**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:**
***Bryan v. C.R. Bard, Inc., et al.***
**Case No. 2:18-cv-1440**

# DISPOSITIVE MOTIONS ORDER NO. 9

Defendants C.R. Bard, Inc. and Davol, Inc. seek summary judgment on each of Plaintiff Jacob Bryan's claims. For the reasons that follow, Defendants' motion (ECF No. 65) is **GRANTED IN PART**, **DENIED IN PART AS MOOT**, and **RESERVED IN PART**.

## I. Background[1]

Plaintiff's case is the fourth bellwether case 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 Florida law claims against Defendants based on the implantation of Defendants' 3DMax hernia mesh device. (ECF No. 4.)

[1] Docket citations are to the docket in the instant case, Case No. 18-cv-1440, unless otherwise noted.

The 3DMax is "a pre-formed, three-dimensional piece of curved polypropylene mesh designed specifically to fit the inguinal anatomy" and is used in the laparoscopic repair of inguinal hernias. (ECF No. 65 at PageID #943.) It is constructed with "knitted 7.5 mil polypropylene, which allows the device to stretch in both directions." (*Id.* at PageID #944.) The 3DMax has a curved top edge and a straight bottom edge with a notch that aligns with the external iliac vessels, and the edges are "ultrasonically welded and s[e]mi-rigid to facilitate placement and positioning." (*Id.*) The 3DMax was originally developed by a French physician in the mid-1990s as the Marlex 3P mesh. (*Id.*) Medium and Large sizes of the device were then introduced in the United States in 1999 through a "no-510(k) rationale" relying on "Bard's Visilex Mesh, Usher's Marlex Tubular Mesh, and Bard Mesh devices."[2] (*Id.*) In 2001–2002, Defendants extended the 3DMax product line to include an Extra-Large size, also under the no-510(k) process. (*Id.* at PageID #945.) After "the addition of the medial marker and changes to the medial marker material supplier," Defendants submitted a 510(k) application for the 3DMax in 2008. (*Id.*) The FDA issued a 510(k) clearance for all sizes of the 3DMax. (*Id.*) According to Defendants, in its almost 25 years on the market, the 3DMax has been used successfully in hundreds of thousands of hernia repair surgeries and is "the number one selling laparoscopic inguinal product line on the market and has been for many years, including at the time of Plaintiff's implant." (*Id.*)

The parties disagree as to the relevance of Plaintiff's medical history. Along with information about his 2012 implant surgery and subsequent complications, Defendants describe several emergency room visits from the months before the implant surgery, and appointments and treatments for back, hip, and leg issues that occurred between Plaintiff's implant surgery and his

[2] The 510(k) process has been described previously in this MDL in Motions *in Limine* ("MIL") Order No. 4 (18-cv-1509, ECF No. 355 at PageID #18767–69).

2017 explant surgery. (ECF No. 65 at PageID #945–50.) Plaintiff's response includes portions of his medical history starting with the 2012 implant surgery. (ECF No. 85 at PageID #3309–3315.)

Plaintiff Jacob Bryan is a 38-year-old male who claims to suffer from chronic groin pain, testicular pain, dysejaculation, and depression. (*Id.* at PageID #3308.) According to Defendants, Plaintiff's pre-implant medical history is significant and relevant to showing his "long history of chronic pain" and testicular pain, among other things. (ECF No. 65 at PageID #945.) According to Defendants, as early as March 2002 Plaintiff "underwent a CT [scan] of his abdomen and an ultrasound of his pelvis due to complaints of abdominal pain in his lower right quadrant and a history of right-sided testicular pain," and the ultrasound showed "a small amount of fluid on the right side of the scrotum and a small developmental defect on the left." (*Id.* at PageID #945–46.) Defendants claim that no medical records were available from April 2002 through May 2010, nor from May 2018 through November 2022. (*Id.* at PageID #946.)

In August of 2012, Plaintiff visited the emergency room for lower back pain and reported a two-month history of intermittent lower back pain that had become constant and was gradually worsening. (ECF No. 65-2 at PageID #1044–45.) On September 23, 2012, Plaintiff again visited the emergency room, this time for worsening left groin pain. (*Id.* at PageID #1045.) He reported nausea, vomiting, abdominal pain, and testicular pain. (*Id.*) An exam showed tenderness but no mass or swelling in his left testicle, and ultrasound showed a defect in his left testicle, unchanged since 2002. (*Id.*) Plaintiff returned to the emergency room on October 9, 2012, and reported sharp left inguinal pain at night. (*Id.*) An inguinal hernia was suspected, but not identified. (*Id.*)

On October 22, 2012, Plaintiff saw Dr. Angel Caban, a general surgeon, for complaints of abdominal pain that was "more prominent when straining, walking and sitting." (ECF No. 65-7 at PageID #1331.) Dr. Caban diagnosed Plaintiff with a small reducible left inguinal hernia. (*Id.* at

PageID #1333.) Dr. Caban determined that Plaintiff was a good candidate for laparoscopic hernia repair with mesh and discussed the risks of the procedure with Plaintiff. (*Id.*)

On November 20, 2012, Dr. Caban performed a laparoscopic inguinal hernia repair on Plaintiff using a Large 3DMax mesh with no complications. (ECF No. 65-10.) Dr. Caban looked for direct and indirect defects and fixated the mesh with absorbable tacks; he reported that the surgical outcome was "excellent" and the 3DMax performed as he intended and expected. (ECF No. 65-8 at PageID #1348, 70:5–71:14.) After his post-surgery follow-up appointment on December 10, 2012, Dr. Caban reported that Plaintiff's "postoperative period was unremarkable, . . . his pre surgical symptoms have resolved[, and h]e has progressively returned to his daily activities with no complications." (ECF No. 65-10.)

