

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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## 1 BACKGROUND

2 The Parties agree to the following undisputed facts:

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

8 In January 2010, Dr. Menefee was familiar with the risk of complications from  
9 pelvic mesh products generally, including exposure or erosion, infection, acute and/or  
10 chronic pain, urinary problems, recurrence or failure, bowel/bladder/blood vessel  
11 perforation during insertion, bleeding, wound complications, inflammation, fistula  
12 formation, vaginal scarring, organ or nerve damage, neuromuscular problems, need for  
13 additional surgeries, foreign body response, contraction or shrinkage of tissue, dyspareunia  
14 (pain with intercourse), and a decrease in patient quality of life. (*Id.* at 3 (citing ECF No.  
15 34-4 at 97:9–99:4, 101:12–103:7).) However, Dr. Menefee was not aware of all the risks  
16 associated with the transvaginal use of Gynemesh PS at the time of Plaintiff’s surgery.  
17 (MSJ Opp’n at 2 (citing ECF No. 44-1 at 56:8–59:22, 60:1–21, 61:22–62:22).)

18 Through the years, Dr. Menefee has read most Instructions for Use (“IFUs”)  
19 accompanying mesh products because they come as a package insert; nonetheless, it is not  
20 his practice to read them before every surgery. (MSJ Mem. at 3 (citing ECF No. 34-4 at  
21 141:13–17).) He also could not recall whether he had read the Gynemesh PS IFUs before  
22 Plaintiff’s surgery in January 2010, (*id.* at 4), although he believed that he had. (MSJ  
23 Opp’n at 2 (citing ECF No. 44-1 at 141:18–23).)

24 Dr. Menefee testified that he does not rely on IFUs, including the Gynemesh PS  
25 IFUs, in making his surgical decisions, (MSJ Mem. at 3 (citing ECF No. 34-4 at  
26 140:4–7)), and that he did not rely on the Gynemesh PS IFUs in performing Plaintiff’s  
27 surgery. (*Id.* at 4 (citing ECF No. 34-4 at 148:20–149:1).) Instead, Dr. Menefee believes  
28 that surgical decision-making should be based on the best clinical evidence available, a

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

5 Based on that information and in his medical judgment, Dr. Menefee determined that  
6 the benefits of using a sling to treat Plaintiff's stress urinary incontinence outweighed the  
7 risk at that time. (*Id.* at 2 (citing ECF No. 34-4 at 71:25–72:9).) Dr. Menefee also believed  
8 that his decision to use Gynemesh PS for Plaintiff was an appropriate alternative for the  
9 surgical management of her prolapse in 2010. (*Id.* at 3 (citing ECF No. 34-4 at  
10 139:23–140:3).)

11 Dr. Menefee does not recall giving Plaintiff an industry brochure, (*id.* at 4 (citing  
12 ECF No. 34-4 at 148:20–149:1)), and Plaintiff does not recall receiving any documents  
13 from Dr. Menefee. (*Id.* at 2 (citing ECF No. 34-3 at 15:11–19, 21:17–20).) Plaintiff  
14 testified that Dr. Menefee did not advise her to look at the U.S. Food and Drug  
15 Administration's consumer website. (*Id.* at 2 (citing ECF No. 34-3 at 15:11–19,  
16 21:17–20).) Plaintiff's decision to proceed with the surgery was based solely on  
17 Dr. Menefee's recommendation, (*id.* (citing ECF No. 34-3 at 25:12–15)), and she did not  
18 perform any independent research either before or after the surgery. (*Id.* (citing ECF No.  
19 34-3 at 25:12–15).)

20 Plaintiff filed her lawsuit directly in the *In re Ethicon, Inc. Pelvic Repair System*  
21 *Products Liability Litigation*, MDL No. 2327 (S.D. W.Va.), on February 13, 2014. (MSJ  
22 Mem. at 4 (citing ECF No. 1).) She has designated one case-specific expert, Dr. Daniel S.  
23 Elliott. (*Id.* (citing ECF No. 34-5).) Dr. Elliott opines that the Gynemesh product caused  
24 Plaintiff's alleged vaginal scarring and narrowing, resulting in a "severe compromise in  
25 Ms. Parks' quality of life." (*Id.* (quoting ECF No. 34-6 at 62).) He further opines that she  
26 has pelvic pain, pelvic floor myalgia, and dyspareunia and that it is highly unlikely that  
27 these conditions will resolve completely. (*Id.* (citing ECF No. 34-6 at 62).) Dr. Elliott also  
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1 believes that this “long-term negative impact” could lead to “feelings of isolation,  
 2 loneliness, depression and suicide.” (*Id.* (quoting ECF No. 34-6 at 62).)

