



McBroom v. Ethicon Incorporated et al

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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

Amanda McBroom,

Plaintiff, v. Ethicon, Inc.; and Johnson & Johnson,

Defendants.

No. CV-20-02127-PHX-DGC ORDER

This products liability action involves pelvic mesh devices made by Defendants Ethicon, Inc. and Johnson & Johnson. Plaintiff Amanda McBroom received implants of and claims they are defective and caused her serious injury. Plaintiff filed this suit in 2015 as part of a mult proceeding in West Virginia. Doc. 1; see *In re Ethicon, Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, MDL No. 2327 (S.D. W. Va. 2012). The case was transferred to this Court on November 4, 2020. Docs. 41, 56.

design-based claims began on March 7, 2022. The parties have submitted proposed final jury instructions. Doc. 170. This order addresses several disputed instructions. See *id.* at 35, 38-46; Doc. 177-1 at 17-23. I. Background.

Defendants design and manufacture polypropylene-based pelvic mesh devices to treat female stress urinary incontinence and pelvic organ prolapse. In 2007, Plaintiff was implanted with two of pelvic mesh devices the Gynecare TVT Secur System

Gynecare Prolift Pelvic Floor Repair System . Docs. 1 ¶¶ 8-10, 30-1 at 3. Plaintiff claims that she began experiencing adverse symptoms from the products in 2011. Doc. 30-1 at 4. She asserts various claims and seeks compensatory and punitive damages. Doc. 1; see *McBroom v. Ethicon, Inc.*, No. 2:15-cv-03043 (S.D. W. Va. Mar. 13, 2015). The parties agree that Arizona law governs this case. Doc. 177-1 at 5.

T summary judgment motion in part, and has found that punitive damages are not available to



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Plaintiff. Docs. 83, 278. Plaintiff has withdrawn her claim for negligent infliction of emotional distress. Docs. 282, 284. The following claims remain: negligent design (Count I) and strict liability design defect (Count V). II. Design Defect Instruction Defective and Unreasonably Dangerous Defined. The jury will be tasked with deciding whether Defendants designed a defective and unreasonably dangerous product. See Doc. 170 at 33. For the strict liability design defect claim, Plaintiff proposes the following instruction from the current edition of the Revised

A product is defective and unreasonably dangerous because of a design defect if the harmful characteristics or consequences of its design outweigh the benefits of the design.

A manufacturer or seller is presumed to have known at all relevant times the facts that this accident and this trial have revealed about the harmful characteristics or consequences of the product's design, whether or not the manufacturer or seller actually knew those facts. If you find that it would not be reasonable for a manufacturer or seller, with such presumed knowledge, to have put this product on the market without changing the design, then the product is defective and unreasonably dangerous because of a design defect. *Id.* at 38 (citing RAJI (CIVIL) 7th Product Liability Instruction 3). The first paragraph of the instruction is the Byrns risk/benefit balancing test. RAJI (CIVIL) 7th PLI 3, cmt. 1; *Byrns v. Riddell, Inc.*, 550 P.2d 1065 (Ariz. 1976). 1

The second paragraph 1 The parties agree that a risk/benefit instruction is appropriate in this case (see Doc. 170 at 39-40), and do not propose instruction. See RAJI (CIVIL) 7th PLI A product is also defective and unreasonably dangerous because of a design defect if it fails to perform as safely as an ordinary consumer would expect

of proposed instruction is the Dart RAJI (CIVIL) 7th PLI 3, cmt. 1; *Dart v. Wiebe Mfg., Inc.*, 709 P.2d 876, 881 (Ariz. 1985). Defendants object to an instruction on the Dart hindsight test and propose this instruction based on Restatement (Third) of Torts § 6(c) (1998):

You may find the TVT-Secur or Prolift defective and unreasonably dangerous only if Plaintiff proves that reasonable health-care providers, have prescribed it for any class of patients. This means that if a reasonable health-care provider would have prescribed TVT-Secur or Prolift for any class of patients, it cannot be found to be defective. Doc. 170 at 38-39.

