IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WISCONSIN

KAREN SHERER-SMITH,

Plaintiff,

OPINION and ORDER

v.

19-cv-903-jdp

C.R. BARD, INC.,

Defendant.

Over the course of several years, plaintiff Karen Sherer-Smith had three surgeries that implanted five transvaginal mesh products to treat the symptoms of pelvic organ prolapse. The transvaginal mesh products were not effective, and Sherer-Smith experienced adverse reactions including considerable pain.

Four of the mesh products were manufactured by American Medical Systems, Inc. (AMS). One of the mesh products was manufactured by defendant C.R. Bard, Inc. Sherer-Smith filed claims against both manufacturers in a multidistrict litigation in another district. Sherer-Smith settled her claims against AMS; her claims against Bard have been transferred to this court for resolution.

Bard has filed a motion for summary judgment, Dkt. 36, along with a motion to exclude the opinion of Sherer-Smith's causation expert, Dr. William Porter. Dkt. 34. The court concludes that, although Porter is a well-qualified urologist with experience in surgical treatment of pelvic organ prolapse, his opinion that Bard's mesh contributed to Sherer-Smith's injuries is merely conclusory and thus unreliable and inadmissible. Because Sherer-Smith relies exclusively on Porter to establish causation, an essential element of all her claims, Bard is entitled to summary judgment.

BACKGROUND

A. Factual background

The following facts are undisputed.

For many years, Sherer-Smith suffered with the symptoms of pelvic organ prolapse including urinary incontinence.[1] In May 2008, her urologist, Dr. Richard M. Roach, implanted three AMS mesh products to repair the prolapses and resolve the incontinence. Within two months of that surgery, Sherer-Smith got a urinary tract infection; six to eight months post-surgery, some of her symptoms recurred. Dr. Roach diagnosed her with a second cystocele.[2]

Dr. Roach performed a second surgical repair on June 3, 2009. This time, he implanted a Bard mesh product—the Avaulta Solo Anterior Synthetic Support System. Following the implant of the Avaulta mesh, Sherer-Smith's pelvic issues resolved for well over a year. Dkt. 36-1, at 25 (Sherer-Smith Dep. 119:12-19). But in 2011, her cystocele recurred. Dr. Roach recommend a third surgery, and on September 19, 2011, he implanted another AMS mesh product. Following this third surgery, Sherer-Smith complained of severe dyspareunia (painful sexual intercourse).

In December 2014, Sherer-Smith saw Dr. John W. Utrie about her "excruciating knifelike pain with any attempted intercourse." Dkt. 36-4, at 2 (Utrie's treatment notes). Utrie told Sherer-Smith that it looked like the meshes had been "slapped on top of one another."

---

[1] Pelvic organ prolapse is a common disorder in which female pelvic organs are not adequately supported and collapse to the pelvic floor or into the vagina. Symptoms include pelvic pressure, pain, difficulty urinating or defecating, and painful sexual intercourse. Dkt. 36-5, at 4.

[2] Cystocele is the most common type of pelvic organ prolapse, in which the bladder drops into or out of the vagina. *See* Office on Women's Health, U.S. Dep't of Health & Hum. Servs., Pelvic Organ Prolapse, https://www.womenshealth.gov/a-z-topics/pelvic-organ-prolapse (last visited Mar. 18, 2020).

Dkt. 36-1, at 34 (Sherer-Smith Dep. 142:1). Utrie's clinical notes stated that the washers on the last AMS mesh product that Roach had implanted had "eroded into the pelvic sidewall and pushing on them reproduces the discomfort she is complaining of." Dkt. 36-4, at 6.

Utrie performed two surgeries to remove the mesh. In March 2015, he excised some of her anterior mesh, but because of the overlay of multiple mesh products, he could not determine exactly which mesh product (or products) he was removing. In February 2016, he performed a second surgery, during which he excised portions of the posterior AMS mesh.

