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UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

ANDREW RODRIGUEZ,
Plaintiff-Appellant,

v.

STRYKER CORPORATION, a Michigan Corporation; STRYKER SALES CORPORATION, a Michigan Corporation,
Defendants-Appellees.

No. 11-5335

Appeal from the United States District Court
for the Middle District of Tennessee at Cookeville.
No. 2:08-cv-124—Aleta Arthur Trauger, District Judge.

Argued: April 18, 2012

Decided and Filed: May 21, 2012

Before: GIBBONS and SUTTON, Circuit Judges; DUGGAN, District Judge.[*]

COUNSEL

ARGUED: James T. Blanch, PARSONS BEHLE & LATIMER, Salt Lake City, Utah, for Appellant. Hall R. Marston, SEDGWICK, Los Angeles, California, for Appellees. **ON BRIEF:** James T. Blanch, Richard E. Mrazik, Alan S. Mouritsen, PARSONS BEHLE & LATIMER, Salt Lake City, Utah, for Appellant. Robert M. Connolly, STITES & HARBISON, Louisville, Kentucky, for Appellees.

[*]The Honorable Patrick J. Duggan, United States District Judge for the Eastern District of Michigan, sitting by designation.

OPINION

SUTTON, Circuit Judge. Stryker Corporation and its sales affiliate, Stryker Sales Corporation (together, "Stryker"), make and sell a pain pump, which a doctor prescribed for Andrew Rodriguez after his shoulder surgery. When the pump allegedly damaged the cartilage in Rodriguez's shoulder, he sued the companies, seeking recovery for the injury. The district court granted summary judgment to Stryker. We affirm.

I.

In November 2004, Rodriguez had arthroscopic surgery to treat pain and instability in his shoulder joint. Dr. John Kuhn performed the operation, and at the end of the procedure he implanted a pain-pump catheter in Rodriguez's shoulder. Over the next two days, a Stryker pain pump delivered a regular dose of a local anesthetic, bupivicaine, to the shoulder joint. Rodriguez's condition improved after surgery but worsened over time, and in 2008 he learned he no longer had any cartilage remaining in his shoulder, a condition called chondrolysis.

Rodriguez sued Stryker in 2008, alleging strict liability, negligence and breach of warranty. Stryker moved for summary judgment and to exclude or limit the testimony of Rodriguez's experts on *Daubert* grounds. Even accepting the admissibility of the expert testimony for the sake of argument, the district court concluded that Stryker could not reasonably have known about the risk of chondrolysis in 2004 and thus had no duty to warn of the risk. The court also held that Rodriguez failed as a matter of law to prove causation.

II.

Under Tennessee law, a manufacturer must warn users about non-obvious dangers caused by its product. *Pittman v. Upjohn Co.*, 890 S.W.2d 425, 428–29 (Tenn. 1994); *Evridge v. Am. Honda Motor Co.*, 685 S.W.2d 632, 636 (Tenn. 1985). The duty

to warn extends to known dangers or dangers that a manufacturer "could [have] discover[ed] through the exercise of reasonable care." *Allen v. Upjohn Co.*, No. 833, 1981 WL 649508, at *4 (Tenn. Ct. App. Dec. 30, 1981).

Rodriguez does not claim that Stryker *knew* its pumps could cause chondrolysis. That would not be possible. Even though doctors, including Rodriguez's doctors, had been using pain pumps to provide anesthetics to post-operative joints for years, no reported case of chondrolysis linked to anesthetics appears until 2005—after Rodriguez's November 2004 surgery. Rodriguez claims instead that Stryker *should have known* about the risk. But "the state of scientific and technological knowledge available to the manufacturer . . . at the time the product was placed on the market," Tenn. Code Ann. § 29-28-105(b), *see Allen*, 1981 WL 649508, at *5, defeats this claim as a matter of law.

