IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

MARY CASTILLO,	§	
	§	
Plaintiff,	§	
	§	
v.	§	1:20-CV-513-RP
	§	
BOSTON SCIENTIFIC CORPORATION,	§	
	§	
Defendant.	§	

ORDER

Before the Court is Defendant Boston Scientific Corporation's ("BSC") motion for summary judgment, (Dkt. 47), and Plaintiff Mary Castillo's ("Castillo") response, (Dkt. 50), as well as Castillo's motion to limit or exclude the opinions of BSC's expert, (Dkt. 48), and BSC's response, (Dkt. 49).[1] After considering the parties' arguments, the record, and the relevant law, the Court grants in part and denies in part BSC's motion for summary judgment and grants in part and denies in part Castillo's motion to limit or exclude the opinions of BSC's expert.

I. FACTUAL BACKGROUND AND PROCEDURAL HISTORY

Castillo, who lives in Texas, sought gynecological care. (Mot. Summ. J., Dkt. 47, at 1–2). The physician to whom she was referred, Dr. Amanda White ("White"), recommended a medical device called the "Advantage Fit System" ("AFS"), "a polypropylene mesh implant to treat [stress urinary incontinence ("SUI")] resulting from urethral hypermobility and/or intrinsic sphincter deficiency," manufactured by BSC. (*Id.* at 2). A number of physicians' professional organizations, as well as an FDA panel, have stated that devices like the AFS are normally relatively safe and effective. (*Id.* at 5–6).

[1] Neither party filed a reply to the opposing party's response.

One of White's residents, Dr. Emily Goulet ("Goulet"), "handled the pre-operative appointments with Plaintiff where the risks and benefits of the procedure were discussed, in part, to establish informed consent for the procedure," and ultimately implanted the AFS in Castillo on November 15, 2011. (*Id.* at 2–3). The parties dispute the extent to which Goulet was aware of the various risks posed by the implantation procedure and by the AFS once implanted. (*Compare id.*, with Resp. Mot. Summ. J., Dkt. 50, at 10–11). After Goulet implanted the AFS in Castillo, Castillo asserts that the AFS caused her "chronic pelvic pain, vaginal pain, dyspareunia, suprapubic pain, recurrent urinary tract infections, and chronic urinary dysfunction (including dysuria, frequency, urgency, and urge incontinence)." (Resp. Mot. Summ. J., Dkt. 50, at 8; *cf.* Mot. Summ. J., Dkt. 47, at 6 ("[Castillo] alleges that her implant caused her '[u]rinary problems, bowel problems, bleeding, dyspareunia, and pain.'")).

The AFS's directions for use ("DFU") note a number of potential risks and complications and specify that the AFS should be used only by "clinicians with adequate training and experience" and that the clinician should "consult the medical literature" prior to implanting the device. (*Id.*; *see also* DFU, Def.'s Ex. C, Dkt. 47-3). The parties dispute whether Goulet reviewed the DFU prior to the procedure and whether additional contact from a BSC representative would have prompted her to review it further. (*Compare id.* at 3, *with* Resp. Mot. Summ. J., Dkt. 50, at 10). Castillo, meanwhile, "relied on Dr. Goulet and Dr. White to choose the best approach for treatment of her SUI, and [she] has no criticism of how that treatment was handled." (Mot. Summ. J., Dkt. 47, at 3). Castillo herself did not speak with anyone at BSC and does not recall whether she received any additional literature from BSC prior to the AFS's implantation. (*Id.*).

This case was collected in a multidistrict litigation ("MDL") in the Southern District of West Virginia, one of several concerning devices similar to the AFS. *In re Boston Sci. Corp. Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-md-02326, MDL No. 2326 (S.D.W. Va.). Castillo filed her short form

complaint on March 23, 2015, (Dkt. 1), which complements the MDL's master long form complaint, (Dkt. 52-4). On May 12, 2020, this case was transferred to the Western District of Texas and the undersigned's docket. (Dkt. 53; *see also* Transfer Order, Dkt. 51, at 1 ("For the convenience of the parties and in order to promote the final resolution of these cases, it appears to the court that the cases would be more expeditiously concluded in the venues from which they arise.")). Prior to the transfer, BSC filed its motion for summary judgment on May 13, 2019, (Dkt. 47), and Castillo filed her motion to limit or exclude the opinions of BSC's expert, (Dkt. 48), the same day.

II. BSC'S MOTION FOR SUMMARY JUDGMENT

A. Legal Standard

Summary judgment is appropriate under Federal Rule of Civil Procedure 56 only "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A dispute is genuine only if the evidence is such that a reasonable jury could return a verdict for the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 254 (1986). "A fact issue is 'material' if its resolution could affect the outcome of the action." *Poole v. City of Shreveport*, 691 F.3d 624, 627 (5th Cir. 2012).

