UNITED STATES DISTRICT COURT FOR THE
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

ALICIA ROSE and LARRY DUNNING, *Plaintiffs*, v. BOSTON SCIENTIFIC CORPORATION, *Defendant*.	CASE NO. 2:20-cv-00716-BJR ORDER GRANTING IN PART AND DENYING IN PART PLAINTIFFS' MOTION TO EXCLUDE CERTAIN OPINIONS AND TESTIMONY AND DENYING DEFENDANT'S MOTION TO EXCLUDE CERTAIN OPINIONS AND TESTIMONY

I. INTRODUCTION

Before the Court are two motions to exclude expert opinions and testimony. Plaintiffs move to exclude certain opinions of Dr. Steven Swift. Dkt. Nos. 42, 43. Defendants move to exclude certain opinions of Dr. Neeraj Kohli. Dkt. No. 44. Having reviewed the motions, the oppositions thereto, the record of the case, and the relevant legal authorities, the Court will grant in part and deny in part Plaintiffs' motion and deny Defendant's motion. The reasoning for the Court's decision follows.

II. BACKGROUND

The Court laid out the background of this case in its recent Order Granting in Part and

Denying in Part Defendant's Motion for Summary Judgment. *See* Dkt. No. 71. In brief, the case involves the transobturator midurethral sling, known as the Obtryx Device, which Ms. Rose had surgical implanted to treat her stress urinary incontinence, but now complains is defective. Both parties now move to exclude certain opinions and testimony of the other's case-specific expert.

III. LEGAL STANDARD

Federal Rule of Evidence 702 provides that an expert qualified by "knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise" if that testimony meets certain indicia of relevance and reliability. FED. R. EVID. 702;[1] *see also United States v. Ruvalcaba-Garcia*, 923 F.3d 1183, 1188 (9th Cir. 2019) (quoting *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993)) ("[b]efore admitting expert testimony into evidence, the district court must perform a 'gatekeeping role' of ensuring that the testimony is both 'relevant' and 'reliable' under Rule 702"). Testimony is relevant where "the evidence logically advance[s] a material aspect of the party's case," *Estate of Barabin v. AstenJohnson, Inc.*, 740 F.3d 457, 463 (9th Cir. 2014) (quoting *Cooper v. Brown*, 510 F.3d 870, 942 (9th Cir. 2007)), and reliable where it has "a reliable basis in the knowledge and experience of the relevant discipline," *id.* (quoting *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 149 (1999)).

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[1] In full, Rule 702 provides

> 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.
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> FED. R. EVID. 702.

The reliability inquiry is a "'flexible one'" and while the Supreme Court has suggested several factors helpful in determining reliability, *see Daubert*, 509 U.S. at 592–94, District Courts are given "broad latitude in determining the appropriate form of the inquiry," *United States v. Wells*, 879 F.3d 900, 934 (9th Cir. 2018) (quoting *Kumho Tire*, 526 U.S. at 150); *see also Barabin*, 740 F.3d at 463. The inquiry also favors admission of testimony as "[s]haky but admissible evidence is to be attacked by cross examination, contrary evidence, and attention to the burden of proof, not exclusion." *Primiano v. Cook*, 598 F.3d 558, 564 (9th Cir. 2010) (citing *Daubert*, 509 U.S. at 596). The party proffering the expert testimony has the burden of establishing its admissibility under a preponderance of the evidence standard. *Daubert*, 509 U.S. at 592 n.10.

IV. PLAINTIFFS' MOTION TO EXCLUDE TESTIMONY OF STEVEN SWIFT, M.D.

Plaintiffs' motion seeks to exclude opinions and testimony by Defendant's case-specific expert, Dr. Steven Swift,[2] on three specific topics: (1) the adequacy of the Obtryx Device's Directions for Use ("DFU"); (2) complication rates of patients in his own practice; and (3) the physical properties of the polypropylene mesh used in the Obtryx Device. Dkt. No. 42 at 1.

