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No. 20-6040

**UNITED STATES COURT OF APPEALS**
**FOR THE SIXTH CIRCUIT**

**FILED**
Aug 25, 2021
DEBORAH S. HUNT, Clerk

JENESTA CUTTER; LARRY A. CUTTER,

Plaintiffs-Appellants,

v.

ETHICON, INC.; ETHICON WOMEN'S HEALTH AND UROLOGY, a Division of Ethicon, Inc.; GYNECARE; JOHNSON & JOHNSON,

Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF KENTUCKY

OPINION

**BEFORE: KETHLEDGE, STRANCH, and NALBANDIAN, Circuit Judges.**

**JANE B. STRANCH, Circuit Judge.** In 2006, Jenesta (Sue) Cutter underwent implantation of a Prolift-brand mesh device manufactured by Defendants to treat her pelvic prolapse and pelvic pain. But her symptoms soon returned. Over the course of the next several years, she sought relief from multiple doctors and underwent several revision surgeries. In May 2012, after Cutter came to believe that her problems were being caused by a defect in the Prolift itself, she and her husband, Larry Cutter, brought suit against Defendants. The district court granted summary judgment dismissing their complaint. The Cutters appeal the district court's dismissal of their product-liability, negligence, and loss-of-consortium claims as barred by Kentucky's statute of limitations, and its dismissal of their failure to warn claim on the alternate

ground that Defendants' warnings were not the proximate cause of the Cutters' harms. For the reasons stated below, we **AFFIRM** in part and **REVERSE** in part.

## I. BACKGROUND

### A. Factual Background

The facts are presented in the light most favorable to the Cutters. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986).

In April 2006, Sue Cutter sought treatment from Dr. Michael Guiler for a constellation of conditions and symptoms, including pelvic organ prolapse (an uncomfortable condition in which her uterus was pushing down into her vagina), ovarian cysts, fibroids, pain during sexual intercourse, pelvic pain, back pain, frequent urination, hot flashes, and moodiness. At Guiler's recommendation, Cutter agreed to undergo a hysterectomy and implantation of a Prolift brand pelvic mesh, manufactured by Ethicon, a subsidiary of Johnson & Johnson. At the time, Cutter believed the implant was something "natural" rather than a "synthetic" manufactured product. And her husband Larry had previously received a mesh implant for a fistula, with no adverse effects. Guiler performed the procedure in June 2006, and at first Cutter's symptoms improved. But by the end of 2007, she was again reporting pain and issues with urination.

Cutter returned to Guiler's office in the fall of 2008 to seek treatment for her continuing pelvic and back pain, pain with intercourse, and point tenderness near the implant. According to Cutter, after conducting a battery of tests, including a colonoscopy and a neurological exam, Guiler informed her that the right arm of the Prolift had come loose, causing the tenderness. Cutter recalled that Guiler proposed "go[ing] in and repair[ing]" the mesh, her husband believed Guiler was going to "put the arm back" because it "had come loose." Guiler testified that he believed Cutter's pain was associated with scar tissue that had developed on the loose arm of the implant,

and so he removed the scar tissue as well as part of the mesh arm to provide "complete relief." That type of scarring, he explained to her, was a standard risk that could "occur with any surgery."

Guiler performed the revision surgery soon afterwards, removing the loose right arm. At a post-operative checkup, Guiler observed that Cutter was "healing well." But Cutter continued to experience pain with intercourse; her pelvic pain improved for a "short while" before it too returned. In August 2010, Cutter sought a second opinion from Dr. Charles Papp, who told her that the Prolift appeared to be "rolled up" in the area where she was having pain. Cutter did not remember Papp telling her that her pain was related to the mesh. And according to Papp's notes, he was unable to palpate the mesh, but thought it was "possible" that the mesh was "contributing to her symptoms." He referred Cutter to Dr. Van Jenkins for a second opinion.

Jenkins confirmed that the Prolift was rolled up and recommended removing a portion of the mesh. Cutter understood Jenkins' and Papp's statements to mean that her pain was being caused by "the way [the mesh] was rolled up and that, you know, my body wasn't accepting it." In September 2010, Jenkins removed certain pieces of the implant vaginally. He reported afterwards that everything looked good. During intercourse two months later, however, Cutter's husband felt a "sharp scrape" that caused "some pretty deep scratch marks on the head of [his] penis." Cutter went back to Jenkins to report that injury and her own continuing pain. Jenkins's notes did not attribute either of these issues to the implant; he observed that he was unable to palpate the mesh but noted separation of the vaginal tissue. He prescribed painkillers, silver nitrate, and an antibacterial gel to treat the separation and advised Cutter to use warming jelly and increase foreplay during intercourse.

Throughout the spring of 2011, Cutter returned to Jenkins for multiple follow-up appointments, continuing to report pain and discomfort. In February, Jenkins noted the continuing

separation of her vaginal tissue and discussed with Cutter the possibility of "excising this area that seems to separate and actually suturing it back together." He wrote that "[t]here was no palpable mesh in that area." On March 9, Jenkins noted that the separation appeared to have improved and proposed monitoring the area, but if it continued to separate, suggested the possibility of excising that area. He continued to monitor her in April and May; on May 11, for example, Jenkins noted improvement to Cutter's pain and the separated area, as well as an asymptomatic granular excoriation near her cervix, which he treated with medication. Nowhere in his notes did Jenkins suggest that he thought the Prolift was causing Cutter's problems nor that it needed to be removed. Cutter recalled that Jenkins at some point recommended removing more of the implant but did not suggest that her symptoms were due to the implant itself.

According to Jenkins' notes, on June 22, 2011, Cutter told him that she believed her symptoms were "from [the] mesh," and they discussed removing the rest of it abdominally at that appointment and again in July. Jenkins did not express his view of Cutter's belief, but ultimately declined to perform the procedure himself for personal health reasons. Cutter then visited several other doctors and eventually underwent two additional revision surgeries to remove more of the mesh in March 2012 and January 2019. In November 2011, the Cutters saw an advertisement on television describing the Prolift's alleged defects.

### B. Procedural History

The Cutters sued Ethicon in May 2012, asserting 18 claims under Kentucky law. The case was transferred into a multi-district litigation concerning the Prolift. The MDL master complaint, which the Cutters have incorporated by reference in a short-form complaint, alleged that the Prolift is made of a biologically incompatible material that causes adverse immune responses, is prone to contamination, degrades and deforms after implantation, degrades surrounding tissue, causes

nerve damage, and more. Plaintiffs allege that Defendants knew of these problems and the risks of the Prolift and its implantation procedure but misrepresented and concealed them.

