in footnote 14 of that opinion, where the court discusses a hypothetical in which "the plaintiff was the actual 'user' of the product, but not the one to whom a misrepresentation was made," such as "the wife of the purchaser of an automobile who is

permitted by him to drive it." *Herzog*, 2003 WL 1785795 at *10, n.14 (internal citation omitted). As opposed to *Herzog*, Plaintiff contends that this case does not involve a unique surgical tool meant for use by a surgeon "but, instead, a medical device implanted by a surgeon but meant for use by a patient, such as [Plaintiff]." (ECF No. 124 at PageID #4858.)

Defendants challenge Plaintiff's reliance on *In re Neurontin*, a case from the District of Massachusetts that was decided based on Massachusetts law. According to Defendants, *Herzog* is dispositive and clearly establishes that Plaintiff cannot bring a misrepresentation claim on Dr. Tan's behalf, nor was he the ultimate "user" of the PerFix Plug. (ECF No. 144 at PageID #5940.) In *Herzog*, the court noted that surgical tools are not marketed to the general public, and "manufacturers and sellers of surgical products make their representations directly to surgeons and other medical personnel." *Herzog*, 2003 WL 1785795 at *9. Similar to the situation in *Herzog*, the PerFix Plug is a medical device not marketed to the general public. The conclusion in *In re Neurontin* was based on Massachusetts law, and this case is based on Maine law. The Court does not agree with Plaintiff's attempt to distinguish *Herzog* by claiming that he was the ultimate user of the PerFix Plug. The Court finds that this case is analogous to *Herzog* and agrees that a misrepresentation to Dr. Tan about the PerFix Plug does not support a misrepresentation claim by Plaintiff. Accordingly, Defendants' motion for summary judgment as to Plaintiff's fraud and fraudulent misrepresentation claim is **GRANTED**.

3. Fraudulent Concealment Claim

Next, Defendants argue that Plaintiff's fraudulent concealment claim must fail. Under Maine law:

> [T]o prevail on a claim for fraudulent concealment, a plaintiff must prove, by clear and convincing evidence, (1) a failure to disclose, (2) a material fact, (3) when a legal or equitable duty to disclose exists, (4) with the intention of inducing another to act or refrain from acting in reliance on the non-disclosure, and (5) the plaintiff

in fact relied upon the non-disclosure to the plaintiff's detriment.

Picher v. Roman Cath. Bishop of Portland, 2013 ME 99, ¶ 3, 82 A.3d 101, 102–03 (internal citations omitted). According to Defendants, Plaintiff's claim for fraudulent concealment must fail because there is no special relationship between the parties, Plaintiff has not identified any intentional material omission by Defendants, Plaintiff has never communicated with Defendants, and Plaintiff cannot bring a fraudulent concealment claim on Dr. Tan's behalf. (ECF No. 89 at PageID #603–04.)

According to Plaintiff, Defendants owe a duty to users of their products and because Plaintiff was implanted with the PerFix Plug, Defendants owed him a duty. (ECF No. 124 at PageID #4859 (citing *Canning v. Broan-Nutone, LLC*, No. CIV 05-15-B-W, 2007 WL 1112355, at *17 (D. Me. Mar. 30, 2007)).) Additionally, Plaintiff points to scientific literature and evidence that the medical research community knew of the PerFix Plug's risks to show that Defendants "knew, or should have known, about the risks of the PerFix Plug and that their failure to adequately warn about those risks would harm patients such as [Plaintiff]." (*Id.* at PageID #4859–4860.) Plaintiff points to that same evidence in arguing that there is a genuine issue of material fact as to whether Defendants acted intentionally in failing to disclose the risks of the PerFix Plug in its IFU. (*Id.* at PageID #4860.) Plaintiff again relies on *In re Neurontin* to support his argument that he can bring a claim based on third party reliance where Dr. Tan "relied on the PerFix Plug's incomplete and inadequate IFU." (*Id.*)