The party moving for summary judgment bears the initial burden of "informing the district court of the basis for its motion[] and identifying those portions of [the record] which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). "[T]he moving party may [also] meet its burden by simply pointing to an absence of evidence to support the nonmoving party's case." *Boudreaux v. Swift Transp. Co.*, 402 F.3d 536, 544 (5th Cir. 2005). The burden then shifts to the nonmoving party to establish the existence of a genuine issue for trial. *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 585–87 (1986); *Wise v. E.I. Dupont de Nemours & Co.*, 58 F.3d 193, 195 (5th Cir. 1995). Throughout this process, the court must view the evidence in the light most favorable to the nonmovant and draw all

inferences in the nonmoving party's favor. *Rosado v. Deters*, 5 F.3d 119, 122–23 (5th Cir. 1993). It may not make credibility determinations or weigh the evidence. *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000).

Unsubstantiated assertions, improbable inferences, and unsupported speculation are not competent summary judgment evidence, and thus are insufficient to defeat a motion for summary judgment. *Turner v. Baylor Richardson Med. Ctr.*, 476 F.3d 337, 343 (5th Cir. 2007). Furthermore, the nonmoving party is required to identify specific evidence in the record and to articulate the precise way that evidence supports his claim. *Adams v. Travelers Indem. Co. of Conn.*, 465 F.3d 156, 164 (5th Cir. 2006). Rule 56 allows the court to "consider other materials in the record" in addition to what the parties cite as evidence. Fed R. Civ. P. 56(c)(3). But it does not impose a duty on the court to "sift through the record in search of evidence" to support the nonmoving party's opposition to the motion for summary judgment. *Adams*, 465 F.3d at 164.

After the nonmoving party has been given the opportunity to raise a genuine factual issue, if no reasonable juror could find in its favor, summary judgment will be granted. *Miss. River Basin Alliance v. Westphal*, 230 F.3d 170, 175 (5th Cir. 2000). When the nonmoving party does not respond, the Court treats the facts the moving party has raised as "undisputed for the purposes of the motion." Fed. R. Civ. P. 56(e)(2); *Eversley v. MBank Dallas*, 843 F.2d 172, 174 (5th Cir. 1988).

B. Analysis

Two initial matters merit discussion. First, Castillo originally brought claims for (I) negligence;[2] (II) strict liability for design defect; (III) strict liability for manufacturing defect; (IV) strict liability for failure to warn; (V) breach of express warranty; (VI) breach of implied warranty,

[2] While listed as a separate count, this claim is effectively an additional theory of liability for design defect, manufacturing defect, failure to warn, breach of express warranty, and breach of implied warranty. (*See* Long Form Compl., Dkt. 52-4, at 17–20).

(VIII) discovery rule, tolling, and fraudulent concealment; and (IX) punitive damages.[3] (Short Form Compl., Dkt. 1, at 4–5; Long Form Compl., Dkt. 52-4, at 17–32). BSC seeks summary judgment on counts (I)–(VI), and the fraudulent concealment portion of count (VIII), but "has not independently moved for summary judgment" on the discovery rule and tolling parts of count (VIII) or count (IX). (Mot. Summ. J., Dkt. 47, at 1; *see* Resp. Mot. Summ. J., Dkt. 50, at 1–2). But Castillo states that she "will not pursue, and therefore does not object to the dismissal of," her claims for (III) strict liability for manufacturing defect ("relating solely to a claim related to composition or construction"), (V) breach of express warranty, (VI) breach of implied warranty, and the fraudulent concealment part of count (VIII). (Resp., Dkt. 50, at 1). The Court concludes that given that Castillo does not oppose this aspect of BSC's motion and "acquiesces in the dismissal" of these claims, there is good cause to dismiss those claims. *McCracken v. Hardberger*, No. SA-06-CA-0988-XR, 2008 WL 11411279, at *2 (W.D. Tex. July 15, 2008). So, the Court's analysis below concerns only the remaining claims Castillo brings on which BSC seeks summary judgment:

1. (I) and (II), negligence and strict liability for design defect; and
2. (I) and (IV), negligence and strict liability for failure to warn.

Second, the parties agree that Texas law applies to these remaining claims. (Mot. Summ. J., Dkt. 47, at 6–7; Resp. Mot. Summ. J., Dkt. 50, at 2). The Court accepts the parties' reasoning and accordingly will apply Texas law when appropriate. *See Sanchez v. Boston Sci. Corp.*, No. 2:12-cv-05762, 2014 WL 202787, at *3–4 (S.D.W. Va. Jan. 17, 2014).

1. <u>(I) and (II): Design Defect</u>

To prevail on her design defect claims under Texas law, Castillo must prove that "(1) the [AFS] was defectively designed so as to render it unreasonably dangerous; (2) a safer alternative design existed; and (3) the defect was a producing cause of the injury for which [Castillo] seeks

[3] The counts' numbering follows the complaints' numbering. Castillo did not bring a claim for loss of consortium, which the complaints numbered "VII." (Short Form Compl., Dkt. 1, at 5).

recovery." *In re DePuy Orthopaedics, Inc., Pinnacle Hip Implant Prod. Liab. Litig.*, 888 F.3d 753, 765 (5th Cir. 2018) (quoting *Casey v. Toyota Motor Eng'g & Mfg. N.A.*, 770 F.3d 322, 330 (5th Cir. 2014)); *see also* Tex. Civ. Prac. & Rem. Code § 82.005(a). The Court finds that BSC is not entitled to summary judgment on these claims.