3 **DAUBERT MOTION**

4 **I. Legal Standard**

5 Federal Rule of Evidence 702 provides:

6 A witness who is qualified as an expert by knowledge, skill,  
 7 experience, training, or education may testify in the form of an  
 8 opinion or otherwise if: (a) the expert’s scientific, technical, or  
 9 other specialized knowledge will help the trier of fact to  
 10 understand the evidence or to determine a fact in issue; (b) the  
 11 testimony is based on sufficient facts or data; (c) the testimony is  
 12 the product of reliable principles and methods; and (d) the expert  
 13 has reliably applied the principles and methods to the facts of the  
 14 case.

15 Rule 702 “contemplates a broad conception of expert qualifications.” *Hangarter v.*  
 16 *Provident Life & Accident Ins. Co.*, 373 F.3d 998, 1015 (9th Cir. 2004) (quoting *Thomas*  
 17 *v. Newton Int’l Enters.*, 42 F.3d 1266, 1269 (9th Cir. 1994)). “Shaky but admissible  
 18 evidence is to be attacked by cross examination, contrary evidence, and attention to the  
 19 burden of proof, not exclusion.” *Primiano v. Cook*, 598 F.3d 558, 564 (9th Cir. 2010).

20 Additionally, under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579  
 21 (1993), “the district court judge must ensure that all admitted expert testimony is both  
 22 relevant and reliable.” *Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227, 1232 (9th Cir.  
 23 2017); *see also Grodzitsky v. Am. Honda Motor Co.*, 957 F.3d 979, 984–85 (9th Cir. 2020).  
 24 “The focus of the district court’s analysis ‘must be solely on principles and methodology,  
 25 not on the conclusions that they generate,’” and “the court’s ‘task . . . is to analyze not what  
 26 the experts say, but what basis they have for saying it.’” *Wendell*, 858 F.3d at 1232  
 27 (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  
 28 experts are testifying ‘about matters growing naturally’ out of their own independent

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

3 “These factors are illustrative, and they are not all applicable in each case.” *Id.*  
 4 “The inquiry is flexible, . . . and Rule 702 should be applied with a liberal thrust favoring  
 5 admission.” *Id.* (citation and quotation marks omitted). “*Daubert*’s list of specific factors  
 6 neither necessarily nor exclusively applies to all experts or in every case. Rather the law  
 7 grants a district court the same broad latitude when it decides how to determine reliability  
 8 as [the court] enjoys in respect to its ultimate reliability determination.” *Kumho Tire Co.*  
 9 *v. Carmichael*, 526 U.S. 137 (1999); *see also Abarca v. Franklin Cnty. Water Dist.*, 761 F.  
 10 Supp. 2d 1007, 1021 (E.D. Cal. 2011) (citations omitted).

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

## 14 **II. Analysis**

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

### 18 **A. Plaintiff’s Future Mental Health**

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

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1           1.     *Dr. Elliott's Qualifications*

2           Defendants argue that Dr. Elliott is not qualified to offer an opinion on Plaintiff's  
 3 mental health because he "is a urologist and pelvic surgeon, not a psychiatrist" and he "does  
 4 not treat patients for mental health conditions." (*Daubert* Mem. at 2.) Plaintiff counters  
 5 that "[q]uality of life assessments are central to the treatment of pelvic organ prolapse,  
 6 including mesh surgery, and Dr. Elliott . . . is well-qualified to offer testimony on  
 7 Ms. Parks['] quality of life." (ECF No. 43 ("*Daubert* Opp'n") at 2 (citing Fed. R. Evid.  
 8 702).)

