IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

PAMELA A. AHMED, Plaintiff, v. JOHNSON & JOHNSON HEALTHCARE SYSTEMS, INC.; et al., Defendants.	)	CASE NO. 1:22-cv-00190-KD-N

JOINT PRETRIAL DOCUMENT

Based on the Court's February 20, 2024, Order (doc. 76) ("Order"),[1] the sole pending claim is the breach of implied warranty of merchantability claim (sometimes "Implied Warranty Claim") alleged in Count Five. In this Joint Pretrial Document, the parties set forth a trial plan for the Implied Warranty Claim.

A.
JURISDICTION AND PARTIES

Jurisdiction Exists.

The parties stipulate that the Court has jurisdiction over this action because the parties are completely diverse and the amount in controversy exclusive of interest and costs exceeds $75,000. *See* 28 U.S.C. § 1332(a).

[1] On February 29, 2024, Defendants filed (a) Defendants' Motion for Reconsideration of February 20, 2024, Order to The Extent It Denied Defendants' Motion for Summary Judgment, or in the Alternative, Motion to Certify Questions to the Alabama Supreme Court (doc. 77) ("Motion for Reconsideration"), and (b) Memorandum of Law in Support of the Motion (doc. 78). These filings show the Court erred in denying Defendants' motion for summary judgment as to the Implied Warranty Claim, and that the Court should reconsider and reverse its denial of the motion for summary judgment as to that claim. Defendants reserve all objections to and their rights to challenge and appeal all factual findings and legal conclusions stated in the Order. Plaintiff opposes this motion.

Parties:

Plaintiff, Pamela A. Ahmed ("Plaintiff"), is an Alabama citizen residing in Mobile, Alabama.

Defendant, Medical Device Business Services, Inc., f/k/a DePuy Orthopaedics, Inc. ("DePuy"), is a corporation organized and existing under the laws of the State of Indiana with its principal place of business in Warsaw, Indiana, and, therefore, is a citizen of the State of Indiana for purposes of determining diversity. 28 U.S.C. § 1332(c)(1). DePuy is engaged in the business of designing, developing, manufacturing, marketing, and selling orthopedic devices.

The parties agree and stipulate that Defendant, J&J Healthcare Systems, Inc ("J&J Healthcare"), may be dismissed from this action without prejudice and will file a Stipulation of Dismissal to that effect contemporaneously with the filing of this Joint Pretrial Document. J&J Healthcare is a corporation organized and existing under the laws of the State of New Jersey with its principal place of business in Piscataway, New Jersey, and is therefore a citizen of the State of New Jersey for the purposes of determining diversity. 28 U.S.C. § 1332(c)(1). J&J Healthcare had no responsibility for or involvement in the design, manufacture, labeling, inspection, packaging, or preparation of the device at issue. Its only involvement *may have been* distributing a boxed and sealed component to Alabama. J&J Healthcare had no responsibility for or involvement in any activity that was or could have been causally related to the product's configuration or condition at the time of sale. In addition, J&J Healthcare did not alter or modify the product at any time. Accordingly, based on Alabama Code § 6– 5– 521, it has been agreed that J&J Healthcare should be dismissed without prejudice from this action.

B.
STATEMENT OF THE CASE

By Plaintiff:

This is a civil case brought on behalf of Pamela Ahmed, who underwent a total hip replacement surgery on November 4, 2020, during which time the doctor implanted an artificial hip system manufactured by Defendant DePuy Orthopaedics, Inc. Within weeks, Defendant's hip product began failing and had to be replaced on March 1, 2021. In the aftermath of this March 1, 2021, surgery, Ms. Ahmed experienced infections and other complications, requiring further surgery, additional hospitalizations, additional hip dislocations, and resulting in Ms. Ahmed's permanent disability.

The Pinnacle cup used in Ms. Ahmed, while generally a successful product, has nonetheless been the subject of numerous reports of liner disassociations – the exact complication that caused Ms. Ahmed's liner to fail. Compared to its two major competitors, its liner is the weakest of the three. Previous versions of the Pinnacle hip system were stronger, but about twenty years ago there were changes to design and the material which decreased its strength. In the aftermath of that design change, the Pinnacle system has been the subject of disproportionate reports of liner failures. The liners tend to fail because the six tabs which hold them into place break or shear off. The cup into which the liner is placed has slots for twelve tabs, but DePuy chose to ignore their own design and instead only put six tabs on the liner used in Ms. Ahmed.

Ms. Ahmed thus brings this case against the manufacturer of the hip replacement system, Defendant DePuy Orthopedics, claiming it breached the implied warranty of merchantability by providing plaintiff with a product that was not fit for its intended use, a violation of Alabama law. Defendant denies the Plaintiff's claim.

By Defendants:

Plaintiff alleges the product at issue – the AltrX™ polyethylene liner of the Pinnacle Cup System -- was not fit for its ordinary purpose *due to a defective design that made the product unreasonably dangerous*. Defendants deny this claim. The evidence will show the liner is properly designed, is not unreasonably dangerous, and is "fit for the ordinary purposes for which such goods are used," as required by Alabama law. Ala. Code § 7-2-314 (2)(c).

The AltrX™ polyethylene liner is DePuy's latest generation of cross-linked polyethylene and has been on the market since 2007. The best evidence of "fitness for ordinary purposes" is that the implanting orthopedic surgeon, Dr. Todd Engerson, still uses the Pinnacle Cup System, including the AltrX™ liner. This continued use establishes Dr. Engerson believes the liner is fit for its "ordinary purposes" and is not defective; he has also testified the Pinnacle Cup System is "state of the art". Dr. Engerson implanted another AltrX™ in Plaintiff during her revision surgery. The new liner has performed well in Plaintiff since the revision, again indicating the AltrX™ liner is fit for its "ordinary purposes". In the National Joint Registry for England and Wales—the biggest national joint registry in the world—the Pinnacle Cup System with ceramic heads and polyethylene liners, including the AltrX™ liner, has a survival rate from 97.7 to 98.4% at 10 years, which is as good as or better than any other total hip device on the market today. Clinically, the Pinnacle Acetabular Cup System is *one of the best performing hip implants of all time*. The Pinnacle Cup System and the AltrX™ liner meet all industry and FDA requirements. Their benefits greatly outweigh the risks associated with their use. They are safe and effective products. They are fit for their ordinary use, and thus Plaintiff's Implied Warranty Claim lacks any merit.

Other factors caused the liner failure. Ms. Ahmed's severely deformed spinal anatomy, her surgeon's choice to use a lipped liner, and/or placement of the cup in a substantially anteverted

orientation resulted in repeated contact of the metal stem of the femoral neck with the plastic liner, leading to fracture of the liner and its failure. No witness will testify that a different manufacturer's liner would have survived this severe force.

C.
PLAINTIFF'S STATEMENT OF TRIABLE CLAIMS

1. Plaintiff alleges Defendant breached the implied warranty of merchantability when Defendant's product failed when put to its intended use.

a. **Legal Elements:** Plaintiff must show, by a preponderance of the evidence, that Defendant was (1) regularly in the business of selling the hip replacement system; (2) that the Defendant supplied the product for use in Ms. Ahmed's hip surgery; (3) the product was not suitable or fit for the ordinary purpose for which hip replacement systems are used; and (4) Ms. Ahmed was caused harm as a result. 2 Ala. Pattern Jury Instr. Civ. 32.21 (3d ed.).

