UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

DAVID CHAO, M.D., OASIS MSO Inc., and DAVID J. CHAO MD, INC., Plaintiffs, vs. SMITH & NEPHEW, INC., SMITH & NEPHEW PLC, and DOES 1 through 10, Defendants.	CASE NO. 13-CV-0114-H (BLM) [Doc. No. 20.] **ORDER GRANTING IN PART AND DENYING IN PART DEFENDANT'S MOTION FOR SUMMARY JUDGMENT**

On August 29, 2013, Defendant Smith & Nephew, Inc. ("Defendant" or "Smith & Nephew") filed a motion for summary judgment. (Doc. No. 20.) On September 6, 2013, the Court, for good cause shown, granted the parties' joint motion to continue the motion hearing and the related filing deadlines. (Doc. No. 22.) On September 30, 2013, Plaintiffs David Chao, M.D., Oasis MSO Inc., and David J. Chao MD, Inc. ("Plaintiffs" or "Dr. Chao") filed their response in opposition to Defendant's motion. On October 11, 2013, Defendant filed its reply. (Doc. No. 33.) On October 18, 2013, the Court held a hearing regarding the motion. John W. Shaw, James B. Irwin, and David Wayne O'Quinn appeared for Defendant. Louis B. Edleson appeared for Plaintiffs. For the reasons set forth below, the Court grants in part and denies in part Defendant's motion for summary judgment.

Background

This indemnity action arises from a medical malpractice arbitration award. On May 30, 2007, Dr. Chao performed a hip replacement on a patient. (Doc. No. 25-2 at 7.) Dr. Chao used hip prosthesis components and surgical techniques collectively known as the Birmingham Hip Resurfacing ("BHR") system. (Id. at 2) During the surgery, Dr. Chao lacerated the patient's femoral artery and damaged other structures. (Id. at 7.) The patient and her husband sued Dr. Chao in California state court, alleging that Dr. Chao was negligent in conducting the surgery. (Id. at 7-8.) The California state court referred the patient's suit against Dr. Chao to arbitration. (Id. at 8.) On January 6, 2011, the arbitration panel found that Dr. Chao had committed professional negligence and awarded the patient and her husband $2.2 million dollars. (Id.)

The BHR system is designed and manufactured by Smith & Nephew. (Id. at 2.) On May 9, 2006, the Food and Drug Administration ("FDA") granted pre-market approval to Smith & Nephew for its BHR system. (Id.; see Doc. No. 20-6.)

On January 4, 2013, Plaintiffs filed a complaint for indemnity against Smith & Nephew in the Superior Court of California, County of San Diego. (Doc. No. 25-2 at 9.) In their complaint, Plaintiffs allege that Smith & Nephew is responsible for the arbitration award due to its failure to properly develop reasonably safe surgical procedures and equipment, as well as its failure to provide appropriate training and warnings to Dr. Chao. (Id. at 10.) On January 15, 2013, Defendant Smith & Nephew removed this action to federal court on diversity grounds. (Doc. No. 1.) On August 29, 2013, Defendant filed a motion for summary judgment on the grounds that Plaintiffs' state court claim is preempted by the Medical Device Amendments ("MDA") to the Food, Drug and Cosmetic Act. (Doc. No. 20-1 at 6); 21 U.S.C. § 360k(a).

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Discussion

I. Summary Judgment Standard

Summary judgment is appropriate under Rule 56 of the Federal Rules of Civil Procedure if the moving party demonstrates the absence of a genuine issue of material fact and entitlement to judgment as a matter of law. Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986). A fact is material when, under the governing substantive law, it could affect the outcome of the case. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986); Nat'l Ass'n of Optometrists & Opticians v. Harris, 682 F.3d 1144, 1147 (9th Cir. 2012) cert. denied, 133 S. Ct. 1241 (2013). A dispute is genuine if a reasonable jury could return a verdict for the nonmoving party. Anderson, 477 U.S. at 248.

A party seeking summary judgment always bears the initial burden of establishing the absence of a genuine issue of material fact. Celotex, 477 U.S. at 323. The moving party can satisfy this burden in two ways: (1) by presenting evidence that negates an essential element of the nonmoving party's case; or (2) by demonstrating that the nonmoving party failed to establish an essential element of the nonmoving party's case on which the nonmoving party bears the burden of proving at trial. Id. at 322-23. "Disputes over irrelevant or unnecessary facts will not preclude a grant of summary judgment." T.W. Elec. Serv., Inc. v. Pacific Elec. Contractors Ass'n, 809 F.2d 626, 630 (9th Cir. 1987). Once the moving party establishes the absence of genuine issues of material fact, the burden shifts to the nonmoving party to set forth facts showing that a genuine issue of disputed fact remains. Celotex, 477 U.S. at 322. The nonmoving party cannot oppose a properly supported summary judgment motion by "rest[ing] on mere allegations or denials of his pleadings." Anderson, 477 U.S. at 256. "The 'opponent must do more than simply show that there is some metaphysical doubt as to the material fact.'" Kennedy v. Allied Mut. Ins. Co., 952 F.2d 262, 265–66 (9th Cir. 1991) (citing Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586 (1986)). Furthermore, the nonmoving party generally "cannot create an issue of fact by an affidavit contradicting his prior deposition testimony." Van Asdale v. Int'l Game

Tech., 577 F.3d 989, 998 (9th Cir. 2009) (citing Kennedy, 952 F.2d at 266).

