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UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

CONNIE J. THACKER,

Plaintiff-Appellant,

v.

ETHICON, INC.; JOHNSON & JOHNSON,

Defendants-Appellees.

No. 21-6193

Appeal from the United States District Court for the Eastern District of Kentucky at Lexington.
No. 5:20-cv-00050—Joseph M. Hood, District Judge.

Argued: June 9, 2022

Decided and Filed: August 26, 2022

Before: CLAY, ROGERS, and KETHLEDGE, Circuit Judges.

COUNSEL

ARGUED: G. Sean Jez, FLEMING, NOLEN & JEZ, LLP, Houston, Texas, for Appellant. Amy M. Pepke, BUTLER SNOW LLP, Memphis, Tennessee, for Appellees. **ON BRIEF:** G. Sean Jez, Gregory D. Brown, Sylvia Davidow, FLEMING, NOLEN & JEZ, LLP, Houston, Texas, for Appellant. Amy M. Pepke, Susanna M. Moldoveanu, BUTLER SNOW LLP, Memphis, Tennessee, Charles A. Byrd, BUTLER SNOW LLP, Ridgeland, Mississippi, for Appellees.

OPINION

CLAY, Circuit Judge. Plaintiff Connie Thacker sued Defendants Ethicon Inc. and its parent company Johnson & Johnson (collectively "Ethicon") alleging that two medical devices that Ethicon manufactured caused Thacker to suffer several injuries. She brought strict liability

and negligence claims under the Kentucky Product Liability Act ("KPLA") alleging design defect and failure to warn. *See* Ky. Rev. Stat. § 411.300–411.340. After the close of discovery, Ethicon moved for summary judgment. The district court granted Ethicon's motion for summary judgment on Thacker's KPLA claims. *See Thacker v. Ethicon, Inc.*, 571 F. Supp. 3d 691, 695 (E.D. Ky. 2021). For the reasons set forth below, we **REVERSE** the district court's order and **REMAND** for further proceedings.

I. BACKGROUND

A. Factual Background

1. Ethicon's Pelvic Mesh Devices

This litigation involves two medical devices (the "Pelvic Mesh Devices") manufactured by Ethicon. The first is a mesh sling called TVT-Secur. Ethicon introduced the TVT line of devices in 1998. It developed the TVT-Secur to treat stress urinary incontinence ("SUI"). SUI "is the involuntary leakage of urine during moments of physical activity that increases abdominal pressure, such as coughing, sneezing, laughing, or exercise." (Rosenzweig General Rep., R. 225-9, Page ID #10597.) Ethicon launched the second device, a posterior mesh called Prolift, in March 2005. Prolift was designed to treat pelvic organ prolapse ("POP"). POP "is a condition in which one or more of the female pelvic organs (bladder, rectum, uterus, and/or intestines) drop into the vagina to varying degrees . . . to form a bulge or fullness in the vagina." (Elliot Rep., R. 225-12, Page ID #12228.) Both devices must be surgically implanted into a woman's pelvic walls. When Ethicon distributed the devices, it included a packet of Instructions for Use ("IFU") that gave various warnings and disclosures about the devices.

Both devices use a type of mesh called Prolene. Prolene mesh is made of a material called polypropylene. It was developed in 1974 for use in hernia repairs. Prolene is considered a "small pore, heavyweight mesh[]." (Rosenzweig General Rep., R. 225-9, Page ID #10616.) Eventually, Ethicon stopped using Prolene mesh for hernia repairs, but it continued to use it in its Pelvic Mesh Devices. For the hernia repairs, Ethicon switched to a "large pore, lighter weight mesh[]" called Ultrapro, which was shown to "minimize the complications seen with heavyweight meshes like the Prolene" found in the Pelvic Mesh Devices. (*Id.* at Page ID

#10606, #10616.) Lighter weight meshes with larger pores were known to be a "superior mesh design to prevent" certain severe side effects associated with smaller pore meshes like Prolene. (*Id.* at Page ID #10623–24.) Ultrapro also contained less polypropylene than the Prolene mesh used in TVT-Secur and Prolift. Over the years, studies have shown that using polypropylene mesh in a permanent implant in a woman's pelvic walls can cause additional side effects "because of the chemical composition and structure of the mesh." (*Id.* at Page ID #10606–07.)

2. Thacker's Medical History and Treatment

Plaintiff Connie Thacker is approximately 60 years old. In early 2009, Thacker began seeing a board-certified obstetrician-gynecologist named Dr. Michael Guiler. She reported symptoms including pelvic pressure, discomfort during intercourse, and frequent and urgent urination (particularly at night). Dr. Guiler diagnosed her with rectocele[1] (a type of POP) and mild SUI. He recommended surgery to implant the TVT-Secur to treat Thacker's SUI and Prolift to treat her rectocele. Dr. Guiler told Thacker that the devices were "something new" and that they were the "gold standard" and a "good product." (Thacker Dep., R. 159-4, Page ID #2891.) On May 8, 2009, Dr. Guiler surgically implanted both devices. Before the surgery, Thacker reviewed and signed an informed consent form. The form listed several risks of surgery including: "infections and/or erosions of the mesh" which could require additional follow-up surgeries; "urinary retention" meaning "the inability to empty the bladder fully;" "[p]ainful intercourse and vaginal shortening," although this side effect was said to be "uncommon" and was rarely permanent; and treatment failure (meaning continued POP and SUI). (Informed Consent Form, R. 225-8, Page ID #10591.)

After the surgery, Thacker's incontinence worsened, and she suffered from shooting pain in her groin area and severe abdominal swelling and bloating. In 2010, Thacker started experiencing severe and unbearable pain during intercourse (known as dyspareunia). Thacker reported these problems to Dr. Guiler in a 2012 follow-up appointment, and she also told her primary physician and a therapist whom she was seeing at the time. Her primary physician sent her to a specialist, who examined her and told her that some of the mesh from the implanted

[1]Rectocele is "a condition that occurs when the rectal tissues bulge into the vaginal cavity due to weakened pelvic floor muscles." (Def. Statement of Material Facts ("SMF"), R. 159-10, Page ID #3077.)