According to Defendants Plaintiff's reliance on *Canning v. Broan-Nutone* to support his claim that Defendants owe a duty to "those who use their products" is misplaced, because *Canning* was a case about negligence and that plaintiff did not bring a fraud claim. (ECF No. 144 at PageID #5942.) Defendants claim that the standard for when they owe a duty is much more stringent for

a fraud claim than it is for a negligence claim. (*Id.*) Defendants also raise the same arguments against Plaintiff's third party reliance claim as discussed above. (*Id.*) The Court agrees with Defendants that the same principles regarding third party reliance as discussed in Section III.G.2 of this opinion also apply to Plaintiff's fraudulent concealment claim. Accordingly, Defendants' motion for summary judgment as to Plaintiff's fraudulent concealment claim is **GRANTED**.

4. Negligent Misrepresentation Claim

Under Maine law, negligent misrepresentation has been defined as follows:

> One who, in the course of his business, profession or employment, or in any other transaction in which he has a pecuniary interest, supplies false information for the guidance of others in their business transactions, is subject to liability for pecuniary loss caused to them by their justifiable reliance upon the information, if he fails to exercise reasonable care or competence in obtaining or communicating the information.

Chapman v. Rideout, 568 A.2d 829, 830 (Me. 1990) (emphasis omitted) (quoting Restatement (Second) of Torts § 552(1) (1977)). According to Defendants, because Plaintiff was not involved in any business transaction with Defendants, has not communicated with Defendants, and has not identified any misrepresentation or false information provided by Defendants, his claim for negligent misrepresentation must fail. (ECF No. 89 at PageID #604–05.)

Plaintiff responds that he is not asserting a claim for negligent misrepresentation for pecuniary loss as described in § 522 of the Restatement. Instead, Plaintiff is asserting a negligent misrepresentation claim for physical harm as described in § 311. (ECF No. 124 at PageID #4861.) According to § 311:

> (1) One who negligently gives false information to another is subject to liability for physical harm caused by action taken by the other in reasonable reliance upon such information, where such harm results
>
> (a) to the other, or
>
> (b) to such third persons as the actor should expect to be put in peril by the

action taken.

(2) Such negligence may consist of failure to exercise reasonable care

(a) in ascertaining the accuracy of the information, or

(b) in the manner in which it is communicated.

Restatement (Second) of Torts § 311 (1965). In response to Defendants' arguments that Plaintiff has not identified any misrepresentations made by Defendants, Plaintiff points to the allegedly false information in the PerFix Plug IFU. (ECF No. 124 at PageID #4862.)

Defendants dispute that a cause of action for negligent misrepresentation arising under § 311 exists in Maine. (ECF No. 144 at PageID #5943.) In *Dow v. Maier*, a Maine trial court stated that § 311 was "potentially applicable" in a medical malpractice case and noted that comment b to § 311 specifically references the physician-patient relationship. *Dow v. Maier*, No. CIV.A. CV-93-276, 2000 WL 33675683, at *3 (Me. Super. Mar. 15, 2000). Comment b states that:

> The rule stated in this Section finds particular application where it is a part of the actor's business or profession to give information upon which the safety of the recipient or a third person depends. Thus it is as much a part of the professional duty of a physician to give correct information as to the character of the disease from which his patient is suffering, where such knowledge is necessary to the safety of the patient or others, as it is to make a correct diagnosis or to prescribe the appropriate medicine. The rule is not, however, limited to information given in a business or professional capacity, or to those engaged in a business or profession. It extends to any person who, in the course of an activity which is in furtherance of his own interests, undertakes to give information to another, and knows or should realize that the safety of the person of others may depend upon the accuracy of the information.

Restatement (Second) of Torts § 311 cmt. b (1965). However, since *Dow*, it appears that no other courts applying Maine law have relied on § 311. Defendants argue that even if this Court were to find that § 311 applies here, Plaintiff never communicated with Defendants, and has not shown that Defendants communicated any false information to Dr. Tan, but instead only criticizes the lack of information in the IFU. (ECF No. 144 at PageID #5943–44.) Instead, Plaintiff simply

criticizes the lack of information in the IFU. (*Id.*) Defendants also claim that Plaintiff has not proven that Dr. Tan relied on any false information and that Plaintiff was injured as a result. (*Id.* at PageID #5944.) Therefore, Defendants contend that a claim for negligent misrepresentation under § 311 still fails.

