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: **ANTONIO MILANESI, et al.**	**Case No.: 2:18-cv-01320**

DEFENDANTS C. R. BARD, INC. AND DAVOL INC.'S POST-VERDICT RENEWED MOTION FOR JUDGMENT AS A MATTER OF LAW PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 50(b)

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INTRODUCTION

Pursuant to Federal Rule of Civil Procedure 50(b), Defendants C. R. Bard, Inc., and Davol Inc. ("Bard") hereby renew their pre-verdict motion for judgment as a matter law ("JMOL") as to Plaintiffs' negligent design and derivative loss of consortium claims. In making this renewed motion, Bard recognizes that the Court has not yet ruled on its pre-verdict JMOL motion and therefore has discretion to convert Bard's pre-verdict JMOL motion into a post-verdict JMOL motion. *See Embotelladora Electropura S.A. de C.V. v. Accutek Packaging Equip. Co.*, No. 3:16-cv-00724-GPC-MSB, 2019 U.S. Dist. LEXIS 123624, *14-*15 (S.D. Cal. July 24, 2019) (citing cases about how a court has discretion to convert a pre-verdict JMOL motion and converting it into post-verdict renewed JMOL). Yet, at the same time, Bard is mindful of the appellate case law holding that "to preserve for appeal a challenge to the denial of a pre-verdict motion for judgment as a matter of law, a movant *must renew* that motion after verdict." *Norton v. Sam's Club*, 145 F.3d 114, 117 (2d Cir. 1998) (emphasis added). Thus, out of an abundance of caution, Bard is renewing its JMOL motion to ensure those issues are preserved for any potential appeal or cross-appeal.

As to the grounds for JMOL, they are the same five grounds already addressed in Bard's pre-verdict JMOL motion, to which Plaintiffs have already filed and response and Bard has filed a reply. For the reasons set forth below, the Court should grant JMOL in Bard's favor.

LEGAL STANDARD

Federal Rule of Civil Procedure 50(b) governs post-verdict renewed motions for JMOL. *See* Fed. R. Civ. P. 50(b) ("No later than 28 days after the entry of judgment . . . the movant may file a renewed motion for judgment as a matter of law and may include an alternative or joint request for new trial under Rule 59."). By moving pre-verdict under Rule 50(a), *see* ECF No. 371, Bard has preserved its right to present these grounds post-verdict under Rule 50(b), *see American*

& Foreign Ins. Co. v. Bolt, 106 F.3d 155, 159-60 (6th Cir. 1997) (a pre-verdict Rule 50(a) motion is a jurisdictional prerequisite to a post-verdict Rule 50(b) motion). This Court, in turn, should grant JMOL when "a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue . . . ." Fed. R. Civ. P. 50(a). Under this standard, JMOL is warranted "'when viewing the evidence in a light most favorable to the non-moving party, giving that party the benefit of all reasonable inferences, there is no genuine issue of material fact for the jury, and reasonable minds could come to but one conclusion in favor of the moving party.'" *Tuttle v. Metro. Gov't*, 474 F.3d 307, 315 (6th Cir. 2007) (quoting *Barnes v. City of Cincinnati*, 401 F.3d 729, 736 (6th Cir. 2005)).

ARGUMENT

Although Bard moved pre-verdict for JMOL on all of Plaintiffs' claims, in light of the jury's verdict in Bard's favor on the strict liability design defect, negligent failure to warn, and misrepresentation claims, as well as on Plaintiffs' request for punitive damages, Bard's request for JMOL as to those issues is moot.[1] *See* Jury Verdict, ECF No. 380 at 1-2, 5-10, 14. Given the jury's verdict, Bard only moves for JMOL post-verdict on the two issues the jury decided against it: the negligent design defect claim and derivative loss of consortium claim. As explained below, and in the briefing the parties previously submitted on Bard's pre-verdict motion, JMOL is warranted on those remaining claims for five reasons: (i) Plaintiffs failed to prove defect; (ii) Plaintiffs failed to establish causation; (iii) comment k operates as a bar to any design defect claim; (iv) Bard's device was state of the art at the time it was sold; and (v) Plaintiffs failed to present

[1] Although Bard's request for JMOL on the matters on which it prevailed at trial is moot, Bard reserves the right to renew those JMOL grounds in response to whatever post-trial relief Plaintiffs may seek as alternative grounds supporting the portions of the jury's verdict in Bard's favor. *See, e.g., Allied Erecting & Dismantling Co. v. U.S. Steel Corp.*, 814 F. App'x 21, 27-28 (6th Cir. 2020) (considering JMOL arguments as alternative grounds for affirmance when a new trial was sought).

competent expert testimony. Thus, the Court should grant JMOL in Bard's favor.

