UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
HAMMOND DIVISION

JOVASCEA WILLIAMS-ROBERTS, and AVISHOOV ROBERTS,	)	
Plaintiffs,	)	
v.	)	**No. 2:19 CV 42**
COLOPLAST CORP., *et al.*,	)	
Defendants.	)	

OPINION and ORDER

I. BACKGROUND

In 2017, plaintiff Jovascea Williams-Roberts was implanted with a pelvic mesh device, "Restorelle," which was manufactured by defendant Coloplast Corp. (DE # 14 ¶ 72.) Plaintiff alleges she experienced severe and debilitating injuries as a result of the implantation following a number of invasive surgeries. (*Id.* ¶ 84.) Plaintiff and her husband Avishoov Roberts sued defendant, alleging, *inter alia*, failure to warn in violation of the Indiana Products Liability Act ("IPLA"), Ind Code § 34-20-1-1 *et seq.* (DE # 14, Count IV.)

Plaintiffs have moved for partial summary judgment on Count IV. (DE # 48.) A redacted but otherwise identical version of this motion also appears on the docket. (DE # 63.) Defendants opposed the motion (DE # 57), and plaintiffs replied (DE # 59). The motion is now fully briefed and ripe for ruling.

II. LEGAL STANDARD

Summary judgment is governed by Federal Rule of Civil Procedure 56. "[S]ummary judgment is appropriate — in fact, is mandated — where there are no disputed issues of material fact and the movant must prevail as a matter of law." *Dempsey v. Atchison, Topeka, & Santa Fe Ry. Co.,* 16 F.3d 832, 836 (7th Cir. 1994) (citations and quotation marks omitted). The parties' summary judgment burdens depend on whether the movant would ultimately bear the burden of proof on a disputed issue at trial. Where the movant does not bear the burden of proof at trial, the oft-quoted burden-shifting framework of *Celotex Corp. v. Catrett,* 477 U.S. 317 (1986), applies.

However, in the relatively unusual instance (such as this one) where the movant is the same party who would bear the burden of proof at trial, the movant "must show that the evidence . . . is 'so one-sided that . . . [the movant] must prevail as a matter of law'" in order to obtain summary judgment in its favor. *Reserve Supply Corp. v. Owens-Corning Fiberglass Corp.,* 971 F.2d 37, 42 (7th Cir. 1992) (quoting *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 251-52 (1986)); *Addicks Servs., Inc., v. GGP-Bridgeland, LP,* 596 F.3d 286, 293 (5th Cir. 2010) (where movant also bears burden of proof, "movant must establish beyond peradventure" all essential elements in order to warrant judgment in his favor); Moore's Fed. Practice 3d, § 56.13[1] (where party moves for summary judgment and bears the burden of proof on the issue, it must show that the evidence is so powerful that no reasonable jury would be free to disbelieve it).

The court's role in deciding a summary judgment motion is not to evaluate the truth of the matter, but instead to determine whether there is a genuine issue of triable fact. *Anderson,* 477 U.S. at 249-50; *Doe v. R.R. Donnelley & Sons Co.,* 42 F.3d 439, 443 (7th Cir. 1994). In viewing the facts presented on a motion for summary judgment, a court must construe all facts in a light most favorable to the non-moving party and draw all legitimate inferences and resolve all doubts in favor of that party. *NLFC, Inc. v. Devcom Mid-Am., Inc.,* 45 F.3d 231, 234 (7th Cir. 1995).

III. DISCUSSION

Plaintiffs' motion for partial summary judgment concerns the IPLA's failure-to-warn liability provision. Under this part of the IPLA, a product is defective if a seller does not "properly package or label the product to give reasonable warnings of danger about the product . . . when the seller, by exercising reasonable diligence, could have made such warnings or instructions available to the user or consumer." Ind. Code § 34-20-4-2. "Put another way, [a seller has] a 'duty to warn with respect to latent dangerous characteristics of the product, even though there is no "defect" in the product itself.'" *Kaiser v. Johnson & Johnson,* 947 F.3d 996, 1015 (7th Cir. 2020) (quoting *Nat. Gas Odorizing, Inc. v. Downs,* 685 N.E.2d 155, 161 (Ind. Ct. App. 1997)). "Under Indiana's learned-intermediary doctrine, a medical-device manufacturer can discharge this duty by providing adequate warnings to physicians." *Id.*

As noted above, the present motion is unusual, as it is *plaintiffs* moving for summary judgment, rather than defendant. The fact that plaintiffs ultimately have the

burden of proof in this case means that plaintiffs have a daunting task: to convince the court that the evidence is "so one-sided" that no reasonable jurors could disagree that plaintiffs should prevail. *Reserve Supply,* 971 F.2d at 42. In this instance, plaintiffs' motion must be denied because, as explained below, reasonable jurors could disagree about at least two elements of a failure-to-warn claim in this case: breach and causation.

A. Breach

Defendant argues that, at the least, there exist genuine issues of material fact as to whether defendant breached its duty to warn in this case. Defendant contends that the "Instructions for Use" (IFU) applicable to Restorelle warned of "every single injury alleged by plaintiffs." (DE # 57 at 1.) To illustrate this point, defendant points out the list of injuries alleged in this case as articulated by plaintiffs' expert:

> multiple pelvic abscesses, vaginal cuff and fascial dehiscences, mesh erosion into the rectum and vagina, chronic inflammation, foreign-body giant cell reaction, pelvic abscess, fistula, dense adhesions, bowel obstruction, intractable abdominal pain, dyspareunia, frequent urinary tract infections, stress urinary incontinence, cutaneous abscess, acute parametritis, pelvic cellulitis, and acute vaginitis.

