Defendants Beware: Did the Sixth Circuit Just Make Prescriber Testimony Irrelevant in Failure to Warn Cases?

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I. WHY IT MADE THE LIST

It is axiomatic that a plaintiff bears the burden of proof on each element of her claim. In pharmaceutical and medical device failure to warn claims, this means the plaintiff must prove that 1) the product instructions were inadequate in some regard; and 2) had the instructions contained an alternative adequate warning, the prescribing physician would have made a different treatment decision. In nearly every case, the latter element requires affirmative testimony from the prescribing physician.

In *Thacker v. Ethicon, Inc.*, however, the Sixth Circuit ignored this longstanding framework, resolving ambiguities in the prescribing doctor's testimony in favor of the plaintiff and allowing plaintiff to defeat summary judgment on the basis of the plaintiff's expert opinion that a reasonable doctor would not have made the same decision if presented with the precise warnings at issue, despite prescriber testimony to the contrary.[1] There, the plaintiff sued the manufacturers of two different vaginal mesh devices, alleging that they caused a potpourri of injuries generally attributable to either (or both) devices. Despite testimony from the prescribing physician that, even knowing what he knows today, he believes the devices were "safe and effective treatments," the Sixth Circuit overturned the lower court's grant of summary judgment. The Sixth Circuit did not do so because the plaintiff pointed to affirmative prescriber testimony that the doctor would have made a different decision had the product instructions contained alternative warnings. Rather, the Sixth Circuit found that in the absence of testimony on that exact question, a jury could conclude from circumstantial evidence (i.e., the plaintiff's expert) that he would have acted differently.

The Sixth Circuit's decision contradicts the learned intermediary doctrine, suggesting (incorrectly) that "courts have struggled to pinpoint what kinds of evidence the plaintiff can or must use to support proximate causation at the summary judgment stage."[2] Not so. Healthcare providers are considered learned intermediaries who know how to read, interpret, and, when appropriate, disregard risk information contained in

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1 47 F.4th 451 (6th Cir. 2022).

2 *Id.* at 460.

a wide variety of available sources. In other words, healthcare providers make independent medical decisions on a case-by-case basis, and it is their recommendation—not the manufacturer's—that the patient relies on.[3] Accordingly, courts routinely apply a subjective standard, requiring plaintiffs to present testimony from the prescribing physician *who treated the plaintiff* that he or she would not have prescribed the product had it contained an adequate warning. If a plaintiff cannot produce clear testimony on this point, she cannot get to trial.

By allowing the plaintiff to defeat summary judgment through expert testimony of what a "reasonable physician would do," however, the Sixth Circuit adopted an objective standard whereby deficiencies in the prescriber's testimony inure to the benefit of the plaintiff and plaintiffs can get to trial without sufficient evidence to meet their ultimate burden of proof.

II. DISCUSSION

A. The Facts

This case stems from a 2009 surgery involving two medical devices: the TVT-Secur and the Prolift. The TVT-Secur is a mesh sling introduced in the late 1990's to treat stress urinary incontinence (SUI), the involuntary leakage of urine during physical activity such as coughing, laughing, or exercise.[4] The Prolift was launched several years later to treat pelvic organ prolapse (POP), a condition where weakened muscles in the pelvis cause organs to sag or drop into the vagina.[5] Like the TVT-Secur, the Prolift uses Prolene mesh.

Plaintiff, a 60-year-old woman, was diagnosed with POP and SUI and was surgically implanted with both devices. After surgery, however, plaintiff's symptoms worsened and she attempted to have the devices removed.[6] She was subsequently diagnosed with "debilitating pelvic pain due to vaginal mesh, severe dyspareunia, urinary frequency, and urinary dysfunction," which she alleged was caused by the TVT-Secur and Prolift.[7]

The plaintiff brought suit against the manufacturer of the devices, Ethicon, Inc., and its parent company Johnson & Johnson, in the Eastern District of Kentucky, alleging strict liability failure to warn and design defect under the Kentucky Product Liability Act (Ky. Rev. Stat. § 411.300) and negligence.[8] Her case was transferred to a multidistrict litigation in West Virginia, where it lingered for several years until it was eventually remanded back to the Eastern District of Kentucky.

Following remand, defendants filed a motion for summary judgment against each of plaintiff's claims. As to the failure to warn claims, defendants argued that plaintiff could not establish proximate causation because: 1) the prescribing doctor did not rely on the Information for Use (IFU) in making treatment decisions;[9] 2) the prescribing

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3 *See* Larkin v. Pfizer, Inc., 153 S.W.3d 758, 763 (2004).

