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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard Implanted Port Catheter Products Liability Litigation	MDL No. 3081
Kimberly Divelbliss, Individual Plaintiff, v. Becton Dickinson and Company, et al., Defendants.	No. CV-23-01627-PHX-DGC **ORDER**

This multidistrict litigation ("MDL") involves thousands of personal injury cases related to implanted port catheters ("IPCs" or "ports") designed, manufactured, and marketed by Defendants Becton Dickenson and Company, C. R. Bard, Inc., Bard Access Systems, Inc., and Bard Peripheral Vascular, Inc. (collectively, "Defendants" or "Bard"). The MDL Plaintiffs received implants of Bard IPCs and claim they are defective and have caused serious injury.

Plaintiff Kimberly Divelbliss brings one of the MDL cases. She received a Bard IPC that fractured. Her case has been chosen as one of several bellwether cases and is set for trial in August 2026.

Defendants have filed a motion for summary judgment. Doc. 7092. The motion is fully briefed and no party requests oral argument. *See* Docs. 7418, 7663. For reasons stated below, the Court will deny the motion.

I. Background.

An IPC is a medical device surgically implanted under the skin to provide repeated access to a patient's vascular system without the need for multiple needlesticks into peripheral veins. IPCs are used to deliver chemotherapy and immunotherapy medication, intravenous fluids, blood transfusions, and parenteral nutrition. IPCs can remain in place for weeks, months, or even years until treatment is completed.

IPCs consist of a port and a catheter. The port is a small reservoir disc with a self-sealing silicone center where a needle can be inserted to deliver medication. The port typically is implanted beneath the chest skin and below the collarbone. The port is attached to a catheter, which is a thin flexible tube for delivery of the medication to a vein. The catheter is tunneled under the skin to an insertion point in a central vein. Catheters vary in width and are made of silicone or polyurethane. IPCs typically are implanted by an interventional radiologist or a vascular surgeon. A nurse or other medical professional then accesses the IPC to inject the medication, which flows from the port to the catheter and into the vein.

II. Plaintiff Divelbliss.

Plaintiff Divelbliss has received seven IPCs for intravenous immunoglobulin infusions to treat an immunodeficiency. The Bard IPC at issue in this case (Plaintiff's second) is a PowerPort with a Groshong silicone catheter. Plaintiff received the PowerPort on July 13, 2017, at Gerald Champion Medical Center in Alamogordo, New Mexico. Dr. Gregory Richardson, a general surgeon, implanted the PowerPort. On December 13, 2019, Plaintiff was hospitalized after the catheter fractured. A catheter fragment had embolized to the right atrium of Plaintiff's heart and was removed on December 19, 2019.[1]

Plaintiff claims the fractured catheter fragment caused her to suffer heart muscle injuries and cardiac arrhythmia. She alleges the PowerPort was defectively designed because the silicone used in the Groshong catheter is weak and prone to flex fatigue, and

[1] Dr. Jorge Aguila performed the removal procedure. He subsequently implanted five more IPCs in Plaintiff.

the barium sulfate in the catheter (which makes it visible on diagnostic imaging) degrades its mechanical integrity, leading to surface irregularities and fracture. Plaintiff also alleges that Bard failed to warn about and concealed the PowerPort's fracture risks, and made misrepresentations about the PowerPort.

Plaintiff asserts various claims under New Mexico law, some of which have been withdrawn.[2] The following claims remain: design defect (Counts I and II), failure to warn (Counts III and IV), manufacturing defect (Counts V and VI), misrepresentation and concealment (Counts IX, X, and XI), unjust enrichment (Count XIII), and punitive damages. *See* Doc. 175 (amended short-form complaint); Doc. 1889 (amended master complaint).[3] Defendants move for summary judgment on these claims. Doc. 7092 at 2.

III. Summary Judgment Standard.

Summary judgment is appropriate if the moving party shows there is no genuine dispute as to any material fact and it is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). Summary judgment is also appropriate against a party who "fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 322, 323 (1986).

The moving party "bears the initial responsibility of informing the court of the basis for its motion, and identifying those portions of [the record] which it believes demonstrate the absence of a genuine issue of material fact." *Celotex*, 477 U.S. at 323. Only disputes over facts that might affect the outcome of the suit will preclude the entry of summary judgment, and the disputed evidence must be "such that a reasonable jury could return a

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[2] The parties agree that New Mexico law governs Plaintiff's claims. *See* Docs. 7092 at 5, 7418 at 2.

[3] The master complaint sets forth allegations and claims the MDL Plaintiffs assert generally. *See* Doc. 145. Plaintiff-specific allegations are contained in individual short-form complaints, profile forms, and fact sheets. *See id.*; Docs. 476, 477. The master complaint asserts seventeen claims and seeks both compensatory and punitive damages. Doc. 1889 ¶¶ 268-487. Plaintiff Divelbliss does not assert loss of consortium, wrongful death, or survival claims set forth in the master complaint (Counts XIV-XVI), and has withdrawn claims for breach of warranty (Counts VII and VIII), deceptive trade practices (Count XII), and successor liability (Doc. XVII). *See* Doc. 7092 at 2 n.1.

verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The Court must view the evidence in the light most favorable to the nonmoving party, *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986), and draw justifiable inferences in that party's favor, *Anderson*, 477 U.S. at 255.

