UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

DONNA PARKS; DELBERT PARKS,

Plaintiffs,

v.

ETHICON, INC.; JOHNSON & JOHNSON,

Defendants.

Case No.: 20-CV-989 TWR (RBB)

ORDER (1) DENYING DEFENDANTS' MOTION TO EXCLUDE EXPERT TESTIMONY, AND (2) GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

(ECF Nos. 34, 36)

Presently before the Court are Defendants Ethicon, Inc. and Johnson & Johnson's Motions for Summary Judgment ("MSJ," ECF No. 34) and to Exclude Certain Case-Specific Opinions of Daniel Elliott, M.D. ("*Daubert* Mot.," ECF No. 36). The Court held a hearing on October 15, 2020, at which the Parties agreed to submit the motions on the briefing. (*See* ECF No. 108.) Having carefully considered the Parties' arguments, evidence, and the law, the Court **DENIES** Defendants' *Daubert* Motion and **GRANTS IN PART AND DENIES IN PART** Defendants' Motion for Summary Judgment as follows.

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BACKGROUND

The Parties agree to the following undisputed facts:

Plaintiff Donna Parks, a resident of California, visited Dr. Shawn Menefee in 2010 with complaints of pelvic organ prolapse. (ECF No. 35 ("MSJ Mem.") at 2 (citing ECF No. 1 ¶ 4; ECF No. 34-1 at 6).) On January 8, 2010, Dr. Menefee implanted Gynemesh PS at Kaiser Hospital in San Diego, California. (*Id.* (citing ECF No. 34-2; ECF No. 34-3 at 77:6–17).)

In January 2010, Dr. Menefee was familiar with the risk of complications from pelvic mesh products generally, including exposure or erosion, infection, acute and/or chronic pain, urinary problems, recurrence or failure, bowel/bladder/blood vessel perforation during insertion, bleeding, wound complications, inflammation, fistula formation, vaginal scarring, organ or nerve damage, neuromuscular problems, need for additional surgeries, foreign body response, contraction or shrinkage of tissue, dyspareunia (pain with intercourse), and a decrease in patient quality of life. (*Id.* at 3 (citing ECF No. 34-4 at 97:9–99:4, 101:12–103:7).) However, Dr. Menefee was not aware of all the risks associated with the transvaginal use of Gynemesh PS at the time of Plaintiff's surgery. (MSJ Opp'n at 2 (citing ECF No. 44-1 at 56:8–59:22, 60:1–21, 61:22–62:22).)

Through the years, Dr. Menefee has read most Instructions for Use ("IFUs") accompanying mesh products because they come as a package insert; nonetheless, it is not his practice to read them before every surgery. (MSJ Mem. at 3 (citing ECF No. 34-4 at 141:13–17).) He also could not recall whether he had read the Gynemesh PS IFUs before Plaintiff's surgery in January 2010, (*id.* at 4), although he believed that he had. (MSJ Opp'n at 2 (citing ECF No. 44-1 at 141:18–23).)

Dr. Menefee testified that he does not rely on IFUs, including the Gynemesh PS IFUs, in making his surgical decisions, (MSJ Mem. at 3 (citing ECF No. 34-4 at 140:4–7)), and that he did not rely on the Gynemesh PS IFUs in performing Plaintiff's surgery. (*Id.* at 4 (citing ECF No. 34-4 at 148:20–149:1).) Instead, Dr. Menefee believes that surgical decision-making should be based on the best clinical evidence available, a

physician's clinical experience, and the experience of a physician's peers. (*Id.* at 3 (citing ECF No. 34-4 at 140:9–16).) Dr. Menefee therefore based his decision to use Gynemesh PS for Plaintiff on his clinical experience, discussions with peers, and the then-available medical research. (*Id.* (citing ECF No. 34-4 at 140:17–20).)

Based on that information and in his medical judgment, Dr. Menefee determined that the benefits of using a sling to treat Plaintiff's stress urinary incontinence outweighed the risk at that time. (*Id.* at 2 (citing ECF No. 34-4 at 71:25–72:9).) Dr. Menefee also believed that his decision to use Gynemesh PS for Plaintiff was an appropriate alternative for the surgical management of her prolapse in 2010. (*Id.* at 3 (citing ECF No. 34-4 at 139:23–140:3).)

Dr. Menefee does not recall giving Plaintiff an industry brochure, (*id.* at 4 (citing ECF No. 34-4 at 148:20–149:1)), and Plaintiff does not recall receiving any documents from Dr. Menefee. (*Id.* at 2 (citing ECF No. 34-3 at 15:11–19, 21:17–20).) Plaintiff testified that Dr. Menefee did not advise her to look at the U.S. Food and Drug Administration's consumer website. (*Id.* at 2 (citing ECF No. 34-3 at 15:11–19, 21:17–20).) Plaintiff's decision to proceed with the surgery was based solely on Dr. Menefee's recommendation, (*id.* (citing ECF No. 34-3 at 25:12–15)), and she did not perform any independent research either before or after the surgery. (*Id.* (citing ECF No. 34-3 at 25:12–15).)

