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6 **IN THE UNITED STATES DISTRICT COURT**
7 **FOR THE DISTRICT OF ARIZONA**

8
9 Amanda McBroom,
10 Plaintiff,

11 v.

12 Ethicon, Inc.; and Johnsons & Johnson,
13 Defendants.

No. CV-20-02127-PHX-DGC

ORDER

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15 This products liability action involves pelvic mesh devices manufactured and sold
16 by Defendants Ethicon, Inc. and Johnson & Johnson to treat stress urinary incontinence
17 and pelvic organ prolapse. Plaintiff Amanda McBroom received implants of Defendants'
18 devices and claims they are defective and caused her serious injury. Plaintiff filed suit in
19 2015 as part of a multidistrict litigation ("MDL") proceeding in West Virginia. Doc. 1; *see*
20 *In re Ethicon, Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, MDL No. 2327 (S.D. W. Va.
21 2012). The case was transferred to this Court on November 4, 2020. Docs. 41, 56.

22 Defendants have filed a motion to exclude the case-specific expert opinions of
23 Dr. Donald Ostergard. Doc. 32. The motion is fully briefed (Docs. 37, 39), and neither
24 side requests oral argument. For reasons stated below, the Court will grant the motion in
25 part and deny it in part.¹

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27 ¹ Defendants also have filed a motion to exclude the general opinions of Dr.
28 Ostergard and Plaintiff's other experts. Doc. 80. The Court will address that motion, along
with Plaintiff's motion to exclude expert opinions (Doc. 79), in a separate order. As set
forth below, the Court will require the parties to file a joint report identifying any arguments
that are moot in light of the Court's recent summary judgment order. *See* Doc. 83.

1 **I. Background.**

2 Plaintiff was implanted with Defendants’ Gynecare Prolift and TVT Secur pelvic
3 mesh devices on April 26, 2007. Docs. 1 ¶¶ 8-10, 30-1 at 3. Dr. Scott Crawford performed
4 the surgical procedure at Banner Good Samaritan Medical Center in Phoenix, Arizona.
5 Doc. 1 ¶¶ 10-12. Plaintiff claims that she began experiencing adverse symptoms from the
6 Prolift and TVT devices in 2011. Doc. 30-1 at 4. In July 2014, Plaintiff had surgery to
7 remove an exposed portion of Prolift mesh. Doc. 32-3 ¶ 39.

8 Plaintiff brought this action in 2015, asserting a host of state law claims and seeking
9 compensatory and punitive damages. Doc. 1; *see McBroom v. Ethicon, Inc.*, No. 2:15-cv-
10 03043 (S.D. W. Va. Mar. 13, 2015). Specifically, Plaintiff asserts the following claims
11 under Arizona law: negligence and gross negligence (Counts I and XIV); strict liability
12 manufacturing defect, failure to warn, defective product, and design defect (Counts II-V);
13 common law fraud, fraudulent concealment, and constructive fraud (Counts VI-VIII);
14 negligent misrepresentation (Count IX); negligent infliction of emotional distress
15 (Count X); breach of express and implied warranty (Counts XI and XII); violation of
16 consumer protection laws (Count XIII); unjust enrichment (Count XV); and punitive
17 damages (Count XVII). Doc. 1 ¶ 13.²

18 On March 4, 2021, the Court granted in part Defendants’ motion for partial
19 summary judgment. Docs. 30, 83. The following claims remain for trial: design defect,
20 negligence and negligent infliction to the extent these claims are based on negligent design,
21 and punitive damages (Counts I, V, X and XVII). *See* Doc. 83 at 10-11.³

22 Plaintiff designated Dr. Ostergard as an expert witness in August 2019. Doc. 32-1.
23 Dr. Ostergard has been a board-certified obstetrician and gynecologist since 1970.
24 Doc. 32-2 ¶ 1. From 1979 to 2011, he served as a clinical professor of obstetrics,

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26 ² Arizona law governs Plaintiff’s claims because Arizona is where she resides,
27 received the implants, and suffered her alleged injuries. Docs. 31 at 3-4, 35 at 2; *see also*
28 Doc. 83 at 2 n.2.