IV. Discussion.

A. Design Defect Claims (Counts I and II).

Plaintiff asserts strict liability and negligent design defect claims. Docs. 175 ¶ 15, 1889 ¶¶ 268-300. Under New Mexico law, "[a] negligence claim is premised on the notion that 'the supplier of a product has a duty to use ordinary care to avoid a foreseeable risk of injury caused by a condition of the product or manner in which it is used.'" *Magoffe v. JLG Indus., Inc.*, No. CIV 06-0973 MCA/ACT, 2008 WL 2967653, at *9 (D.N.M. May 7, 2008) (quoting New Mexico Uniform Jury Instruction – Civil ("UJI") 13-1402). A strict products-liability theory does not depend on the degree of care exercised by the supplier. The focus is on the product, not the supplier, and considers the risk of injury the product presents. Thus, "'under the strict products liability theory, a supplier of products is liable for harm proximately caused by an unreasonable risk of injury resulting from a condition of the product or from a manner of its use.'" *Id.* (quoting *Smith ex rel. Smith v. Bryco Arms*, 33 P.3d 638, 644 (N.M. Ct. App. 2001)); *see also* UJI 13-1406 ("Under the 'products liability' claim, a supplier in the business of putting a product on the market is liable for harm caused by an unreasonable risk of injury resulting from a condition of the product or from a manner of its use. Such a risk makes the product defective."); *Rimbert v. Eli Lilly & Co.*, 577 F. Supp. 2d 1174, 1202 (D.N.M. 2008) ("To recover under the strict liability theory, a plaintiff must prove that a defect in the product as manufactured, designed, or marketed created an unreasonably dangerous risk of injury.").

Defendants argue that Plaintiff's design defect claims fail because: (1) the PowerPort is an "unavoidably unsafe product" under comment k to Restatement § 402A and UJI 13-1419; and (2) Plaintiff has presented no evidence that the PowerPort's risks outweigh its benefits. Doc. 7092 at 3, 12-17.

1. Comment k and UJI 13-1419.

Comment k to Restatement § 402A provides an exemption from strict liability for certain "unavoidably unsafe products," explaining:

> There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous.

Restatement § 402A, cmt. k.[4]

New Mexico has adopted the strict product liability standards in Restatement § 402A, with some exceptions and modifications. *See McDonald v. Zimmer Inc.*, 461 P.3d 930, 944 (N.M. Ct. App. 2019). New Mexico's "unavoidably unsafe products" exemption from strict liability is set forth in UJI 13-1419, which provides:

> There are some products which, even when properly prepared and labeled, cannot be made safe for their intended and ordinary use. Because of the nature of ingredients or natural characteristics of the products, use of these products involves substantial risk of injury, and some users will necessarily be harmed. Such products are said to be unavoidably unsafe.
>
> Unless the product unreasonably exposes users to risk of injury, there is no liability for supplying an unavoidably unsafe product. Whether users are unreasonably exposed to risk of injury turns upon a balancing of the dangers and benefits resulting from the product's use.

UJI 13-1419; *see also Zimmer*, 461 P.3d at 945 (noting that UJI 13-1419 is "New Mexico's iteration of comment k").

Defendants contend that Plaintiff's design defect claims are precluded under comment k and UJI 13-1419 because fracture is an inherent risk of all IPCs and the PowerPort's generic condition gave rise to the risk of injury alleged by Plaintiff. Doc. 7092 at 14. Plaintiff counters that comment k and UJI 13-1419 do not categorically shield

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[4] Comment k further explains that unavoidably unsafe products "are especially common in the field of drugs." *Id.* "An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve." *Id.*

Defendants from liability on the design defect claims. Doc. 7418 at 3-5. The Court agrees with Plaintiff.

UJI 13-1419 applies only where a product "cannot be made safe" for its intended use and its "generic condition . . . gives rise to the risk of injury[.]" UJI 13-1419, use note. It does not apply where the risk arises "from inadequacies of design, manufacture or labeling." *Id.*; *see Zimmer*, 461 P.3d at 945. Plaintiff claims the risk of injury in this case arises from inadequate design, manufacturing, and labeling. *See* Docs. 175 ¶ 15, 7418 at 4-5. And she has presented evidence from which a jury reasonably could agree. *See* Doc. 7418-1 ¶¶ 75, 91-99, 102-07, 119-36, 159-75, 231-60.

As the *Zimmer* court noted, UJI 13-1419 "expressly adopts a case-by-case inquiry, as it contains a caveat that there may be strict liability even for an unavoidably unsafe product, where the product 'unreasonably exposes users to risk of injury.'" 461 P.3d at 945 (quoting UJI 13-1419). The risk-benefit determination "is a question of fact for the jury[.]" *Id.* (quoting UJI 13-1419, comm. cmt.).