When ruling on a summary judgment motion, the district court must view all inferences drawn from the underlying facts in the light most favorable to the nonmoving party. Matsushita, 475 U.S. at 587. The district court does not make credibility determinations with respect to evidence offered. See T.W. Elec., 809 F.2d at 630-31 (citing Matsushita, 475 U.S. at 587). Summary judgment is therefore not appropriate "where contradictory inferences may reasonably be drawn from undisputed evidentiary facts." Hollingsworth Solderless Terminal Co. v. Turley, 622 F.2d 1324, 1335 (9th Cir. 1980).

II. Analysis

A. Plaintiffs' Claim Regarding the BHR Scissors

Plaintiffs allege that "Smith & Nephew instructed Dr. Chao to perform the BHR procedure with a large, long pair of special surgical scissors, and provided a set of surgical equipment that included the scissors." (Doc. No. 1. Ex. A. ("Compl.") at 13.) Plaintiffs then allege that Smith & Nephew was responsible for the injuries suffered by the patient and her husband in part because the design of the scissors was not reasonably safe. (Id.)

Defendant argues that any claims by Plaintiff related to the scissors are preempted by Section 360k of the MDA. (Doc. No. 20-1 at 12.) Section 360k of the MDA preempts any state law claims that would impose different or additional requirements on medical devices that have received pre-market approval ("PMA") from the FDA. 21 U.S.C. § 360k; see Riegel v. Medtronic, 552 U.S. 312, 324-25 (2008); see also In re Medtronic, Inc. Sprint Fidelis Leads Products Liab. Litig., 592 F. Supp. 2d 1147, 1161 (D. Minn. 2009) (holding design-defect claims seek to impose requirements that are different or additional to those of the FDA) aff'd sub nom. In re Medtronic, Inc., Sprint Fidelis Leads Products Liab. Litig., 623 F.3d 1200 (8th Cir. 2010). Defendants present, and Plaintiffs do not dispute, evidence that the FDA approved the design of the scissors as part of the PMA process. (Doc. No. 25-2 at 3-5.)

The Court concludes that Plaintiffs' claim related to the design of the scissors is preempted by Section 360k(a). Since Plaintiffs' have other theories, the Court proceeds to Plaintiffs' alternative arguments.

B. Plaintiffs' Claims That Defendant Smith & Nephew Failed to Comply with Applicable FDA Training Standards

Plaintiffs allege that Defendant Smith & Nephew taught surgical techniques that deviated from those in the FDA approved BHR Surgical Technique Brochure and failed to provide physician training as required by the FDA. (Doc. No. 25 at 4.) Although most claims against a medical device manufacturer are preempted by Section 360k, the Supreme Court held that "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations . . . ." Riegel, 552 U.S. at 330; Stengel v. Medtronic Inc., 704 F.3d 1224, 1228 (9th Cir. 2013) (en banc) ("[T]he MDA does not preempt a state-law claim for violating a state-law duty that parallels a federal-law duty under the MDA."). Defendant contends that summary judgment is nonetheless appropriate on the basis of the record and that no genuine issue of material fact remains. (Doc. No. 35 at 1-2.)

The parties agree that as part of the PMA process for the BHR, the FDA required Smith & Nephew to provide a surgical technique brochure and instructive training videos to surgeons who would be using the BHR system. (Doc. No. 25-2 at 4-5.) Plaintiffs allege that the instructions in the Smith & Nephew produced training videos diverged in numerous respects from the FDA approved instructions in the surgical technique brochure. (Doc. No. 25 at 8-9.) Plaintiffs allege that there is an issue of material fact as to whether these divergent video instructions were responsible for Dr. Chao's negligence during the operation. (Id. at 8.) Defendant submitted several exhibits purporting to show that there were no meaningful differences between the videos and the surgical technique brochure. (See Doc. No. 35, Exs. H, H-1, I, I-1, J, J-1.) But at the summary judgment stage, viewing all inferences in the light most favorable to the non-moving party, Matsushita, 475 U.S. at 587, the present record does not warrant

summary judgment of whether the instructional videos conformed to the FDA approved instructions.

Plaintiffs also allege that Defendant violated FDA regulations by failing to provide Dr. Chao with sufficient in-person training. (Doc. No. 25 at 5-6.) Plaintiffs contend that Smith & Nephew was supposed to provide Dr. Chao with scrub-in training and cadaver training, but instead had Dr. Ronan Treacy proctor Dr. Chao. (Id. at 6-7.) Furthermore Plaintiffs assert that Dr. Chao walked through a cadaver lab where other physicians were undergoing training on the BHR procedure, but did not participate himself. (Doc. No. 25-1, ("Chao Decl.") ¶ 12.)

