UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

DONNA PARKS,

Plaintiff,

v.

ETHICON, INC.; JOHNSON & JOHNSON,

Defendants.

Case No.: 20cv989-LL-RBB

ORDER GRANTING IN PART AND DENYING IN PART RESERVED *DAUBERT* ISSUES

[ECF Nos. 178, 179]

Before the Court are Defendants' fully briefed Motion to Exclude certain expert opinions of Donald Ostergard, M.D., Dionysios K. Veronikis, M.D., and Scott Guelcher, Ph.D. [ECF Nos. 178, 184, 186] and Plaintiff's fully briefed Motion to Exclude certain expert opinions of Peter Rosenblatt, M.D., Robert Rogers, M.D., Edward Stanford, M.D., Douglas Grier, M.D., Shelby Thames, M.D., and Timothy Ulatowski [ECF Nos. 179, 183]. For the reasons stated below, the Court **GRANTS IN PART and DENIES IN PART** the Motions to Exclude.

I. BACKGROUND

Plaintiff filed this lawsuit in 2014 as part of a large multidistrict litigation ("MDL") action before the Honorable Joseph R. Goodwin in the Southern District of West Virginia asserting medical products liability. ECF No. 1; *In re Ethicon, Inc. Pelvic Repair System*

Products Liability Litigation, MDL No. 2327 (S.D. W. Va.). The action stems from the surgical implantation of Defendants' pelvic mesh product Gynemesh/Gynemesh PS in January 2010. ECF No. 1 at 3–4; ECF No. 56-1. Plaintiff alleges the following causes of action: (1) negligence, (2) strict liability – manufacturing defect, (3) strict liability – failure to warn, (4) strict liability – defective product, (5) strict liability – design defect, (6) common law fraud, (7) fraudulent concealment, (8) negligent misrepresentation, (9) breach of express warranty, (10) breach of implied warranty, (11) violation of consumer protection laws, (12) loss of consortium, (13) punitive damages, and (14) discovery rule and tolling. ECF No. 1 at 4–5. On October 16, 2020, the Court granted Defendants' motion for summary judgment as to the following causes of action in their entirety: (1) strict liability – manufacturing defect, (2) strict liability – defective product, (3) strict liability – design defect, (4) loss of consortium, (5) breach of express warranty, and (6) breach of implied warranty. ECF No. 109 at 11–12, 18–19.

The MDL court ruled on certain motions challenging expert opinions under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993), but reserved some arguments for resolution by the trial court. ECF No. 120 at 2–3, 7.

On May 28, 2020, the MDL court transferred this matter back to this district for trial. ECF No. 55 at 2. On January 5, 2022, this matter was transferred to the undersigned. ECF No. 182.

II. LEGAL STANDARD

Federal Rule of Evidence 702 permits experts qualified by "knowledge, skill, experience, training, or education" to testify "in the form of an opinion or otherwise" based on "scientific, technical, or other specialized knowledge" if that knowledge will "help the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702. The expert's testimony must be "based on sufficient facts or data," "the product of reliable principles and methods," and the expert must have "reliably applied the principles and methods to the facts of the case." *Id.*

Rule 702 "contemplates a *broad conception* of expert qualifications." *Hangarter v. Provident Life & Accident Ins. Co.*, 373 F.3d 998, 1015 (9th Cir. 2004) (quoting *Thomas v. Newton Int'l Enterprises.*, 42 F.3d 1266, 1269 (9th Cir. 1994)). "Shaky 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) (citation omitted). The proponent of the expert bears the burden of establishing admissibility by a preponderance of the evidence. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 592 & n.10 (1993) [hereinafter *Daubert I*].

"[T]he district judge must ensure that all admitted expert testimony is both relevant and reliable." *Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227, 1232 (9th Cir. 2017). "The focus of the district court's analysis 'must be solely on principles and methodology, not on the conclusions that they generate,'" and "the court's 'task . . . is to analyze not what the experts say, but what basis they have for saying it.'" *Id.* (quoting *Daubert I*, 509 U.S. at 595; *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1316 (9th Cir. 1995) [hereinafter *Daubert II*]). Courts also consider "whether experts are testifying 'about matters growing naturally' out of their own independent research, or if 'they have developed their opinions expressly for purposes of testifying.'" *Id.* (quoting *Daubert II*, 43 F.3d at 1317).