On December 13, 2012, three days after his post-surgery follow-up appointment, Plaintiff visited the emergency room for lower left back pain radiating to the left calf, which he had been experience for about a month. (ECF No. 65-11 at PageID #1357.) He reported no abdominal pain. (*Id.*) The emergency room report described Plaintiff's reported history of back pain from "several years ago when on a job where he was unloading trucks." (*Id.*) Plaintiff was diagnosed with lumbar strain with left sided sciatica and sacroiliitis, and was prescribed a muscle relaxant and pain medication. (*Id.* at PageID #1358–59.) Plaintiff returned to the emergency room on January 28, 2013, again for lower back pain that had worsened and was radiating down his left leg. (ECF No. 65-2 at PageID #1046.)

On February 12, 2013, Plaintiff saw Dr. Machek for lower back pain and reported having slipped and fallen while fishing. (*Id.*) Dr. Machek diagnosed Plaintiff with lumbar strain with radiculopathy. (*Id.*) At another visit with Dr. Machek on March 28, 2013, Plaintiff reported that his pain had not changed. (*Id.*) On July 9, 2013, Plaintiff again reported continuing lower back

pain to Dr. Machek, and planned to do lumbar spine physical therapy. (*Id.*)

On September 10, 2013, Plaintiff again visited the emergency room because of back pain and reported that he slipped and fell. (*Id.*) He also reported blood in his urine. (*Id.*) Plaintiff was diagnosed with musculoskeletal strain, radiculopathy, nephrolithiasis, and back pain. (*Id.*) In September of 2015, Plaintiff suffered an accident at work which caused pain in his right lower back and hip. (*Id.* at PageID #1047.) After the accident the plan was for Plaintiff to undergo physical therapy, which he began sometime around late October or early November of 2015. (*Id.* at PageID #1047–48.) At follow-up appointments after the accident, Plaintiff reported episodes of numbness in his legs. (*Id.*)

In the summer of 2015, while walking on the beach with friends Plaintiff suddenly experienced pain in his left testicle, inner thigh, and lower left abdomen. He testified that this was the first time since the implant surgery that he had experienced pain in his groin, testicles, or abdominal region. (ECF No. 65-12 at PageID #1368, 128:20–129:21.) He described the pain as a "squeeze in [his] left testicle" that lasted for "a few minutes and then it subsided a little bit," as well as a burning sensation in his lower left abdomen and numbness in his left inner thigh that lasted until his explant surgery in 2017. (*Id.* at PageID #1368, 128:24–131:22.)

On November 20, 2015, Plaintiff underwent an MRI that showed "1) L2-3 large disc herniation with extrusion with severe canal stenosis with recess narrowing without foraminal stenosis; 2) L1-2 disc herniation with extrusion, moderate to severe left-sided canal stenosis; 3) T11-12 disc bulge/disc herniation with canal stenosis; 4) Disc bulges at L3-4 and L4-5 with canal stenosis and foraminal narrowing; congenitally short pedicles present with congenital spinal stenosis identified with superimposed acquired disc bulges present [which were chronic;] 5) L5-S1 disc bulge/facet hypertrophy with mild canal stenosis with facet disease present." (ECF No. 65-2

at PageID #1048.) Throughout 2015 and 2016 Plaintiff sought treatment for his ongoing and worsening back pain and declined surgical intervention. (*Id.* at PageID #1048–50.) At an appointment for his back pain in March of 2016, Plaintiff denied any problems of sexual dysfunction. (*Id.* at PageID #1050.)

On April 1, 2017, Plaintiff visited the emergency room and reported that he had been experiencing left groin and testicular pain for about a month and described the pain as 10/10 at times. (*Id.*) An ultrasound did not show torsion, a mass, epididymitis, or a hernia. (*Id.* at PageID #1050–51.) On July 6, 2017, Plaintiff again visited the emergency room with complaints of burning lower left abdominal pain and groin pain. (*Id.* at PageID #1051.) Plaintiff claimed that these symptoms began after his 2012 hernia surgery but had gradually worsened the night before. (*Id.*) He denied any testicular pain, redness, or swelling. On August 22, 2017, Plaintiff saw a surgeon, Dr. Rose, and reported having had pain since his 2012 surgery in his left groin which radiated to his thigh. (*Id.*) The examination showed no hernia, and Dr. Rose and Plaintiff discussed surgical options. (*Id.*) At a follow-up visit on October 10, 2017, Dr. Rose and Plaintiff discussed performing exploratory surgery and potential partial removal of the 3DMax mesh. (*Id.*)

On October 20, 2017, Plaintiff underwent a partial explant surgery. (ECF No. 65-14.) In Dr. Rose's surgical report, he noted that the 3DMax "actually looked like it laid fairly flat against the peritoneum," with a "buckle in the midpoint [which] seemed to have a little bit more dense scar." (*Id.* at PageID #1383.) Other than the scarring, "[t]here were no obvious signs of an abnormality." (*Id.*) He noted "an area of dense adhesions that seemed to involve the nerve running in that area," which was "carefully freed to ensure that there was no damage to the nerve." (*Id.*) Dr. Rose observed "no sign of overt injury" and "no signs of bleeding[,] . . . hernia sac or signs of weakness that would become [a] hernia in the near future." (*Id.*) Dr. Rose reported that there were

no complications with the surgery. (*Id.*) Dr. Rose testified that he believed a nerve was involved in the "buckle of the 3DMax and the dense adhesions." (ECF No. 85-4 at PageID #3426, 34:3–6.) He also testified that he thought that "the adhesions or the scar tissue on [Plaintiff's] [spermatic] cord caused his [pre-explant] symptoms." (*Id.* at 34:16–19.)