Plaintiff filed her lawsuit directly in the *In re Ethicon, Inc. Pelvic Repair System Products Liability Litigation*, MDL No. 2327 (S.D. W.Va.), on February 13, 2014. (MSJ Mem. at 4 (citing ECF No. 1).) She has designated one case-specific expert, Dr. Daniel S. Elliott. (*Id.* (citing ECF No. 34-5).) Dr. Elliott opines that the Gynemesh product caused Plaintiff's alleged vaginal scarring and narrowing, resulting in a "severe compromise in Ms. Parks' quality of life." (*Id.* (quoting ECF No. 34-6 at 62).) He further opines that she has pelvic pain, pelvic floor myalgia, and dyspareunia and that it is highly unlikely that these conditions will resolve completely. (*Id.* (citing ECF No. 34-6 at 62).) Dr. Elliott also

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believes that this "long-term negative impact" could lead to "feelings of isolation, loneliness, depression and suicide." (*Id.* (quoting ECF No. 34-6 at 62).)

DAUBERT MOTION

I. Legal Standard

Federal Rule of Evidence 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.

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 Enters.*, 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).

Additionally, under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), "the district court 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); *see also Grodzitsky v. Am. Honda Motor Co.*, 957 F.3d 979, 984–85 (9th Cir. 2020). "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.'" *Wendell*, 858 F.3d at 1232 (alteration in original) (quoting *Daubert*, 509 U.S. at 595; *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1316 (9th Cir. 1995) ("*Daubert II*")). Courts also consider "whether experts are testifying 'about matters growing naturally' out of their own independent

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research, or if 'they have developed their opinions expressly for purposes of testifying.'" *Id.* (quoting *Daubert II*, 43 F.3d at 1316).

"These factors are illustrative, and they are not all applicable in each case." *Id.* "The inquiry is flexible, . . . and Rule 702 should be applied with a liberal thrust favoring admission." *Id.* (citation and 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 (1999); *see also Abarca v. Franklin Cnty. Water Dist.*, 761 F. Supp. 2d 1007, 1021 (E.D. Cal. 2011) (citations omitted).

"[T]he proponent [of the proposed expert] has the burden of establishing that the pertinent admissibility requirements are met by a preponderance of the evidence." Fed. R. Evid. 702 advisory committee's note (2000).

II. Analysis

Defendants request that the Court preclude Dr. Elliott's case-specific opinions relating to two issues: (1) Plaintiff's future mental health, and (2) Plaintiff's informed consent process. (*See Daubert* Mot. at 1; *see also* ECF No. 37 ("*Daubert* Mem.") at 1.)

A. Plaintiff's Future Mental Health

In his expert report, Dr. Elliott indicates that "[t]he long-term impact [of Plaintiff's lack of quality, pain-free physical intimacy] on [Plaintiff's] quality of life is difficult to accurately ascertain[;] however, many studies have shown the long-term negative impact leading to feelings of isolation, loneliness, depression and suicide." (ECF No. 36-1 at 62.) Defendants urge the Court to preclude Dr. Elliott from offering such opinions at trial because "he is not qualified to opine about mental health and because he has not opined that Plaintiff has suffered from or will suffer from such mental health issues." (*See Daubert* Mem. at 1–2.)

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1. Dr. Elliott's Qualifications

Defendants argue that Dr. Elliott is not qualified to offer an opinion on Plaintiff's mental health because he "is a urologist and pelvic surgeon, not a psychiatrist" and he "does not treat patients for mental health conditions." (*Daubert* Mem. at 2.) Plaintiff counters that "[q]uality of life assessments are central to the treatment of pelvic organ prolapse, including mesh surgery, and Dr. Elliott . . . is well-qualified to offer testimony on Ms. Parks['] quality of life." (ECF No. 43 ("*Daubert* Opp'n") at 2 (citing Fed. R. Evid. 702).)