"Texas law defines a safer alternative design as one that "would have prevented or significantly reduced the risk of the claimant's personal injury . . . without substantially impairing the product's utility," while remaining "economically and scientifically feasible." *DePuy*, 888 F.3d at 765 & n.6 (quoting Tex. Civ. Prac. & Rem. Code § 82.005(b)). "Consistent with this risk-utility framework, a plaintiff 'must show the safety benefits from [the] proposed design are foreseeably greater than the resulting costs, including any diminished usefulness or diminished safety.'" *Id.* at 765–66 (quoting *Casey*, 770 F.3d at 331)).

"The Texas Supreme Court and intermediate courts have held that a 'substantially different product' cannot constitute a safer alternative design." *Id.* at 766. Consequently, Texas courts have rejected plaintiffs' "proposed alternative for failing to perform the discrete *kinds* of functions for which the alleged defective was designed," as opposed to a "slight difference in *degree*" of how well the intended function is performed. *Id.* at 767. "Texas's risk-utility test plainly contemplates that a proposed alternative design might reduce a product's utility—that is, its capacity to perform a function for which it was designed—without rendering the alternative an entirely different product." *Id.*

The parties' disagreement on this issue centers on factor (2) of the overall design-defect test: whether the opinion of Castillo's expert witness, Dr. Bruce Rosenzweig ("Rosenzweig"), that a number of safer, feasible alternative designs for the AFS exist is sufficient.[4] (*See* Resp. Mot. Summ.

[4] In its motion, BSC only presents argument on element (2) of the design-defect test. (*See* Mot. Summ. J., Dkt. 47, at 10). Finding that BSC is not entitled to summary judgment on Castillo's design-defect claims for this reason, the Court does not reach the test's other elements.

J., Dkt. 50, at 3–4). BSC contends that Castillo "has provided no evidence that any alleged safer alternative designs to the [AFS] could have significantly reduced the risk of her claimed injuries 'without substantially impairing the [AFS's] utility,'" characterizing Rosenzweig's opinion as not establishing that "the proffered 'safer alternative designs' would have provided the same utility." (Mot. Summ. J., Dkt. 47, at 10). In this view, Castillo "has failed to provide evidence that would allow a reasonable factfinder to conclude a safer alternative design existed under Texas law." (*Id.*). Castillo responds that Rosenzweig's opinion constitutes sufficient evidence that safer, similarly functional alternative designs for the AFS existed to survive summary judgment. (*See* Resp. Mot. Summ. J., Dkt. 50, at 4).

The AFS is a medical device made of "a knitted polypropylene monofilament fiber mesh." (Rosenzweig Gen. Rep., Pl.'s Ex. B, Dkt. 50-2, at 7). It was intended for "permanent transvaginal implantation" to treat "stress urinary incontinence of pelvic organ prolapse." (*Id.*). Rosenzweig suggests four specific alternative "designs" for the AFS: (1) "the use of sutures, including delayed absorbable sutures like PDS, in a colposuspension procedure, like the Burch," (2) "an autologous fascia sling," (3) "an allograft sling such as Repliform," and (4) "a sling with less polypropylene such as Ultrapro." (Rosenzweig Specific Rep., Pl.'s Ex. A, Dkt. 50-1, at 29–30).

Designs (1), (2), and (3) do not satisfy the "substantially different product" rule. *See Depuy*, 888 F.3d at 766–67. As Rosenzweig himself indicates, Design (1) is a separate and distinct surgical procedure from the implantation of the AFS. (*See* Rosenzweig Gen. Rep., Pl.'s Ex. B, Dkt. 50-2, at 11–12). Similarly, designs (2) and (3) are composed of entirely different materials than the AFS: biological tissue rather than synthetic material. (*Id.* at 12–13). Thus, these suggestions as alternative designs are a "categorical attack" on the AFS, even though they and the AFS serve "the same general purpose"; they are not proposed modifications or improvements of the AFS itself. *Depuy*, 888 F.3d at 766 (quoting *Brockert v. Wyeth Pharm., Inc.*, 287 S.W.3d 760, 769 (Tex. App.—Houston

[14th Dist.] 2009, no pet.)). "The Texas Supreme Court has held that a plaintiff cannot prove design defect by claiming that [the] defendant should have sold an entirely different product." *Brockert*, 287 S.W.3d at 770 (citing *Caterpillar, Inc. v. Shears*, 911 S.W.2d 379, 384–85 (Tex. 1995)).