"These factors are illustrative, and they are not all applicable in each case." *Id*. (citing *Daubert II*, 43 F.3d at 1317). "The inquiry is flexible, . . . and Rule 702 should be applied with a liberal thrust favoring admission." *Id.* (citations and internal quotation marks omitted). "*Daubert*'s list of specific factors neither necessarily nor exclusively applies to all experts or in every case. Rather the law grants a district court the same broad latitude when it decides *how* to determine reliability as [the court] enjoys in respect to its ultimate reliability determination." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141–42 (1999).

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III. DISCUSSION

Defendants and Plaintiff seek resolution of their challenges to certain expert opinions that were reserved by the MDL court for the trial court to decide.

A. Plaintiff's Experts

1. Donald Ostergard, M.D.

Defendants seek to exclude the following opinions of Donald Ostergard, M.D.: (1) testimony on FDA regulatory requirements and whether Defendants' warning labels satisfied those requirements, and (2) testimony on the adequacy of the warning accompanying Defendants' Gynemesh PS mesh product's Instructions for Use ("IFU"). ECF No. 178 at 6–8. Plaintiff does not oppose and states that "[c]onsistent with prior rulings by the MDL Court and the vast majority of transferee courts addressing this specific issue, Plaintiff agrees to withdraw any of Dr. Ostergard's opinions as to whether the Gynemesh PS IFU warnings were adequate (either legally or for regulatory purposes) but asserts that Dr. Ostergard, as an experienced urogynecologist, can testify about the specific risks of implanting the Gynemesh PS and opine about risks that are obvious to pelvic mesh surgeons and may testify as to knowledge common within the medical community." ECF No. 184 at 2. In its reply, Defendants "agree[] that this is the appropriate standard to apply to each side's experts." ECF No. 186 at 2. Because Plaintiff does not oppose, the Court **GRANTS** Defendants' Motion to Exclude certain testimony of Dr. Ostergard.

2. Dionysios Veronikis, M.D.

Defendants seek to exclude the following opinions of Dionysios Veronikis, M.D.: (1) testimony about safer alternative designs and (2) testimony about the adequacy of the warnings in the IFU for the Gynemesh PS. ECF No. 178 at 8, 11–12.

a. Adequacy of Warnings in the IFU

Plaintiff "agrees to withdraw any of Dr. Veronikis's opinions as to whether the Gynemesh IFU warnings were adequate (either legally or for regulatory purposes) but asserts that Dr. Veronikis, as an experienced urogynecologist, can testify about the specific risks of implanting Gynemesh PS and opine about risks that are obvious to pelvic mesh

surgeons and may testify as to knowledge common within the medical community." ECF No. 184 at 8. Because Plaintiff does not oppose Defendants' Motion to Exclude Dr. Veronikis's testimony about the adequacy of the warnings in the IFU for the Gynemesh PS, the Court **GRANTS** this portion of Defendants' Motion.

b. Safer Alternative Designs

In his expert report, Dr. Veronikis opines that "[d]espite having safer, equally as effective, alternative materials Ethicon used the polypropylene mesh that is known to contract and degrade in the human body." ECF No. 60-1 at 53. He includes a footnote after the word "materials" that includes quotations from several internal Ethicon emails discussing products called "PVDF" and "Pronova" "as a more stable filament" than polypropylene. ECF No. 60-1 at 53 n.22, 67–68. The full footnote is as follows:

> HMESH_ETH_02860031 (7/06/07 internal e-mail from Ethicon Research Fellow regarding prior "dog" study) – "I recall the long-term dog study did show some 'fibrillation' of PROLENE suture where none was observed for PRONOVA suture. My polymer colleagues tell me that PP has the potential to do this because of its molecular structure."); ETH.MESH.00857704 (2/12/09 internal e-mail regarding development of potential new mesh product constructed of PVDF "Pronova") – "I think we have multiple advantages over +M like:…If we use PRONOVA a more elastic fiber which show less degradation than PP. Better, longer function of Implant."); HMESH_ETH_00228962 (2/17/10 internal e-mail chain discussing polypropylene literature) – "[W]e know from literature that polyester and even polypropylene tend to alter over time in the body…. [H]ow has the general surgery group responded to this [degradation literature]?...[W]e proposed for several new product developments...to use PVDF or PRONOVA as a more stable filament, however Senior Management decided to go ahead with PP as a standard." (HMESH_ETH_00228961)).

Id.