The Court agrees with Plaintiff. Dr. Elliott's report is based, among other things, on his "[i]ndependent, personal clinical and laboratory mesh-specific research and research with synthetic mesh-specific function and complications," (ECF No. 43-1 at 1), and sixteen years of "personal surgical and clinical experience as a Female Pelvic Medicine and Reconstructive surgical specialist at a high volume tertiary center managing highly complicated Pelvic Organ Prolapse patients and SUI patients and the management of mesh-related complications." (*Id.* at 2; *see also id.* at 3–4; ECF No. 36-2.) Based on this experience, Dr. Elliott discusses several complications observed in Gynemesh repairs, (*see generally* ECF No. 43-1 at 22–35), including pain syndromes and sexual dysfunction. (*See generally id.* at 33–35.) With respect to pain syndromes, Dr. Elliott notes that pelvic meshes can "lead[] to chronic pain syndromes involving the pelvis, vagina, and buttocks," as a result of which "it is not unusual for the woman to be greatly limited in her activities and have a significant negative impact on her [quality of life]." (*Id.* at 33–34.) Dr. Elliott also opines that "[p]ainful sexual activity (dyspareunia) and any functional sexual disorder [that] makes satisfactory sexual activity for the female and her partner painful will have a significant negative impact upon a patient's [quality of life]." (*Id.* at 34.) He adds that "[t]he true impact and negative effect on [quality of life] from embarrassment, loss of intimacy, pain, and depression for a woman affected with this condition cannot be truly estimated[,] but a vast amount of medical literature exists documenting how impaired sexual function significantly impacts a woman's [quality of life]." (*Id.*)

Although it is true that Dr. Elliott is not a psychologist or psychiatrist, it is clear from both his expert report and his curriculum vitae that he has significant clinical experience treating patients suffering mesh-related complications, including chronic pain and sexual disfunction, which in turn are accompanied by loss of intimacy and depression. The Court therefore concludes that Dr. Elliott is qualified to offer testimony regarding the mesh-related complications Plaintiff may experience in the future, including those pertaining to her quality of life and mental health. *See, e.g.*, *Linares v. Crown Equip. Corp.*, No. EDCV161637JGBKKX, 2017 WL 10403360, at *3 (C.D. Cal. Sept. 19, 2017) (concluding that medical doctor whose practice focused on pain management was qualified to opine on the plaintiff's post-traumatic stress disorder).

2. Future Prognosis

Defendants also contend that Dr. Elliott's opinion about Plaintiff's future prognosis should be excluded because Dr. Elliott "does not opine that Plaintiff has sustained those mental health issues or that it is probable that she will sustain those conditions." (*Daubert* Mem. at 2.) Plaintiff responds that Dr. Elliott's opinions are helpful to the jury because he "connects the injuries Ms. Park suffered, including emotional injuries, to the Gynemesh PS." (*Daubert* Opp'n at 2 (citing ECF No. 43-1 at 22–35, 61–63).)

The Court concludes that Dr. Elliott's testimony concerning Plaintiff's future prognosis is admissible. Under California law, "[d]amages may be awarded . . . for detriment . . . certain to result in the future." *Garcia v. Duro Dyne Corp.*, 156 Cal. App. 4th 92, 97 (2007) (alterations in original) (quoting Cal. Civ. Code § 3283). California courts have interpreted this to mean that "[a]n injured plaintiff is entitled to recover the reasonable value of medical services that are reasonably certain to be necessary in the future." *Martinez v. United States*, No. 116CV01556LJOSKO, 2019 WL 266213, at *9 (E.D. Cal. Jan. 18, 2019) (quoting *Corenbaum v. Lampkin*, 215 Cal. App. 4th 1308, 1330, *as modified* (May 13, 2013)). The courts caution, however, that "[i]t is for the [finder of fact] to determine the probabilities as to whether future detriment is reasonably certain to occur in any particular case." *Id.* (quoting *Garcia v. Duro Dyne Corp.*, 156 Cal. App. 4th

92, 97 (2007)). Accordingly, "[i]t is 'not required' for a doctor to 'testify that he [is] reasonably certain that the plaintiff would be disabled in the future. All that is required to establish future disability is that from all the evidence, including the expert testimony, if there be any, it satisfactorily appears that such disability will occur with reasonable certainty.'" *Regalado v. Callaghan*, 3 Cal. App. 5th 582, 602 (2016) (alteration in original) (quoting *Paolini v. City & Cty. of San Francisco*, 72 Cal. App. 2d 579, 591 (1946)).

In *Cusack v. BendPak, Inc.*, for example, the plaintiff's expert opined that, "over the next ten years, [the plaintiff] may need a cortisone shot once or twice a year to deal with the pain from th[e underlying] accident." No. 4:17-CV-00003-DCN, 2018 WL 3939318, at *11 (D. Idaho Aug. 15, 2018). In its *Daubert* motion, the defendant contended that, "because [the plaintiff] ha[d] not needed a cortisone shot to date, there [wa]s no reason to suggest he w[ould] need any in the future." *Id.* The court rejected the defendant's argument as "pure speculation," noting that "[t]he real contention here [wa]s that [the defendant's experts] feel that it [wa]s *more likely than not* that these treatments w[ould] be *unnecessary*, whereas [the plaintiff's expert]'s opinion [wa]s that *more likely than not* these treatments w[ould] be *necessary*." *Id.* (emphasis in original). The court therefore declined to exclude the plaintiff's expert's opinion, noting that "[t]his [wa]s a classic battle of the experts [that had to] play out at trial before a jury where cross-examination and exploration c[ould] take place." *Id.*

