

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF FLORIDA**

**CASE NO. 13-62260-CIV-COHN/SELTZER**

NORMA OLMO, PLAINTIFF )  
 )  
 )  
v. )  
 )  
 )  
DAVOL, INC. and C.R. BARD, INC. )  
\_\_\_\_\_ )

**NOTICE OF APPEAL**

Notice is hereby given that Norma Olmo and Nelson Olmo, Plaintiffs in the above-named case, hereby file this notice of appeal to the United States Court of Appeals for the Eleventh Circuit from the district court's Final Judgment entered in this action April 7, 2017 [DE 38], (*attached hereto as Plaintiffs' Exhibit "A"*), including the district Court's Omnibus Order granting Defendants' Motion for Summary Judgment [DE-MDL 5185] (*attached hereto as Plaintiffs' Exhibit "B"*).

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**RULE 7.1(3) CERTIFICATION**

**WE HEREBY CERTIFY** that prior to the filing of this motion, the undersigned conferred with counsel for Defendant who does not oppose the motion subject to Defendant being available on any new date.

**KOCH PARAFINCZUK & WOLF**

*Attorneys for the Plaintiff*

110 E. Broward Boulevard

Suite 1630

Fort Lauderdale, FL 33301

Phone: (954) 462-6700

Facsimile: (954) 462-6567

By: /s/ Justin Parafinczuk

JUSTIN PARAFINCZUK

Fla. Bar. No.: 039898

**CERTIFICATE OF SERVICE**

I, Marcus Susen, hereby certify that a copy of the foregoing was electronically filed. Those attorneys who are registered with the Electronic Filing System may access these filings through the Court's System, and notice of these filings will be sent to these parties by operation of the Court's Electronic Filing System.

Dated: April 17, 2017.

**KOCH PARAFINCZUK & WOLF, P.A.**

*Attorneys for Plaintiff*

110 East Broward Boulevard, Suite 1630

Fort Lauderdale, Florida 33301

Telephone: (954) 763-7600

Facsimile: (954) 763-7300

*/s/ Justin Parafinczuk*

By: \_\_\_\_\_

JUSTIN PARAFINCZUK, ESQ.

Fla. Bar No.: 039898

[Parafinczuk@kpwlaw.com](mailto:Parafinczuk@kpwlaw.com)

MARCUS SUSEN, ESQ.

Fla. Bar No. 70789

[Susen@kpwlaw.com](mailto:Susen@kpwlaw.com)

**Service:** [Pleadings@kpwlaw.com](mailto:Pleadings@kpwlaw.com)

# PLAINTIFFS' EXHIBIT "A"

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF FLORIDA

CASE NO. 13-62260-CIV-COHN/SELTZER

NORMA OLMO and NELSON OLMO,

Plaintiffs,

v.

DAVOL, INC. and C.R. BARD, INC.,

Defendants.

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**FINAL JUDGMENT**

**THIS CAUSE** is before the Court upon its separately entered Omnibus Order [DE 38], granting summary judgment in favor of Defendants. It is thereupon

**ORDERED AND ADJUDGED** as follows:

1. Judgment is entered in favor of Defendants Davol, Inc. and C.R. Bard, Inc. and against Plaintiffs Norma Olmo and Nelson Olmo on Counts I–IV and XI–XIV of Plaintiffs' Amended Complaint [DE-MDL 4910].<sup>1</sup>
2. Plaintiffs shall take nothing from Defendants on these claims.
3. All pending motions are **DENIED as moot**, and the Clerk of Court is directed to **CLOSE** this case.

**DONE AND ORDERED** in Chambers at Fort Lauderdale, Broward County, Florida, this 7th day of April, 2017.

  
JAMES I. COHN  
United States District Judge

Copies provided to:  
Counsel of record via CM/ECF

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<sup>1</sup> The "DE-MDL" citation refers to docket entries in In Re: Kugel Mesh Hernia Patch Prods. Liability Litig., MDL No. 1842, Case No. 1:07-md-01842-ML (D.R.I.), which can also be found at DE 13 in this action.

# PLAINTIFFS' EXHIBIT "B"

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF FLORIDA

CASE NO. 13-62260-CIV-COHN/SELTZER

NORMA OLMO and NELSON OLMO,

Plaintiffs,

v.

DAVOL, INC. and C.R. BARD, INC.,

Defendants.