Pelvic Mesh Devices "was all bunched up on the left side." (Thacker Dep., R. 159-4, Page ID #2897.) The specialist sent her to Dr. Marie Fidela Paraiso at the Cleveland Clinic. Dr. Paraiso diagnosed Thacker with "[d]ebilitating pelvic pain due to vaginal mesh, severe dyspareunia, urinary frequency, and urinary dysfunction." (Rosenzweig Specific Rep., R. 225-4, Page ID #10421.) On September 27, 2012, Dr. Paraiso revised Thacker's TVT-Secur sling and removed a portion of the Prolift device. Without the Prolift, Thacker risked recurrent POP, so Dr. Paraiso performed a different procedure to correct Thacker's rectocele. Thacker reported that her pain and side effects from the Pelvic Mesh Devices worsened after the 2012 surgery. Over the next several years, Thacker continued to report severe dyspareunia, pelvic pressure, and urinary and fecal incontinence to her primary physician. Sometime in 2016, she discovered a piece of the mesh from one of the devices in her urine.

On January 27, 2019, Thacker began seeing Dr. Dionysios Veronikis, who specializes in female pelvic medicine and reconstructive surgery. Dr. Veronikis recommended surgery to remove the remaining mesh arms of both the TVT-Secur and Prolift devices. He operated on Thacker on March 1, 2019, but he was only able to locate and remove the TVT-Secur. He was unable to locate and remove the mesh arms of the Prolift device. Thacker said that her pelvic pain decreased after this surgery, but she was still in pain. She continued to struggle with urinary and fecal incontinence. All said, Thacker claims that the 2009 surgical implantation of the Pelvic Mesh Devices caused her several injuries including:

> Mesh erosion into pelvic floor muscles, pelvic pain, suprapubic pain, vaginal pain, dyspareunia, recurrent urinary tract infections, voiding [urinary] dysfunction, incomplete bladder emptying, mixed urinary incontinence, bowel dysfunction, rectal pain, levator [rectal] spasm[,] and leg pain.

(Rosenzweig Dep., R. 225-3, Page ID #10365.)

3. Dr. Guiler's Deposition Testimony

Dr. Guiler was deposed more than eleven years after Thacker's surgery. While most of his deposition gave details about Thacker's surgery, he was also asked about his experience with Ethicon's Pelvic Mesh Devices. By May 2009, he had performed about 300 surgeries using the TVT-Secur and 75 to 100 surgeries using the Prolift. Before surgically implanting those devices

into Thacker, Dr. Guiler did a risk-benefit analysis and concluded that the devices were the best option for treating her SUI and POP.

Dr. Guiler had learned about the devices through his education, training, and experience; his personal familiarity with the devices; medical journals and conferences; the IFUs; and input from other physicians who were doing similar procedures. He testified that he would expect Ethicon to disclose the severity and probability of certain complications in the IFUs. Had Ethicon disclosed certain risks, that additional information would have impacted his risk-benefit assessment for Thacker's treatment plan. However, he said that he continued to believe that the TVT-Secur and Prolift were safe and effective treatment options back in 2009, even with the knowledge he had at the time of his deposition. He did not explain what he had since learned about the Pelvic Mesh Devices in the years after Thacker's surgery.

4. Expert Witness Reports and Testimony

The summary judgment briefing included expert reports from two of Plaintiff's witnesses: Dr. Bruce Rosenzweig and Dr. Daniel Elliot. Dr. Rosenzweig submitted two expert reports, one that he created for Thacker's case (the "specific report") and one that he produced for the multidistrict litigation ("MDL") related to Ethicon's Pelvic Mesh Devices (the "general report"). In his specific report, Dr. Rosenzweig opined on both TVT-Secur and Prolift and offered several conclusions. He opined that: (1) the devices were defectively designed because the Prolene mesh in both devices created a high risk of severe and permanent injuries; (2) Ethicon could have used a feasible alternative design by using Ultrapro instead of Prolene mesh; (3) the devices' IFUs did not adequately disclose the risks of Prolene mesh; (4) failure to disclose these risks caused Thacker's injuries. His specific report incorporated the findings from his general report, which was about TVT-Secur, and the findings in Dr. Elliot's report, which was about Prolift. Dr. Elliot's expert report, though limited to the Prolift device, similarly concluded that the device was defective because, *inter alia*, the Prolene mesh would "degrade, fragment, and elongate in some patients" leading to "permanent mesh based dyspareunia" and "permanent pelvic pain." (Elliot Rep., R. 225-12, Page ID #11278.) Dr. Elliot also opined that Ethicon "fail[ed] to appropriately warn patients and healthcare providers of the range, severity and magnitude of the risks and complications" of the Prolift device. (*Id.*)

B. Procedural Background

Thacker filed suit in the Eastern District of Kentucky on July 10, 2012. Her amended short form complaint asserted four KPLA claims against Ethicon: strict liability failure to warn, strict liability design defect, negligence, and gross negligence.[2] *See* Ky. Rev. Stat. § 411.320. Pursuant to 28 U.S.C. § 1407, the district court transferred the case to the Southern District of West Virginia as part of the ongoing MDL over the Pelvic Mesh Devices. *See In re Ethicon, Inc. Pelvic Repair Sys. Products Liability Litig.*, No. 12-MD-02327 (S.D.W. Va.). But Thacker's case lingered on the MDL's inactive docket for some time.[3] As the rest of the MDL wound up, the MDL court remanded Thacker's case back to the Eastern District of Kentucky on February 10, 2020. The parties then proceeded with case-specific discovery.

