UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

BARBARA HEINRICH and GREGORY HEINRICH,

Plaintiffs

v.

ETHICON, INC.; ETHICON LLC; and JOHNSON & JOHNSON,

Defendants

Case No.: 2:20-cv-00166-APG-VCF

Order Granting in Part the Defendants' Motion to Exclude Opinions of Bruce Rosenzweig

[ECF No. 102]

This case was part of multidistrict litigation (MDL) assigned to the United States District Court for the Southern District of West Virginia concerning the use of transvaginal surgical mesh to treat stress urinary incontinence (SUI). Plaintiff Barbara Heinrich alleges that she suffered injuries after having the TVT-SECUR (TVT-S) product implanted. The TVT-S was designed and manufactured by defendants Johnson & Johnson and Ethicon, Inc. ECF No. 4 at 3.

The defendants move to preclude Dr. Bruce Rosenzweig from: (1) testifying that non-synthetic mesh procedures, such as autologous or allograft slings, or Burch colposuspensions, are safer alternatives to TVT-S; (2) opining that mechanical cut mesh is a safer alternative to laser cut mesh; and (3) testifying about duties a medical device manufacturer owes regarding adverse event collection and physician training.

The parties are familiar with the facts, so I recount them here only as necessary to resolve the motion. I grant the motion in part.

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I. ANALYSIS

Federal Rule of Evidence 702 governs the admissibility of Dr. Rosenzweig's opinions. Under Rule 702, a witness "who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if":

> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and
> (d) the expert has reliably applied the principles and methods to the facts of the case.

To be admissible, expert testimony thus must be both relevant and reliable. "Expert opinion testimony is relevant if the knowledge underlying it has a valid connection to the pertinent inquiry. And it is reliable if the knowledge underlying it has a reliable basis in the knowledge and experience of the relevant discipline." *Primiano v. Cook*, 598 F.3d 558, 565 (9th Cir. 2010) (quotation omitted), *as amended* (Apr. 27, 2010). Medical expert testimony should be admitted "if physicians would accept it as useful and reliable, but it need not be conclusive because medical knowledge is often uncertain." *Id.* (quotation omitted). Where there is a sufficient foundation for the testimony, it is up to the jury to evaluate the expert's credibility. *Id.* at 565-66.

The proponent of expert testimony "has the burden to establish its admissibility." *United States v. 87.98 Acres of Land More or Less in the Cnty. of Merced*, 530 F.3d 899, 904 (9th Cir. 2008). But Rule 702's inquiry is "flexible," and should be applied in favor of admitting the evidence. *Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227, 1232 (9th Cir. 2017) (quotation omitted). "Shaky but admissible evidence is to be attacked by cross examination, contrary evidence, and attention to the burden of proof, not exclusion." *Primiano*, 598 F.3d at 564.

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A. Alternative Procedures

The defendants argue that Dr. Rosenzweig should not be allowed to opine that autologous or allograft slings, or Burch colposuspensions are safer alternative procedures for the treatment of SUI because these are alternative surgical procedures, not alternative safer designs of the defendants' medical device, so his testimony on this point is irrelevant. The defendants assert that identifying safer alternative procedures takes issue with Heinrich's implanting surgeon's decision to recommend the TVT-S over these other procedures, but does not reflect whether there is a safer alternative design for the TVT-S.

Heinrich responds that Dr. Rosenzweig's opinions are relevant to whether the TVT-S was unreasonably dangerous because the comparison with alternative procedures may show that the TVT-S was more dangerous than the ordinary user would contemplate given other efficacious options with fewer complications. Heinrich also contends that Dr. Rosenzweig's opinions are relevant to her negligence claim to "explain to the jury that women with [SUI] are not restricted to mesh devices and that synthetic slings are not the most successful procedures for SUI." ECF No. 106 at 5. She also asserts that the opinions are relevant to her request for punitive damages because "[m]any doctors who used non-mesh procedures later used synthetic mesh devices after manufacturers were willing to pay the doctors for 'teaching' the use of their products." *Id.* Finally, Heinrich contends that the evidence is relevant to rebut Ethicon's assertions that the TVT-S was the safest and most effective treatment for SUI.

To establish a strict products liability claim under Nevada law, a plaintiff must show: "1) the product had a defect which rendered it unreasonably dangerous, 2) the defect existed at the time the product left the manufacturer, and 3) the defect caused the plaintiff's injury." *Fyssakis v. Knight Equip. Corp.*, 826 P.2d 570, 571 (Nev. 1992). A product is unreasonably

dangerous if it fails to perform "in the manner reasonably to be expected in light of [its] nature and intended function" and "was more dangerous [than] would be contemplated by the ordinary user having the ordinary knowledge available in the community." *Allison v. Merck & Co., Inc.*, 878 P.2d 948, 952 (Nev. 1994) (quotation omitted). Evidence that the product in question "lacked adequate safety features or that a safer alternative design was feasible at the time of manufacture will support a strict liabilities claim." *Fyssakis*, 826 P.2d at 572. However, proving that an alternative safer design existed is not required for the plaintiff to prove her case. *Ford Motor Co. v. Trejo*, 402 P.3d 649, 655-57 (Nev. 2017) (en banc).