The articles. Rodriguez submits thirteen articles published at various times during the seventy years before the surgery, which allegedly put Stryker on notice about the danger of using its pain pumps inside a joint. Yet none of the articles draws a connection between pain pumps and chondrolysis, leaving Rodriguez to argue something more inferential: that the studies "document[ ] significant damage to articular cartilage after prolonged exposure to foreign solutions, including bupivicaine." Rodriguez Br. at 32. Even that is a stretch, however, given what the articles say.

A 1933 article shows that injecting rabbit joints with various water and saline solutions produces chronic arthritis. J. Albert Key, *The Production of Chronic Arthritis by the Injection of Weak Acids, Alkalies, Distilled Water, and Salt Solution in Joints*, 15 J. Bone & Joint Surgery 67, 84 (1933). The injections in this study, however, took place over a period of weeks, far longer than the two-day pain pump used here, not to mention that the study did not use bupicivaine (or for that matter humans). *Id*. at 67–68.

Three other articles compare solutions typically used in arthroscopic surgery and recommend the best solution for cartilage. Brian F. Reagan et al., *Irrigating Solutions for Arthroscopy*, 65 J. Bone & Joint Surgery 629–31 (1983); S.K. Bulstra et al., *The Effect In Vitro of Irrigating Solutions on Intact Rat Articular Cartilage*, 76 J. Bone &

Joint Surgery 468–70 (1994); J.S. Jurvelin et al., *Effects of Different Irrigation Liquids and Times on Articular Cartilage*, 10 Arthroscopy 667–72 (1994). But they do not warn against using solutions in the joint space; they recommend only which solution should be used.

Four other articles address the risk of chondrolysis. But they tie the risk to gentian violet (a dye) and chlorhexidine (an antiseptic), not bupivicaine (an anesthetic). Kazuya Tamai et al., *Chondrolysis of the Shoulder Following a "Color Test"-Assisted Rotator Cuff Repair—A Report of 2 Cases*, 68 Acta Orthopaedica Scandinavica 401–02 (1997); Y. Shibata et al., *Chondrolysis of the Glenohumeral Joint Following a Color Test Using Gentian Violet*, 25 International Orthopaedics 401–03 (2001); C.M. Douw et al., *Clinical and Pathological Changes in the Knee After Accidental Chlorhexidine Irrigation During Arthroscopy*, 80 J. Bone & Joint Surgery 437–40 (1997); A.L. van Huyssteen & D.J. Bracey, *Chlorhexidine and Chondrolysis in the Knee*, 81 J. Bone & Joint Surgery 995–96 (1999).

Three other articles address the use of bupivicaine within a joint. But they fail to say that such use is unsafe. John P. Fulkerson & Thomas F. Winters, Jr., *Articular Cartilage Response to Arthroscopic Surgery*, 2 Arthroscopy 184, 186 (1986) (bupivicaine can inhibit cartilage but "it appears that this effect on cartilage is transient"); John W. Jaureguito et al., *The Effects of Morphine on Human Articular Cartilage of the Knee*, 18 Arthroscopy 631, 635 (2002) (combination of morphine and bupivicaine "does not have a deleterious effect on human articular cartilage"); Roberta Nole et al., *Bupivicaine and Saline Effects on Articular Cartilage*, 1 Arthroscopy 123, 126 (1985) ("[b]upivicaine itself seems to be fairly well tolerated by articular cartilage").

Another article describes a patient who developed chondrolysis and says the patient used a pain pump with bupivicaine after surgery. Damon H. Petty, *Glenohumeral Chondrolysis After Shoulder Arthroscopy*, 32 Am. J. Sports Med. 509, 511 (2004). But the article is a series of three case studies, each listing an outcome the authors cannot explain (chondrolysis) and *all* of the factors that *might* have played a role in the outcome. *Id*. at 511, 514. It makes no claim that chondrolysis and pain pumps are

linked, and in two of the case studies the patients developed chondrolysis even though no pain-pump use is mentioned. *Id*. at 514.