The Cutters' suit was remanded to the Eastern District of Kentucky on November 4, 2019. Ethicon moved for summary judgment, arguing in part that the Cutters' negligence, loss-of-consortium, and product-liability claims were barred by Kentucky's one-year statute of limitations. The district court granted the motion in January 2020, holding that as a matter of law, the Cutters' "injury" from the Prolift arose no later than March 2011, more than one year before they filed suit. It noted that the Cutters' failure to warn products liability claim also failed for lack of proximate cause. In April, the district court issued an order resolving various outstanding *Daubert* motions, noting that some of these motions had been rendered moot by its earlier summary judgment order. Ethicon then filed a second motion for summary judgment directed at the Cutters' negligent infliction of emotional distress and fraud by omission. The district court granted the motion and entered final judgment against the Cutters on August 14, 2020. The Cutters timely appealed the judgment, and challenge the district court's dismissal of their negligence, loss-of-consortium, and product-liability claims.

## II. ANALYSIS

### A. Standard of Review

We review a grant of summary judgment de novo. *See Kalich v. AT&T Mobility, LLC*, 679 F.3d 464, 469 (6th Cir. 2012). Summary judgment is appropriate where "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(c)). The moving party bears the burden of demonstrating there is no dispute of fact; if the movant succeeds, the nonmoving party "must set forth specific facts showing that there is a genuine issue for trial." *Anderson v. Liberty Lobby*, 477 U.S. 242, 250 (1986) (quoting Fed. R.

Civ. P. 56(e)). And a genuine issue for trial exists where "there is sufficient evidence favoring the nonmoving party" that a reasonable jury could return a verdict in her favor. *Id.* In conducting this analysis, we do not judge credibility or weigh conflicting evidence; instead, we accept the evidence of the nonmoving party, and draw "all justifiable inferences" in her favor. *Id.* at 255.

**B. The Statute of Limitations and the Discovery Rule**

Kentucky law provides that personal injury suits must be filed within one year after the cause of action accrued. Ky. Rev. Stat. § 413.140(1)(a). But under the discovery rule, for certain suits the limitations period begins to run "on the date of the discovery of the injury, or from the date it should, in the exercise of ordinary care and diligence, have been discovered." *Wiseman v. Alliant Hosps., Inc.*, 37 S.W.3d 709, 712 (Ky. 2000) (quoting *Hackworth v. Hart*, 474 S.W.2d 377, 379 (Ky. 1971)). The knowledge required is two-pronged: the limitations period is triggered when the plaintiff knows or should know "not only that [s]he has been injured but also that h[er] injury may have been caused by the defendant's conduct." *Id.* (quoting *Hazel v. General Motors Corp.*, 863 F. Supp. 435, 438 (W.D. Ky. 1994)).

The discovery rule originated in the medical malpractice context, *see Tomlinson v. Siehl*, 459 S.W.2d 166 (1970), and was codified by statute for such claims in 1974, *see* K.R.S. §§ 413.140(1)(e), (2). It has since been extended at common law to certain other suits, beginning with *Louisville Trust Co. v. Johns-Manville Prods. Corp.*, 580 S.W.2d 497, 499–501 (Ky. 1979) (internal quotation marks omitted)), which applied the discovery rule to a personal injury claim—the plaintiff had contracted lung cancer from exposure to asbestos dust—because the injury was "of an inherently unknowable nature." As the Kentucky Supreme Court explained, there is "no compelling policy-based reason for a distinction between when a plaintiff injured by medical malpractice and when a plaintiff injured by latent disease caused by exposure to a harmful

substance must bring a lawsuit or be barred by limitations." *Id.* at 500–501. Using that logic, Kentucky courts have applied the discovery rule to a range of other causes of action as long as the injury is "latent"[1]—when "the fact of injury or offending instrumentality is not immediately evident or discoverable with the exercise of reasonable diligence." *Fluke Corp. v. LeMaster*, 306 S.W.3d 55, 60 (Ky. 2010); *see also, e.g., Perkins v. Ne. Log Homes*, 808 S.W.2d 809, 818 (Ky. 1991), *overruled on other grounds by Calloway Cnty. Sheriff's Dep't v. Woodall*, 607 S.W.3d 557 (Ky. 2020) (products liability based on exposure to toxic preservative in construction material); *Michals v. Baxter Healthcare Corp.*, 289 F.3d 402, 407–08 (6th Cir. 2002) (products liability based on defective breast implants); *Rehm v. Ford Motor Co.*, 365 S.W.3d 570, 578 (Ky. Ct. App. 2011) (loss of consortium based on premises liability); *Salsman v. Sears, Roebuck & Co.*, No. 2008-CA-000743-MR, 2010 WL 918068, at *6 (Ky. Ct. App. Mar. 12, 2010) (negligence action); *Johnson v. Sandoz Pharms. Corp.*, 24 F. App'x 533, 537 (6th Cir. 2001) (products liability based on medication). The courts have generally refused to extend the discovery rule any further in the absence of legislative authorization. *See, e.g., Middleton v. Sampey*, 522 S.W.3d 875, 878–79 (Ky. Ct. App. 2017).

Ultimately, the applicability of the common law discovery rule turns on the character of the plaintiff's injury, not on the label for her cause of action. *See, e.g.*, cases cited *supra* at 8; *Bridgefield Cas. Ins. Co. v. Yamaha Motor Mfg. Corp. of Am.*, 385 S.W.3d 430, 434 (Ky. Ct. App. 2012) (declining to apply discovery rule in subrogation case based on products liability because claimant's "injuries and the [motorcycle's] potential role in causing the accident were immediately

[1] In so doing, the courts have freely applied caselaw from the medical malpractice context, including *Wiseman*, to other types of suits. *See, e.g., Michals v. Baxter Healthcare Corp.*, 289 F.3d 402, 407–08 (6th Cir. 2002); *R.T. Vanderbilt Co. v. Franklin*, 290 S.W.3d 654, 660 (Ky. Ct. App. 2009). As the Kentucky Supreme Court has explained, the statutory discovery rule for malpractice "is merely a codification of the common law principle stated by this Court in *Tomlinson v. Siehl*, Ky., 459 S.W.2d 166 (1970), as elaborated upon in *Louisville Trust Co. v. Johns–Manville Products*, Ky., 580 S.W.2d 497 (1979)." *Michels v. Sklavos*, 869 S.W.2d 728, 732 (Ky. 1994).

evident from the accident itself."); *Wal-Mart Real Est. Bus. Tr. v. Hopkins Cnty. Coal, LLC*, No. 2019-CA-1369-MR, 2020 WL 7418992, at *3 (Ky. Ct. App. Dec. 18, 2020) (in declining to apply discovery rule to property damage claim, court stated that "[t]he dispositive question . . . is whether the offending instrumentality, *i.e.*, subsidence resulting from Appellees' alleged negligence, was immediately evident or discoverable with the exercise of reasonable diligence.")