The Court declines to apply § 311 in this case. The only case Plaintiff cites to in support of his argument that § 311 applies, *Dow v. Maier*, is a 23-year-old trial court decision which stated that § 311 was "potentially applicable" in a medical malpractice case, not a products liability case. *See also Engren v. Johnson & Johnson, Inc.*, No. CV 21-10333-RGS, 2021 WL 4255296, at *5, n.9 (D. Mass. Sept. 17, 2021) (polypropylene mesh products liability case in which federal court declined to apply § 311 when it had not been adopted by the Massachusetts state courts). As for § 522, Plaintiff was not involved in a business transaction with Defendants, nor did he ever communicate directly with Defendants. And for the same reasons stated in Section III.G.2, an alleged misrepresentation to Dr. Tan does not support a claim for negligent misrepresentation by Plaintiff. Accordingly, Defendants' motion for summary judgment as to Plaintiff's negligent misrepresentation claim is **GRANTED**.

H. Breach of Express Warranty Claim

Similar to their arguments regarding Plaintiff's misrepresentation claims, Defendants claim that the breach of express warranty claim must fail because Plaintiff has admitted that he never communicated with Defendants. (ECF No. 89 at PageID #605.) According to Maine law, express warranties are created by:

> (a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.
>
> (b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description. In the

> case of consumer goods sold by a merchant with respect to such goods, the description affirms that the goods are fit for the ordinary purposes for which such goods are used.
>
> (c) Any sample or model which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the sample or model.

11 M.R.S. § 2-313. Defendants claim that Plaintiff has not communicated with Defendants, nor did any affirmation or promise become the basis of any bargain between Plaintiff and Defendants. (ECF No. 89 at PageID #606.) Defendants claim that Plaintiff also has not identified any such communications from Defendants to Dr. Tan. (*Id.*) Therefore, according to Defendants, "Plaintiff has not established even one element of his burden, and summary judgment is appropriate." (*Id.*)

Defendants argue that there can be no express warranty because Plaintiff and Defendants never communicated directly. (ECF No. 89 at PageID #606.) However, as Plaintiff points out, there is not always a need for privity between the parties to prove an express warranty. (ECF No. 124 at PageID #4863.) Even if a plaintiff does not purchase a product directly from a manufacturer, there may still be liability when the plaintiff is "a person who [the manufacturer] might reasonably have expected to use, or be affected by," the product. *Sullivan v. Young Bros. & Co.*, 91 F.3d 242, 250 (1st Cir. 1996). "The need for a plaintiff to show reliance has been obviated in certain cases, such as that in which a surgeon relies upon a manufacturer's express warranties in choosing a medical device for implantation into a plaintiff." *Unicomp, Inc. v. Elementis Pigments, Inc.*, No. CIV97-55-P-H, 1999 WL 1995400, at *23 (D. Me. Feb. 10, 1999).

As for Defendants' argument that Plaintiff has shown no affirmation or promise that became the basis of a bargain between Defendants and Dr. Tan, Plaintiff points to the IFU for the PerFix Plug as "a description of the goods" which "creates an express warranty that the goods shall conform to the description" consistent with § 2-313(b). (ECF No. 124 at PageID #4863.) In *McLaughlin v. Denharco, Inc.*, a sales brochure for a product constituted an express warranty and

the basis for a bargain because the plaintiff viewed and considered promotional materials before deciding to purchase the product over other products. *McLaughlin v. Denharco, Inc.*, 129 F. Supp. 2d 32, 39 (D. Me. 2001). Dr. Tan testified that she expected the information contained in the PerFix Plug's IFU to be both accurate and up to date, and that she relied on manufacturers such as Defendants to provide her with accurate information about the risks of their devices. (ECF No. 124-1 at PageID #4883–84.) Dr. Tan also testified that the risks of a product weigh into her decision to use that product. (*Id.* at PageID #4890, 4892, 4893, 4895.) Therefore, Plaintiff has presented enough evidence to show that a genuine dispute of material fact exists as to whether the IFU created a basis for a bargain. Accordingly, Defendants' motion for summary judgment as to Plaintiff's claim for breach of express warranty is **DENIED**.