A. Dr. Swift's Testimony on the Adequacy of the Obtryx Device's Directions for Use

Plaintiffs seek to exclude the opinions and testimony of Dr. Swift as to the adequacy of the Obtryx Device's DFU, or the warnings therein, claiming that he has conceded to not being qualified to offer such expertise. Dkt. No. 42 at 1; Dkt. No. 43 at 4–6. As evidence of this claimed

[2] Dr. Swift is a board-certified urogynecologist and is currently the Director of the Division of Urogynecology, Vice Chair of the Institutional Review Board for investigator-initiated studies, and a tenured Professor in the Department of Obstetrics and Gynecology at the Medical University of South Carolina. *See* Dkt. No. 42-3 (Curriculum Vitae of Steven Swift, M.D.).

concession to lack of expertise, Plaintiffs point to statements Dr. Swift made during his deposition, including: "I don't understand what a DFU is for because prior to this litigation, I've never even heard the term," Dkt. No. 42-2 at 63:7–9, and "I'm familiar with FDA requirements. I am by no means an expert in FDA regulatory…," *id.* at 63:17–64:23. Plaintiffs also point to six relevant statements in Dr. Swift's expert report (Dkt. No. 42-1). Dkt. No. 43 at 4.

Defendant contends that the opinions and testimony that Dr. Swift will proffer on this subject are well within his expertise. Dkt. No. 46 at 3–6. Defendant points out that Dr. Swift will not be testifying on the adequacy of the DFU in general, but, rather, he will "identify specific mesh complications alleged by Plaintiffs or their experts and opine that such complications are included in the Obtryx DFU." *Id.* at 4.

The Court has reviewed both Dr. Swift's expert report and his deposition. Dr. Swift is a highly qualified and experienced doctor in this field which, according to the MDL that preceded this Court, makes him fit to "opine about the risks of the [Obtryx Device] and pelvic mesh surgery and whether those risks were adequately expressed [i]n the [Obtryx Device's DFU]." *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 704 (S.D. W. Va. 2014). As that Court held, Dr. Swift "need not be an expert on product warnings per se" but, instead, "is qualified to testify about the risks of implanting the [Obtryx Device] and whether those risks were adequately expressed [i]n the [Obtryx Device's DFU]" including "the completeness and accuracy of [Defendant's] warning and—'it follows from that—the extent to which any inaccuracies or omissions could either deprive a reader or mislead a reader of what the risks and benefits' of the Obtryx Device was when the warnings were published." *Id.* at 719 (quoting *In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liab. Litig.*, MDL 1203, 2000 WL 876900, at *11 (E.D. Pa. June 20,

2000)); *see also Tyree v. Bos. Sci. Corp.*, No. 12-cv-08633, 2014 WL 5486694, at *47 (S.D. W. Va. Oct. 29, 2014).

Reviewing the statements identified by Plaintiffs in Dr. Swift's report, and the report as a whole, the Court concludes that Dr. Swift has not strayed into regulatory interpretation but, instead, has expressed an opinion as to what other doctors and surgeons would find relevant in the DFUs. As such, the Court will deny Plaintiffs' motion on these grounds.[3]

B. Dr. Swift's Testimony on Complication Rates of Patients in His Practice

Plaintiffs argue that Dr. Swift should not be permitted to testify on complication rates in his own practice. Dkt. No 42 at 1; Dkt. No. 43 at 6–8. Plaintiffs take issue with several statements in Dr. Swift's report in which he opines that, in his practice, complications with the Obtryx Device are "uncommon," "rare," and "consistent with complications reported in the clinical literature." Dkt. No 43 at 6 (quoting 42-1 at 5, 6, 7, 8–9, 11). Such testimony, according to Plaintiffs, is inappropriate because it lacks a verifiable methodology, as Dr. Swift's practice does not maintain a database tracking patient outcomes and he is, therefore, unable to provide a concrete complication rate. Defendant opposes and argues that Dr. Swift should be permitted to testify on opinions developed based on his own experience. Dkt. No. 46 at 8–10.

