In the

United States Court of Appeals

For the Seventh Circuit

No. 16-3957

IN RE: ZIMMER, NEXGEN KNEE IMPLANT PRODUCTS LIABILITY LITIGATION

APPEAL OF: THEODORE F. JOAS and DARLENE A. JOAS

Appeal from the United States District Court
for the Northern District of Illinois, Eastern Division.
No. 13 C 9216 — **Rebecca R. Pallmeyer**, *Judge.*

ARGUED MAY 22, 2017 — DECIDED MARCH 8, 2018

Before FLAUM, EASTERBROOK, and SYKES, *Circuit Judges.*

SYKES, *Circuit Judge.* Theodore Joas underwent a total knee replacement at a Wisconsin hospital and received a Zimmer NexGen Flex knee implant. Within a few years, he began experiencing pain in his new knee. X-rays confirmed that the implant had loosened and required a surgical fix. Joas brought a panoply of claims against Zimmer, Inc., the implant manufacturer. His case was transferred to a multi-district litigation in the Northern District of Illinois, where it was eventually treated as a bellwether case. Applying Wisconsin law, the presiding judge entered summary judgment for Zimmer.

Joas asks us to reinstate a single claim based on a theory of inadequate warning. His appeal raises some unresolved issues in Wisconsin product-liability law—most notably, the application of the "learned intermediary" doctrine, which the Wisconsin Supreme Court has not yet had an opportunity to address. We predict that the state high court would follow the lead of other states and adopt this doctrine. We affirm the judgment.

I. Background

Joas's suit is the second bellwether case in a multidistrict litigation concerning Zimmer NexGen Flex knee implants. Plaintiffs in the litigation allege that they have suffered pain and loss of movement because the NexGen Flex is prone to premature loosening.[1]

In 2008 Joas had knee-replacement surgery at a hospital in Eau Claire, Wisconsin. His surgeon used a Zimmer NexGen Flex implant. At the time Joas worked for Pepsi Bottling Group, and his job required him to lift and carry heavy loads and to squat repeatedly throughout the day. Soon after the surgery he was able to engage in physical therapy, return to work, and participate in recreational activities like hunting and canoeing. By 2011, however, Joas began to feel pain in his new knee. An x-ray and bone scan revealed aseptic loosening of the tibial component of the implant. Translation: the bond between the implant and the shinbone had weakened. He had revision surgery in October 2012.

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[1] The first case resulted in a jury verdict for Zimmer. *See Batty v. Zimmer Inc.*, No. 12-cv-6279, 2015 WL 11142538 (N.D. Ill. Nov. 6, 2015).

In 2013 Joas sued Zimmer alleging that the NexGen Flex design causes premature loosening for total-knee-replacement patients who engage in activities that require a high degree of knee flexibility. He filed his suit in federal court in New Jersey and raised product-liability claims premised on allegations of defective design, manufacture, and warning.[2] (He also alleged misrepresentation and statutory consumer-protection claims, but he abandoned them at summary judgment.) The New Jersey court transferred the case to a multidistrict proceeding then underway in the Northern District of Illinois addressing lawsuits against Zimmer based on its NexGen Flex implant.

The judge designated Joas's case as a bellwether and scheduled a trial. In the meantime Zimmer moved for summary judgment on all claims. Among other things, the manufacturer sought to exclude the testimony of Dr. Joseph Fetto, Joas's expert witness. Dr. Fetto's report indicated that his opinion testimony would be based on a differential etiology methodology, which entailed identifying and ruling out potential causes of the tibial loosening to arrive at the likeliest cause of Joas's injury. Applying Rule 702 of the Federal Rules of Civil Procedure and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the judge excluded Dr. Fetto's testimony as unreliable because he did not have any discernible basis for determining which potential causes of the loosening were reasonable and which were not.

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[2] Joas's wife is also a plaintiff, but her claims are entirely derivative. The New Jersey venue choice was curious. Joas and his wife are citizens of Wisconsin; the surgery was performed there; and Zimmer is a Delaware corporation with its principal place of business in Indiana.

Dr. Fetto was Joas's only expert who would testify that a defect in the knee implant caused his injury. With his expert's testimony excluded, Joas could not prevail on his claims based on defective design or manufacture. The exclusion of Dr. Fetto's testimony also left a causation gap in Joas's claim based on inadequate warning. To the extent that this claim could survive without Dr. Fetto's testimony, the judge rejected it as deficient in other respects and entered summary judgment for Zimmer on all claims.

II. Discussion

Joas limits his appeal to his claim based on defective warning. The claim rests on two theories. Joas argues that Zimmer (1) failed to issue proper warnings directly to him as the recipient of the knee replacement; and (2) failed to issue proper warnings to his surgeon, who implanted the device.