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**OMNIBUS ORDER**

**THIS CAUSE** is before the Court upon Defendants' Motion for Summary Judgment [DE-MDL 5185] and Motion to Exclude the Testimony of Plaintiffs' Expert Dr. Paul Ducheyne, Ph.D. [DE-MDL 5188] (collectively, "Motions").<sup>1</sup> The Court has considered the Motions, Plaintiffs' Responses, Defendants' Replies, the evidence presented at the Daubert hearing held on March 31, 2017, and the relevant portions of the record, and is otherwise advised in the premises. For the reasons stated below, the Court will grant the Motions.

**I. BACKGROUND**

This case involves a hernia repair patch designed and manufactured by Defendants Davol, Inc. and C.R. Bard, Inc. (collectively, "Bard"), which allegedly caused injuries to Plaintiff Norma Olmo. On August 4, 2005, Dr. Roberto Comperatore implanted Ms. Olmo with Bard's extra-large Composix Kugel hernia patch ("CK Patch"). DE-MDL 5186 ¶ 3. The top polypropylene layer of the CK Patch fixes against the

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<sup>1</sup> The "DE-MDL" citations herein refer to the docket entry numbers in In Re: Kugel Mesh Hernia Patch Prods. Liability Litig., MDL No. 1842, Case No. 1:07-md-01842-ML (D.R.I.), which can also be found at DE 13 in this action.

abdominal wall under the hernia to encourage tissue growth and repair, and the smooth, bottom ePTFE surface faces the bowels to minimize adhesions. Id. ¶¶ 15–16. The extra-large CK Patch contains two PET memory recoil rings intended to provide stability to the device. DE-MDL 5185-11. The Instructions for Use (“IFU”) accompanying the CK Patch at issue contained an “ADVERSE REACTIONS” section cautioning that: “Possible complications include seroma, adhesions, hematomas, inflammation, extrusion, fistula formation and recurrence of the hernia or soft tissue defect.” Id.

In 2011, Ms. Olmo was experiencing abdominal pain and underwent an elective hernia repair in which Dr. Brian Weinstein explanted her CK Patch and replaced it with a different hernia mesh product. DE-MDL 5186 ¶ 30. Dr. Weinstein observed that a corner of the CK Patch had lost fixation and folded under, causing “mesh erosion into the bowel.” DE-MDL 5185-2 at 12:1–17. Dr. Weinstein did not observe any buckling in the explanted device, and he did not determine whether a ring break had occurred or what caused the fold. Id. at 15:25–16:10; 52:17–53:25, 111:1–6. The hospital where Dr. Weinstein performed Ms. Olmo’s surgery discarded the explanted CK Patch, and neither the device itself nor pictures of it were available for expert examination. See DE-MDL 5211 at 4.

Ms. Olmo filed this lawsuit on October 3, 2013. DE 1-1. The case was transferred on October 21, 2013, to the U.S. District Court for the District of Rhode Island by the Judicial Panel on Multidistrict Litigation for coordinated pretrial proceedings. DE 10. Throughout the multidistrict litigation, plaintiffs have presented two general defect and causation theories: (1) a “break” of a memory recoil ring in the CK Patch; and (2) a “buckle” in which the polypropylene side of the CK Patch came into

contact with the bowel. The Panel selected one “break” and one “buckle” case to serve as bellwether cases. The “buckle” case, Whitfield v. Davol Inc., No. 1:07-cv-001918, 1:07-md-01842, MDL No. 1842 (D.R.I.), ended in a defense verdict in favor of Bard. The “break” case, Thorpe v. Davol Inc., No. 1:08-cv-0463, 1:07-md-01842, MDL No. 1842 (D.R.I.), ended in a verdict in favor of the plaintiffs, but the court granted Bard’s motion for judgment as to punitive damages and failure to warn.

On August 18, 2015, the operative First Amended Complaint was filed in this action, adding Ms. Olmo’s husband, Nelson Olmo, as a Plaintiff. DE-MDL 4910. On November 22, 2016, the case was remanded back to this Court for further proceedings. DE 12. The claims remaining at this stage of the litigation are: negligence for design defect (Counts I & II), strict liability for design defect (Counts III & IV), failure to warn (Counts XI & XII), loss of consortium (XIII & XIV), and punitive damages. Id.; DE-MDL 4906 (withdrawing negligent and intentional infliction of emotional distress claims and breach of implied warranty claims); DE-MDL 5209 at 25 (withdrawing manufacturing defect claim).