Dr. Veronikis is a urogynecologist with board certifications in Female Pelvic Medicine and Reconstructive Surgery as well Obstetrics and Gynecology. ECF No. 60-1 at 10. He has been the Chief of Gynecology and Director of Vaginal Reconstructive Surgery and Urogynecology at St. John's Mercy Medical Center in St. Louis, Missouri from 1997 to at least the time of his expert report in 2016. *Id.* at 11, 25. Since 1994,

Dr. Veronikis's surgical practice has focused exclusively on vaginal reconstructive surgery and urogynecology with over 600 cases annually. *Id.* at 12. He has performed nearly 10,000 vaginal reconstructive surgeries for incontinence and pelvic organ prolapse and implanted thousands of mesh products. *Id.*

Defendants contend that Dr. Veronikis's opinion regarding safer alternative designs should be excluded because it is unreliable, irrelevant, and not helpful to the jury. ECF No. 178 at 11. Defendants argue that Dr. Veronikis's opinion is unreliable because he does not base this opinion on his experience with the alternative material, but instead on "nothing more than internal company documents he saw during his preparation for this case." *Id.* at 9. Defendants argue that this opinion is also irrelevant and not helpful to the jury because Dr. Veronikis fails to demonstrate that Pronova was available or feasible. *Id.* at 9–10. Defendants state that Pronova "is a suture indicated for use in general soft tissue approximation or ligation, including cardiovascular, ophthalmic and neurological surgery and was cleared by the FDA only for those uses" and argue that its lack of FDA approval for other uses renders it not feasible as an alternative design. *Id.* at 10.

Plaintiff argues that Dr. Veronikis's opinion regarding Pronova as a safer alternative design than Gynemesh PS is reliable because it is based primarily on his own experience as well as four internal Ethicon documents. ECF No. 184 at 5. Plaintiff states that Dr. Veronikis has extensive knowledge of the properties of a safer mesh based on his extensive experience in using mesh implants to treat pelvic organ prolapse and treating women suffering from complications of mesh implants, including the removal of hundreds of transvaginal mesh products. *Id.* at 6. Plaintiff also states that Dr. Veronikis cites journal articles that discuss which properties of mesh make a safer mesh. *Id.* Plaintiff further contends that Dr. Veronikis need not have used the alternative design material himself to have the requisite experience to support a safer alternative design opinion. *Id.* at 5.

The Court finds Plaintiff has met her burden to show Dr. Veronikis's alternative design opinions are admissible. A transferee court in the Central District of California faced similar arguments regarding Dr. Veronikis and denied the motion to exclude his alternative

design opinions, finding that it is appropriate for Dr. Veronikis to use Defendants' internal documents to show that other, safer designs were feasible and that Defendants' arguments are a basis for cross-examination rather than exclusion. ECF No. 183-2 at 4, 6; *Acosta v. Ethicon, Inc.*, No. 20cv5992-DSF-GJS, at 3, 5 (C.D. Cal. Dec. 13, 2021) (order regarding *Daubert* motions). This Court agrees with the Central District of California court. In his expert report, Dr. Veronikis opines—with references to Defendants' internal documents, other studies, or his own observations—that certain properties of polypropylene mesh can create problems and that Defendants at one point proposed "to use PVDF or PRONOVA as a more stable filament." ECF No. 60-1 at 40–42, 52–55. Dr. Veronikis's experience and his reference to Defendants' internal documents are sufficient to show his opinions on alternative designs are reliable. He does not need to have personal experience with the alternative design. *See Ramirez v. ITW Food Equip. Grp., LLC*, 686 F. App'x 435, 440 (9th Cir. 2017) ("Given that a plaintiff need not show an alternative, safer design is already used in similar products, it follows that her expert is not required to have experience with that safer design in such products."). Dr. Veronikis's opinions are also relevant because the material he references discuss using Pronova as the material to make up a mesh rather than Pronova sutures as an alternative procedure. ECF No. 60-1 at 62–63 (n.4), 67–68 (n.22).

The Court is also not persuaded by Defendants' arguments regarding feasibility and FDA approval. In this situation, disputes over feasibility go to weight, rather than admissibility of the opinions. *See Ramirez v. ITW Food Equip. Grp., LLC,* 686 F. App'x 435, 438 (9th Cir. 2017) ("[T]he feasibility of alternative safety devices is irrelevant under the consumer-expectations test and, under the risk-benefit test, the *defendant* bears the burden to prove the lack of feasible safety devices." (citing *Chavez v. Glock, Inc.,* 207 Cal. App. 4th 1283, 1303 (2012))); *Eisenbise v. Crown Equip. Corp.*, 260 F. Supp. 3d 1250, 1260 n.3 (S.D. Cal. 2017) (denying the defendant's motion to exclude an expert's alternative design opinions that defendant claimed would not prevent the problem in all circumstances because "it is not Plaintiffs' burden to present feasible alternative designs at