I. NEGLIGENT DESIGN

In moving for JMOL pre-verdict, Bard explained that, under Florida law, the substantive elements of a design defect claim are the same regardless of whether the claim is brought in strict liability or negligence. *See* JMOL Mot., ECF No. 371 at 2-3 (citing *Cooper v. Old Williamsburg Candle Corp.*, 653 F. Supp. 2d 1220 (M.D. Fla. 2009) and explaining that "defect and causation are elements of a product liability claim—whether in strict liability or negligence"). In their opposition to Bard's pre-verdict JMOL motion, Plaintiffs do not dispute this legal proposition. *See* JMOL Opp., ECF No. 382 at 3-11 (not disputing that proposition). As a result, the parties appear to be in agreement that the same five grounds apply to both of Plaintiffs' design defect claims, even though only the negligent design defect claim was decided against Bard at trial.[2]

A. Plaintiffs Failed To Prove Defect.

At trial, the Court instructed the jury on both the consumer expectations test and risk-utility test. *See* Day 16 Rough at 122:6-12 ("A product is unreasonable dangerous because of its design if the Ventralex failed to perform as safely as an ordinary consumer—meaning, in this case, Mr. Milanesi's implanting surgeon, Dr. Gill—would expect when used as intended or in a manner reasonable foreseeable by the manufacturer or [if] the risk of danger in the design outweighs the benefits.").

In cases involving complex medical devices, however, controlling Florida law provides that *only* the risk-utility test may be utilized to determine whether a product has a defective design.

[2] For similar reasons, the jury's verdict on the strict liability design defect and negligent design defect claims is arguably inconsistent. However, by electing not to raise any potential inconsistency concerns before the jury was discharged, the parties made the tactical decision to forgo any potential inconsistency challenge to the verdict. *See Innovation Ventures, LLC v. N2G Distr.*, 763 F.3d 524, 538 (6th Cir. 2014) ("Our settled interpretation of this Rule required Defendants to raise their inconsistency objection before the jury was discharged.").

See Cavanaugh v. Stryker Corp., 308 So. 3d 149, 155 (Fla. 4th DCA 2020) (holding that "the consumer expectation test cannot logically be applied [] where the product in question is a complex medical device available to an ordinary consumer only as an incident to a medical procedure" and applying the risk-utility test); *accord Cates v. Zeltiq Aesthetics, Inc.*, 535 F. Supp. 2d 1222, 1230 (M.D. Fla. 2021) (citing *Cavanaugh* as controlling and concluding consumer expectation test was inapplicable in case involving medical device). That is because, as the Florida District Court of Appeal explained in *Cavanaugh*, "[t]he rationale for the consumer expectations test—that a manufacturer plays a central role in establishing the consumers' expectations for a particular product, which in turn motivates consumers to purchase the product—simply does not apply to [a complex medical] device." *Cavanaugh*, 308 So. 3d at 155.

For their part, Plaintiffs have attempted to escape *Cavanaugh*'s holding that the consumer expectation test does not apply to medical devices by arguing that *Cavanaugh* is irrelevant because the Florida Supreme Court has spoken and reached a different conclusion.[3] *See* JMOL Opp., ECF No. 382 at 3-5. Pointing to *Aubin v. Union Carbine Corp.*, 177 So. 3d 489 (Fla. 2015), Plaintiffs have asserted that, in that case, the Florida Supreme Court held that the consumer expectations test governs in product liability cases. *See* JMOL Opp., ECF No. 382 at 3-4. That matters, so Plaintiffs' argument goes, because under Sixth Circuit precedent, intermediate court of appeal