B. Procedural history

In 2012, Sherer-Smith filed this lawsuit directly into one of the several pelvic mesh-related multidistrict litigations (MDLs) then pending in the United States District Court for the Southern District of West Virginia. *See In Re American Medical Systems, Inc. Pelvic Repair Sys. Prod. Liability Litig.*, No. 2:12-md-2325 (S.D. W. Va. filed Feb. 7, 2012). She named AMS and Bard as defendants. *See* Dkt. 17. In 2018, AMS settled with the MDL plaintiffs, including Sherer-Smith, Dkt. 31, leaving Bard as the sole defendant in Sherer-Smith's case.

Bard had filed a motion for summary judgment, Dkt. 36, along with a motion to exclude the testimony of Sherer-Smith's causation expert, Dkt. 34. Those motions had been pending for several months when Sherer-Smith's case was transferred to the MDL adjudicating product liability claims against Bard, *In Re C.R. Bard, Inc. Pelvic Repair Sys. Prod. Liability Litig*, No. 2:10-md-2187 (S.D. W. Va. filed Oct. 12, 2010). Six more months passed, by which point Sherer-Smith's case was one of only 32 remaining cases in the Bard MDL. The presiding judge transferred 16 of those cases to the plaintiffs' home districts, reasoning that they "would be more expeditiously concluded in the venues from which they arise." Dkt. 44, at 1. Sherer-Smith is a Wisconsin citizen and she received the Avaulta implant in Wisconsin, so her case was

transferred here. Bard is a New Jersey corporation with its principal place of business in New Jersey.

ANALYSIS

A. Governing law and summary judgment standard

The court has jurisdiction because the parties are of diverse citizenship and the amount in controversy exceeds $75,000. Because the court's jurisdiction is based on diversity of the parties under 28 U.S.C. § 1332, it applies state substantive law and federal procedural law. *Gacek v. Am. Airlines, Inc.*, 614 F.3d 298, 301 (7th Cir. 2010) (citing *Erie R.R. Co. v. Tompkins*, 304 U.S. 64 (1938)). Even though Sherer-Smith originally filed this action into the West Virginia MDL, the parties agree that Wisconsin substantive law governs her claims because her Avaulta mesh implantation occurred in Wisconsin. *See In re Watson Fentanyl Patch Prod. Liab. Litig.*, 977 F. Supp. 2d 885, 888 (N.D. Ill. 2013) (collecting cases for the proposition that "the prevailing rule" when a case is directly filed in the MDL transferee court is to apply the law of "the state where the case originated"). So the court will analyze Sherer-Smith's claims under the elements of Wisconsin products liability and negligence law. It will apply the familiar federal procedural standards in assessing whether Bard is entitled to summary judgment under Federal Rule of Civil Procedure 56 or exclusion of Porter's expert opinion under Federal Rule of Evidence 702.

Summary judgment is appropriate only if there is no genuine dispute as to any material fact. Fed. R. Civ. P. 56(a). In ruling on a motion for summary judgment, the court views all facts and draws all inferences in the light most favorable to the non-moving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). Summary judgment will not be granted unless

"the record taken as a whole could not lead a rational trier of fact to find for the non-moving party." *Sarver v. Experian Info. Sols.*, 390 F.3d 969, 970 (7th Cir. 2004) (quoting *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586–87 (1986)).

B. Scope of Sherer-Smith's claims

The court begins by identifying the claims that are still pending and pertinent to Bard's motion for summary judgment. For context, Wisconsin recognizes three types of product liability claims: defective design; defective manufacture; and failure to warn.

Sherer-Smith originally asserted more than a dozen claims: (1) strict liability design defect; (2) strict liability manufacturing defect; (3) strict liability failure to warn; (4) strict liability defective product; (5) negligence; (6) breach of express warranty; (7) breach of implied warranty; (8) fraudulent concealment; (9) constructive fraud; (10) discovery rule, tolling, and fraudulent concealment; (11) negligent misrepresentation; (12) negligent infliction of emotional distress; (13) violation of Wisconsin consumer protection laws; (14) gross negligence; (15) unjust enrichment; and (16) punitive damages. Dkt. 17, at 4.

The parties have stipulated to dismiss any claims based on manufacturing defects. Dkt. 33.