Defendants' Position: This is an incorrect statement of the law in this context, where (1) the implied warranty is allegedly as to "safety" of a medical device designed and intended to be selected, assembled, and implanted by a qualified and licensed surgeon pursuant to labeling, including Instructions for Use approved by the U. S. Food and Drug Administration ("FDA", and (2) the breach of implied warranty is allegedly due to a design defect causing the product to be "unsafe" or "unreasonably dangerous". *See, inter alia,* Defendants' Motion for Summary Judgment and related original and reply briefs in support of that motion and Defendants' Motion for Reconsideration (doc. 77) and Memorandum in Support (doc. 78).

b. **Agreed Facts:**

i. Plaintiff Pamela Ahmed underwent a right Total Hip Arthroplasty (THA) – a hip replacement surgery -- at age 61 to provide relief from pain that she had been experiencing.

ii. Dr. Todd Engerson performed Ms. Ahmed's hip replacement surgery on November 4, 2020.

iii. During the surgery, Dr. Engerson decided to use a prosthetic hip replacement device manufactured by DePuy called the Pinnacle Cup System.

iv. Dr. Engerson selected, assembled, and implanted in Ms. Ahmed the components of the Pinnacle Acetabular Cup System, which included: (1) a Pinnacle acetabular cup, constructed of titanium, that functioned as the new artificial hip socket; (2) an AltrX™ highly cross-linked polyethylene acetabular liner, which Dr. Engerson placed into the cup; (3) a Summit femoral stem that Dr. Engerson inserted in the femur; and (4) a Biolox™ ceramic ball/head that he attached to the femoral component (the stem).

v. A dislocation is where the ball of the femur comes out of the hip socket (cup and liner). In an artificial hip, a dislocation is where the ceramic ball attached to the component placed in the femur comes out of the hip socket (cup and liner) located in the pelvis.

vi. At Ms. Ahmed's February 25, 2021 doctor's visit, based on Ms. Ahmed's complaints and symptoms at the time, Dr. Engerson evaluated her hip and determined she needed further surgery, called a revision.

vii. On March 1, 2021, Dr. Engerson performed the revision surgery. He removed the femoral head and acetabular liner that had been implanted in November 2020.

viii. Dr. Engerson testified that he determined the neck of the femoral component had been impinging on the lipped liner and had disrupted the locking mechanism. When he removed the implant, he discovered the acetabular liner was no longer locked into the titanium cup – that the liner was still present in the cup but not engaged or locked into the cup.

ix. A new Biolox™ femoral head and AltrX acetabular liner were replaced during the March 1, 2021, revision surgery. The cup itself was not damaged, so it was not replaced.

x. During the revision surgery, Dr. Engerson chose to use a neutral AltrX™ liner, which does not have the face-changing or lipped characteristics of the liner he initially selected.

xi. After the March 1, 2021, revision surgery, Ms. Ahmed contracted an infection. The infection prompted the decision to perform an additional revision with ball exchange on March 19, 2021.

xii. On June 20, 2021, and August 12, 2021, Ms. Ahmed experienced two posterior hip dislocations.

c. **Disputed Facts:**

i. Whether an implied warranty of merchantability existed under the present facts involving, *inter alia,* (a) supply of the products at issue (the Pinnacle Cup System and AltrX™ liner) to Plaintiff's surgeon with FDA-approved packaging and

labeling, including Instructions for Use ("IFU"), which contained detailed information and warnings of risks associated with use of the products and (b) the assembly, placement, and implantation of the products (the acetabular cup and liner) by the orthopedic surgeon, a sophisticated and learned intermediary.

ii. Whether there is any or sufficient evidence of breach of the implied warranty.

iii. Whether Plaintiff's alleged injuries and damages proximately resulted from the breach.

iv. Whether Plaintiff had a long history of orthopedic issues, including a severely deformed spine and a stiff pelvis that prevented her pelvis from rotating normally when she changed from a sitting to a standing or walking position. Her pelvis was in a "stuck-seated position", which is not normal.

v. Whether Dr. Engerson selected an AltrX™ liner that was face-changing and lipped, which meant that the inside of the liner was oriented to change the angle of how the ball rode in the cup, the edge of the liner was thicker than the side wall, and the lip of the liner protruded above the edge of the cup. This type of liner was selected by Dr. Engerson to restrict the range of motion of Plaintiff's right left hip and to increase its stability—that is, to prevent Plaintiff from suffering a dislocation of the hip.

vi. Whether the excessive mechanical force of the impingement was the cause of the failure of the liner. Whether the liner was forced out by the force of the impingement.

vii. Whether the single separate piece of broken plastic from the liner was caused by the impingement.

viii. Whether Dr. Engerson selected the neutral liner to reduce the risk of Ms. Ahmed again experiencing impingement of the femoral neck on the liner.

ix. Whether the neutral AltrX™ liner that Dr. Engerson decided to use in the revision surgery is made of the same polyethylene material and has the same locking mechanism and anti-rotational tabs as the lipped, face changing AltrX™ liner initially selected and placed by Dr. Engerson.

x. The purpose of the anti-rotation tabs.

xi. The nature of the locking mechanism.

xii. Whether the design, material composition, and structure of the locking mechanism and its component parts were the cause of its failure.

xiii. Whether more, differently shaped, or stronger tabs would have better secured the device and prevented liner failure.

xiv. Whether the Pinnacle cup has been the subject of numerous reports of liner disassociations – the exact complication that caused Ms. Ahmed's liner to fail.

xv. Whether, compared to its two major competitors, its liner is the weakest of the three.

xvi. Whether previous versions of the Pinnacle hip system were stronger, but in the early 2000s, there were changes to design and the material which decreased its strength.

xvii. Whether, in the aftermath of that design change, the Pinnacle system has been the subject of disproportionate reports of liner disassociations.

xviii. Whether the liners tend to fail because the six tabs which hold them into place break or shear off. The cup into which the liner is placed has slots for twelve tabs, but DePuy chose to only put six on the liner used in Ms. Ahmed.

xix. Whether although impingement can be a contributing factor in disassociations, impingement is "not uncommon," even though liner disassociation is.

xx. Whether over 56% of total hip replacements report impingement problems, but only a small fraction of these result in liner disassociations, and those disassociations are disproportionately Pinnacle liners.

xxi. Whether Plaintiff still has in place the Pinnacle Cup System with the new ball and neutral liner placed by Dr. Engerson during the first revision surgery on March 1, 2021.

xxii. Whether, because of the failure of the hip replacement device and her multiple consequential surgeries, infections, and dislocations, Ms. Ahmed suffers from permanent injury to the soft tissue surrounding her hip and lives in constant fear of another dislocation.

