IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO
Judge R. Brooke Jackson

Civil Action No. 1:20-cv-01932-RBJ

CHRISTINE HEATHERMAN and
TERRY WEAVER,

Plaintiffs,

v.

ETHICON, INC., and
JOHNSON & JOHNSON,

Defendants.

ORDER

This matter is before the Court on defendants' motion to exclude certain opinions of Robert Brian Raybon, M.D., offered by plaintiff as an expert. For the reasons discussed below, defendants' motion is GRANTED in part and DENIED in part.

I. FACTUAL AND PROCEDURAL BACKGROUND

This case has a long and tortured history. It was filed in 2012 and merged with hundreds of other similar cases in multi-district litigation for the purpose of resolving pre-trial matters. ECF No. 1; *see also* ECF No. 13. Until earlier this year the case was before the Honorable Judge Joseph R. Goodwin of Southern District of West Virginia. The case was then transferred to the District of Colorado on July 1, 2020. ECF No. 68; ECF No. 82.

The plaintiffs in this case are Ms. Christine Heatherman, the injured party, and Mr. Terry Weaver, her spouse. ECF No. 1 at 1. Defendants are two corporations, Ethicon, Inc. and Johnson & Johnson (collectively referred to as "Ethicon"). *Id.* The motion before the Court involves an expert offered on behalf of Ms. Heatherman. Defendants challenge the reliability and relevance of certain opinions of that expert. I briefly summarize the background facts and procedural history in order to provide context for defendants' *Daubert* motion [ECF No. 40].

Ms. Heatherman is a resident of Colorado and has been since the start of these proceedings. ECF No. 22 at 2. For years she suffered from a devastating array of health issues, including cancer, seizure disorder, pelvic prolapse, and other gynecological problems. *See e.g.* ECF 66-2 at 2; ECF No. 43-2 at 6. In 2002 she had a tension-free vaginal tape ("TVT") sling implanted in order to treat stress urinary incontinence. *Id.* Susan E. Peck, MD was the implanting physician. *Id.* Ms. Heatherman suffered various injuries that she attributed to the mesh implant, including vaginal pain, vaginal scarring, inability to have sexual relations and pain during sex (dyspareunia), pain while sitting, inability to sit in a car for more than twenty minutes, general chronic pelvic pain and vaginal pain, and emotional stress. ECF No. 22 at 7. She had portions of the mesh product removed between 2004 and 2015 by Dr. Kenneth Petri and Dr. Terry Dunn. *Id.* at 6.

The TVT sling is a product of defendant Ethicon, one of its multiple "pelvic mesh implants." ECF No. 1 at 3. The TVT is the basis for this litigation. Ms. Heatherman filed suit in 2012 after suspecting that the TVT product was causing her new, painful health problems. ECF No. 22 at 7. She brings the following claims relevant to this motion: negligence; manufacturing defect; failure to warn; defective product; and design defect. ECF No. 1 at 4–5.

The parties have fought extensively over virtually every expert proposed by either side throughout this litigation. *See e.g.* ECF Nos. 70–81. Though the Southern District of West Virginia Court resolved most of these issues, a few remained after the transfer. At issue here is the anticipated testimony of Robert Brian Raybon, MD, who is offered by Ms. Heatherman as an expert on urogynecology. ECF. 43-2; ECF 43-4 at 2. At plaintiff's request Dr. Raybon produced a report ("Case Specific Rule 26 Expert Report of Brian Raybon, M.D.") that outlines his background and draws conclusions about whether Ms. Heatherman's health problems are related to Ethicon's TVT implant. ECF No. 43-2. On October 23, 2017 defendants filed a motion to exclude certain expert opinions of Dr. Raybon. ECF. No. 41. Defendants challenge four opinions from Dr. Raybon's report. *Id.* Plaintiff filed a response on November 6, 2017. ECF No. 43. This Court held a *Daubert* hearing on September 4, 2020 on the relevance and reliability of Dr. Raybon's challenged opinions. *See* ECF Nos. 104–105. The Court heard arguments from both parties and relies on those arguments as part of the basis for this Order.

II. STANDARDS GOVERNING EXPERT TESTIMONY

Under Rule 702 of the Federal Rules of Evidence, a qualified expert may provide opinion testimony if his specialized knowledge would assist the jury. Put another way, the evidence must be both relevant and reliable. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 589 (1993). Expert opinions are relevant if they would "help the trier of fact to understand the evidence or to determine a fact in issue." FED. R. EVID. 702; *see also Daubert*, 509 U.S. at 591. They are reliable if, in addition to the expert being qualified, his opinions are "scientifically valid" and based on "reasoning or methodology [that] properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 593.

The proponent of expert testimony has the burden to show that the testimony is admissible. *United States v. Nacchio*, 555 F.3d 1234, 1241 (10th Cir. 2009). The trial court plays a "gatekeeping" role. It must assess the "reasoning and methodology underlying the expert's opinion" and must ultimately determine "whether it is scientifically valid and applicable to a particular set of facts." *Goebel v. Denver and Rio Grande Western R.R. Co.*, 215 F.3d 1083, 1087 (10th Cir. 2000). To be admissible "an inference or assertion must be derived by the scientific method . . . [and] must be supported by appropriate validation—i.e. 'good grounds,' based on what is known." *Id.* at 991 (citing *Daubert*, 509 U.S. at 590).