all; rather, it is [defendant's]" (citing *Ramirez,* 686 F. App'x at 438)).[1] Defendants' reliance on *Trejo v. Johnson & Johnson,* 13 Cal. App. 5th 110 (2017), for the proposition that an alternative design must be FDA approved is also misplaced. In *Trejo,* the court found that federal law preempted the plaintiff's design defect claim for a drug because unilaterally altering the chemical composition of an FDA-approved drug is prohibited by federal law. *Trejo*, 13 Cal. App. 5th at 154–55. Whether a federal law preempts Plaintiff's design defect claim is not at issue here. Accordingly, the Court **DENIES** Defendants' Motion to Exclude Dr. Veronikis's opinions regarding safer alternative designs.

3. Scott Guelcher, Ph.D.

Defendants seek to exclude the following opinions of Scott Guelcher, Ph.D.: (1) potential alternative designs and (2) the effects of Prolene mesh degradation in a patient's body. ECF No. 178 at 12–13. Dr. Guelcher has a Ph.D. in chemical engineering and was a post-doctoral research associate in biomedical engineering. ECF No. 57-1 at 10; ECF No. 57-8 at 9.

a. Alternative Designs

In his expert report, Dr. Guelcher opines about alternative designs as follows:[2]

> Using autologous fascia lata, allograft, sutures (including polypropylene sutures), or polyvinylidene fluoride (PVDF) mesh does not present with the same chronic complications associated with the material properties of Ethicon's PP mesh. All of these alternative materials, including using a less

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[1] In a strict liability action based on defective design, a product can be found to be defective using a consumer-expectation test or a risk-benefit test. *Merrill v. Navegar, Inc.*, 26 Cal. 4th 465, 479, 28 P.3d 116, 125 (2001) (citing *Barker v. Lull Eng'g Co.*, 20 Cal. 3d 413, 418, 573 P.2d 443, 446 (1978)). In a product liability action based on negligent design, "'most of the evidentiary matters' relevant to applying the risk/benefit test in strict liability cases 'are similar to issues typically presented in a negligent design case.'" *Id.* (quoting *Barker*, 20 Cal. 3d at 431).

[2] Defendants cited to an expert report by Dr. Guelcher that does not contain an opinion on alternative designs. ECF No. 178 at 13 (citing ECF No. 57-1 at 17–20). The Court located the correct report. *See* ECF No. 57-8 at 9.

> dense version of its PP mesh, were available when Ethicon's SUI and POP meshes were first commercialized.

ECF No. 57-8 at 11, 33.

Defendants contend that Dr. Guelcher's alternative design opinions are irrelevant because they present alternative treatment options rather than alternative designs to Ethicon's mesh device. ECF No. 178 at 13. To support their argument, Defendants cite to decisions by the MDL court and other transferee courts to exclude testimony about alternative procedures as not relevant. *Id.* at 13–16.

Plaintiff opposes, arguing that the cited cases are inapposite because none of them involved a claim of negligent design defect under California law. ECF No. 184 at 9–10.

The Court finds some of Dr. Guelcher's opinions as to alternative designs are irrelevant. The Court is persuaded by the MDL court's finding that "alternative procedures/surgeries do not inform the issue of whether an alternative design for a product exists." *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). Dr. Guelcher's report appears to describe sutures, autologous fascia lata (or "autografts"), and allografts as alternative procedures or treatments to Ethicon's synthetic mesh product, instead of as materials to create a safer design for it. *See* ECF No. 57-8 at 33–35; *see also Enborg v. Ethicon, Inc.*, No. 220CV02477AWIBAK, 2022 WL 800879, at *5 (E.D. Cal. Mar. 16, 2022) (excluding Dr. Guelcher's opinions as to autologous fascia lata, allografts, and sutures because they are alternative procedures that are not relevant to the question of alternative design).[3]

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[3] The Court is not persuaded by Plaintiff's argument that the cases cited by Defendants distinguishing between alternative procedures and alternative designs are inapposite because they did not consider negligent design defect claims under California law. A recent opinion issued after briefing on the instant motions was completed considered California design defect law and found that an alternative procedure does not offer insight on whether a safer alternative design exists. *See Enborg*, 2022 WL 800879, at *5 (considering the inquiries for design defect under California law, including negligent design, and finding

Additionally, Plaintiff does not argue that autologous fascia lata, allografts, and sutures are not alternative procedures or treatments. However, PVDF mesh and "a less dense version of [Ethicon's] PP mesh" appear to be alternative materials, and therefore relevant to the issue of a safer alternative design. *See* ECF No. 57-8 at 36; *Enborg*, 2022 WL 800879, at *4–5 (finding PVDF was recognized as a "mesh alternative"). Accordingly, the Court **GRANTS IN PART and DENIES IN PART** Defendants' Motion to Exclude Dr. Guelcher's alternative design opinions by excluding his opinions as to autologous fascia lata, allografts, and sutures.

b. Mesh Degradation

Dr. Guelcher opines in his expert report that the Prolene mesh—made almost entire of polypropylene—used in Ethicon devices to treat stress urinary incontinence and pelvic organ prolapse degrades over time as a result of oxidation caused by reaction with chemicals in the body. ECF No. 57-8 at 11–12.