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

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

11           2. *Future Prognosis*

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

18       The Court concludes that Dr. Elliott's testimony concerning Plaintiff's future  
 19 prognosis is admissible. Under California law, "[d]amages may be awarded . . . for  
 20 detriment . . . certain to result in the future." *Garcia v. Duro Dyne Corp.*, 156 Cal. App.  
 21 4th 92, 97 (2007) (alterations in original) (quoting Cal. Civ. Code § 3283). California  
 22 courts have interpreted this to mean that "[a]n injured plaintiff is entitled to recover the  
 23 reasonable value of medical services that are reasonably certain to be necessary in the  
 24 future." *Martinez v. United States*, No. 116CV01556LJOSKO, 2019 WL 266213, at \*9  
 25 (E.D. Cal. Jan. 18, 2019) (quoting *Corenbaum v. Lampkin*, 215 Cal. App. 4th 1308, 1330,  
 26 *as modified* (May 13, 2013)). The courts caution, however, that "[i]t is for the [finder of  
 27 fact] to determine the probabilities as to whether future detriment is reasonably certain to  
 28 occur in any particular case." *Id.* (quoting *Garcia v. Duro Dyne Corp.*, 156 Cal. App. 4th

1 92, 97 (2007)). Accordingly, “[i]t is ‘not required’ for a doctor to ‘testify that he [is]  
 2 reasonably certain that the plaintiff would be disabled in the future. All that is required to  
 3 establish future disability is that from all the evidence, including the expert testimony, if  
 4 there be any, it satisfactorily appears that such disability will occur with reasonable  
 5 certainty.’” *Regalado v. Callaghan*, 3 Cal. App. 5th 582, 602 (2016) (alteration in original)  
 6 (quoting *Paolini v. City & Cty. of San Francisco*, 72 Cal. App. 2d 579, 591 (1946)).

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

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

1 No. 50 (“*Daubert* Reply”) at 1.) While ‘Dr. [Elliott]’s testimony may ultimately prove too  
 2 speculative to carry the burden of establishing by a preponderance of the evidence that the  
 3 injury is reasonably certain[,] . . . the opinion outlined in his expert report is” sufficient to  
 4 proceed to the jury. *See Martinez*, 2019 WL 266213, at \*11; *see also Primiano v. Cook*,  
 5 598 F.3d 558, 565 (9th Cir.), *as amended* (Apr. 27, 2010) (recognizing that expert  
 6 testimony need not be conclusive because “medical knowledge is often uncertain” and that,  
 7 “[w]here the foundation is sufficient, the litigant is ‘entitled to have the jury decide upon  
 8 [the experts’] credibility, rather than the judge,’” quoting *United States v. Sandoval-*  
 9 *Mendoza*, 472 F.3d 645, 656 (9th Cir. 2006)); *Triant v. Am. Med. Sys. Inc.*, No. CV-12-  
 10 00450-PHX-DGC, 2020 WL 4049844, at \*9 (D. Ariz. July 20, 2020) (denying the  
 11 defendant’s *Daubert* motion as to expert’s opinion that the plaintiff’s “prognosis is poor  
 12 and that she will need medical treatment ‘for the rest of her life’” where the expert’s  
 13 “prognosis opinion [wa]s based on his examination of [the plaintiff], her medical records,  
 14 his substantial experience treating similar patients and conditions, and medical literature  
 15 cited in his report”).

16        ***B. Informed Consent***

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

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

8 The Court agrees with Plaintiff. “Dr. [Elliott] does not purport to opine on  
9 Dr. [Menefee]’s state of mind. Instead, []he opines that the [Gynemesh] product had a  
10 higher risk of failure[;] that the defendants failed to advise physicians of this risk[;] and[,]  
11 as a result, Dr. [Menefee] (like any other physician) lacked information to perform a  
12 comprehensive risk/benefit analysis of using this particular product as opposed to some  
13 other product or procedure.” *See Heinrich v. Ethicon, Inc.*, No. 220CV00166APGVCF,  
14 2020 WL 1916871, at \*1 (D. Nev. Apr. 17, 2020). Accordingly, the Court **DENIES**  
15 Defendants’ *Daubert* Motion.

## 16 MOTION FOR SUMMARY JUDGMENT

### 17 I. Legal Standard

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

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

10       Once the moving party satisfies this initial burden, the nonmoving party must  
11 identify specific facts showing that there is a genuine dispute for trial. *Celotex*, 477 U.S.  
12 at 324. This requires “more than simply show[ing] that there is some metaphysical doubt  
13 as to the material facts.” *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574,  
14 586 (1986). Rather, to survive summary judgment, the nonmoving party must “go beyond  
15 the pleadings and by her own affidavits, or by the ‘depositions, answers to interrogatories,  
16 and admissions on file,’ designate ‘specific facts’” that would allow a reasonable fact finder  
17 to return a verdict for the non-moving party. *Celotex*, 477 U.S. at 324; *see also Anderson*,  
18 477 U.S. at 248. Accordingly, the non-moving party cannot oppose a properly supported  
19 summary judgment motion by “rest[ing] upon mere allegations or denials of his pleading.”  
20 *Anderson*, 477 U.S. at 256.