Plaintiff claims to have "chronic left groin and left testicular pain that has significantly affected his life." (ECF No. 85 at PageID #3313.) Between November 7, 2017, and January 11, 2023, he "saw no doctors for any reason related to the 3DMax implant." (ECF No. 85-7 at PageID #3455, 37:8–11.) In January of 2023 he went back to see Dr. Rose because of left testicular pain; he had planned to discuss his problems with painful ejaculation but ultimately did not discuss that at the January 2023 appointment. (*Id.* at PageID #3455–56, 37:12–39:20; 41:14–23.) Plaintiff had scheduled another groin exploratory surgery to "ligate the ilioinguinal nerve," but the surgery was cancelled by the surgical facility. (ECF No. 85 at PageID #3313.) Plaintiff also saw Dr. Al-Monsour in 2023, but he did not discuss any painful ejaculation or sexual dysfunction. (ECF No. 65-13 at PageID #1375, 66:2–18.) Plaintiff "continues to suffer chronic groin pain, testicular pain, dysejaculation, and depression." (ECF No. 85 at PageID #3308.)

The crux of Plaintiff's claims is that Defendants knew of certain risks presented by the 3DMax 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 3DMax incites a greater and longer inflammatory response than it should, causing scarring, fibrosis, chronic pain, and other injuries. (*Id.* at PageID #3318.) According to Plaintiff, Defendants "knew the significant risks of the 3DMax before [Plaintiff]'s implant surgery in 2012 but disregarded and downplayed those risks and refused to warn surgeons or patients about them." (*Id.* at PageID #3308.)

On January 21, 2019, Plaintiff filed his amended complaint in which he raises claims for

(1) defective design (strict liability); (2) failure to warn (strict liability); (3) manufacturing defect (strict liability)[3]; (4) negligence; (5) negligence per se; (6) gross negligence; (7) state consumer protection laws; (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 misrepresentation; (14) fraudulent concealment; and (15) punitive damages. (ECF No. 4.) Defendants seek summary judgment on all claims. (ECF No. 65.)

## 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

[3] Plaintiff has agreed to withdraw his claims for manufacturing defect, negligence per se, and state consumer protection law claims. (ECF No. 65-4; ECF No. 85 at PageID #3319.) In his response to the motion for summary judgment, he also withdrew his claim for negligent infliction of emotional distress. (*Id.*)

action would have been filed in Florida absent Case Management Order No. 2 permitting direct filing with this Court. (ECF No. 4 at PageID #36.) Thus, Florida choice-of-law rules apply.

Under Florida choice-of-law rules, Florida law applies here. Florida applies the Restatement (Second) of Conflict of Laws approach, the most significant relationship analysis, to tort-law claims, including product-liability claims. *Bishop v. Fla. Specialty Paint Co.*, 389 So.2d 999, 1001 (Fla. 1980); *Tune v. Philip Morris Inc.*, 766 So.2d 350, 353 (Fla. Dist. Ct. App. 2000). Here, all pertinent events took place in Florida—Plaintiff lives there, the surgeries occurred there, and any alleged injuries occurred there. *See* Restatement (Second) of Conflict of Laws § 145(2) (1971). The parties do not dispute the application of Florida 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 that genuine disputes of material fact exist for trial. Defendants raise arguments for each of Plaintiff's claims: failure to warn; design defect; negligence; gross negligence and punitive damages; negligent misrepresentation, fraud, fraudulent misrepresentation, and fraudulent concealment; breach of express and implied warranty; intentional infliction of emotional distress; and negligent infliction of emotional distress. (ECF No. 65.)

### A. Failure to Warn Claim

Defendants first argue that Plaintiff's failure to warn claim fails because (1) Defendants had no duty to warn of obvious or known risks and the 3DMax Instructions for Use ("IFU") was adequate; and (2) Plaintiff cannot establish that an inadequate warning proximately caused his injuries. (ECF No. 65 at PageID #957–63.) Under Florida law, "[s]trict liability and negligent failure to warn cases boil down to three elements that Plaintiff must prove: 1) that the warnings accompanying the item were inadequate; 2) that the inadequacy of the warnings proximately caused Plaintiff's injury; and 3) that Plaintiff in fact suffered an injury by using the product." *Colville v. Pharmacia & Upjohn Co. LLC*, 565 F. Supp. 2d 1314, 1320 (N.D. Fla. 2008) (collecting Florida cases).