However, the trial court has discretion as to how to perform this gatekeeping function. *Id.* It is not a role that emphasizes exclusion of expert testimony. Judge Kane aptly summarized the thrust of *Daubert* in interpreting and applying Rule 702:

> A key but sometimes forgotten principle of Rule 702 and *Daubert* is that Rule 702, both before and after *Daubert*, was intended to relax traditional barriers to admission of expert opinion testimony. Accordingly, courts are in agreement that Rule 702 mandates a liberal standard for the admissibility of expert testimony. As the Advisory Committee to the 2000 amendments to Rule 702 noted with apparent approval, "[a] review of the caselaw after *Daubert* shows that the rejection of expert testimony is the exception rather than the rule."

Cook v. Rockwell Int'l Corp., 580 F. Supp. 2d 1071, 1082 (D. Colo. 2006) (citations omitted).

If a court deems expert testimony relevant and reliable, further challenges to that testimony should be directed to its weight, not its admissibility. The challenging party has many tools at its disposal even if the testimony is admitted. "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert*, 509 U.S. at 596.

III. ANALYSIS

Dr. Raybon is a board-certified physician in gynecology and female pelvic medicine and reconstructive surgery. ECF No. 43-1 at 3. He has bachelor's degrees in Chemistry and Chemical Engineering from North Carolina State University and a medical degree from the University of North Carolina at Chapel Hill. He completed his medical residency at Emory University in Gynecology and Obstetrics. *Id.* at 2. Dr. Raybon works in private practice in Georgia and was appointed to be Clinical Assistant Professor at the Medical College of Georgia three years ago. *Id.*; ECF No. 43-2 at 3. He helped develop mesh slings for companies and institutions such as CR Bard and American Medical Systems. ECF No. 43-2 at 3. He has also implanted and removed hundreds of mesh slings during his career. *Id.*

Defendants challenge four opinions from Dr. Raybon's report. I address each of these challenged opinions in turn.

A. <u>Conclusion about the cause of plaintiff's ailments</u>

The first opinion defendants challenge is Dr. Raybon's conclusion that TVT is the cause of Ms. Heatherman's vaginal pain, dyspareunia, pelvic pain, and erosion. Dr. Raybon's report concludes "it is my opinion to a reasonable degree of medical probability that the cause of chronic vaginal pain, dyspareunia, worsening pelvic pain, and vaginal mesh erosion suffered by Ms. Heatherman is the direct result of the implanted Gynecare TVT mesh product produced by Ethicon." ECF No. 43-2 at 8. Defendants challenge this conclusion on the basis that Dr. Raybon did not perform a reliable differential diagnosis because he failed to consider and rule out potential other causes of these injuries. ECF No. 41 at 2. Defendants essentially argue that Dr. Raybon's methodology—his differential diagnosis—was done improperly. This a reliability challenge under Rule 702(c–d).

A brief overview of injury causation for purposes of tort litigation is helpful here. The Tenth Circuit in *Norris* held that for products liability cases, "plaintiffs must show both general and specific causation. . . . General causation is whether a substance is capable of causing a particular injury or condition in the general population and specific causation is whether a substance caused a particular individual's injury." *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 881 (10th Cir. 2005). This court has articulated the *Norris* standard as a three-part test that requires first, determining general causation; second, determining whether there is a temporal relationship between the plaintiff's injury and the alleged cause; and third, performing the differential diagnosis. *Etherton v. Owners Ins. Co.*, 35 F. Supp. 3d 1360, 1367–69 (D. Colo. 2014), *aff'd*, 829 F.3d 1209 (10th Cir. 2016); *see also Dillon v. Auto-owners Ins. Co.*, No. 14-CV-00246-LTB-MJW, 2016 WL 943775, at *4 (D. Colo. Mar. 14, 2016).

The Tenth Circuit and this court have often found differential diagnoses a reliable basis for expert testimony in the past. *See e.g. id.*; *Bitler v. A.O. Smith Corp.*, 400 F.3d 1227, 1236–38 (10th Cir. 2005). However,

> Calling something a 'differential diagnosis' . . . does not by itself answer the reliability question but prompts three more: (1) Did the expert make an accurate diagnosis of the nature of the disease? (2) Did the expert reliably rule in the possible causes of it? (3) Did the expert reliably rule out the rejected causes? If the court answers 'no' to any of these questions, the court must exclude the ultimate conclusion reached.

Huerta v. BioScrip Pharmacy Servs., Inc., 429 F. App'x 768, 773 (10th Cir. 2011) (citing *Pluck v. BP Oil Pipeline Co.*, 640 F.3d 671, 678–79 (6th Cir. 2011)). A differential diagnosis is reliable if the physician follows a standard and accepted methodology in arriving at the diagnosis; adequately explains why the patient might not exhibit every symptom of a certain condition; and adequately considers and rules out some alternative explanations even if he does

not rule out every single one. *Goebel v. Denver & Rio Grande W. R. Co.*, 346 F.3d 987, 999 (10th Cir. 2003).