Defendants assert that Arizona courts have rejected the hindsight test for design- defect claims involving a prescription-only product. Docs. 170 at 38, 177-1 at 22 (citing *Gaston v. Hunter*, 588 P.2d 326, 340 (Ariz. Ct. App. 1978)). Defendants also note that Restatement § 6(c) has been applied in many Arizona district court cases. Docs. 170 at 38-39, 177-1 at 20-21 (citations omitted instruction, noting that Arizona c . Docs. 170

at 39, 177-1 at 19-20 (quoting *Barnes v. Outlaw*, 188 Ariz. 401, 405 (1996)). For reasons stated below, the Court will give the RAJI instruction proposed by Plaintiff. In Dart, the Arizona Supreme Court



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explain the difference in the application of a risk/benefit analysis in a negligent design case and the same analysis in a strict liability design case. The difference is significant, for it shifts the central focus of the inquiry from the conduct of the manufacturer (negligence) to the quality of the product. *Id.* at 880 (emphasis in original). The court elaborated that the analysis and strict liability cases applying the same word formulation is the time frame in

which this determination is made. *Id.* In negligence cases, the reasonableness of the time when the product is used in a reasonably foreseeable manner. (brackets omitted). Because consumers do not have regular experience with pelvic mesh from which to form an expectation, the Court will not give a consumer expectation instruction. See *id.*

Id. at 880-81 (his test is nothing more than the familiar negligence standard). In strict liability cases, however, the product is the focus of the inquiry, and the quality of the product may be measured not only by the information available to the manufacturer at the time of design, but also by the information available to the trier of fact at the time of trial. *Id.* at 880-81. His hindsight test is generally recommended by the commentators, and by precedent, if the case is to be pursued in strict liability. *Id.* at 881 (citations omitted). 2 Defendants note that in refusing to extend the hindsight test to failure to warn claims, the Arizona Court of Appeals relied on [.] *Docs.* 170 at 38, 177-1 at 22 (quoting *Powers v.*

, 174 P.3d 777, 782-84 (Ariz. Ct. App. 2007)). But the court in *Powers* made clear that, of course, bound by the Arizona Supreme Court's holding in *Dart* as it applies to design defect cases, even though the authorities the court relied upon in *Dart* have been modified. 174 P.3d at 782-83.

While the *Dart* hindsight test for design defect claims has received some criticism, it has never been overruled and is followed by the Arizona Court of Appeals. See *id.*; *Gomulka v. Yavapai Mach. & Auto Parts, Inc.*, 745 P.2d 986, 988-89 (Ariz. Ct. App. 1987) [W]e will summarize the current state of products liability law. Our summary is derived from *Dart*. . . . A negligent design case focuses time of design of the product. A strict liability design defect case, where the risk/benefit analysis *Golonka v. Gen. Motors Corp.*, 65 P.3d 956, 963 (Ariz. Ct. App. 2003) After noting the confusion generated by application of the risk/benefit analysis factors in both strict liability design cases and negligent design cases, the supreme court in *Dart* distinguished the theories.

2 whether a hindsight test is to be applied to strict liability cases involving failure to warn. *Id.* at 881 n.2.

Many Arizona district court cases, including very recent ones, have cited *Dart* and its progeny favorably. See *Peralta v. Worthington Indus. Inc.*, No. CV-17-03195-PHX- *Dart* Court, drawing a distinction between strict liability and negligence analysis for product liability cases, noted that negligence cases are more concerned with the conduct of the defendant, while strict



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Walsh v. LG Chem Am., No. CV-18-01545-PHX-SPL, 2021 WL 5177864, at *2 (D. Ariz. Golonka);
Dehart v. Johnson & Johnson, No. CV-