It is well established that an expert may testify based on his "personal knowledge or experience." *Kumho Tire*, 526 U.S. at 150 ("relevant reliability concerns may focus upon personal

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[3] To the extent that Plaintiffs argue that Dr. Swift's testimony should be excluded because the MDL Court excluded his testimony on the Obtryx Device's DFU in *Flores-Banda v. Bos. Sci. Corp.*, No. 13-cv-04434, 2016 WL 2939522, at *17 (S.D. W. Va. May 19, 2016), the Court agrees with Defendant that Dr. Swift has not limited his testimony in this case as he did there. *See Flores-Banda*, 2016 WL 2939522, at *17 ("[i]n his deposition, Dr. Swift stated that he had no intention of opining on the DFU").

knowledge or experience"); *see also* FED. R. EVID. 702 (an expert qualified by "knowledge, skill, experience, training, or education may testify"); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. MDL 2327, 2016 WL 4944331, at *3 (S.D. W. Va. Aug. 31, 2016) (Doctors can "offer general complications opinions based on [their] clinical observations"). At the same time, expert testimony should be "the product of reliable principles and methods." FED. R. EVID. 702(c). Thus, as the MDL Court has already established, experts cannot testify on personal complication rates where they have not provided "objective data to back up [such] assertion[s]." *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658, 701 (S.D. W. Va. 2014). That Court consistently prohibited experts from testifying on specific personal complication rates where the expert was unable to provide verifiable data from the expert's practice. *See Ethicon*, 2016 WL 4944331, at *3; *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2327, 2016 WL 4958312, at *3 (S.D. W. Va. Aug. 25, 2016); *Eghnayem*, 57 F. Supp. 3d at 701; *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 521, 523 (S.D. W. Va. 2014), *as amended* (Oct. 29, 2014); *Huskey*, 29 F. Supp. 3d at 721; *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 606–07 (S.D. W. Va. 2013), *on reconsideration in part* (June 14, 2013).

Based on these principles, the Court will exclude Dr. Swift's testimony on complications rates in his personal practice. His testimony that complications are "rare" or "uncommon" are inadmissible as both unsupported by verifiable data and irrelevant to the questions at hand. There are only two reasons why Defendant would want to introduce such testimony. The first, as Dr. Swift provided in his report, is to relate his complications rates with those occurring in the general population as expressed in medical literature. He may not do so, however, because he has not provided the data from his practice to quantify his actual rates. Thus, the terms "rare" or

"uncommon" are vague and unverifiable.

The second reason to introduce such testimony is to provide observations limited only to his own practice, which aligns with an expert's ability to testify on personal knowledge and experience. Again, however, such terms are devoid of relevance without quantifiability. Further, observations from his own practice are not relevant to the trier of fact as his own practice is not the subject of this litigation. *See* FED. R. EVID. 702(a) (expert may testify if "the expert's . . . knowledge will help the trier of fact to understand the evidence or to determine a fact in issue"). Based on the foregoing, the Court will grant Plaintiffs' motion on these grounds and exclude Dr. Swift's testimony on complication rates in his personal practice.

C. Dr. Swift's Testimony on the Physical Properties of Polypropylene Mesh

Plaintiffs urge the Court to exclude testimony by Dr. Swift as to the physical properties of the polypropylene mesh used in the Obtryx Device, including that it does not degrade, contract, or elicit a continual foreign body response. Dkt. No. 42 at 1; Dkt. No. 43 at 8–9. According to Plaintiffs, Dr. Swift lacks expertise in biomaterials, biomedical engineering, and medical device manufacture and design. Defendant counters that Dr. Swift is qualified to opine on the polypropylene as a medical expert who frequently sees the material in his practice as well as medical literature. Dkt. No. 46 at 6–8.