DEFENDANTS' AFFIRMATIVE AND OTHER DEFENSES

1. **Affirmative and Other Defenses**

a. Ala. Code § 6-5-521 Bars Any Claims Against J&J Healthcare [Twenty-seventh Defense, PageID #:105]

A breach of implied warranty claim does not lie against J&J Healthcare based on the protections afforded by Ala. Code 6-5-521. J&J Healthcare was (at most) a distributor which was not "the manufacturer or assembler of the final product," "did not exercise substantial control over the design, testing, manufacture, packaging, or labeling of the product," did not alter or modify the product, and was a "mere

conduit for distribution of the product" (if that) and thus should be dismissed pursuant to Ala. Code § 6-5-521 (a) and (b)(1)-(4).

b. J&J Healthcare Not a Seller of Goods of the Type at Issue. [Twenty-third Defense, PageID #:104]

J&J Healthcare was and is not a "seller" of the product at issue or "of goods of that kind" and thus an implied warranty of merchantability is not applicable to J&J Healthcare pursuant to Ala. Code § 7-2-314 (1).

c. Learned Intermediary Doctrine Bars the Implied Warranty Claim. [Third Defense, PageID #:101]

The Implied Warranty Claim is barred by the learned intermediary and/or sophisticated user doctrines because, at all relevant times, Plaintiff's physicians and surgeons were in the position of learned intermediaries and sophisticated users, knowledgeable and informed with respect to the use, risks, and benefits of the product at issue. *Toole v. McClintock,* 999 F.2d 1430 (11th Cir. 1993); *Stone v. Smith, Kline & French Labs*., 447 So. 2d 1301 (Ala. 1984); *Morguson v. 3M Company,* 857 So. 2d 796 (Ala. 2003). The implanting surgeon Dr. Engerson selected, assembled, placed, and implanted the products at issue in Plaintiff because in his opinion they are fit for their ordinary purposes. He has testified the products he used in Plaintiff's initial THA are not defective and that excessive mechanical forces due to impingement caused the liner failure. Dr. Engerson used a neutral Altrx™ liner – with the same material composition, locking mechanism, and anti-rotational tabs as the liner initially used -- during the revision surgery. Even after Plaintiff's case, Dr. Engerson continues to use the Pinnacle Cup System and liner at issue. Dr. Engerson's actions (and his deposition testimony) indicate he believes

Pinnacle Cup System and liner at issue were, and still are, "fit for their ordinary purposes."

Plaintiff's Position: Learned intermediaries do not invalidate the implied warranty of merchantability. Defendant's cited authority is to cases considering failure to warn claims, not implied warranty claims.

d. Intervening or Superseding Cause Bars the Implied Warranty Claim. [Fifth Defense, PageID #:101]

Plaintiff's alleged injuries and damages attributable to the breach of the implied warranty of merchantability were not legally caused by the alleged breach but instead were legally caused by intervening and/or superseding causes or circumstances, including plaintiff's severe spinal deformities and pelvis in the "stuck seated" position and/or by implant selection, assembly, and positioning (excessive anteversion) that led to the impingement that mechanically destroyed the liner and caused it to fail.

Plaintiff's Position: Plaintiff disputes that any spinal or pelvic particularities or implant selection or positioning caused the device's failure; rather, it was due to the failure of the device's locking mechanism when put to its normal, intended use.

e. The State-of-the-Art Defense Bars the Implied Warranty Claim. [Eighth Defense, PageID #:102]

Plaintiff's Implied Warranty Claim is barred because, at all material times (and as confirmed by the implanting surgeon Dr. Engerson at his deposition), the product at issue conformed to the state-of-the-art for such product, in that the methods, standards, and techniques used in the design and preparation of the product at issue were (and are) in conformity with the generally recognized state of medical and

scientific knowledge, with common and accepted practices and procedures in the medical and scientific fields, and with the state of the art. In the context of a claim that a medical device is not fit for its ordinary purposes due to a design defect rendering it unsafe, the state-of-the-art defense bars the claim.

Plaintiff's Position: Plaintiff can find no legal basis for this alleged affirmative defense.

f. The Doctrines of Informed Consent, Release and Waiver Bar the Implied Warranty Claim. [Twelfth Defense, PageID #:102-03 and]

Plaintiff's claims are barred by the doctrines of informed consent, release, and/or waiver, in that it is undisputed Plaintiff executed an informed consent acknowledging and consenting to the risks of the surgery by Dr. Engerson and use of the products at issue, including but not limited to the risk of revision surgery (or need for "additional surgery," as Dr. Engerson testified), fracture of the components, infection, dislocation, and death.

Plaintiff's Position: Plaintiff did not consent to the use of a product that was not fit for its intended use.

g. Assumption of the Risk Bars the Implied Warranty Claim. [Fourteenth Defense, PageID #:103]

By signing the informed consent and agreeing to the procedure and the selection, assembly, placement, implantation and use of the products at issue by the implanting surgeon, Dr. Engerson, Plaintiff knowingly and voluntarily assumed any and all risks associated with the use of the products at issue and with their selection, assembly, placement, and implantation by Dr. Engerson, and such assumption of the risks bars in whole or in part the damages Plaintiff seeks to

recover. The risks specifically disclosed by Dr. Engerson to Plaintiff included dislocation, infection, and the potential for revision or "additional surgery" and other risks, and Plaintiff accepted such risks by signing the consent form and going forward with the THA procedure.

Plaintiff's Position: Plaintiff did not assume the risk of use of a product that was not fit for its intended use.

h. An Idiosyncratic Reaction to the Product Bars Plaintiff's Implied Warranty Claim. [Nineteenth Defense, PageID #:103-04]

If Plaintiff's injuries were caused by the product at issue (which is denied), her injuries and damages were the result of an idiosyncratic reaction to the product based on her unique and severely deformed anatomy that made her use of the product uniquely difficult and risky, and Defendants are not responsible or liable for such injuries and damages. *Griggs v. Combe, Inc.*, 456 So. 2d 790 (Ala. 1984). Plaintiff's spine was severely deformed, her pelvis was stiff and in a "stuck-seated" position so that it did not rotate like the pelvis of a normal person, and the impingement of the femoral component on the liner resulted from plaintiff's unusual anatomy—and not because the Pinnacle Cup System and liner at issue were not fit for their ordinary purposes.

Plaintiff's Position: Plaintiff disputes that any idiosyncratic reaction caused the device's failure; rather, it was due to the failure of the device's locking mechanism when put to its normal, intended use.

i. Pre-existing Medical Conditions Caused Plaintiff's Damages. [Twentieth Defense, PageID #:104]

Plaintiff's alleged injuries and damages are a result of pre-existing and/or unrelated medical conditions, including her severely deformed spine and stiff pelvis as described above and other anatomy, for which Defendant is not legally responsible.

Plaintiff's Position: Plaintiff disputes that any spinal or pelvic particularities caused the device's failure; rather, it was due to the failure of the device's locking mechanism when put to its normal, intended use.

j. Unavoidably Unsafe Product Doctrine (Comment k) Bars Plaintiff's Implied Warranty Claim. [Twenty-second Defense, PageID #:104]

If the product at issue was unsafe (which is denied), it was unavoidably unsafe. Plaintiff's claims are, therefore, barred by Comment k of § 402A of the Restatement (Second) of Torts and/or other applicable law because the Pinnacle Cup System and liner at issue were accompanied by proper directions and warnings, including the IFU approved by FDA. *Smith, Kline & French Labs*., 447 So. 2d 1301 (Ala. 1984); Comment k to § 402A of Restatement (Second) of Torts (1965). In the context of a claim that a medical device is not fit for its ordinary purposes due to a design defect rendering it unsafe, the unavoidably unsafe defense provided by Comment k defense bars the claim.