However, Castillo has established, via Rosenzweig's reports, that whether design (4) is a valid safer and functional alternative design for the AFS is a genuinely disputed material fact. Castillo has not "proffered extensive evidence" of this alternative design, via Rosenzweig's reports or otherwise, that design (4) would "have reduced [Castillo's] injuries, would not have affected the product's utility, and would have been economically and technologically feasible." *Lankston v. Ethicon, Inc.*, No. 2:12-CV-00755, 2016 WL 5843723, at *3 (S.D.W. Va. Oct. 4, 2016). But the fact that she can point to an extant product as an example of the proposed alternative design strongly suggests that the design is indeed less harmful, as functional, and as feasible. *Cf. Caterpillar*, 911 S.W.2d at 384 ("Because Shears offered no evidence of a safer design for a loader that could perform the same tasks as the Caterpillar model 920, we hold that this product is not defectively designed as a matter of law."). A proposed alternative "design need only prove 'capable of being developed.'" *Gen. Motors Corp. v. Sanchez*, 997 S.W.2d 584, 592 (Tex. 1999) (quoting *Boatland of Houston, Inc. v. Bailey*, 609 S.W.2d 743, 748 (Tex. 1980)). Moreover, "qualified expert testimony on the issue suffices . . . if it reasonably supports the conclusion that a reasonable alternative design could have been practically adopted at the time of sale." *Id.* (quoting *Restatement (Third) of Torts* § 2 cmt. f (Am. Law. Inst. 1998)). Rosenzweig's report may do that here, particularly when inferences are drawn in Castillo's favor as the nonmoving party at this stage. *See Rosado*, 5 F.3d at 122–23. A jury is well-situated to evaluate his testimony against that of BSC's competing expert. *See Reeves*, 530 U.S. at 150. Therefore, BSC is not entitled to summary judgment on Castillo's design-defect claims.

2. (I) and (IV): Failure to Warn

Next, BSC argues that the learned intermediary doctrine bars Castillo's failure-to-warn claims "[w]hether sounding in strict liability, negligence, or breach of express or implied warranties." (Mot. Summ. J., Dkt. 47, at 11). The Court agrees: though the DFU was likely defective, Castillo has not shown the required causation.

The learned intermediary doctrine applies to medical devices such as the AFS. *Porterfield v. Ethicon, Inc.*, 183 F.3d 464, 468 (5th Cir. 1999). "In order to recover for a failure to warn under the learned intermediary doctrine, a plaintiff must show: (1) the warning was defective; and (2) the failure to warn [the intermediary, i.e., the doctor] was a producing cause of the plaintiff's condition or injury." *Id.* But "if the warning to the intermediary was inadequate or misleading, then the manufacturer remains liable for injuries sustained by the end user." *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 170 (Tex. 2012); *cf. id.* at 158 ("A prescription drug manufacturer fulfills its duty to warn end users of its product's risks by providing adequate warnings to the intermediaries who prescribe the drug and, once fulfilled, it has no further duty to warn the end users directly.").

a. Adequacy of Warning

"Texas law generally holds that the adequacy of a product's warning is a question of fact to be determined by the jury." *McNeil v. Wyeth*, 462 F.3d 364, 368 (5th Cir. 2006). But if the "warning specifically mentions the circumstances complained of, the warning is adequate as a matter of law." *Id.* (quoting *Rolen v. Burroughs Wellcome Co.,* 856 S.W.2d 607, 609 (Tex. App.—Waco 1993, writ denied)). However, when the warning mentions the circumstances complained of, but is "misleading as to the risk level for developing the condition," the Fifth Circuit has "appl[ied] the default Texas rule that adequacy questions go to the jury." *Id.* The rationale is that "[w]arning the learned intermediary of a much lower risk than the actual risk could render the warning not just misleading, but ineffective." *Id.*

BSC maintains that it "adequately warned Dr. Goulet of the risks associated with the device at issue, including the very injuries now claimed by Plaintiff" via the DFU included with the AFS. (Mot. Summ. J., Dkt. 47, at 12). Castillo responds that the DFU was inadequate because it "[did] not specifically mention all of Ms. Castillo's injuries or the specific circumstances that caused her injuries, and it reported risks much lower than the actual risks." (Resp. Mot. Summ. J., Dkt. 50, at 7).

The DFU specifies contraindications; a general warning; precautions to be taken before, during, and after implantation; adverse events that "have been reported" after implantation; and potential complications that "have been reported as consequences that may occur in a suburethral sling procedure." (DFU, Def.'s Ex. C, Dkt. 47-3, at 3–5, 8). Of these DFU sections, the "potential complications" portion is most salient. (*Id.* at 8). That portion does not specify a likelihood of each complication occurring, whether in relative or quantitative terms, beyond that they "may occur." *See McNeil*, 462 F.3d at 368 ("[I]f the manufacturer decides to label a risk as 'comparatively rare' and also to provide a numerical quantification of that risk, that number must be within a certain degree of accuracy.").