[3] Plaintiffs have also argued that *Cavanaugh* does not reject the consumer expectations in cases "involving a complex medical product" and instead holds only that the standard jury instruction "would 'need to be modified' based upon the learned intermediary doctrine 'to inform the jury that the relevant expectations are those of the health care professional.'" JMOL Opp., ECF No. 382 at 5 (internal citations omitted). That is not, however, what *Cavanaugh* holds and Plaintiffs' quote from *Cavanaugh* is taken out of context. In *Cavanaugh*, the Fourth District unequivocally rejected application of the consumer expectations test to medical devices, proclaiming that: "The rationale for the consumer expectations test . . . simply does not apply to [a complex medical] device." *Cavanaugh*, 308 So. 3d at 155. *Cavanaugh* then went on to address yet another reason why the proposed instruction was erroneous, explaining that "*[e]ven assuming that some version of the consumer expectations test should apply to complex medical products which are provided to a consumer through a learned intermediary*, the standard instruction would need to be modified in order to inform the jury the jury that the relevant expectations are those of the health care professional." *Id.* at 156 (emphasis added). It is only by omitting the italicized language from the portion of *Cavanaugh* that Plaintiffs are able to make this argument.

decisions are only persuasive evidence of the state of Florida law "if state law is unsettled," which Plaintiffs maintain it is not given *Aubin*. *See* JMOL Opp., ECF No. 382 at 5-6 (quoting *Melson v. Prime Ins. Syndicate, Inc.*, 429 F.3d 633 (6th Cir. 2005)). Plaintiffs have painted with far too broad a brush and *Aubin* does not stand for the sweeping proposition that Plaintiffs draw from that decision.

For its part, *Aubin* was not a complex medical device and thus had no occasion to consider the question of the proper standard to apply in the medical device context. Instead, *Aubin* dealt with the question of what the default design defect standard should be and whether Florida would adopt the risk-utility test the Third Restatement has proposed as the default standard from the Restatement (Third) of Products Liability § 2 or instead stick with the Second Restatement's default of the consumer expectations test. *See Aubin*, 177 So. 3d at 505-12 (declining to adopt the Third Restatement's risk-utility defect standard). This is significant because, as *Cavanaugh* explains, a long line of pre-*Aubin* cases applying Florida law had recognized that there was a subset of products, those that were "too complex for a logical application of the consumer expectations test," that *Aubin* did not disturb. *See Cavanaugh*, 308 So. 3d at 155 ("Notably, *Aubin* did not express disagreement with or disapproval of cases recognizing that some products may be too complex for a logical application of the consumer expectations test.") (citing *Force v. Ford Motor Co.*, 879 So. 2d 103, 109-10 (Fla. 5th DCA 2004), *Tillman v. C.R. Bard, Inc.*, 96 F. Supp. 3d 1307, 1339 (M.D. Fla. 2015), and *In re Fosamax Products Liab. Litig.*, 742 F. Supp. 2d 460, 470 n.4 (S.D.N.Y. 2010)). And, it was those pre-*Aubin* cases that *Cavanaugh* relied upon in concluding that *Aubin* did not address this issue and ultimately holding that the consumer expectation test was the wrong test to apply when dealing with complex medical devices. *See id.* ("*Aubin* did not decide whether the consumer expectations test can logically be applied to a complex medical device

accessible to the consumer only through a medical professional. That is the issue we must decide in this case.").

Thus, it is inaccurate to suggest, as Plaintiffs have argued, that Florida law is so well settled that *Cavanaugh* can be simply be cast aside. To the contrary, reasoned analysis reveals that this is the type of circumstance in which Sixth Circuit precedent instructs that "[i]ntermediate state appellate courts decisions," such as *Cavanaugh*, should be followed. *Bear Stearns Gov't Sec., Inc. v. Dow Corning Corp.*, 419 F.3d 543, 549 (6th Cir. 2005); *see also Ziebart Int'l v. CAN Ins. Co.*, 78 F.3d 245, 251 (6th Cir. 1996) (A court sitting in diversity "should not reject a state rule just because it was not announced by the highest court of the state, even if [the court] believe[s] that the rule is 'unsound'"). That is particularly so when one also considers that the Florida Supreme Court had the opportunity to review *Cavanaugh*, but declined to do so, *see Cavanaugh v. Stryker Corp.*, 2021 Fla. LEXIS 1325 (Fla. Aug. 9, 2021), a decision that is decidedly difficult to square with Plaintiffs' *Cavanaugh*-got-it-wrong refrain.