In determining whether the discovery rule applies and if so, when the limitations period begins to run, Kentucky law distinguishes injury from harm. Harm is "the existence of loss or detriment in fact of any kind to a person resulting from any cause," while injury is "the invasion of any legally protected interest of another," or stated differently, the wrongdoing that caused the harm. *Wiseman*, 37 S.W.3d at 712–13 (quoting Restatement (Second of Torts § 7, cmt. (1965)). So regardless of when a plaintiff experienced "harm," a "legally recognizable injury does not exist until the plaintiff discovers the defendant's wrongful conduct" or the fact of the misconduct becomes "objectively ascertainable." *Id.* at 713.

In a federal diversity case concerning a cause of action under Kentucky state law, the ultimate validity of a statute of limitations defense is a question of law. *Elam v. Menzies*, 594 F.3d 463, 467 (6th Cir. 2010). But it is the jury's role to resolve any disputes of fact, including disputed inferences, as to when a plaintiff discovered or should have discovered her cause of action. *Id.* (citing *Lynn Mining Co. v. Kelly*, 394 S.W.2d 755, 759 (Ky. 1965)); *see also 3M Co. v. Engle*, 328 S.W.3d 184, 189 (Ky. 2010) ("When a plaintiff is put on notice of his injury is a question of fact for the jury.").

We begin with the threshold question of whether the injury Cutter suffered was latent, such that the discovery rule applies. The Prolift mesh did not immediately cause Cutter pain—her symptoms only returned at the end of 2007, a year and a half after implantation. The problems

then came and went over the years, sometimes improving slightly with treatment or revision, and then later returning. The device, moreover, was inside her body; its relationship with her symptoms was not "immediately evident or discoverable." *Fluke*, 306 S.W.3d at 60; *see also Wiseman*, 37 S.W.3d at 712 (applying discovery rule to medical malpractice claim based on surgeon's failure to remove medical instrument from surgical site); *Michals*, 289 F.3d at 407–08 (applying discovery rule to products liability suit based on defective breast implants).

Defendants argue that *Fluke*, which did not involve a latent injury, applies here. There, a voltage meter manufactured by the defendant incorrectly indicated there was no electricity flowing to a circuit breaker, but when the plaintiff started working on the unit, an electrical arc blasted through the breaker and injured him. *Fluke*, 306 S.W.3d at 57, 60–61. As the court explained, the flow of electricity through the breaker showed that the voltage meter's reading was incorrect. Because the plaintiffs' injury and its instrumentality were immediately apparent, the discovery rule did not apply. *Id.* at 60–61. In contrast, the harm Cutter suffered was internal and manifested belatedly and inconsistently; her injury and the instrumentality of that injury were therefore "inherently unknowable." *Louisville Trust*, 580 S.W.2d at 499. These qualities also differentiate this case from *Davis*, in which the Kentucky Supreme Court declined to apply the discovery rule to a claim based on a harm the dissent contends had the appearance of "some latency." In fact, similar to the plaintiffs in *Fluke*, Davis developed externally visible injuries at the same time as he began using a new wheelchair. *Davis v. All Care Med., Inc.*, 986 S.W.2d 902, 903 (Ky. 1999). Thus, the harm was "immediately evident or discoverable"; it was not latent. Sue Cutter's was. *Compare with id.; Hazel v. Gen. Motors Corp.*, 83 F.3d 422 (6th Cir. 1996) (Table) (plaintiff's negligence claim accrued at the time of the truck accident that caused his burns, when he "knew of both his injury and the instrumentality that caused it").

The district court concluded that the limitations period began to run no later than March 2011, when, according to Cutter's testimony, a doctor recommended she undergo a third revision surgery. In the court's view, that recommendation—in conjunction with the previous revisions and the scrape experienced by Larry Cutter—was sufficient to put Sue Cutter "on notice of the device's potential defects" and trigger her duty to investigate. Cutter contends, however, that when the limitations period began to run is a question for the jury, and that the triggering event occurred in June 2011, when she and Jenkins first discussed the possibility that a defect in the mesh itself was causing her symptoms and proposed removing it altogether.

Resolving the question of when Cutter had the requisite knowledge of her injury and its instrumentality is guided by the summary judgment standard, which requires that all reasonable inferences be drawn in favor of the Cutters. *Elam v. Menzies*, 594 F.3d 463, 466 (6th Cir. 2010). And in determining when a plaintiff had or should have had the knowledge required to trigger the limitations period under the discovery rule, "a court must give special consideration to the patient's perspective" because her lack of medical knowledge may impede her ability to discover her injury. *Id.* at 470 (citing *Wiseman*, 37 S.W.3d at 712–13). As the Kentucky Supreme Court explained, "predicting medical results" is inherently "tenuous," and a patient has the "right to rely on [her] physician's knowledge and skill." *Wiseman*, 37 S.W.3d at 713. In *Wiseman*, a medical malpractice plaintiff visited multiple doctors seeking treatment for post-surgical pain, but they were all "indefinitive as to the origin of her pain and attributed it to a tailbone injury." *Id.* at 712. While the plaintiff "may have suspected that something went wrong during the surgery, that in and of itself was insufficient to accrue a cause of action," because all she had was a "mere suspicion of injury due to medically unexplainable pain." *Id.* at 712–13. The *Wiseman* court determined that the cause of action accrued when "the fact of her injury became objectively ascertainable"—

when another surgeon operated and found that the first surgeon had left behind a piece of a medical instrument. *Id.* at 711, 713.