In her response to Bard's summary judgment motion, Sherer-Smith abandoned all claims except for (1) strict liability design defect; (2) strict liability failure to warn; (3) strict liability defective product; (4) negligence; (5) gross negligence; and (6) punitive damages. The court will grant summary judgment on the claims that Sherer-Smith has abandoned.

But among the six claims that Sherer-Smith intends to pursue, only three are viable substantive claims. She concedes that her "strict liability defective product" claim "is, for all practical purposes, the same as her design defect and failure to warn claims," so it does not

require separate analysis. Dkt. 39, at 2 n.1. Sherer-Smith's claims for gross negligence and punitive damages aren't causes of action under Wisconsin law, which govern her claims. The concept of "gross negligence" was abolished by the Wisconsin Supreme Court in 1962. *See Bielski v. Schulze*, 16 Wis.2d 1, 17–19, 114 N.W.2d 105, 113–14 (1962), *overruled on other grounds by Wangen v. Ford Motor Co.*, 97 Wis.2d 260, 294 N.W.2d 437 (1980). In Wisconsin, punitive damages are a remedy, not a cause of action. *See Brown v. Maxey*, 124 Wis. 2d 426, 431, 369 N.W.2d 677 (1985).

So that leaves Sherer-Smith's claims for (1) strict liability design defect; (2) strict liability failure to warn; and (3) negligence in both design and warning.

C. Sherer-Smith's defective design claims

Under Wisconsin law, a strict product liability claim has five elements: (1) the product was defective; (2) the defect rendered the product unreasonably dangerous; (3) the defect existed when the product left the control of the manufacturer; (4) the product reached the consumer without substantial change; and (5) the defect caused the claimant's damages. Wis. Stat. § 895.047(1). For a claim based on negligence,[3] a plaintiff must prove that the defendant failed to exercise reasonable care in the design of the product, and that the defendant's failure caused plaintiff's injuries. *Smaxwell v. Bayard*, 2004 WI 101, ¶ 32, 274 Wis.2d 278, 682 N.W.2d 923.

[3] The Wisconsin legislature enacted its product liability statute in 2011. The Wisconsin Supreme Court has not stated whether preexisting common law still applies where consistent with the product liability statute. But this court has previously determined that it does. *See State Farm Fire & Cas. Co. v. Amazon.com, Inc.*, 390 F. Supp. 3d 964, 971 (W.D. Wis. 2019). Because both parties cite common law that predates the statute, and because there is no authority to the contrary, the court assumes that Wisconsin's common law of negligence still applies to defective design claims, at least where it does not contradict the terms of the statute.

Bard contends that it is entitled to summary judgment because Sherer-Smith cannot meet the causation element—which requires Sherer-Smith to adduce evidence that the alleged defect in the Bard Avaulta mesh caused her injuries. To be considered a "cause," the defect need not be the sole cause or even the primary cause; it is sufficient to show that the defect was a substantial factor in causing the injury. "The phrase 'substantial factor' denotes that the defendant's conduct has such an effect in producing the harm as to lead the trier of fact, as a reasonable person, to regard it as a cause, using that word in the popular sense." *Sumnicht v. Toyota Motor Sales, U.S.A., Inc.*, 121 Wis. 2d 338, 358, 360 N.W.2d 2, 11 (1984) (citations and quotation marks omitted).

As evidence of causation, Sherer-Smith relies exclusively on the testimony of her causation expert, Dr. William Porter. Porter's report offers the opinion that "the cause of Ms. Sherer-Smith's pain, mesh erosion, and dyspareunia is directly related to her [AMS] Perigee and [AMS] Elevate Mesh and was likely exacerbated by the Avaulta implant." Dkt. 39-1, at 6. Sherer-Smith contends that Porter's opinion is sufficient to create a genuine dispute of material fact about causation. But Bard contends that Porter's report is unreliable and should be excluded under principles set out in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and its progeny, which require the court to ensure that expert testimony meets the requirements of Federal Rule of Evidence 702 before the evidence is admitted. Sherer-Smith, as the proponent of Porter's testimony, bears the burden of establishing its admissibility under Rule 702 and the *Daubert* standard. *Brown v. Burlington N. Santa Fe Ry. Co.*, 765 F.3d 765, 772 (7th Cir. 2014).

