COURT OF APPEALS
SECOND DISTRICT OF TEXAS
FORT WORTH

NO. 2-05-071-CV

ETHICON ENDO-SURGERY, INC. APPELLANT

V.

DIANNE MEYER APPELLEE

FROM THE 393RD DISTRICT COURT OF DENTON COUNTY

OPINION

Introduction

This is a marketing-defect products liability case. The product in question is the TLC-55 linear cutter/surgical stapler designed, manufactured, and marketed by Appellant Ethicon Endo-Surgery, Inc. ("Ethicon"). Ethicon appeals from a jury verdict and judgment in favor of Appellee Dianne Meyer. The key question is whether the surgeon who used the TLC-55 on Meyer conclusively negated producing cause when he testified that he had independent knowledge of the risks of which Meyer claims Ethicon should have warned him. We answer "yes" to that question, reverse the trial court's judgment, and render a take-nothing judgment.

Background

On February 7, 2000, Dr. Curtis Mosier performed an exploratory laparoscopy on Meyer in an attempt to find the cause of her generalized abdominal pain. On February 9, 2000, Dr. Mosier discovered that a loop of Meyer's small bowel had herniated through the laparoscopy incision, lost its supply of oxygen, and burst.

That same day, Dr. Mosier performed a second laparoscopy on Meyer to repair the damage to her intestines by resectioning part of her small bowel. The resectioning involved removing a three-foot length of Meyer's intestines and reconnecting the cut ends. Dr. Mosier performed the surgery with the assistance of a TLC-55 linear cutter designed, manufactured, and marketed by Ethicon. A linear cutter is a surgical device that creates parallel lines of staples and cuts the tissue between the staple lines, all with one "firing" of the device. In this particular procedure, Dr. Mosier used the TLC-55 to staple and cut Meyer's bowel on either side of the part to be removed. He then also used the TLC-55 to attach the remaining portion of the bowel together and create an "anastomosis" between the cut ends of the bowel by stapling, rather than suturing, them together and cutting an opening between them to restore the flow of bowel contents. Dr. Mosier testified that he

"milked" or tested the anastomosis to ensure that gas and fluid could pass through the opening without leaking out of Meyer's bowel. Dr. Mosier made sure the staples were holding and that there was no leakage, and he thought that the anastomosis was working well.

In the days following the surgery, Meyer's condition first improved, then declined. By February 17, enteric fluid, or bowel content, was leaking out of the laparoscopy incisions in Meyer's abdomen. On February 21, 2000, Meyer was transferred to another hospital, where a second surgeon, Dr. George Shires, performed a third operation. Dr. Shires discovered that one of the staple lines from the February 9 anastomosis had "dehisced," or separated, allowing bowel contents to leak into Meyer's abdomen and cause a serious infection. As a result of the dehiscence and infection, Meyer underwent several additional surgical procedures and a lengthy hospitalization.

Meyer sued Dr. Mosier for medical negligence on August 31, 2001. On March 11, 2002—two years and nineteen days after the February 9, 2000 surgery—Meyer amended her petition and sued Ethicon for products liability, alleging design, manufacturing, and marketing defects in the TLC-55. Meyer eventually settled with Dr. Mosier, dismissed other defendants, and proceeded to trial against Ethicon. A jury found that the TLC-55 was defectively marketed and awarded $538,281.73 in damages to Meyer,[1] and the trial court entered judgment accordingly. On appeal, Ethicon argues, among other things, that Meyer's claim was barred by limitations and that Dr. Mosier's testimony regarding his independent knowledge of the risks of using a linear cutter/stapler conclusively negated producing cause with regard to the TLC-55's alleged marketing defect.

Producing Cause

In the second part of its fourth issue, Ethicon argues that the evidence conclusively

negated producing cause because Dr. Mosier testified that he had independent knowledge of the risks of using the TLC-55 even if Ethicon failed to warn him of those risks. We agree.

This is a legal sufficiency challenge. We will sustain a legal sufficiency challenge when the evidence establishes conclusively the opposite of a vital fact. *Uniroyal Goodrich Tire Co. v. Martinez*, 977 S.W.2d 328, 334 (Tex. 1998), *cert. denied*, 526 U.S. 1040 (1999); Robert W. Calvert, *"No Evidence" and "Insufficient Evidence" Points of Error*, 38 TEX. L. REV. 361, 362-63 (1960). In determining whether there is legally sufficient evidence to support the finding under review, we must consider evidence favorable to the finding if a reasonable factfinder could, and disregard evidence contrary to the finding unless a reasonable factfinder could not. *City of Keller v. Wilson*, 168 S.W.3d 802, 827 (Tex. 2005).