So, too, here: Dr. Elliott opines that, "without a major reduction in [Plaintiff's dyspareunia] symptoms she is unlikely to ever regain the benefit of physical intimacy again in her life," which is "a major component to her quality of life" and which "many studies have shown . . . lead[s] to feelings of isolation, loneliness, depression and suicide." (ECF No. 43-1 at 62.) Further, "[t]here is no effective treatment for dyspareunia," and "it is not uncommon for up to 50% of patients to have permanent pain with sexual activity." (*Id.* at 35.) As in *Cusack*, Plaintiff's expert opines that she is more likely than not to suffer permanent condition (dyspareunia) that would negatively affect her quality of life (and mental health), while Defendants contend that Dr. Elliott's opinion is "speculative." (ECF

No. 50 ("*Daubert* Reply") at 1.) While "Dr. [Elliott]'s testimony may ultimately prove too speculative to carry the burden of establishing by a preponderance of the evidence that the injury is reasonably certain[,] . . . the opinion outlined in his expert report is" sufficient to proceed to the jury. *See Martinez*, 2019 WL 266213, at *11; *see also Primiano v. Cook*, 598 F.3d 558, 565 (9th Cir.), *as amended* (Apr. 27, 2010) (recognizing that expert testimony need not be conclusive because "medical knowledge is often uncertain" and that, "[w]here the foundation is sufficient, the litigant is 'entitled to have the jury decide upon [the experts'] credibility, rather than the judge,'" quoting *United States v. Sandoval-Mendoza*, 472 F.3d 645, 656 (9th Cir. 2006))); *Triant v. Am. Med. Sys. Inc.*, No. CV-12-00450-PHX-DGC, 2020 WL 4049844, at *9 (D. Ariz. July 20, 2020) (denying the defendant's *Daubert* motion as to expert's opinion that the plaintiff's "prognosis is poor and that she will need medical treatment 'for the rest of her life'" where the expert's "prognosis opinion [wa]s based on his examination of [the plaintiff], her medical records, his substantial experience treating similar patients and conditions, and medical literature cited in his report").

B. Informed Consent

Dr. Elliott also opines both that Plaintiff "was not able to make a fully informed medical decision regarding the implantation of GYNEMESH because Ethicon failed to fully disclose the risks, complications (both early and late) in the GYNEMESH Instruction for Use" and that Plaintiff's "implanting surgeon was not able to provide the necessary and required information to Ms. Parks for an informed consent because Ethicon failed to fully reveal such information and failed to fully evaluate said information prior to launch." (ECF No. 36-1 at 63.) Defendants request that the Court exclude these opinions as "unreliable and irrelevant." (*See Daubert* Mem. at 2.) First, Defendants argue, "there is no lack of informed consent claim in this case, and Dr. Elliott does not make reference to any informed consent standard in his report." (*Id.*) "In any event, there is no reliable basis for Dr. Elliott to speculate what Plaintiff's implanter, Dr. Shawn Menefee, or any other clinician[,] knew about the risks of Gynemesh PS." (*Id.* at 3.)

Plaintiff responds that, in the MDL, the Honorable Joseph R. Goodwin concluded that Dr. Elliott could offer testimony concerning the risks of implanting the mesh product, whether those risks were disclosed on the IFU, the adequacy of warnings, and the knowledge of the medical community in general. (*See Daubert* Opp'n at 4.) Because "Dr. Elliott is opining on the significant, adverse events and risks that were known by the greater medical community but not included in the Gynemesh IFUs," (*id.* at 7 (citing ECF No. 43-1 at 35–38)), Plaintiff contends that his testimony is admissible. (*See id.* at 7–8.)

The Court agrees with Plaintiff. "Dr. [Elliott] does not purport to opine on Dr. [Menefee]'s state of mind. Instead, []he opines that the [Gynemesh] product had a higher risk of failure[;] that the defendants failed to advise physicians of this risk[;] and[,] as a result, Dr. [Menefee] (like any other physician) lacked information to perform a comprehensive risk/benefit analysis of using this particular product as opposed to some other product or procedure." *See Heinrich v. Ethicon, Inc.*, No. 220CV00166APGVCF, 2020 WL 1916871, at *1 (D. Nev. Apr. 17, 2020). Accordingly, the Court **DENIES** Defendants' *Daubert* Motion.

MOTION FOR SUMMARY JUDGMENT

I. Legal Standard

Under Federal Rule of Civil Procedure 56, a party may move for summary judgment as to a claim or defense or part of a claim or defense. Fed. R. Civ. P. 56(a). Summary judgment is appropriate where "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). Although materiality is determined by substantive law, "[o]nly disputes over facts that might affect the outcome of the suit . . . will properly preclude the entry of summary judgment." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, (1986). A dispute is "genuine" only "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.* When considering the evidence presented by the parties, "[t]he evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor." *Id.* at 255.