Bard does not challenge Porter's qualifications or the use of the "differential etiology" approach. Differential etiology is an uncontroversial strategy by which experts "systematically

'rule in' and 'rule out' potential causes" to arrive at an ultimate conclusion on causation. *Higgins v. Koch Dev. Corp.*, 794 F.3d 697, 705 (7th Cir. 2015); *see also Myers v. Illinois Cent. R. Co.*, 629 F.3d 639, 644 (7th Cir. 2010). But actual medical expertise applies not in adopting the differential etiology approach, but in the specific decisions to rule in or rule out the potential causes. To put it in terms of the Federal Rules of Evidence, Rule 702(c) requires that the expert use reliable methods; Rule 702(d) requires that he reliably apply those methods to the facts of the case. A differential etiology need not rule out every conceivable cause. But a differential etiology is deficient if it ignores a significant potential cause, or if the decision to rule in or rule out a potential cause is not based on reliable methods or sufficient data. And an expert's opinion is not admissible if it gives only the expert's bottom line, without explaining how the expert's conclusion is connected to the facts of the case. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

With these principles in mind, the court turns to the question of whether Porter's opinion about the Bard mesh is reliable enough to be admissible. The court notes that Porter's opinion was proffered in the original MDL against both AMS and Bard. But now that Sherer-Smith has settled with AMS, only Porter's opinions about Bard are at issue.

One problem with Porter's report is that he dismisses several causes without explanation. He purports to consider some other potential causes, including the effects of her previous surgery and vaginal atrophy, but he gives no explanation for his decision to rule them out. These opinions would be excludable because they are merely conclusory.[4]

[4] In his deposition, Porter discussed some other potential causes and gave more thorough explanations for ruling them out. But under Seventh Circuit law, Porter would be limited to the opinions expressed in his report. *Salgado by Salgado v. Gen. Motors Corp.*, 150 F.3d 735,

The more fundamental problem concerns Porter's consideration of the AMS meshes. As Sherer-Smith concedes, a differential etiology would be fatally defective if the expert entirely ignores an apparent alternative cause. Dkt. 39, at 6. So, had Porter simply failed to consider the four AMS meshes as a potential cause of Sherer-Smith's injuries, his opinions about the Bard mesh would have to be excluded. Of course, Porter did not ignore the AMS meshes; after all, his report was proffered against AMS, too. Porter recognized the extensive and compelling evidence showing that the AMS meshes were a cause of Sherer-Smith's suffering. For example, during her second surgery (when the Avaulta mesh was installed), Roach observed tissue erosion and trimmed the fibers of the existing AMS mesh. In 2014, Utrie noted that Sherer-Smith experienced pain when he touched the washers of the AMS Elevate mesh, linking the AMS Elevate mesh directly to Sherer-Smith's dyspareunia, her primary complaint at the time. Porter also opined that the "mesh load" from leaving the AMS meshes in place when the Bard Avaulta mesh was implanted placed Sherer-Smith at an elevated risk of complications. In his report, Porter stated that he found no fault with any of the physicians who treated Sherer-Smith, but during his deposition he testified that he would not have left multiple meshes in place. Dkt. 39-2, at 3 (Porter Dep. 44:20–22). So, Porter identified causes that would be sufficient to produce Sherer-Smith's symptoms, even without considering the Bard mesh.