We applied these principles to the summary judgment inquiry in *Elam*. Elam began experiencing chest pain after a stenting procedure, which the cardiologist attributed to scar tissue. Elam later underwent a cardiac catheterization by another doctor. 594 F.3d at 465–66. Eventually, after coming to believe that his pain had been caused by the original stents, Elam sued the first doctor. *Id.* The defendant argued that the suit was untimely because the limitations period began to run when Elam met with a second doctor, who had apparently told him that some stents were placed where they should not have been. *Id.* at 468. The record also contained statements indicating that Elam had a reasonable belief that his condition was the result of an independent cause rather than malpractice. We explained that "knowledge [of wrongdoing] should not be presumed . . . by '[o]ne who possesses no medical knowledge.'" *Id.* at 471 (second alteration in original) (quoting *Wiseman*, 37 S.W.3d at 712–13). We also noted conflicting evidence from other witnesses and a lack of testimony from the doctor whose comments defendants claimed triggered the discovery rule, permitting the trier of fact to draw an adverse inference against defendants. *Id.* at 468–70. We concluded that summary judgment was inappropriate because "the application of the discovery rule turn[ed] on a factual dispute." *Id.* at 470.

*Wiseman*'s teachings apply equally in the products liability context. *See Johnson*, 24 Fed. App'x at 538. Johnson took a medication called Parlodel after the birth of her second child, having previously taken it without incident after her first child was born. *Id.* at 534. When she began experiencing severe headaches and escalating symptoms, she sought medical attention from hospital staffers and her own physician. *Id.* The first three times, doctors responded with additional testing along with pain and diarrhea medication; on her fourth attempt, she was

diagnosed as having had a stroke. *Id.* During those visits, no doctor warned her about the risk of stroke from her medication or suggested that it might have caused her symptoms. *Id.* Three years after the stroke, Johnson saw an advertisement targeting women who had taken that medication and suffered strokes or heart attacks; she filed suit within a year thereafter. *Id.* at 534–35. The district court dismissed the case, holding that under Kentucky law, the claim had accrued when Johnson suffered her stroke. *Id.* at 535.

We reversed, finding issues of fact existed concerning when Johnson knew or should have known in the exercise of reasonable diligence "of the alleged causal relationship between Parlodel and her stroke." *Id.* at 537–38. We noted that Johnson had previously taken the medication without problems, and that Parlodel was not the only medication she was taking in the weeks leading up to the stroke. *Id.* We found it particularly significant that Johnson had sought medical attention several times to report her symptoms, but "was never informed by her doctors of the risk of stroke associated with Parlodel." *Id.* From those facts, we reasoned:

> [A] fact-finder might conclude . . . that the doctors and nurses treating Johnson . . . were aware of the medications Johnson was taking, but also that a reasonable person in Johnson's position would *believe* they were aware of them and would advise her of any associated risks at the time she reported her symptoms.

*Id.* at 538. Invoking *Wiseman's* observation that a patient has a right to "rely on [her] physician's knowledge and skill," we held that "[t]he question of whether Johnson's conduct fell short of reasonable diligence under those circumstances is one for the jury to decide." *Id.*

Viewed in her favor, the record suggests that Sue Cutter received inconclusive and contradictory guidance on the cause of her symptoms from the multiple medical professionals she consulted, just like the plaintiffs in *Wiseman*, *Elam*, and *Johnson*. When Cutter visited Dr. Guiler two years after the surgery to report the return of her symptoms, Guiler never suggested the cause was the implant itself. Instead, he thought the source of her problems was scar tissue that had

developed on the loose arm of the implant—a standard risk of any surgery—and believed removing that tissue and the arm would provide Cutter with "complete relief." [R. 82-6, PageID 1252 (Guiler Dep. 50:14-51:15), PageID 1268–69 (*id.* at 117:19-118:7)] So nothing about Cutter's first revision surgery suggested that the implant was defective and was itself the cause of the harm. Instead, a reasonable juror could conclude, Dr. Guiler's approach suggested the problem was *not* with the mesh but with the ordinary scarring that had developed.

Following the revision surgery, Cutter continued to experience pelvic pain and pain with intercourse. In August 2010, Dr. Papp observed that the mesh had "rolled up" and believed it was "possible" that the mesh was "contributing" to Cutter's symptoms; he then referred her for a second opinion. [R. 82-3, PageID 1153 (S. Cutter Dep. 99:4-24, 100:5-20); R. 79-1, PageID 470 (Papp Notes, Aug. 2010)] Then Dr. Jenkins, like Dr. Guiler, recommended removing only part of the mesh, and reported after doing the procedure that everything looked good. [R. 82-3, PageID 1155 (S. Cutter Dep. Tr. 104:22-105:9)] If a doctor advises a patient that everything looks good even though portions of the implant remain in her body, a reasonable patient could interpret that to mean that her pain was not caused by defects in the implant itself. Indeed, Sue Cutter testified that her understanding of the statements of Papp and Jenkins was that her pain was being caused by "the way [the mesh] was rolled up and that, you know, my body wasn't accepting it." [*Id.*, PageID 1153 (S. Cutter Dep. Tr. 101:4-5)]

After seeking medical treatment from several different physicians, Cutter went back to Jenkins in December 2010 to report continuing pain and the scrape to her husband's penis. Dr. Jenkins once again did not attribute these symptoms to the mesh. In fact, his notes observed that he could not even palpate the mesh (as a patient might expect a doctor to be able to do if the device were protruding enough to cause a scrape), but he did observe separation of the vaginal tissue.

[*Id.*, PageID 1155 (S. Cutter Dep. Tr. 108:20-109:24); R. 82-9, PageID 1349–50] Jenkins' notes did not attribute this separation to the mesh either, and he prescribed treatment directed towards the separation, including painkillers, silver nitrate, and an antibacterial gel, and advised Cutter to use warming jelly and increase foreplay during intercourse. [*Id.*; R. 82-3, PageID 1155 (S. Cutter Dep. Tr. 108:20-109:24)] A reasonable jury might find Dr. Jenkins' observations and guidance suggested to Cutter that her symptoms were due to the separation and/or to her body's lack of arousal or natural lubrication.

Defendants contend that Cutter testified that she was "explicitly told" that her injuries were related to the Prolift. Cutter did testify that after she returned to Dr. Jenkins in 2011, he recommended surgery to remove the mesh, but she also testified that Jenkins did not attribute her problems to the mesh itself:

> Q: It looks like you returned to [Jenkins] a few months later, in March of 2011, and you said that your dyspareunia[2] was continuing; is that correct?
> A: Yes.
> Q: Do you recall what you told – what Dr. Jenkins told you at that time?
> A: I don't recall.
> Q: Did he say that you were having any problems with your mesh?
> A: No.
> Q: Did he recommend surgery to remove mesh at that time?
> A: Yes.