After discovery closed, the parties filed a flurry of motions. Collectively, they filed roughly fifty motions in limine and motions to exclude. In two of these motions, Ethicon asked the district court to exclude Dr. Rosenzweig's and Dr. Elliot's opinions. Ethicon argued that Thacker failed to properly designate Dr. Rosenzweig as a general causation expert and that his opinions were inadmissible under *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993). Ethicon also asked the district court to prevent Dr. Rosenzweig from relying on Dr. Elliot's expert report because Thacker had not designated Dr. Elliot as an expert in this case, nor did she produce his expert report during discovery.

Amongst the avalanche of evidentiary motions, Ethicon also moved for summary judgment on all of Thacker's claims. Thacker opposed summary judgment on her four KPLA claims. The district court granted Ethicon's motion for summary judgment as to each claim. *See Thacker*, 571 F. Supp. 3d at 695. *First*, it found that Thacker's failure to warn claim failed because she had not pointed to any facts showing that any inadequacy in the IFUs proximately caused her injuries. *Id.* at 696–702. *Second*, it held that the design defect claim failed because

[2]The short form complaint also included several common law tort claims including fraud, unjust enrichment, negligent infliction of emotional distress, and breach of warranty. Thacker voluntarily dismissed these claims, and they are not at issue in this appeal.

[3]Thacker's case ended up on the inactive docket after the parties informed the MDL court that they had reached a settlement agreement. But the parties apparently never reached a final agreement, and thus never moved to dismiss the case.

Thacker had not produced sufficient evidence showing that there was a feasible alternative design for the Pelvic Mesh Devices. *Id.* at 702–07. *Finally*, it found that her claims for negligence and gross negligence failed because the two elements that Thacker failed to prove as to her strict liability claims were also elements of the related negligence and gross negligence claims. *Id.* at 702–08. Therefore, Thacker's inability to show proximate causation (for failure to warn) and a feasible alternative design (for design defect) doomed both her strict liability claims and her negligence claims. *See id.* Notably, the district court refused to consider any arguments made in the parties' outstanding evidentiary motions. *Id.* at 708. Rather, Ethicon was "entitled to summary judgment *even if* all [of its] motions to exclude [were] denied and all expert testimony [was] permitted." *Id.* (emphasis added). There was therefore "no need to address the merits of [those evidentiary] motions." *Id.* Thacker timely appealed.

II. DISCUSSION

A. Standard of Review

"We review the district court's grant of summary judgment *de novo*." *Kirilenko-Ison v. Bd. of Edu. of Danville Indep. Schs.*, 974 F.3d 652, 660 (6th Cir. 2020) (quoting *George v. Youngstown State Univ.*, 966 F.3d 446, 458 (6th Cir. 2020)). Summary judgment is proper "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "A dispute of a material fact is genuine so long as 'the evidence is such that a reasonable jury could return a verdict for the non-moving party.'" *Kirilenko-Ison*, 974 F.3d at 660 (quoting *Jackson v. VHS Detroit Receiving Hosp., Inc.*, 814 F.3d 769, 775 (6th Cir. 2016)).

"When evaluating a motion for summary judgment, this Court views the evidence in the light most favorable to the party opposing the motion." *Id.* (citing *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986)). "This includes drawing 'all justifiable inferences' in the nonmoving party's favor." *Id.* (quoting *George*, 966 F.3d at 458). Moreover, "[i]n reviewing a summary judgment motion, credibility judgments and weighing of the evidence are prohibited." *Id.* (quoting *Biegas v. Quickway Carriers, Inc.*, 573 F.3d 365, 374 (6th Cir. 2009)). When summary judgment turns largely on factual issues found in an expert report or

opinion, then those "[e]xpert reports must include 'how' and 'why' the expert reached a particular result, not merely the expert's conclusory opinions." *Automated Solutions Corp. v. Paragon Data Sys., Inc.*, 756 F.3d 504, 521 (6th Cir. 2014) (quoting *R.C. Olmstead, Inc. v. CU Interface, LLC*, 606 F.3d 262, 271 (6th Cir. 2010)).

B. Analysis

The KPLA "defines a 'product liability action' as 'any action brought for or on account of personal injury, death or property damage caused by or resulting from the manufacture, construction, design, formulation, . . . warning, instructing, marketing, advertising, packaging or labeling of any product.'" *Smith v. Wyeth, Inc.*, 657 F.3d 420, 423 (6th Cir. 2011) (quoting Ky. Rev. Stat. § 411.300(1) (2010)). The KPLA applies to all product liability claims whether the claim is based on a theory of strict liability or negligence. *Monsanto Co. v. Reed*, 950 S.W.2d 811, 814 (Ky. 1997). Thacker brought claims under both of these theories.

1. Strict Liability Claims

The KPLA adopts the strict liability standards set forth in Section 402A of the Restatement (Second) of Torts (1965). *Morales v. Am. Honda Motor Co.*, 151 F.3d 500, 506 (6th Cir. 1998) (citing *Dealers Transp. Co. v. Battery Distrib. Co.*, 402 S.W.2d 441 (Ky. 1965)). To make out a strict liability claim, the plaintiff must establish that the product was "in a defective condition unreasonably dangerous to the user." *Radcliff Homes, Inc. v. Jackson*, 766 S.W.2d 63, 68 (Ky. Ct. App. 1989) (citing Restatement (Second) of Torts, § 402A (1965)). A product can be defective "in a number of ways, including defective design, manufacturing defects, and a failure to warn." *CertainTeed Corp. v. Dexter*, 330 S.W.3d 64, 79 (Ky. 2010) (citing *Clark v. Hauck Mfg. Co.*, 910 S.W.2d 247, 250 (Ky. 1995), *overruled on other grounds by Martin v. Ohio Cnty. Hosp. Corp.*, 295 S.W.3d 104 (Ky. 2009)). Thacker brought claims under two of these theories: failure to warn and design defect.

a. *Failure to Warn*

The district court erred in granting Ethicon's motion for summary judgment on Thacker's failure to warn claim. In a failure to warn case, "liability for a manufacturer follows only if it knew or should have known of the inherent dangerousness of the product and failed to

'accompany . . . it with the quantum of warning which would be calculated to adequately guard against the inherent danger.'" *CertainTeed Corp.*, 330 S.W.3d at 79 (quoting *Post v. Am. Cleaning Equip. Corp.*, 437 S.W.2d 516, 520 (Ky. 1968)). Additionally, the plaintiff must establish that the failure to warn proximately caused her injuries. *Morales*, 151 F.3d at 507 (citing *Morales v. Am. Honda Motor Co.*, 71 F.3d 531, 537 (6th Cir. 1995)).