³ The Court granted summary judgment on the negligence and negligent infliction
claims to the extent they are based on an alleged failure to warn. *Id.* at 9-11.

1 gynecology, and women’s health at the University of Louisville School of Medicine. *Id.*
2 He presently serves as a professor-in-residence at the UCLA School of Medicine and
3 Harbor-UCLA Medical Center in Torrance, California. *Id.* He has authored numerous
4 articles on transvaginal mesh that have been published in peer-reviewed medical journals.
5 *Id.* ¶ 2.

6 Dr. Ostergard has provided two written reports in this case under Rule 26(a)(2)(B) –
7 an initial report dated August 19, 2019 and a supplemental report dated October 11, 2019.
8 Docs. 32-2, 32-3.⁴ He was deposed on October 18, 2019. Doc. 32-4. Defendants move to
9 exclude Dr. Ostergard’s opinions and testimony under Federal Rule of Evidence 702 and
10 *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). Doc. 32 at 1.

11 **II. Rule 702 and *Daubert* Standards.**

12 Under Rule 702, an expert may offer “scientific, technical, or other specialized
13 knowledge” if it “will assist the trier of fact to understand the evidence,” provided the
14 testimony rests on “sufficient facts or data” and “reliable principles and methods,” and “the
15 witness has reliably applied the principles and methods to the facts of the case.” Fed. R.
16 Evid. 702(a)-(d). The proponent of expert testimony has the ultimate burden of showing,
17 by a preponderance of the evidence, that the proposed testimony is admissible under
18 Rule 702. *See* Fed. R. Evid. 104(a); *Cooper v. Brown*, 510 F.3d 870, 942 (9th Cir. 2007).
19 The trial court acts as a gatekeeper for expert testimony to assure that it “both rests on a
20 reliable foundation and is relevant to the task at hand.” *Daubert*, 509 U.S. at 597; *see Davis*
21 *v. McKesson Corp.*, No. CV-18-1157-PHX-DGC, 2019 WL 3532179, at *3-4 (D. Ariz.
22 Aug. 2, 2019).

23 **III. Defendants’ Motion.**

24 Defendants argue that the Court should exclude Dr. Ostergard’s opinions and
25 testimony because: (1) he offers opinions about complications from the Prolift and TVT

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27 ⁴ The reports are largely the same, although it appears that the supplemental report
28 was prepared to update Plaintiff’s medical history (Doc. 32-3 ¶¶ 35, 45), to address
Plaintiff’s deposition (*id.* ¶ 46), and to correct an erroneous reference to the TVT device
instead of the Prolift (*compare id.* ¶ 39 with Doc. 32-2 ¶ 38).

1 that are not at issue in this case; (2) he fails to identify the defect in those devices that
2 allegedly caused Plaintiff's injuries; (3) his opinions about future complications are
3 unreliable, irrelevant, and unduly prejudicial; (4) his opinions concerning informed consent
4 are improper state of mind opinions; and (5) he improperly uses legal terminology and
5 reaches legal conclusions in calling the TVT and Prolift "defective." Doc. 32 at 3-11. The
6 Court will address each argument.

7 **A. First and Third Arguments – Opinions About Complications.**

8 **1. Complications that Plaintiff Allegedly Has Not Experienced.**

9 Dr. Ostergard opines that removal of the TVT and Prolift is the preferred treatment
10 option when the devices cause certain complications, such as: allergic reactions; vaginal
11 mucosal dehiscence; mesh exposure and erosion; chronic pelvic, abdominal, and vaginal
12 pain; nerve entrapment pain; tissue fibrosis and scarring; urinary problems and tract
13 infections; mesh contracture and shrinkage causing painful intercourse (dyspareunia); and
14 vaginal tenderness and rigidity. Docs. 32-2, 32-3 ¶¶ 7 (TVT), 11 (Prolift). Dr. Ostergard
15 further opines that TVT and Prolift removal is very difficult due to tissue fibrosis and
16 scarring that develops where the devices reside, that removal attempts may damage nearby
17 organs, that multiple removal surgeries frequently are required, and that narcotic pain
18 medication may be required to treat pelvic pain syndrome which occurs when the devices
19 cannot be removed completely. *Id.*