Defendants argue that Dr. Guelcher's opinions on mesh degradation are irrelevant because the case-specific expert did not opine that Plaintiff's mesh degraded or that degradation caused any of her injuries. ECF No. 178 at 17. Defendants also contend that Dr. Guelcher's opinions are unreliable because he relies on a research paper previously found to be unreliable by the MDL court, and other articles he relies on are inapposite. *Id.* at 17–18.

Plaintiff opposes, arguing that other courts have found Dr. Guelcher's opinions on mesh degradation to be reliable and relevant, and Defendants' criticisms go to the weight of the opinion, not admissibility. ECF No. 184 at 10–11.

The Court finds that Dr. Guelcher's opinions on mesh degradation are relevant. Defendants point the Court to the report of Plaintiff's case-specific expert Dr. Daniel S. Elliott, arguing that Dr. Elliott did not opine that mesh degradation occurred in this case.

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that alternative procedures that make no use of the device at issue are not relevant to the question of safer alternative design).

ECF No. 186 at 5. However, the expert report cited is obviously incomplete because the pages do not logically follow each other. ECF No. 36-1 at 2–5. Therefore, the Court cannot ascertain if Dr. Elliott did not find mesh degradation to be an issue in Plaintiff's case.

Furthermore, the Court finds mesh degradation to be relevant to the issue of Ethicon's alleged negligence. The California Supreme Court explained that "the test of negligent design 'involves a balancing of the likelihood of harm to be expected from a machine with a given design and the gravity of harm if it happens against the burden of the precaution which would be effective to avoid the harm.'" *Merrill v. Navegar, Inc.*, 26 Cal. 4th 465, 479 (2001) (citation omitted). The issue of mesh degradation and what was known about it is relevant to this inquiry.

The Court also finds that Dr. Guelcher's opinions on mesh degradation are sufficiently reliable to be admissible. In 2015 the MDL court found a test in one of the studies that Dr. Guelcher relied on to be unreliable because the testing "failed to follow a written protocol or utilize a sufficiently large sample size." *Mathison v. Bos. Sci. Corp.*, No. 2:13-CV-05851, 2015 WL 2124991, at *22 (S.D.W. Va. May 6, 2015). The test was performed by Russell Dunn, Ph.D., and was included in a peer-reviewed paper referred to as the "Talley study" published by Dr. Guelcher and others in 2017 in the *Journal of Biomaterials Science*. *Id.*; *see also* ECF No. 178 at 17; ECF No. 57-8 at 78. In Dr. Guelcher's deposition, he stated that they "did not repeat the experiment, but [they] did more work on the analysis to basically present the paper in a form that could be published." ECF No. 57-8 at 78. It appears to the Court that in 2015 the MDL court did not have the 2017 published paper before it. Although the test at issue was not redone, there was additional analysis, and the paper was subsequently peer-reviewed and published.

Moreover, the Talley study was only one of the many articles that Dr. Guelcher relied on. Defendants argue that none of the articles specifically states that Prolene oxidizes and degrades in the body. However, Dr. Guelcher cites to articles involving oxidative degradation of polypropylene in the body, which lends support to his opinion because Prolene is "more than 97% polypropylene." See ECF No. 57-8 at 12, 18, 20. The Court

finds that Defendants' criticisms of Dr. Guelcher's opinion go to weight rather than admissibility. *See Clausen v. M/V NEW CARISSA*, 339 F.3d 1049, 1060 (9th Cir. 2003), *as amended on denial of reh'g* (Sept. 25, 2003) ("The fact that a cause-effect relationship . . . has not been conclusively established does not render [the expert's] testimony inadmissible." (citation omitted)); *Gomez v. Am. Med. Sys. Inc.*, No. CV-20-00393-PHX-ROS, 2021 WL 1163087, at *13 (D. Ariz. Mar. 26, 2021) ("Offering a hypothesis as an opinion goes to weight, not admissibility, so long as there is support in objective evidence."); *Wood v. Am. Med. Sys. Inc.*, No. 120CV00441DDDKLM, 2021 WL 1178547, at *5 (D. Colo. Mar. 26, 2021) (finding similar criticisms of the articles relied on by Dr. Guelcher to be "legitimate bases for cross examination, but they don't fundamentally undermine the reliability of Dr. Guelcher or Dr. Mays's testimony"). Accordingly, the Court **DENIES** Defendants' Motion to Exclude Dr. Guelcher's opinions about mesh degradation.