Importantly, Joas does not quarrel with the exclusion of Dr. Fetto's testimony. Rather, he urges us to allow this claim to go forward based on the testimony of Dr. John Dearborn, Zimmer's expert witness. Dr. Dearborn testified in deposition that he would have used two bags of cement to properly bond a knee implant to the patient's shinbone. Joas's surgeon, Dr. Bryan Larson, used only one bag of cement, consistent with his normal practice. Joas maintains that Zimmer had a duty to warn that two bags of cement are needed to achieve a proper bond.

The judge disallowed the claim for two reasons. First, she applied the learned-intermediary doctrine, which (as relevant here) holds that the manufacturer of a medical device has no duty to warn the patient as long as the manufacturer provides adequate warnings to the physician. Second, the judge held that even if Zimmer had a duty to warn the

surgeon, Joas has no evidence of causation because Dr. Larson testified in deposition that he did not read the packaging material Zimmer sent with the NexGen Flex implant. Rather, he testified that he based his surgical technique entirely on his general medical training and his surgical fellowship. So an improved warning, the judge held, would not have made any difference.

To overcome this factual deficit, Joas asked the judge to recognize and apply a legal presumption that the surgeon would have heeded an improved warning had Zimmer provided one. The judge declined to do so, holding that the proposed "heeding presumption" has no support in Wisconsin law.

Both aspects of the failure-to-warn claim raise novel questions under Wisconsin law. We turn first to Joas's claim that Zimmer breached a duty to directly warn *him*. That inquiry requires us to predict whether the Wisconsin Supreme Court would recognize the learned-intermediary doctrine for use in defective-warning cases involving medical devices. We then turn our attention to Joas's argument that Zimmer failed to adequately warn the surgeon.

A. Alleged Failure to Warn the Patient

We begin with the learned-intermediary doctrine, which if applicable defeats Joas's claim that Zimmer had a duty to directly warn *him*. The doctrine holds that the manufacturer of a prescription drug or medical device fulfills its duty to warn of the product's risks by informing the prescribing physician of those risks. Neither the Wisconsin Supreme Court nor the state's intermediate appellate courts have addressed the doctrine.

"When interpreting state law, a federal court's task is to determine how the state's highest court would rule." *Rodas v. Seidlin*, 656 F.3d 610, 626 (7th Cir. 2011). If the state's supreme court has not yet addressed the issue, the federal court should "consult and follow the decisions of intermediate appellate courts" to predict how the supreme court would act given the chance, unless "there is a convincing reason to predict the state's highest court would disagree." *ADT Sec. Servs., Inc. v. Lisle-Woodridge Fire Prot. Dist.*, 672 F.3d 492, 498 (7th Cir. 2012). And absent "any authority from the relevant state courts, [the federal court] ... shall examine the reasoning of courts in other jurisdictions addressing the same issue and applying their own law for whatever guidance about the probable direction of state law they may provide." *Pisciotta v. Old Nat'l Bancorp*, 499 F.3d 629, 635 (7th Cir. 2007).

As we've noted, no Wisconsin appellate court has yet addressed this topic. As best we can tell, just one Wisconsin trial-court decision addresses the learned-intermediary doctrine. In *Straub v. Berg*, the judge applied the doctrine, noting that "courts of numerous other jurisdictions almost universally hold that in the case of prescription drugs, a manufacturer's provision of proper warnings to a prescribing physician will satisfy the manufacturer's duty to warn since the patient cannot obtain the drug except through the physician." No. 00-cv-0117, 2003 WL 26468454, at *6 (Wis. Cir. Ct. Jan. 6, 2003).

A few federal district courts applying Wisconsin law have also invoked the learned-intermediary doctrine. *See Menges v. Depuy Motech, Inc.*, 61 F. Supp. 2d 817, 830 (N.D. Ind. 1999) (holding that since the medical device at issue is "available only upon prescription of a duly licensed physi-

cian, the warning required is not to the general public or to the patient, but to the prescribing doctor") (quotation marks omitted); *Monson v. Acromed Corp.*, No. 96-C-1336, 1999 WL 1133273, at *20 (E.D. Wis. May 12, 1999) (holding in a medical-devices failure-to-warn case that the manufacturer's duty to warn ran only to the treating doctor because he "is in the best position to understand the patient's needs and assess the risks and benefits of a particular course of treatment") (quotation marks omitted); *Lukaszewicz v. Ortho Pharm. Corp.*, 510 F. Supp. 961, 963 (E.D. Wis. 1981) (noting that "the provision of proper warnings to a physician will satisfy the manufacturer's duty to warn since the patient cannot obtain the drug except through the physician").