Plaintiff's Position: This doctrine applies to AEMLD claims, not implied warranty claims. In any event, the product was not unavoidably unsafe. Additional tabs were contemplated by the manufacturer and could have been added to make the liner more secure.

k. Applicable Warranty Defenses Bar Plaintiff's Implied Warranty Claim. [Twenty-third Defense, PageID #:104]

i. Defendant did not breach any implied warranties. The Implied Warranty Claim is barred by failure of Plaintiff or Plaintiff's representatives to give timely notice to Defendant of any alleged breach of warranty under Ala. Code § 7-2-607(3)(a). Defendant further specifically pleads as to any breach of warranty claim all affirmative defenses under the Uniform Commercial Code existing and which may arise in the future.

ii. More specifically, the Implied Warranty Claim is barred because it was "excluded or modified by course of dealing or course of performance or usage of trade", Ala. Code § 7-2-316 (3) (c), in that the Pinnacle Cup System and AltrX™ liner were sold with approved packaging and labeling, including the FDA-approved Instructions for Use, which listed detailed information and warnings regarding the products, which could only be used, assembled, placed and implanted by a licensed and qualified surgeon, such as Dr. Engerson. The IFU alerted the implanting surgeon to known risks associated with use of the products, including but not limited to the risk of revision surgery (or need for "additional surgery," as Dr. Engerson testified), fracture of the components, infection, dislocation, and death.

Plaintiff's Position: The involvement of a learned intermediary does not negate the implied warranty of merchantability. The product was used and implanted by Dr. Engerson as intended. Plaintiff did not consent to the use of a product unfit for its intended use.

l. The Lack of any Evidence of a Safer, Practical, Alternative Design Bars the Implied Warranty Claim.

i. Plaintiff is barred or limited from recovering any damages for breach of an implied warranty of merchantability based on a defectively designed and unreasonably dangerous product because there was no practical or technically feasible alternative design or formulation that would have prevented the harm alleged by Plaintiff without substantially impairing the usefulness or intended purpose of the products. *See* Defendants' Motion for Reconsideration (doc. 77) and Memorandum in Support (doc. 78).

ii. To prove breach of the implied warranty of merchantability based on a defective and unreasonably dangerous design – the allegation here – Plaintiff must show an alternative, practical, safer design, and Plaintiff's expert Edwards has admitted at deposition he offers no such alternative design. Accordingly, judgment as a matter of law should be entered for Defendants. *See*, *generally*, Defendants' Motion for Reconsideration (doc. 77) and Memorandum in Support (doc. 78) discussing the relevant case law on this issue.

Plaintiff's Position: Plaintiff need not prove a safer alternative design. *Garrison v. Sturm, Ruger & Company, Inc*., 322 F. Supp. 3d 1217, 1235 (N.D. Ala. 2018); *Worsham v. AH Robbins Co*., 734 F. 2d 676, 690 (11th Cir. 1984).

m. Plaintiff's Damages Resulted from Unavoidable Circumstances. [Thirty-third Defense, PageID#: 106]

Plaintiff's alleged injuries and damages, if any, were the result of unavoidable circumstances that could not have been prevented by any person or entity, including Defendant, in that Plaintiff's severely deformed spine and other anatomy were the precipitating cause of her injuries and damages—not any breach of an Implied Warranty that may exist in this context (which is denied).

Plaintiff's Position: Plaintiff disputes that any spinal or pelvic particularities caused the device's failure; rather, it was due to the failure of the device's locking mechanism when put to its normal, intended use.

n. An Implied Warranty of Merchantability Does Not Exist As To "Safety" of a Product in the Usage of the Trade (Orthopedic Surgery Joint Replacement) or Under Alabama Law. [Thirtieth Defense, PageID #: 106]

i. Plaintiff and her surgeon Dr. Engerson had full knowledge of and accepted all risks and possible adverse effects related to the use of the products at issue.

ii. DePuy sold the liner subject to the FDA-approved Instructions for Use, which should be considered in determining if an implied warranty of merchantability existed under the facts at issue here. The IFU does not warrant the "safety" of the liner at issue but instead provides detailed information and warnings concerning the products, including but not limited to the risk of revision surgery (or need for "additional surgery," as Dr. Engerson testified), fracture of the components, infection, dislocation, and death.

iii. Under Alabama law, as correctly understood and applied in this case, the implied warranty of merchantability is subsumed into the Plaintiff's Claim under the Alabama Extended Manufacturers' Liability Doctrine ("AEMLD"), as to which the Court has properly granted Defendants' motion for summary judgment. Accordingly, judgment as a matter of law should be entered for Defendants. *See*, *generally*, Defendants' Motion for Reconsideration (doc. 77) and Memorandum in Support (doc. 78) discussing the relevant case law on this issue.

Plaintiff's Position: The implied warranty is a separate and distinct claim from one pursuant to the AEMLD; it is not subsumed. *Spain v. Brown & Williamson Tobacco Corp.*, 872 So.2d 101, 111 (Ala. 2003) ("[A] claim alleging breach of an implied warranty of merchantability is separate and distinct from an AEMLD claim and is viable to redress an injury caused by an unreasonably dangerous product."); *Vesta Fire Ins. Corp. v. Milam & Co. Constr., Inc.*, 901 So.2d 84, 103 (Ala. 2004) (holding breach-of-warranty claim not subsumed by AEMLD claim).

o. There is No or Insufficient Admissible Evidence of Breach of An Implied Warranty or of Proximate Causation. [Sixth Defense, PageID#; 101-02]

i. A vague reference to other companies' hip products with different overall design concepts and different material composition, locking mechanism, anti-rotation tab designs – but with similar or poorer overall clinical performance -- is insufficient, both factually and as a matter of law, to show an alternative design for the Pinnacle Cup System or breach of an implied warranty based on a defective design. This is especially true here, where

no witness will testify that any other liner design of any other manufacturer would have survived the impingement forces that caused the liner at issue to fail. Accordingly, judgment as a matter of law should be entered for Defendants.

Plaintiff's Position: Plaintiff need not prove a safer alternative design to establish her implied warranty claim. *Garrison v. Sturm, Ruger & Company, Inc.*, 322 F. Supp. 3d 1217, 1235 (N.D. Ala. 2018); *Worsham v. AH Robbins Co.*, 734 F. 2d 676, 690 (11th Cir. 1984).

ii. Plaintiff cannot prove breach of the implied warranty of merchantability because the implanting orthopedic surgeon Dr Engerson still uses the AltrX™ liner; the different AltrX™ liner used in the revision surgery had the same design features at issue – same material composition, locking mechanism, and anti-rotation tabs – and has performed well to date in Ms. Ahmed; and, the best evidence of fitness for ordinary use (the largest registry data) establishes the Pinnacle Cup System and polyethylene liners including the AltrX™ liner are best in class with a 97.7% to 98.4% survival rate for all causes at 10 years.