21 **II. Analysis**

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

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

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

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

8 Defendants contend that summary adjudication of Plaintiff’s failure to warn and  
9 other warnings or fraud-based claims is appropriate under the learned intermediary  
10 doctrine. (See MSJ Mem. at 6.) Under California’s learned intermediary doctrine,<sup>1</sup> “the  
11 manufacturer’s duty to warn in the case of medical devices runs only to the physician—  
12 not the patient.” *Crissma v. Ethicon, Inc*, No. CV205426MWPLAX, 2020 WL 5440357,  
13 at \*4 (C.D. Cal. Aug. 31, 2020) (citing *Carlin v. Super. Ct.*, 13 Cal. 4th 1104, 1116 (1996);  
14 *Plenger v. Alza Corp.*, 11 Cal. App. 4th 349, 362 (1992); *Dilley v. C.R. Bard, Inc.*, No. CV  
15 14-01795 ODW (ASx), 2014 WL 1338877, at \*4 (C.D. Cal. Apr. 3, 2014)). “Where the  
16 doctrine applies, a plaintiff must prove ‘not only that no warning was provided or that the  
17 warning was inadequate, but also that the inadequacy or absence of the warning caused the  
18 plaintiff’s injury.’” *Id.* (quoting *Motus v. Pfizer Inc.*, 196 F. Supp. 2d 984, 991 (C.D. Cal.  
19 2001), *aff’d*, 358 F.3d 659 (9th Cir. 2004)) (citing *Latiolais v. Merck & Co.*, 302 F. App’x  
20 756, 757 (9th Cir. 2008)). “Where a physician did not read the manufacturer’s product  
21 warnings, there is no causal connection on the failure to warn claim as a matter of law.”  
22 *Id.* (citing *Motus*, 358 F.3d at 661).

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

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28 <sup>1</sup> The Parties agree that California substantive law applies. (See MSJ Mem. at 5; MSJ Opp’n at 3–4.)

1 device for Plaintiff,” (MSJ Mem. at 6), the Court agrees with Plaintiff that there exist  
2 disputed issues of material fact precluding summary adjudication. (See MSJ Opp’n at  
3 4–9.) Dr. Menefee did testify that, prior to Plaintiff’s surgery in January 2010, he was  
4 aware of the risks associated with the use of surgical mesh devices to repair pelvic organ  
5 prolapse. (See ECF No. 34-4 at 97:9–103:7.) He also indicated that he “do[es] not rely on  
6 the IFUs to base [his] surgical decision making.” (*Id.* at 140:4–7; *see also id.* at  
7 148:23–149:1.) Dr. Menefee also testified, however, that “it’s important to have a package  
8 insert” even though he does not “use that as [his] primary basis for [his surgical] decisions,”  
9 (*id.* at 140:14–16), and that he “believe[d]” he had read the Gynemesh IFU before  
10 Plaintiff’s surgery (although he “c[ould ]not tell [counsel] that” definitively). (*Id.* at  
11 141:18–23.) Dr. Menefee further testified that he “felt in 2010 . . . based on the evidence  
12 that was available, [the Gynemesh procedure] was an appropriate treatment option for  
13 [Plaintiff].” (ECF No. 44-1 at 145:3–18.) According to Plaintiff’s expert, however, the  
14 Gynemesh IFU failed adequately to warn of the risks of mesh contraction, (*see ECF No.*  
15 43-1 at 26); inflammatory response, (*see id.* at 29–30); polypropylene degradation, (*see id.*  
16 at 32–33); and dyspareunia. (See *id.* at 34–35; *see also id.* at 36–38 (listing additional  
17 perceived deficiencies in the Gynemesh PS IFU).) Dr. Menefee testified that some of these  
18 considerations—such as the claimed permanence of polypropylene mesh—were relevant  
19 to his surgical decision-making. (See ECF No. 44-1 at 147:9–15.)