[R. 82-3, PageID 1156 (S. Cutter Dep. 110:4-18)] Jenkins' notes reflect that at follow-up visits in February, March, April, and May 2011, he repeatedly observed that the mesh was not palpable and that he was focusing on monitoring the tissue separation; as treatment he proposed excising the separated tissue and suturing the remainder together. [R. 82-9, PageID 1350–52)] Jenkins' notes did not suggest that the mesh might be the cause of any of these issues until June 22, 2011, when Cutter apparently expressed her view that the mesh was the source of her problems. [*Id.*, PageID

[2] Dyspareunia refers to pain with intercourse.

1353] Though Dr. Jenkins focused on treating Cutter's vaginal separation rather than the mesh, and Defendants seek to rely on Cutter's somewhat unclear testimony about Jenkins' alleged statements as the trigger of the discovery rule, Defendants never deposed Jenkins. "Because we must draw all inferences in favor of [the Cutters], and because [Defendants] ha[ve] the burden of proof to show that [Jenkins'] comments triggered the discovery rule, we may draw an inference that [Jenkins'] testimony would have been adverse to [Defendants]." *Elam*, 594 F.3d at 469.

More broadly, a reasonable jury could conclude from the evidence that Sue Cutter, despite diligently investigating the harm she was suffering, reasonably believed until June 2011 that her symptoms were due to a problem with her body rather than with the manufacture of the mesh. That conclusion would fit comfortably within our precedent. First, considering the perspective of the plaintiff, *see Elam*, 594 F.3d at 466, Sue Cutter did not graduate from high school, and only later obtained her GED; she was not a doctor and had no special medical knowledge. At the time she underwent the initial implant surgery to treat her multiple symptoms, she believed the mesh was something "natural" rather than a "synthetic" manufactured product [*Id.*, PageID 1147 (S. Cutter Dep. 71:10-23)]. And her husband had previously received a successful mesh implant for a fistula. [*Id.*, PageID 1138 (S. Cutter Dep. 38:19-39:11)] In addition, "the surrounding circumstances made the alleged causal relationship" between the Prolift's defects and Cutter's symptoms far from "obvious to a lay person." *Johnson*, 24 F. App'x at 538. Not only was the implant internal, but Cutter had a history of pelvic pain due to multiple different health conditions that might have obscured the cause of her pain—just like the many medications taken by Johnson might have caused confusion for her.

And it is undisputed that Cutter visited numerous doctors over the course of multiple years to identify the source of her symptoms and obtain treatment for them. But viewing the record in

her favor, none of these medical professionals attributed her pain to a defect in the Prolift, instead explicitly suggesting the cause was *not* the Prolift, but rather scar tissue (in Dr. Guiler's case) or tissue separation (in Dr. Jenkins' case). A patient has a "right to rely on [her] physician's knowledge and skill," *Wiseman*, 37 S.W.3d at 713, and so a jury could find that Cutter genuinely and reasonably believed that her problems were the fault of her own body. *See Elam*, 594 F.3d at 470. These facts distinguish this case from *Michals*, relied upon by Defendants. In *Michals*, a products liability suit based on defective breast implants, Sherry Michals had been advised by her physician to remove her implants and replace them with a different brand "in order to ameliorate the injury." 289 F.3d at 407–08. Her decision to do so, we concluded, reflected that Michals "specifically attributed these injuries" to the defendants' implants, in contrast with the plaintiff "in *Wiseman* who experienced pain but was unaware that the pain was attributable to the uterine probe left in her body." *Id.* at 407. This record contains evidence that Cutter, like the plaintiff in *Wiseman* and unlike the plaintiff in *Michals*, experienced pain but because of her doctors' advice, was unaware that it was attributable to defects in the Prolift.

The dissent argues that despite the doctors' actions and statements, Cutter should nevertheless have known by May 2012 that the Prolift was a "potential cause" of her pain and should have brought suit. But it is not clear that she could have done so in good faith: multiple doctors gave her the distinct impression that the Prolift was *not* the cause.[3] Similarly, Defendants

[3] In addition, the dissent's argument relies on its conclusion that knowledge of either the "fact of injury or offending instrumentality" is "enough to start the clock immediately" for the discovery rule. (Dissenting. Op. 5) This misapprehends Kentucky's discovery rule. *Fluke* teaches that the clock begins when a plaintiff is aware of her "injury and of the instrumentality causing the injury." 306 S.W.3d at 64 (quoting *Reese v. Gen. Am. Door Co.*, 6 S.W.3d 380, 383 (Ky. Ct. App. 1998)). The discovery rule delays the clock when the plaintiff lacks immediate knowledge of "the fact of injury *or* offending instrumentality." *Id.* at 60 (emphasis added). *Fluke* makes clear that "the fact of injury" and the "offending instrumentality" are both necessary conditions and lack of knowledge of either permits application of the discovery rule. Consider an equivalent real-world example: school is cancelled only when it rains or snows. The dissent's converse rule analysis would conclude that one condition controls: if it does not snow, school will not be cancelled. But that is incorrect because the other condition applies as well—if it is raining (instead of snowing),

contend that Cutter should have investigated further. But the record shows that she did: she saw Dr. Jenkins on multiple occasions after March 2011, and subsequently consulted with several other doctors for alternate opinions. A jury could find these efforts to be reasonably diligent.

Under Kentucky law, the statute of limitations for a cause of action based on a latent injury does not begin to run until a person knows or should know that "[s]he has been wronged,' and this knowledge should not be presumed . . . by '[o]ne who possesses no medical knowledge.'" *Elam*, 594 F.3d at 471 (quoting *Wiseman*, 37 S.W.3d at 712–13). In light of Sue Cutter's testimony that she believed her body had rejected the Prolift, and the evidence that multiple medical professionals also did not attribute her symptoms to the Prolift mesh until Cutter herself raised it with her doctor in June 2011, the question of when she should have known that she had been wronged by Defendants' actions is a question of fact entrusted to the jury.

### C. Strict Liability – Failure to Warn Claim

The district court also concluded that even if it were timely, Plaintiffs' strict liability – failure to warn claim failed for lack of proximate cause. To survive summary judgment on a failure to warn claim, a plaintiff must provide evidence showing that (1) the defendant manufacturer had a duty to warn, (2) any warnings given were inadequate, (3) and the inadequate warnings were the

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school will also be cancelled. As here, the converse of the proposition is that school is not cancelled only if it is *both* not raining and not snowing.