Plaintiff's Position: The device failed, nearly immediately, when put to its intended use. As Mr. Edwards will testify, it failed to due to an insufficiently strong locking mechanism.

iii. Plaintiff cannot prove breach of the implied warranty of merchantability because she lacks any admissible evidence that the liner failed due to a design defect.

Plaintiff's Position: The device failed, nearly immediately, when put to its intended use. As Mr. Edwards will testify, it failed to due to an insufficiently strong locking mechanism.

iv. Plaintiff cannot prove breach of the implied warranty of merchantability because there is no admissible evidence that the design of the AltrX™ liner features at issue -- material composition, locking mechanism, and anti-rotation tabs – are defective. In fact, the undisputed evidence establishes the opposite: on revision, Plaintiff received a different neutral AltrX™ liner that had the same design features at issue – same material composition, locking mechanism, and anti-rotation tabs – and this neutral has performed well to date, showing the design is not defective and that the liner is fit for its ordinary purposes.

Plaintiff's Position: The device failed, nearly immediately, when put to its intended use. As Mr. Edwards will testify, it failed to due to an insufficiently strong locking mechanism.

v. Plaintiff cannot prove proximate causation because there is no admissible evidence that a different liner would have survived the forces placed on the liner at issue due to the severe femoral neck impingement, which deformed and broke the liner.

Plaintiff's Position: The device failed, nearly immediately, when put to its intended use. As Mr. Edwards will testify, it failed to due to an insufficiently strong locking mechanism. Its failure proximately caused Plaintiff's injuries, as is obvious and as Dr. Engerson will testify.

vi. Plaintiff cannot prove proximate causation because there is no admissible evidence that the design features at issue -- material composition, locking mechanism, and anti-rotation tabs – resulted in the failure of the liner.

Plaintiff's Position: The device failed, nearly immediately, when put to its intended use. As Mr. Edwards will testify, it failed to due to an insufficiently strong locking mechanism. Its failure proximately caused Plaintiff's injuries.

vii. Plaintiff cannot prove proximate causation because the admissible evidence overwhelming establishes that the failure of the liner was due to repeated and forceful femoral neck impingement resulting from Ms. Ahmed's severely deformed spinal anatomy and/or placement of the liner by the implanting surgeon—and not to any defect in the product.

Plaintiff's Position: The device failed because its locking mechanism was insufficiently strong when put to its normal, intended use.

2. Agreed and Stipulated Facts Relevant to Affirmative and Other Defenses:

i. Ms. Ahmed has a history of back problems dating back to a traffic accident in approximately 1988. (Dep. of Pamela Ahmed ("Ahmed Dep.") 9:2-3, 10:23-11:2, 15:19-22, May 17, 2023 (Ex. 3).)

ii. By 2004, Ms. Ahmed had nerve damage to her back (*Id.* 18:4-13), and by 2014, she was diagnosed with multilevel degenerative disc disease, causing her significant pain in her lower back (Expert Report of Steven A. Barrington, M.D. ("Barrington Rep.") at 2, Aug. 30, 2023 (Ex. 4); Ahmed Dep. 15:11-18).

iii. Ms. Ahmed underwent a right total hip arthroplasty on November 4, 2020, during which Dr. Engerson implanted her with a Pinnacle AltrX™ polyethylene liner, Pinnacle cup, and Biolox ceramic femoral head. (Compl. ¶¶ 8-9; Ahmed Dep. 151:6-9.)

iv. Dr. Engerson did not read any of defendants' warnings in choosing Ms. Ahmed's implant (Engerson Dep. 126:2-7, 127:12-14), but he was independently aware of the risks of implant surgery (*Id.* 135:8-10).

v. On January 25, 2021, during a post-operative visit, Ms. Ahmed reported to Dr. Engerson that she was hearing "loud popping" coming from her hip and that it sometimes locked up. Ex. 1, Engerson Dep. at 70-71; Ex. 3, Medical Records at 188.

iii. At her February 25, 2021 doctor's visit, Ms. Ahmed reported that she had fallen and that a week prior to the fall, she started to hear squeaking coming from the joint. Ex. 1, Engerson Dep. at 75-76, 78; Ex. 3, Medical Records at 181-182.

vi. Ms. Ahmed underwent a revision hip arthroplasty in March 2021, and received a new femoral head and acetabular liner. (*Id.*)

vii. On March 19, 2021, Ms. Ahmed underwent additional surgery because of an infection. (Barrington Rep. at 3.)

viii. In June and August 2021, Ms. Ahmed experienced two incidences of hip dislocation. (*Id.* at 4.)

c. Disputed Facts Relevant to Affirmative and Other Defenses:

i. Whether Ms. Ahmed had a severely deformed spine and her pelvis was in a "stuck seated" orientation.

ii. Whether by 2020, Ms. Ahmed had a litany of "bad orthopedic issues," leading Dr. Engerson to deem her an "orthopedic disaster." (Engerson Dep. 155:13-16.) She began to experience significant hip arthritis, and Dr. Engerson diagnosed her with end-stage osteoarthritis. (Id. 39:24-40:2.)

iii. Whether the relevant risks of hip implant surgery stated in the IFU include dislocation, revision surgery, infection, and fracture of the components.

iv. Whether Dr. Engerson selected a lipped face changing AltrX™ liner because he deemed Ms. Ahmed to be at increased risk of dislocation.

v. Whether Dr. Engerson oriented the face-changing liner to prevent posterior dislocation.

vi. Whether, as Dr. Engerson testified, he believed the hip implant failed because of "abnormal forces that were being put on it and, you know anything – anything if you put abnormal forces on it can fail." (Engerson Dep. 110:1-7; see also Id. 124:20-125:6 ("I think the reason was not because of some defective manufacturing process. It was because there were abnormal forces placed on the device that it couldn't help but fail. It just – it was too much mechanical stress.").)

vii. Whether Dr. Engerson also made clear that he did not represent to Ms. Ahmed that her hip implant suffered from any defect. (Id. 97:12-22 ("Q.

But you don't remember telling Ms. Ahmed that there was a defect in the hip? A. No, I don't. I think I explained to her, you know, why I think what happened happened."); Id. 96:5-97:5.)

viii. At the time of her initial revision surgery on March 1, 2021, Dr. Engerson told Ms. Ahmed that he had the same problem with having to replace a failed hip replacement on another patient the prior week, and that the problem with the other patient's had been the same as Ms. Ahmed's. Ex. 2, Ahmed Dep. at 132. Ms. Ahmed asked Dr. Engerson what made the hip replacement fail. He stated that it was nothing she had done, and nothing he had done; "it was a defect in the part." *Id.* at 190.

ix. Plaintiff's expert Mr. Edwards does not offer any alternative design. (Edwards Dep. 213:10-22, 207:9-10.)

x. Whether the repeated and severe forces placed on the AltrXTM liner at issue due impingement of the femoral neck on the liner caused the liner to deform, break, and then to dislodge or disassociate.

xi. Whether, because of the failure of the hip replacement device and her multiple consequential surgeries, infections, and dislocations, Ms. Ahmed suffers from permanent injury to the soft tissue surrounding her hip and lives in constant fear of another dislocation. Engerson Dep. at 117, 120.

xii. Whether, at the time of her initial revision surgery on March 1, 2021, Dr. Engerson told Ms. Ahmed that he had the same problem with having to replace a failed hip replacement on another patient the prior week, and that the problem with the other patient's had been the same as Ms. Ahmed's.

