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United States District Court
Central District of California

HILDA MUNOZ, et al.,

Plaintiffs,

v.

AMERICAN MEDICAL SYSTEMS, INC.,

Defendant.

Case No. 2:20-cv-01640-ODW (JPRx)

ORDER GRANTING DEFENDANT'S MOTION FOR PARTIAL SUMMARY JUDGMENT [80]

I. INTRODUCTION

Plaintiff Hilda Munoz[1] alleges she sustained injuries from two pelvic mesh devices manufactured by Defendant Astora Women's Health, LLC (fka American Medical Systems, Inc.). (*See* Compl.) Defendant moves for partial summary judgment on Plaintiff's failure-to-warn claim (Count IV), and the parties have fully briefed the matter. (Def.'s Mot. Partial Summ. J. ("MPSJ"), ECF No. 80; Opp'n, ECF

[1] The Short Form Complaint names both Plaintiff Hilda Munoz and her spouse, Guillermo Munoz, as "Plaintiffs" in this action. (*See* Short Form Compl. ("Compl."), ECF No. 1.) None of the claims at issue in this Order concern Guillermo Munoz, thus, the Court utilizes the singular, "Plaintiff."

No. 83; Reply, ECF No. 84.) For the following reasons, the Court **GRANTS** Defendant's Motion.[2]

II. BACKGROUND

In May 2007, Plaintiff consulted with a board-certified urologist, Dr. B.J. Patel, in an attempt to remedy various urinary tract conditions. (*See* Defendant's Statement of Uncontroverted Facts ("DUF") 2, 12, ECF No. 80-1.) Dr. Patel conducted several exams and determined that surgical intervention was necessary; he recommended an implant of Defendant's Monarc Subfascial Hammock ("Monarc") pelvic mesh sling. (*Id.* 1, 3–4.) In July 2007, Dr. Patel implanted the Monarc in Plaintiff but removed it five months later because Plaintiff complained of pain, and an exam confirmed that part of the sling had eroded. (*Id.* 4, 6–8.) In October 2008, Dr. Patel implanted a different device, Defendant's MiniArc mid-urethral sling ("MiniArc"), in Plaintiff because non-surgical treatments had failed to treat her various conditions. (*Id.* 9.)

After the two procedures, Plaintiff experienced many ailments, including various infections, pain, and bleeding. (*Id.* 20.) Plaintiff underwent three revision surgeries as a result of complications from Defendant's Monarc and Miniarc slings (collectively, the "Slings"). (*See* DUF 19; Pl.'s Separate Statement of Genuine Disputed Facts ("PSF") 31, ECF No. 83-8.)

On December 22, 2015, Plaintiff filed a Short Form Complaint in the multi-district litigation, *In re: American Medical Systems, Inc., Pelvic Repair System Products Liability Litigation*, MDL No. 2325, asserting sixteen causes of action against Defendant. (Compl.) On February 6, 2020, Plaintiff's case was transferred to this Court, and later that year, the parties stipulated to dismissal of ten of Plaintiff's claims. (Transfer Order, ECF No. 40; Order Granting Joint Stip. to Dismiss, ECF No. 79.) Defendant now moves for partial summary judgment on Plaintiff's claim for failure to warn (Count IV). (MPSJ.)

[2] Having carefully considered the papers filed in connection with the Motion, the Court deemed the matter appropriate for decision without oral argument. Fed. R. Civ. P. 78; C.D. Cal. L.R. 7-15.

III. LEGAL STANDARD

A court "shall grant summary judgment if 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). Courts must view the facts and draw reasonable inferences in the light most favorable to the nonmoving party. *Scott v. Harris*, 550 U.S. 372, 378 (2007). A disputed fact is "material" where the resolution of that fact might affect the outcome of the suit under the governing law, and the dispute is "genuine" where "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Conclusory or speculative testimony in affidavits is insufficient to raise genuine issues of fact and defeat summary judgment. *Thornhill Publ'g Co. v. GTE Corp.*, 594 F.2d 730, 738 (9th Cir. 1979). Moreover, though the Court may not weigh conflicting evidence or make credibility determinations, there must be more than a mere scintilla of contradictory evidence to survive summary judgment. *Addisu v. Fred Meyer, Inc.*, 198 F.3d 1130, 1134 (9th Cir. 2000).

Once the moving party satisfies its burden, the nonmoving party cannot simply rest on the pleadings or argue that any disagreement or "metaphysical doubt" about a material issue of fact precludes summary judgment. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986); *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986); *Cal. Architectural Bldg. Prods., Inc. v. Franciscan Ceramics*, *Inc.*, 818 F.2d 1466, 1468 (9th Cir. 1987). Nor will uncorroborated allegations and "self-serving testimony" create a genuine issue of material fact. *Villiarimo v. Aloha Island Air, Inc.*, 281 F.3d 1054, 1061 (9th Cir. 2002). The Court should grant summary judgment against a party who fails to demonstrate facts sufficient to establish an element essential to his case when that party will ultimately bear the burden of proof at trial. *See Celotex*, 477 U.S. at 322.