Defendants move for summary judgment as to each of the remaining claims. They also seek to exclude the testimony of Plaintiffs’ expert witness, Dr. Ducheyne.<sup>2</sup> This Order addresses both Motions.

## **II. LEGAL STANDARDS**

### **A. Motion to Exclude Expert**

Rule 702 of the Federal Rules of Evidence governs the admission of expert

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<sup>2</sup> In addition to Dr. Ducheyne’s testimony, Defendants have moved to exclude the testimony of Plaintiffs’ expert Dr. Stephen Ferzoco [DE-MDL 5187] and limit the testimony of Plaintiffs’ expert Dr. Suzanne Parisian [DE-MDL 5189]. The Court need not address Defendants’ challenges to the testimony of Dr. Ferzoco and Dr. Parisian, as the Court finds that Defendants are entitled to summary judgment even considering the testimony of these experts.



testimony, as explained by Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 113 (1993) and its progeny.<sup>3</sup> In applying Rule 702, “district courts must act as ‘gatekeepers’ which admit expert testimony only if it is both reliable and relevant.” Rink v. Cheminova, Inc., 400 F.3d 1286, 1291 (11th Cir. 2005) (citing Daubert, 509 U.S. at 589). “District courts are charged with this gatekeeping function to ensure that speculative, unreliable expert testimony does not reach the jury under the mantle of reliability that accompanies the appellation ‘expert testimony.’” Id. (internal quotation marks omitted). To meet this obligation, courts must perform “a rigorous inquiry” to determine whether:

(1) the expert is qualified to testify competently regarding the matters he intends to address; (2) the methodology by which the expert reaches his conclusions is sufficiently reliable . . . ; and (3) the testimony assists the trier of fact, through the application of scientific, technical, or specialized expertise, to understand the evidence or to determine a fact in issue.

Id. at 1291–92 (internal quotation marks omitted). “The party offering the expert has the burden of satisfying each of these three elements by a preponderance of the evidence.” Id. at 1292.

Even if proposed expert testimony is admissible under Rule 702, that evidence may be excluded if it is irrelevant or if “its probative value is substantially outweighed by a danger of . . . unfair prejudice, confusing the issues, [or] misleading the jury.” Fed. R. Evid. 403; accord Allison v. McGhan Med. Corp., 184 F.3d 1300, 1309–10 (11th Cir. 1999). Because “expert testimony may be assigned talismanic significance in the eyes

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<sup>3</sup> Rule 702 states that a witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

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

of lay jurors,” a district court “must take care to weigh the value of such evidence against its potential to mislead or confuse.” United States v. Frazier, 387 F.3d 1244, 1263 (11th Cir. 2004) (en banc).

### **B. Summary Judgment**

A district court “shall grant summary judgment if 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 “always bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of [the record] which it believes demonstrate the absence of a genuine issue of material fact.” Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). To satisfy this burden, the movant must show the court that “there is an absence of evidence to support the nonmoving party’s case.” Id. at 325.

After the movant has met its burden under Rule 56(a), the burden of production shifts, and the nonmoving party “must do more than simply show that there is some metaphysical doubt as to the material facts.” Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586 (1986). As Rule 56 explains, “[i]f a party fails to properly support an assertion of fact or fails to properly address another party’s assertion of fact . . . the court may . . . grant summary judgment if the motion and supporting materials—including the facts considered undisputed—show that the movant is entitled to it.” Fed. R. Civ. P. 56(e)(3). Therefore, the nonmoving party “may not rest upon the mere allegations or denials in its pleadings” but instead must present “specific facts showing that there is a genuine issue for trial.” Walker v. Darby, 911 F.2d 1573, 1576–77 (11th Cir. 1990).

In deciding a summary-judgment motion, the Court must view the facts in the light most favorable to the nonmoving party. Davis v. Williams, 451 F.3d 759, 763 (11th Cir. 2006). The Court also must resolve all ambiguities and draw all justifiable inferences in favor of the nonmoving party. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986).

### III. DISCUSSION

#### A. Motion to Exclude Dr. Ducheyne's Testimony

Dr. Ducheyne's specific opinion—that one or both rings in Ms. Olmo's CK Patch broke—does not satisfy the requirements of Daubert.<sup>4</sup> Dr. Ducheyne is by all accounts qualified to testify as a bioengineering expert in this case, and Defendants do not contest his general qualifications. However, Plaintiffs have not established by a preponderance of the evidence that Dr. Ducheyne's stated methodology for forming his opinion that a ring break occurred in Ms. Olmo's CK Patch is sufficiently reliable.