Kentucky caselaw, moreover, does not treat a plaintiff's knowledge of injury and knowledge of instrumentality as distinct inquiries, and the dissent cites no cases in support of that approach. *Fluke*, for example, seems to loosely use the term "injury" to refer to what *Wiseman* characterizes as "harm," and "instrumentality" to refer to what *Wiseman* characterizes as injury—the "wrongdoing" that caused the harm. *Wiseman*, 37 S.W.3d at 712–13. In *Fluke*, the court did not apply the discovery rule because the LeMasters did "not dispute that their injuries were immediately apparent" and because an electric explosion occurred, "they should have reasonably suspected that the voltage meter was not working" and was "a potential cause of the explosion." *Id.* at 61. Similarly, in *Wal-Mart Real Est. Bus. Tr. v. Hopkins Cnty. Coal, LLC*, 2020 WL 7418992, at *4, the Kentucky Court of Appeals held that "the dispositive question" was "whether the offending instrumentality, *i.e.*, subsidence resulting from Appellees' alleged negligence, was immediately evident or discoverable with the exercise of reasonable diligence." *See also Bland v. City of Mt. Washington*, No. 2011-CA-001239-MR, 2012 WL 2892362, at *4 (Ky. Ct. App. July 13, 2012) (discovery rule did not apply when "there was no question that Bland knew she had fallen into a hole, and that the fall was directly responsible for her injury").

proximate cause of the injury. *Stewart v. Gen. Motors Corp.*, 102 F. App'x 961, 964 (6th Cir. 2004) (citing *Morales v. Am. Honda Motor Co.*, 71 F.3d 531, 537 (6th Cir. 1995)). The learned intermediary doctrine 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. *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 761–65 (Ky. 2004).

The district court concluded that Defendants' warnings were not the proximate cause of the Cutters' alleged injuries because Dr. Guiler did not consult Defendants' materials, relying solely on personal surgical experience and demonstrations to inform his knowledge of the potential risk. On appeal, Plaintiffs do not take issue with the district court's analysis of the evidence that was before it. Instead, they offer testimony by Guiler from 2019 in another case to show that additional information from Defendants would have made Dr. Guiler "look at the device differently." Plaintiffs did not provide this evidence to the district court in the 2016 failure to warn briefing, nor did they seek reconsideration of that decision on the basis of newly discovered evidence. They did offer it in connection with Defendants' 2020 supplemental motion for summary judgment, arguing that the learned intermediary doctrine did not bar their fraud by omission claim. But the district court rejected that argument, dismissing the fraud by omission claim, which the Cutters did not appeal.

We review "the case presented to the district court," and a party "may not by-pass the fact-finding process of the lower court and introduce new facts in its brief on appeal." *Bormuth v. Cnty. of Jackson*, 870 F.3d 494, 501 (6th Cir. 2017) (quoting *DaimlerChrysler Corp. Healthcare Benefits Plan v. Durden*, 448 F.3d 918, 922 (6th Cir. 2006) and *Sovereign News Co. v. United States*, 690 F.2d 569, 571 (6th Cir. 1982)). We decline to consider Dr. Guiler's 2019 testimony for the first time on appeal, and so affirm the dismissal of the failure to warn claim.

### D. Remand

Defendants offer a number of alternative reasons why summary judgment should be granted to them on the Cutters' design defect, negligence, gross negligence, defective product, and loss-of-consortium claims. The district court, having found the claims barred as untimely, did not address these arguments. We decline to do so and instead remand to the district court for its consideration in the first instance. *See Rosebrough v. Buckeye Valley High Schl.*, 690 F.3d 427, 433 (6th Cir. 2012); *Yeschick v. Mineta*, 521 F.3d 498, 506 (6th Cir. 2008). We also note that on remand, the district court should revisit the evidentiary motions it previously concluded were mooted by the grant of summary judgment on statute of limitations grounds.

## III. CONCLUSION

For the foregoing reasons, we **REVERSE** the district court's dismissal of the Cutters' negligence, gross negligence, strict liability – defective product, strict liability – design defect, and loss-of-consortium claims, **AFFIRM** the district court's dismissal of their strict liability – failure to warn claim, and **REMAND** for further proceedings consistent with this opinion.

**NALBANDIAN, J., dissenting.** A one-year statute of limitations applies to personal injury suits in Kentucky. Ky. Rev. Stat. § 413.140(a)(1). When Kentucky's discovery rule applies, however, "the statute begins to run on the date of the discovery of the injury, or from the date it should, in the exercise of ordinary care and diligence, have been discovered." *Hackworth v. Hart*, 474 S.W.2d 377, 379 (Ky. 1971). Assuming the discovery rule applies in this products-liability case, Sue Cutter's lawsuit is barred because she "should, in the exercise of ordinary care and diligence, have . . . discovered" enough to bring her claim more than a year before May 2012. *See id.* I would affirm.

I.

When Kentucky's discovery rule applies, it mitigates the state's short one-year limitations period for personal-injury suits. But it does not apply in all personal-injury suits. *See, e.g.*, *Fluke Corp. v. LeMaster*, 306 S.W.3d 55, 60 (Ky. 2010); *Davis v. All Care Med., Inc.*, 986 S.W.2d 902, 906 (Ky. 1999). And it is unclear whether the rule applies to the facts here at all.

In rejecting the rule's application in a product-liability case, the Kentucky Supreme Court held that the rule applies in three types of cases: "cases . . . involving latent injuries, latent illnesses, or professional malpractice." *Fluke*, 306 S.W.3d at 56. And it has "refuse[d] to extend application of the discovery rule" to other situations. *Id.*; *see id.* at 61 (refusing to apply the rule because plaintiffs should have known that a voltage-measuring instrument had said there was no current before an electrical explosion).

It's not apparent to me that this case falls into one of the three categories listed by *Fluke*. In those categories of cases, the persons injured had no idea they were sick or harmed until long after exposure to a harmful substance like asbestos. *See Louisville Tr. Co. v. Johns-Manville Prod. Corp.*, 580 S.W.2d 497, 498 (Ky. 1979) ("From October 1967 until his death in February, 1972,

Sampson was not exposed to asbestos dust. He did not become ill until 1971 and lung cancer was not diagnosed until August 26, 1971."); *Davis*, 986 S.W.2d at 906 (describing latent diseases as "injuries of an inherently unknowable nature"). Or they did not learn about a potential connection between a harm and a defendant's harmful conduct. *See 3M Co. v. Engle*, 328 S.W.3d 184, 189 (Ky. 2010), *as corrected* (Dec. 27, 2010) (holding that client-attorney communications were not privileged given plaintiffs' discovery-rule theory because "when the Plaintiffs' attorneys learned of a possible connection between the Defendants' [respirator] equipment and [coal workers' pneumoconiosis]" was "at issue").