Below is a chart listing the conditions Castillo asserts that she suffered after the AFS's implantation and the notations in the DFU's "potential complications" portion that most closely correspond to them:[5]

Castillo's conditions (Resp. Mot. Summ. J., Dkt. 50, at 8)	*The DFU's "potential complications" (DFU, Def.'s Ex. C, Dkt. 47-3, at 8)*
chronic pelvic pain	pelvic, vaginal pain
vaginal pain	pelvic, vaginal pain
dyspareunia	dysparenia [sic]
suprapubic pain	pelvic, vaginal pain
recurrent urinary tract infections	infection
chronic urinary dysfunction (including dysuria, frequency, urgency, and urge incontinence)	irritative voiding symptoms including urgency and urge incontinence urinary retention recurrent stress urinary incontinence

[5] Each entry in the chart is a quote, but the chart omits quotation marks and modifies capitalization.

While the DFU appears to list each of the conditions Castillo suffered after her AFS's implantation, it states only that each "may occur." Castillo maintains that the DFU "do[es] not sufficiently or adequately advise physicians on the permanence, frequency, or severity of the complications that can arise from the use of the devices." (Resp. Mot. Summ. J., Dkt. 50, at 7). She also identifies several conditions, besides the ones from which she suffers, that the AFS could cause and that the DFU does not list—in particular, several other harmful "polypropylene mesh characteristics" in addition to the overarching point that the polypropylene in the AFS "was not intended for use as a permanent implant in the human body." (*Id.* at 7–8; *see also* Rosenzweig Gen. Rep., Pl.'s Ex. B, Dkt. 50-2, at 54–55[6]). And she notes that "BSC admits occurrence rates for adverse events were not disclosed in their brochures or DFUs." (*Id.*).

"The issue therefore is whether there is a genuine issue of material fact as to whether the [DFU] was misleading. This must be viewed in terms of significant differences between the disclosed risk and the actual risk." *McNeil*, 462 F.3d at 369; *see also DePuy*, 888 F.3d at 773 ("[I]n determining whether warnings are adequate as a matter of law, Texas courts subject them to a demanding standard of specificity."). "When the differences in risk" between the levels expressed in the DFU and the actual levels "are significant, their potential misleading impact is a question for the jury." *McNeil*, 462 F.3d at 368 n.4; *see also id.* (citing *Salmon v. Parke, Davis & Co.*, 520 F.2d 1359, 1363 (4th Cir. 1975)) ("Other courts have also recognized that warnings that are 'unreasonably diluted' may be misleading and thus inadequate."). The DFU makes a limited claim about the potential

[6] "The Mesh Products' DFUs do not inform the physician that the devices can chemically and biologically degrade, shrink, contract, rope, curl, fold, flake, crack, embrittle, stiffen, harden, elongate, or otherwise alter inside the human body. . . . The Mesh Products' DFUs do not inform physicians that a woman's tissue responses to BSC's meshes can induce a greater foreign body, enhanced inflammatory response, excessive scarring, multiple erosions that persist for life, chronic and debilitating pelvic pain and new pain syndromes, recurrence, worsening or de novo incontinence, chronic and permanent dyspareunia, new infections, rejection of the mesh, permanent sexual dysfunction, defecatory dysfunction, vaginal scarring; wound healing problems, or injury to ureters, bladder, and urethra."

complications' likelihood: they "may occur." But this is in fact a double claim. It states a probability of complications occurring—the DFU uses "may," when it could have used "will" or "are likely to," for example. And it states a prediction of permanency—the DFU's use of "may occur" suggests that the complication may arise, rather than that it may both arise and last for an extended period of time.

Whether this disclosed level of risk is significantly different than the actual level of risk, when considered in combination with the additional possible complications Castillo identifies that the DFU does not list, would be a question of fact for the jury. BSC would be "free to argue, to a jury, its view of the proper weight to be given" to Castillo's assertions of high risk. *Id.* at 371.

b. Causation

However, to prevail on her failure-to-warn claims, Castillo must present sufficient evidence both of the DFU's inadequacy and that "the inadequate warning was the producing cause of [her] injuries." *Centocor*, 372 S.W.3d at 170; *see also McNeil*, 462 F.3d at 372. This is a conjunctive test. The Court finds that Castillo does not present sufficient evidence of causation, entitling BSC to summary judgment on Castillo's failure-to-warn claims.

"In the LI context, causation entails *two distinct factual predicates*: first, that the doctor would have read or encountered the adequate warning; and second that the adequate warning would have altered his treatment decision for, or risk-related disclosures to, the patient." *DePuy*, 888 F.3d at 775. BSC challenges Castillo's ability to establish the first predicate, contending that because "Goulet did not review the DFU before implanting the device at issue into [Castillo]" and "was aware of potential risks involved with the procedure," Castillo cannot establish that the inadequate warning was the producing cause of her injuries. (Mot. Summ. J., Dkt. 47, at 14). Castillo responds by pointing to Goulet's testimony that she "sometimes [did] read through [DFUs]," but that she could not "recall for this case or at the time regarding this device," i.e., Castillo's AFS. (Goulet Dep., Pl.'s

Ex. C, Dkt. 50-3, at 73:8–73:11;[7] Resp. Mot. Summ. J., Dkt. 50, at 10). When asked if "at some point [she] would have reviewed the directions for use for the [AFS], Goulet answered that she was "not sure." (Goulet Dep., Pl.'s Ex. C, Dkt. 50-3, at 73:15–73:19).