I. Breach of Implied Warranty Claim

According to Defendants, because Plaintiff "cannot prove a defect specific to the PerFix Plug that caused his injuries," he cannot show a breach of implied warranty. (ECF No. 89 at PageID #606–07.) Maine law recognizes two types of implied warranty: the implied warranty of merchantability, and the implied warranty of fitness. Plaintiff is only bringing a claim for breach of implied warranty of merchantability. (ECF No. 124 at PageID #4864.) The implied warranty of merchantability is defined as follows:

> (1) Unless excluded or modified by section 2-316, a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind. Under this section the serving for value of food or drink to be consumed either on the premises or elsewhere is a sale.
>
> (2) Goods to be merchantable must at least be such as
>
> (a) Pass without objection in the trade under the contract description; and
>
> (b) In the case of fungible goods, are of fair average quality within the description; and
>
> (c) Are fit for the ordinary purposes for which such goods are used; and
>
> (d) Run, within the variations permitted by the agreement, of even kind,

> quality and quantity within each unit and among all units involved; and
>
> (e) Are adequately contained, packaged and labeled as the agreement may require; and
>
> (f) Conform to the promises or affirmations of fact made on the container or label if any.
>
> (3) Unless excluded or modified by section 2-316, other implied warranties may arise from course of dealing or usage of trade.

11 M.R.S. § 2-314. To show a breach of the implied warrant of merchantability, a plaintiff must show that a product "because of defects either did not work properly or w[as] unexpectedly harmful." *Lorfano v. Dura Stone Steps, Inc.*, 569 A.2d 195, 197 (Me. 1990) (internal quotation omitted). Defendants argue that because Maine law requires a product to be defective for a plaintiff to succeed on a breach of implied warranty claim, and Plaintiff cannot show that the PerFix Plug was defective, his claim for breach of implied warranty fails. (ECF No. 89 at PageID #606.) However, as the Court discussed in Section III.B, there is a genuine issue of material fact as to Plaintiff's defect claim. Accordingly, Defendants' motion for summary judgment as to Plaintiff's breach of implied warranty claim is **DENIED**.

J. Intentional Infliction of Emotional Distress and Negligent Infliction of Emotional Distress Claims

Defendants seek summary judgment on Plaintiff's claims for intentional infliction of emotional distress and negligent infliction of emotional distress. (ECF No. 89 at PageID #607–10.) Plaintiff responds that he does not intend to pursue these claims at trial and Defendants' arguments are moot. (ECF No. 124 at PageID #4865.) Therefore, Defendants' Motion for Summary Judgment as to Plaintiff's intentional infliction of emotional distress and negligent

infliction of emotional distress claims is **DENIED AS MOOT**.

K. Damages

1. Punitive Damages

Defendants argue that they are entitled to summary judgment on certain of Plaintiff's claims for damages. First, Defendants claim that Plaintiff cannot establish that Defendants acted with malice, and therefore cannot recover punitive damages. (ECF No. 89 at PageID #610.) Plaintiff responds that "[w]hen viewed in the light most favorable to Mr. Stinson, the evidence shows that Defendants knew the significant and potentially deadly risks of the PerFix Plug years before Mr. Stinson's implant surgery but disregarded and downplayed those risks and refused to warn surgeons or patients about them." (ECF No. 124 at PageID #4865.) According to Plaintiff, there was enough scientific evidence that heavyweight, small pore polypropylene mesh was causing many complications by the early 2000s. (*Id.* at PageID #4866.) Plaintiff also points to several specific actions or inactions on Defendants' part: (1) Defendants' failure to conduct animal studies involving the PerFix Plug or Marlex Dart; (2) Defendants' failure to conduct post-marketing clinical observational studies regarding the PerFix Plug before Plaintiff's implant; (3) Defendants' failure to change the design of the PerFix Plug; (4) Defendants' failure to include warnings about the risks of migration, chronic pain, and excessive contracture in the IFU; and (5) Defendants' actively minimizing the risk of chronic pain in the PerFix Plug marketing literature. (*Id.* at PageID #4868–70.)