All of this matters because one of the fundamental purposes behind this Court's predictive *Erie* function is to try and prevent different results from being reached in state and federal courts. *See Gasperini v. Ctr. For Humanities*, 518 U.S. 415, 428 (1996) ("Where a federal court is exercising jurisdiction solely because of the diversity of citizenship of the parties, the outcome of the litigation in the federal court should be substantially the same, so far as legal rules determine the outcome of a litigation, as it would be if tried in a State court."). Yet, here, while *Cavanaugh* would clearly control were this case tried in Florida state court, Plaintiffs have urged the Court to just cast that decision aside and treat it as if it were an aberration, even though it remains on the books and the Florida Supreme Court saw no need to take it up. Respectfully, Plaintiffs are mistaken and their attempts to evade *Cavanaugh*'s significance are off-base.

The inapplicability of the consumer expectation test matters because, at trial, Plaintiffs failed to adduce sufficient evidence that the Ventralex's risks outweighed its benefits. To the extent Plaintiffs take issue with the biocompatibility of polypropylene, the benefits of polypropylene in hernia repairs are well settled. *See* Day 6 Rough at 101:14-17, 109:9-14, 146:20-24 (Plaintiffs' expert admitting polypropylene is the ***number one*** material used for hernia repair devices in the United States and it has been used to repair hernias since the 1960s). Indeed, Dr. Krpata is himself a regular user of polypropylene devices for the repair of hernias in his own practice, Day 3 Rough at 75:7-23, and testified that no change in the polypropylene side of the Ventralex large would have altered the outcome in this case, Day 4 Rough at 62:21-25. Further, as for Plaintiffs' differential contracture claim, Dr. Krpata admitted that there are benefits to the use of the ePTFE barrier and that he could not quantify whether the Ventralex had a higher complication rate than other intraperitoneal products. *See* Day 3 Rough at 62:21-25 & 75:7-23, Day 4 Rough at 177:14-178:10, & Day 6 Rough at 101:14-17, 109:9-14 & 146:20-24.

Stated simply, if there are benefits to the Ventralex's design (which there are indisputably are), then it is impossible for Plaintiffs to have carried their evidentiary burden under the risk-utility test without attempting to quantify the Ventralex's alleged risks (which Plaintiffs indisputably failed to do). For that straightforward reason, Plaintiffs failed to introduce sufficient evidence of defect and JMOL is warranted.[4]

[4] Even under the consumer expectation test, Plaintiffs failed to carry their burden. That is because the only evidence of what an implanting surgeon would have expected of the Ventralex that Plaintiffs introduced came from Dr. Krpata, when he testified that "the Ventralex Large failed to perform as safely as an ordinary surgeon would expect." *See* JMOL Opp., ECF No. 382 at 4. The problem, however, is that Dr. Krpata was not a physician in 2007 and, by his own admission, made no attempt to consider the state of the art in 2007. *See* Day 3 Rough 172:4-14, 184:21-186:26. And, for his part, Dr. Gill testified that the Ventralex had benefits and that he understood that all intraperitoneal devices have some risk of bowl erosion, fistula, and infection. *See* Exhibit 003 at 171:14-174:22, 175:10-176:4, 176:15-177:4 (acknowledging benefits of Ventralex to patents); 164:17-23, 176:15-177:4, 252:8-19 (recognizing that all hernia surgeries have risks and that intraperitoneal placement carries increased risk of adhesion, fistula, and bowel obstruction, but in his experience, the repair "hold[s] out a whole lot better" and has less recurrence rate).

B. Plaintiffs Failed To Prove Causation.

Causation is also an essential element of Plaintiffs' defect claims. *See Cooper*, 653 F. Supp. 2d at 1223. This legal proposition is not in dispute. *Compare* JMOL Mot., ECF No. 371 at 6-7 (citing Cooper, 653 F. Supp. 2d at 1223, for the proposition causation is an essential element of a design defect claim), *with* JMOL Opp., ECF No. 382 at 7-9 (not disputing that point). Yet, at trial, Plaintiffs failed to introduce sufficient evidence demonstrating that any purported defect caused Mr. Milanesi's alleged injuries. JMOL is warranted for this reason as well.