Thacker alleges that the IFUs accompanying the TVT-Secur and Prolift failed to list certain known complications—such as mesh degradation and deformities leading to lifelong inflammatory responses—and minimized other known complications by failing to disclose their "severity, permanency, [or] treatability." (Rosenzweig Dep., R. 225-3, Page ID #10390–91.) She argues that she would not have used the Pelvic Mesh Devices to treat her SUI and POP had the IFUs included sufficient warnings. In response, Ethicon does not argue that the IFUs gave adequate warnings. Rather, it argues that, even if Ethicon failed to warn of the complications associated with the Pelvic Mesh Devices, that failure did not proximately cause Thacker's injuries.

Kentucky uses the substantial factor test for proximate causation: "was the defendant's conduct a substantial factor in bringing about plaintiff's harm?" *Morales*, 151 F.3d at 507; *see also CertainTeed Corp.*, 330 S.W.3d at 77 (quoting Restatement (Second) of Torts, § 431). To satisfy this requirement, a plaintiff may rely on circumstantial evidence, but "the evidence must be sufficient to tilt the balance from possibility to probability." *Morales*, 151 F.3d at 507 (quoting *Calhoun v. Honda Motor Co.*, 738 F.2d 126, 130 (6th Cir. 1984)). Because this inquiry involves thorny factual questions, Kentucky courts ordinarily leave questions of proximate causation to a jury. *Id.*

In medical device cases, Kentucky applies the learned intermediary rule, which "provides that a manufacturer's duty to warn of the foreseeable risks of a medical device is satisfied if it gives adequate warnings to the patient's healthcare provider." *Cutter v. Ethicon, Inc.*, No. 20-6040, 2021 WL 3754245, at *9 (6th Cir. Aug. 25, 2021) (citing *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 761–65 (Ky. 2004)). Although the learned intermediary rule defines the manufacturer's *duty*, it also shapes the proximate cause analysis. In a run-of-the-mill failure to warn case, the proximate cause inquiry focuses on the consumer. *See Morales*, 151 F.3d at 507.

For example, in *Morales*, this Court focused on the following question: had a motorcycle manufacturer added a safety flag on its bikes, would a driver have been able to see that flag and react in time to prevent an imminent accident? *Id.* This consumer-specific inquiry does not neatly transfer to medical device cases where there are more links in the causal chain. In medical device cases, the causal chain involves the doctor's reading and relying on the warnings, conveying that information to the plaintiff, and making an informed recommendation about the best treatment plan. The plaintiff must then give informed consent to proceed with that treatment. *See Larkin*, 153 S.W.3d at 769–70. With this many steps, courts have struggled to pinpoint what kinds of evidence the plaintiff can or must use to support proximate causation at the summary judgment stage.

Accordingly, the proximate cause inquiry in medical device cases involves two steps: (1) did the treating physician rely on the relevant warning (*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). *See Thacker*, 571 F. Supp. 3d at 697–99. As to the first prong, the district court found that Thacker pointed to sufficient evidence to create a genuine dispute of material fact regarding whether Dr. Guiler relied on the IFUs. *Id.* at 698 (citing *Sexton v. Ethicon, Inc.*, 20-cv-282, 2021 WL 4138399, at *3 (E.D. Ky. Sept. 10, 2021)); *see also Cutter*, 2021 WL 3754245, at *9. Ethicon does not challenge this finding on appeal. Therefore, the issue before this Court is whether Thacker has presented evidence showing that she likely would not have used the Pelvic Mesh Devices had Ethicon given adequate IFUs. We conclude that she has. To reach this conclusion we must first assess what type of evidence a plaintiff may use to support her proximate causation arguments.

Both Thacker and Ethicon focus on whether Dr. Guiler would have recommended the Pelvic Mesh Devices had Ethicon given adequate IFUs. Ethicon argues that a single type of evidence, testimony from the treating physician, will almost always make or break the proximate cause determination. According to Ethicon, "where it is undisputed that additional warnings would not have affected the implanting physician's treatment decisions, any alleged inadequacy in the warning is not the proximate cause of the plaintiff's injury." (Def. Br. at 31.) Thacker

disagrees with this narrow approach, arguing that it would allow courts to "ignore[] the record" and "disregard[] other evidence." (Pl. Br. at 12.)

Several lower courts have adopted some version of Ethicon's suggested approach and limited the proximate cause inquiry to testimony from the treating physician. *See, e.g., Mitchell v. Ethicon, Inc.*, No. 20-cv-157, 2020 WL 4550898, at *6 (E.D. Ky. Aug. 6, 2020) ("While it does not appear that any Kentucky court has issued a bright-line rule for causation in this scenario, many others have required the plaintiff to produce evidence that an additional warning would have changed the treating physician's prescribing decision." (collecting cases)). The district court adopted this approach and focused solely on Dr. Guiler's testimony:

> [W]hen the defendant . . . present[s] 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 in order to show a genuine issue of material fact exists.