One district judge has said in passing that "Wisconsin does not apply the learned intermediary doctrine." *Maynard v. Abbott Labs.*, No. 12-C-0939, 2013 WL 695817 (E.D. Wis. Feb. 26, 2013). That statement is incorrect—the Wisconsin Supreme Court has never weighed in on the topic. *Maynard* itself is bereft of any analysis on the point.

The doctrine enjoys broad support in other jurisdictions. As the Texas Supreme Court has recently explained, "[t]he highest courts of at least thirty-five states have adopted some form of the learned intermediary doctrine within the prescription drug products-liability context or cited favorably to its application within this context." *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 158 n.17 (Tex. 2012) (collecting cases). And the intermediate appellate courts in another 13 states have applied the learned-intermediary doctrine or have predicted that their supreme courts would do so. *See Tyree v. Boston Sci. Corp.*, 56 F. Supp. 3d 826, 828 n.3 (S.D. W. Va. 2014) (confirming *Centocor*'s count and collecting other appellate-court decisions).

The justification for adopting the learned-intermediary doctrine in cases involving prescription drugs applies even more forcefully in cases involving surgical implants. As one district judge has explained, patients "could conceivably gain access to prescription drugs without their doctor's assistance, [but] it is not reasonably conceivable that an individual could obtain and implant a device that requires a trained surgeon without the intervention of a physician." *Beale v. Biomet, Inc.*, 492 F. Supp. 2d 1360, 1368 (S.D. Fla. 2007).

In short, there is good reason to think that given the opportunity, the Wisconsin Supreme Court would join the vast majority of state supreme courts and adopt the learned-intermediary doctrine for use in defective-warning cases like this one involving a surgical implant. We predict that the state high court would do so. Accordingly, to the extent that Joas's defective-warning claim is based on Zimmer's duty to warn *him*, it is foreclosed by the learned-intermediary doctrine.

That point aside, summary judgment for Zimmer was proper on this aspect of the claim for a number of additional reasons. To start, although as a general matter a manufacturer owes a duty to warn consumers of dangers associated with the proper use of its product, Joas has not identified any danger that Zimmer should have warned him about. *Strasser v. Transtech Mobile Fleet Serv., Inc.*, 613 N.W.2d 142, 154 (Wis. 2000). He claims in his brief that he thought the implant would last at least 20 years based on some Zimmer marketing materials he read.[3] But as we've noted, he aban-

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[3] The marketing material Joas points to is a pamphlet provided to him by his doctor that he assumed "was probably from Zimmer" but which the

doned his misrepresentation and consumer-protection claims on summary judgment. He cannot resurrect them on appeal by repackaging them as a new iteration of his defective-warning claim.

Summary judgment for Zimmer was also proper on this claim because Joas has no evidence to support causation. "A plaintiff who has established both a duty and a failure to warn must also establish causation by showing that, if properly warned, he or she would have altered behavior and avoided injury." *Kurer v. Parke, Davis & Co.*, 679 N.W.2d 867, 876 (Wis. Ct. App. 2004). Joas argues that if Zimmer had warned him of a risk of early failure, he would have "heeded the warning and been inclined to choose an implant with a known greater longevity."

But Joas didn't select the NexGen Flex implant. Dr. Larson did, and he made his decision based on his own past experience, not on any marketing materials or information provided by Zimmer.

> Q. In the case of Mr. Joas, is it true that you chose the products that you thought would best treat his medical condition?
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> A. Yes.
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> Q. And, again, what did you base your selection of the LPS-Flex and the stemmed tibial component for Mr. Joas on?

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doctor testified was not actually produced by Zimmer but, rather, by the "general academy source down in Eau Claire."

> A. On my experience with it and what it's provided for patients that I've done previous to that particular individual.

Moreover, Joas has not identified another implant that is known to have greater longevity that he would have selected if he had made the choice himself. "Even in the event that a warning is inadequate, proximate cause is not presumed." *Id.* "Absent proof that a more complete or explicit warning would have prevented" his acceptance of the NexGen Flex implant, Joas "cannot establish that [Zimmer's] alleged failure to warn was the proximate cause of [his] injuries." *Id.* Indeed, Joas testified in deposition that even if he had been warned that a certain percentage of these implants might loosen or fail, he still would have gone through with the surgery. The judge was right to award summary judgment to Zimmer on this aspect of Joas's defective-warning claim.