20 Defendants argue that complications Plaintiff has not experienced are not at issue
21 in this case and should be excluded as irrelevant, confusing, prejudicial, and not helpful to
22 the jury. Doc. 32 at 2-5 (citing *Bellew v. Ethicon, Inc.*, 2014 WL 12685965, at *10 (S.D.
23 W. Va. Nov. 20, 2014) ("Evidence of complications that the plaintiff did not experience is
24 irrelevant and lacking in probative value.")). Defendants contend that to the extent Dr.
25 Ostergard is permitted to testify at all, he should be limited to discussing complications
26 that he actually relates to Plaintiff's injuries. Doc. 39 at 2. Plaintiff counters that the
27 challenged complications are at issue because she still has pelvic mesh in her body and is
28 at risk for experiencing complications in the future. Doc. 37 at 3-4.

1 Several complications that Dr. Ostergard opines about – mesh exposure and erosion,
2 abdominal, pelvic, and vaginal pain, painful intercourse, scarring, and urinary problems –
3 are injuries Plaintiff has suffered according to her own testimony and Dr. Ostergard’s
4 reports. *See* Docs. 30-1 at 4; 30-2 at 4-6; 32-3 ¶¶ 24-39, 47, 50-56. Dr. Ostergard’s
5 opinions about these complications clearly are relevant to Plaintiff’s claims and would be
6 helpful to the jury. *See* Fed. Rs. Evid. 401, 702(a). Defendants have not shown that the
7 probative value of those opinions is substantially outweighed by the danger of confusing
8 the issues or unfair prejudice. *See* Fed. R. Evid. 403. Similarly, Dr. Ostergard’s opinions
9 about the removal of TVT and Secur mesh are admissible because Plaintiff already has had
10 a surgical procedure to remove a portion of exposed mesh that had eroded into her vagina
11 causing pelvic pain, and Dr. Ostergard opines that future surgeries may be needed.
12 Doc. 32-3 ¶¶ 39, 57. But it appears that Plaintiff has not experienced certain other
13 complications – allergic reaction, vaginal mucosal dehiscence, and nerve entrapment – and
14 Dr. Ostergard does not opine that these are potential future complications. *See id.* ¶ 57.

15 The Court will preclude Dr. Ostergard from opining at trial about complications that
16 Plaintiff has not suffered and will not experience in the future. *See Bellew*, 2014 WL
17 12685965, at *10. The Court will need to draw precise lines during trial. Defendants may
18 object if they believe Dr. Ostergard crosses the line into inadmissible opinions about
19 complications, and the Court will rule on the objections as they are made. *See id.* (“To the
20 extent that the parties disagree as to what complications the plaintiff suffered, these
21 objections are better suited for trial.”). Defendants’ motion is granted in part and denied
22 in part on this issue.

23 2. Future Complications.

24 Dr. Ostergard provides this opinion about future complications:

25 **Future Possible Adverse Events:** Since some of the implanted Ethicon
26 TVT SECUR sling and POSTERIOR PROLIFT mesh remains in the dense
27 fibrotic tissue produced by these devices in Ms. McBroom’s body, the
28 *potential exists* for continuing overactive bladder symptoms, continued stress
urinary incontinence, continued dyspareunia, along with infections,
abscesses, vaginal, and pelvic pain, mesh contraction and degradation, SIN

1 Syndrome, Central Sensitization, Complex Regional Pain Syndrome, cancer
2 associated with the mesh and infection for as long as the mesh remains in her
3 body which may necessitate future surgical and medical treatments.