Thacker, F. Supp. 3d at 702 (internal citations omitted) (citing *Corder v. Ethicon, Inc.*, 473 F. Supp. 3d 749, 758 n.7 (E.D. Ky. 2020); *Sexton*, 2021 WL 4138399, at *4; *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 736, 743 (S.D.W. Va. 2014)). Such an approach essentially boils the claim down to the testimony of the treating physician. But Kentucky law does not support such a narrow approach. *See Corder*, 473 F. Supp. 3d at 758 n.7 ("Ethicon's contention is, strictly, that *only* proof from or concerning the specific prescribing physician would suffice. *Kentucky has not said that*." (emphasis added)).

Rather, plaintiffs can support their proximate cause arguments with various types of evidence. For example, plaintiffs may point to evidence suggesting that, with an adequate warning: the treating physician would not have recommended the device; a reasonable physician would not have recommended the device; the treating physician (or a reasonable physician) would have given the plaintiff more information about the severity and likelihood of the risks; or the plaintiff would not have consented to, or elected to proceed with, the treatment. *See, e.g.*, *Corder*, 473 F. Supp. 3d at 758 n.7, 760; *Cutter v. Ethicon, Inc.*, No. 19-443, 2020 WL 109809, at *8 (E.D. Ky. Jan. 9, 2020); *Clark v. Danek Med., Inc.*, No. 94-cv-634, 1999 WL 613316, at *5 (W.D. Ky. Mar. 29, 1999) (citing *Snawder v. Cohen*, 749 F. Supp. 1473, 1479–80 (W.D. Ky. 1990)). 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." *Clark*, 1999 WL 613316, at *6.

The evidence in this case cuts in different directions. We turn first to Dr. Guiler's testimony. On the one hand, Dr. Guiler testified that, assuming the Pelvic Mesh Devices caused more severe complications than those listed in the IFUs, he would have expected Ethicon to disclose that information. He explained that, had Ethicon disclosed these risks—such as chronic pelvic pain and dyspareunia—that information would have affected his risk-benefit analysis when recommending the Pelvic Mesh Devices to Thacker. Additionally, when asked why he recommended TVT-Secur and Prolift for Thacker in 2009, Dr. Guiler said that, "*At the time*, [he] felt like that was certainly the best options [*sic*] for her circumstances." (Guiler Dep., R. 159-2, Page ID #2826 (emphasis added).) These portions of his testimony suggest that he likely would have recommended a different course of treatment had Ethicon given adequate IFUs.

On the other hand, Dr. Guiler also testified 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. (*Id.* at Page ID #2832.) Ethicon argues that this one statement dooms Thacker's failure to warn claim. However, Dr. Guiler did not say that he would stand by his recommendation *had he received a complete and accurate IFU*. He merely said that he still thought that the Pelvic Mesh Devices were generally safe and effective. But his testimony did not explain what new information he had since learned. For instance, he did not say that he had further researched these devices, read newly published clinical studies, or seen the more recent data showing that these devices had abnormally high rates of severe complications. (*See* Rosenzweig General Rep., R. 225-9, Page ID #10612–13 (citing case study where 34 out of 58 Prolene mesh implants had cracked after implantation).) And there is nothing indicating that, on the day of his deposition, Dr. Guiler was given every warning that Thacker says should have been included in the IFUs. Since the question is whether Dr. Guiler would have acted differently *with an adequate warning*, not whether he would make the same recommendation with some amount of unidentified new knowledge, this evidence is not as strong as Ethicon suggests. What is left is a handful of arguably contradictory statements from Dr. Guiler about how he would have treated Thacker had Ethicon given sufficient IFUs

back in 2009. Weighing contradictory statements of this nature is a task for the jury, not for this Court. *See Kirilenko-Ison*, 974 F.3d at 660. This is particularly true in the medical field, where treating physicians may have an interest in protecting their professional reputations and defending past treatment decisions, even if the case is not focused on their standards of care.

The other record evidence supports Thacker's proximate causation arguments. Thacker's expert, Dr. Rosenzweig, testified that *no reasonable physician* would have used the Pelvic Mesh Devices to treat Thacker had Ethicon given adequate IFUs in 2009. According to Dr. Rosenzweig, Dr. Guiler would have made a different treatment recommendation had Ethicon given him all the necessary information. This evidence creates a genuine dispute of material fact on the proximate cause element. A jury could hear from both doctors and choose to believe Dr. Rosenzweig's opinion that no reasonable doctor, with adequate warnings, would have implanted Thacker with the TVT-Secur and Prolift. Dr. Rosenzweig's testimony is "sufficient to tilt the balance from possibility to probability," *Morales*, 71 F.3d at 537 (quoting *Calhoun*, 738 F.2d at 130), and courts must not weigh competing evidence at the summary judgment stage, *Kirilenko-Ison*, 974 F.3d at 660. Thacker therefore produced sufficient evidence to establish proximate causation at this stage, and the district court erred in granting summary judgment on her failure to warn claim.

b. *Design Defect*

The district court also erred in granting Ethicon's motion for summary judgment on Thacker's strict liability design defect claim. "Kentucky applies a risk-utility test in design defect cases." *Burgett v. Troy-Bilt LLC*, 579 F. App'x 372, 378 (6th Cir. 2014) (quoting *Toyota Motor Corp. v. Gregory*, 136 S.W.3d 35, 42 (Ky. 2004)). "The test in these cases is 'whether an ordinarily prudent company being fully aware of the risk, would not have put the product on the market.'" *Id.* (quoting *Toyota Motor Corp.*, 136 S.W.3d at 42). In all cases, "design defect liability requires proof of a feasible alternative design." *Toyota Motor Corp.*, 136 S.W.3d at 42.

