In the

United States Court of Appeals

For the Seventh Circuit

No. 18-2944

BARBARA KAISER,

Plaintiff-Appellee,

v.

JOHNSON & JOHNSON and ETHICON, INC.,

Defendants-Appellants.

Appeal from the United States District Court for the
Northern District of Indiana, Hammond Division.
No. 2:17-cv-00114 — **Phillip P. Simon**, *Judge*.

ARGUED MAY 21, 2019 — DECIDED JANUARY 14, 2020

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

SYKES, *Circuit Judge*. Barbara Kaiser had surgery to implant the Prolift Anterior Pelvic Floor Repair System, a transvaginal mesh medical device that supports the pelvic muscles. Within a few years of her surgery, Kaiser began experiencing severe pelvic pain, bladder spasms, and pain during intercourse. Her physician attributed these conditions to contractions in the mesh of the Prolift. Kaiser had revision surgery to remove the device, but her surgeon could

not completely extract it. He informed her that the painful complications she was experiencing were likely permanent.

Kaiser sued Ethicon, Inc., Prolift's manufacturer, and Johnson & Johnson, its parent company, seeking damages under the Indiana Products Liability Act, IND. CODE §§ 34-20-1-1 to 34-20-9-1. (Johnson & Johnson has no distinct role in this litigation, so we refer to the defendants collectively as "Ethicon.") After a two-week trial, a jury found Ethicon liable for defectively designing the Prolift device and failing to adequately warn about its complications. The jury awarded a hefty sum: $10 million in compensatory damages and $25 million in punitive damages, though the judge granted Ethicon's motion for remittitur and reduced the punitive award to $10 million.

Ethicon's appeal is a broad-spectrum attack on the judgment, starting with an argument about federal preemption and moving through several issues of Indiana product-liability law, a claimed evidentiary error, and challenges to the compensatory and punitive damages. We reject these arguments and affirm.

One issue in particular warrants special mention upfront. Our caselaw interprets the Indiana Product Liability Act to require a plaintiff in a design-defect case to produce evidence of a reasonable alternative design for the product. The Indiana Supreme Court disagrees. *See TRW Vehicle Safety Sys., Inc. v. Moore*, 936 N.E.2d 201, 209 (Ind. 2010). The state supreme court's decision controls on a matter of state law, so we apply *TRW* rather than our own contrary precedent.

I. Background

A. Prolift

Barbara Kaiser suffers from pelvic-organ prolapse, a nonlife-threatening condition that occurs when pelvic muscles loosen, causing nearby organs to press into the vagina. This condition can lead to several medical complications like uncomfortable pelvic pressure and incontinence.

Ethicon developed Prolift as a treatment option for patients with this condition, and in 2009 Kaiser had surgery to implant the device. Some detail about Prolift is necessary to understand her case and the arguments raised on appeal. The device is essentially a precut section of polypropylene mesh connected to six mesh arms. A surgeon inserts it through the vagina, pulls it through the vaginal wall, and anchors the arms to muscles in the hip, thigh, and groin. The device was designed to reinforce the pelvic muscles and prevent further organ displacement.

Ethicon began marketing Prolift in 2005. It included an "Instructions for Use" package insert that warned: "Potential adverse reactions are those typically associated with surgically implantable materials, including infection potentiation, inflammation, adhesion formation, fistula formation, erosion, extrusion and scarring that results in implant contraction." It also cautioned that "[t]ransient leg pain may occur and can usually be managed with mild analgesics."

Patients soon reported serious problems with the Prolift. Relevant here, the mesh would often contract, causing severe pain and bladder problems. Scar tissue could also form around the device, preventing a complete removal if complications occurred. In these cases Prolift's complications

frequently became permanent. Following years of complaints and FDA scrutiny, Ethicon took Prolift off the market in 2012.

B. Regulatory Background

The FDA cleared Prolift for sale in 2007. The clearance process features prominently in this appeal, so we take a moment to describe the FDA's role in regulating medical devices. The Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. §§ 360c–360k, 379–379a, establishes the framework for federal regulation of medical devices. As amended, the MDA requires the FDA to place a device into one of three classes reflecting different levels of regulation.