Defendants note that New Mexico courts have applied comment k to medical devices. Doc. 7092 at 13 (citing *Perfetti v. McGhan Med.*, 662 P.2d 646 (N.M. Ct. App. 1983)). In *Perfetti*, however, there was no evidence of an inadequate design, and whether the subject product (a mammary prosthesis) was unavoidably unsafe was a question of fact for the jury. 662 P.2d at 650. Defendants cite no New Mexico case finding as a matter of law that a medical device is an unavoidably unsafe product. *Cf. Zimmer*, 461 P.3d at 945 ("As the evidence in this case makes clear, a finding that all modular hip implants present some risk of corrosion is not a finding that all modular hip implants present an unavoidable risk of metallosis."); *Aguirre v. Atrium Med. Corp.*, No. 2:18-CV-0153-WJ-GBW, 2019 WL 2210801, at *6 (D.N.M. May 22, 2019) (denying motion to dismiss where the defendant cited no case concluding as a matter of law that all hernia mesh is incapable of being made safe).

The Court will deny Defendants' motion based on comment k and UJI 13-1419. Doc. 7092 at 12-14.

2. Risk-Benefit Analysis.

Under New Mexico law, "an unreasonable risk of injury resulting from a condition of the product . . . makes the product defective." UJI 13-1406. "An unreasonable risk of injury is a risk which a reasonably prudent person having full knowledge of the risk would find unacceptable." UJI 13-1407. "In determining whether a product design poses an unreasonable risk of injury, the fact-finder conducts a risk-benefit analysis, and considers 'the ability to eliminate the risk without seriously impairing the usefulness of the product or making it unduly expensive.'" *Zimmer*, 461 P.3d at 940 (quoting UJI 13-1407).

The risk-benefit analysis is guided by seven criteria identified in *Brooks v. Beech Aircraft Corp.*, 902 P.2d 54 (N.M. 1995), and incorporated into UJI 13-1407's committee commentary. *See id.* at 942. The criteria include: (1) the usefulness and desirability of the product; (2) the availability of other and safer products to meet the same need; (3) the likelihood of injury and its probable seriousness, i.e., "risk"; (4) the obviousness of the danger; (5) common knowledge and normal public expectation of the danger (particularly for established products); (6) the avoidability of injury by care in use of the product (including the effect of instructions or warnings); and (7) the ability to eliminate the danger without seriously impairing the usefulness of the product or making it unduly expensive. *See id.*; UJI 13-1407, comm. cmt.; *Brooks*, 902 P.2d at 61 n.2 (citing John W. Wade, *The Nature of Strict Tort Liability for Products*, 44 Miss. L. J. 825, 837-38 (1973)).

Defendants contend that summary judgment is warranted on the design defect claims because Plaintiff cannot show the PowerPort is unreasonably dangerous under the risk-benefit analysis. Doc. 7418 at 14. Specifically, Defendants argue that Plaintiff's experts did not consider all seven risk-benefit factors. *Id.* at 15-17. But as Plaintiff notes, the factors are guideposts for argument at trial and jury deliberations, not a checklist for summary judgment. Doc. 7418 at 2; *see also* UJI 13-1419, comm. cmt. ("Whether a risk is reasonable is a question for the jury, balancing the benefits and hazards of the product."). "UJI 13-1407 states in the committee commentary that 'criteria for determining whether a risk of injury is unreasonable have not been provided in the instruction because the

committee feels this falls within the unique domain of advocacy under the circumstances of proof in each case.' The commentary then lists the seven risk-benefit criteria *suggested* by Professor John W. Wade[.]" *Zimmer*, 461 P.3d at 942 (quoting UJI 13-1407, comm. cmt.). There is simply "no support for [Defendants'] contention that all seven factors must be considered for every design defect claim." *Id.*

Defendants assert that Plaintiff has identified no alternative design. Doc. 7092 at 15. "[C]onsideration of alternative designs is but one of several risk-benefit considerations that a jury *may* balance in determining whether a product created an unreasonable risk of injury." *Zimmer*, 461 P.3d at 942-43 (quoting *Bustos v. Hyundai Motor Co.*, 243 P.3d 440, 452 (N.M. Ct. App. 2010)). "[C]ontrary to Defendants' argument, a specific finding on this issue is not required." *Bustos*, 243 P.3d at 452. Even so, Plaintiff's experts do address alternative designs, opining that catheters made of polyurethane or mesh reinforcements would reduce the risk of fracture. Doc. 7092 at 15; *see* Doc. 7418 at 7. Plaintiff identifies multiple ports already on the market that she claims are economically feasible and more fracture resistant than the PowerPort. *See* Doc. 7418 at 7.[5]

Defendants further argue that Plaintiff offers no evidence of obviousness, common knowledge, or inadequate warnings. Doc. 7092 at 16. But again, there is no checklist of factors for summary judgment. The jury will decide whether the product was unreasonably dangerous in light of Plaintiff's evidence of allegedly high fracture rates in Defendants' Groshong catheters and the availability of safer designs. The Court also finds a question of fact on the adequacy of Defendants' warnings, as explained below.