Ethicon's only argument against Thacker's design defect claim is that she failed to present evidence of a feasible alternative design for the Pelvic Mesh Devices at the time of her surgery. In response, Thacker points to Dr. Rosenzweig's opinion that "a product with less

polypropylene such as Ultrapro [mesh]" was a feasible alternative design for the Prolift and TVT-Secur,[4] which both used the polypropylene-based Prolene mesh. (Rosenzweig Specific Rep., R. 225-4, Page ID #10478–79.) The district court found that Dr. Rosenzweig's opinion did not sufficiently explain why Ultrapro was feasible, and it dismissed his opinion as "a mere declaration with no support." *Thacker*, 571 F. Supp. 3d at 706. On appeal, Ethicon defends the district court's conclusion, arguing that Thacker failed to produce evidence showing that Ultrapro mesh was a feasible alternative design. Ethicon further argues that using Ultrapro instead of Prolene mesh in the Pelvic Mesh Devices would not have prevented Thacker's injuries.

First, Dr. Rosenzweig's opinion sufficiently supports Thacker's claim that Ultrapro mesh was a feasible alternative design that was available at the time. "In establishing a defect in product design, a plaintiff must show something more than that it was 'theoretically probable that a different design would have been feasible.'" *Brock v. Caterpillar, Inc.*, 94 F.3d 220, 224 (6th Cir. 1996) (quoting *Ingersoll-Rand Co. v. Rice*, 775 S.W.2d 924, 928 (Ky. Ct. App. 1988)). Rather, a plaintiff must show "that a reasonable alternative design could have been *practically* adopted at the time" the plaintiff used the product. *Johnson v. Manitowoc Boom Trucks, Inc.*, 484 F.3d 426, 433 (6th Cir. 2007) (quoting *Martin v. Michelin N. Am., Inc.*, 92 F. Supp. 2d 745, 753 (E.D. Tenn. 2000)) (emphasis in original). Thacker has done so in this case.

Dr. Rosenzweig's expert report stated that "based on [his] experience and review of the medical literature and other materials" he believed that Ultrapro was a "safer and feasible" design for both the Prolift and TVT-Secur. (Rosenzweig Specific Rep., R. 225-4, Page ID #10478.) Ethicon argues, and the district court agreed, that Dr. Rosenzweig provided no basis or explanation for this opinion, and therefore it was not evidence of a feasible alternative design. Specifically, Ethicon says that Dr. Rosenzweig did "not cite[] any record evidence to support his opinions on Ultrapro." (Def. Br. at 26.) This is simply false. In fact, Dr. Rosenzweig cited several documents, including internal Ethicon emails, about Ultrapro when explaining why

[4]Dr. Rosenzweig listed three other alternative designs for the Prolift and TVT-Secur. The district court found that these "three listed alternatives do not qualify as proper alternatives because they are not appropriately analogous to the mesh products actually used" in Thacker's surgery. *Thacker*, 571 F. Supp. 3d at 703. Thacker does not challenge this finding on appeal, leaving only her argument that Ultrapro was a feasible alternative design.

Ultrapro was a feasible alternative design. (*See* Rosenzweig General Rep., R. 225-9, Page ID #10616 n.41, #10623 n.64, #10629 ns.85–86, #10713–14, #10760.)

Ethicon next argues that Dr. Rosenzweig only gave detailed opinions about TVT-Secur and not Prolift. Admittedly, Dr. Rosenzweig's general causation report only addressed TVT-Secur. But the conclusions in his general report suggest that Ultrapro could have replaced Prolene mesh (which was used in *both* devices) to treat both POP (treated with the Prolift) and SUI (treated with the TVT-Secur). Indeed, Dr. Rosenzweig relied on witness testimony to conclude that:

> [D]espite having incorporated the use of lightweight, large pore Ultrapro mesh in vaginal tissues for the treatment of pelvic organ prolapse [like rectocele], the Ultrapro was never used by Ethicon in a device used for the treatment of [SUI] largely because the company wanted to continue to rely on [older clinical] studies.

(*Id.* at Page ID #10628–29.) The district court recognized this part of Dr. Rosenzweig's report, but it concluded that this statement only "suggest[s that] Ultrapro existed," and Thacker could not show that Ultrapro was a feasible alternative "simply because it existed." *Thacker*, 571 F. Supp. 3d at 706. But Dr. Rosenzweig's expert report says more than that. Indeed, it indicated that Ultrapro was feasible because it *was being used* to treat POP and it *could easily be used* to treat SUI, but Ethicon chose not to use it for that purpose because it would not be able to use more favorable (but outdated) clinical studies. Dr. Rosenzweig also explained that the properties of Ultrapro mesh (*i.e.*, a lighter weight, larger pore mesh using less polypropylene) would have worked well in the Pelvic Mesh Devices. Accordingly, the evidence in the record would allow a jury to find that Ultrapro was a feasible alternative design for both the Prolift and the TVT-Secur at the time of Thacker's surgery.[5]

[5]Ethicon suggests in passing that Ultrapro was not a feasible alternative design because the Food and Drug Administration ("FDA") "never cleared Ultrapro for use in the treatment of SUI." (Def. Br. at 10.) Ethicon emphasized this argument in its motion for summary judgment. In a lengthy footnote, the district court agreed and suggested that Kentucky courts would likely side with a minority of courts in Texas that hold that, without FDA approval, an alternative design is not feasible. *See Thacker*, 571 F. Supp. 3d at 706 n.4 (citing *Pizzitola v. Ethicon, Inc.*, No. 20-cv2256, 2020 WL 6365545, at *4 (S.D. Tex. Aug. 31, 2020)). But the district court's reasoning is flawed for several reasons. *First*, it is illogical to say that an *alternative design*—that, *by definition*, was never put on the market—must have been approved by the FDA to support a design defect claim. To require FDA approval for a design that never came to fruition would likely doom all design defect claims in the medical device context. *Second*, the record in this case shows that Ethicon marketed and sold the Prolift device for *over three years before it*