A final article says that single intra-articular injections "probably do[ ] not cause permanent alterations in . . . articular cartilage" but that "[r]epeated injections . . . should be approached with caution." J. Neidel et al., *Intra-Articular Injections and Articular Cartilage Metabolism*, 111 Archives of Orthopaedic and Trauma Surgery 237, 240 (1992). The article concludes that "the microtrauma caused by [an] injection," when repeated, plays a role in the permanent damage along with the foreign solution. *Id*. Yet pain pumps do not present that risk—they are designed, indeed, to eliminate it—as they are "[p]lace[d] . . . at the desired location" once in order to deliver continuous doses of anesthetic. R.162-10 at 3. When all is said and done, not one of Rodriguez's thirteen articles shows that medical experts understood in 2004 that infusing a joint with bupivicaine for two days could cause irreversible cartilage damage. Stryker had no duty to understand what the relevant medical literature did not.

Expert report. Rodriguez's expert does not fill this gap. Dr. Stephen Trippel submitted an expert report, claiming that general medical knowledge about articular cartilage, combined with the then-extant scientific literature, should have put Stryker on notice that this pain pump would harm cartilage. "[C]ourts have a duty to inspect the reasoning of qualified scientific experts" in determining whether a case should go to a jury, *Kalamazoo River Study Group v. Rockwell Int'l Corp.*, 171 F.3d 1065, 1072 (6th Cir. 1999); *cf. Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 670 (6th Cir. 2010), including whether an expert's sources support his conclusions, *see Conde v. Velsicol Chem. Corp.*, 24 F.3d 809, 813 (6th Cir. 1994). This last requirement undermines Trippel's report. He relies on several articles published *after* Rodriguez's surgery, which do not speak to what Stryker should have known months or years earlier based on expert knowledge at the time. He also relies on articles published before Rodriguez's surgery, but they are the same thirteen articles discussed above, and none of them supports the conclusion that Stryker reasonably should have known about the risk that its pumps could cause chondrolysis. The thirteen articles, indeed, undermine the expert report because they

show that medical experts did not understand the risks posed to cartilage by pain pumps in 2004, when Rodriguez had his surgery. That presumably is why Dr. Trippel testified in another case that, consistent with these articles, no studies linked chondrolysis to a patient's pain pump prior to 2005:

> Q: And can you identify, Dr. Trippel, in one article where the author has concluded—let's talk about through . . . June 23, 2005—where the author wrote that some patient had experienced an outcome that affected their cartilage and they attributed it to any local anesthetic administered to the patient in any way or manner?
>
> A: Well, . . . the answer to the question is no.

R.116-9 at 3.

Rodriguez submits that the pre-2004 articles, as interpreted by Dr. Trippel, show some knowledge that cartilage could be weakened by lengthy exposure to foreign solutions. Judge Trauger asked and aptly answered the same question in her opinion below:

> While the pre-2004 medical articles raise the general notion that health of (usually animal) cartilage could be weakened by prolonged exposure to certain "foreign elements," it is a bridge way too far to say that Stryker—in the context in which infusion pumps were broadly used and medically accepted without reservation— should have, prior to marketing the pain pump, culled through seven decades of literature, found the sporadic articles raising this concern, ignored all the authority/evidence to the contrary, and then independently concluded that its pain pump could cause chondrolysis, particularly where no one in the medical community connected the destruction of cartilage to the use of pain pumps until after the plaintiff's surgery.

R.183 at 12–13; *see Krumpelbeck v. Breg, Inc.*, 759 F. Supp. 2d 958, 974 (S.D. Ohio 2010) (same).

Rodriguez insists that determining how many inferences to draw based on an expert's opinion "is the jury's prerogative, not the court's." Br. at 33. Yes and no. Yes, it is the jury's prerogative to draw reasonable inferences from the competing evidence presented at trial. But no, juries do not determine whether and when a party presents

sufficient evidence to create a triable issue of fact. Trial and appellate courts must decide whether the inferences a party asks the jury to draw are too speculative to be reasonable. *See Tamraz*, 620 F.3d at 672. "Courts need not submit to the jury negligence cases containing only a spark or glimmer of evidence that requires the finder-of-fact to make a leap of faith to find the defendant liable for the plaintiff's injury." *Morris v. Wal-Mart Stores, Inc.*, 330 F.3d 854, 865 (6th Cir. 2003).