[5] Contrary to Defendants' assertion (Doc. 7092 at 15), the proposed alternative designs need not completely eliminate the risk of fracture. *See* Doc. 7418 at 6; *Zimmer*, 461 P.3d at 943 (noting that the alternative design "virtually" eliminated the risk of metallosis). And Defendants cite no legal authority suggesting that an alternative design must be FDA-cleared or commercially available in the United States to be relevant to the risk-benefit analysis under New Mexico law. *See Thacker v. Ethicon, Inc.*, 47 F.4th 451, 464 (6th Cir. 2022) ("[I]t is illogical to say that an *alternative design* – that, *by definition*, was never put on the market – must have been approved by the FDA to support a design defect claim."); *In re Ethicon Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, No. MDL 2327, 2020 WL 1060970, at *3 (S.D.W. Va. Feb. 13, 2020) (explaining that FDA-clearance "has no bearing on whether PVDF mesh is a safer alternative to other mesh products").

The Court will deny Defendants' motion based on an alleged absence of evidence that the PowerPort's risks outweigh its benefits. Doc. 7092 at 14-17.

B. Failure to Warn Claims (Counts III and IV).

To establish a failure to warn claim under New Mexico law, a plaintiff must prove: (1) no warning was provided or the warning was inadequate, and (2) the absence or the inadequacy of the warning caused the plaintiff's injury. *See Suttman-Villars v. Argon Med. Devices, Inc.*, 553 F. Supp. 3d 946, 961 (D.N.M. 2021); *Richards v. Upjohn Co.*, 625 P.2d 1192, 1195 (N.M. Ct. App. 1980). In the context of a failure to warn claim involving a medical device, the manufacturer must warn the doctor – the "learned intermediary" – not the patient. *Suttman-Villars*, 553 F. Supp. 3d at 961 (citation omitted); *see also Perfetti*, 662 P.2d at 650 ("A manufacturer of a product which is obtainable only through the services of a physician, fulfills its duty if it warns the physician of the dangers attendant upon its use, and need not warn the patient as well." (citation modified)); *Richards*, 625 P.2d at 1195 ("A drug manufacturer has a duty to warn the medical profession of the dangers of its drugs which it knew or should have known to exist.").

Plaintiff asserts strict liability and negligent failure to warn claims. Docs. 175 ¶ 15, 1889 ¶¶ 301-34. For purposes of a negligence claim, the medical device manufacturer "must make reasonable efforts to warn." *Richards*, 625 P.2d at 1196; *see* UJI 13-1415 (the manufacture "must use ordinary care to warn of a risk of injury"). The manufacturer's failure to provide an adequate warning renders the medical device "unreasonably dangerous, and the [device] is then a defective product for purposes of strict products liability." *Richards*, 625 P.2d at 1196; *see* UJI 13-1415 ("Under plaintiff's claim of 'products liability', a product presents an unreasonable risk of injury if put on the market without warning of a risk which could be avoided by the giving of an adequate warning.").

Defendants argue that summary judgment is warranted because: (1) the warnings provided in the PowerPort's Instructions for Use ("IFU") are adequate as a matter of law, and (2) the learned intermediary doctrine forecloses the failure to warn claims. Doc. 7092 at 3, 7-12.

1. Adequacy of the Warning.

Defendants contend that the IFU for Plaintiff's PowerPort identifies the risks and injuries that Plaintiff alleges she experienced. *Id.* at 7 (citing Doc. 7092-1 ¶¶ 57-63). The IFU warns about certain catheter fractures and lists various cardiac injuries as possible complications, including arrhythmia. *See* Doc. 7092-1 ¶¶ 58-61; Doc. 7092-6.

A warning is adequate only if it discloses both "the nature and extent of the danger." *Suttman-Villars*, 553 F. Supp. 3d at 961 (quoting *Jones v. Minn. Min. & Mfg. Co.*, 100 N.M. 268, 669 (N.M. Ct. App. 1983)). The warning "must adequately indicate the scope of the danger" and "reasonably communicate the extent or seriousness of the harm" that could result from use of the device. *Richards*, 625 P.2d at 1196. "[A] simple directive warning may be inadequate when it fails to indicate the consequences that might result from failure to follow it[.]" *Id.*; *see also* UJI 13-1418 ("To be adequate, a warning . . . must disclose the nature and extent of the danger . . . [and] there must be specified any harmful consequence which a reasonably foreseeable user would not understand from a general warning of the product's danger or from a simple directive[.]").