First, with respect to Plaintiffs' degradation/biocompatibility theory, Plaintiffs introduced no evidence that any alleged degradation actually led to the only cognizable injury remaining in this litigation—the fistula that led to infection. Plaintiffs offered no expert and, indeed no testimony of any kind, attempting to tether the alleged degradation of polypropylene to Mr. Milanesi's fistula. That is significant because Plaintiffs' only specific causation expert, Dr. Krpata, admitted that he has no issues with the polypropylene aspect of Bard's device and was not suggesting that a different material would have led to a different outcome. *See* Day 3 Rough at 75:7-23. The implanting surgeon, Dr. Gill, testified to similar effect about how polypropylene mesh has been the "go-to for close to six decades." *See* Exhibit 003 at 222:2-6, 229:22-230:1.

Second, as to Plaintiff's differential contracture/"buckling" assertions, Plaintiffs again offered no evidence linking any alleged design defect to Mr. Milanesi's injuries. On the contrary, as noted, Dr. Krpata testified that the risk of injuries suffered by Mr. Milanesi were inherent to ***intraperitoneal placement***. *See* Day 3 Rough at 221:12-17, Day 4 Rough at 177:14-178:10, 231:11-232:14, 234:14-15, 234:19-235:18. In other words, there was no evidence that a specific design aspect of Mr. Milanesi's Ventralex, as opposed to the placement Dr. Gill chose, caused Mr. Milanesi's injuries—because there is no evidence the risk of those injuries could be reduced or avoided. That is because those risks are inherent in intraperitoneal placement.

In their opposition to Bard's pre-verdict JMOL motion, Plaintiffs effectively disclaimed their degradation/biocompatibility theory as a distinct defect theory. Instead, they have argued that when polypropylene degrades it becomes hard, stiff, and brittle, which can lead to shrinkage and the differential contracture/"buckling" that Dr. Krpata opined caused Mr. Milanesi's injuries. *See* JMOL Opp., ECF No. 382 at 8. What is more, as to Plaintiffs' differential contracture/"buckling" assertions, Plaintiffs argued that Dr. Krpata did not acknowledge his criticisms of the Ventralex were really criticisms of intraperitoneal placement. *See* JMOL Opp., ECF No. 382 at 8-9. According to Plaintiffs, Dr. Krpata merely acknowledged there is always an inherent risk of complications and that no device is completely safe and what Bard is attempting to do is require Plaintiffs to propose a potential alternative design, which the Florida Supreme Court has said Plaintiffs are not required to do. *See id.* This is pure misdirection that does not respond to the substance of Bard's argument.

What Plaintiffs ignore, and the critical point for purposes of JMOL on causation, is that Dr. Krpata *acknowledged* there are inherent risks with intraperitoneal placement (including the specific risks of the very complications Mr. Milanesi experienced), that no device is risk free, and that he had no study showing higher risks of complications with Ventralex. *See* Day 3 Rough at 221:12-17, Day 4 Rough at 177:14-178:10, 231:11-232:14, 234:14-15, 234:19-235:18. As a result of that testimony, what Plaintiffs were required to introduce to prove causation was some tangible evidence suggesting that it was the allegedly defective features of *Bard's product*, as opposed to the inherent risks with intraperitoneal placement or all intraperitoneal mesh, that *caused* the specific complication Mr. Milanesi suffered. That is, however, what Plaintiffs, and Dr. Krpata, failed to establish and why JMOL is warranted. Plaintiffs' silence on this point, and failure to explain how they demonstrated that it was the alleged defect with Bard's device, as opposed to the

inherent risks of intraperitoneal placement, that was responsible for Mr. Milanesi's injuries, is deafening.

In short, Plaintiffs' failure of proof on causation independently supports JMOL on Plaintiffs' design defect claims.

C. Comment K Applies And Barred Plaintiffs' Defect Claims.

Under Florida law, comment k operates as an affirmative defense to design defect claims. *Adams v. G.D. Searle & Co.*, 576 So. 2d 728, 731-31 (Fla. 2nd DCA 1991). To establish the applicability of this defense, Bard had to show that at the time of Mr. Milanesi's implant in 2007, the Ventralex was as safe as the then-current testing and research permitted and that the Ventralex's benefits outweighed the known risks as of the date it was distributed. *See Tillman*, 96 F. Supp. 3d at 1340 (stating that "comment k 'is an affirmative defense to a strict liability claim'" and "to be protected under comment k, a defendant must show that the product is as safe as current testing and research permit, and that the product's benefits outweigh the known risks as of the date the product is distributed") (citing *Adams*, 576 So. 2d at 733); *see also* Fla. Std. Jury Instr. (CIV) 403.18 n.6 (noting that in Florida, comment k has been applied to medical devices, drugs, and vaccines).