Second, Ethicon argues that, even if Ultrapro was a feasible alternative design, Thacker has not shown that using Ultrapro mesh would have prevented her injuries. Under Kentucky law, a plaintiff must produce evidence that would allow a jury to find that the alternative design "would have prevented [the plaintiff's] injury." *Toyota Motor Corp.*, 136 S.W.3d at 42 (quoting *Ingersoll-Rand Co.*, 775 S.W.2d at 929). This principle emerged from cases where an intervening event led to the injury, such that a different design would not have prevented the injury. *See Jones v. Hutchinson Mfg., Inc.*, 502 S.W.2d 66, 70–71 (Ky. 1973); *Ingersoll-Rand Co.*, 775 S.W.2d at 928–29. Nonetheless, lower courts applying Kentucky law have used this standard in medical device cases even when there is no apparent intervening cause such as medical malpractice by the treating physician. *See, e.g.*, *Sexton*, 2021 WL 4138399, at *5; *Dalton v. Animas Corp.*, 913 F. Supp. 2d 370, 375 (W.D. Ky. 2012) (quoting *Cummins v. BIC USA, Inc.*, 835 F. Supp. 2d 322, 326 (W.D. Ky. 2011)). However, in medical device cases, an expert's opinion that the alternative design would have prevented the injury is sufficient to create a genuine factual dispute. *See Dalton*, 913 F. Supp. 2d at 375–76 (denying summary judgment based on expert opinion on this issue). Thus, the issue is whether the expert evidence in this case would allow a jury to conclude that using Ultrapro rather than Prolene mesh would have prevented or lessened Thacker's injuries.

Both parties point to Dr. Rosenzweig's statements in support of their respective positions. Thacker points to his specific report where he opined that using Ultrapro mesh was "capable of preventing Ms. Thacker's injuries and damages." (Rosenzweig Specific Rep., R. 225-4, Page ID #10479.) Dr. Rosenzweig explained that:

> [Thacker's injuries] were a result of the specific design flaws of the TVT-S[ecur] and Prolift polypropylene, including degradation, cytotoxicity, stiffness, migration, deformation, fraying, roping, cording, curling, banding, scarring,

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ever received FDA approval. If the allegedly defective device was not even FDA approved when it hit the market, it defies logic to require FDA approval for the proposed alternative design. *Third*, there is scant legal support for such a rule in the case law. *See, e.g., In re Ethicon Inc. Pelvic Repair Sys. Product Liab. Litig.*, 12-MD-2327, 2020 WL 1060970, at *3 (S.D.W. Va. Feb. 13. 2020) (finding that plaintiffs could use evidence of an alternative mesh design even though that alternative was not approved by the FDA to treat the plaintiffs' conditions).

However, we need not decide this issue at this time. Although relying heavily on this argument below, Ethicon provided no argumentation about FDA approval in its appellate brief. Ethicon only mentioned FDA approval once in the background section. It thus did not preserve this issue on appeal. *See Bard v. Brown Cnty.*, 970 F.3d 738, 749 (6th Cir. 2020).

> shrinkage/contraction, scar plate formation, chronic inflammation, chronic foreign body reaction, loss of pore size with tension, dense, heavy, and frayed, rough edges. *If [Ultrapro mesh had] been used for Ms. Thacker, she would not have suffered the injuries*.

(*Id.* (emphasis added).) In response, Ethicon points to the following portion of Dr. Rosenzweig's deposition testimony:

> Q: And then, finally, we have got your opinion on the sling or rectocele repair using Ultrapro?
>
> A: Correct.
>
> Q: And would a rectocele repair or sling with Ultrapro have eliminated the risks of complications for Miss Thacker that you attribute to her TVT Secur and Prolift?
>
> A: Eliminate, no.

(Rosenzweig Dep., R. 225-3, Page ID #10393.)

Having found that Thacker did not even identify a feasible alternative design, the district court did not consider whether Ultrapro would have prevented her injuries. *See generally Thacker*, 571 F. Supp. 3d at 702–07. But Thacker points to a nearly identical case—involving the same type of mesh device, the same expert witness, and even the same district judge—to support her argument that Dr. Rosenzweig's expert report is enough to survive summary judgment on this issue. *See Sexton*, 2021 WL 4138399, at *6. In *Sexton*, the plaintiff relied on an expert report from Dr. Rosenzweig to make an identical argument: Ethicon could have used Ultrapro mesh instead of meshes with more polypropylene in them when designing its TVT line of devices. *See id.* The district court denied summary judgment in that case and found that a jury could rely on Dr. Rosenzweig's testimony to conclude that Ultrapro mesh would have prevented the injury. *Id.* Specifically, the court held that:

> It is arguable that less polypropylene mesh could have resulted in less harm to Plaintiff than that found in the product used in her treatment. The test is whether there was a safer design alternative that would have prevented Plaintiff's injuries *not whether there was a design alternative that eliminated all risks with absolute certainty*. Less polypropylene mesh *may* have prevented, *or at least lessened*, Plaintiff's injuries. Ethicon may cross-examine Dr. Rosenzweig at trial about . . . whether less polypropylene mesh would have been safer.

Id. (emphasis added). This reasoning applies with equal force in this case. At most, the evidence Ethicon highlights shows that Ultrapro may not have eliminated *all* risks. But that does not mean that it would not have prevented or lessened some, or even most, of Thacker's injuries. Because a jury could accept Dr. Rosenzweig's opinion that a feasible alternative design would have prevented Thacker's injuries, Thacker has raised a genuine dispute on this prong of her design defect claim. Therefore, Thacker has raised sufficient evidence to allow a jury to find that Ultrapro was a feasible alternative design that would have prevented her injuries.

But Ethicon raises a final overarching argument. Perhaps recognizing that it had little defense against the substance of Dr. Rosenzweig's opinions, Ethicon spent much of its brief arguing that this Court should not consider Dr. Rosenzweig's testimony because it is inadmissible and unreliable. Admittedly, without Dr. Rosenzweig's testimony, Thacker would not be able to point to evidence of a feasible alternative design. However, Ethicon's evidentiary arguments are not within the scope of this appeal, and the Court will not entertain them.