B. Defendants' Experts

1. Edward Stanford, M.D.

Plaintiff seeks to exclude the opinion of Edward Stanford, M.D., regarding the adequacy of Defendants' warnings regarding the Prolene Soft mesh.[4] ECF No. 179 at 34. Plaintiff noted that when this same issue was brought before another transferee court, Defendants "concede[d] that Dr. Stanford is not a regulatory expert and will not opine on the adequacy of product warnings even if such opinions were relevant to the remaining claims." *Id.* at 4 (quoting *McBroom v. Ethicon, Inc.*, No. CV-20-02127-PHX-DGC, 2021 WL 2709292, at *15 (D. Ariz. July 1, 2021)). Defendants state that they stand by their prior concession. ECF No. 183 at 3. Because Defendants assert that Dr. Stanford will not offer

[4] Plaintiff had previously sought to exclude the following additional opinions of Dr. Stanford: (1) other physicians knew about the risks of these transvaginal mesh devices, (2) his personal experience with Ethicon's Prolene mesh products, and (3) mesh degradation. ECF No. 179 at 3–5. However, Plaintiff states that she withdraws her arguments regarding these opinions given other transferee courts' decisions allowing these opinions. *Id.* at 4–5.

this opinion, the Court **DENIES AS MOOT** Plaintiff's Motion to Exclude Dr. Stanford's opinion regarding the adequacy of Defendants' warnings regarding the Prolene Soft mesh.

2. Robert Rogers, M.D.

Plaintiff seeks to exclude the opinion of Robert Rogers, M.D., that Ethicon behaved admirably, was a "good company," and that the development of Ethicon mesh products was done "with the patient's best interests at the top of each agenda." ECF No. 179 at 5–6. Dr. Rogers is board certified in Obstetrics and Gynecology since 1986 and in Female Pelvic Medicine and Reconstructive Surgery since 2013. ECF No. 183-3, TVT and TVT-O Expert Report of Robert M. Rogers, Jr. M.D. (Ex. C), at 3. He practices gynecologic surgery and urogynecology. *Id.* Dr. Rogers has performed over 700 surgeries since 2008 "for reconstruction of various vaginal support defects, with several hundred of these cases involved with placement of Gynemesh PS and the Prolift products from Ethicon," including over 200 midurethral slings with most of those involving TVT, TVT-O, and TVT-Secur products from Ethicon.[5] *Id.* at 6.

In his expert report, Dr. Rogers stated that "[f]rom the late 1990s to 2007, I was asked by the research and clinical scientists at Ethicon to consult with them on the design and performance of the Prolift, TVT-O, TVT-Secur products, as well as one or two other developing products."[6] *Id.* He opined, "I found that at Ethicon all my contacts, discussions and work with the research scientists, biomedical engineers and clinicians were consistently respectful, appreciated, and honest." *Id.* at 8. He further opined, "All the product development in which I was involved was thoroughly evaluated and reevaluated step by step, in accordance to the Ethicon standards, the industry standards, and of course, the FDA and federal government standards." *Id.* Dr. Rogers summarized a trip he

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[5] The TVT and its variations are pelvic mesh products designed to treat stress urinary incontinence in women. ECF No. 56-1 ¶¶ 17–18.

[6] Prolift is a pelvic mesh product for the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. ECF No. 56-1 ¶¶ 14–15, 18.

participated in during the fall of 2003 to France and Belgium to observe and question Prolift inventors and the urologist who developed the TVT-O. *Id.* He opined, "Upon returning to Ethicon in New Jersey, the development of the Prolift products and TVT products continued in earnest with the patients' best interests always at the top of each agenda." *Id.* at 9.

Plaintiff contends that Dr. Rogers's opinions that Ethicon behaved admirably, was a "good company," and that the development of Ethicon mesh products was done "with the patient's best interests at the top of each agenda" should be excluded as inadmissible character evidence and because they are irrelevant and any probative value is substantially outweighed by its prejudicial value. ECF No. 179 at 6.