20 On this record, the Court concludes that “there is a genuine dispute as to whether  
21 Dr. [Menefee] read [and relied upon] the IFU” and as to “whether [Defendants adequately]  
22 warned Dr. [Menefee] of the . . . risk to patients from” use of Gynemesh PS. *See Crissma*  
23 *v. Ethicon, Inc.*, 2020 WL 5440357, at \*5 (citing *Conte v. Wyeth, Inc.*, 168 Cal. App. 4th  
24 89, 99 (2008)); *see also Sanchez v. Bos. Sci. Corp.*, 38 F. Supp. 3d 727, 735–36 (S.D.W.  
25 Va. 2014) (denying motion for summary judgment on failure to warn claims where there  
26 were disputes of fact as to whether the physician had read and relied on the directions for  
27 use of transvaginal surgical mesh product) (applying California law). Accordingly, the  
28 ///

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

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

4       Defendants urge the Court to dismiss Plaintiff's negligence-based claims for failure  
5 to establish that a defect in the Gynemesh PS caused her injuries. (See MSJ Mem. at  
6 10–12.) Plaintiff responds that causation is a disputed question of material fact. (See MSJ  
7 Opp'n at 12.) For the reasons discussed above, *see supra* Section II.A, the Court **DENIES**  
8 Defendants' Motion for Summary Judgment as Plaintiff's negligence-based claims.

9       ***C. Consumer Protection Claim (Count XIII)***

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

13       ***1. CLRA***

14      Defendants contend that Plaintiff's consumer protection claim, to the extent it is  
15 alleged under the CLRA, is barred by Plaintiff's failure to comply with the CLRA's  
16 requirement that a plaintiff give notice to the defendant "[t]hirty days or more prior to the  
17 commencement of an action for damages pursuant to th[e CLRA]." *See* Cal. Civ. Code  
18 § 1782(a); *see also* MSJ Mem. at 12 (citing Cal. Civ. Code § 1782(a)). Plaintiff responds  
19 that she "need not comply with the notice requirement to assert a claim for relief other than  
20 damages," (MSJ Opp'n at 13), because "[a]n action for injunctive relief brought under the  
21 [CLRA] may be commenced without compliance with" the notice requirement. Cal. Civ.  
22 Code § 1782(d). Further, the CLRA allows a plaintiff to provide notice after filing, in  
23 which case "the consumer may amend his or her complaint without leave of court to include  
24 a request for damages." *Id.*; *see also* MSJ Opp'n at 13. Defendants rejoin that "Plaintiff  
25 has *not* amended her complaint." (ECF No. 47 ("MSJ Reply") at 5 (emphasis in original).)

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

1 **IN PART** Defendants' Motion for Summary Judgment as to Plaintiff's CLRA claim to the  
2 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  
4 for failure to provide notice where the "plaintiffs do not seek damages under the CLRA"  
5 because "they are authorized to seek injunctive relief, restitution, and [a]ny other relief that  
6 the court deems proper" (internal quotation marks omitted) (quoting *Gonzales v. CarMax  
Auto Superstores, LLC*, 845 F.3d 916, 918 (9th Cir. 2017))).

8 To the extent Plaintiff seeks damages under the CLRA, however, the Court agrees  
9 with Defendants. Although Plaintiff urges the Court to "liberally construe[]" her  
10 "numerous settlement demand letters" as satisfying the notice requirement of Section 1782,  
11 (*see* MSJ Opp'n at 13–14), such elements "of the post-complaint litigation process[] do not  
12 satisfy the requirements of § 1782." *See Von Grabe v. Sprint PCS*, 312 F. Supp. 2d 1285,  
13 1304 (S.D. Cal. 2003). Further, Defendants are correct that Plaintiff has failed to amend  
14 her Complaint to allege compliance with Section 1782(d), (*see* MSJ Reply at 5), and the  
15 time to amend Plaintiff's Complaint has long expired. (*See* ECF Nos. 15, 22; *see also* Fed.  
16 R. Civ. P. 16(b)(4) (requiring "good cause" to amend the scheduling order).) Indeed, this  
17 case was transferred to this Court in May 2020 to be "**immediately set . . . for trial.**" (ECF  
18 No. 55 at 1 (emphasis in original).) Further amendment is not warranted at this late stage,  
19 particularly where Plaintiff has been on notice since at least December 2019 that  
20 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  
21 where the plaintiff failed to amend his complaint after providing notice to the defendant)  
22 (applying California law). Accordingly, the Court **GRANTS IN PART** Defendants'  
23 Motion for Summary Judgment as Plaintiff's consumer protection claim to the extent it  
24 seeks damages under the CLRA.