Heinrich does not argue that Dr. Rosenzweig should be allowed to testify that the Burch procedure or autologous or allograft slings are feasible alternative designs for the TVT-S product. She thus does not appear to contest Judge Goodwin's analysis in *Mullins v. Johnson & Johnson*:

> 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 plaintiff's injuries.

236 F. Supp. 3d 940, 943 (S.D. W. Va. 2017) (emphasis omitted). Because Heinrich bears the burden of showing Dr. Rosenzweig's testimony is admissible, and she does not argue that it is admissible for the purpose of showing alternative feasible designs, Dr. Rosenzweig's testimony about the alternative procedures is inadmissible to show alternative feasible safer designs of mesh devices existed.

Dr. Rosenzweig's testimony about other procedures also is not relevant to whether the TVT-S is unreasonably dangerous or whether the defendants were negligent because it takes issue with the choice of treatment recommended by Heinrich's implanting physician, Dr. Hsieh. Even if there was some relevance to this evidence, the probative value is substantially outweighed by the danger of unfair prejudice, confusion, and waste of time. Fed. R. Evid. 403. This evidence would result in exploration of whether Dr. Hsieh made the proper medical choice among available alternatives for Heinrich's particular circumstances, instead of whether the defendants' product is unreasonably dangerous for its intended use or the defendants were negligent. *Mullins*, 236 F. Supp. 3d at 943.

Heinrich does not explain how the alternative procedures are relevant to punitive damages. To the extent the defendants paid doctors to use their product over other options, that does not make admissible Dr. Rosenzweig's opinion that these other procedures are safer alternatives.

However, Dr. Rosenzweig's opinions may be relevant to rebut the defendants' evidence at trial. Heinrich notes that the defendants and their experts often tout TVT-S as the "gold standard" for treating SUI while it was on the market. Evidence that other available procedures were just as efficacious without the attendant alleged complications is relevant to rebut that testimony. Consequently, Dr. Rosenzweig's testimony may be admissible if the defendants open the door at trial. I therefore grant in part and deny in part this portion of the defendants' motion.

B. Mechanical Versus Laser Cut Mesh

The defendants argue that Dr. Rosenzweig should not be able to opine that mechanical cut mesh is a safer alternative to the laser cut mesh in the TVT-S because he has opined that both laser and mechanical cut mesh are unsafe. According to defendants, when Dr. Rosenzweig

testifies in a case involving laser cut mesh, he opines that the mesh is too stiff and that makes it more dangerous than mechanical cut mesh. But when he testifies in a case involving mechanically cut mesh, he opines that the mesh can rope, curl, and fray, and that makes it more dangerous than laser cut mesh. Additionally, the defendants argue that mechanically cut mesh was not an available option for the TVT-S, no expert has opined that Heinrich was injured by the way the mesh was cut, and Dr. Rosenzweig cites no studies in support of his conclusion.

Heinrich responds that the issue under Nevada law is not whether mechanically cut mesh would be safer, but whether laser cut mesh is unreasonably dangerous. She contends that Dr. Rosenzweig opines that laser cut is unreasonably dangerous because it is too stiff and rigid, and her other expert, Dr. Kim, opines that the stiffness and rigidity caused Heinrich's injuries. As to Dr. Rosenzweig's inconsistent positions, Heinrich argues that is a matter for cross examination, not exclusion.

In his TVT-S report, Dr. Rosenzweig opines that laser cut mesh is stiffer than mechanically cut mesh. ECF No. 102-1 at 14. He states that laser cut mesh "can cause a statistically higher incidence of erosion and sexual dysfunction than mechanically cut mesh." *Id.* at 15. Finally, he opines that laser cut mesh "is defective because it is too stiff and rigid. As a result, the mesh increases complications including chronic pain, chronic dyspareunia, erosions, and urinary dysfunction." *Id.*

In his report on TVT products generally, he concludes that mechanically cut mesh is defective because it is subject to particle loss, fraying, roping, curling, deformation, and loss of pore size that leads to various complications. ECF No. 102-4 at 38-50. At his deposition in another case, Dr. Rosenzweig confirmed that he finds SUI slings defective when they are both laser cut and mechanically cut. ECF No. 102-7 at 3. And in another case, he testified that laser

and mechanically cut mesh lead to the same complications, albeit by "different mechanisms." ECF No. 102-8 at 3.