Ms. Ahmed asked Dr. Engerson what made the hip replacement fail. He stated that it was nothing she had done, and nothing he had done; "it was a defect in the part."

xiii. Whether Plaintiff's engineering expert, Mr. Edwards, has a basis for his conclusion that the AltrX liner failed because the locking mechanism was not sufficiently strong to withstand the forces to which it was subject. Whether the prevalence of the sheared anti-rotation tabs indicated a problem with the anti-rotation design. Whether Edwards has any basis to opine that more tabs and/or larger tabs were needed to retain the liner within the cup and prevent disassociation, particularly given the high rate of impingement experienced by THA patients. Whether the DePuy's AltrX™ liner's competitors have stronger locking mechanisms and fail at a lesser rate than Depuy's.

xiv. Plaintiff's orthopedic expert, Dr. Sands, noted that previous iterations of the device implanted in Ms. Ahmed used to be much stronger, but that in the early 2000's there were changes to the design "to accommodate different bearing surfaces and the introduction of highly cross-linked polyethylene which improves wear but decrease mechanical strength." Sands Rep. at 6.

xv. There are twelve openings into which tabs can fit, but only six tabs. Ex. 4, Edwards Rep. at 10, 11, 13. Whether Depuy apparently contemplated up to twelve tabs when designing the cup.

xvi. Whether the Pinnacle system has disproportionate reports of liner disassociations in the literature, particularly when compared with its competitors. Ex. 6, Sands Rep. at 6; Ex. 4, Edwards Rep. at 8.

D.
TRIAL TIME

The parties estimate the case will take 3 to 4 days to try, exclusive of jury selection but including opening statements and closing arguments.

E.
TYPE OF TRIAL: JURY

1. **Jury Size:** The parties agree to a jury of eight (8) persons.

2. **Voir Dire Questions:**

   a. Plaintiff's proposed voir dire questions are attached as **Exhibit A**.

   b. Defendants' objections to Plaintiff's proposed voir dire questions are attached as **Exhibit B**

   c. Defendant's proposed voir dire questions are attached as **Exhibit C.**

   d. Plaintiff's objections to Defendants' proposed voir dire questions are attached as **Exhibit D**.

F.
MOTIONS

1. **Plaintiff's Pending Motions: None.**

2. **Plaintiff's Anticipated Motions:**

   a. Motion to exclude evidence, testimony, statement, suggestion, or argument regarding any prior lawsuits in which Dr. Sands was involved and which have no bearing or relevance to this case.

b. Motion to exclude evidence, testimony, statement, suggestion, or argument regarding the circumstances of Dr. Sands' departure from his former practice which have no bearing or relevance to this case.

c. Motion to Appoint Mediator to Mediate the Case Prior to Trial.

3. **Defendants' Pending Motions:**

a. Motion for Reconsideration of February 20, 2024, Order to the Extent it Denied Defendants' Motion for Summary Judgment, or in the Alternative, Motion To Certify Questions to the Alabama Supreme Court.

4. **Defendants' Anticipated Motions:**

a. Motion In Limine Regarding References to the ASR Hip System and Other Metal on Metal Hip Systems.

b. Motion In Limine Regarding References by Plaintiff's Counsel or Witnesses to Documents and Information Being Withheld from Them by Defendants.

c. Motion in Limine Regarding Manufacturing Defect.

d. Motion in Limine Regarding Another Manufacturer's Liner Would Have Survived the Femoral Neck Impingement Present Here.

e. Motion in Limine Regarding References to any Lost Wages by Plaintiff.

f. Motion in Limine Regarding Other DePuy Product Recalls or Issues Related to DePuy Products that are Not Hip Replacement Components.

g. Motion in Limine Regarding References to any Issues or Litigation Involving Non-Hip Products Manufactured by Subsidiaries of Johnson & Johnson.

h. Motion in Limine Regarding Golden Rule Arguments.

i. Motion for Judgment as Matter of Law at Close of Plaintiff's Case.

j. Motion for Judgment as Matter of Law at Close of Evidence.

G.
DEPOSITIONS

1. **Plaintiff:**

At this time, and subject to the availability of subpoenaed witnesses, Plaintiff does not anticipate introducing direct testimony via deposition. Should any witness previously deposed be unable to appear at trial, including Dr. Engerson, Plaintiff expressly reserves the right to designate relevant deposition testimony for that witness. Plaintiff also reserves the right to use depositions taken in the case for impeachment or rebuttal purposes.

2. **Defendants:**

During their case, Defendants may present the testimony of the treating surgeon, Dr. Todd Engerson, M.D., by reading or playing portions of his video deposition as designated on the attached **Exhibit E** Defendants reserve the right to use any other deposition taken in the case for impeachment or rebuttal purposes. Plaintiff's objections to Defendant's deposition designations are attached hereto as **Exhibit F**.

H.
WITNESSES

1. **Plaintiff's Witnesses**

Plaintiff expects to call the following witnesses at trial:

a. **Pamela Ahmed**

b. **Richard Edwards (retained expert, CV attached as Exhibit G)**

Opinions: Mr. Edwards will testify, consistent with his expert report (incorporated herein by reference), to the following main opinions: that Ms. Ahmed's total hip arthroplasty (THA) failed less than three months after its implantation due to a dislocated

(disassociated) cross-linked Altrx acetabular liner. Ex. 4, Edwards Report at 1. Mr. Edwards will describe his methodology, including reviewing the operating doctor, Dr. Engerson's, deposition and exhibits, Ms. Ahmed's medical records; examining the Altrx® plastic liner and Biolox® ceramic, femoral head, measuring the thickness of the liner, and studying over twenty publications pertaining to the implanted hip device at issue in this case. *See Id.* at pp. 3-6. After analyzing the liner, Mr. Edwards noted damage consisting of "significant permanent deformation of the lip and anti-rotation tabs. Five of six anti-rotation tabs are sheared off." *Id.* at 7. Based on the orientation of the damage and the medical literature analyzing same, Mr. Edwards concluded that "more material, oriented perpendicular to the pole-equator direction, is needed in the anti-rotation tabs." *Id.* at 9. He will state, further, "[a]s the liner dissociates from the cup, the anti-rotation tabs are sheared off. More tabs and/or larger tabs could serve to retain the liner within the cup, preventing dissociation." *Id.* at 10.

Mr. Edwards will also testify that he analyzed the force acting on the device and concluded, "[b]ased on this analysis and the damage to the Altrx® liner, it is concluded that rotational forces are overcoming the locking method and the antirotation tabs as the probable mode of failure." *Id.* at 11, 13. Mr. Edwards will testify that he ruled out manufacturing defects in the femoral head or cup itself, placing blame on the device's failure on the locking mechanism. *Id.* He suggests that the anti-rotation tabs be made larger, increased in number to as many as twelve, and of a different shape (in order to remove the mechanical advantage of the sloped sides) to retain the liner within the cup and prevent disassociation. *Id.* at 10-11, 13.