Plaintiff presents evidence that Defendants' warnings were inadequate because the IFU does not warn that catheter fracture can be catastrophic and life-threatening, that fracture of their catheters commonly occurs, or that barium sulfate, weak silicone, flex fatigue, and subclavian placement increase the risk of fracture. Doc. 7418 at 8 (citing Doc. 7418-1 ¶¶ 91-93, 102-07, 134-36, 231-60). Plaintiff also presents evidence that the IFU inadequately warned about the risk of arrhythmia and misrepresented that the catheter materials are biocompatible. *Id.* at 8-9 (citing Doc. 7418-1 ¶¶ 164, 231-33, 245). Plaintiff's evidence creates a question of fact on whether Defendants adequately warned about the scope of the danger and the extent or seriousness of the harm that could result from use of the PowerPort.

Defendants rely on *Serna v. Roche Laboratories*, 684 P.2d 1187 (N.M. Ct. App. 1984), but the plaintiff in that case "introduced no evidence which would support a factual question as to the adequacy of the warnings." 684 P.2d at 1190. When the nonmovant

presents evidence of the inadequacy of the warnings, as Plaintiff does here, "it is improper for the court to grant summary judgment for the . . . manufacturer." *Id.*; *see also Perfetti*, 662 P.2d at 650 ("The Committee Comment to [UJI 13-1418] points out that the adequacy of a warning is ordinarily a question of fact."); *Richards*, 625 P.2d at 1196 ("Richards has presented evidence that [the] warnings were inadequate. . . . There is also evidence that the warnings which were given by Upjohn were unclear, and that they did not effectively communicate to physicians the dangers from using the drug to irrigate wounds. In these circumstances, there is a genuine issue as to whether Upjohn's warnings were adequate."); *Rimbert*, 577 F. Supp. 2d at 1230 ("Rimbert has presented some evidence that the Prozac warnings may have been inadequate. . . . The Court cannot say that, as a matter of law, the Prozac warnings in 2003 were adequate. There is an issue of material fact regarding whether the warnings were adequate, and thus Eli Lilly is not entitled to summary judgment[.]").

The Court will deny Defendants' motion based on their argument that the PowerPort's warnings were adequate as a matter of law. Doc. 7092 at 7-8.

2. Learned Intermediary Doctrine.

Defendants contend that the failure to warn claims are foreclosed by the learned intermediary doctrine because Dr. Richardson was aware of the information Plaintiff claims Defendants failed to provide and because a different warning would not have changed his decision to treat Plaintiff with the PowerPort. Doc. 7092 at 8-12. Plaintiff argues that fact disputes preclude summary judgment based on the learned intermediary doctrine. Doc. 7418 at 9-12.

a. Dr. Richardson's Knowledge of the PowerPort's Risks.

Dr. Richardson testified that he has implanted and removed hundreds of IPCs and that when making treatment decisions, he primarily relies on his education, training, and forty years of experience. Doc. 7092 at 8 (citing Doc. 7092-1 ¶¶ 23-25, 30-31, 34-35, 38); *see also* Doc. 7092-16. Defendants note that Dr. Richardson also testified that he was aware of the risk of fracture, catheter embolization, and cardiac arrhythmia, and that

everything that occurred with Plaintiff was a known potential risk of having an IPC implanted. Doc. 7092 at 8 (citing Doc. 7092-1 ¶¶ 24-35, 38, 47); *see also* Doc. 7092-16. But as Plaintiff argues, this testimony shows Dr. Richardson had general knowledge of IPC fracture risks and related complications, but not that he knew the specific information Plaintiff claims Bard failed to provide regarding the increased risks associated with the PowerPort's Groshong silicone catheter. Doc. 7418 at 9-10; *see also Jones*, 669 P.2d at 750 ("[T]he radiotherapists knew the risks of excessive dosage – injury to structures in the immediate area of the prostate, rectal injuries that could require colostomies, urethral strictures that could require surgical correction, the development of fistulae. 3M states that these risks were exactly the same as the injuries plaintiffs allege they received. Thus, 3M asserts the actual knowledge requirement was met. We do not agree because this argument goes only to general knowledge of the danger in implanting I-125 seeds.").

Dr. Richardson testified that he read the PowerPort's IFU, expected it to be accurate, and would expect the manufacturer to have more information about the device and to let him know if the device had problems. Doc. 7418 at 9 (citing Doc. 7418-1 ¶¶ 250-53). He also testified that he was not aware of specific risks Plaintiff claims existed in the PowerPort, including that (1) Groshong silicone catheters were weaker and more prone to fracture than other catheters; (2) the potential for barium sulfate to separate from the catheter made it more prone to fracture; (3) catheter fracture was not uncommon; (4) lifelong cardiac arrhythmia (as opposed to reversible arrhythmia) is a possible complication; and (5) subclavian placement should be avoided. *Id.* at 9-10 (citing Doc. 7092-1 ¶ 255); *see also* Doc. 7419-57 at 16, 20, 22, 26-27. Plaintiff presents evidence to support these alleged shortcomings. Doc. 7418-1 ¶¶ 85, 91-93, 102-03, 107, 120-22, 130, 135-42, 145-46, 160-65, 172, 233, 242, 247-48. Defendants dispute these facts, but the evidence must be viewed in Plaintiff's favor at this stage. *See Anderson*, 477 U.S. at 255. If the jury believes the evidence of these alleged risks in the PowerPort, Defendants have presented no evidence that Dr. Richardson knew about them.