I find Dr. Raybon's differential diagnosis sufficiently reliable to admit his opinion. Dr. Raybon identifies the specific injuries that Ms. Heatherman experienced that were relevant to his diagnosis. ECF No. 43-2 at 6. He discusses the problems that mesh in the vagina can cause based on his experience treating patients with and without mesh, educating physicians on prolapse surgery and mesh use, and reviewing mesh complication literature. *Id.* at 7. Based on his knowledge and experience he ruled in the TVT mesh implant as a possible cause of Ms. Heatherman's conditions. He concluded it could have caused them, particularly given his review of patients with similar complications that were caused by the same mesh implant. *Id.* Dr. Raybon then ruled out other potential causes based on a review of her many pre-existing conditions. *Id.* at 6–7. His opinion was based on reviewing Ms. Heatherman's medical history, including records from Dr. Peck, Dr. Petri, and Dr. Dunn. *Id.* at 5–6. He concluded that Ms. Heatherman's relevant health problems "would not present so severely" if caused by her prior medical conditions. He also noted that her mesh tenderness, scarring, and severe penetrating pain during sex presented after her "first surgeries" to implant mesh, and that her sexual intercourse-related complaints improved after "multiple mesh revisions." *Id.* at 7–8.

Defendants argue that Dr. Raybon's differential diagnosis is unreliable because he failed to review the testimony of either Dr. Peck, who implanted the TVT, or of Dr. Dunn, who performed surgery on Ms. Heatherman after a prolapse. ECF No. 41 at 7. But Dr. Raybon stated in his report that he reviewed information from both physicians. ECF No. 43-2 at 5. The law

does not require that Dr. Raybon base his differential diagnosis on these doctors' litigation testimony instead of their actual records.

Dr. Raybon's methodology is also flawed, defendants assert, because he did not himself conduct a physical examination of Ms. Heatherman. ECF No. 41 at 7. Defendants cite no law suggesting that this is necessary for a reliable differential diagnosis. In fact, the Tenth Circuit has found reliable a differential diagnosis by a doctor who did not himself conduct a patient's physical exams but who examined the patient's medical records, diagnostic testing, past examinations by other providers. *Etherton v. Owners Ins. Co.*, 829 F.3d 1209, 1221 (10th Cir. 2016).

Finally, defendants take issue with Dr. Raybon's failure to consider and rule out the two other medical procedures Ms. Heatherman underwent at the same time as her TVT implant surgery on August 13, 2002. ECF No. 41 at 8. According to defendants "Dr. Raybon relies heavily on the timing of the supposed onset" of Ms. Heatherman's symptoms by comparing them before and after the 2002 surgery. *Id.* at 8. These other procedures—anterior and posterior prolapse repair—are potential causes of Ms. Heatherman's health issues that Dr. Raybon did not account for in his differential diagnosis.

With respect to timing "an expert may consider temporal connection as one factor in assessing causation so long as it is not the sole factor relied upon." *Etherton*, F. Supp. 3d at 1369 (citing *Goebel*, 346 F.3d at 999). Timing was not the only factor Dr. Raybon considered. He also mentioned the severity of Ms. Heatherman's conditions and the presentation of mesh tenderness and scarring, among other factors, in coming to his conclusion. ECF No. 43-2 at 7. As for the alternative surgical procedures, a "[d]ifferential diagnosis can be admissible even if

the expert does not 'explicitly rule out' every possible alternative cause." *Murphy-Sims v. Owners Ins. Co.*, No. 16-CV-0759-CMA-MLC, 2018 WL 8838811, at *6 (D. Colo. Feb. 27, 2018) (citing *Goebel*, 346 F.3d at 999). Rule 702 does not require an expert to categorically exclude every single alternative. *Etherton*, 829 F.3d at 1222. As a result, Dr. Raybon's opinion that the TVT implant caused Ms. Heatherman's health conditions is not inadmissible simply because he failed to address the two other procedures she received in August 2002.

This does not mean defendants are without recourse as to the accuracy of Dr. Raybon's conclusion, however. When several possible causes of a condition are not eliminated in a differential diagnosis, this goes to the accuracy of the conclusion and not the soundness of the methodology. *Murphy-Sims*, 2018 WL 8838811, at *7 (citing *Jahn v. Equine Servs., PSC*, 233 F.3d 382, 390 (6th Cir. 2000)). Defendants are free to attack the weaknesses they perceive in Dr. Raybon's differential diagnosis and his conclusion through "cross examination, rebuttal expert testimony, and presentation of contrary evidence." *Id.*

Defendants' motion to exclude Dr. Raybon's opinion that TVT caused plaintiff's complications, based on his differential diagnosis, is DENIED.