While Bard carried the burden of proof with respect to this defense, it sustained that burden at trial. Bard did so by introducing testimony from Dr. Gill, Mr. Milanesi's implanting surgeon, who lauded the Ventralex's composite design, with ePTFE on the visceral side that allowed for placement intraperitoneally. *See* Exhibit 003 at 47:19-21, 47:23-48:11, 77:4-78:8. Further, on cross-examination, Bard elicited testimony from Plaintiffs' expert, Dr. Krpata, that made plain that there is no safer alternative design for the Ventralex device. *See* Day 4 Rough at 231:11-232:14, 234:14-15, 234:19-235:18. And, as shown by the jury's verdict on the failure to warn claim, Bard's warnings were plainly adequate given the known risks. *See* Jury Verdict, ECF No. 380 at 5-6.

For their part, Plaintiffs have attempted to escape comment k's application to their design defect claim by arguing that comment k "is simply a backdoor effort to require Plaintiffs to satisfy the risk-utility test and provide evidence of an alternative design," when the Florida Supreme Court rejected those requirements in *Aubin*. JMOL Opp., ECF No. 382 at 9-10. In other words, Plaintiffs ask the Court to interpret *Aubin* as having abolished comment k as a matter of Florida law. *See id.* Unsurprisingly, there is no legal support for this argument and it runs directly contrary to the Court's prior ruling at summary judgment that Florida recognizes comment k and applies it as an affirmative defense.

The problem with Plaintiffs' argument is that there is a long line of Florida cases that have applied comment k in the context of medical devices. *See, e.g., Adams*, 576 So. 2d at 731; *Tillman*, 96 F. Supp. 3d at 1340). Indeed, the application of comment k in this context is so well settled that Florida's Standard Jury Instructions, which are approved by the Florida Supreme Court and to which the Court has previously stated it would defer, specifically address this issue and make clear that Florida follows comment k and applies it to medical devises.[5] *See* Fla. Std. Jury Instr. (CIV) 403.18 n.6 (noting that, in Florida, comment k has been applied to medical devices, drugs, and vaccines, but not other products). In arguing against the applicability of comment k, Plaintiffs are not only urging the Court to depart from Florida case law, but also what Florida's Standard Jury Instructions have to say about the state of Florida law.

What is more, for its part, *Aubin* does not even hint at an intent to disturb long-standing Florida law applying comment k to complex medical devices. Indeed, the phrase "comment k" appears nowhere in *Aubin* (which makes sense as *Aubin* was an asbestos case and therefore did

[5] During the charge conference, Bard requested a comment k instruction and Plaintiffs objected on the grounds that comment k is "not the law" in Florida, arguing that comment k is "not part of the pattern instruction." *See* Day 15 Rough at 291:7-292:12. Of course, that is plainly wrong. Comment k is, very clearly, referenced in Florida's Standard Jury Instructions and part of Florida law. *See* Fla. Std. Jury Instr. (CIV) 403.18 n.6.

not involve one of the three classes of products to which comment k has been applied in Florida). *See Aubin*, 177 So. 3d at 505-518. What is more, *Aubin*'s discussion of the question of which substantive products liability standard to follow—the one set forth in the Second Restatement or the one set forth in the Third Restatement—is itself fundamentally incongruent with Plaintiffs' argument. *See id.* at 506-516. That is because, in *Aubin*, the Florida Supreme Court made the policy choice to continue to apply the Second Restatement in Florida, and it is the Second Restatement that contains the very "comment k" to which Florida adheres. *See Adams*, 576 So. 2d at 731 (adopting "comment k" from the Restatement (Second) of Torts, § 402A). For that straightforward reason, *Aubin*'s ultimate holding (that Florida will continue to follow the Second Restatement) is fundamentally incongruent with Plaintiffs' argument that *Aubin* should be read as suggesting an intent to abandon the constituent parts of the Restatement Second that Florida had previously adopted—including, specifically, comment k. If anything, *Aubin*'s holding suggests the exact opposite.