A marketing defect occurs when a defendant knows or should know of a potential risk of harm presented by the product but markets it without adequately warning of the danger or providing instructions for safe use. *Bristol-Myers Co. v. Gonzales*, 561 S.W.2d 801, 804 (Tex. 1978); *Benavides v. Cushman, Inc.,* 189 S.W.3d 875, 881 (Tex. App.—Houston [1st Dist.] 2006, no pet.); *USX Corp. v. Salinas,* 818 S.W.2d 473, 482 (Tex. App.—San Antonio 1991, writ denied) (op. on reh'g). A marketing defect cause of action consists of five elements: (1) a risk of harm that is inherent in the product or that may arise from the intended or reasonably anticipated use of the product must exist, (2) the product supplier must actually know or reasonably foresee the risk of harm at the time the product is marketed, (3) the product must possess a marketing defect, (4) the absence of the warning or instructions must render the product unreasonably dangerous to the ultimate user or consumer of the product, and (5) the failure to warn or instruct must constitute a causative nexus in the product user's injury. *Salinas*, 818 S.W.2d at 482-83.

When a product's user is aware of the possible risks involved with a product's use but decides to use it anyway, the inadequacy of the product's warning is not, as a matter of law, a producing cause of an injury resulting from such use. *Stewart v. Janssen Pharmaceutica, Inc*., 780 S.W.2d 910, 912 (Tex. App.—El Paso 1989, writ denied). In *Janssen*, the plaintiff suffered respiratory arrest after his anesthesiologist administered a drug manufactured by the defendant. *Id.* at 911. The anesthesiologist testified that he was aware of the risk of respiratory depression with any anesthetic, regardless of any warning from the manufacturer. *Id*. at 912. The court held that the anesthesiologist's testimony negated producing cause as a matter of law. *Id.; see also Boswell v. Burroughs Wellcome Co.*, No. 05-95-01389-CV, 1997 WL 198746, at *2-3 (Tex. App.—Dallas April 24, 1997, writ denied) (holding producing cause negated in defectively-marketed-drug case when anesthesiologist testified that he was aware of the risks arising from drug's use). While Texas courts have thus far applied the independent knowledge doctrine to drug cases only, no court has rejected its application to medical device cases, and at least one court applying Texas law has applied the doctrine in the medical device context. *See Porterfield v. Ethicon, Inc.*, 183 F.3d 464, 468 (5th Cir. 1999) (holding producing cause negated when plaintiff alleged marketing defect in surgical mesh that caused abdominal infection, but surgeon testified that he was aware of the risk of infection and decided to use the mesh anyway); *see also Dyer v. Danek Med., Inc.*, 115 F. Supp. 2d 732, 741 (N.D. Tex. 2000) (applying doctrine to spinal fixation device). Many other jurisdictions have likewise applied the independent knowledge doctrine in the medical device context. *See, e.g., Kirsch v. Picker Int'l, Inc.*, 753 F.2d 670, 671-72 (8th Cir. 1985) (applying Missouri law) (applying doctrine to x-ray therapy machine)*; King v. Danek Med., Inc*., 37 S.W.3d 429, 453 (Tenn. Ct. App. 2000) (applying doctrine to

spinal fixation device); *Rosburg v. Min. Mining & Mfg. Co.*, 181 Cal. App. 3d 726, 735 (Cal. Ct. App. 1986) (applying doctrine to breast implant).[2]

We first identify the warning that Meyer claims Ethicon should have given to Dr. Mosier. Meyer's expert witness, Jeff Butler,[3] testified that Ethicon should have warned physicians of the risk of catastrophic staple-line failure even if the physician operates the stapler properly. He highlighted the absence of a warning that a staple line can fail even after the surgeon has checked the integrity of the staple line as the crux of this case:

> Q. Is there anything in that package insert with the device that advise[s] physicians if they check the staple line appropriately and there is hemostasis, that staple line dehiscence or failure can still later occur?
>
> A No. And I believe that's the crux of the matter here.

Butler testified that he could not say how the TLC-55 failed in Meyer's surgery nor how it caused her anastomosis failure. Butler apparently prepared a document reciting several proposed warnings that he thought Ethicon should have given with regard to the TLC-55, but that document was not admitted into evidence.