Class I covers devices for which the MDA's "general controls" that apply to all medical devices "are sufficient to provide reasonable assurance of the safety and effectiveness of the device." 21 U.S.C. § 360c(a)(1)(A)(i). These general controls include measures like the MDA's prohibition on misbranding a device. The FDA typically places low risk devices like bandages and tongue depressors in Class I.

The FDA places a device in Class II when the MDA's "general controls by themselves are insufficient to provide reasonable assurance of … safety and effectiveness" but enough information exists "to establish special controls to provide such assurance." *Id.* § 360c(a)(1)(B). "Special controls" are regulations tailored to the device such as performance standards and postmarket surveillance. *See id.* Most medical devices fall into Class II.

Finally, a Class III device is one for which "insufficient information exists to determine" that either general or special controls "would provide reasonable assurance of …

safety and effectiveness." *Id.* § 360c(a)(1)(C)(i). These devices "present[] a potential unreasonable risk of illness or injury" or are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health." *Id.* § 360c(a)(1)(C)(ii). Before marketing, a Class III device undergoes "a rigorous regime of premarket approval." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317 (2008).

The particulars of the premarket approval process aren't important here; it's enough to note that it requires extensive submissions by the device manufacturer and a thorough review by the FDA. *See generally* 21 U.S.C. §§ 360c, 360e. The FDA has broad discretion to withhold approval throughout the process. *See* 21 C.F.R. § 861.1(b) (permitting the FDA to set performance standards for Class II and III devices); *see also* Nicholas R. Parrillo, *Federal Agency Guidance and the Power to Bind: An Empirical Study of Agencies and Industries*, 36 YALE J. ON REG. 165, 186–87 (2019).

The MDA automatically places a new medical device in Class III. 21 U.S.C. § 360c(f)(1). But three broad exceptions largely overshadow this rule. To start, medical devices on the market before the MDA's enactment in 1976 are subject only to the MDA's general controls until the FDA promulgates device-specific regulations to classify and regulate them. *Id.* § 360e(b).

Post-1976 devices can escape rigorous premarket review through the MDA's "premarket notification" process. Almost every manufacturer of a new device must submit a notification to the FDA at least 90 days before marketing the device. *See* 21 C.F.R. § 807.81(a); *see also id.* § 807.81(a)(3) (requiring a manufacturer to file a premarket notification

when it alters an existing device if the alteration "could significantly affect the safety or effectiveness of the device" or if it creates a "major change or modification in the intended use of the device"). The FDA may clear a device for sale without premarket approval based on this notification if it is satisfied the device falls into one of the two other exceptions.

First, the MDA exempts from premarket review any device that receives what's known as a "§ 510(k) clearance" from the FDA. To get this clearance, a device must be "substantially equivalent" to either a pre-1976 device that the FDA hasn't yet classified or a Class I or II device already on the market. § 360c(f)(1). Most medical devices enter the market through this exception. *See* 2 JAMES T. O'REILLY & KATHARINE A. VAN TASSEL, FOOD AND DRUG ADMINISTRATION § 18.22, at 464 (4th ed. 2019).

Second, if a device isn't substantially equivalent to an unclassified pre-1976 device or a Class I or II device, it can still avoid premarket review through "de novo" § 510(k) clearance. *See* 21 U.S.C. § 360c(f)(2)(A). Specifically, a manufacturer may petition the FDA that a device meets the criteria for Class I or II. If the FDA agrees, the device is exempted from premarket review. *Id.*; O'REILLY & VAN TASSEL, *supra*, § 18.26, at 470–71.