Importantly, I don't think that the Kentucky cases, especially *Wiseman* and *Fluke*, speak with one voice on the application of the discovery rule in cases like this one. *Fluke* seems to tightly circumscribe the application of the discovery rule. *Wiseman* appears to apply it more broadly. *Wiseman v. Alliant Hosps., Inc.*, 37 S.W.3d 709, 711, 713 (Ky. 2000) (applying the discovery rule in a malpractice case in which a plaintiff began experiencing pain "[i]mmediately following . . . surgery" because "[a] mere suspicion of injury due to medically unexplainable pain following an invasive surgery does not equate to discovery of medical negligence," and concluding that discovery did not happen "until the discovery" that a "piece of uterine probe" had been left in her body during the operation).

And looking at the mixed signals in Kentucky caselaw, I'm left puzzling over the difficult question of where this case fits in Kentucky's discovery-rule landscape. This case is not exactly like a case involving a product that causes an immediately apparent or obvious injury. Here, although the initial operation involved implanting a foreign object at the location of her subsequent pain, it was not obviously and immediately unsuccessful; unlike *Fluke*, nothing exploded and caused immediate and obvious harm. *See* 306 S.W.3d at 61. And the Kentucky Supreme Court has

applied the discovery rule in an asbestos context where the instrument, injury, and causation were not immediately apparent. *See Louisville Tr.*, 580 S.W.2d at 498, 501. But I hesitate to say that in Kentucky, there are cases from a timing, instrumentality, injury, and causation standpoint that perfectly mirror this one and clearly tell us the discovery rule applies. In *Davis*, for example, there was some latency in the appearance of the harm but the court did not apply the discovery rule. 986 S.W.2d at 903 (refusing to apply the rule in a case in which the plaintiff "began developing decubitus ulcers on his toes and heel within two months" of "receiving [a] wheelchair" and also "developed a sore behind his knee and . . . on his low back" "[o]ver the next few months").

This case is difficult because I believe there is some latency in Cutter's harm but it lies somewhere between *Wiseman* and the typical asbestos case and *Davis*. Not applying the discovery rule would be harsh here given Kentucky's short one-year statute of limitations (at least in *Davis*, the harm manifested itself within months and within the statute of limitations). But also consider that *Wiseman*, on its face, falls into *Fluke*'s "malpractice" category. Indeed, *Fluke* does not even mention *Wiseman*. Also, even though *Wiseman* was a medical malpractice case, the malpractice involved a medical instrument that a doctor left in the patient plaintiff's body. *See* 37 S.W.3d at 711. And that offending instrumentality was itself not discovered until years after the initial procedure. *Id.* Moreover, in *Fluke*, the relevant product was not the product that immediately and obviously caused the injuries. 306 S.W.3d at 57. The bottom line is that in order for the discovery rule to apply here, Cutter must fall into one of the latency categories that *Fluke* carves out and I'm not sure that's true.

Regardless, even though determining whether the Kentucky Supreme Court would apply the discovery rule here is a difficult question, it is ultimately unnecessary to deciding this case.

Even if the discovery rule initially did delay the limitations clock here, Cutter's case was still untimely for the reasons below.

II.

Putting aside questions about the threshold application of the discovery rule in cases like this one, we know that the Kentucky Supreme Court has shaped the contours of the rule in two types of cases. First, it has explained the rule when applying it—most significantly here in *Wiseman.* Second, it has shaped the rule when it has decided the rule does not apply—most significantly here in *Fluke*.

The majority opinion focuses most of its attention on the former cases. And those cases are, of course, important as we try to decide this case as if we were the Kentucky Supreme Court. *See Savedoff v. Access Grp., Inc.*, 524 F.3d 754, 762 (6th Cir. 2008). But it unconvincingly brushes *Fluke* aside in deciding whether Cutter knew enough to trigger the rule more than a year before May 2012. And by so doing, it misses crucial aspects of Kentucky's discovery rule that should decide this case in Ethicon's favor.

As I read Kentucky's caselaw, there are two ways to trigger a limitations period under the discovery rule. The majority opinion focuses on the first way to the exclusion of the second. This is error.

First, what we agree on. No one disagrees that under the discovery rule a cause of action can accrue when "the plaintiff discovers, or in the exercise of reasonable diligence should have discovered, not only that he has been injured but also that his injury may have been caused by the defendant's conduct." *Wiseman,* 37 S.W.3d at 712 (citation omitted). Thus the focus for this trigger is injury. And the Kentucky Supreme Court has told us that injury is distinct from harm: "[I]t is the date of the actual or constructive knowledge of the injury," not the harm, "which triggers the

running of the statute of limitations." *Id.* Injury is "the invasion of any legally protected interest of another." *Id.* So "[a] legally recognizable injury does not exist until the plaintiff discovers the defendant's wrongful conduct." *Id.* at 713. In *Wiseman*'s malpractice context, the injury was the malpractice itself.

*Wiseman* goes a long way in defining the contours of the discovery rule, but it doesn't occupy the field. Ten years later, as I note above, the Kentucky Supreme Court "refuse[d] to extend application of the discovery rule to cases not involving latent injuries, latent illnesses, or professional malpractice." *Fluke*, 306 S.W.3d at 56. And in so doing, it explained that injury discovery is not the only trigger for a limitations period. When a product is involved, the harm combined with knowledge that an "instrumentality" may have caused that harm can also start the clock.