#### 1. Adequacy of Warning

In this case, "the issue is whether the warning provided to the physician is adequate." *Rounds v. Genzyme Corp.*, 440 F. App'x 753, 755 (11th Cir. 2011); *see also Beale v. Biomet, Inc.*, 492 F. Supp. 2d 1360, 1366 (S.D. Fla. 2007). This is because the learned intermediary doctrine

applies under Florida law. *Beale*, 492 F. Supp. 2d at 1335. Therefore, "the duty to warn is directed to physicians rather than patients under the 'learned intermediary' doctrine." *Hoffmann-La Roche Inc. v. Mason*, 27 So.3d 75, 77 (Fla. Dist. Ct. App. 2009). "[T]o warn adequately, the product label must make apparent the potential harmful consequences. The warning should be of such intensity as to cause a reasonable man to exercise for his own safety caution commensurate with the potential danger." *Scheman-Gonzalez v. Saber Mfg. Co.*, 816 So.2d 1133, 1139 (Fla. Dist. Ct. App. 2002) (quoting *Am. Cyanamid Co. v. Roy*, 466 So.2d 1079, 1082 (Fla. Dist. Ct. App. 1984)). But "[w]hen a warning is designed to inform a 'learned intermediary,' it is somewhat easier to establish the adequacy of the warning because it will be read and considered by a trained expert." *Hayes v. Spartan Chem. Co., Inc.*, 622 So.2d 1352, 1354 (Fla. Dist. Ct. App. 1993).

Typically, a plaintiff must provide expert testimony to demonstrate that a defendant's warnings were in adequate; otherwise, summary judgment on plaintiff's failure to warn claim is appropriate. *Nunez v. Coloplast Corp.*, 461 F. Supp. 3d 1260, 1266 (S.D. Fla. 2020); *see also Upjohn Co. v. MacMurdo*, 562 So.2d 680, 683 (Fla. 1990) ("Therefore, the adequacy or inadequacy of the warning to inform a physician must, except in the more obvious situations, be proved by expert testimony."). On the other hand, "[t]he sufficiency and reasonableness of the warnings are questions of fact best left for the jury unless the warnings are accurate, clear, and unambiguous." *Thomas v. Bombardier Recreational Prods, Inc.*, 682 F. Supp. 2d 1297, 1300 (M.D. Fla. 2010) (citing *Scheman-Gonzalez*, 816 So.2d at 1139–40). In other words, "the adequacy of the warnings can be resolved as a matter of law if they are 'accurate, clear, and unambiguous.'" *Nunez*, 461 F. Supp. 3d at 1260 (quoting *Farias v. Mr. Heater, Inc.*, 757 F. Supp. 2d 1284, 1293 (S.D. Fla. 2010)).

Defendants argue that the warnings for the 3DMax were not inadequate because they had

no duty to warn of obvious or known risks. (ECF No. 65 at PageID #958–60.) However, as the Court explains in Section III.A.2 below, Plaintiff has not established that any allegedly inadequate warning caused his injuries. Therefore, the Court need not delve into the adequacy of the warnings.

**2. Causation**

Defendants next argue that Plaintiff's failure to warn claim fails because he cannot show that any inadequate warning was the proximate cause of his injuries. (ECF No. 65 at PageID #960–963.) To support this argument, they rely on Dr. Caban's testimony that he did not rely on the 3DMax IFU in selecting the device for Plaintiff's hernia repair. (*Id.*) In his deposition, Dr. Caban testified that he not only did not rely on the IFU in selecting the 3DMax for Plaintiff's operation, but that he had never even seen or read the IFU. (ECF No. 65-8 at PageID #1338, 28:6–29:17.)

As Defendants point out, to establish causation for a failure to warn claim, Plaintiff must show that Dr. Caban would not have used the product had adequate warnings been provided. *Salinero v. Johnson & Johnson*, 400 F. Supp. 3d 1334, 1344–45 (S.D. Fla. 2019), *aff'd*, 995 F.3d 959 (11th Cir. 2021). "Where a physician fails to review the warnings issued by the manufacturer, proximate cause cannot be established." *Fields v. Mylan Pharms., Inc.*, 751 F. Supp. 2d 1260, 1263 (N.D. Fla. 2009) ("Even if the warnings were deficient, however, Dr. Paek's testimony establishes that the phenytoin labeling and warnings played no role in the physician's decision to prescribe phenytoin to Plaintiff. Moreover, different labeling would not have led Dr. Paek to decide not to prescribe the drug to Plaintiff because Dr. Paek never consulted the labeling in the first place."); see also *Fitzsimmons v. Biomet Orthopedics, Inc.*, No. 219CV182FTM29NPM, 2021 WL 211267, at *5 (M.D. Fla. Jan. 21, 2021); *Rydzewski v. DePuy Orthopaedics, Inc.*, No.

11-80007-CIV, 2012 WL 7997961, at *7 (S.D. Fla. Aug. 14, 2012).

Plaintiff responds that Dr. Caban's failure to review the IFU is not dispositive, and that his failure to warn claim should survive summary judgment. (ECF No. 85 at PageID #3327.) Plaintiff first argues that "Defendants identify no Florida state court that has adopted their extreme position regarding a surgeon's failure to review an IFU." (ECF No. 85 at PageID #3327.) But the cases Plaintiff cites in support of his argument are based on Georgia law (*Coker v. C.R. Bard, Inc.*, No. 1:13-CV-515-TWT, 2021 WL 6932559 (N.D. Ga. Mar. 29, 2021); *In re Bard IVC Filters Prod. Liab. Litig.*, No. CV-16-00782-PHX-DGC, 2018 WL 1256768, (D. Ariz. Mar. 12, 2018)), Pennsylvania law (*Moultrie v. Coloplast Corp.*, No. CV 18-231, 2020 WL 1249354 (W.D. Pa. Mar. 16, 2020)), Texas law (*In re DePuy Orthopaedics, Inc., Pinnacle Hip Implant Prod. Liab. Litig.*, 888 F.3d 753 (5th Cir. 2018)), and Arkansas law (*Fuller v. Ethicon Inc.*, No. 4:20-CV-00800-BRW, 2020 WL 4043517 (E.D. Ark. July 17, 2020)). Although Defendants do not cite to Florida state court cases, this Court finds persuasive the cases Defendants cite from Florida federal courts applying Florida law. *See Salinero*, 400 F. Supp. 3d 1334; *Fields*, 751 F. Supp. 2d 1260; *Fitzsimmons*, 2021 WL 211267; *Rydzewski*, 2012 WL 7997961.