Defendants argue that Dr. Rogers did not opine that Ethicon was "a good company" and that he instead offered admissible opinion based on his "specialized knowledge regarding product development, clinical studies, and professional education, and his experiences working with Ethicon in these areas." ECF No. 183 at 4.

Two transferee courts have ruled on arguments similar to Plaintiff's regarding Dr. Rogers's opinions. A district court in South Dakota excluded Dr. Rogers's opinions "about Ethicon's work environment being 'consistently respectful, appreciated, and honest,' or that Ethicon behaved admirably or as a 'good' company." *Foster v. Ethicon, Inc.,* No. 4:20-CV-04076-RAL, 2021 WL 4476642, at *4 (D.S.D. Sept. 30, 2021). A district court in the Central District of California also excluded some of Dr. Rogers's opinions regarding "his general experience with Ethicon, its general dedication to patient safety, and his general interactions with Ethicon staff." ECF No. 183-2 at 2–3; *Acosta v. Ethicon, Inc.*, No. 20cv5992-DSF-GJS, at 1–2 (C.D. Cal. Dec. 13, 2021) (order regarding *Daubert* motions). The California court found that "[t]o the degree that Rogers is not discussing specific interactions regarding the specific product at issue in this case," it is inadmissible character evidence pursuant to Federal Rule of Evidence 404(a). *Id.* at 3. However, the court ruled that Dr. Rogers was "free to testify regarding the Ethicon product

development process, its application to the relevant product in this case, and as to his opinion whether this process was up to industry standards." *Id.*

The Court finds that to the extent that Dr. Rogers has opinions about the general character of Ethicon, they are inadmissible character evidence and irrelevant. However, his opinions regarding Ethicon's product development process as it relates to this case is relevant to the issue of Plaintiff's product liability and negligence claims. Accordingly, the Court **GRANTS** Plaintiff's Motion to Exclude Dr. Rogers's opinions that development of the Ethicon mesh products was done "in earnest" and "with the patient's best interests always at the top of each agenda" (i.e., opinions regarding the general affect, character, or demeanor of the Ethicon staff and its subjective commitment to patient safety). Plaintiff does not appear to seek to exclude other opinions of Dr. Rogers, but the Court will clarify that Dr. Rogers may testify regarding the Ethicon product development process, its application to the relevant product in this case, and whether this process was up to industry standards.

3. Timothy Ulatowski

Plaintiff seeks to exclude the following opinions of regulatory consultant Timothy Ulatowski: (1) the 510(k) review process is robust and a basis for the determination of the safety and effectiveness of medical devices; (2) Prolene, the primary material used in Prolene Soft Mesh, is safe and effective from a regulatory perspective; and (3) a change in material or Prolene weave specifications for the Prolene Soft Mesh would require the submission of a new 510(k) to the FDA and clearance by the FDA before the modified device could be marketed. ECF No. 179 at 7–10. However, Defendants state that Mr. Ulatowski is not a currently designated expert. ECF No. 183 at 2 n.1. They aver that if the Court allows FDA evidence, then Defendants may then seek to substitute Mr. Ulatowski in place of one of their five designated experts. *Id.* Defendants contend that the issue of whether FDA evidence may be allowed is more appropriate for a motion in limine and not a *Daubert* challenge. *Id.* Accordingly, because Mr. Ulatowski is not currently a designated expert, the Court **DENIES AS MOOT** Plaintiff's Motion to Exclude Mr. Ulatowski's

opinions related to regulatory issues, but without prejudice should Mr. Ulatowski be substituted in as an expert.

4. Recurring Reserved Issues for General Causation Experts

Plaintiff seeks to exclude the following general types of recurring opinions from Defendants' general causation experts: (1) opinions on Ethicon's compliance with design control and risk management standards; and (2) opinions regarding the adequacy of Ethicon's clinical testing and research, physician outreach, or particular product development procedures and assessments. ECF No. 179 at 10. Plaintiff argues that they both "implicate the [FDA's section] 510(k) regulatory process which has repeatedly been excluded by the MDL court and transferee courts." *Id.* Plaintiff adds that it seeks exclusion of these reserved issues under Federal Rule of Evidence 403, so their admissibility is "probably more appropriately addressed as a motion in limine." *Id.* at 11.

Defendants oppose on several grounds: (1) Plaintiff fails to identify where any of their experts provide these opinions; (2) Plaintiff fails to cite to any specific challenge to these opinions in her MDL briefing; and (3) evidence of Defendants' compliance with industry standards and clinical testing is directly relevant to Plaintiff's claims of product liability and negligence and to Defendants' defense. ECF No. 183 at 7.