B. <u>Opinions about potential complications from mesh</u>

Defendants next challenge what they call Dr. Raybon's "general causation opinions" about the complications that TVT can cause. Defendants point to a sentence in Dr. Raybon's report that states the following:

> The most common mesh related complications include pelvic pain, scarring in the vagina and pelvic floor, pain into the legs and thighs, dyspareunia, dyspareunia for partners, sexual impairment, urinary dysfunction, chronic inflammation of tissue, scar bands or scar plates in the vagina, vaginal shortening or stenosis, erosion of mesh into tissues or organs, and nerve entrapment.

ECF No. 43-2 at 3–4. Defendants also take issue with a paragraph later in Dr. Raybon's report:

> Mesh use in the vagina can cause chronic inflammation, infection, scarring in the tissue which is painful, restricts movement in the vagina pelvis, causes tissue shrinkage due to scarification, and can cause persistent delayed healing of the vaginal mucosa with subsequent mesh exposure/erosion. The mesh can also deform, contract and cause complications/injuries due to the route and method of placement.

Id. at 7. Defendants argue both statements should be excluded as irrelevant because Ms. Heatherman did not suffer any of the complications that Dr. Raybon mentions. ECF No. 41 at 2. In addition, they assert that "Plaintiff designated Dr. Raybon to testify about case-specific causation only" and that these opinions, by contrast, "are general opinions beyond the scope of Plaintiff's expert designations." *Id.* at 10. These arguments effectively challenge the relevance of Dr. Raybon's opinion under Rule 702(a).

Plaintiff first counters in her response brief that she "never claimed Dr. Raybon's opinions would be limited to case-specific issues" and that the Federal Rules of Civil Procedure do not require an expert be classified as general versus case-specific. ECF No. 43 at 7. I find this argument somewhat disingenuous. In the *Daubert* hearing on September 4, 2020, plaintiff's attorney explicitly said that Dr. Raybon was a case-specific expert and that he would not be doing the "heavy lifting" as a general expert in this case. ECF No. 105 at 24:18–20. Plaintiff's attorney then clarified that Dr. Raybon's "general causation" opinions were included partly so that he could properly introduce himself and his qualifications, and partly as the foundation for his conclusions about Ms. Heatherman's health problems. *Id.* at 24:20–25:21.

With respect to the first statement defendants challenge, I take plaintiff's attorney at his word. I also consider counsel's statements in the hearing to supersede the arguments in plaintiff's brief to the extent they conflict. I find that the sentence listing twelve mesh-related

complications (starting with "The most common . . .", ECF No. 43-2 at 2–3) is not necessary for the jury to understand Dr. Raybon's background and qualifications, despite its presence in the section titled "Background and Qualifications." Further, because this sentence is not in the report section in which Dr. Raybon assesses Ms. Heatherman's conditions, it cannot be linked to her specific complications. This opinion will not help the jury better understand Dr. Raybon's differential diagnosis of Ms. Heatherman's injuries as required under Rule 702.

This specific testimony from Dr. Raybon is thus EXCLUDED. Dr. Raybon may not opine on the various complications that mesh implants can cause when he is introducing himself to the jury and discussing his academic degrees, former and current jobs, or his experience working with mesh and treating patients with mesh implants.

As for the second set of statements in question (the paragraph at ECF No. 43-2 at 7), plaintiff and defendants dispute whether Dr. Raybon ties any of these potential complications to those Ms. Heatherman herself faced. Defendants reiterate that Dr. Raybon's "complete list of complications . . . [is] irrelevant because he does not contend that these complications afflict Ms. Heatherman." ECF No. 41 at 12. Plaintiff responds that Dr. Raybon *does* make this link, and he simply uses different wordings for the same complications. For example, Ms. Heatherman's scarring is another way of saying "tissue shrinkage due to scarification," and her "mesh exposure" could be "persistent, delayed healing of the vaginal mucosa." ECF No. 43 at 10. I do see plaintiff's point, particularly given the vague description of some of her symptoms like "vaginal pain" which could seemingly track to listed complications like "inflammation" or "infection." However, I am not in a position to assess whether each of the complications Dr. Raybon mentions as part of his differential diagnosis were in fact suffered by Ms. Heatherman,

though described using different terminology. Exercising that level of detailed medical expertise is beyond this Court's gatekeeping function *Daubert*.

Plaintiff's more cogent argument is that Dr. Raybon's knowledge of mesh complications formed a vital basis for his differential diagnosis. I am inclined to agree. Under FED. R. CIV. P. 26(a)(2)(B) an expert report must include "the basis and reasons" for the expert witness's opinions and "the facts or data considered by the witness" in forming his opinions. Defendants claim this paragraph would be "confusing, unfairly prejudicial, and unhelpful to the jury." ECF No. 41 at 12. I find the opposite to be true. I believe the jury will find this opinion both relevant and helpful for understanding how Dr. Raybon decided that the TVT mesh caused Ms. Heatherman's injuries. The fact that Dr. Raybon treated other patients for the mesh-related complications will assist the jury in assessing Dr. Raybon's conclusion that Ms. Heatherman's complications resulted from the TVT mesh sling. Defendants are free to cross-examine Dr. Raybon and to present their own experts to ensure the jury knows exactly which complications Ms. Heatherman did and did not suffer. I therefore DENY defendants' motion as to the paragraph on ECF No. 43-2 at 7. Dr. Raybon is free to testify about his experience with mesh complications in patients to the extent that they supported his conclusion about the cause of Ms. Heatherman's injuries in this case.