*Fluke* said two things that lead me to this conclusion. First, in explaining when the discovery rule applies at all, the court held that "the discovery rule is available only in cases where the fact of injury *or offending instrumentality* is not immediately evident or discoverable with the exercise of reasonable diligence." *Id.* at 60 (emphasis added). So conversely, the rule is not available when "the fact of injury or offending instrumentality *is* . . . immediately evident or discoverable." *Id.* (emphasis added). Why? Either there's nothing left to discover or there's enough information that "the plaintiff . . . should have discovered . . . . the fact of injury or offending instrumentality." *Id.* Knowledge of either is enough to start the clock immediately. Knowledge of either is "discovery." And if an evident or discoverable "injury or offending instrumentality" is enough to start the clock at time zero, then it follows that discovery of either later on would be

enough to trigger the limitations period then. So in a products liability case involving the discovery rule, later discovery of the harming "instrumentality" starts the clock.[1]

Second, the *Fluke* court also explained that "plaintiffs have a duty to inquire into the safety of products where it is apparent from the facts that the product may have been a potential cause of an injury." 306 S.W.3d at 64. Although it included this statement in a section discussing equitable estoppel, it followed it up by quoting a pre-*Wiseman* discovery rule decision that held that "[i]n the products liability context, a potential plaintiff's awareness of an injury and of the instrumentality causing the injury is enough to trigger the limitations clock and to impose on the plaintiff the duty to discover the responsible parties." *Id.* (quoting *Reese v. Gen. Am. Door Co.*, 6 S.W.3d 380, 383 (Ky. Ct. App. 1998)).

*Fluke* thus tells us that knowledge of either an "injury" or an "offending instrumentality"—a product that causes harm—is "discovery" for limitations purposes in Kentucky. *Id.* at 60. And the level of knowledge required is just enough facts to know "that the product *may* have been a *potential* cause." *Id.* at 64 (emphases added).

[1] The majority explains its disagreement with this reading of *Fluke* in a footnote by comparing the *Fluke* language to a sentence about adverse weather conditions that bears little to no syntactic resemblance to the language here. Its sentence for comparison is "school is cancelled only when it rains or snows." (Majority Op. at 18.) Calling the alternative sentence "an alternative real-world example" is a stretch. (*Id.*) Focusing here on the actual relevant language, here's an "equivalent real-world example" that simply alters the actual quote from *Fluke*: "[Mail forwarding] is available only in cases where the [addressee's new address] or [the spouse's address] is not immediately evident or discoverable with the exercise of reasonable diligence . . . ." *Fluke*, 306 S.W.3d at 60. When is mail forwarding then not available? To me, it seems obvious that the answer is when neither the new address nor the spouse's address is evident or discoverable. When one is known, forwarding would be inappropriate. But I leave it to the reader to make their own judgment.

It should have been "apparent from the facts that the product"—the Prolift—"may have been a potential cause of" of Cutter's pelvic pain more than a year before May 2012. *See id.* And that means her suit is barred. Consider what she knew at that point. First, she knew that her pain "began after" (albeit not immediately after) "her Prolift procedure in 2006." (R. 76-1, Papp Notes Aug. 2010, 470.) Second, she knew the "mesh was somewhat rolled up in the area corresponding to the area [of her] pain." (R. 82-3, S. Cutter Dep., 1153.) Third, she "knew at that time that the pain . . . could be related to the mesh." (*Id.*) Dr. Papp's notes said that the pain was "possibly secondary to [the] Prolift." (R. 76-1, Papp Notes Aug. 2010, 470.) He "sent [her] to get a second opinion regarding" "the rolled up mesh." (*Id.*) And "Dr. Jenkins "confirmed that it was rolled up and thought that" removal might "help [her] pain." (R. 82-3, S. Cutter Dep., 1153.) She said that her "understanding at the time" of the "cause[]" of her pain was "the way [the mesh] was rolled up." (*Id.*) Fourth, she knew that the surgery would involve more than just unrolling the mesh or removing that part. Dr. Jenkins told her that "he was going to have to excise the rolled area of mesh along with the central aspects of the Prolift and remove the arms." (R. 76-3, S. Cutter Dep., 483.) Taken together, she knew enough to suspect that the mesh "may have been a potential" "offending instrumentality." *See Fluke*, 306 S.W.3d at 64.

The majority resists this conclusion because Cutter had "a right to 'rely on [her] physician's knowledge and skill'" given the internal nature of her injury. (Majority at 13 (quoting *Johnson v. Sandoz Pharms. Corp.*, 24 F. App'x 533, 538 (6th Cir. 2001).) And it believes that Cutter merely "received inconclusive guidance on her symptoms from multiple medical professionals." (*Id.*) It observes that when Cutter visited Dr. Guiler two years after her surgery, he suggested that her pain's source was scar tissue surrounding a loose arm on her Prolift implant, not the Prolift itself. (*Id.*) After her second revision surgery, Dr. Jenkins told her that everything looked good despite

only partial removal of the mesh. (*Id.* at 14.) And when pain continued and Cutter reported that something had scraped her husband during intercourse, Dr. Jenkins could not palpate the mesh and suggested the problem might be something else. (*Id.*) It suggests these facts, viewed in the light most favorable to Cutter, show that she was not on notice for limitations purposes.

The majority glosses over the crucial appointments where her doctors put her on notice that the mesh was a potential offending instrumentality—something sufficient in isolation under Kentucky law. Look at the facts in context. I agree that the initial appointment with Dr. Guiler was not enough. He said the problem was detachment and scar tissue, suggesting problems with the attachment of the Prolifit and normal risks of surgery. (*See* R. 82-6, Guiler Dep., 1252, 1268-69.) But fixing those problems did not give her relief, suggesting that ordinary scarring was not the problem. And the next set of doctors both confirmed that might be the case, telling her that the pain might be related to the mesh and informing her the mesh itself was doing something it wasn't supposed to do—rolling up. (*See* R. 82-3, S. Cutter Dep., 1153.) Rather than just unrolling it, Dr. Jenkins told Cutter that they would "excis[e] as much [of the mesh] as [they] could." (R. 82-11, Jenkins Notes, 1375.) At that point, Cutter admitted that she said that she understood that "the way [the mesh] was rolled up" was the root of her problem. (R. 82-3, S. Cutter Dep., 1153.) And only after removing most of the mesh did Dr. Jenkins say everything looked good. (*See id.* at 1155.) True, Cutter also said that she thought that her body was just rejecting the mesh. (*Id.* at 1153.) But notice of a defect is not required; notice of the "offending instrumentality" is enough. *See Fluke*, 306 S.W.3d at 60, 64. She had notice of that fact (she arguably even had notice of a possible defect given evidence of rolling). And so the clock started, rendering her May 2012 lawsuit untimely. What happened after her 2010 revision operation does not alter that she knew enough to be on notice of a possible products liability claim. In any event, her post-2010 revision history confirms

that she was on notice that the mesh might be an "offending instrumentality"; when problems persisted, Dr. Jenkins recommended further mesh removal in March 2011. (R. 82-3, S. Cutter Dep., 1156.)

Because Cutter had notice of the potential "offending instrumentality" more than a year before she sued, I respectfully dissent. I would affirm.