Pursuant to the Local Rules, parties moving for summary judgment must file a proposed "Statement of Uncontroverted Facts and Conclusions of Law" that sets out

"the material facts as to which the moving party contends there is no genuine dispute." C.D. Cal. L.R. 56-1. A party opposing the motion must file a "Statement of Genuine Disputes" setting forth all material facts as to which it contends there exists a genuine dispute. C.D. Cal. L.R. 56-2. "[T]he Court may assume that material facts as claimed and adequately supported by the moving party are admitted to exist without controversy except to the extent that such material facts are (a) included in the 'Statement of Genuine Disputes' and (b) controverted by declaration or other written evidence filed in opposition to the motion." C.D. Cal. L.R. 56-3.

IV. DISCUSSION

Defendant moves for partial summary judgment on Plaintiff's failure-to-warn claim (Count IV). (MPSJ.) Defendant argues that Dr. Patel was aware of the relevant risks associated with the Slings at the time of Plaintiff's surgeries, and thus, Defendant fulfilled its duty to warn as a matter of law. (MPSJ 2, 4.) Alternatively, Defendant contends that Plaintiff's failure-to-warn claim fails because she cannot demonstrate causation. (MPSJ 5–6.) In opposition, Plaintiff argues that genuine issues of material fact exist concerning whether Defendant's Instructions for Use ("IFUs") adequately warned Dr. Patel of the risks associated with the Slings, and whether Dr. Patel would have implanted the Slings if Defendant had provided stronger warnings. (Opp'n 1.)

"California follows the learned-intermediary doctrine, which provides that the manufacturer's duty to warn in the case of medical devices runs only to the physician—not the patient." *Andrea Crissma v. Ethicon, Inc.*, No. CV 20-5426 MWF (PLAx), 2020 WL 5440357, at *4 (C.D. Cal. Aug. 31, 2020) (collecting cases). Where the learned intermediary doctrine applies, the plaintiff must prove that: (1) "no warning was provided or the warning was inadequate," and (2) "the inadequate warning was the proximate cause of her injury." *See Motus v. Pfizer Inc.*, 196 F. Supp. 2d 984, 991 (C.D. Cal. 2001), *aff'd sub nom. Motus v. Pfizer Inc. (Roerig Div.)*, 358 F.3d 659 (9th Cir. 2004). To satisfy the second element—causation—the plaintiff must show that the prescribing physician would have acted differently if provided

with adequate warnings. *See id.* ("[Defendant] may prevail in its motion for summary judgment if [plaintiff] has failed to adduce evidence that [the prescribing physician] would have acted differently had [defendant] provided an adequate warning . . . .").

A. Inadequate Warnings

First, the Court addresses whether Defendant provided adequate warnings to Dr. Patel. *See Motus*, 196 F. Supp. 2d at 991. Defendant submits Dr. Patel's deposition testimony to show that the warnings in its IFUs adequately informed Dr. Patel of all the risks associated with the Slings. (*See* MPSJ 4.) Plaintiff, on the other hand, contends that the same deposition testimony proves Defendant failed to warn Dr. Patel of several relevant risks. (Opp'n 6.) On this issue, Plaintiff is correct.

It is undisputed that Dr. Patel relied on Defendant's IFUs in making his decision to implant the Slings in Plaintiff. (DUF 15–16; PSF 24.) The IFUs stated that risks associated with the Slings included "local irritation" or "foreign body response." (DUF 16; PSF 23–24.) However, Dr. Patel testified that he interpreted these warnings as only risks of "transient" or "temporary" tissue responses to the Slings. (PSF 26–28; *see* Def.'s MPSJ, Ex. B, Deposition of Bharat Patel ("Patel Dep.") 50:5–50:23, ECF No. 80-3.) Defendant's IFUs did not warn Dr. Patel that risks associated with the Slings included chronic tissue responses, chronic pain, chronic infections, or chronic erosions. (PSF 26, 29.) Indeed, when asked whether Defendant informed Dr. Patel that chronic pain was possible, Dr. Patel answered, "They didn't tell [me] that." (Patel Dep. 57:11–57:14.) Thus, viewing the evidence in the light most favorable to Plaintiff, Defendant has failed to demonstrate that its warnings were adequate as a matter of law.

B. Causation

Second, the Court addresses whether Plaintiff has demonstrated causation. *See Motus*, 196 F. Supp. 2d at 991. Defendant contends that Dr. Patel unequivocally stated he would have implanted the Slings even if Defendant had provided stronger warnings, e.g., if he had been warned that the Slings could cause chronic conditions.

(MPSJ 5–6.) Plaintiff interprets Dr. Patel's testimony differently, as stating he would have considered *not* implanting the devices had he been provided with stronger warnings. (Opp'n 13.) On this issue, the Court agrees with Defendant.