20-02493-PHX-DWL, 2021 WL 4427066, at *6 (D. Ariz. Sept. 27, 2021) Dart emphasized that a claim for strict liability is, in the final analysis, similar to (but easier from the plaintiff's perspective to prove than) a claim for negligence Granillo v. Johnson & Johnson, No. CV-19-00529-TUC-CKJ (MSA) 2020 WL 913300, at *2 (D. Ariz. Feb. 12, 2020) (citing Dart); Jones v. Medtronic Inc., 411 F. Supp. 3d 521, 532 (D. Ariz. 2019) (for strict

liability claims, he fact- reasonable for a manufacturer with knowledge of the product's potentially dangerous consequences, Gomulka); Celaya v. Hankook Tire Am. Corp., No. CV-11-00429-TUC-RM (LCK), 2018

employed in the two contexts is slightly different. The central focus of inquiry in strict liability design cases is whether the product was unreasonably dangerous, while the focus

of Dart and Gomulka); Miller v. Stryker Instruments, No. CV 09-813-PHX-SRB, 2012 WL 1718825, at *15 (D. Ariz. Mar. 29, manufacturer, as opposed to the quality of the product (strict liability)) (citing Dart);

Calvert v. I-Flow Corp., No. CV 09-1586-PHX-SRB, 2010 WL 11519168, at *2 (D. Ariz. e, the

manufacturer at the time of design but also by the information available to the trier of fact quoting Dart). 3

Defendants note that several Arizona district court cases have applied Restatement § 6(c) to design defect claims. Docs. 170 at 38-39, 177-1 at 20-21. The first case to do so was Gebhardt v. Mentor Corp., 191 F.R.D. 180 (D. Ariz. 1999). But in that case, the parties and the court agreed that § 6(c) should apply, and there was no discussion of Dart or any other Arizona state court case. Gebhardt, Court agree that, although no Arizona case has formally adopted the Restatement (Third)

of Torts, Arizona has demonstrated a willingness to look to the Restatement (Third) as the current statement of the law. . . . Accordingly, this Court will look to [Restatement § 6(c)] 4

Other district court cases have simply followed Gebhardt without considering Dart. See Mills v. Bristol-Myers Squibb Co., No. CV 11-00968-PHX-FJM, 2011 WL 4708850, at *2 (D. Ariz. Oct. 7, 2011); Staub v. Breg, Inc., No. CV 10-02038-PHX-FJM, 2012 WL 1078335, at *4 (D. Ariz. Mar. 30, 2012); Welch v. Wright Med. Tech., Inc., No. CV-11-2113-PHX-DGC, 2012 WL 4711899, at *2 (D. Ariz. Oct. 3, 2012); D Agnese v. Novartis Pharm. Corp., 952 F. Supp. 2d 880, 889 n.7 (D. Ariz.

3 See also Bellew v. Ethicon, Inc., No. 2:13-CV-22473, 2014 WL 6886129, at *4 (S.D.W. Va. Nov. 24,



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2014) (noting that Ethicon admitted that Restatement § 6(c) has not been specifically adopted by Arizona state courts, and denying summary judgment on the not to make an argument under binding (citing Dart and Golonka); Stilwell v. Smith & Nephew, Inc., 482 F.3d 1187, 1194 (9th Cir. 2007) (citing Dart, Gomulka, and Golonka courts have described the myriad standards applied to determine whether a product is .

4 Gebhardt has received some criticism on this point. See Dustin R. Marlowe, A Dose of Reality for Section 6(c) of the Restatement (Third) of Torts: Products Liability, Gebhardt] was quite willing to look to the Restatement (Third) as the current statement of the law, though it is

2013); Drescher v. Bracco Diagnostics Inc., No. CV-19-00096-TUC-RM (LCK), 2020 WL 699878, at *8 (D. Ariz. Jan. 31, 2020); Richardson v. Wright Med. Tech. Inc., No. CV- 21-00594-PHX-SMB, 2021 WL 5998517, at *4 (D. Ariz. Dec. 17, 2021); see also Harrison v. Howmedica Osteonics Corp., No. CIV 06 0745 PHX RCB, 2008 WL 906585, at *21-22 (D. Ariz. Mar. 31, 2008) (finding that Dart in a sur-reply was compelling reason Gebhardt).