We now examine Dr. Mosier's testimony. Dr. Mosier is a board-certified general surgeon who received his medical degree in 1978 and has practiced surgery in Denton County for twenty years. He specializes in abdominal surgery, including laparoscopic surgery in the abdominal cavity with light and video cameras. Dr. Mosier testified that he has used surgical staplers and linear cutters since his residency to reconnect intestines hundreds to thousands of times. When asked whether the TLC-55 package insert warned of the danger of staple-line dehiscence, Dr. Mosier answered, "I don't recall it, no. But I don't recall reading that package insert."

Dr. Mosier testified that in February 2000, he was aware that a staple line could leak,

and he did not need Ethicon to tell him that a staple-line leak was something that could occur. He testified that he did not need Ethicon to tell him that he needed to check the integrity of the staple line at the time of surgery. Dr. Mosier said that even after checking the integrity of a staple line, there is the possibility that it may leak; "it's just something that happens," and it can happen from a number of possible causes, including tension on the line, damage from radiation, bleeding, and improper nourishment. He testified that a leak in a staple line can result in total staple-line dehiscence. Dr. Mosier stated that if he received a safety alert that gave him no more knowledge than he already had, it probably would not affect his approach to a surgery. He testified that he did not know, and there was no way to say with any certainty, what caused Meyer's staple line to dehisce.[4]

Dr. Mosier also testified about his first-hand knowledge of the risk of total staple-line dehiscence that he learned from the outcome of a procedure he performed on another patient two months before Meyer's surgery. Dr. Mosier testified that in December 1999 he created an anastomosis with a surgical stapler between "Patient Y's" stomach and intestine. The staple line totally dehisced. Dr. Mosier said that although he had reported Patient Y's dehiscence as involving the TLC-55, it in fact involved another kind of surgical stapler, and he was not sure whether it was made by Ethicon or a competitor.

It is clear from Dr. Mosier's testimony that he had independent knowledge of the risk that Butler testified Ethicon should have warned him about: that a staple line may completely fail even if the surgeon tests the staple line and is satisfied with its integrity. Moreover, Dr. Jay Hoppenstein, Ethicon's expert, testified that the possibility of staple-line failure was common knowledge among the relevant medical community, general surgeons.

Meyer argues that Dr. Mosier's testimony is insufficiently specific to negate causation because he did not state that he had independent knowledge of the exact risk that befell

her. But Dr. Mosier testified that it was impossible to determine what caused Meyer's staple line to dehisce, and Meyer's own expert was unable to state how the TLC-55 caused the dehiscence. Therefore, there is no evidence that the failure to warn of any specific or exact risk caused Meyer's injury.[5] It is undisputed that Meyer suffered a total staple-line dehiscence, and while the cause of the dehiscence may be unknown, Dr. Mosier testified that he was a aware of the risk of dehiscence as "just something that happens."

Meyer next argues that Dr. Mosier's testimony supports the jury's verdict on causation with regard to two of the specific warnings that Meyer contends Ethicon should have given to him. First, Meyer states that Dr. Mosier "specifically testified" that he would not have used the TLC-55 on Meyer if he had been made aware by Ethicon of the extent of adverse-result reports from other product users. As Meyer concedes, Dr. Mosier's testimony on this point is less than clear:

> Q. [] If you had seen a "Dear Doctor" letter related to this product and related to any idiopathic failures of the device, what would have been your election with regard to that letter moving forward?
>
> [Lengthy objections from Defense Counsel.]
>
> Q. Do you remember the question, Dr. Mosier?
>
> A. I do. I don't think there is any question at this point that that's correct. If I -- looking back, if I had gotten a product warning letter from the company, I would have taken that very seriously. *However, I didn't get that letter and it is speculation to know* since I had not had a problem with the product before *what I would have done*. But looking back, the answer is yes.[6] [Emphasis added.]

Dr. Mosier testified that he did not know what he would have done, not that he would have refrained from using the TLC-55. Thus, there is no evidence that Dr. Mosier would not have used the TLC-55 if Ethicon had warned him about bad results experienced by other patients.

Second, Meyer states that Dr. Mosier testified that he would not have used the TLC-55 on a patient who had a certain condition if Ethicon had warned him such condition contraindicated the stapler's use and that Ethicon's expert witness, Dr. Hoppenstein, identified several conditions that contraindicate the use of a stapler. Our own review of the record shows that Dr. Mosier testified that he would not have used the TLC-55 on a patient with diabetes if Ethicon had warned that diabetes can lead to staple-line dehiscence. Nothing in the record suggests that Meyer was diabetic. Dr. Hoppenstein identified several other conditions that could cause an anastomosis to fail, regardless of whether it was stapled or hand-sewn, and that the likelihood of failure is the same regardless of whether the anastomosis is stapled or hand-sewn. The conditions about which Dr. Hoppenstein testified are germane to the risks of anastomoses generally and not to the risks of using a surgical stapler specifically. Assuming that the general anastomosis risk factors identified by Dr. Hoppenstein could form the basis of an appropriate warning, there is no evidence that the lack of such a warning caused Meyer's injury.