In her brief plaintiff also argues that Dr. Raybon's general complications opinions are relevant for her strict liability failure-to-warn claim. Citing Tenth Circuit law, she states that his opinions speak to the various dangers the mesh implant product generally presents. ECF No. 43 at 10; *Oja v. Howmedica Inc.*, 111 F.3d 782 (10th Cir. 1997). This argument is more appropriate

for Section D, under defendants' challenge to Dr. Raybon's opinion about the adequacy of the TVT implant's warnings. I therefore do not address it here.

Defendants' motion as to the opinions of Dr. Raybon regarding general mesh-related complications is therefore GRANTED in part and DENIED in part.

C. <u>Opinion on alternative non-mesh procedures and products</u>

Defendants next challenge Dr. Raybon's opinion that there are safer alternatives to the TVT procedure. In relevant part Dr. Raybon's report states "[t]here were safer alternatives to the TVT procedure at the time Mrs. Heatherman had her surgery which would have eliminated or greatly reduced the risks and injuries. These include an autologous sling procedure and a Burch procedure performed abdominally or laparoscopically." ECF No. 43-2 at 8. According to defendants the Court should exclude this opinion because Dr. Raybon mentions alternative *procedures* as opposed to alternative *products*, and because he fails to claim that the alternative procedures he proposes are equally effective as the TVT. ECF No. 41 at 2, 13. This is a challenge to the relevance of Dr. Raybon's testimony under Rule 702(a).

Ms. Heatherman brings multiple claims, one of which is defective product. This court has previously applied a seven-factor test to determine whether a product is defective. As both defendants and Ms. Heatherman point out, the seven factors are:

> (1) The usefulness and desirability of the product—its utility to the user and to the public as a whole.
> (2) The safety aspects of the product—the likelihood that it will cause injury and the probable seriousness of the injury.
> (3) The availability of the substitute product which would meet the same need and not be as unsafe.
> (4) The manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility.
> (5) The user's ability to avoid danger by the exercise of care in the use of the product.

> (6) The user's anticipated awareness of the dangers inherent in the product and their avoidability because of general public knowledge of the obvious condition of the product, or of the existence of suitable warnings or instructions.
> (7) The feasibility, on the part of the manufacturer, of spreading the loss by setting the price of the product or carrying liability insurance.

Armentrout v. FMC Corp., 842 P.2d 175, 184 (Colo. 1992) (citing *Ortho Pharm. Corp. v. Heath*, 722 P.2d 410, 414 (Colo. 1986), *overruled on other grounds*); *Bartholic v. Scripto-Tokai Corp.*, 140 F. Supp. 2d 1098, 1110–11 (D. Colo. 2000). This list "is not exclusive, but merely illustrative of factors which may assist in determining whether a design is unreasonably dangerous. Depending on the circumstances of each case, flexibility is necessary to decide which factors are to be applied, and the list of factors may be expanded or contracted as needed." *Armentrout*, 842 P.2d at 184.

Defendants' argument rests on the assumption that Dr. Raybon's testimony is offered to speak solely to factor three, i.e. "a substitute product which would meet the same need and not be unsafe." ECF No. 41 at 14 (quoting *Camacho*, 741 P.2d at 1247). According to defendants, "Dr. Raybon's testimony does not address a then-existing product design alternative for TVT that was both reasonably feasible and advisable" because the autologous sling procedure and the Burch procedure are not products. Therefore his opinion about them is irrelevant. *Id.*

Plaintiff's counterarguments are somewhat conflicting. During the *Daubert* hearing plaintiff's counsel implied that Dr. Raybon's opinion *was* intended to speak to alternative product designs. ECF No. 105 at 27:5–7 ("So those are his opinions regarding a safer alternative design . . ."). Plaintiff's counsel also consistently referred to the autologous sling and Burch procedure as "devices." *Id.* at 26:16, 21; *id.* at 27:5. But in her response brief plaintiff argues that the availability of alternative methods to treat SUIs is relevant to other factors from the test

articulated in *Armentrout*. Ms. Heatherman states it is relevant, for example, to whether the TVT is unreasonably dangerous (factor four) and to the product's utility to the user and to the public (factor one). ECF No. 43 at 13. Plaintiff also asserts that Dr. Raybon's testimony is relevant to "whether Ethicon was generally negligent in designing the product" and to her completely separate negligence claim. *Id.* Finally, she argues in the alternative that, at a minimum, testimony about the autologous sling should be admitted because it actually is a product, even if the Burch procedure is not.

I interpret Ms. Heatherman's position as seeking to introduce Dr. Raybon's opinion not just as evidence of substitute products but more broadly for her defective product claim and other claims. I therefore analyze the relevance of Dr. Raybon's opinion for each.