The Court finds that Plaintiff's arguments are deficient. Plaintiff fails to provide enough specificity to identify the challenged opinions because she does not cite to the specific opinions, but rather to the MDL court orders reserving ruling on these two types of general recurring opinions for Dr. Thames, Dr. Rosenblatt, Dr. Grier, and Dr. Rogers.[7] ECF No. 179 at 10. And although it is true that the MDL court excluded evidence regarding the FDA's section 510(k) clearance process and was inclined to doubt the relevance of the two general types of opinions challenged by Plaintiff, Judge Goodwin also stated the following:

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[7] Plaintiff also cites to Mr. Ulatowski's expert report, but Defendants stated that Mr. Ulatowski is not currently a designated expert. *See supra* Section III.B.3.

> Nevertheless, because the nuances of products liability law vary by state, I will refrain from issuing a blanket exclusion on design process and control standards testimony, whether rooted in the FDA or otherwise. Each standard must be assessed for its applicability to the safety questions at issue in this litigation, consistent with state law. I am without sufficient information to make these findings at this time.

ECF No. 76-1 at 9–10. Judge Goodwin also reserved ruling on the relevancy of opinions on Ethicon's clinical testing and research, physician outreach, or particular product development procedures and assessments for the same reason. *Id.* at 10. However, Plaintiff provides no arguments as to how these opinions are not relevant under California law. Accordingly, the Court **DENIES** Plaintiff's Motion to Exclude these two general types of expert opinions, without prejudice to being raised as motions in limine.

IV. CONCLUSION

The Court adopts the MDL court's previous rulings as to experts from prior waves of cases except to the degree that those rulings are contradicted by orders from this Court. *See* ECF No. 120 at 7–17.

For the reasons stated above, the Court **GRANTS IN PART AND DENIES IN PART** the parties' Motions to Exclude certain expert opinions as follows:

1. The Court **GRANTS** Defendants' Motion to Exclude the following opinions of Donald Ostergard: (1) FDA regulatory requirements and whether Defendants' warning labels satisfied those requirements, and (2) the adequacy of the warning accompanying Defendants' Gynemesh PS mesh product's Instructions for Use. Dr. Ostergard may testify about (1) the specific risks of implanting the Gynemesh PS, (2) risks that are obvious to pelvic mesh surgeons, and (3) knowledge common within the medical community.

2. The Court **GRANTS** Defendants' Motion to Exclude Dionysios Veronikis's opinions about the adequacy of the warnings in the IFU for the Gynemesh PS. Dr. Veronikis may testify about (1) the specific risks of implanting the Gynemesh PS, (2) risks that are obvious to pelvic mesh surgeons, and (3) knowledge common within the medical community.

3. The Court **DENIES** Defendants' Motion to Exclude Dionysios Veronikis's opinions about safer alternative designs.

4. The Court **GRANTS IN PART and DENIES IN PART** Defendants' Motion to Exclude Scott Guelcher's alternative design opinions by excluding his opinions as to autologous fascia lata, allografts, and sutures.

5. The Court **DENIES** Defendants' Motion to Exclude Scott Guelcher's opinions about mesh degradation.

6. The Court **DENIES AS MOOT** Plaintiff's Motion to Exclude Edward Stanford's opinions regarding the adequacy of Defendants' warnings regarding the Prolene Soft mesh.

7. The Court **GRANTS** Plaintiff's Motion to Exclude Robert Rogers's opinions that development of the Ethicon mesh products was done "in earnest" and "with the patient's best interests always at the top of each agenda" (i.e., opinions regarding the general affect, character, or demeanor of the Ethicon staff and its subjective commitment to patient safety).

8. The Court **DENIES AS MOOT** Plaintiff's Motion to Exclude Timothy Ulatowski's opinions related to regulatory issues, but without prejudice should Mr. Ulatowski be substituted in as an expert.

9. The Court **DENIES** Plaintiff's Motion to Exclude the following general types of recurring opinions from Defendants' general causation experts: (1) opinions on Ethicon's compliance with design control and risk management standards; and (2) opinions regarding the adequacy of Ethicon's clinical testing and research, physician outreach, or particular product development procedures and assessments, without prejudice to being raised as motions in limine.

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Additionally, the Court **ORDERS** the parties to contact the chambers of the magistrate judge on or before **June 9, 2022** to schedule a settlement conference in a further effort to resolve their differences prior to trial.

IT IS SO ORDERED.

Dated: June 2, 2022

Honorable Linda Lopez
United States District Judge