The initial burden of establishing the absence of a genuine issue of material fact falls on the moving party. *Celotex*, 477 U.S. at 323. The moving party may meet this burden by "identifying those portions of 'the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any,' which it believes demonstrate the absence of a genuine issue of material fact." *Id.* "When the party moving for summary judgment would bear the burden of proof at trial, 'it must come forward with evidence which would entitle it to a directed verdict if the evidence went uncontroverted at trial.'" *C.A.R. Transp. Brokerage Co. v. Darden Rests., Inc.*, 213 F.3d 474, 480 (9th Cir. 2000) (quoting *Houghton v. South*, 965 F.2d 1532, 1536 (9th Cir. 1992)).

Once the moving party satisfies this initial burden, the nonmoving party must identify specific facts showing that there is a genuine dispute for trial. *Celotex*, 477 U.S. at 324. This requires "more than simply show[ing] that there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). Rather, to survive summary judgment, the nonmoving party must "go beyond the pleadings and by her own affidavits, or by the 'depositions, answers to interrogatories, and admissions on file,' designate 'specific facts'" that would allow a reasonable fact finder to return a verdict for the non-moving party. *Celotex*, 477 U.S. at 324; *see also Anderson*, 477 U.S. at 248. Accordingly, the non-moving party cannot oppose a properly supported summary judgment motion by "rest[ing] upon mere allegations or denials of his pleading." *Anderson*, 477 U.S. at 256.

II. Analysis

Plaintiff alleges fourteen causes of action for negligence (Count I), strict liability – manufacturing defect (Count II), strict liability – failure to warn (Count III), strict liability – defective product (Count IV), strict liability – design defect (Count V), common law fraud (Count VI), fraudulent concealment (Count VII), negligent misrepresentation (Count IX), breach of express warranty (Count XI), breach of implied warranty (Count XII), violation of consumer protection laws (Count XIII), loss of consortium (Count XVI), punitive damages (Count XVII), and discovery rule and tolling (Count XVIII). (*See*

generally ECF No. 1 at 4–5.) Defendants seek summary adjudication in their favor as to each of Plaintiff's claims. (*See generally* MSJ.)

Plaintiff concedes that dismissal is appropriate as to Counts II, IV, V, and XVI, (*see* MSJ Opp'n at 2 n.1, 11–12, 18); accordingly, the Court **GRANTS** Defendants' Motion for Summary Judgment as to Counts II, IV, V, and XVI. The Court analyzes Plaintiff's remaining claims below.

A. Warning and Fraud-Based Claims (Counts III, VI, and VII)

Defendants contend that summary adjudication of Plaintiff's failure to warn and other warnings or fraud-based claims is appropriate under the learned intermediary doctrine. (*See* MSJ Mem. at 6.) Under California's learned intermediary doctrine,[1] "the manufacturer's duty to warn in the case of medical devices runs only to the physician—not the patient." *Crissma v. Ethicon, Inc*, No. CV205426MWFPLAX, 2020 WL 5440357, at *4 (C.D. Cal. Aug. 31, 2020) (citing *Carlin v. Super. Ct.*, 13 Cal. 4th 1104, 1116 (1996); *Plenger v. Alza Corp.*, 11 Cal. App. 4th 349, 362 (1992); *Dilley v. C.R. Bard, Inc.*, No. CV 14-01795 ODW (ASx), 2014 WL 1338877, at *4 (C.D. Cal. Apr. 3, 2014)). "Where the doctrine applies, a plaintiff must prove 'not only that no warning was provided or that the warning was inadequate, but also that the inadequacy or absence of the warning caused the plaintiff's injury.'" *Id.* (quoting *Motus v. Pfizer Inc.*, 196 F. Supp. 2d 984, 991 (C.D. Cal. 2001), *aff'd*, 358 F.3d 659 (9th Cir. 2004)) (citing *Latiolais v. Merck & Co.*, 302 F. App'x 756, 757 (9th Cir. 2008)). "Where a physician did not read the manufacturer's product warnings, there is no causal connection on the failure to warn claim as a matter of law." *Id.* (citing *Motus*, 358 F.3d at 661).