4 Doc. 32-3 ¶ 57 (italics added). Defendants contend that Dr. Ostergard’s opinion about the
5 potential development of “abscesses, mesh contraction and degradation, SIN Syndrome,
6 and cancer associated with the mesh” should be excluded as mere speculation because he
7 cannot say that any of these complications “will occur in the future.” Doc. 32 at 6-7 (citing
8 Doc. 32-4 at 19 (Dep. Tr. at 68:5-12)); *see also* Doc. 39 at 2 (“Dr. Ostergard admits that it
9 cannot be stated . . . that any of his listed potential future complications will ever occur.”).
10 Plaintiff argues that these complications are at issue because she still has pelvic mesh in
11 her body, and Dr. Ostergard plainly is qualified to opine on what that mesh might do to
12 her. *Id.* at 3-5.

13 Under Arizona law, Plaintiff may recover damages for pain and suffering, disability,
14 mental anguish, and medical expenses “reasonably probable” to be experienced in the
15 future as a result of her injuries. *See Lewis v. N.J. Riebe Enters., Inc.*, 825 P.2d 5, 18-19
16 (Ariz. 1992); *Ahmad v. State*, 432 P.3d 932, 936 (Ariz. Ct. App. 2018); *see also* Revised
17 Arizona Jury Instructions (Civil) 6th, Personal Injury Damages 1 (Measure of Damages)
18 (citing *Saide v. Stanton*, 659 P.2d 35, 37 (Ariz. 1983)); *Romo v. United States*, No. 4:12-
19 CV-041-TUC-JAS, 2015 WL 12940759, at *7 (D. Ariz. Feb. 6, 2015) (“Arizona law
20 specifically authorizes damages . . . ‘reasonably probable to be experienced in the future
21 as a result of the injury.’”) (quoting RAJI (Civil) 5th). Contrary to Defendants’ assertion,
22 Dr. Ostergard does not need to “predict the future” for his opinions about potential
23 complications to be relevant and reliable. Doc. 39 at 2; *see Saide*, 659 P.2d at 37 (evidence
24 supported the jury’s finding that the plaintiff probably would need more dental work even
25 though the expert admitted that “without ‘a crystal ball’ there was no way of being certain
26 exactly whether, when and under what circumstances [plaintiff] would require these future
27 procedures”).

1 The Arizona Supreme Court made clear in *Saide* that whether future complications
2 and medical expenses “are reasonably probable or certain is determined ‘from all the
3 relevant circumstances which are before the court.’” 659 P.2d at 37 (citation omitted); *see*
4 *also Gill v. Curletta*, No. 1 CA-CV 07-0437, 2009 WL 2634651, at *5 (Ariz. Ct. App. Aug.
5 27, 2009) (same). “The use or refusal of an expert to use a ‘magic word’ or phrase such as
6 ‘probability’ is not determinative. The trier of fact is allowed to determine probability or
7 lack thereof if the evidence, taken as a whole, is sufficient to warrant such a conclusion.”
8 *Saide*, 659 P.2d at 37; *see also In re Ethicon, Inc. Pelvic Repair Sys. Prods. Liab. Litig.*,
9 No. 2327, 2016 WL 4536456, at *3 (S.D. W. Va. Aug. 30, 2016) (“A single expert need
10 not provide all the pieces of the puzzle for their testimony to be useful to the jury in
11 determining the ultimate issues in the case.”).

12 The Court cannot, on the present record, conclude that Dr. Ostergard’s opinions
13 about potential future complications from Plaintiff’s injuries and the mesh in her body (*see*
14 Doc. 32-3 ¶ 57) should be excluded as irrelevant under Rule 402 or unreliable under
15 Rule 702(c)-(d). Nor can the Court conclude that such opinions should be excluded under
16 Rule 403.