4 *Id.* at 455.

5 *Id.* at 455–56.

6 *Id.* at 456.

7 *Id.*

8 *Id.* at 457.

9 Thacker v. Ethicon, Inc., 571 F. Supp. 3d 691, 697 (E.D. Ky. 2021).

doctor was independently aware of the risks;[10] and 3) even if the doctor had read the IFU, "Plaintiff cannot establish that additional warnings would have altered [the doctor's] treatment decisions."[11]

B. Analysis and Holding

1. District Court

The district court agreed with defendants.

Although the district court found that there was a disputed fact as to whether the physician had relied on the IFU—he testified at deposition that he "did not review the IFU with [plaintiff] as part of her risk analysis" but that he '"probably' reviewed and read the IFUs when training"—it held that it was undisputed that he would not have made a different treatment decision even if the IFU had contained additional warnings.[12] Here, defendants presented affirmative deposition testimony that the physician would not have made a different treatment decision.[13] Plaintiff offered no contrary testimony, but rather argued that she could rely on circumstantial evidence such as her expert's opinion.[14]

The district court held that plaintiffs' expert could not overcome affirmative doctor testimony. "[W]hen the defendant does present affirmative testamentary evidence that the doctor would not have changed his course of action with the additional warning, the plaintiff must present evidence to the contrary."[15] The district court accordingly granted defendants' motion for summary judgment.

2. The Sixth Circuit

Plaintiff appealed and the Sixth Circuit reversed and remanded.[16]

Because the parties did not dispute whether the IFU contained the relevant warnings, the Sixth Circuit's analysis centered on whether the prescribing physician would have used the same medical devices had the IFU contained different warnings.[17] The doctor testified at deposition that he "felt like that was certainly the best options [sic] for her circumstances," and that "even 'with the knowledge [he] ha[d] at the time of his deposition, he still believed that the Pelvic Mesh Devices 'were safe and effective treatments for . . . SUI and POP in women' back in 2009.'"[18]

Defendants maintained that only "testimony from the treating physician" could determine whether the doctor would have acted differently.[19] Plaintiff countered that because Kentucky's "substantial factor test" permits reliance on circumstantial evidence generally, she could satisfy her burden through expert testimony that no

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[10] *Id.* at 699.

[11] *Id.*

[12] 571 F. Supp. 3d 697–99.

[13] *Id.* at 702.

[14] *Id.* at 699.

[15] *Id.* at 702.

[16] Thacker v. Ethicon, Inc., 47 F.4th 451 (6th Cir. 2022).

[17] *Id.* at 460.

[18] *Id.* at 462.

[19] *Id.* at 461.

reasonable physician would have used the devices with adequate warnings.[20] The Sixth Circuit agreed with plaintiff.

Specifically, the Sixth Circuit found that the prescribing doctor's testimony was ambiguous because he did not explain what exact new information he had learned and had not testified specifically that "he would stand by his recommendation *had he received a complete and accurate IFU*."[21] Moreover, because the doctor had also testified that certain risk information would have "affected his risk-benefit analysis," the Sixth Circuit concluded that it was left with, at most, "a handful of arguably contradictory statements."[22] Accordingly, a "jury could . . . choose to believe that" no reasonable doctor would have implanted the plaintiff with the devices had the IFU contained adequate warnings on the basis of the expert's opinion. "In sum, the plaintiff must simply provide 'some evidence from which a jury might conclude that an adequate warning would have altered the conduct that led to the injury.'"[23]

III. THE IMPACT

In traditional product liability failure to warn cases, the plaintiff bears the burden of proving that the defendant's failure to warn the plaintiff of some risk caused the plaintiff's injury. Like nearly every other state, however, Kentucky recognizes the learned intermediary doctrine, which relieves the manufacturer of its duty to warn the patient so long as it provides an adequate warning to the prescribing physician.