Although Defendants contend that summary adjudication is warranted under the learned intermediary doctrine because Plaintiff's physician "knew the risk of Gynemesh PS" and "did not rely on the Instructions for Use of the Gynemesh PS in prescribing the

[1] The Parties agree that California substantive law applies. (*See* MSJ Mem. at 5; MSJ Opp'n at 3–4.)

device for Plaintiff," (MSJ Mem. at 6), the Court agrees with Plaintiff that there exist disputed issues of material fact precluding summary adjudication. (*See* MSJ Opp'n at 4–9.) Dr. Menefee did testify that, prior to Plaintiff's surgery in January 2010, he was aware of the risks associated with the use of surgical mesh devices to repair pelvic organ prolapse. (*See* ECF No. 34-4 at 97:9–103:7.) He also indicated that he "do[es] not rely on the IFUs to base [his] surgical decision making." (*Id.* at 140:4–7; *see also id.* at 148:23–149:1.) Dr. Menefee also testified, however, that "it's important to have a package insert" even though he does not "use that as [his] primary basis for [his surgical] decisions," (*id.* at 140:14–16), and that he "believe[d]" he had read the Gynemesh IFU before Plaintiff's surgery (although he "c[ould]not tell [counsel] that" definitively). (*Id.* at 141:18–23.) Dr. Menefee further testified that he "felt in 2010 . . . based on the evidence that was available, [the Gynemesh procedure] was an appropriate treatment option for [Plaintiff]." (ECF No. 44-1 at 145:3–18.) According to Plaintiff's expert, however, the Gynemesh IFU failed adequately to warn of the risks of mesh contraction, (*see* ECF No. 43-1 at 26); inflammatory response, (*see id.* at 29–30); polypropylene degradation, (*see id.* at 32–33); and dyspareunia. (*See id.* at 34–35; *see also id.* at 36–38 (listing additional perceived deficiencies in the Gynemesh PS IFU).) Dr. Menefee testified that some of these considerations—such as the claimed permanence of polypropylene mesh—were relevant to his surgical decision-making. (*See* ECF No. 44-1 at 147:9–15.)

On this record, the Court concludes that "there is a genuine dispute as to whether Dr. [Menefee] read [and relied upon] the IFU" and as to "whether [Defendants adequately] warned Dr. [Menefee] of the . . . risk to patients from" use of Gynemesh PS. *See Crissma v. Ethicon, Inc*, 2020 WL 5440357, at *5 (citing *Conte v. Wyeth, Inc.*, 168 Cal. App. 4th 89, 99 (2008)); *see also Sanchez v. Bos. Sci. Corp.*, 38 F. Supp. 3d 727, 735–36 (S.D.W. Va. 2014) (denying motion for summary judgment on failure to warn claims where there were disputes of fact as to whether the physician had read and relied on the directions for use of transvaginal surgical mesh product) (applying California law). Accordingly, the

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Court **DENIES** Defendants' Motion for Summary Judgment as to Plaintiff's warning and fraud-based claims.

B. Negligence-Based Claims (Counts I and IX)

Defendants urge the Court to dismiss Plaintiff's negligence-based claims for failure to establish that a defect in the Gynemesh PS caused her injuries. (*See* MSJ Mem. at 10–12.) Plaintiff responds that causation is a disputed question of material fact. (*See* MSJ Opp'n at 12.) For the reasons discussed above, *see supra* Section II.A, the Court **DENIES** Defendants' Motion for Summary Judgment as Plaintiff's negligence-based claims.

C. Consumer Protection Claim (Count XIII)

Defendants argue that Plaintiff's consumer protection claim is defective whether asserted under the Consumer Legal Remedies Act ("CLRA") or California's Unfair Competition Law ("UCL"), mandating dismissal. (*See* MSJ Mem. at 12–13.)

1. CLRA

Defendants contend that Plaintiff's consumer protection claim, to the extent it is alleged under the CLRA, is barred by Plaintiff's failure to comply with the CLRA's requirement that a plaintiff give notice to the defendant "[t]hirty days or more prior to the commencement of an action for damages pursuant to th[e CLRA]." *See* Cal. Civ. Code § 1782(a); *see also* MSJ Mem. at 12 (citing Cal. Civ. Code § 1782(a)). Plaintiff responds that she "need not comply with the notice requirement to assert a claim for relief other than damages," (MSJ Opp'n at 13), because "[a]n action for injunctive relief brought under the [CLRA] may be commenced without compliance with" the notice requirement. Cal. Civ. Code § 1782(d). Further, the CLRA allows a plaintiff to provide notice after filing, in which case "the consumer may amend his or her complaint without leave of court to include a request for damages." *Id.*; *see also* MSJ Opp'n at 13. Defendants rejoin that "Plaintiff has *not* amended her complaint." (ECF No. 47 ("MSJ Reply") at 5 (emphasis in original).)

Here, in addition to damages, Plaintiff seeks "[r]estitution and disgorgement of profits." (ECF No. 56-1 at Prayer ¶ 2.) Because Plaintiff was not required to provide notice to seek these equitable remedies pursuant to Section 1782(d), the Court **DENIES**

IN PART Defendants' Motion for Summary Judgment as to Plaintiff's CLRA claim to the extent it seeks relief other than damages. *See, e.g.*, *Estakhrian v. Obenstine*, 233 F. Supp. 3d 824, 846 (C.D. Cal. 2017) (denying motion for summary adjudication as to CLRA claim for failure to provide notice where the "plaintiffs do not seek damages under the CLRA" because "they are authorized to seek injunctive relief, restitution, and [a]ny other relief that the court deems proper" (internal quotation marks omitted) (quoting *Gonzales v. CarMax Auto Superstores, LLC*, 845 F.3d 916, 918 (9th Cir. 2017))).