Defendants have not shown, as a matter of undisputed fact, that Dr. Richardson knew the information Defendants allegedly failed to provide. *See Jones*, 669 P.2d at 751 (finding "a factual issue as to the radiotherapists' knowledge of the nature and extent of the danger of excessive radiation in implanting I-125 seeds in treating cancer of the prostate," and that "summary judgment was improper").

b. Dr. Richardson's Decision to Implant a PowerPort IPC.

Defendants contend, as a matter of law, that a different warning would not have changed Dr. Richardson's decision to treat Plaintiff with the subject PowerPort. Doc. 7092 at 9-12. They argue that Dr. Richardson testified he did not rely solely on warnings contained in the PowerPort's IFU and gave more credence to his own experience implanting IPCs, that he could not answer hypothetical questions about specific risks "out of context," and that it would be "pure speculation" as to whether he would have used a better IPC if one had been available. *Id.* at 9-11 (citing Doc. 7092-1 ¶¶ 24-25, 38, 41, 45). Defendants emphasize that when asked whether, in retrospect, he would have changed his decision to treat Plaintiff with the PowerPort, he answered: "I don't believe so." *Id.* at 11 (citing Doc. 7092-1 ¶ 45); *see also* Doc. 7092-16 at 52.

But Dr. Richardson also testified that he would not implant an IPC in a patient if the manufacturer had told him it was unsafe; that he would have considered placing a more fracture-resistant catheter in his patients; and that if Defendants had made him aware that Groshong silicone catheters were weaker and more prone to fracture than other available catheters, he would have factored that into his decision-making. Doc. 7418 at 10 (citing Doc. 7418-1 ¶¶ 255-57); *see also* Doc. 7419-57 at 27. Construed in the light most favorable to Plaintiff, the evidence creates a triable issue as to whether Dr. Richardson would have acted differently if Defendants had provided additional warnings and information. *See Richards*, 625 P.2d at 1195 (explaining that "[p]roximate cause is a factual issue, unless all facts regarding causation are undisputed").

Defendants' reliance on *Silva v. Smithkline Beecham Corp.*, No. 31,276, 2013 WL 4516160 (N.M. Ct. App. Feb. 7, 2013), is misplaced. Doc. 7092 at 9. The undisputed

evidence in that case established that the prescribing physician did not rely on any warning provided by the defendant when she prescribed the drug to the plaintiff, that she was aware of the specific risks that the plaintiff claimed should have been included in the warning, and that she held an "unequivocal" position to prescribe the drug irrespective of the adequacy of the warning. *Silva*, 2013 WL 4516160, at *3.

The Court will deny Defendants' motion based on the learned intermediary doctrine. Doc. 7092 at 8-12.

C. Manufacturing Defect Claims (Counts V and VI).

Plaintiff asserts strict liability and negligent manufacturing defect claims. Docs. 175 ¶ 15, 1889 ¶¶ 335-66. Under New Mexico law, a product "contains a manufacturing defect when the product departs from its intended design[,]" and strict liability exists "even though all possible care was exercised in the preparation and marketing of the product." *Parker v. St. Vincent Hosp.*, 919 P.2d 1104, 1108 (N.M. Ct. App. 1996); *see also Spectron Dev. Lab'y v. Am. Hollow Boring Co.*, 936 P.2d 852, 856 (N.M. Ct. App. 1997) (same).

Defendants argue that Plaintiff's manufacturing defect claims fail as a matter of law because she has produced no evidence that the PowerPort deviated from Defendants' design specifications. Doc. 7092 at 17. Specifically, Defendants assert that Dr. Ahmed El-Ghannam, Plaintiff's biomaterials expert, admitted that he did not look at design specifications. Doc. 7092-1 ¶ 10.

Viewed in the light more favorable to Plaintiff, she has identified Bard documents showing that barium sulfate should be evenly distributed in the Groshong catheter to make it less fragile. Doc. 7418 at 13 (citing Doc. 7418-1 ¶ 165); *see also* Docs. 7418-71 at 8, 7418-12 at 2. Dr. El-Ghannam states in his report that a common observation of his catheter testing was the non-homogenous dispersion of barium-sulfate. Doc. 7418-14 at 8. A jury reasonably could conclude from this evidence that the manufactured catheter departed from its intended design.

New Mexico law does not require a plaintiff to identify specifically how a manufacturing defect occurred. *Parker*, 919 P.2d at 1108 ("When . . . a product comes off the assembly line with a manufacturing defect, it may be very difficult for a plaintiff to establish what went wrong on the assembly line, much less prove that the error was the result of negligence. In this regard, strict products liability can be viewed as simply an extension of the doctrine of res ipsa loquitur. [And the] existence of a manufacturing defect in itself may imply that the manufacturer was negligent."). Defendants' citation to *Figueroa v. Ethicon, Inc.*, No. 2:19-cv-01188 KWR/KRS, 2020 WL 1434249, at *3 (D.N.M. Mar. 24, 2020), is misplaced because the plaintiff in that case did not allege that the product deviated from its intended design.