In support of his argument that Dr. Caban's failure to read the IFU is not dispositive, Plaintiff points to *In re DePuy Orthopaedics, Inc.*, in which the surgeon did not read the IFUs for the product at issue, but he testified that he relied on other information provided by the company in making his decisions. *In re DePuy Orthopaedics*, 888 F.3d at 776–77. He testified that he "got his information from a DePuy consensus panel, a brochure that his DePuy representative gave him, word of mouth, from his partners, and from the literature [and] scientific journals." *Id.* (internal quotations omitted). That is not the case here. Dr. Caban testified that he not only did not read the IFU, but he did not base his treatment decisions on information he received from sales

representatives. (ECF No. 65-8 at PageID #1341, 41:2–12; #1338, 26:6–20 ("So whatever influence the rep has, it has absolutely zero influence in my clinical decisions. Zero.") (objections omitted).) Plaintiff also points to *Moultrie v. Coloplast Corp.*, but in that case the surgeon "had reviewed the IFU at some point prior to [the plaintiff's] surgery" and "testified that he was bothered by the general warnings in the IFU." *Moultrie*, 2020 WL 1249354, at *13. The other cases that Plaintiff relied on can also be distinguished. *See Fuller*, 2020 WL 4043517, at *2 (finding that "[t]he fact that [the surgeon] did not read the insert before this particular surgery does not change the fact that he may have relied on the information that he read in the past"); *Coker*, 2021 WL 6932559, at *6 (explaining that the court's causation analysis is under Georgia law); *In re Bard IVC Filters*, 2018 WL 1256768, at *3 n.4 (finding a genuine factual dispute where the parties disputed whether the surgeon had read the IFU; he had testified that he sometimes reads IFUs but did not recall if he had read that device's IFU specifically).

Here, Dr. Caban testified clearly and unambiguously that he did not rely on the 3DMax IFU. During his deposition, he testified:

> Q. Doctor . . . can you tell me what this is?
>
> A. I [have] never seen this before, but it looks like instructions for use for 3DMax mesh.
>
> Q. And when you say you have never seen it before, I think we were talking about those little tiny booklets that come with the product. This is—this is a larger version of the same thing. Does this appear to be the tiny booklet that comes with the 3DMax mesh, just in larger form?
>
> A. I have no idea.
>
> Q. Okay. Have you ever read the instructions for use for the 3DMax mesh?
>
> A. No, I have not.
>
> . . .
>
> Q. Okay. And fair to say that sitting here today you have no recollection of having reviewed the instructions for use document pertaining to the 3DMax?
>
> A. Yes.
>
> Q. Okay. Given that you don't recall having reviewed this document prior to Mr.

> Bryan's surgery in 2012, would it be fair to say that you didn't rely on the instructions for use document in selecting to use the 3DMax for Mr. Bryan's repair?
>
> A. Yes.
>
> . . .
>
> Q. Okay. Given that you can't—you have no recollection of having reviewed the instructions for use document, would it be fair to say that if there were additional language or different types of warnings in that document that that would have no effect on your decision-making process whether or not to use the 3DMax, true?
>
> A. True.

(ECF No. 65-8 at PageID #1338, 28:6–29:17; #1345, 54:16–55:2, 55:22–56:5 (objections omitted).) Dr. Caban confirmed that even if there had been additional warnings in the IFU, it would not have affected his decision to use the 3DMax because he did not read or rely on the IFU. Therefore, Plaintiff cannot demonstrate that any inadequate warnings were the cause of his injuries. Accordingly, Defendants' motion for summary judgment as to Plaintiff's strict liability failure to warn claim is **GRANTED**.

**B. Strict Liability Design Defect**

Defendants next argue that Plaintiff's strict liability design defect claim fails. (ECF No. 65 at PageID #963–75.) The Court **RESERVES RULING** on this portion of Defendants' motion for summary judgment.

**C. Negligence**

Defendants argue that Plaintiff's negligence claim should be "subsumed under Plaintiff's defective design and failure to warn claims." (*Id.* at PageID #976.) The Court **RESERVES RULING** on this portion of Defendants' motion for summary judgment.

**D. Gross Negligence and Punitive Damages**

Defendants next argue that Plaintiff cannot meet his burden to establish a claim for gross negligence and/or punitive damages. (*Id.* at PageID #976–78.) The Court **RESERVES RULING**

on this portion of Defendants' motion for summary judgment.