Beyond intimating that Florida no longer applies comment k, the only additional argument Plaintiffs have offered as to why JMOL is not warranted on the basis of comment k is their one sentence assertion that Plaintiffs introduced evidence showing the Ventralex "was not state of the art or as safe as the then-current testing and research permitted." JMOL Opp., ECF No. 382 at 10. In support of that statement, Plaintiffs have cited Dr. Mays's rebuttal testimony about how Bard should have understood, in 2007, that polypropylene degrades and that polypropylene and ePTFE contract at different rates in vivo, which can lead to the alleged "potato-chipping" or "buckling." *See id.* (citing Day 15 Rough at 258:6-16, 261:10-18, 262:25-263:3). The problem with Plaintiffs' reliance on that testimony, however, is that even if credited, it does not show that Bard had a way to make its device *safer*—which is the relevant question that comment k asks. *See Adams*, 576

So. 2d at 731 ("[B]y its terms comment k applies to products *which current knowledge and technology cannot make safe* for their ordinary use, but for which society has a need great enough to justify using the product despite its dangers."). On that critical safety point, the relevant evidence remains the testimony from Dr. Krpata, which makes plain that there is no safer alternative design for the Ventralex device—even today. *See* Day 4 Rough at 231:11-232:14, 234:14-15, 234:19-235:18. And, thus, Plaintiffs have proffered no reason why comment k does not bar any design defect claim.

D. The Ventralex Was State Of The Art When Sold In 2007.

Under Florida law, in an action based upon a defective design, the factfinder must "consider the state of the art of scientific and technical knowledge and other circumstances that existed at the time of manufacture, not at the time of loss or injury." Fla. Stat. § 768.1257. This provision allows a manufacturer "to show that its design of the product was state-of-the-art and, therefore, not defective since it complied with the best known and available technology." *Kaufman v. Wyeth, LLC*, No. 1:02-cv-22692, 2011 WL 10483576, *6 (S.D. Fla. Aug. 15, 2011).

The evidence at trial established that the Ventralex was the state of the art in 2007. Bard's material science expert, Dr. Maureen Reitman, confirmed that the Ventralex large "[was] a state-of-the-art device when it was launched in 2006," *see* Day 12 Rough, 63:2-6, as well as by Bard's witnesses, *see* Day 7 Rough at 163:10-20 (Mr. Darois's testimony that Bard was not aware of any supposed differential contracture issues in 2007). Plaintiffs nevertheless maintain that a different conclusion can be reached from the testimony of Bard's former quality engineer, Christopher Paolo, and the rebuttal testimony of their materials expert, Dr. Mays. *See* JMOL Opp., ECF No. 382 at 11. However, Mr. Paolo in fact gave uncontradicted testimony that Bard's quality management system during the time was "***state-of-the-art***," Day 12 Rough at 195:3-16, 196:17 (emphasis added), and Bard's quality systems expert Kimberly Trautman testified that the

Ventralex's design history file was "solid" under the quality system regulation, Day 13 Rough at 215:9-14.

Further, as to Dr. Mays's rebuttal testimony, Bard continues to maintain it was improperly admitted in violation of Rule 26. *See* Bard's Trial Brief to Exclude Dr. Mays's "State of the Art" Opinion, ECF No. 368 at 3-6. For its part, Bard properly disclosed Dr. Reitman's state of the art opinion as Rule 26 requires in her expert report and gave Plaintiffs their opportunity to consider, and challenge, that opinion pre-trial. Yet, for their part, Plaintiffs unfairly sprung Dr. Mays's supposed "rebuttal" testimony on Bard at trial, without providing Bard an adequate opportunity to understand the basis of Dr. Mays's opinions or examine him about them pre-trial. During the heat of trial, the Court disagreed that exclusion was warranted, reasoning that this was "classic rebuttal" and Dr. Mays was therefore not required to disclose anything more than he did. *See* Day 15 Rough at 2:22-3:12. But, respectfully, that is not what Rule 26 requires—both in terms of Plaintiffs' affirmative obligation to disclose any rebuttal expert opinions, and the bases for them, 30 days after the service of the expert's report that is to be rebutted, Fed. R. Civ. P. 26(a)(2)(D)(ii), and in terms of Plaintiffs' duty to supplement Dr. Mays's report with "[a]ny additions or changes" to his opinions or the bases for them, Fed. R. Civ. P. 26(e)(2). And, here, the prejudice resulting from that non-disclosure was manifest, as it precluded Bard from adequately challenging Dr. Mays' previously-undisclosed opinion at trial. *See Southern States Rack & Fixture, Inc. v. Sherwin-Williams Co.*, 318 F.3d 592, 598-59 (4th Cir. 2003) (endorsing trial court's conclusion that "the ability to simply cross-examine an expert concerning a new opinion at trial is not the ability to cure" unfair surprise).