To the extent Plaintiff seeks damages under the CLRA, however, the Court agrees with Defendants. Although Plaintiff urges the Court to "liberally construe[]" her "numerous settlement demand letters" as satisfying the notice requirement of Section 1782, (*see* MSJ Opp'n at 13–14), such elements "of the post-complaint litigation process[] do not satisfy the requirements of § 1782." *See Von Grabe v. Sprint PCS*, 312 F. Supp. 2d 1285, 1304 (S.D. Cal. 2003). Further, Defendants are correct that Plaintiff has failed to amend her Complaint to allege compliance with Section 1782(d), (*see* MSJ Reply at 5), and the time to amend Plaintiff's Complaint has long expired. (*See* ECF Nos. 15, 22; *see also* Fed. R. Civ. P. 16(b)(4) (requiring "good cause" to amend the scheduling order).) Indeed, this case was transferred to this Court in May 2020 to be "***immediately set . . . for trial***." (ECF No. 55 at 1 (emphasis in original).) Further amendment is not warranted at this late stage, particularly where Plaintiff has been on notice since at least December 2019 that amendment was required to seek damages under the CLRA. *See, e.g.*, *Beck v. FCA US LLC*, 273 F. Supp. 3d 735, 748 (E.D. Mich. 2017) (dismissing CLRA claim for damages where the plaintiff failed to amend his complaint after providing notice to the defendant) (applying California law). Accordingly, the Court **GRANTS IN PART** Defendants' Motion for Summary Judgment as Plaintiff's consumer protection claim to the extent it seeks damages under the CLRA.

2. UCL

To the extent Plaintiff's consumer protection claim is alleged under the UCL, Defendants raise two challenges. First, Defendants claim that Plaintiff lacks standing

because she has failed to demonstrate that she "has suffered injury in fact and has lost money or property as a result of the unfair competition." Cal. Bus. & Prof. Code § 17204; *see also* MSJ Mem. at 12. Second, Defendants fault Plaintiff for seeking monetary damages because the UCL provides for only equitable remedies. (*See* MSJ Mem. at 12–13.) Plaintiff contends that she "has standing by virtue of [her] economic losses." (MSJ Opp'n at 15.) And while "Plaintiff agrees she cannot obtain damages under the UCL" she argues that "she can obtain injunctive relief, restitution and restitutionary disgorgement of profits." (*Id.* at 14.)

First, the Court concludes that Plaintiff has established statutory standing under the UCL. "There are innumerable ways a plaintiff may demonstrate economic injury, including . . . 'be[ing] required to enter into a transaction, costing money or property, that would otherwise have been unnecessary.'" *Obesity Research Inst., LLC v. Fiber Research Int'l, LLC*, 165 F. Supp. 3d 937, 947–48 (S.D. Cal. 2016) (quoting *Kwikset Corp. v. Super. Ct.*, 51 Cal. 4th 310, 323 (2011)). Here, Plaintiff underwent three surgeries to remove Defendants' mesh product. *See* ECF No. 34-1 at 7. According to Plaintiff, these procedures—and their attendant costs—would not have been necessary had Defendants not deceptively advertised their mesh product. (*See* ECF No. 56-1 ¶¶ 197–215.) The Court therefore concludes that Plaintiff has statutory standing under the UCL and **DENIES IN PART** Defendants' Motion for Summary Judgment as to that issue. *See, e.g.*, *Sarun v. Dignity Health*, 232 Cal. App. 4th 1159, 1169 (2014), *as modified* (Jan. 13, 2015) (concluding that liability for medical bills incurred as a result of deceptive business practices suffice to establish standing).

Second, because Plaintiff concedes that she cannot pursue damages under the UCL, the Court **GRANTS IN PART** Defendants' Motion for Summary Judgment to the extent Plaintiff seeks damages. *See Cel-Tech Commc'ns, Inc. v. L.A. Cellular Tel. Co.*, 20 Cal. 4th 163, 179 (1999) (holding that "[p]revailing plaintiffs are generally limited to injunctive relief and restitution" and "may not receive damages" (citing Cal. Bus. & Prof. Code § 17203; *ABC Int'l Traders, Inc. v. Matsushita Elec. Corp.*, 14 Cal. 4th 1247, 1268 (1997);

Bank of the W. v. Super. Ct., 2 Cal. 4th 1254, 1266 (1992); *Consumers Union of U.S., Inc. v. Fisher Dev., Inc.*, 208 Cal. App. 3d 1433, 1443 (1989))). Nonetheless, "[r]estitutionary disgorgement, which focuses on the victim's loss, may be recovered under the UCL." *Estakhrian v. Obenstine*, 233 F. Supp. 3d 824, 844 (C.D. Cal. 2017) (quoting *SkinMedica, Inc. v. Histogen Inc.*, 869 F.Supp.2d 1176, 1184 (S.D. Cal. 2012)). The Court therefore **DENIES IN PART** Defendants' Motion for Summary Judgment to the extent Plaintiff seeks remedies other than damages under the UCL.