17 The Court will deny Defendants’ motion in this regard, but with the caveat that
18 Defendants may object at trial if they believe Plaintiff intends to elicit testimony from Dr.
19 Ostergard about complications that Plaintiff does not claim are reasonably probable to
20 occur in the future. *See Bodden v. Quigley*, No. 13-CV-21834, 2014 WL 12527753, at *1
21 (S.D. Fla. Nov. 10, 2014) (“Defendant seeks to exclude evidence of future damages
22 grounded in testimony about ‘possible’ future complications or medical treatment that
23 Plaintiff ‘might’ need. . . . This issue should be reserved for objection at trial.”); *Coston v.*
24 *Windfall Inc.*, No. CV 15-1809, 2016 WL 1660199, at *4 (E.D. La. Apr. 27, 2016)
25 (“Although at trial it will be Plaintiff’s burden to demonstrate that her future medical
26 expenses will more probably than not be incurred, the Court cannot now state, without the
27 context of testimony and evidence as developed through trial, that she will be unable to do
28 so. The Court therefore concludes that it need not exclude Dr. Rice’s report or testimony

1 concerning Plaintiff’s future medical expenses[.]”); *Dennis v. C. R. Bard, Inc.*, No. 2:16-
2 CV-10815, 2018 WL 691341, at *3 (S.D. W. Va. Feb. 1, 2018) (“Bard next argues that I
3 should exclude Dr. Zipper’s testimony regarding potential future complications because
4 that testimony is speculative and unreliable. However, after reviewing the record, I
5 determine that the challenged testimony is sufficiently grounded to move forward.”).⁵

6 **B. Second Argument – Alleged Failure to Identify a Defect Causing Injury.**

7 Defendants argue that Dr. Ostergard’s opinions should be excluded in their entirety
8 because he does not connect any of Plaintiff’s injuries to a defect in the TVT and Prolift.
9 Doc. 32 at 5-6. The Court does not agree.

10 Dr. Ostergard employed a “differential diagnosis” in reaching his causation
11 opinions, concluding that Plaintiff suffered her injuries “[a]s a result of the presence of [the
12 TVT and Prolift] in her body[.]” Doc. 32-3 ¶ 49.⁶ Defendants contend that the mere
13 assertion that the *presence* of the devices caused injury is not sufficient to render Dr.
14 Ostergard’s causation opinions relevant and reliable because Plaintiff ultimately must
15 prove that a *defect* in the devices was a proximate cause of her injuries. Doc. 32 at 5-6
16 (citing *Bellew v. Ethicon, Inc.*, No. 2:13-CV-22473, 2014 WL 6610685, at *4 (S.D. W. Va.
17 Nov. 20, 2014); *Jimenez v. Sears, Roebuck & Co.*, 904 P.2d 861, 864 (Ariz. 1995) (“A
18 prima facie case of strict products liability [requires a] showing that . . . the defect was a
19 proximate cause of plaintiff’s injuries.”)); *see also Anderson v. Nissei ASB Mach. Co.*, 3
20 P.3d 1088, 1092 (Ariz. Ct. App. 1999) (“To succeed in a products liability lawsuit based
21 upon a design defect claim, a plaintiff must establish that . . . the defective condition
22 proximately caused the plaintiff’s injury[.]”) (citing *Jimenez*).

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25 ⁵ Defendants’ reliance on *In re Ethicon*, 2016 WL 4536456, at *3, and *Bellew*, 2014
26 WL 12685965, at *10, is misplaced because future complications were not addressed by
the parties or the court in those cases.

27 ⁶ “A differential diagnosis is ‘a patient-specific process of elimination that medical
28 practitioners use to identify the most likely cause of a set of signs and symptoms from a
list of possible causes.’” *Stanley v. Novartis Pharms. Corp.*, 11 F. Supp. 3d 987, 1000
(C.D. Cal. 2014) (quoting *Ruggiero v. Warner-Lambert Co.*, 424 F.3d 249, 254 (2d Cir.
2005)).