(DE # 57 Ex. A, Blaivas Rep. at 19.) Defendant implores the court to compare this list of injuries to the IFU's list of "adverse effects," which stated:

> Adverse effects associated with the use of Restorelle Y Contour include: transient local wound irritation, foreign body inflammatory response, hematoma, seroma, adhesions, pain, abscess, infection/potentiation of infection, wound dehiscence, erosion, extrusion, exposure of mesh, puncture or laceration of vessels, nerves, or viscera (bladder or bowel), fistula, nerve damage, scarring/contracture, urinary incontinence, voiding dysfunction, urinary retention/obstruction, defecatory

> dysfunction, ileus or small bowel obstruction, uretera obstruction or laceration, dyspareunia and procedure failure and/or recurrent prolapse may occur.

(DE # 57 Ex. B.) Defendant further notes that in its "Warnings and Precautions" section, the IFU states that "[t]he implant procedure carries an inherent risk of infection and bleeding, as do similar urological procedures." (*Id.*) Defendant argues the IFU also advises that "[p]atient counseling should include a discussion that the mesh to be implanted is a permanent implant, and that some complications associated with the implanted mesh may require additional surgery." (*Id.*) Finally, defendant asserts that the IFU states that "[s]erious adverse tissue responses or infection may require removal of mesh." (*Id.*) Defendants argues that, when cross-referenced, every alleged injury is warned against in the IFU, negating any assertion that it breached a duty to warn.

Plaintiffs, on the other hand, argue that the IFU is deficient and does not warn of every single injury. (DE # 59 at 3.) For example, according to plaintiffs, the IFU lists "transient local wound irritation," when defendants actually knew that "chronic local wound irritation" could occur. (*Id.*) Further, plaintiffs argue, the IFU fails to detail the extent and frequency of known complications. (*Id.*) Plaintiffs insist that the IFU does not warn of all of the latent dangerous characteristics associated with the product, including "deformation, shrinkage/contracture, and degradation."(*Id.*)

Plaintiffs' alleged discrepancies between the IFU and the injuries alleged simply bolster what the court must conclude in this instance: that plaintiffs have not met their burden on their own motion for summary judgment to establish that *no reasonable jurors*

could disagree about whether plaintiff should prevail on this element. Indeed, a reasonable juror could agree with plaintiffs. But, a reasonable juror could also side with defendant, concluding that the IFU contained reasonable warnings of the injuries alleged by plaintiffs. The Seventh Circuit has noted that "whether a warning is 'reasonable' is 'generally a question of fact for the trier of fact to resolve.'" *Kaiser,* 947 F.3d at 1015 (quoting *Cook v. Ford Motor Co.,* 913 N.E.2d 311, 319 (Ind. Ct. App. 2009)). This case fits squarely into that general rule. Whether defendant breached its duty to warn in this instance cannot be determined as a matter of law in plaintiffs' favor.

B. Causation

Plaintiffs also cannot establish that reasonable jurors could only side for them on the issue of causation. Like breach, "'causation-in-fact is ordinarily a factual question reserved for determination by the jury.'" *Kaiser,* 947 F.3d at 1016 (quoting *Kovach v. Caligor Midwest,* 913 N.E.2d 193, 198 (Ind. 2009)). Only where "reasonable minds cannot disagree" does the question of causation become a question of law for the court. *Id.*

The duty of a manufacturer to warn extends only to the medical profession, and not the ultimate users. *Ortho Pharm Corp. v. Chapman,* 338 N.E.2d 541, 548-49 (Ind. Ct. App. 1979). Thus, in the context of a medical device manufacturer's warnings, the causation question is "relatively straightforward: Would [the physician] have used the . . . device to treat [the condition] if [the manufacturer] had provided additional warnings?" *Kaiser,* 947 F.3d at 1016.

Plaintiffs points to statements by the treating physician in this case, in which he indicated that he could not say whether he would have prescribed Restorelle had he been informed about, for example, the frequency and extent of mesh erosions and extrusions. (DE # 59 at 3.) Though the IFU did include the terms "erosion" and "extrusion" (DE # 57 Ex. B), a juror might nonetheless credit the physician's testimony and conclude that causation was established. But it is quite another matter to surmise that *all* jurors would credit the physician's testimony and ultimately come to such a conclusion, and that none would disagree. Certainly, the court cannot make such a determination on the present record; the issue of causation cannot be determined as a matter of law in plaintiffs' favor.

IV. CONCLUSION

Because plaintiffs have failed to establish that they are entitled to judgment in their favor as a matter of law on Count IV, their motion for partial summary judgment is **DENIED**. (DE # 48.) The court also directs the clerk to **TERMINATE** the pending nature of the subsequent redacted version of this motion. (DE # 63.)

SO ORDERED.

Date: September 7, 2021

s/ James T. Moody
JUDGE JAMES T. MOODY
UNITED STATES DISTRICT COURT