D. Warranty Claims (Counts XI and XII)

Next, Defendants urge dismissal of Plaintiff's warranty claims for several reasons. (*See* MSJ Mem. at 14–15.) Because the Court concludes that Plaintiff's warranty claims are time-barred, the Court need not reach Defendants' other arguments.

Under California's Commercial Code, "[a]n action for breach of any contract for sale must be commenced within four years after the cause of action has accrued," Cal. Com. Code § 2725(1), which is "when the breach occurs, regardless of the aggrieved party's lack of knowledge of the breach." Cal. Com. Code § 2725(2). "A breach of warranty occurs when tender of delivery is made, except that where a warranty explicitly extends to future performance of the goods and discovery of the breach must await the time of such performance the cause of action accrues when the breach is or should have been discovered." *Id.*

Defendants argue that Plaintiff's warranty claims are time-barred under these provisions because "tender of delivery" of the Gynemesh PS was made on the date of Plaintiff's surgery, January 8, 2010, which was more than four years before Plaintiff filed suit on February 13, 2014. (MSJ Mem. at 14 (citing Cal. Com. Code §§ 2725(1)–(2)).) Plaintiff responds that her warranty claims are not time-barred because her claims accrued "when [s]he discover[ed] or should have discovered the breach[,]" which was in 2013. (MSJ Opp'n at 15–16 (quoting Cal. Com. Code § 2725(4)) (citing *Yi v. BMW of N. Am.*, No. 2:17-cv-06467-SVW, 2018 WL 3359016, at *17–18 (C.D. Cal. May 24, 2018); *Mills v. Forestex Co.*, 108 Cal. App. 4th 625, 642 (2003)).) Defendants counter that because the

warranty here "does not explicitly extend to future performance of the product . . . , there is no discovery rule applicable." (MSJ Reply at 7 (citing *Lucas v. Breg, Inc.*, 212 F. Supp. 3d 950 (S.D. Cal. 2016).)

Because Plaintiff has failed to introduce evidence that the warranty "explicitly extends to future performance," her warranty claims accrued "when tender of delivery [wa]s made," *i.e.*, January 8, 2010. *See* Cal. Com. Code § 2725(2). Plaintiff's warranty claims, filed February 13, 2014, are therefore untimely. Accordingly, the Court **GRANTS** Defendants' Motion for Summary Judgment as to Plaintiff's warranty claims.

E. Remaining Claims (Counts XVII and XVIII)

Finally, Defendants contend in a footnote that Plaintiff's claims for "discovery rule and tolling" (Count XVIII) and punitive damages (XVII) should be dismissed because they are not independent causes of action. (*See* MSJ Mem. at 1 n.1.) Although there is some merit to Defendants' argument, *see, e.g.*, *Ismail v. Cty. of Orange*, 917 F. Supp. 2d 1060, 1073 (C.D. Cal. 2012) (recognizing that a request for punitive damages is not an independent cause of action), *aff'd*, 676 F. App'x 690 (9th Cir. 2017); *Soderstrom v. Nicholas*, No. C 08-05310 JW, 2009 WL 10697266, at *8 (N.D. Cal. May 20, 2009) (declining to treat claim for fraudulent concealment as a separate cause of action where it was pled as a means of tolling the statute of limitations), a footnote does not "adequately raise [an] issue for summary judgment." *See Troester v. Starbucks Corp.*, No. CV1207677CJCPJWX, 2019 WL 2902487, at *1 (C.D. Cal. May 21, 2019). The Court therefore **DECLINES** to dismiss Counts XVII and XVIII.

CONCLUSION

In light of the foregoing, the Court **DENIES** Defendants' *Daubert* Motion (ECF No. 36) and **GRANTS IN PART AND DENIES IN PART** Defendants' Motion for Summary Judgment (ECF No. 34). Specifically, the Court **GRANTS** Defendants' Motion for Summary Judgment as to Counts II, IV, V, XI, XII, and XVI in their entirety and as to Count XIII to the extent Plaintiff seeks damages, and **DENIES** Defendants' Motion as to

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Counts I, III, VI, VII, IX, XVII, and XVIII in their entirety and as to Count XIII to the extent Plaintiff seeks remedies other than damages.

IT IS SO ORDERED.

Dated: October 16, 2020

Honorable Todd W. Robinson
United States District Court