The Ninth Circuit has held that a failure-to-warn claim cannot survive summary judgment "if stronger warnings would not have altered the conduct of the prescribing physician." *See, Motus*, 358 F.3d at 661 (affirming summary judgment on a failure-to-warn claim where the "[plaintiff] failed to establish proof that stronger warnings would have changed her husband's medical treatment"). In other words, Plaintiff must put forth evidence that Dr. Patel would not have implanted the Slings if he had been warned that they could cause the various chronic conditions discussed above. *See id.* Otherwise, Defendant prevails on this claim.

Plaintiff's counsel deposed Dr. Patel and repeatedly asked him whether he would recommend a different treatment if Defendant had provided stronger warnings; Dr. Patel repeatedly stated he would not. For example, Plaintiff's counsel asked Dr. Patel the following: "If [Defendant] told you that they knew that chronic infections was a risk, would you have reconsidered using the [S]lings?" Dr. Patel answered: "No." (Patel Dep. 59:22–59:25.)

Dr. Patel's remaining testimony is just as clear—even if Defendant's IFUs included stronger warnings, he would still have implanted the Slings. (*See, e.g.*, Patel Dep. 54:2–54:10; 54:22–55:6; 56:7–56:21; 59:22–59:25; 64:8–64:13.) Dr. Patel explained that he made his decisions based on his many years of experience, literature, and what was prevailing in the community, (*id.* at 61:18–61:21), and that even if he had been warned about the risk of chronic conditions, he would still have implanted the Slings because "at that time that was the best treatment available" for Plaintiff's conditions, (*id.* at 54:2–54:10).

Plaintiff attempts to create a triable issue of material fact by pointing to one instance where Dr. Patel stated he "would have reconsidered" using the Slings to treat Plaintiff. (*See* Opp'n 11 (citing Patel Dep. 54:2–54:10).) However, Plaintiff

overstates the significance of Dr. Patel's response. Plaintiff's counsel asked Dr. Patel, "If [Defendant] had warned you and alerted you back in 2007 and 2008 that these listed tissue responses could be chronic in its IFUs, would you have reconsidered using the [Slings] to treat [Plaintiff]?" Dr. Patel responded, "I would have reconsidered. *But I would still do the sling because at that time that was the best treatment available*." (Patel Dep. 54:2–54:10 (emphasis added).) Thus, when Dr. Patel's response is read in its entirety, it is obvious that he meant "reconsidered" in the sense that he would have reflected upon the new information—not that he would have altered his treatment in any way. *See Reconsider*, Merriam-Webster Online Dictionary, https://www.merriam-webster.com/dictionary/reconsider (last visited March 29, 2020) ("To consider something again."). Moreover, this conclusion is bolstered by the fact that later in his deposition, Dr. Patel states at least four additional times, in no uncertain terms, that he would have still implanted the slings if Defendant had warned him of the risks of chronic tissue responses. (*See* Patel Depo. 54:22–55:6; 56:7–56:21; 59:22–59–25; 64:8–64:13.)

In a final attempt to create a triable issue of material fact, Plaintiff claims that if Defendant had provided stronger warnings, Dr. Patel would have shared those warnings with Plaintiff. (Opp'n 13–14.) She contends that this demonstrates that Dr. Patel would have altered his treatment, and that this proves causation. (*Id.*) However, Plaintiff's argument ignores that where there is a learned intermediary, the issue of causation concerns whether the physician would have altered his recommendation concerning treatment, not whether he would have shared the stronger warnings with his patient. *See, e.g.*, *Motus*, 196 F. Supp. 2d at 997. Dr. Patel's testimony that he would have passed along the additional information to Plaintiff is insufficient on its own to deny summary judgment. *See id.* (finding testimony that the physician would have provided additional warnings to the plaintiff did not raise a triable issue of fact on the issue of causation).

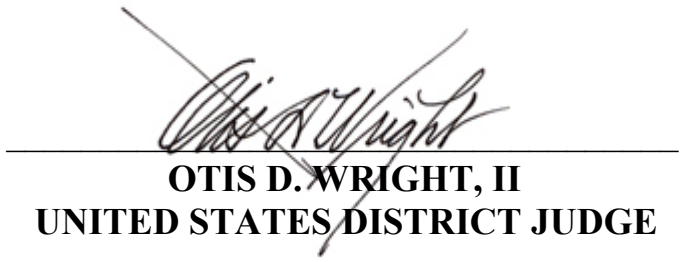
Therefore, on this record, Plaintiff fails to create a question of fact for the jury. Accordingly, the Court **GRANTS** Defendant's Motion.

V. CONCLUSION

For the foregoing reasons, the Court **GRANTS** Defendant's Motion for Partial Summary Judgment on Plaintiff's failure-to-warn claim (Count IV).

IT IS SO ORDERED.

March 30, 2021



OTIS D. WRIGHT, II
UNITED STATES DISTRICT JUDGE