The Court will deny Defendants' motion on the manufacturing defect claims. Doc. 7092 at 17.

D. Misrepresentation Claims (Counts IX and X).

Plaintiff asserts negligent and fraudulent misrepresentation claims. Docs. 175 ¶ 15, 1889 ¶¶ 394-426. Under New Mexico law, misrepresentation claims require proof that the defendant made a material misrepresentation that was relied on to the plaintiff's detriment. *See Robey v. Parnell*, 392 P.3d 642, 652 (N.M. Ct. App. 2017); *Robertson v. Carmel Builders Real Est.*, 92 P.3d 653, 662 (N.M. Ct. App. 2003); UJI 13-1632, 13-1633. New Mexico law does not require that a misrepresentation be made directly to the plaintiff. *See R.A. Peck, Inc. v. Liberty Fed. Sav. Bank*, 766 P.2d 928, 932 (N.M. Ct. App. 1988). Rather, the requirement is that "the defendant intend that the information be received by the plaintiff or a group of persons of which plaintiff was a member." *Healthsource, Inc. v. X-Ray Assoc. of N.M.*, 116 P.3d 861, 871 (N.M. Ct. App. 2005).

Defendants argue that summary judgment is warranted because neither Plaintiff nor Dr. Richardson relied on a Bard representation in making the treatment decision. Docs. 7092 at 18, 7663 at 10-11. Plaintiff has presented evidence that Defendants' IFU misrepresents that all materials are biocompatible, that catheter fracture is preventable and rare, and that pinch-off can be avoided by proper placement. Doc. 7418 at 14 (citing

Doc. 7418-1 ¶¶ 231-241, 246-249). Plaintiff also presents evidence that Dr. Richardson read and considered the IFU, would expect the information in the IFU to be accurate, and implanted Plaintiff's PowerPort in compliance with the IFU. *Id.* (citing Doc. 7481-1 ¶¶ 241, 250-53, 256-57). This evidence creates a triable issue as to whether Defendants made a material misrepresentation that Dr. Richardson relied on to Plaintiff's detriment.

The Court will deny Defendants' motion on the negligent and fraudulent misrepresentation claims. Doc. 7092 at 17-18.

E. Fraudulent Concealment Claim (Count XI).

Plaintiff presents evidence that the IFU omits known risks – flex fatigue, silicone weakness, and barium sulfate separation – that increase the risk of catheter fracture. Doc. 7418 at 14 (citing Doc. 7418-1 ¶¶ 242-45). Defendants do not address these alleged omissions, nor do they otherwise address the elements of a fraudulent concealment claim. *See R.A. Peck*, 766 P.2d at 932 ("An action for fraud may be predicated on concealment where there is a duty to disclose. Fraud may arise by omission as well as by commission. Thus, where one is under a duty to speak but remains silent and fails to disclose a material fact, he may be liable for fraud."); *Farmer v. Walmart, Inc.*, 729 F. Supp. 3d 1202, 1234 (D.N.M. 2024) ("Actionable fraud is found if a party to a transaction knows of material facts, has a duty to disclose, and remains silent."). The Court will deny Defendants' motion to the extent they seek summary judgment on Plaintiff's concealment claim. *See* Doc. 7092 at 17; *see also* Docs. 175 ¶ 15, 1889 ¶¶ 427-38.[6]

F. Unjust Enrichment Claim (Count XIII).

"New Mexico has long recognized actions for unjust enrichment, that is, in quantum meruit or assumpsit. To prevail on such a claim, one must show that: (1) another has been knowingly benefitted at one's expense (2) in a manner such that allowance of the other to

[6] Defendants argue that summary judgment is warranted on the fraud claims (Counts X and XI) because the claims are not pled with particularity under Federal Rule of Civil Procedure 9(b). Doc. 7092 at 18. Defendants rightly withdrew this argument in their reply brief. Doc. 7663 at 10 n.3; *see Cable & Computer Tech. Inc. v. Lockheed Sanders, Inc.*, 214 F.3d 1030, 1038 (9th Cir. 2000) (explaining that the district court "appears to have inappropriately applied Fed.R.Civ.P. 9(b), requiring particularity in the pleading of fraud, to a summary judgment motion where evidence, not pleading, was to be considered").

retain the benefit would be unjust." *Ontiveros Insulation Co. v. Sanchez*, 3 P.3d 695, 698 (N.M. Ct. App. 2000) (citations omitted).