Dr. Mosier's testimony established that he was aware of the risk of a total staple-line failure and complete dehiscence regardless of whether Ethicon failed to provide an adequate warning. We hold that Dr. Mosier's independent knowledge of the risk identified by Meyer's own expert conclusively negated causation, and we sustain the second part of Ethicon's fourth issue.

Conclusion

Having sustained Ethicon's fourth issue in part, and not reaching its remaining issues, we reverse the trial court's judgment and render judgment that Meyer take nothing. *See* TEX. R. APP. P. 43.2(c), 47.1.

ANNE GARDNER
JUSTICE

PANEL A: DAUPHINOT and GARDNER, JJ.; and WILLIAM H. BRIGHAM, J. (Senior Justice, Retired, Sitting by Assignment).

DAUPHINOT, J. filed a dissenting opinion.

DELIVERED: April 12, 2007

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FROM THE 393RD DISTRICT COURT OF DENTON COUNTY

DISSENTING OPINION

I must respectfully dissent from the majority's reversing the jury's verdict and substituting its own judgment because the evidence supports the jury's verdict.

Dr. Mosier's testimony does not conclusively negate the producing cause element.

Although Dr. Mosier testified that he was aware of the risks of using the TLC-55, his testimony clearly revealed that he was not aware of the full extent of the risks at the time of Ms. Meyer's surgery. The majority finds that Dr. Mosier's testimony was unclear. Apparently the jury, however, who was faced not with a cold record but a live witness, clearly understood Dr. Mosier's testimony. He testified that he would have taken a warning letter very seriously, but he received none. He further explained,

> If [safety alerts] come from the company, it means that the company has had a chance to really review the product itself, whether it be a medication or a medical device product, enough that they are taking the time to warn you about these—these situations. It's different when it comes from the company than if it's just something that you heard or just a report that was given.

Because of the knowledge that Dr. Mosier gained through Ms. Meyer's treatment and the litigation, he has abandoned his use of Ethicon's stapler. He also contacted Ethicon to report the problems he had experienced with the TLC-55 in treating Ms. Meyer and at least one other patient.

Based on the record as a whole, I would hold that there was evidence to support the jury's determination of causation.[7] Because anything more than a scintilla of evidence is legally sufficient to support the jury finding,[8] I dissent from the majority's reversing and rendering on this ground.

LEE ANN DAUPHINOT
JUSTICE

DELIVERED: April 12, 2007

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[1] The jury also found negligence on the part of Dr. Mosier and assigned 50% proportionate responsibility each to Ethicon and Dr. Mosier.

[2] On appeal, Meyer does not contest the applicability of the doctrine to this case; rather, she argues that the facts of this case do not negate causation when the doctrine is

applied.

[3] Two of Ethicon's issues address Butler's qualifications and the admissibility of his opinions. We have serious reservations about Butler's qualifications, but for the sake of argument we will assume that Butler was qualified to testify and that his opinions were admissible.

[4] Dr. Shires, the surgeon who repaired Meyer's failed anastomosis, also testified that he had no opinion as to what caused the staple line to fail.

[5] *See Rosburg*, 181 Cal. App.3d at 735 n.5 ("Plaintiff in this case failed to establish that any specific defect caused the [breast-implant] deflation; thus, she cannot urge that a more specific warning could have prevented her injury.").

[6] The dissent disagrees with our—and Meyer's—assessment of Dr. Mosier's testimony as unclear and cites a portion of Dr. Mosier's testimony where he said he would have taken a "dear doctor" letter seriously. But his testimony that he would have taken a safety alert seriously is no evidence that he would have discontinued use of the TLC-55. The dissent presumes to know what Dr. Mosier would have done when Dr. Mosier himself said that he could only speculate. Speculation is not evidence. *Joe v. Two Thirty Nine Joint Venture*, 145 S.W.3d 150, 164 (Tex. 2004).

[7] *See Cont'l Coffee Prods. Co. v. Cazarez*, 937 S.W.2d 444, 450 (Tex. 1996); *Leitch v. Hornsby*, 935 S.W.2d 114, 118 (Tex. 1996).

[8] *Cazarez*, 937 S.W.2d at 450; *Leitch*, 935 S.W.2d at 118.