1. Relevance of Dr. Raybon's opinion to the existence of a substitute product

The first question is whether Dr. Raybon's opinion about safer alternatives to TVT—the autologous sling procedure and the Burch procedure—are relevant to the existence of substitute products under the third factor in *Armentrout.*

To my knowledge there is no Tenth Circuit or Colorado law that addresses whether a "procedure" can ever be considered a "product" for the purposes of proving the existence of a safer alternative product design. However, decisions from other jurisdictions have addressed this exact question on mesh implants for SUIs. Judge Goodwin ruled on an almost identical issue in a prior order in this multi-district litigation. Judge Goodwin stated "I am convinced that an alternative, feasible design must be examined in the context of products—not surgeries or procedures." *Mullins v. Johnson & Johnson*, 236 F. Supp. 3d 940, 942 (S.D.W. Va. 2017). He

ruled that polypropylene sutures were not an alternative, feasible design for the TVT as a matter of law, reasoning that

> Evidence that a surgical procedure should have been used in place of a device is not an alternative, feasible design in relation to the TVT. Whether an alternative procedure could have been performed without the use of the TVT does nothing to inform the jury on the issue of an alternative, feasible design for the TVT. Instead, alternative surgeries or procedures raise issues wholly within the context of what a treating physician has recommended for patients based on the individual needs and risk factors associated with individual patients. In other words, alternative surgeries or procedures concern the medical judgment of the doctors who use TVT devices to treat stress urinary incontinence ("SUI"); other surgeries or procedures do not inform the jury on how the TVT's design could have feasibly been made safer to eliminate the risks that caused the plaintiffs' injuries.

Id. at 943.

Other courts have followed Judge Goodwin's reasoning in *Mullins*. *See e.g. In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. MDL 2327, 2017 WL 1264620, at *3 (S.D.W. Va. Mar. 29, 2017) ("I agree with Ethicon that alternative procedures/surgeries do not inform the issue of whether an alternative design for a product exists."); *Willet v. Johnson & Johnson*, No. 112CV00034JAJRAW, 2020 WL 2988299, at *8–9 (S.D. Iowa June 3, 2020) (excluding expert opinion on "native tissue repair and surgical procedures using human and animal donor tissue" because neither is classified as a medical device and thus the opinion was not relevant to the existence of an alternative pelvic mesh medical device); *Moultrie v. Coloplast Corp.*, No. CV 18-231, 2020 WL 1249354, at *11 n. 20 (W.D. Pa. Mar. 16, 2020) (noting that the autologous fascia sling and the Burch colposuspension "appear to be medical procedures rather than medical devices" and that the expert "did not address the issue of how [defendant] could have 'modified' its Aris device by abandoning it altogether in favor of a surgical procedure"); *Salinero v. Johnson & Johnson*, No. 1:18-CV-23643-UU, 2019 WL 7753453, at

*17 (S.D. Fla. Sept. 5, 2019), *reh'g denied*, No. 1:18-CV-23643-UU, 2019 WL 7753439 (S.D. Fla. Oct. 25, 2019) (agreeing with Judge Goodwin that surgical procedures such as biological grafts are not alternative designs to synthetic pelvic mesh products, and thus excluding testimony that autologous fascia lata and allografts are "safer alternative designs"). *See also Talley v. Danek Med., Inc.*, 179 F.3d 154, 162 (4th Cir. 1999) (expert testimony about the relative success of procedures that did versus did not use spinal fixation devices failed to indicate a design flaw in defendant's device but instead "questioned the medical judgment of doctors who use spinal fixation devices in surgery.").

I agree with Judge Goodwin's analysis. The existence of alternative *procedures* to the one Ms. Heatherman underwent goes to medical malpractice, not to any defect in Ethicon's TVT *product*. Whether Dr. Raybon's opinion is relevant to factor three, the availability of a substitute product, thus turns on whether the autologous sling and Burch procedure can be considered "products." Linguistically speaking, procedure and product obviously describe different things. But medically the two are often intertwined. In Ms. Heatherman's case her physician implanted a product—defendants' TVT sling—but the process of surgical implantation was itself a procedure. I thus find it helpful to begin with a brief description of the Burch procedure and autologous sling.

In their motion defendants write "[i]n autologous sling procedures, surgeons harvest tissue from the patient and use the native tissue as a sling to suspend the neck of the bladder." ECF No. 41 at 13 n. 3. They define a Burch procedure as "a surgical procedure in which the neck of the bladder is suspended from nearby ligaments with sutures." *Id.* at 13 n. 4. Plaintiff does not contest these definitions. I thus adopt them for purposes of my analysis.

Ms. Heatherman never argues that the Burch procedure is anything other than a procedure. ECF No. 43 at 11–16. In the *Daubert* hearing plaintiff's counsel mentioned sutures as part of the Burch procedure, ECF No. 105 at 27:3–5, but from the procedure's description it seems clear that the sutures themselves could not stand in for the TVT as an alternative device. Thus, like Judge Goodwin's ruling on the polypropylene sutures, I conclude as a matter of law that the Burch procedure cannot be an alternative product to the TVT. Defendants' motion to exclude Dr. Raybon's opinion about the Burch procedure as a "safer alternative" to the TVT is GRANTED to the extent that plaintiff would offer it as evidence of the "availability of [a] substitute product which would meet the same need and not be as unsafe."