Defendants' Objections: Defendants object to testimony of Plaintiff's expert Richard Edwards for the reasons set forth in their Rule 702 Motion to Exclude Testimony of Plaintiff's Expert Richard Edwards and Memorandum in Support (docs. 51-52), which are incorporated herein by reference.

c. Dr. Todd Engerson, M. D. (implanting and revising orthopedic surgeon, CV attached as Exhibit H)

Opinions: Dr. Engerson is expected to testify to his treatment of Ms. Ahmed, the failure of the Defendant's hip implant device, and the resulting injury and damages to Ms. Ahmed.

Defendants' Objections: Defendants object to any testimony to opinions by Dr. Engerson that are not stated in his May 22, 2023, deposition transcript.

d. Dr. Kenneth Sands, M.D. (retained expert, CV attached as Exhibit I)

Opinions: Dr. Sands is expected to testify, consistent with his expert report (incorporated herein by reference), to the following main opinions. He is a board-certified orthopedic surgeon. Ex. 6, Sands Report at 3. His opinions are based on a review of Ms. Ahmed's medical records; thirteen medical journal articles regarding total hip replacement systems, their component parts, and their complications; the deposition, medical records, notes, and CV of Ms. Ahmed's treating physician, Dr. Todd Engerson; Defendant's Expert Dr. Barrington's expert report, CV, and deposition; the design rationale of the Pinnacle Acetabular Design; the expert report of Plaintiff's engineering expert, Richard Edwards; and other case-related documents. See Ex. 6, Sands Report at 1-3. Based on his review of these records and his extensive experience with hip replacement surgeries (Ex. 8, Sands Dep. at 77), Dr. Sands opines that Ms. Ahmed's failed total hip replacement was "multi-factorial," and Ms. Ahmed's spino-pelvic issues combined with the placement of a face

changing liner "created an impingement situation." Ex. 6, Sands Report at 5. Dr. Sands also will state that the Pinnacle cup used in Ms. Ahmed has been the subject of numerous reports of liner disassociations, and that it required the least amount of force to disassociate the liner compared to its two major competitors; in other words, it was the weakest of the three. *Id.* The literature he reviewed indicated that the Pinnacle cup used to be much stronger in its previous iterations, but that in the early 2000's there were changes to the design "to accommodate different bearing surfaces and the introduction of highly cross linked polyethylene which improves wear but decreases mechanical strength." *Id*. at 6. He also will opine that the Pinnacle system has disproportionate reports of liner disassociations. Id. Further, he will testify that a consistent finding in the literature is that the problem is attributable to a specific design problem in the Pinnacle system, as Pinnacle's anti-rotation tabs tend to shear off. *Id*. at 6.

Dr. Sands also will testify that impingement can be a contributing factor in disassociations, but impingement is "not uncommon," even though liner disassociation is. Ex. 6, Sands Report at 6. In fact, over 56% of total hip replacements report impingement problems, but only a small fraction of these result in liner disassociations, and those disassociations are disproportionately Pinnacle liners. Id. Therefore, Dr. Sands will testify that the Pinnacle device cannot be excluded as a major contributing factor to Ms. Ahmed's failed total hip replacement. *Id*. at 6.

Defendants' Objections: Defendants object to testimony of Plaintiff's expert Kenneth Sands, M.D., for the reasons set forth in their Rule 702 Motion to Exclude Testimony of Plaintiff's Expert Kenneth Sands, M.D. and Memorandum in Support (docs. 53-54), which are incorporated herein by reference.

e. **Charles Havard**
9651 Royal Woods Ct.
Mobile, AL 36608

f. **Janice Pritchard**
435 Wedgefield Dr. S.
Mobile, AL 36608

g. **Steve Pierce**
10501 Presley's Outing Road
Moss Point, MS 39562

Plaintiff may call the following witnesses at trial:

h. Records custodian(s) to authenticate medical or business records if agreement can't be reached between the parties.

i. Any non-objectionable witness listed by Defendants.

j. Any witness to authenticate exhibits.

k. Any witness for impeachment or rebuttal.

2. **Defendants' witnesses:**

Defendants *may call* the following witnesses:

a. Leanne Turner (a DePuy mechanical engineer and expert, CV attached as Exhibit J)

Opinions: Ms. Turner has not been retained or specially employed to provide expert testimony in this litigation and her duties as a DePuy employee do not regularly involve giving expert testimony. She may offer testimony under Fed. R. EvId. 601, 602, 702, 703, or 705 on the following subject matters. Ms. Turner is qualified to opine about these subject matters. Ms. Turner is a mechanical engineer with nearly 25 years of orthopedic experience and was one of the engineers involved in the design of the Pinnacle Acetabular Cup.

- Design of the Pinnacle Cup
- Various DePuy design and development procedures
- Various Pinnacle cup project files and documentation
- Regulatory submissions and clearance of various Pinnacle cup components
- Various parameters of the design of total hip components
- Measurements of various design parameters
- Mechanical and wear testing of Pinnacle Cups and liners
- Risk analyses (DFMEAs, etc.) conducted during the Pinnacle Cup project and following post-market surveillance
- Advantages and disadvantages of modular hip implants
- Clinical performance of the Pinnacle cup components
- Various DePuy procedures

More specifically, Ms. Turner is expected to testify to these facts and/or opinions:

- The Pinnacle Cup System and the AltrX™ liner were appropriately conceived, researched, tested, and designed by a team of highly qualified and experienced experts in the design and testing of orthopedic hip replacement systems, including biomedical and biomechanical engineers, metallurgical and materials engineers, mechanical engineers, specialized and highly trained and experienced scientists, technicians, and other experts.
- The Pinnacle Cup System and the AltrX™ liner have no design defects, including with respect to the liner's material composition, locking mechanism and anti-rotational tabs.

- The Pinnacle Cup System and the AltrX™ liner are fit for use in their ordinary and intended purposes.
- The Pinnacle Cup System and the AltrX™ liner meet all industry standards and FDA requirements.
- The FDA authorized DePuy to make, market, and sell the Pinnacle Cup System and the AltrX™ liner with the approved IFU, and DePuy has at all times made, marketed, and sold the products pursuant to this FDA authorization.
- As reported in the national joint replacement registries (generally accepted in the industry to be the most robust and informative databases), the clinical performance of the Pinnacle Cup System and AltrX™ liner (ceramic on polyethylene construct) are excellent and best in class. It is among the most successful hip implants ever designed, based on this data.
- The benefits of the Pinnacle Cup System and AltrX™ liner greatly outweigh the risks associated with their ordinary and intended use.
- The Pinnacle Cup System and AltrX™ liner are safe and effective products.
- There is no material difference in the design of the AltrX™ face-changing liner used by Dr. Engerson during the index surgery and the neutral AltrX™ liner used by him during the revision surgery, with respect to material composition, locking mechanism or anti-rotational tabs.

- While impingement of the femoral neck on the liner is known to occur in a small percentage of hip replacements, failure of the polyethylene liner due to metal femoral neck impingement is not evidence of a defectively designed hip implant system as all manufacturers' hip devices experience such impingement episodes and failures.