Defendant's motion for summary judgment initially stated that the PMA required didactic lectures, cadaver training, and observation of an actual surgery. (Doc. No 20-2 ¶ 7.) Subsequently, in its reply, Defendant has argued that the PMA did not require any live surgical training for surgeons such as Dr. Chao, because he was not a "core surgeon." (Doc. No. 35-7 Ex. F.)[1] Plaintiffs did not have a chance to respond in writing regarding the distinction between core surgeons and other interested US surgeons, and the implications of this distinction on the training Dr. Chao should have received.

If Defendant failed to provide Dr. Chao with the training required by the FDA's PMA, then Plaintiffs' indemnity claim would not be barred by Section 360k. Stengel v. Medtronic Inc., 704 F.3d at 1228. Based on the current record, the Court denies without prejudice Defendant's motion for summary judgment regarding the types of training the FDA's PMA required Dr. Chao to have. Since fact and expert discovery are not yet completed, the parties may file an additional motion for summary judgment, in accordance with the Court's case management order. (Doc. No. 12.)

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[1] Defendant also submitted transcripts of arbitration testimony by Dr. Chao that indicate he received some forms of hands-on training. (Doc. No. 35-5, Ex. E-1 ("Chao Depo.") at 85-92.) Defendant asserts that this transcript conflicts with Dr. Chao's more recent declaration, and thus that there is no genuine issue of material fact as to the training Dr. Chao received. Van Asdale, 577 F.3d at 998. Plaintiff contests Defendant's characterization of Dr. Chao's deposition testimony, and asserts that Defendant has taken segments of the deposition transcript out of context.

C. Plaintiffs' Claim That Defendant Smith & Nephew Failed to Caution Dr. Chao Against Using the BHR With an Obese Patient

Plaintiffs allege that Defendant Smith & Nephew was "directly involved in patient selection for use of the BHR, and Dr. Chao significantly relied on their expertise" in selecting patients for the BHR procedure. (Doc. No. 25 at 9-10.) Plaintiffs allege that Smith & Nephew was responsible for the injuries suffered by the patient and her husband in part because Smith & Nephew did not counsel Dr. Chao against using the BHR with the patient. (Id. at 10.)

California law imposes a duty on the manufacturer of an implant to warn the doctor of potential risks posed by the product. Valentine v. Baxter Healthcare Corp., 68 Cal. App. 4th 1467, 1483 (Cal. Ct. App. 1999). Under the learned intermediary doctrine the manufacturer's duty extends only to warning the physician, not the patient, of the properties and proper use of the implant. Tucker v. Wright Med. Tech., Inc., 11-CV-03086-YGR, 2013 WL 1149717, at * 12 (N.D. Cal. Mar. 19, 2013) (citing Valentine, 68 Cal. App. 4th at 1483). "A manufacturer . . . discharges its duty to warn if it provides an adequate warning to the physician about any known or reasonably knowable dangerous side effects of a medicine, regardless of whether the warning reaches the patient." Wendell v. Johnson & Johnson, C 09-04124 CW, 2012 WL 3042302 (N.D. Cal. July 25, 2012) (citing Carlin v. Superior Court, 13 Cal. 4th 1104, 1116-17 (1996)).

The parties agree that the Smith & Nephew's training materials warned that the BHR device was contraindicated in obese patients. (Doc. No. 35 at 9; Chao Decl. ¶ 17.) Furthermore, the parties agree that Dr. Chao specifically obtained the patient's consent regarding potential complications with the BHR procedure because Dr. Chao was worried about complications due to the patient's obesity. (Chao Decl. ¶ 17.) Finally, in the arbitration, Dr. Chao testified that it is the surgeon, not the device manufacturer, who makes the final determination regarding patient selection. (Chao Depo. at 100.)

Plaintiffs have cited no legal authority nor FDA regulation for the proposition

that a device manufacturer owes a duty, beyond providing a warning, to dissuade a physician from using a device on a particular patient. Nor have Plaintiffs in this case alleged that the warning included with the FDA approved materials was insufficient. (See Doc. No. 25-2 ¶ 22; Doc. 20-12, Ex. E at 5.) And Plaintiffs do not allege that Defendant Smith & Nephew failed to adequately train Dr. Chao regarding appropriate candidates for the BHR procedure. (Cf. Chao Depo. at 100.)

The evidence before the court shows that Defendant Smith & Nephew provided adequate warning to Dr. Chao regarding the danger of performing the BHR procedure on an overweight patient, and that Dr. Chao decided to proceed anyway. The Court declines to impose an additional duty on a device manufacturer to second guess a practicing physician when that physician has already received the FDA mandated warnings. Accordingly, the Court grants Defendant's motion for summary judgment with regard to the failure to warn.

Conclusion

For the reasons set forth above, the Court grants in part and denies in part Defendant Smith & Nephew's motion for summary judgment. The Court grants Defendant's motion for summary judgment on claims related to the design of the BHR scissors and Smith & Nephew's alleged failure to warn. The Court denies Defendant's motion for summary judgment on claims related to Defendant's alleged failure to comply with applicable FDA training standards.

IT IS SO ORDERED.

DATED: October 22, 2013

MARILYN L. HUFF, District Judge
UNITED STATES DISTRICT COURT