Typically in determining the reliability of a particular scientific expert opinion, courts consider, to the extent possible: "(1) whether the expert's theory can be and has been tested; (2) whether the theory has been subjected to peer review and publication; (3) the known or potential rate of error of the particular scientific technique; and (4) whether the technique is generally accepted in the scientific community." Quiet Tech. DC-8, Inc. v. Hurel-Dubois UK Ltd., 326 F.3d 1333, 1341 (11th Cir. 2003). "Notably, however, these factors do not exhaust the universe of considerations that may bear on the reliability of a given expert opinion, and a federal court should consider any additional factors that may advance its Rule 702 analysis." Id. (citing Kumho Tire Co. v.

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<sup>4</sup> Plaintiffs concede that Dr. Ducheyne is not offering opinions on warnings, alternative design, medical causation, or revisions of the IFU. DE-MDL 5211 at 6, 21, 23.

Carmichael, 526 U.S. 137, 150 (1999)). A court applying Daubert has “broad latitude” both in selecting the criteria by which to judge the reliability of proffered evidence and discretion in deciding whether the criteria are satisfied. Kumho Tire Co., 526 U.S. at 152–53.

“[N]othing in either Daubert or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.” Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997). “A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.” Id. “An expert must substantiate his opinion; providing only an ultimate conclusion with no analysis is meaningless.” Clark v. Takata Corp., 192 F.3d 750, 757 (7th Cir. 1999) (internal quotations and citations omitted).

Here, there is too great an analytical gap between the data upon which Dr. Ducheyne relied and his opinion that at least one ring broke in Ms. Olmo’s CK Patch for that opinion to be reliable. Dr. Ducheyne’s Report states under the heading “Macroscopic Observations - Pathology Findings”:

[T]he fact that the mesh had folded such that the porous poly(propylene) layer contacted internal organs, unequivocally leads to the conclusion that the outer and perhaps also the inner memory recoil rings did not prevent folding, which is only possible subsequent to excessive ring bending (which is not a logical explanation, as this is highly unlikely to the extent needed for folding), or breakage (which is the likely event before folding of the patch).

DE-MDL 5188-2. The remainder of the report is devoted almost entirely to explaining why Dr. Ducheyne believes that Bard’s product testing and design of the CK Patch were unsatisfactory, and it does not explain why folding necessarily leads to the conclusion that a ring break occurred. See id. Dr. Ducheyne’s deposition testimony does little to fill in the analytical gap. When asked how he reached his ring-break conclusion, Dr.

Ducheyne responded only that Dr. Weinstein's description of "major folding of the device" is only possible when at least one of the rings breaks. DE-MDL 5188-3 at 74:22–75:5, 77:18–21, 79:12–18, 109:15–25. At the Daubert hearing, Dr. Ducheyne added that the folding and deformation of Ms. Olmo's CK Patch was greater than that he had observed in other cases involving a documented ring break, but he was unable to identify any of those cases to Defendants' counsel.<sup>5</sup>

Dr. Ducheyne did not conduct any tests to support his ring-break theory. Nor did he perform work to rule out the alternative theory that Ms. Olmo's CK Patch lost fixation without a ring break. Dr. Ducheyne is not aware of any scientific studies or literature concluding that the folding described in this case evidences a ring break. And Dr. Ducheyne has not pointed to any evidence that the engineering or medical communities would accept the premise that the folding described by Dr. Weinstein is only possible with a ring break.

The methodological problems with Dr. Ducheyne's opinion are similar to those of the plaintiffs' causation experts in Bowersock v. Davol, Inc., another product liability case involving a Bard CK Patch. Id., No. 108CV01313LJMTAB, 2017 WL 711849 (S.D. Ind. Feb. 23, 2017). The plaintiffs' biomedical engineering expert, Dr. William Hyman, and medical expert, Dr. Stephen Ferzoco, who is also an expert witness in this case, offered opinions on causation and appeared qualified to render them. Id. at \*7–9. The court nevertheless excluded Dr. Hyman's and Dr. Ferzoco's testimony because the plaintiffs had failed to establish that their opinions were sufficiently reliable. Id. Dr. Ferzoco, like Dr. Ducheyne, relied primarily on his personal knowledge, training, and