As stated above, Dr. Swift is qualified by experience to discuss the cases he has treated involving degradation, contraction, and continual foreign body response. His report does not offer opinions pertinent to biomedical engineering, but, instead, observations rooted in his experience as a practitioner. *See* Dkt. No. 42-1 at 11 ("*I have not seen evidence* of polypropylene degradation, systemic infection, mesh shrinkage/contracture, or other unexpected adverse outcomes following

placement of an Obtryx sling."), 14 ("*I see no evidence* of mesh degradation, contracture or infection caused by the Obtryx sling Ms. Rose received") (emphasis added).

The Court is also mindful that the MDL Court reserved judgment on this question. *See Flores-Banda*, 2016 WL 2939522, at *16–17. That Court determined that it was "without sufficient information at this time to determine the reliability of Dr. Swift's opinions on the physical properties of mesh." *Id.* at *17. Having reviewed Dr. Swift's expert report in this case, this Court is convinced that his experience with such materials based on personal observation is relevant and would be helpful to the jury. *See* FED. R. EVID. 702(a). The Court will, therefore, allow Dr. Swift to testify on this subject.

V. DEFENDANT'S MOTION TO EXCLUDE TESTIMONY OF DR. NEERAJ KOHLI, M.D.

Defendant moves to exclude the testimony of Plaintiffs' expert witness, Dr. Neeraj Kohli,[4] in which he opines on the causation of Ms. Rose's complications and attributes them to the Obtryx Device. Dkt. No. 44. Defendant claims Dr. Kohli conceded in his deposition that he does not have a reasonable basis to conclude that the Obtryx Device "caused Plaintiff's worsening defecatory dysfunction and hypertonic pelvic floor." *Id.* at 2.[5] Plaintiffs explain that Dr. Kohli will not testify

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[4] Dr. Kohli is a board certified obstetrician-gynecologists specializing in urogynecology and currently serves as Medical Director for Boston Urogyn. He also maintains an academic teaching appointment at Harvard Medical School and teaches in the Ob/Gyn Residency Program at Brigham and Women's Hospital in Boston. *See* Dkt. No. 44-1 at 2–4.

[5] Specifically, Defendant cites the following portion of Dr. Kohli's deposition

> Q. Just so I have it clear you're not offering an opinion to a reasonable degree of medical certainty as to the cause of Ms. Rose's defecatory dysfunction, correct?
> A. Correct.
> Q. And you're not offering an opinion to a reasonable degree of medical certainty as to the cause of her

as to the cause of these conditions, but, rather, that the Obtryx Device exacerbated them. Dkt. No. 47 at 3–5.

As Plaintiffs point out, in his expert report, Dr. Kohli does not address the root causes of Ms. Rose's complications, but, instead, concentrates on his contention that the Obtryx Device had a worsening effect on her condition. *Id.* at 4–5. Dr. Kohli deposition testimony is consistent with this. *See* Dkt. No. 47-2 at 38:11–23. The Court, therefore, will deny Defendant's motion.

VI. CONCLUSION

For the foregoing reasons, the Court ORDERS as follows:

1. Plaintiffs' motion to exclude Dr. Swift's testimony on the adequacy of the Obtryx Device's Directions for Use is DENIED;
2. Plaintiffs' motion to exclude Dr. Swift's testimony on complication rates of patients in his practice is GRANTED;
3. Plaintiffs' motion to exclude Dr. Swift's Testimony on the physical properties of polypropylene mesh is DENIED; and
4. Defendant's motion to exclude the testimony of Dr. Kohli is DENIED.

DATED this 21st day of July, 2020.

Barbara J. Rothstein

BARBARA J. ROTHSTEIN
UNITED STATES DISTRICT JUDGE

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hyper tonic pelvic floor, correct?
A. Correct.

Dkt. No. 44-2 at 58:4–14.