Any inconsistencies in Dr. Rosenzweig's opinions about whether laser versus mechanically cut mesh are safer alternative designs to each other are matters for cross examination, not exclusion. *See Ellerbee v. Ethicon, Inc.*, No. 8:20-CV-1514-TPB-AEP, 2021 WL 2010640, at *3 (M.D. Fla. May 20, 2021); *Laderbush v. Ethicon, Inc.*, No. 20-CV-62-JD, 2020 WL 3001958, at *2 (D.N.H. June 4, 2020). And the evidence is relevant in this case. Dr. Rosenzweig opines that laser cut mesh is stiffer than mechanically cut mesh, and Dr. Kim opines that the mesh's stiffness and rigidity contributed to Heinrich's injuries. ECF Nos. 102-1 at 4, 14-15; 102-6 at 15-16. I therefore deny this portion of the defendants' motion.

C. Manufacturer Duties

1. Adverse Events

In their motion, the defendants argue that Dr. Rosenzweig should not be allowed to testify that Ethicon's collection and report of adverse events and complications was incomplete, inaccurate, and misleading. In their reply, they narrow their request to exclude only his opinion that Ethicon's collection of adverse events and complications was incomplete, inaccurate, or misleading.[1] ECF No. 113 at 109-10. The defendants contend that Dr. Rozenzweig has no experience in the medical device industry that would make him qualified to opine on the standard of care for a medical device manufacturer to collect adverse event information. They also assert his opinion is merely a recitation of corporate documents.

[1] Dr. Rosenzweig therefore is not precluded from opining about whether Ethicon adequately reported (as opposed to collected) adverse events and complications.

Heinrich responds that Dr. Rosenzweig's opinion goes to Ethicon's failure to warn physicians and patients of adverse events. She also contends it is relevant to whether Ethicon acted with conscious disregard to patient safety because it failed to collect and report adverse events and complications to physicians and patients.

Dr. Rosenzweig opines that "Ethicon's collection and reporting of adverse events and complications to physicians and patients is misleading, inaccurate and incomplete." ECF No. 102-1 at 5. He critiques Ethicon's "passive system of measuring how many and what type of adverse events the TVT-S was causing." *Id.* at 66-67. And he contends that internal documents show Ethicon was actively avoiding collecting complaints from physicians and had flawed systems for collecting complaints. *Id.* at 67-70.

Heinrich cites to various pages of Dr. Rosenzweig's depositions, but she does not identify what in his experience or education qualifies him to opine on the quality of a medical device manufacturer's system for collecting adverse event reports. She therefore has not met her burden of showing Dr. Rosenzweig's testimony on adverse report collection is admissible. And, as the MDL court has ruled, she may not use an expert "solely [as] a conduit for corporate information." ECF No. at 20-21. Consequently, I grant this portion of the defendants' motion as narrowed in its reply brief.

2. Physician Training

The defendants argue Dr. Rosenzweig should be precluded from opining that Ethicon did not properly train physicians on how to use the TVT-S because he is not qualified to opine on what training a medical device manufacturer should provide. Additionally, the defendants argue this evidence is irrelevant because no one has opined that Heinrich's implanting physician, Dr. Hsieh, improperly implanted the device.

Heinrich responds that Dr. Rosenzweig is qualified to render those opinions because he testified to his qualifications and the basis of his conclusion that Ethicon provided inadequate training, and because he has trained other physicians in surgical techniques. She also argues that the MDL court has already ruled that Dr. Rosenzweig is qualified to testify about the sufficiency of the warnings and training materials for the TVT-O, and those same qualifications would apply to the TVT-S. She contends that Dr. Rosenzweig is qualified to testify about the training actually provided and whether it was adequate. As for Dr. Hsieh, she argues that Ethicon undertook the duty to train him, and its failure to do so increased the risk of harm to Heinrich.[2]

Dr. Rosenzweig may not opine that Dr. Hsieh was inadequately trained because Heinrich has not shown that anyone will opine that Dr. Hsieh was inadequately trained or that he improperly implanted the TVT-S. Consequently, whether the defendants failed to train Dr. Hsieh is irrelevant to the issues in this case because there is no evidence that any failure to train led to Heinrich's injuries.

Additionally, Dr. Rosenzweig may not opine that despite being aware of problems associated with the implantation of the TVT-S, "Ethicon failed to offer adequate training/retraining to physicians." ECF No. at 79. Heinrich does not point to anything in Dr. Rosenzweig's experience or education that would qualify him to opine on what duty (if any) a manufacturer has to train physicians on the proper use of its product. And, as discussed above, she may not use an expert "solely [as] a conduit for corporate information." ECF No. at 20-21. Consequently, I grant this portion of the defendants' motion.

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[2] Heinrich asserts that this evidence may be admissible on rebuttal. The defendants do not respond to that argument. I reserve that issue for trial should it arise.

II. CONCLUSION

I THEREFORE ORDER that the defendants' motion to exclude certain opinions of Dr. Bruce Rosenzweig **(ECF No. 102) is GRANTED in part**.

DATED this 4th day of June, 2021.

ANDREW P. GORDON
UNITED STATES DISTRICT JUDGE