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<sup>5</sup> Dr. Ducheyne's testimony at the hearing also appears to conflict with his deposition testimony that he did not rely on specific patient experiences in forming his opinion. DE-MDL 1588-3 at 54:15–21.

experience but did not identify or produce the records of the patients in whom he had observed the effect that he believed caused the plaintiff's injury. Id. at \*4, 8. The court found that “[b]y simply alluding to prior patient experience to support his causation theory without providing any explicit details that could be explored by Bard’s counsel, Dr. Ferzoco’s opinions [could not] be deemed sufficiently reliable under Rule 702.” Id. at \*9. The Court also held that Hyman’s opinion failed to satisfy the requirements of Daubert. Id. Hyman, like Dr. Ducheyne, never examined the explanted patch or images of it after removal, never performed any testing on his causation theory or the CK Patch itself, did not estimate or quantify the amount of deformation required to cause the alleged injury, and “was unaware of any test or study demonstrating his proposed failure mechanism or any test that resulted in a bowel injury due to the deformation of the CK Patch as he described it.” Id.

Plaintiffs highlight that Dr. Ducheyne was permitted to render expert testimony in Thorpe over Defendants’ objection. However, Dr. Ducheyne’s testimony in Thorpe is distinguishable. There, Dr. Ducheyne offered the specific opinion that scar contracture may have caused the well-documented ring break in Thorpe’s CK Patch. Dr. Ducheyne explained in detail how he arrived at this conclusion and relied on: (1) his personal observation of, among other things, “a sample patch, the explanted patch, Thorpe’s medical and surgical records, and the images made of the patch”; (2) “the generally known and accepted phenomenon of contraction due to scar tissue formation”; and (3) “the known properties of polypropylene.” Thorpe v. Davol, Inc., No., C.A. 008-463ML, 2011 WL 470613, at \*17, \*25 (D.R.I. Feb. 4, 2011). Dr. Ducheyne has provided no such detailed explanation for his conclusion in this case.

Dr. Ducheyne's testimony is Plaintiffs' only evidence of a ring break in Ms. Olmo's CK Patch, and his general opinions are limited to testing and design with relation to ring break and its consequences. DE-MDL 5188-3 at 12:3–7. Because the Court finds that Dr. Ducheyne's specific opinion must be excluded, his general opinions on testing and design no longer have a valid scientific connection, or "fit," to the facts of this case. See Daubert, 509 U.S. at 591–92 (describing "fit" requirement). Thus, his general opinions must be excluded as well.

### **B. Motion for Summary Judgment**

"Florida tort law provides that the manufacturer of a defective product may be subject to liability under two theories: negligence and strict liability." Small v. Amgen, Inc., 134 F. Supp. 3d 1358, 1366 (M.D. Fla. 2015). A product may be defective under Florida law "by virtue of a design defect, a manufacturing defect, or an inadequate warning." Jennings v. BIC Corp., 181 F.3d 1250, 1255 (11th Cir. 1999) (quoting Ferayorni v. Hyundai Motor Co., 711 So. 2d 1167, 1170 (Fla. 4th DCA 1998)).

In this case, Plaintiffs claim that Ms. Olmo's CK Patch was defective by virtue of its inadequate warnings and design, and they assert liability under both negligence and strict liability theories. Plaintiffs also seek loss of consortium for Mr. Olmo and punitive damages. For the reasons that follow, Plaintiffs have not demonstrated that they can carry their burden as to each element of their product defect claims. Therefore, summary judgment in favor of Defendants is warranted.

#### **1. Failure to Warn**

To establish liability under Florida law for failure to warn, a plaintiff must prove that the defendant (1) "is a manufacturer or distributor of the product at issue," and (2)

“did not adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of the manufacture and distribution.” Thomas v. Bombardier Recreational Prod., Inc., 682 F. Supp. 2d 1297, 1300 (M.D. Fla. 2010) (citation omitted). The plaintiff must also establish by a preponderance of the evidence, with “reasonable medical probability,” that the inadequate warning was a proximate cause of her injury. Small, 134 F. Supp. at 1367 (citing Hoffmann La Roche, Inc. v. Mason, 27 So. 3d 75, 77 (Fla. 5th DCA 2009)); Colville v. Pharmacia & Upjohn Co. LLC, 565 F. Supp. 2d 1314, 1322 (N.D. Fla. 2008) (citation omitted).