### E. Negligent Misrepresentation, Fraud, Fraudulent Misrepresentation, and Fraudulent Concealment

Defendants next argue that Plaintiff's fraud-based claims "collapse into his failure to warn claims," and must fail for the same reasons. (*Id.* at PageID #979–981.) Although the Court rejected this argument in the second bellwether case, *Milanesi, et al. v. C.R. Bard, Inc., et al.* (Case No. 18-cv-1320, Dispositive Motions Order No. 3, ECF No. 167 at PageID #13631–32), Defendants argue that the claims here differ because "no specific representations were made to Dr. Caban, and Dr. Caban explicitly testified that he did not rely on any representations from [Defendants] in his treatment of Plaintiff." (ECF No. 65 at PageID #979.) The Court finds no more merit in this reasoning than it did in *Milanesi*, and rejects the argument that Plaintiff's fraud-based claims collapse into his failure to warn claims. However, Plaintiff's fraud-based claims fail for other reasons, stated below.

#### 1. Fraud, Fraudulent Misrepresentation, and Fraudulent Concealment

Under Florida law, "a claim for fraudulent concealment is the same as one for fraudulent misrepresentation." *Dugas v. 3M Co.*, 101 F. Supp. 3d 1246, 1253 (M.D. Fla. 2015) (citing *Grills v. Philip Morris USA, Inc.,* 645 F. Supp. 2d 1107, 1119 (M.D. Fla.2009)). For a claim of fraudulent misrepresentation or concealment, a plaintiff must show:

> (1) a misrepresentation of material fact or suppression of the truth;
>
> (2) [a] knowledge of the representor of the misrepresentation, or [b] representations made by the representor without knowledge as to either the truth or falsity, or [c] representations made under circumstances in which the representor ought to have known, if he did not know, of the falsity thereof;
>
> (3) an intention that the representor induce another to act on it; and
>
> (4) resulting injury to the party acting in justifiable reliance on the representation.

*Dugas*, 101 F. Supp. 3d at 1254 (quoting *Jones v. Gen. Motors Corp.*, 24 F. Supp. 2d 1335, 1339

(M.D. Fla. 1998)). According to Defendants, Plaintiff "cannot present any evidence that a material misrepresentation was made to Dr. Caban, let alone one that was false." (ECF No. 65 at PageID #980.) Defendants also claim that Plaintiff failed to prove that Dr. Caban relied on any alleged misrepresentation. (*Id.*) Plaintiff responds that he can support his fraud-based claims based on Defendants' suppression of the truth regarding the 3DMax's risks, and that he has presented sufficient evidence of Dr. Caban's reliance. (ECF No. 85 at PageID #3352–53.)

As with the failure to warn claim, Dr. Caban's testimony is key to determining whether there is a genuine issue of material fact as to Plaintiff's fraud, fraudulent misrepresentation, and fraudulent concealment claims. The following testimony shows that Dr. Caban did not rely on any representations, including the IFU or statements from Defendants' sales representatives, in selecting the 3DMax for Plaintiff's hernia repair:

> Q. Okay. And fair to say that sitting here today you have no recollection of having reviewed the instructions for use document pertaining to the 3DMax?
>
> A. Yes.
>
> Q. Okay. Given that you don't recall having reviewed this document prior to Mr. Bryan's surgery in 2012, would it be fair to say that you didn't rely on the instructions for use document in selecting to use the 3DMax for Mr. Bryan's repair?
>
> A. Yes.
>
> . . .
>
> Q. Okay. At the end of the day, when you select to use a product, it's fair to say that you use—you're basing that on your own clinical judgment as opposed to what a sales representative would be presenting to you?
>
> A. Absolutely.
>
> Q. Okay. Have any of the Bard or Davol sales representatives influenced you to use the 3DMax versus your personal experience with the product?
>
> A. No.
>
> . . .
>
> Q. Okay. And has Brad or Austin or anyone else from Bard ever t[old] you that you were doing your surgeries incorrectly?
>
> A. Absolutely not. . . . And if they did, that's not their problem. I do the surgeries based on my own training, not on what any rep will say. Not only Bard or Lynx or

> anybody else. I have plenty of reps that will come to my office to offer their products, and I don't take them because I don't think they're good products. So whatever influence the rep has, it has absolutely zero influence in my clinical decisions. Zero.

(ECF No. 65-8 at PageID #1345, 54:16–55:2; #1341, 41:2–12; #1338, 26:6–20 (objections omitted).) There is no genuine issue of material fact as to the reliance issue. Dr. Caban specifically testified that if there were additional warnings or language in the IFU, it would have not affected his decision to use the 3DMax because he did not read or rely on the document. (*Id.* at PageID #1345, 55:22–56:5.) Dr. Caban also made clear that representations made by sales representatives "ha[ve] absolutely zero influence in [his] clinical decisions." (*Id.* at PageID #1338, 26:12–20.) Accordingly, Defendants' motion for summary judgment as to Plaintiff's fraud, fraudulent concealment, and fraudulent misrepresentation claims is **GRANTED**.

**2. Negligent Misrepresentation**

To prevail on a claim for negligent misrepresentation under Florida law, Plaintiff must show that:

> (1) the defendant made a misrepresentation of material fact that he believed to be true but which was in fact false;
>
> (2) the defendant was negligent in making the statement because he should have known the representation was false;
>
> (3) the defendant intended to induce the plaintiff to rely and [sic] on the misrepresentation; and
>
> (4) injury resulted to the plaintiff acting in justifiable reliance upon the misrepresentation.