That is just the problem here. Rodriguez asks a jury to find that because there were isolated instances over seventy years when evidence showed that a few foreign solutions caused temporary harm to joint cartilage, Stryker should have known (and warned) that using its pain pump in a joint with bupivicaine would cause permanent damage. On this record, the theory requires two speculative leaps. It requires the inference that evidence of harm resulting from *other* solutions meant that anesthetics would cause the same harm. And it requires the inference that evidence of *transient* harm to joints meant that irreversible cartilage damage was likely. Both are far too conjectural and too many steps removed from the problem that developed. Just because ingesting one type of liquid over a period of time may cause a problem does not mean that ingesting another liquid will cause the same problem. And just because cleaning a wound with rubbing alcohol causes temporary discomfort does not permit the inference that cleaning a wound more than once will produce permanent discomfort. To conclude otherwise would establish a claim for hindsight negligence, not common law negligence.

The 510(k) notification process. Rodriguez claims that Stryker should have known that its pain pump was not safe to use in a joint because the Food and Drug Administration had twice denied permission to market the pump for that use. Yet the FDA's denials say nothing about the safety (or danger) of using Stryker's pump. The FDA gave Stryker permission to market its pump through the 510(k) notification procedure, a streamlined process that determines only whether a medical device is "substantially equivalent" to another approved device already on the market. 21 U.S.C. § 360c(f)(1)(A); *id*. § 360(k); 21 C.F.R. § 807.100. Stryker received permission through the 510(k) process to market its pump with a single indication for use: "to provide

continuous infusion of a local anesthetic directly into the intra-operative site for postoperative pain management." R.162-10 at 2. The FDA twice denied requests, however, to add a specific indication for using the pump in a joint. Rodriguez claims this should have put Stryker on notice that using the pump in a joint was not safe.

Two considerations undo this argument. First, "the 510(k) process is focused on *equivalence*, not safety." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493 (1996). The FDA's action means only that no other device on the market carried that indication for use. It does not mean that the pump was (or might potentially be) dangerous to use in the joint space. The 510(k) process does not comment on safety. *Id.* Second, the indication for use that the FDA *did* approve—using the pump at the "intra-operative site"—covers the use of the pump in a joint. The pain-pump package echoed those instructions, without saying anything more about where to place the pain pump, whether in the joint space or elsewhere. The most Stryker could have concluded from the FDA's actions was that no other pain pump on the market was indicated for use in a joint, and that other pain pumps instead carried a broader indication for use at the site of an operation. None of this information would have given Stryker a hint that its device was unsafe for use in a joint or that it should warn users of that danger.

Duty to test. Rodriguez argues that Stryker breached its duty to test its pain pump by not conducting a study about the effects of using the pump in a joint. This argument collapses into the failure-to-warn claim. A manufacturer has a duty to exercise "ordinary and reasonable care not to expose the public to an unreasonable risk of harm" from its product. *Pittman*, 890 S.W.2d at 428. As it applies to testing, that means the manufacturer must exercise ordinary and reasonable care in testing a product for potential danger. *See Allen*, 1981 WL 649508, at *4. Rodriguez's evidence shows only that in 2004 the medical community knew that some foreign solutions could have a harmful effect on joints, and that the damage could be permanent in the case of gentian violet and chlorhexidine. The articles do not show that local anesthetics like bupivicaine could cause permanent cartilage damage. At most they indicate that bupivicaine might cause temporary, not lasting, cartilage damage, which does not suffice to inform Stryker

it needed to conduct a study determining the long-term effects of using bupivicaine in a joint. The law does not require a company to test for hidden risks that neither it nor the medical community had a reasonable basis to suspect. "A manufacturer is not an insurer of a product that is . . . incapable of causing injury." *Fulton v. Pfizer Hosp. Prods. Group, Inc.*, 872 S.W.2d 908, 912 (Tenn Ct. App. 1993).