26       2.       ***UCL***

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

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

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

23 Second, because Plaintiff concedes that she cannot pursue damages under the UCL,  
24 the Court **GRANTS IN PART** Defendants’ Motion for Summary Judgment to the extent  
25 Plaintiff seeks damages. *See Cel-Tech Commc’ns, Inc. v. L.A. Cellular Tel. Co.*, 20 Cal.  
26 4th 163, 179 (1999) (holding that “[p]revailing plaintiffs are generally limited to injunctive  
27 relief and restitution” and “may not receive damages” (citing Cal. Bus. & Prof. Code  
28 § 17203; *ABC Int’l Traders, Inc. v. Matsushita Elec. Corp.*, 14 Cal. 4th 1247, 1268 (1997);

1 *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.”

2 *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

3 **DENIES IN PART** Defendants’ Motion for Summary Judgment to the extent Plaintiff

4 seeks remedies other than damages under the UCL.

5 **D. Warranty Claims (Counts XI and XII)**

6 Next, Defendants urge dismissal of Plaintiff’s warranty claims for several reasons.

7 (*See* MSJ Mem. at 14–15.) Because the Court concludes that Plaintiff’s warranty claims

8 are time-barred, the Court need not reach Defendants’ other arguments.

9 Under California’s Commercial Code, “[a]n action for breach of any contract for

10 sale must be commenced within four years after the cause of action has accrued,” Cal.

11 Com. Code § 2725(1), which is “when the breach occurs, regardless of the aggrieved

12 party’s lack of knowledge of the breach.” Cal. Com. Code § 2725(2). “A breach of

13 warranty occurs when tender of delivery is made, except that where a warranty explicitly

14 extends to future performance of the goods and discovery of the breach must await the time

15 of such performance the cause of action accrues when the breach is or should have been

16 discovered.” *Id.*

17 Defendants argue that Plaintiff’s warranty claims are time-barred under these

18 provisions because “tender of delivery” of the Gynemesh PS was made on the date of

19 Plaintiff’s surgery, January 8, 2010, which was more than four years before Plaintiff filed

20 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

21 “when [s]he discover[ed] or should have discovered the breach[,]” which was in 2013.

22 (MSJ Opp’n at 15–16 (quoting Cal. Com. Code § 2725(4)) (citing *Yi v. BMW of N. Am.*,

23 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

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

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

9 ***E. Remaining Claims (Counts XVII and XVIII)***

10 Finally, Defendants contend in a footnote that Plaintiff’s claims for “discovery rule  
11 and tolling” (Count XVIII) and punitive damages (XVII) should be dismissed because they  
12 are not independent causes of action. (*See* MSJ Mem. at 1 n.1.) Although there is some  
13 merit to Defendants’ argument, *see, e.g.*, *Ismail v. Cty. of Orange*, 917 F. Supp. 2d 1060,  
14 1073 (C.D. Cal. 2012) (recognizing that a request for punitive damages is not an  
15 independent cause of action), *aff’d*, 676 F. App’x 690 (9th Cir. 2017); *Soderstrom v.*  
16 *Nicholas*, No. C 08-05310 JW, 2009 WL 10697266, at \*8 (N.D. Cal. May 20, 2009)  
17 (declining to treat claim for fraudulent concealment as a separate cause of action where it  
18 was pled as a means of tolling the statute of limitations), a footnote does not “adequately  
19 raise [an] issue for summary judgment.” *See Troester v. Starbucks Corp.*, No.  
20 CV1207677CJCPJWX, 2019 WL 2902487, at \*1 (C.D. Cal. May 21, 2019). The Court  
21 therefore **DECLINES** to dismiss Counts XVII and XVIII.

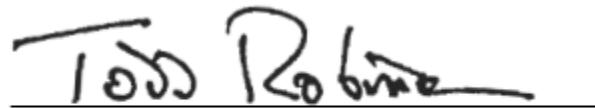
22 **CONCLUSION**

23 In light of the foregoing, the Court **DENIES** Defendants’ *Daubert* Motion (ECF No.  
24 36) and **GRANTS IN PART AND DENIES IN PART** Defendants’ Motion for Summary  
25 Judgment (ECF No. 34). Specifically, the Court **GRANTS** Defendants’ Motion for  
26 Summary Judgment as to Counts II, IV, V, XI, XII, and XVI in their entirety and as to  
27 Count XIII to the extent Plaintiff seeks damages, and **DENIES** Defendants’ Motion as to  
28 // /

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

3 **IT IS SO ORDERED.**

4  
5 Dated: October 16, 2020



6  
7 Honorable Todd W. Robinson  
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9 United States District Court  
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