After discovery closed, the parties filed a plethora of evidentiary motions, including Ethicon's motions to exclude Dr. Rosenzweig's opinions. Ethicon filed its motion for summary judgment at the same time. Its motion for summary judgment did not raise any evidentiary arguments about the expert opinions or reports. For purposes of summary judgment, the district court assumed that all of Thacker's expert evidence was admissible. *See Thacker*, 571 F. Supp. 3d at 708. It therefore denied the evidentiary motions as moot when it granted Ethicon's motion for summary judgment. *Id.* Nonetheless, on appeal, Ethicon raises several arguments from its evidentiary motions, including that: (1) Thacker failed to properly designate Dr. Rosenzweig as a general expert; (2) Dr. Rosenzweig improperly relied on and incorporated Dr. Elliot's opinions; (3) the expert reports are inadmissible hearsay;[6] and (4) Dr. Rosenzweig's opinion is unreliable and therefore inadmissible under Federal Rule of Evidence 702(b). Thacker argues that the Court should not consider these arguments because they were "not made in [Ethicon's] underlying summary judgment briefing." (Pl. Reply Br. at 2.) In response, Ethicon cites the well-established principle that "matters raised below as alternative grounds in support of a

[6]It does not appear that Ethicon raised this argument in *any* of its evidentiary motions before the district court.

judgment are properly before this Court even in the absence of a cross-appeal." (Def. Br. at 20 n.1 (quoting *United States v. True*, 250 F.3d 410, 419 (6th Cir. 2001)).) According to Ethicon, "it is appropriate for this Court to address the admissibility of these [expert] opinions as part of its *de novo* review." (*Id.*) That is incorrect.

While courts may refuse to consider certain types of inadmissible evidence when ruling on a motion for summary judgment, *see Alexander v. CareSource*, 576 F.3d 551, 558–59 (6th Cir. 2009), Ethicon never asked the district court to disregard Dr. Rosenzweig's opinions for the purpose of summary judgment. In fact, Ethicon's motion for summary judgment *relied on* the expert reports that it now asks this Court to disregard. Therefore, Ethicon's evidentiary arguments are not "alternative grounds" for summary judgment at all. *See True*, 250 F.3d at 419. Rather, Ethicon is trying to transplant arguments from its evidentiary motions that the district court never considered. Even if some of these arguments may have merit, they are not within the scope of this appeal. We therefore take the same approach as the district court and assume that the expert testimony is admissible for the purpose of summary judgment. Ethicon did not advocate for any other approach in its motion for summary judgment, and we decline to permit Ethicon to change its litigation strategy on appeal. Assuming all the evidence attached to the summary judgment briefs is admissible, Thacker has raised genuine disputes of material fact concerning the feasibility of Ultrapro as an alternative design to the Prolene mesh used in both the Prolift and the TVT-Secur.

2. Negligence and Gross Negligence Claims

Thacker brought similar product liability claims under negligence and gross negligence theories. Under Kentucky law, plaintiffs may bring design defect and failure to warn claims under either a strict liability or a negligence theory. *Ostendorf v. Clark Equipment Co.*, 122 S.W.3d 530, 535 (Ky. 2003) (citing *Williams v. Fulmer*, 695 S.W.2d 411 (1985)). "In defective design cases, 'the distinction between the so-called strict liability principle and negligence is of no practical significance.'" *Sexton*, 926 F.2d at 336 (quoting *Jones*, 502 S.W.2d at 69–70). And in negligent failure to warn cases, the elements overlap with a strict liability claim because the plaintiff must establish that the inadequate warning proximately caused her injuries. *See Holbrook v. Rose*, 458 S.W.2d 155, 157 (Ky. 1970).

Ethicon's only argument against these claims in its motion for summary judgment was that Thacker "cannot prove the strict liability counterparts of any of her products liability claims, and her negligence and gross negligence claims fail for the same reasons." (Mot. Summ. J., R. 159, Page ID #2778; Def. Br. at 36–37.) That is, Ethicon argues that Thacker's negligence claims fail because she did not produce evidence of a feasible alternative design (for negligent design defect) or proximate causation (for negligent failure to warn). In granting summary judgment, the district court agreed and found that "[b]ecause a negligence theory under the two claims [of design defect and failure to warn] requires the same" showings of alternative feasible design and proximate causation, "the negligence claim[s] must fail as well." *Thacker*, 571 F. Supp. 3d at 707. Because Thacker has raised genuine disputes of fact on these elements for her strict liability claims, she has raised the same disputes for her negligence claims. Therefore, the district court erred in granting summary judgment on these claims.[7]

III. CONCLUSION

For these reasons, we **REVERSE** the district court's order granting Ethicon's motion for summary judgment and **REMAND** for further proceedings.

[7]Thacker's complaint also stated claims for punitive damages and "discovery rule/tolling." (Opp'n Mot. Summ. J., R. 225, Page ID #10348.) Thacker relinquished any tolling argument in her opposition to summary judgment, admitting that this argument was moot because Ethicon never asserted a statute of limitations defense. However, she maintains that she should be able to seek punitive damages. She argues that her request for punitive damages was consistent with "pleading doctrines," and it was "not [a] cause[] of action." (Pl. Br. at 33.) Thus, she contends that the district court could not dismiss her request for punitive damages. The district court agreed to some extent and held that "there is no claim to grant or deny summary judgment upon." *Thacker*, 571 F. Supp. 3d at 708. However, the district court did conclude that "since [it] granted summary judgment on all claims for the defendants, there can be no punitive damages." *Id.* Under Kentucky law, Thacker may be able to seek punitive damages if she prevails at trial. *See generally Jones v. IC Bus, LLC*, 626 S.W.3d 661, 682 (Ky. Ct. App. 2020).