The Fifth Circuit's decision in *Pustejovsky v. Pliva, Inc.* is instructive. 623 F.3d 271 (5th Cir. 2010) (applying Texas law). After determining that the plaintiff's doctor "was not fully aware of the risk" of the drug at issue, the court concluded that the plaintiff had not carried her summary-judgment burden to "show that a proper warning would have changed" the doctor's decision. *Id.* at 277. The doctor "did not recall ever reading the package insert for the drug or consulting the Physician's Desk Reference," and so the plaintiff "[l]acked any evidence that [the doctor] was aware of" the warning. *Id.* The Fifth Circuit reasoned that the doctor's "lack of memory, of course, does not preclude the possibility that she had read these materials, but neither can it sustain [the plaintiff's] burden" on summary judgment. *Id.* The plaintiff suggested other ways in which the doctor could have learned of an adequate warning but "provided evidentiary support for none of them." *Id.* The Fifth Circuit arrived at a similar conclusion eight years later in *DePuy*, considering the "discrete evidentiary voids" about whether and how the doctors in that case "actually read or encountered defendants' inadequate warnings" to be dispositive. 888 F.3d at 775.

Similarly, here, assuming that the warning was deficient and that Goulet was not fully aware of the risks the AFS posed to Castillo,[8] Castillo has not established that a proper warning would have changed Goulet's decision to offer the AFS. As in *Pustejovsky*, Goulet did not affirmatively testify that she ever reviewed the AFS's DFU, but rather that she could not recall if she had ever

[7] Unlike other citations in this Order, which refer to CM/ECF-assigned page numbers, citations to deposition transcripts refer to the page number printed in the transcript.

[8] Goulet testified that she had been unaware, prior to Castillo's procedure, that "chronic vaginal pain" was "a risk associated with the [AFS]." (Goulet Dep., Pl.'s Ex. C, Dkt. 50-3, at 79:2–79:9). Had she been aware, Goulet testified, she "wouldn't have offered the [AFS]" as a treatment. (*Id.* at 79:10–79:19). She was similarly unaware of the other risks that Castillo identified (via Rosenzweig), as described in Part I.B.2.a above. (*See id.* at 79:20–80:3, 80:15–81:4, 81:14–81:19, 81:20–82:2, 90:16–91:5).

done so. While it remains possible that Goulet did review the DFU (whether in general or prior to Castillo's procedure), Castillo has not presented the evidence that Goulet did in fact do so required to defeat summary judgment. Hypothetical situations, such as if a BSC representative had specially contacted Goulet, do not suffice. *See Turner*, 476 F.3d at 343. Therefore, BSC is entitled to summary judgment on Castillo's failure-to-warn claims.

III. CASTILLO'S MOTION TO LIMIT OR EXCLUDE THE OPINIONS OF BSC'S EXPERT

Separately, Castillo asks the Court to exclude or limit the opinions of Dr. Jennifer Anger ("Anger"), BSC's expert, as to general and specific causation. (Mot. Exclude, Dkt. 48, at 1). The Court grants in part and denies in part Castillo's request, excluding Anger's opinions on general causation, but allowing Anger's opinions on specific causation to the extent specified in her report.

A. General Causation

Castillo's first argument is that "Dr. Anger's general causation opinions [are] outside the scope of her Rule 26 designation," since "BSC designated Dr. Anger only as a case specific expert" in its disclosure.[9] (*Id.*).

BSC disclosed Anger as a retained expert witness on March 22, 2019. (BSC Rule 26 Disclosure, Pl.'s Ex. A, Dkt. 48-1, at 3). BSC's disclosure incorporated Anger's expert report, (Anger Expert Rep., Pl.'s Ex. B, Dkt. 48-2), which, as BSC describes it, "contains nearly 8 pages of opinions generally relating to polypropylene mesh midurethral slings and stress urinary incontinence" followed by "several pages of opinions specific to [Castillo] as well as a summary of both her general

[9] In the motion now before the Court, BSC contends that Castillo should not have filed a separate challenge to Anger's general causation opinions, per the MDL court's pretrial order that required a single general causation challenge filed in the MDL itself. (Resp. Mot. Exclude, Dkt. 49, at 3); *see Boston Sci. Corp.*, No. 2:12-md-02326, MDL No. 2326 (S.D.W. Va. filed Oct. 31, 2018) (Pretrial Order # 196, Dkt. 7153). While in the context of an MDL, following administrative orders is of paramount importance to ensure the docket does not become unwieldy, arguments to this effect are less pressing in the context of an individual case transferred from the MDL.

and case specific opinions," (Resp. Mot. Exclude, Dkt. 49, at 2–3). BSC notes that it "makes no delineation between 'general' and 'case-specific' expert witnesses." (*Id.* at 2). Its disclosure lists Anger only as a "retained expert witness[]" and refers to the attached expert report. (BSC Rule 26 Disclosure, Pl.'s Ex. A, Dkt. 48-1, at 3).