1 But Dr. Ostergard specifically identifies the alleged defect that he believes
2 caused Plaintiff's injuries – the TVT and Prolift “are flawed and never should have been
3 inserted into [Plaintiff]” because the “devices are made from polypropylene and the mesh
4 is heavy weight, with small pores, impure, not inert, degrades, [and] shrinks[.]” Doc. 32-3
5 ¶¶ 49, 58; *see also* Doc. 37 at 4 (explaining that the entire list of flaws “is *the* defect”)
6 (emphasis in original). Defendants’ motion will be denied with respect to their argument
7 that Dr. Ostergard has failed to identify a defect causing injury.⁷

8 **C. Fourth Argument – Opinions About Informed Consent.**

9 Dr. Ostergard offers opinions on Plaintiff’s informed consent process with Dr.
10 Crawford before her surgery in April 2007. Doc. 32-3 ¶ 8. Defendants argue that those
11 opinions should be excluded because Dr. Ostergard improperly opines on Dr. Crawford’s
12 state of mind. Docs. 32 at 8-11, 39 at 4. Noting that she has asserted a failure to warn
13 claim, and not, as Defendants suggest, a claim for informed consent, Plaintiff contends that
14 Dr. Ostergard is well qualified to testify about what warnings were or were not available
15 to physicians at the relevant time. Doc. 37 at 8.

16 The Court has now granted summary judgment on Plaintiff’s failure to warn and
17 misrepresentation claims. *See* Doc. 83 at 2-10. The claims remaining for trial are for
18 design defect, negligent design, and punitive damages. *See id.* at 10-11. Dr. Ostergard’s
19 opinions about the informed consent process are not relevant to these claims, and testimony
20 about informed consent would serve only to waste time and confuse the issues. The Court
21 will exclude Dr. Ostergard’s opinions and testimony about informed consent under
22 Rules 402 and 403, and deny Defendants’ challenge under Rule 702 as moot.

23 **D. Fifth Argument – Legal Terms of Art and Conclusions.**

24 Dr. Ostergard states that the TVT and Prolift are “defective” and have “defects.”
25 Docs. 32-3 ¶¶ 7, 11, 58. Defendants argue that Dr. Ostergard should be precluded from
26 using these words or otherwise offering any opinion at trial stating a legal conclusion.

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28 ⁷ Defendants complain in their reply that the list of alleged flaws “is the standard wrap-up paragraph for Dr. Ostergard in virtually every one of his reports” (Doc. 39 at 3), but this is no basis for excluding his opinions.

1 Doc. 32 at 11.⁸ Plaintiff avows that Dr. Ostergard will be able to articulate his opinions
2 without using the words “defective” or “defect.” Doc. 37 at 9. The Court will hold Plaintiff
3 to her word, and is confident Defendants will object if Dr. Ostergard crosses the line into
4 inadmissible legal conclusions. *See In re Bard IVC Filters Prods. Liab. Litig.*, No. MDL
5 15-02641-PHX-DGC, 2017 WL 6523833, at *7 (D. Ariz. Dec. 21, 2017) (“an expert
6 witness may not opine on an ultimate issue of law”). The Court will grant Defendants’
7 motion in this regard.

8 **IT IS ORDERED:**

9 1. Defendants’ motion to exclude opinions and testimony of Dr. Ostergard
10 (Doc. 32) is **granted in part and denied in part** as set forth above.

11 2. By **April 7, 2021**, the parties shall file a joint report identifying arguments in
12 their other motions to exclude expert opinions (Docs. 79, 80) that are moot in light of the
13 Court’s summary judgment order (Doc. 83).

14 Dated this 30th of March, 2021.

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17 David G. Campbell
18 Senior United States District Judge
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27 _____
28 ⁸ The Court notes an inconsistency in Defendants’ arguments as they also contend
that Dr. Ostergard’s opinions should be excluded because “he never says what *defect* in
[the] devices” caused Plaintiff’s injury. *Id.* at 5 (emphasis added).