Pain-pump marketing. Rodriguez claims that Stryker negligently marketed its pain pump because it knew surgeons were using the pump in joints, and it encouraged them to do so. The first problem with this argument is that Rodriguez overstates it. He points to a guide Stryker published for its sales representatives that encourages "coach[ing] the surgeon on catheter placement." Rodriguez Br. at 47. But the guide also tells salespeople to use the examples of placement listed in the guide, none of which includes the glenohumeral joint space, which is the placement used in Rodriguez's surgery and the one now linked to chondrolysis. The only other evidence of coaching is the deposition of another doctor in another case, who says Stryker representatives told him pain pumps could be used in a joint space. That testimony does not do the trick, however, due to a second problem: it makes no difference that Stryker knew surgeons would use its pump in the joint space or even encouraged them to do so since Rodriguez has failed to show that Stryker knew or should have known that the use was dangerous. The FDA approved Stryker's pain pump for use at the intra-operative site, and none of Rodriguez's evidence indicates that Stryker marketed its pump beyond that approved use.

Strict liability. In rejecting Rodriguez's strict liability claim, the district court invoked comment k to the Restatement (Second) of Torts, which insulates from liability manufacturers of unavoidably unsafe products that are properly prepared and accompanied by an adequate warning. Restatement (Second) of Torts § 402A. Rodriguez does not argue that the district court erred in applying comment k to his claim. His only argument is that comment k does not protect Stryker because, based on his other arguments, the company did not adequately warn about the risks of using its

pain pump in a joint. Because Rodriguez's duty-to-warn arguments fail, this argument necessarily fails as well.

III.

The district court also found causation wanting. Even if Stryker had a duty to warn, it added, Rodriguez failed to show that any breach proximately caused his injury. *See Nye v. Bayer Cropscience, Inc.*, 347 S.W.3d 686, 704–05 (Tenn. 2011). We agree.

In his complaint, Rodriguez alleged that Stryker "failed to provide adequate post-marketing warnings and instructions to physicians and medical providers using the pump." R.1 at 9. To prevail on his failure-to-warn claim, Rodriguez bore the burden of showing that, "had [Stryker given] additional warnings . . . , [he] would not have sustained [his] injur[y]." *King v. Danek Med., Inc.*, 37 S.W.3d 429, 453 (Tenn Ct. App. 2000). In attempting to establish causation, he has provided only the deposition of his surgeon, Dr. Kuhn, and it does not help.

By the time of Rodriguez's surgery, Dr. Kuhn had used pain pumps in shoulder joints after surgeries with many patients—more than one hundred times per year since 1994. He learned to use the pumps early in his career and continued using them in the same way. He could not recall how he learned to use the pumps but agreed that, "however [he] got trained in the use of pain pumps, [he] w[as]n't relying on a sales rep for that training." R.116-14 at 7. Dr. Kuhn does not recall ever speaking to a Stryker sales representative. He knew that other brands of pain pumps existed, but he did not participate in decisions about which brands to buy for the hospital. A nurse would deliver the pump to him in the operating room without any packaging or the instructions for use. Dr. Kuhn could not remember ever reviewing Stryker's pump instructions:

> Q: [A]s you sit here today, do you recall reviewing Stryker's instructions for use?
>
> A: I don't recall it.

Id. at 20. And during his more than ten years using the pumps, he knew of no other patients who had the kind of complications Rodriguez developed:

> Q: And based on the information you gave me, that you have been in practice since 1994, performing shoulder surgeries, approximately 300 to 350 a year, and of those at least up through 2006, about a third to half the time, placing a [pain-pump] catheter in the joint; is that correct?
>
> A: Yes.
>
> Q: And Mr. Rodriguez is the only patient you are aware of that has made a claim of chondrolysis; is that correct?
>
> A: Yes.