The Sixth Circuit's analysis got this wrong in two respects. First, it framed the question as: "(1) did the treating physician rely on the relevant warnings (i.e., the IFUs), and (2) would the evidence allow a jury to conclude that, had the manufacturer given a proper warning, *the plaintiff* likely would have followed a different course of treatment (i.e., would not have used the medical device)."[24] Indeed, although not the focus of the opinion, the Sixth Circuit went on to suggest that a plaintiff could defeat summary judgment by showing evidence that "the *plaintiff* would not have consented to, or elected to proceed with, the treatment.[25] Under the learned intermediary doctrine, however, the question is not about what the *plaintiff* would do, but rather whether the *prescribing doctor* would have acted differently "regardless of how or if the physician warns the patient."[26]

Second, the Sixth Circuit's decision to let this case proceed in the absence of affirmative prescriber testimony that he would not have used the medical devices in the face of different warnings essentially erased plaintiff's burden of proof. Although the prescribing doctor's testimony was not a model of clarity, the plaintiff assuredly did not elicit the type of affirmative prescriber testimony that usually defeats summary judgment. Here, the prescriber testified generally that had the defendants "disclosed certain risks, that additional information would have impacted the risk-benefit

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[20] *Id.* at 462.

[21] *Id.*

[22] *Id.*

[23] *Id.* at 461 (quoting Clark v. Danek Med., Inc., 1999 WL 613316, at *6 (W.D. Ky. Mar. 29, 1999).

[24] 47 F.4th at 460 (emphasis added).

[25] *Id.* at 461 (emphasis added).

[26] Larkin v. Pfizer, Inc., 153 S.W. 3d 758, 765 (Ky. 2004).

assessment for [plaintiff's] treatment plan."[27] That is a far cry from testifying that he would not have used the devices, particularly when he also testified that "even with the knowledge he had at the time of his deposition," he "*continued to believe that the TVT-Secur and Prolift were safe and effective treatment options*" for plaintiff.[28]

The Sixth Circuit further faulted defendants for failing to present the doctor with "every warning that [plaintiff] says should have been included in the IFUs." Because he had not been asked the precise question at deposition, plaintiff was given the benefit of the doubt and could point to her expert's opinion to fill the gap—i.e., the Sixth Circuit employed an objective standard about what a theoretical reasonable physician would do in order to let the plaintiff proceed.

Defendants might be left scratching their heads. At first glance, the Sixth Circuit's decision would appear to open the flood gates, allowing plaintiffs to get past clear prescriber testimony without any constraints on the type of evidence that they can use to defeat summary judgment. Taken to its limits, this would make it nearly impossible for a defendant to win at summary judgment. For example, could a plaintiff now overcome unequivocal prescriber testimony that, even with plaintiffs' exact proposed warning, she would have made the exact same treatment decision simply by pointing to an expert's opinion or the plaintiff's own testimony? We think not.

First, this appears to be a case of a federal court getting out ahead of state courts. The Sixth Circuit suggested that there is some growing controversy over how plaintiffs can satisfy their burden of proof in the context of the learned intermediary, relying on another federal court in the Eastern District of Kentucky—*Corder v. Ethicon, Inc.*—for the proposition that prescriber testimony is not necessary.[29] The learned intermediary doctrine has been employed for decades, however, to appropriately balance a manufacturer's duty to warn with the well-established reality that doctors gather information from a variety of sources and are trained in how to make risk benefit analyses for their patients. That is why courts consistently look to the prescribing doctor's testimony to answer these critical questions. There is no reason to think the Kentucky Supreme Court won't do the same.

Second, we think this case will ultimately be limited to its facts. The plaintiff in *Thacker* successfully exploited the ambiguity in the prescriber's testimony, which allowed the court to conclude that a jury might disregard certain statements in favor of others. Indeed, the Sixth Circuit was careful to point out that the prescribing doctor's testimony was "not as strong as Ethicon suggests."[30] Had that ambiguity not existed, we aren't so sure the Sixth Circuit would have reached the same result.

In the meantime, defendants should be mindful when taking a physician's deposition and make sure they walk out of each prescriber's deposition with a clear record of how that doctor would have acted with plaintiff's alternative warnings.

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[27] 47 F.4th at 457.

[28] *Id.* (emphasis added).

[29] 473 F.Supp.3d 749 (E.D. Ken. 2020). In that case, the district court allowed the plaintiff to move forward on a failure to warn claim based on the plaintiff's (who was also a registered nurse) own testimony.

[30] 47 F.4th at 462. Likewise, we doubt the district court in *Corder* would have reached the same conclusion had the prescribing doctor provided clear testimony. In that case, *neither* plaintiff *nor* defendant deposed the prescribing physician, creating a complete vacuum of prescriber testimony. 473 F.Supp.3d at 578–59.