B. Alleged Failure to Warn the Surgeon

Joas also claims that Zimmer failed to issue an adequate warning to his surgeon about the amount of cement needed to properly bond the knee implant. This theory is based entirely on Dr. Dearborn's testimony that he would have used two cement bags during the surgery instead of just one, as Dr. Larson did.[4]

That's not enough to support a defective-warning claim in this context. No evidence supports Joas's contention that it was Zimmer's responsibility to instruct surgeons about the amount of cement they should use in implant surgery. In

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[4] As noted above, Dr. Dearborn was Zimmer's expert witness. Joas's own expert witness testified that there was nothing deficient in the surgeon's technique.

fact, all the record evidence is to the contrary. Dr. Dearborn explained in his expert report that "surgeons are primarily guided in their [implant] technique by the basic medical training received during residency and/or fellowship training." Dr. Larson confirmed as much in his own deposition:

> Q. The technique that you used to implant [the NexGen Flex] products in Mr. Joas in 2008, how'd you learn that technique?
>
> A. From my fellowship training and residency.
>
> Q. And with respect to how to position the components or cement the components, how did you learn that?
>
> A. Again, from the residency and my fellowship training.
>
> Q. Is there any printed material or written material from Zimmer that you relied upon in knowing how to position or implant Mr. Joas's products?
>
> A. No, there is not.
>
> Q. Were you relying exclusively on training and education during your residency and fellowship?
>
> A. That's correct.

In addition, in his expert report, Dr. Dearborn explained that the warnings and instructions Zimmer included with its implant were "reasonable and adequately inform[ed] the relevant healthcare providers" of the foreseeable risks. Surgical cementing techniques and the adequacy of warnings from implant manufacturers are specialized medical

issues and not "within the realm of the ordinary experience of mankind"; expert testimony is required to support a defective-warning claim premised on this theory. *State v. Kandutsch*, 799 N.W.2d 865, 872 (Wis. 2011) (quotation marks omitted). Joas has none.

Beyond the lack of expert support for this theory, no evidence suggests that Dr. Larson would have followed an improved instruction on cementing techniques had Zimmer provided one. Joas argued at the summary-judgment hearing that the judge should allow this claim to go forward based on a "heeding presumption," which permits the factfinder to presume, in the absence of proof, that a proper warning would have been read and heeded. Here again, the state appellate courts have not addressed this doctrine. We seriously doubt that they would adopt it in this context.

To the contrary, as we've already noted, the state court of appeals has recently held that "[a] plaintiff who has established both a duty and a failure to warn must also establish causation by showing that, if properly warned, he or she would have altered behavior and avoided injury." *Kurer*, 679 N.W.2d at 876. The plaintiff in that case failed to show that the relevant actor "would have heeded a different warning," so the court upheld a summary judgment for the defendant. *Id.* at 880.

Joas relies on *Tanner v. Shoupe*, an earlier failure-to-warn case about an exploding car battery. 596 N.W.2d 805 (Wis. Ct. App. 1999). There the defendant argued that additional warnings would have been useless because Tanner, the plaintiff, testified that he did not read any warnings on the battery. But the case turned on whether an improved warning would have been read and heeded by an *earlier* user. The court determined that "[i]f the battery had contained a

warning against pounding on the vent caps, a fact-finder could 'reasonably assume that it [would have been] read and heeded' *by the users prior to Tanner*." *Id.* at 818 (emphasis added) (quoting RESTATEMENT (SECOND) OF TORTS § 492A cmt. j (AM. LAW INST. 1965)).

By its own terms, then, *Tanner* does not apply to an actor who has "admitted he did not read the warnings" himself. *Id.*; *see also Forst v. SmithKline Beecham Corp.*, 602 F. Supp. 2d 960, 970 & n.4 (E.D. Wis. 2009) (applying *Kurer* instead of *Tanner* in a case involving prescription-drug warnings because of its "analogous facts"). *Kurer*, not *Tanner*, controls here.

Dr. Larson testified that he did not read the instructions that accompanied the knee implant. So even if Joas could establish that Zimmer breached a duty to warn the surgeon, summary judgment was appropriate because no evidence shows that "if properly warned, [Dr. Larson] would have altered [his] behavior and avoided injury." *Kurer*, 679 N.W.2d at 876.

As a fallback position, Joas asks us to certify the questions of the learned-intermediary doctrine and the heeding presumption to the Wisconsin Supreme Court. We have no need to take that step. Certification is appropriate if we are "genuinely uncertain about a question of state law that is vital to a correct disposition of the case." *Cleary v. Philip Morris Inc.*, 656 F.3d 511, 520 (7th Cir. 2011) (quotation marks omitted). No genuine uncertainty exists here.

AFFIRMED.