Mere negligence cannot support an award of punitive damages. *Tuttle v. Raymond*, 494 A.2d 1353, 1360 (Me. 1985) (internal citations omitted). To recover punitive damages, a plaintiff must show by clear and convincing evidence that the defendant acted with malice. *Waxler v. Waxler*, 1997 ME 190, ¶ 15, 699 A.2d 1161, 1165. To prove malice, the plaintiff must show that

"the defendant's conduct was motivated by actual ill will or was so outrageous that malice is implied." *Id.* (quoting *Fitzgerald v. Gamester,* 658 A.2d 1065, 1070 (Me.1995)). As described at length above, viewing the facts in the light most favorable to Plaintiff, Plaintiff has shown that a genuine issue of material fact exists as to whether the PerFix Plug contained defects and Defendants knew about those defects prior to Plaintiff's implant surgery. Plaintiff has presented evidence that by the early 2000s the medical research community was aware that heavyweight, small pore polypropylene mesh caused inflammation and scarring, which resulted in chronic pain and other serious complications. (ECF No. 97-11 at PageID #2760.) Plaintiff has also presented evidence that Defendants received reports of an increased risk of chronic pain and considered adding additional warnings to the product but declined to do so. (Case No. 18-md-2846, ECF No. 337-2 at PageID #3868–70; 3873.) Plaintiff has alleged that "Defendants not only sold a defective product, but that Defendants knew the product would cause injuries to users of the product, yet continued to market the product as safe for its intended purpose." *Miller v. Zimmer Biomet Inc.*, No. 2:17-CV-00265-JDL, 2017 WL 5914695, at *7 (D. Me. Nov. 30, 2017), *report and recommendation adopted,* No. 2:17-CV-265-JDL, 2017 WL 6540030 (D. Me. Dec. 20, 2017). Therefore, there is a genuine issue of material fact as to whether Defendants' conduct "was motivated by actual ill will or was so outrageous that malice is implied." *Waxler*, 1997 ME 190, ¶ 15. Accordingly, Defendants' motion for summary judgment as to Plaintiff's claim for punitive damages is **DENIED**.

2. Causation

Defendants next argue that "Plaintiff's damages should likewise be limited to the claimed injuries he supports with causation testimony." (ECF No. 89 at PageID #612.) However, due to ongoing developments regarding Plaintiff's health, the parties have asked that the Court defer

ruling on this issue. Accordingly, the Court **RESERVES JUDGMENT** as to this part of Defendants' motion.

L. Claims Regarding Plaintiff's Current Bard Mesh

In their Motion, Defendants argue that they are entitled to summary judgment on any claims regarding Plaintiff's current Bard Marlex Mesh. (ECF No. 89 at PageID #613–14.) However, due to ongoing developments regarding Plaintiff's health, the parties have asked that the Court defer ruling on this issue. Accordingly, the Court **RESERVES JUDGMENT** as to this part of Defendants' motion.

IV. Objections

Defendants also raise objections to seven exhibits cited in Plaintiff's response brief under Federal Rule of Civil Procedure 56(c)(2). (ECF No. 144-2.) The Court did not rely on any of these exhibits in its summary judgment opinion. Thus, there is no need at this time to resolve Defendants' objections that "the material cited to support or dispute a fact cannot be presented in a form that would be admissible in evidence." Fed. R. Civ. P. 56(c)(2).

V. Conclusion

For the reasons set forth above, Defendants' motion for summary judgment (ECF No. 89) is **GRANTED IN PART, DENIED IN PART, DENIED AS MOOT IN PART**, and **RESERVED IN PART**.

IT IS SO ORDERED.

3/14/2023
DATE

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