The relevance of Dr. Raybon's opinion on the autologous sling is more complex. Some decisions from other courts have ruled that allografts—another word plaintiff uses for autologous slings—are not products. *See e.g. Moultrie*, 2020 WL 1249354, at *11 n. 20; *Salinero*, 2019 WL 7753453, at *17. But those decisions do not directly address the fact that, unlike the Burch procedure, an autologous sling is a tangible thing and not just a process. In her brief Ms. Heatherman argues that "[a]utologous slings are alternative products to treat stress urinary incontinence, using natural material instead of synthetic polypropylene." ECF No. 43 at 15. Plaintiff persuasively points out that companies producing these slings refer to them as "products." *Id.* The description defendants provide in their motion makes clear that the sling is a physical thing, i.e. native tissue formed into a sling. The only difference apparent to the Court between an autologous sling and a TVT sling is the substance from which the slings are made—native tissue versus synthetic material. Based on the information provided by the parties I believe an autologous sling could be properly considered a "substitute product" for the TVT.

While I believe this could be a proper conclusion, it is not for me to decide as a matter of law. Instead, this is a close factual issue that should go to the jury. Indeed, both plaintiff and defendants cite cases that suggest a jury should decide questions of this type. *See Hines v. Wyeth*, No. CIV.A. 2:04-0690, 2011 WL 1990496, at *8 (S.D.W. Va. May 23, 2011) (c*iting Torkie-Tork v. Wyeth*, 739 F. Supp. 2d 895, 900 (E.D. Va. 2010) ("[A]n alternative design is not reasonable if it alters a fundamental and necessary characteristic of the product. This is, of course, typically a question of fact, not law.")); *Keffer v. Wyeth*, 791 F. Supp. 2d 539, 548–50 (S.D.W. Va. 2011). I agree. Though the issue of what constitutes a product is normally a question of law, *Sanders v. Acclaim Entm't, Inc.*, 188 F. Supp. 2d 1264, 1277 (D. Colo. 2002), "[t]he question of whether a product is defective and unreasonably dangerous is generally an issue for the jury." *Bartholic*, 140 F. Supp. 2d at 1107 (citations omitted); *see also McHargue v. Stokes Div. of Pennwalt*, 686 F. Supp. 1428, 1434 (D. Colo. 1988). That includes the "availability of [a] substitute product which would meet the same need and not be as unsafe. *Armentrout*, 842 P.2d at 184.

The narrow question of whether an autologous sling is a "product" for purposes of alternative design under factor three depends heavily on medical information. It requires a fact-intensive determination and not merely an interpretation of Colorado products liability statute like in *Sanders*. A jury is best suited to answer this question. I therefore DENY defendants' motion to exclude Dr. Raybon's opinion on the autologous sling as a "safer alternative" to the extent that plaintiff would offer it as evidence of the existence of a substitute product under *Armentrout* factor three.

I last note that defendants also challenge Dr. Raybon's opinion because he fails to claim that the safer alternatives he proposes are equally effective as the TVT. ECF No. 41 at 13. This argument hast no merit. Under *Armentrout*'s factor three a jury may consider whether there exist substitute products that "meet the same need and not be as unsafe" as defendants' product. Defendants' correctly assert Ms. Heatherman must produce some evidence that alternatives are as effective as the TVT. But there is no requirement that evidence come from Dr. Raybon. This is therefore not a valid basis for excluding his opinion.

2. Relevance of Dr. Raybon's opinion to plaintiff's general defective product design claim or other claims

Next, I must consider whether Dr. Raybon's opinion about safer alternatives to the TVT is relevant to other factors for determining product defects, or for other claims that plaintiff brings. As mentioned above, Ms. Heatherman points out that defendants narrowly focus on the opinion's irrelevance to substitute products under factor three without considering its relevance to anything else. Nowhere do defendants dispute that Dr. Raybon's opinion is relevant to the other factors used to determine product design defects, or to Ms. Heatherman's other claims such as negligence. *See generally* ECF No. 41 at 13–16; ECF. No. 105.

The bar for relevance in the *Daubert* context is whether the "knowledge will assist the trier of fact to understand evidence or determine a fact in issue." FED. R. EVID. 702(a). Plaintiff persuasively contends that the existence of these safer alternatives could help the jury determine the following: whether the TVT is unreasonably dangerous, useful to the user or to the public; whether Ethicon brought its product into a market with existing SUI treatment options; whether Ethicon was negligent in its product design; and whether the TVT is truly the "gold standard" for

SUI treatment as defendants have claimed. ECF No. 43 at 13–14. I agree with plaintiff that this opinion of Dr. Raybon's could assist the jury.