Florida recognizes the learned intermediary doctrine, which provides that, in cases of prescription drugs and prescription medical devices, “the manufacturer’s duty runs to the physician, rather than the patient.” Beale v. Biomet, Inc., 492 F. Supp. 2d 1360, 1365–68 (S.D. Fla. 2007) (citing Felix v. Hoffmann-LaRoche, Inc., 540 So. 2d 102 (Fla.1989)); see also Tillman v. C.R. Bard, Inc., 96 F. Supp. 3d 1307, 1335 (M.D. Fla. 2015) (recognizing that doctrine applies to prescription medical devices). In other words, “the manufacturer owes a duty to warn to the patient’s physician, rather than the patient directly.” Id. “Whether the physician in fact reads the warning, or passes its contents along to the recipient . . . is irrelevant.” Metz v. Wyeth LLC, 872 F. Supp. 2d 1335, 1344 (M.D. Fla. 2012), aff’d, 525 F. App’x 893 (11th Cir. 2013) (quoting E.R. Squibb and Sons, Inc. v. Farnes, 697 So. 2d 825, 827 (Fla. 1997)). “The sufficiency and reasonableness of a warning is generally a question of fact, but ‘can become a question of law where the warning is accurate, clear, and unambiguous.’” Small, 134 F. Supp. 3d at 1367 (quoting Felix, 540 So. 2d at 105). Additionally, “the failure of the



manufacturer to provide the physician with an adequate warning of the risks associated with a prescription product is not the proximate cause of a patient's injury if the prescribing physician had independent knowledge of the risk that the adequate warning should have communicated." Christopher v. Cutter Labs., 53 F.3d 1184, 1192 (11th Cir. 1995).

Plaintiffs have not met their burden to establish that deficiencies in Defendants' warnings regarding the CK Patch proximately caused Ms. Olmo's injuries. Plaintiffs' theory of causation is that one or both of the rings in Ms. Olmo's CK Patch broke, which caused the patch to buckle and harm her. DE-MDL 5209 at 46. They claim that Defendants' failure to warn of the risks of breakage and buckling materially contributed to Ms. Olmo's adhesions and fistula, which caused abdominal pain and necessitated subsequent surgeries.<sup>6</sup> Id. at 46–47.

However, Plaintiffs have not shown that they can support their theory of causation. Without Dr. Ducheyne's testimony, Plaintiffs have no evidence of a ring break. Nor have they pointed to evidence to support an alternative theory that the CK Patch buckled with an intact ring.<sup>7</sup> In fact, Dr. Weinstein testified that he did not observe a buckle in Ms. Olmo's CK Patch, but instead observed a loss of fixation, which

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<sup>6</sup> Plaintiffs also claim that the warnings were inadequate because they should have informed of changes in ring-weld strength, a recall of the product due to complaints of ring breaks, and the extent of testing performed on the ring-weld strength in relation to buckling and fracturing. See DE-MDL 5209 at 29–30, 34. These arguments are irrelevant without evidence of a ring break. Plaintiffs have not established how information regarding changes in ring-weld strength is relevant without evidence that a ring break caused the alleged injuries. Nor could Defendants have warned of the recall, which occurred after Ms. Olmo's implant. And Plaintiffs have not pointed to any evidence that knowledge of alleged inadequacies in Defendants' ring-weld testing would have changed Dr. Comperatore's decision to implant the CK Patch in Ms. Olmo. These alleged deficiencies in Defendants' warnings therefore do not save Plaintiffs' failure to warn claims.

<sup>7</sup> Plaintiffs do contend that Defendants' expert, Dr. Paul Gryska, "considers a fold a buckle." DE-MDL 5209 at 11. However, a close reading of Dr. Gryska's deposition transcript beyond the selective portion cited by Plaintiffs reveals that Dr. Gryska was careful not to equate the fold observed in Ms. Olmo's CK Patch with a buckle. See DE-MDL 5210-3 at 56:1–58:1. When asked, "When you say 'fold,' that means 'buckled' to you, correct?" Dr. Gryska replied, "No. That is not at all what I mean." Id. at 56:8–11.

allowed a portion of the patch to “fold” or “flop down” and come into contact with the bowels. DE-MDL 5185-2 at 52:17–53:20; 111:1–112:1. Loss of fixation is the only theory of causation supported by admissible evidence.