Plaintiff pleads her unjust enrichment claim in the alternative. Docs. 1889 ¶ 461, 7418 at 15. Contrary to Defendants' assertion (Doc. 7092 at 19), a plaintiff may plead an equitable claim as an alternative to a potential adequate remedy at law. *See* Fed. R. Civ. P. 8(a)(3), (d)(2); *Figueroa*, 2020 WL 1434249, at *3 ("Defendants initially argue that [the unjust enrichment] claim must be dismissed because there is an adequate remedy at law. However, Plaintiff may plead alternative, conflicting theories. Fed. R. Civ. P. 8(d)(2), (d)(3) . . . . It would be premature to dismiss the unjust enrichment claim and it is unclear at this time whether Plaintiff has an adequate remedy at law.").

Defendants also assert that there is no implied or quasi contract between Bard and Plaintiff because Bard sold the PowerPort to Gerald Champion Medical Center, not Plaintiff. Doc. 7092 at 19. But unjust enrichment "provide[s] relief where, *in the absence of privity*, a party cannot claim relief in contract and instead must seek refuge in equity." *Ontiveros*, 3 P.3d at 698-99 (emphasis added); *see also Arena Res., Inc. v. Obo, Inc.*, 238 P.3d 357, 361 (N.M. Ct. App. 2010) (explaining that unjust enrichment "implie[s] obligations where, on the basis of justice and equity, *the law will impose a contractual relationship* between parties, regardless of their assent thereto" (citation omitted)).

The Court will deny Defendants' motion on the unjust enrichment claim. Doc. 7092 at 19.

G. Punitive Damages.

Plaintiff seeks an award of punitive damages. Doc. 175 ¶ 15, 1889 ¶¶ 484-87. Under New Mexico law, punitive damages may be awarded to penalize "bad faith" or when the defendant "acts with reckless disregard for the rights of the plaintiff – i.e., when the defendant *knows* of potential harm to the interests of the plaintiff but nonetheless 'utterly fails to exercise care' to avoid harm." *Allsup's Convenience Stores, Inc. v. N. River Ins. Co.*, 976 P.2d 1, 17 (N.M. 1998) (quoting *Paiz v. State Farm Fire & Cas. Co.*, 880 P. 2d 300, 308 (N.M. 1994)); *see also Couch v. Astec Indus., Inc.*, 53 P.3d 398, 411 (N.M. Ct.

App. 2022) ("Because the purpose of punitive damages is to punish a wrongdoer, a wrongdoer must have a culpable mental state to be liable for punitive damages."); UJI 13-1827 (requiring the jury to find that that the defendant's conduct was malicious, willful, reckless, wanton, fraudulent, or in bad faith to award punitive damages).

Defendants argue that Plaintiff lacks evidence that they acted with malicious, intentional, or reckless disregard for her safety. Doc. 7092 at 20. Plaintiff claims that Defendants' actions constitute a reckless disregard for the safety of Plaintiff and other patients given Defendants' knowledge of the increased fracture risks posed by the PowerPort's silicone catheter. Doc. 7418 at 17.

In *Gonzales v. Surgidev Corp.*, 899 P.2d 576 (N.M. 1995), the New Mexico Supreme Court held that a manufacturer could act "recklessly" by "failing to issue a warning regarding the implantation" of a medical device via a particular procedure. 899 P.2d at 588. The *Gonzales* court looked to evidence of data indicating significant long-term problems, data indicating much higher rates of complications, and evidence that the company "was aware that its figures probably underestimated the percentage of complications in patients." *Id.*

Plaintiff has presented evidence that Defendants knew that their port catheters commonly fracture and that the risk of catheter fracture is catastrophic and life-threatening. Doc. 7814 at 17 (citing Doc. 7814-1 ¶¶ 78-81, 91-93, 102-07). Also, that despite knowing the mechanisms that caused the fractures, Defendants disregarded their responsibility to mitigate the risk of fracture and instead artificially lowered the complication rates associated with fracture and manipulated their own risk assessment to avoid redesigning ports. *Id.* (citing Doc. 7814-1 ¶¶ 94-99, 108-46). Plaintiff further presents evidence that Defendants misrepresented the danger and concealed information from the FDA, doctors, and patients. *Id.* (citing Doc. 7814-1 ¶¶ 147-158, 231-249).

This evidence, if believed by the jury, is sufficient to support a finding that Defendants knew of potential harm to Plaintiff from the risk of catheter fracture but

nonetheless utterly failed to exercise care to avoid such harm. *See Allsup's Convenience Stores*, 976 P.2d at 17.

Defendants note that they complied with applicable FDA regulations in bringing the PowerPort to market. Doc. 7092 at 20. While compliance with FDA regulations is relevant on the question of punitive damages, it is not dispositive. *Gonzales*, 899 P.2d at 590. "[C]ompliance with federal regulations does not preclude a finding of recklessness or an award of punitive damages." *Id.* (citations omitted).

The Court will deny Defendants' motion on Plaintiff's request for punitive damages. Doc. 7092 at 19-20.

IT IS ORDERED that Defendants' motion for summary judgment (Doc. 7092) is **denied**.

Dated this 22nd day of July, 2026.

David G. Campbell
Senior United States District Judge