Notwithstanding Porter's identification of other causes of Sherer-Smith's injuries, Porter opined that the Avaulta mesh exacerbated her injuries. Sherer-Smith is correct that, under Wisconsin law, an injury can have more than one cause. But, having identified sufficient causes of Sherer-Smith's injuries, particularly the AMS meshes, Porter had to explain why he

742–43 (7th Cir. 1998). So his opinions about these other causes are immaterial to Bard's motion to exclude Porter's testimony.

would also *rule in* the Bard mesh. *Schultz v. Akzo Nobel Paints, LLC*, 721 F.3d 426, 434 (7th Cir. 2013). In other words, Porter had to explain why the AMS meshes and the overall mesh load were not the sole causes of Sherer-Smith's injuries. Porter's failure to do so is tantamount to ignoring an obvious alternative explanation. It's worth noting that Sherer-Smith's symptoms abated for more than year after the Avaulta implant surgery, and no one has attributed any of her symptoms specifically to the Avaulta mesh.

Porter provided no basis for his decision to rule in the Avaulta mesh as a cause of Sherer-Smith's injuries. Porter acknowledged that he could not determine how much the Avaulta mesh contributed to Sherer-Smith's symptoms, because there is "definitive mesh erosion with the [AMS] Perigree" and "erosion, dyspareunia and pain along the [AMS] Elevate mesh." Dkt. 39-1, at 6. Porter cites other experts in the MDL to establish a general theory of causation, according to which transvaginal mesh surgery can sometimes cause symptoms such as those experienced by Sherer-Smith. For example, Porter cites one study that found dyspareunia following mesh surgery in 36 percent of cases. Of course this finding means that dyspareunia did not result in two-thirds of cases. So the MDL experts' theory of general causation cannot support a reasonable conclusion that the Bard mesh was, more likely than not, a substantial factor in causing Sherer-Smith's injuries.

Porter provided an opinion based on reliable methods and sufficient evidence that the AMS meshes were a substantial factor in causing Sherer-Smith's injuries. But the same cannot be said of his opinion that the Bard mesh was a substantial factor in causing her injuries. Porter's opinion about the Bard mesh is merely ipse dixit, and the court will grant Bard's motion to exclude his testimony. Without Porter's opinion, Sherer-Smith has no admissible evidence that Bard's product caused her injuries, which is fatal to her defective design claims.

D. Sherer-Smith's failure to warn claims

Bard also moves for summary judgment on Sherer-Smith's failure to warn claims, on the ground that at the time of Sherer-Smith's implant surgery, Avaulta instructions disclosed the potential risks of extrusion, erosion, dyspareunia, and recurrence of vaginal wall prolapse. Sherer-Smith contends that there were material facts known to Bard that it did not disclose, such as that the plastic manufacture did not consider its product suitable for surgical implantation. The court need not decide whether Bard's instructions were deficient, because Sherer-Smith's failure to warn claim is also doomed by the exclusion of Porter's testimony.

A failure to warn claim brought under Wisconsin's product liability statute requires a plaintiff to show that the deficient warning was a cause of her injury. Wis. Stat. 895.047(1)(e) (requiring plaintiff to prove by a preponderance of the evidence "[t]hat the defective condition was a cause of the claimant's damages.") Causation is also an element of a failure to warn claim brought under the common law of negligence. *Kessel ex rel. Swenson v. Stansfield Vending, Inc.*, 2006 WI App 68, ¶ 15, 291 Wis. 2d 504, 514, 714 N.W.2d 206, 211.

Without the Porter report, Sherer-Smith has no admissible evidence that she was harmed in any way by Bard's Avaulta product, and thus she cannot show that she was harmed in any way by Bard's failure to warn about the risks posed by that product. Sherer-Smith stands essentially in the same position as a patient who had had successful transvaginal mesh surgery with Bard's Avaulta product, despite its risks. Sherer-Smith has strong evidence that she suffered injuries from AMS's products, but she simply has no evidence that she suffered harm as a result of anything that Bard did.

Bard is entitled to summary judgment on all Sherer-Smith's remaining claims.

ORDER

IT IS ORDERED that:

1. Defendant C.R. Bard's motion to exclude the opinion testimony of Dr. William Porter, Dkt. 34, is GRANTED.

2. Bard's motion for summary judgment, Dkt. 36, is GRANTED.

3. The clerk of court is directed to enter judgment in favor of Bard and close the case.

Entered March 26, 2020.

BY THE COURT:

/s/

_____

JAMES D. PETERSON
District Judge