At a previous point in the MDL from which this case was transferred, the plaintiffs moved to exclude Anger's general causation opinions. *Boston Sci. Corp.*, No. 2:12-md-02326, MDL No. 2326 (S.D.W. Va. filed Jan. 11, 2018) (Mot, Dkt. 4828). The court granted the plaintiffs' motion on the ground that "the time for expert disclosure ha[d] passed and Dr. Anger was disclosed only as a specific causation expert." *Id.* (S.D.W. Va. filed May 29, 2018) (Order, Dkt. 6040, at 5); *see also id.* ("While Dr. Anger is permitted to rely on the general causation opinions proffered by experts who are properly designated to offer such opinions when forming her case-specific opinions relating to particular plaintiffs, she may not exceed the bounds of her designation by offering these opinions herself.").

In the next "wave" of cases, the plaintiffs again moved to exclude Anger's opinions. *Id.* (S.D.W. Va. filed Oct. 18, 2018) (Mot., Dkt. 7003). The court did not rule on the motion, and the plaintiffs adopted that motion and the reply they had previously filed for the subsequent wave, which included this case. *Id.* (S.D.W. Va. filed May 13, 2019) (Notice, Dkt. 8060). BSC did the same for its response to plaintiffs' motion. *Id.* (S.D.W. Va. filed May 28, 2019) (Notice, Dkt. 8147).

The first portion of Anger's expert report in this case, which contains her general opinions, is nearly identical to the iteration of Anger's expert report that the MDL court considered when it granted the MDL plaintiffs' motion to exclude. *Compare id.* (S.D.W. Va. filed Jan. 11, 2018) (Anger Expert Rep., Pl.'s Ex. 1, Dkt. 4828-1, at 2–9), *with* (Anger Expert Rep., Pl.'s Ex. B, Dkt. 48-2, at 2–9). Indeed, BSC's arguments against Castillo's motion in this case overlap substantially with its arguments against the MDL plaintiffs' motion to exclude. *Compare Boston Sci. Corp.*, No. 2:12-md-

02326, MDL No. 2326 (S.D.W. Va. filed Feb. 1, 2018) (Resp. Mot. Exclude, Dkt. 4970, at 3–8), *with* (Resp. Mot. Exclude, Dkt. 49, at 4–11). The Court sees no reason to deviate from the MDL court's order on the previous iteration, which prohibited Anger from offering general causation testimony, including those opinions listed in her expert report in this case under the headings "Urinary Incontinence: Condition and Treatment," "Midurethral Slings," and "Midurethral Slings Are the Standard of Care in Treatment of SUI." *Boston Sci. Corp.*, No. 2:12-md-02326, MDL No. 2326 (Order, Dkt. 6040, at 4–5); (*see* Anger Expert Rep., Pl.'s Ex. B, Dkt. 48-2, at 2–9). While BSC maintains that Castillo's arguments concerning its expert disclosure "lack[] any muster," it does not provide any basis for departing from the MDL court's ruling on a nearly identical record. (Resp. Mot. Exclude, Dkt. 49, at 3).

Reaching a contrary result would contravene the law of the case doctrine, which applies to cases transferred from MDLs. *See McKay v. Novartis Pharm. Corp.*, 751 F.3d 694, 703–05 (5th Cir. 2014). "The law of the case doctrine requires that courts not revisit the determinations of an earlier court unless (i) the evidence on a subsequent trial was substantially different, (ii) controlling authority has since made a contrary decision of the law applicable to such issues, or (iii) the decision was clearly erroneous and would work . . . manifest injustice." *Id.* at 703 (quoting *In re Ford Motor Co.*, 591 F.3d 406, 411–12 (5th Cir. 2009)). The Fifth Circuit has held that allowing parties "to relitigate in the remand court issues decided by the MDL court with arguments that could have been raised but were not would 'frustrate the purposes of centralized pretrial proceedings.'" *Id.* at 705 (quoting *Ford Motor Co.*, 591 F.3d at 411). Transferee courts are well within their discretion to refuse to reconsider the MDL court's rulings. *Id.* Consequently, finding none of the defects justifying reconsideration that the Fifth Circuit has identified, the Court will exercise that discretion here and exclude Anger's general causation opinions in accordance with the MDL court's previous ruling.

B. Specific Causation

Next, Castillo argues that Anger's opinions concerning specific causation, as expressed in her expert report, are insufficiently detailed, violating Federal Rule of Civil Procedure 26(a)(2)(B). (Mot. Exclude, Dkt. 48, at 8–10).