Plaintiff's Objections: While Plaintiff does not object to the calling of Ms. Turner, she reserves her right to object to any specific testimony asked of or elicited from her.

b. Dr. Roy D. Crowninshield, Ph.D. (retained expert, CV attached as Exhibit K)

Opinions: Dr. Crowninshield is expected to testify consistently with his Expert Report dated August 29, 2023, incorporated by reference, including to the following main opinions:

i. The widespread clinical use and reported high success rate of the Pinnacle acetabular components and polyethylene liners do not support the conclusion that the components are defective in design.

ii. Plaintiff's AltrX™ liner suffered damage and failed due to impingement of the femoral neck on the polyethylene liner and/or subluxation of the femoral component within the liner.

iii. The femoral component neck impingement and/or femoral component head loading on the liner caused rocking of the liner on the surface opposite to the loading that damaged the locking mechanism and caused component disassembly.

iv. In the index surgery, Dr. Engerson placed the elevated portion of the face-changing liner posteriorly and placed the acetabular cup in more anteversion than recommended, resulting in a tendency for excessive posterior hip impingement and posterior loading of the liner.

v. The mechanism of the Plaintiff's prosthetic impingement was excessive acetabular anteversion. The impingement was not the result of a design defect.

vi. The symptoms experienced by plaintiff after her index surgery are consistent with excessive femoral component neck impingement on the liner and/or posterior loading of the liner and do not indicate any defect in the Pinnacle Cup System or AltrX^{TM} liner.

vii. Dr. Engerson has correctly described the cause of plaintiff's need for a revision hip surgery: "She did have a lipped liner, and it is very likely that [the femoral neck] was impinging on the lip [of the liner] and it somehow disrupted the locking mechanism".

viii. Plaintiff's expert Mr. Edwards is incorrect and misrepresents the literature (the Shon article) and other generally accepted data in stating that impingement occurs in 56% of well-functioning hip replacements. Hip impingement is an unfortunate occurrence, its causes are understood (and include an excessively anteverted acetabular component and face-changing or elevated liner—both present in plaintiff), it is recognized as contributing to the need for total hip revision, and it is not a fact of life in most total hip patients.

ix. There is no support for Mr. Edwards' theory that additional or larger anti-rotational tabs would have prevented Plaintiff's liner from disassociating. The significant damage to Plaintiff's liner resulting from impingement and/or subluxation caused the liner to disassociate—not the number or size of anti-rotational tabs.

x. In the presence of adverse acetabular component orientation, as was present here, hip impingement and/or subluxation are substantially more likely. The force exerted by the femur and femoral prosthetic component on the liner during hip impingement or dislocation/subluxation will significantly damage the liner, as clearly occurred in this case, and cause the liner to lever out. This is what caused Plaintiff's liner to fail, not the alleged design defect.

Plaintiff's Objections: While Plaintiff does not object to the calling of Dr. Crowninshield, she reserves her right to object to any specific testimony asked of or elicited from him.

c. Dr. Steven Barrington, M.D. (retained expert, CV attached as Exhibit L)

Opinions: Dr. Barrington is expected to testify consistently with his Expert Report dated August 30, 2023, and the relevant and unobjectionable testimony at his deposition taken on November 16, 2023, both of which are incorporated by reference, including to the following main opinions:

i. I have used the Pinnacle Cup System for 20 years. It is my implant of choice. At all times it has met my expectations for quality, ease of use, design, and performance.

ii. The Pinnacle Cup System continues to be a state-of-the-art implant, and I have had no problems with it in routine use.

iii. I have implanted 2500 polyethylene liners using the Pinnacle cup over the last 20 years with no known liner failures, including no liner disassociations.

iv. Plaintiff's hip device failed due to patient-specific factors and not due to a defect in the DePuy components used.

v. Plaintiff had a severely deformed spine and stiffness that led to severe flattening of the normal pelvic tilt while standing, which caused impingement of the neck of the femoral component on the rim of the acetabular component liner, plastic deformation of the liner, and early failure of the liner.

vi. Without the normal dynamic motion of the pelvis, Plaintiff's hip replacement was destined for problems. With a face-changing liner she was stable, but impinged, causing the liner to fail under repeated impact loads. Without the face-changing liner, there was no impingement, but she struggled with instability (dislocations).

vii. Impingement is not a "fact of life" of well-functioning hip devices that are placed in an appropriate position (disagreeing with Mr. Edwards' representation of what the Shon article says).

viii. The liner locking mechanism is not designed to prevent or control impingement. It is designed to lock the liner in the cup.

ix. But for the Plaintiff's stiff spine, which caused the impingement and the resulting deformation and failure of the Plaintiff's liner, the revision surgery would not have been necessary.

Plaintiff's Objections: While Plaintiff does not object to the calling of Dr. Barington, she reserves her right to object to any specific testimony asked of or elicited from him.

d. Dr. Todd Engerson, M. D. (the treating surgeon, by deposition)

Opinions: Dr. Engerson is expected to testify consistently to his deposition dated May 22, 2023, including to the following opinions:

i. The cause of the Plaintiff's AltrX™ liner failure was femoral neck impingement on the liner, and not a defect with the liner.

ii. The excessive force of the femoral neck impingement caused the damage to the liner and its early failure.

iii. "It was because there were abnormal forces placed on the device that it couldn't help but fail. It just—it was too much mechanical stress. It allowed it to pop out." Engerson Depos. 125:3-6.

iv. I did not tell Plaintiff her Pinnacle device failed due to a product defect.

Plaintiff's Objections: While Plaintiff does not object to the calling of Dr. Engerson, she reserves her right to object to any specific testimony asked of or elicited from him.

e. Defendants reserve the right to call the following witnesses at trial:

i. Records custodian(s) to authenticate medical or business records if agreement is not reached between the parties.

ii. Any non-objectionable witness listed by Plaintiff.

iii. Any witness to authenticate exhibits.

I.
EXHIBITS

1. **Plaintiff's Exhibit List is attached as Exhibit M.**
2. **Defendants' Objections to Plaintiff's Exhibits are attached as Exhibit N.**
3. **Defendants' Exhibit List is attached as Exhibit O.**
4. **Plaintiff's Objections to Defendants' Exhibits are attached as Exhibit P.**

J.
DAMAGES

Plaintiff: If Plaintiff prevails as to liability, she seeks an award of $156,952.18 in medical expenses and $1,500,000 in pain, suffering, mental anguish, and permanent disability.

Defendants: In addition to their defenses (mentioned above and in their pretrial and trial motions) that it constitutes reversible error to submit the claim of breach of implied warranty of merchantability to the jury for resolution, Defendants' position is that plaintiff is not entitled to any damages because she cannot prove all elements of a prima facie claim of breach of implied warranty of merchantability under Alabama law. Defendants further dispute the medical expenses as being reasonable or necessary (since plaintiff disclosed the amount only during the afternoon of February 29, 2024) or as resulting from any breach of implied warranty.

K.
ATTORNEYS

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Terri L. Bruksch

Jointly submitted this the 29th day of February, 2024.

s/ John D. Richardson ***(with express consent)***
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