*Specialty Marine & Indus. Supplies, Inc. v. Venus*, 66 So.3d 306, 309 (Fla. Dist. Ct. App. 2011) (alteration in original) (quoting *Simon v. Celebration Co.*, 883 So.2d 826, 832 (Fla. Dist. Ct. App. 2004)). Plaintiff's negligent misrepresentation claim fails for the same reason his fraudulent misrepresentation claim fails. Dr. Caban's testimony makes clear that he did not rely on any representations from Defendants in selecting the 3DMax, therefore there is no genuine issue of

material fact as to whether a negligent misrepresentation could have caused Plaintiff's injuries. Accordingly, Defendants' motion for summary judgment as to Plaintiff's negligent misrepresentation claim is **GRANTED**.

**F. Breach of Express and Implied Warranty**

Defendants next challenge Plaintiff's claims for breach of express warranty and breach of implied warranty. (ECF No. 65 at PageID #981–82.) For a breach of express warranty claim, Plaintiff must show:

> (1) a covered defect existed in the product at the time of sale;
> (2) notice of the defect was given within a reasonable time after the defect was discovered; and
> (3) Defendant[s] w[ere] unable to repair the defect.

*McLaughlin v. Monaco RV LLC*, No. 8:14-CV-703-T-36TGW, 2015 WL 5355465, at *3 (M.D. Fla. Sept. 14, 2015) (internal citations omitted). For a breach of implied warranty claim, he must show that:

> (1) he was a foreseeable user of the product;
> (2) the product was being used in the intended manner at the time of the injury;
> (3) the product was defective when transferred from the warrantor; and
> (4) the defect caused his injury.

*McCarthy v. Fla. Ladder Co.*, 295 So. 2d 707, 709 (Fla. Dist. Ct. App. 1974). As a preliminary matter, "[t]he law of Florida is that to recover for the breach of a warranty, either express or implied, the plaintiff must be in privity of contract with the defendant." *T.W.M. v. Am. Med. Sys., Inc.*, 886 F. Supp. 842, 844 (N.D. Fla. 1995) (internal citations omitted).

Defendants argue that both claims fail because there is no privity between Plaintiff and Defendants, therefore no claim for breach of warranty exists under Florida law. (ECF No. 65 at PageID #981–82.) Defendants point to cases in which the courts found no privity because a

medical device was only available to the plaintiff through a physician, rather than being purchased directly from manufacturers. (*Id.* at PageID #981.) In response, Plaintiff argues that privity is not required here and that "Florida law does not impose a privity requirement in cases like [Plaintiff]'s, where the plaintiff is a third-party beneficiary of the warranty." (ECF No. 85 at PageID #3353–54.) In support of this argument Plaintiff points to *Merino v. Ethicon*, a case in which the court denied a motion to dismiss, not a motion for summary judgment, as to the plaintiff's suit against a medical device manufacturer because she "minimally allege[d] she [wa]s a third-party beneficiary of [the d]efendants' warranties." *Merino v. Ethicon Inc.*, 536 F. Supp. 3d 1271, 1286 (S.D. Fla. 2021).

Although Plaintiff cites to one case that supports his argument that he is a third-party beneficiary, and therefore can bring a breach of warranty claim against Defendants, a strong majority of other cases, including cases that came after *Merino*, have ruled differently. *See T.W.M.*, 886 F. Supp. at 844 ("The complaint does not allege that the plaintiffs purchased the penile implant directly from the defendant, or that they contracted with the defendant. Because the complaint does not allege privity of contract, it fails to state a cause of action for breach of express or implied warranties[.]"); *Kaiser v. Depuy Spine, Inc.*, 944 F. Supp. 2d 1187, 1193 (M.D. Fla. 2013) ("[M]edical devices . . . are available to Plaintiff only through prescription use from a licensed physician or healthcare provider[.] . . . Therefore, any attempt to assert a claim for breach of express warranty in this case would be futile.") (internal citation omitted); *Holland v. Abbott Lab'ys, Inc.*, 626 F. Supp. 3d 1256, 1263 (M.D. Fla. 2022) ("Plaintiff has not pleaded any allegations that she purchased the neurostimulator directly from Defendant. Privity has therefore not been established for either warranty-based claim. . . . Absent allegations of privity between herself and Defendant, Plaintiff fails to state plausible breach of implied warranty and breach of

express warranty claims under Florida law[.]"); *Jackmack v. Bos. Sci. Corp.*, No. 2:20-CV-692-SPC-NPM, 2021 WL 1020981, at *2 (M.D. Fla. Mar. 17, 2021) ("[T]his case concerns a medically implanted device bought without direct contact between the manufacturer and ultimate consumer of the product. Without direct personal contact, . . . Jackmack cannot establish privity under Florida law.") (internal citation omitted); *Wright v. Howmedica Osteonics Corp.*, No. 5:17-CV-459-OC-30PRL, 2017 WL 9939182, at *3 (M.D. Fla. Nov. 21, 2017), *aff'd,* 741 F. App'x 624 (11th Cir. 2018) ("[M]anufacturers contract with surgeons or medical facilities. So it is facially implausible that Plaintiff could state a claim for breach of an implied warranty."); *Pritchett v. Argon Med. Devices, Inc.*, No. 6:21-CV-1400-PGB-GJK, 2022 WL 19914513, at *4 (M.D. Fla. Jan. 13, 2022) ("[T]he Amended Complaint, even read in the light most favorable to Plaintiff, alleges that Defendants marketed their medical device to medical professionals and that Plaintiff received this information secondhand 'through her medical providers.'"). Accordingly, the Court finds that there was no privity between Plaintiff and Defendants, and therefore his claims for breach of warranty cannot survive. Defendants' motion for summary judgment as to Plaintiff's breach of express warranty and breach of implied warranty claims is **GRANTED**.