Other courts have addressed this question in the context of mesh slings and have permitted similar testimony. An Arizona Judge stated that "Plaintiffs have also asserted strict liability claims (Doc. 11-1 at 3), and it is possible that alternative procedures may be admitted to show that a product is unreasonably dangerous." *Triant v. Am. Med. Sys. Inc.*, No. CV-12-00450-PHX-DGC, 2020 WL 4333645, at *3 (D. Ariz. July 28, 2020). In a different case in this multi-district litigation, Judge Goodwin himself refused to exclude testimony on alternative procedures when plaintiff argued it related to other claims. *Sutphin v. Ethicon, Inc.*, No. 2:14-CV-01379, 2020 WL 5079170, at *10 (S.D.W. Va. Aug. 27, 2020), *reconsideration denied*, No. 2:14-CV-01379, 2020 WL 5269409 (S.D.W. Va. Sept. 3, 2020).

At this stage I see no reason to exclude Dr. Raybon's opinion as it bears on these additional issues. Defendants are free to object at trial on relevance or other grounds as Dr. Raybon's testimony unfolds. Defendants are of course also free to cross-examine Dr. Raybon and to rebut his opinions with their own experts and contrary evidence, as they undoubtedly plan to do. Defendants' motion to exclude Dr. Raybon's opinion about the autologous sling and Burch procedure is therefore DENIED to the extent that plaintiff would offer it as evidence of other factors for determining product design defect or of plaintiff's other claims.

D. <u>Opinion on Instructions for Use ("IFU")</u>

Finally, defendants seek to exclude Dr. Raybon's opinion on the inadequacy of warnings on the mesh implant's Instructions for Use ("IFU"). Dr. Raybon's report reads "I reviewed the IFUs for the Gynecare TVT procedure. The IFUs fail to disclose the possibility of chronic

vaginal pain, dyspareunia, and the inability to remove the entire mesh. Without such disclosures, true informed consent of a patient receiving these implants is impossible." ECF No. 43-2 at 8.

Defendants argue this opinion should be excluded because the implanting physician Dr. Peck testified that she knew all relevant risks regarding the mesh implant. ECF No. 41 at 2, 16–17. Defendants assert that the evidence shows Ms. Heatherman discussed these potential complications with Dr. Peck. *Id.* at 17. Therefore Dr. Raybon, according to defendants, both ignored Dr. Peck's testimony when coming to his conclusion and impermissibly speculated about Dr. Peck's state of mind. *Id.* Defendants also contend that, to the extent Dr. Raybon plans to testify about what information should or should not be included in the IFU, his testimony should be barred because he is not qualified to render it. *Id.* at 18. These arguments challenge the relevance of Dr. Raybon's opinion under Rule 702(c–d) and his qualifications to give the testimony under Rule 702 generally.

Plaintiff's response brief states that "Dr. Raybon should be allowed to offer his opinion on the inadequacy of Defendants' warnings." ECF No. 43 at 16. Plaintiff argues that defendants should have raised their relevance argument at the summary judgment stage; that the lack of effective warnings is a factor to be considered for determining if a product design is defective; and that the District Court for the Southern District of Western Virginia ruled in a prior case that Dr. Raybon could opine on the adequacy of product warnings. *Id.* at 16–17. However during the *Daubert* hearing on September 4, plaintiff's attorney articulated the issue before the Court quite differently. Counsel stated that he did not intend to have Dr. Raybon testify as to the adequacy or inadequacy of the mesh product's warning labels, but only to the risks associated with the

product and whether the IFU did or did not warn against each of those risks. ECF No. 105 at 28:23–29:3.

As above, I take plaintiff's counsel at his word. I also note that Judge Goodwin—prior to this case being transferred—ruled on whether Dr. Raybon could opine on the adequacy of label warnings. Judge Goodwin's order stated "Dr. Raybon is not an expert in the development of warning labels . . . [he] does not possess the additional expertise to offer expert testimony about what an IFU should or should not include. Accordingly, Dr. Raybon's expert testimony about these matters is **EXCLUDED**." ECF No. 81-7 at 7 (emphasis in original); *see also In re: Ethicon*, 2016 WL 4536876, at *4. Thus, the narrowed issue is if Dr. Raybon may testify on whether the TVT warning labels included the risks he knows to be associated with mesh.

As I stated in the hearing, there is a very fine line between Dr. Raybon opining on what the IFU *does or does not* say versus what it *should or should not* say. I trust that counsel for both parties can guide their experts to walk this line properly. I have also already agreed to permit defendants' expert, Dr. Kammerer-Doak, to opine on this exact issue on their behalf. *See* ECF No. 104; ECF No. 105 at 3:22–5:16. Therefore, to the extent defendants seek to exclude Dr. Raybon's opinion on the risks associated with mesh and whether they were listed in the TVT implant IFU, their motion is DENIED. Any other opinion of Dr. Raybon's on the IFU warning label is waived per plaintiff's statements in the hearing and is therefore MOOT.

ORDER

Defendants' motion to exclude certain opinions of Robert Brian Raybon, M.D. [ECF No. 40] is GRANTED in part and DENIED in part.

DATED this 29th day of September, 2020.

BY THE COURT:

R. Brooke Jackson
United States District Judge