Id. at 9. On this record, Rodriguez faces a causation problem: He has no evidence that, even if Stryker had placed the proposed warning in the instructions or given it through a sales representative, the warning would have reached Dr. Kuhn or would have prevented the injury.

Trying to sidestep this problem, Rodriguez adds that Stryker should have warned physicians in two other ways: a "Dear Doctor" letter or a label on the pain pump. The first impediment to these arguments is that Rodriguez's complaint claims only that Stryker should have provided "adequate" warnings, not warnings in these forms tailored to reach the practices of Rodriguez's physician. If these warnings were the only "adequate" ones in this setting, it was Rodriguez's burden to argue that and provide evidence showing it.

The second impediment is that Rodriguez raises the option of a "Dear Doctor" letter or direct label in connection with his FDA arguments, not as a way of establishing causation for the duty-to-warn claim. Rodriguez argues that Stryker should have known that it needed to "revise its instructions or at least circulate a Dear Doctor Letter" when the FDA rejected its requests to approve the pump specifically for use in a joint. Reply Br. at 15. As shown, however, the FDA position did not obligate Stryker to send any such letter. At oral argument, Rodriguez suggested that Stryker could have placed a warning directly onto its pain pump. That argument does not appear in Rodriguez's appellate briefs or his complaint. It does receive a short mention in his trial court briefs to the effect that the pump "lacked a warning—placed on the device itself, so that it would be seen by surgeons in the sterile field—that the FDA had not approved use of

Stryker's pain pump in the intra-articular space." R.152 at 15–16. But once again, even if a party could preserve an argument in this way, the FDA position did not require this type of warning.

The third impediment is that these warnings do not establish causation even on their own terms given the evidence at hand as to both the tort *and* FDA theories. As to the "Dear Doctor" letters, Rodriguez points only to this exchange with Dr. Kuhn:

> Q: A Dear Doctor letter is when a company . . . learn[s] . . . they are now getting adverse reports on a particular, either machine, or the drug, [and] they send out a letter called a Dear Doctor letter to warn the doctors or instruct the doctors of what's happened?
>
> A: Yes
>
> Q: You have had that over the years, have you not?
>
> A: I have seen that for medications, yes.

R.162-3 at 12. This exchange conveys only the unsurprising reality that Dr. Kuhn knew what "Dear Doctor" letters were, not that he received and reviewed them, and most importantly not what he would have done with a "Dear Doctor" letter in this case and not what such a letter would have looked like in this instance.

The same problem applies to Rodriguez's direct-label argument. Rodriguez still must show that a direct label would have caused Dr. Kuhn to change his long-standing pain-pump use, *King*, 37 S.W.3d at 429, and Rodriguez makes no attempt at any such showing. He never asked Dr. Kuhn about the possibility of a warning printed on Stryker's pain pump, what that warning might have said, or whether it would have influenced his decisions about using the pump. The only comment of Dr. Kuhn's that comes remotely close is this:

> Q: If there had ever been any black-box warnings about the dose [of bupivicaine] that you ultimately chose for [Rodriguez], if there had been a warning that it destroy[s] cartilage, it stands to reason you wouldn't have used it, correct?
>
> A: That's correct.

R.162-3 at 68. That comment speaks to bupivicaine, not pain pumps, and says nothing about what kind of pain-pump warning would have influenced Dr. Kuhn. Rodriguez has shown only that "it stands to reason" that a warning about *bupivicaine* would have prevented Dr. Kuhn from using *bupivicaine*. Rodriguez has not presented any evidence that a warning on Stryker's pain pump would have caused Dr. Kuhn not to use the device in Rodriguez's joint space, thus preventing his injury. Rodriguez has failed as a matter of law to establish a triable issue of fact over causation on his failure-to-warn claim.

IV.

For these reasons, we affirm.