Defendants cite, and the Court has found, no Arizona state court case applying Restatement § 6(c) to a design defect claim. 5

Because Dart is still good law, the Court will not give an instruction based on Restatement § 6(c) and instead will give the hindsight instruction set forth in RAJI (Civil) 7th PLI 3. See Jones v. Sofamor S.N.C., No. 1:96-CV- 3167-RWS, 1999 WL 1062103, at *5 n.6 (N.D. Ga. Apr. 29, 1999) he Court is hesitant to apply [§ 6(c)] in the cases at bar in the absence of any Georgia precedent on [this] specific section[. Johannsen v. Zimmer, Inc., No. 3:00CV2270 (DJS), 2005 WL

this court will not do so in the absence of some evidence that the Connecticut Supreme Court, considering this issue, would adopt ZimmerLea v. Wyeth LLC, No. 1:03-CV-1339, 2011 WL 13192701, at *12 (E.D. Tex. Oct. 28, 2011) The court s

5 Restatement § 6(c) has been rejected in other jurisdictions. See, e.g., Freeman v. Hoffman-La Roche, Inc., 618 N.W.2d 827, 839 (Neb. 2000) (viewing § 6(c) as too strict of a rule, under which recovery would be nearly impossible there is no support in the case law for the application of a reasonable physician standard in which strict liability for a design defect will apply only when a product is not useful for any class of persons Bryant v. Hoffmann-La Roche, Inc., 585 S.E.2d 723, 727 (Ga. Ct. App. 2003) (refusing to adopt § 6(c) has been criticized for its failure to reflect existing case law, its lack of flexibility with regard to drugs involving differing benefits and risks, its unprecedented application of a reasonable physician standard, and the fact that a consumer s claim could easily be defeated by expert opinion that the drug had some use for someone, despite potentially harmful effects on a large class of individuals); Mele v. Howmedica, Inc., 808 N.E.2d 1026, 1038 (Ill. Ct. App. 2004) represents a substantial departure from established common law throughout the country provides manufacturers with virtual immunity from liability for all medical products [because even] when doctors discover



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unexpected injuries due to a medical device, they may find the device useful in some extreme cases ; see also *Mullins v. Ethicon, Inc.*, 117 F. Supp. 3d 810, 815 n.5 (S.D.W. Va. 2015) (citing *Mele* and noting the hesitant adoption or, in some cases, outright rejection of the Restatement of Torts (Third): Products Liability .

research has failed to unearth any Texas or Fifth Circuit authority applying the standard articulated in § 6(c) in the context of a design defect claim. Thus, in the absence of controlling law, the court declines to rely on § 6(c) ; *Tillman v. C.R. Bard, Inc.*, 96 F. Supp. 3d 1307, 1345 (M.D. Fla. 2015) As no court in Florida has adopted section 6 of the Third Restatement, the Court determines that the risk-utility test articulated in *Cassisi* and embodied in comment k is the appropriate standard. *Lynch v. Olympus Am., Inc.*, No. 18-CV-00512-NYW, 2018 WL 5619327, at *9 (D. Colo. Oct. 30, 2018) ontrary adopted by this Court As a court sitting in diversity over a state law claim, this court must defer [to] the most recent decisions of the state s highest court. Thus, the court is persuaded that the standard set forth in § 402A, as interpreted in recent Colorado Supreme Court cases, remains the governing standard as to a design defect theory 6 III. Negligent Design Claim.

Defendants object to any instruction on the negligent design claim, arguing that this claim and the strict liability claim are redundant. Docs. 170 at 41-42, 177-1 at 19 (citing *Gomulka*, 745 P.2d at 990 (finding the negligence claim redundant because if the plaintiff cannot prove his case in strict liability, he cannot prove it in negligence either *Mills*, 2011 WL 3566131, at *2 (noting that the proof is the same under either theory); *Dehart*, 2021 WL 4427066, at *7 (dismissing negligence claim as redundant)). Plaintiff counters that the cited cases involved dispositive motions, and that Defendants had the opportunity to make their redundancy argument during the pre-trial phase and should not be permitted to litigate this issue on the eve of trial. Docs. 170 at 43, 177-1 at 17-18. 7

Plaintiff also 6 reliance on *Gaston* is misplaced. See Doc. 170 at 38. As Plaintiff notes, *Gaston* considered to § 402 A of the Restatement (Second) of Torts (1965) (unavoidably unsafe products). See Doc. 177-1 at 21-22; *Gaston*, 588 P.2d at 339-40.