What is more, even if considered, the substance of Dr. Mays's opinions was insufficient to establish that the state of the art in 2007 would have allowed Bard to make a safer device. That is

because all Dr. Mays purported to address in rebuttal was whether the alleged degradation of polypropylene and supposed differential contracture rates of polypropylene and ePTFE were things that had been identified in the medical literature as of 2007, *see* Day 15 Rough at 253:1-254:4, 256:22-257:17, which is a fundamentally different opinion than an opinion that "state of the art of scientific and technical knowledge and other circumstances that existed at the time of manufacture" would have allowed Bard to make a safer device back in 2007, *see* Fla. Stat. § 768.1257. On that critical question of whether a safer device could have been made, which informs the state of the art inquiry, Bard's evidence remains unrebutted. *See* Day 4 Rough at 75:62-21-25 (Dr. Krpata testifying no change to the polypropylene side of the Ventralex would have altered the outcome); Day 6 Rough at 100:22-101:9 (Dr. Mays testifying all polypropylene degrades in vivo).

JMOL is therefore called for on Plaintiffs' defective design claims on this ground also.

E. Plaintiffs Failed To Prove Design Defect Or Causation With Competent Expert Testimony.

Bard's final ground for JMOL on Plaintiffs' design defect claim renews Bard's *Daubert* challenge, and associated sufficiency of the evidence arguments, regarding the testimony of Dr. Mays and Dr. Krpata. *See* Mays *Daubert* Motion, ECF No. 70 at 3-18; Krpata *Daubert* Motion, ECF No. 63 at 4-28. Although this issue was previously addressed at summary judgment, because it concerns a sufficiency of the evidence challenge, Bard is required to renew this issue on JMOL under the Supreme Court's decision in *Ortiz v. Jordan*, 562 U.S. 180 (2011) in order to preserve it for appeal. And, as set forth in the prior *Daubert* briefing, Bard continues to maintain that Dr. Mays's and Dr. Krpata's opinions were unreliable and not supported by an adequate foundation. *See* Mays *Daubert* Motion, ECF No. 70 at 3-18; Krpata *Daubert* Motion, ECF No. 63 at 4-28. This becomes a JMOL issue because Florida law requires competent and admissible expert

testimony to sustain a design defect claim and to prove causation in a case involving a complex medical device. *See Cooper*, 653 F. Supp. 2d at 1225.

For their part, Plaintiffs have responded by criticizing Bard for renewing its arguments, proclaiming that "[n]othing has changed" since the Court's prior ruling and that Bard is just "re-hash[ing] arguments" that are "meritless." *See* JMOL Opp., ECF No. 382 at 3. Bard agrees that nothing has changed but, as explained, is required to renew its *Daubert* arguments under *Ortiz* in order to preserve them. If Bard did not renew them, then Bard would have risked waiving them. *See Ortiz*, 562 U.S. at 190. Bard recognizes that the Court can certainly stick with its prior ruling and decide not to revisit this issue, but Plaintiffs' hyperbole and rhetoric is misplaced. Bard is simply doing what the law requires for preservation purposes.

II. LOSS OF CONSORTIUM

"It is well established 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). Plaintiffs do not dispute this legal proposition. *See* JMOL Opp., ECF No. 382 at 16. The parties thus appear to be in agreement that Mrs. Milanesi's loss of consortium claim is derivative in nature and therefore depends on the viability of Mr. Milanesi's negligent design defect claim. Because JMOL is warranted on negligent design defect for the reasons discussed, JMOL is therefore warranted on loss of consortium as well.

CONCLUSION

For the reasons explained, the Court should grant JMOL as to the negligent design and loss of consortium claims, which are the only remaining claims after the jury's verdict.

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Respectfully submitted,
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CERTIFICATE OF SERVICE

I hereby certify that on May 13, 2022, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system, which will send a notice of this electronic filing to all counsel of record.

/s/ Michael K. Brown
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