Both Dr. Comperatore and Dr. Weinstein testified that loss of fixation was a risk associated with hernia repair patches commonly known at the time of Ms. Olmo’s implant and which was not limited to the CK Patch. Id. at 112:6–15; DE-MDL 5185-6 at 34:3–36:16; 38:5–8. Because Dr. Comperatore had independent knowledge of the risk that the CK Patch would lose fixation and the record evidence does not support another theory of causation, Plaintiffs cannot establish that the failure to warn of this risk proximately caused Ms. Olmo’s injuries. See Christopher, 53 F.3d at 1192.

Moreover, the IFU accurately, clearly, and unambiguously warned of the injuries that Ms. Olmo claims to have suffered—that is, adhesions and fistula formation. Dr. Comperatore knew of these risks, as well as the potential need for subsequent surgeries, and elected to implant the patch anyway, believing that it was in the best interest of his patient. DE-MDL 5185-6 at 51:25–52:7; 53:6–13; 70:1–4. Because the warnings in the IFU were legally sufficient with respect to Ms. Olmo’s alleged injuries, Defendants are entitled to summary judgment on Plaintiffs’ failure to warn claims.

## **2. Design Defect**

To sustain a defective design claim under Florida law, whether alleging strict products liability or negligence, a plaintiff must demonstrate that “(1) a defect existed in the product, (2) the defect caused the injury, and (3) the defect in the product existed at the time the product left the possession of the manufacturer.” Cooper v. Old Williamsburg Candle Corp., 653 F. Supp. 2d 1220, 1223 (M.D. Fla. 2009) (citations

omitted). In addition, the plaintiff must establish the elements of each individual claim for strict products liability and negligence. Id.

Plaintiffs have not provided sufficient evidence to support their design defect claims under a theory of either strict liability or negligence because they have not demonstrated that they can prove causation. Plaintiffs' claimed design defect is the presence of a memory recoil ring subject to breaking, buckling, or both. See DE-MDL 5209 at 10, 45–46. As detailed at length above, Plaintiffs have not provided any admissible evidence that this alleged defect caused Ms. Olmo's injuries. Furthermore, Dr. Comperatore testified that the complications that Ms. Olmo experienced—folding, adhesions, and fistulas—were known risks of any hernia patch, with or without a ring, at the time of the implant. Thus, Plaintiffs have not established that an unreasonably dangerous condition of the CK Patch proximately caused Ms. Olmo's injuries, and their design defect claims must fail.

### **3. Loss of Consortium and Punitive Damages**

Plaintiffs' remaining claims for loss of consortium and punitive damages cannot stand independently. "It is well established and uncontested that loss of consortium can be sustained only as a derivative claim." Doran v. City of Clearwater, Fla., 814 F. Supp. 1079, 1080 (M.D. Fla. 1993). Thus, Mr. Olmo's claim for loss of consortium is derivative in nature and wholly dependent on Ms. Olmo's ability to recover. Because the failure to warn and design defect claims cannot withstand summary judgment, Mr. Olmo's loss of consortium claim fails as a matter of law.

Similarly, Plaintiffs' prayer for punitive damages cannot survive on its own. Punitive damages are not an independent cause of action, but rather, are "merely a

remedy that must be asserted in conjunction with a substantive claim.” Philip Morris USA, Inc. v. Hallgren, 124 So. 3d 350, 355 (Fla. Dist. Ct. App. 2013); see also Engle v. Liggett Group, Inc., 945 So.2d 1246, 1262–63 (Fla. 2006) (“A finding of liability necessarily precedes a determination of [punitive] damages . . .”). Therefore, summary judgment in favor of Defendants moots any claim to punitive damages. See Marshall v. City of Cape Coral, Fla., 797 F.2d 1555, 1562 (11th Cir. 1986).

#### IV. CONCLUSION

For the reasons stated herein, it is hereby

**ORDERED AND ADJUDGED** as follows:

1. Defendants’ Motion to Exclude the Testimony of Plaintiffs’ Expert Dr. Paul Ducheyne, Ph.D. [DE-MDL 5188] is **GRANTED**.
2. Defendants’ Motion for Summary Judgment [DE-MDL 5185] is **GRANTED**.  
Summary judgment is entered in favor of Defendants and against Plaintiffs.  
The Court will enter a separate Final Judgment consistent with this Order.

**DONE AND ORDERED** in Chambers at Fort Lauderdale, Broward County, Florida, this 7th day of April, 2017.

  
JAMES I. COHN  
United States District Judge

Copies provided to:  
Counsel of record via CM/ECF