7 In their summary judgment motion, Defendants argued only that the negligence claim was duplicative of the failure to warn claims. See [the negligence claim is] duplicative of, and subsumed by, the strict liability failure to warn claims, summary judgment is also proper as to Plaintiff

notes that permitting the jury to decide the negligence claim and the strict liability claim is not improper or in conflict with *Dart*. Docs. 170 at 43, 177-1 at 17-18 (citing *Dart*, 709 P.2d at 883-84 (finding reversible error where the trial court gave an instruction on strict liability design defect which, in substance, was a negligence instruction); *Wing v. U-Haul Int l, Inc.*, No. 1 CA-CV 18-0765, 2020 WL 773474, at *7 (Ariz. Ct. App. Feb. 18, 2020) (noting that *Gomulka* stand[s] only for the proposition that a jury cannot logically and consistently find for a defendant on a claim of strict liability while simultaneously finding for a plaintiff on a claim of negligent design). The Court agrees with Plaintiff and will give an instruction on the negligent design claim.



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Plaintiff proposes the following instruction:

Plaintiff Amanda McBroom claims that Defendants negligently designed the TVT-Secur and Prolift, resulting in a defective and unreasonably dangerous product. foreseeable risk at the time of design of the product. To recover damages for negligent design, Plaintiff must prove by a preponderance of the evidence:

1. foreseeable risks of injury from use of the products at the time of the design of the TVT-Secur or Prolift; and
2. -Secur or Prolift unreasonably dangerous;
3. That Plaintiff was injured; and 4. Doc. 170 at 41 (citing RAJI (CIVIL) 7th Fault Instructions 1-3 (modified)); Gomulka, 745 P.2d at 989 A negligent design case focuses on whether the defendant s conduct was reasonable in view of a foreseeable risk at the time of design of the product. in original); Golonka, 65 P.3d at plaintiff must prove that the manufacturer acted unreasonably at the time of design or manufacture in light of the foreseeable risk of in)).

language instruction because it does not make clear that this case is a design defect-only case. Doc. 170 at 42. Defendants propose this alternative language:

1. That Defendants negligently designed the TVT-Secur or Prolift; 2. That the negligent design rendered the TVT-Secur or Prolift unreasonably dangerous; Id. The Court agrees with Defendants age may confuse the jury and cause it to find Defendants liable for conduct other than their alleged negligent design. Plaintiff asserts that the instruction should make clear that a negligent design claim focuses on the foreseeable risks of harm at the time of design. Doc. 170 at 43. The Court agrees.

The Court proposes the following instruction on the negligent design claim:

Plaintiff Amanda McBroom claims that Defendants negligently designed the TVT-Secur and Prolift, resulting in defective and unreasonably dangerous products. To recover damages for negligent design, Plaintiff must prove by a preponderance of the evidence:

1. in designing the TVT-Secur or Prolift was unreasonable in view of the foreseeable risks of injury from use of the products at the time of design; and
2. That the negligent design rendered the TVT-Secur or Prolift unreasonably dangerous;



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3. That Plaintiff was injured; and 4. The Court will consider any objections to this proposed instruction when it settles the final jury instructions during trial. 8 IV. State of the Art Instruction. Defendants propose a h PLI 7. Doc. 170 at 46. Plaintiff objects, arguing that the evidence shows that the Prolift was not

8 The Court will issue its proposed final jury instructions in a separate filing.

designed according to the state of the art at the time. Id. (citing Kaiser v. Johnson & Johnson, 947 F.3d 996, 1017 (7th Cir. 2020) (noting that the district court declined to give an instruction on the state-of-the- Ethicon s evidence in support of the [defense] was thin at best Hrymoc v. Ethicon, Inc., 249 A.3d 191, 200 (N.J. Super. Ct. App. Div. 2021) (noting that the trial judge denied reliance upon a state-of-the- art defense, finding their proofs essentially focused on the dangers of alternative surgical . The Court conclu presented evidence in support of the defense. See Kaiser, 947 F.3d at 1017 To justify the instruction, Ethicon needed a legally sufficient evidentiary basis to support the state-of-the-art [defense].

IT IS SO ORDERED. Dated this 6th day of March, 2022.