In federal court, "an expert witness must produce all data she has considered in reaching her conclusions." *Biestek v. Berryhill*, 139 S. Ct. 1148, 1154 (2019) (citing Fed. R. Civ. P. 26(a)(2)(B)). "Expert reports under Rule 26 must be 'detailed and complete,' not 'sketchy and vague.'" *Harmon v. Georgia Gulf Lake Charles L.L.C.*, 476 F. App'x 31, 36 (5th Cir. 2012) (quoting Fed. R. Civ. P. 26 advisory committee's note to 1993 amendment). "Whether an expert report is sufficiently complete, detailed, and in compliance with the Rules so that surprise is eliminated, unnecessary depositions are avoided, and costs are reduced depends on the nature of the expert testimony and the opinions expressed." *Charles v. Sanchez*, No. EP-13-CV-00193-DCG, 2015 WL 808417, at *16 (W.D. Tex. Feb. 24, 2015). "[T]here will be instances in which testimony—although qualifying as opinion testimony that requires an expert report—is not so complicated that it requires something extensive. Because expert testimony can vary widely according to the subject matter of the litigation, the issues in a case, and the nature of the opinions themselves, it is difficult to generalize about how detailed an expert's report should be." *Norris v. United States*, No. 3:11-CV-1351-D, 2012 WL 1231804, at *2 (N.D. Tex. Apr. 12, 2012). Here, Castillo challenges two aspects of Anger's expert report that Rule 26(a)(2)(B) requires: "a complete statement of all opinions the witness will express and the basis and reasons for them" and "the facts or data considered by the witness in forming them."

Anger's expert report contains both of these elements and thus satisfies Rule 26(a)(2)(B)'s requirements. First, she details the aspects of Castillo's medical records that give rise to her conclusions. (Anger Expert Rep., Pl.'s Ex. B, Dkt. 48-2, at 9–13). Second, she explains her opinions about the conditions Castillo suffered and how she derived those opinions. (*Id.* at 12–13). Castillo

complains of Anger's explanations' relative brevity, (*see* Mot. Exclude, Dkt. 48, at 9), but the Court finds that the explanations, though brief, nonetheless satisfy Rule 26's requirements. *See, e.g.*, *Norris*, 2012 WL 1231804, at *2 ("Although Dr. Coburn's report is brief and lacks certain detail that plaintiffs might have preferred to have obtained without taking his deposition, the court cannot say that the report fails to satisfy the requirement that it contain 'a complete statement of all opinions the witness will express and the basis and reasons for them.'"); *cf. Honey-Love v. United States*, 664 F. App'x 358, 361 (5th Cir. 2016) (finding expert report deficient when it did not specifically reference medical records and provided no basis or reasons for opinions).

Nothing in the specific causation portion of Anger's report is "sketchy or vague," Castillo "will not be ambushed at trial by the opinions expressed in the report," and if Anger "testifies at trial, [she] will be limited to the opinions expressed in the report." *Charles*, 2015 WL 808417, at *16. Moreover, as BSC notes, Castillo already had the opportunity to depose Anger and scrutinize the bases for her opinions, (*see* Resp. Mot. Exclude, Dkt. 49, at 11), weakening Castillo's arguments that the written report is lacking. *See Carlton v. Freer Inv. Grp., Ltd.*, No. 5:15-CV-946-DAE, 2017 WL 11046201, at *16 (W.D. Tex. Aug. 8, 2017) ("Defendants having been afforded ample notice of [the expert's] opinions . . . and extensive cross-examination on those opinions, this testimony does not represent the type of ambush at trial which Rule 26(a) is designed to prevent."). Accordingly, the Court will not exclude Anger's specific causation opinions on this basis—the only basis Castillo offers to exclude them.

IV. CONCLUSION

For the reasons discussed above, **IT IS ORDERED** that BSC's motion for summary judgment, (Dkt. 47), is **GRANTED IN PART AND DENIED IN PART**. It is **GRANTED** as to Castillo's failure-to-warn claims, counts (I) and (IV). It is **DENIED** as to Castillo's design-defect claims, counts (I) and (II).

IT IS FURTHER ORDERED that Castillo's failure-to-warn claims, counts (I) and (IV), are **DISMISSED**.

IT IS FURTHER ORDERED that Castillo's claims in counts (III) strict liability for manufacturing defect ("relating solely to a claim related to composition or construction"), (V) breach of express warranty, and (VI) breach of implied warranty, as well as the fraudulent concealment part of count (VIII), are **DISMISSED**.

IT IS FINALLY ORDERED that Castillo's motion to limit or exclude the opinions of BSC's expert, (Dkt. 48), is **GRANTED IN PART AND DENIED IN PART**. It is **GRANTED** as to Anger's opinions on general causation, which are excluded, consistent with the MDL court's previous order. *See Boston Sci. Corp.*, No. 2:12-md-02326, MDL No. 2326 (Order, Dkt. 6040, at 4–5). It is **DENIED** as to Anger's opinions on specific causation, which are admissible to the extent disclosed in her expert report. (*See* Anger Expert Rep., Pl.'s Ex. B, Dkt. 48-2).

SIGNED on May 28, 2020.

ROBERT PITMAN
UNITED STATES DISTRICT JUDGE