**G. Negligent Infliction of Emotional Distress**

In his response, Plaintiff withdrew his claim for negligent infliction of emotional distress. (ECF No. 85 at PageID #3319 n.3.) Accordingly, this portion of Defendants' motion is **DENIED AS MOOT**.

**H. Intentional Infliction of Emotional Distress**

Defendants next argue that Plaintiff's claim for intentional infliction of emotional distress

fails both as a repackaged failure to warn or design defect claim, and on its merits.[4] (ECF No. 65 at PageID #983–86.) Defendants point out that "no Florida court has held that products liability, personal injury allegations like those asserted in this case are sufficient to support a claim for intentional infliction of emotional distress." (*Id.* at PageID #984.) They also argue that Plaintiff cannot establish the required degree of severity of emotional distress. (*Id.* at PageID #985.) Plaintiff's response focuses on the degree of his emotional distress and glosses over Defendants' alleged conduct. (ECF No. 85 at PageID #3356.) As to the "extreme and outrageous conduct" requirement, he offers only a conclusory allegation that Defendants' conduct here is outrageous "because they knowingly failed to warn doctors and patients about the significant risks of an implantable medical device, causing serious, chronic injury to [Plaintiff]." (ECF No. 85 at PageID #3356.) Plaintiff points to no cases in which a court found merit in an intentional infliction of emotional distress claim in a products liability personal injury action.

To succeed on a claim for intentional infliction of emotional distress under Florida law, Plaintiff must show:

> (1) extreme and outrageous conduct;
> (2) an intent to cause, or reckless disregard to the probability of causing, emotional distress;
> (3) severe emotional distress suffered by the plaintiff; and
> (4) that the conduct complained of caused the plaintiff's severe emotional distress.

*Broberg v. Carnival Corp.*, 303 F. Supp. 3d 1313, 1317 (S.D. Fla. 2017). Tortious conduct is not enough, the defendant's conduct must be extreme and outrageous:

> [F]or one's actions to rise to the level of intentional infliction of emotional distress, it must be "so outrageous in character, and so extreme in degree, as to go beyond

[4] The Court notes that none of the prior bellwether plaintiffs has pursued a claim for intentional infliction of emotional distress. Such a claim was either not included in the complaint (Case No. 18-cv-1509, ECF No. 17; Case No. 18-cv-1320, ECF No. 15 at PageID #92) or was voluntarily dismissed (Case No. 18-cv-1022, ECF No. 124 at PageID #4865).

> all possible bounds of decency, and to be regarded as atrocious, and utterly intolerable in a civilized community." *Clemente v. Horne*, 707 So.2d 865, 867 (Fla. 3d DCA 1998) (quotation omitted). It is not "enough that the defendant has acted with an intent which is tortious or even criminal, or that he has intended to inflict emotional distress, or even that his conduct has been characterized by 'malice,' or a degree of aggravation which would entitle the plaintiff to punitive damages for another tort." *Gallogly v. Rodriguez*, 970 So.2d 470, 471–72 (Fla. 2d DCA 2007) (quotation omitted). In other words, even purposeful conduct that one knows is going to hurt another is not outrageous enough to support a claim.

*Deauville Hotel Mgmt., LLC v. Ward*, 219 So. 3d 949, 955 (Fla. Dist. Ct. App. 2017). "Those who pursue rights and objectives in a legally permissible manner cannot be held liable for intentional infliction of emotional distress, even if they know that their conduct will cause emotional distress to the plaintiff." *Gibbs v. Republic Tobacco, L.P.*, 119 F. Supp. 2d 1288, 1296 (M.D. Fla. 2000). As Defendants point out, the 3DMax is an FDA-cleared medical device that is legally on the market. (ECF No. 65 at PageID #985.)

Plaintiff's perfunctory statement that Defendants' conduct "falls into that category" because they "knowingly failed to warn doctors and patients about the significant risks of an implantable medical device, causing serious, chronic injury to [Plaintiff]" is not sufficient. Plaintiff offers no caselaw to back up his claim that an allegation of failure to warn in a products liability case such as this one can support his claim of intentional infliction of emotional distress. It is not enough that Defendants allegedly "acted with an intent which is tortious . . . or even that [their] conduct has been characterized by 'malice' or a degree of aggravation that would entitle [P]aintiff to punitive damages." *Deauville Hotel Mgmt.*, 219 So. 3d at 955 (internal quotation omitted). Instead, the conduct must be "atrocious, and utterly intolerable in a civilized community." *Liberty Mut. Ins. Co. v. Steadman*, 968 So. 2d 592, 595 (Fla. Dist. Ct. App. 2007) (internal quotation omitted). Whether Defendants' conduct rises to the level of intentional infliction of emotional distress "is a question that must be decided as a matter of law." *Deauville*

*Hotel Mgmt.*, 219 So. 3d at 955 (internal quotation omitted). The Court does not find that Defendants' conduct rises to the level of outrageousness required by Florida law to sustain a claim for intentional infliction of emotional distress. Accordingly, Defendants' motion for summary judgment as to Plaintiff's claim for intentional infliction of emotional distress is **GRANTED**.

## IV. Conclusion

For the reasons set forth above, Defendants' motion for summary judgment (ECF No. 65) is **GRANTED IN PART**, **DENIED IN PART AS MOOT**, and **RESERVED IN PART**.

**IT IS SO ORDERED.**

**2/1/2024**
**DATE**

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