The § 510(k) clearance process is central to several issues raised in this appeal. If the FDA is satisfied that a new device is substantially equivalent to a device that is already in Class I or II or meets the standards for these classes through "de novo" § 510(k) review, then it will clear the device for marketing without stringent premarket review. To be substantially equivalent, the device must have "the same intended use as the predicate device" and either (1) have "the

same technological characteristics" as the predicate device *or* (2) be "as safe and effective" as the predicate and "not raise different questions of safety and effectiveness." 21 U.S.C. § 360c(i)(1)(A).

The relevance to safety of the § 510(k) clearance process varies based on context. That's due in part to the MDA's three-tiered system for classifying medical devices. If the FDA places a device in Class I after a de novo § 510(k) review, we know the agency has concluded that the MDA's minimal general controls are enough to "provide reasonable assurance of … safety." § 360c(a)(1)(A). Likewise, when the FDA places a device in Class III following full premarket review, we know that the agency lacks a reasonable assurance of the device's safety. But the FDA's decision to place a device in Class II tells us only that it had enough information about the device to design special controls to provide reasonable assurance of safety. It's hard to draw inferences about a device's safety without knowing what concerns triggered its Class II designation and what special controls the FDA thought were necessary.

A device cleared for market through the § 510(k) "substantial equivalence" process raises additional complications. To start, two of the three ways for a new device to be substantially equivalent to a predicate device have nothing to do with product safety. First, a device can receive clearance if it is substantially equivalent to a pre-1976 device that the FDA hasn't yet classified "regardless of how unsafe or ineffective the grandfathered device happens to be." *Eghnayem v. Bos. Sci. Corp.*, 873 F.3d 1304, 1318 (11th Cir. 2017) (quotation marks omitted). Second—and more pertinent to Prolift—the FDA can clear a device if it has "the

same technological characteristics as [a] predicate device." § 360c(i)(1)(A)(i). This comparison does not consider safety. The MDA defines "different technological characteristics" as "a significant change in the materials, design, energy source, or other features of the device from those of the predicate device." 21 U.S.C. § 360c(i)(1)(B). Underscoring the distinction between safety and similarity of technological characteristics, the FDA does not generally require safety information in a § 510(k) substantial-equivalence premarket notification. *See* 21 C.F.R. § 807.92(a).

Finally, the MDA's authorization of "piggybacking"—clearing a device based on its substantial equivalence to a predicate device that itself received clearance through substantial equivalence—increases the gulf between § 510(k) clearance and comprehensive safety review. Through piggybacking, a medical device moves incrementally further and further away from the "original" predicate device that the FDA actually classified.

In light of these features of the system, it's no surprise that the FDA has promulgated a disclaimer that § 510(k) clearance "does not in any way denote official approval of the device." *Id.* § 807.97. In fact, it's unlawful for a device manufacturer to make such a representation. *See id.* ("Any representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding."); *see also* O'REILLY & VAN TASSEL, *supra*, § 18.22, at 464 ("It is important to note that in the § 510(k) process, the device is not officially approved by the FDA as being safe and effective.").

C. Prolift

Prolift did not weather the full premarket review process. Quite the contrary: Ethicon started marketing Prolift in 2005 without submitting *any* premarket notification to the FDA, reasoning that the device didn't depart materially from a transvaginal mesh product that the agency had previously cleared. In fact, Ethicon did not submit a § 510(k) premarket notification for Prolift until 2007 when the FDA demanded one.

Its 2007 submission asserted that Prolift was substantially equivalent to three devices: the Gynecare Gynamesh PS Prolene Soft Mesh, the AMS Apogee Vault Suspension System, and the AMS Perigee System.[1] According to Ethicon, Prolift had the same technological characteristics as these predicates.

The FDA cleared Prolift based on this submission, sending a form letter that did not identify which particular predicate device it accepted for the substantial-equivalence determination. But the agency did indicate that Prolift's "original" predicates were a group of surgical meshes the FDA classified in a 1988 rulemaking. *See* 21 C.F.R. § 878.3300. When it promulgated that rule, the FDA cautioned that the "surgical mesh has not been implanted in a sufficient number of patients by a sufficient number of medical practitioners to provide adequate evidence on the long-term biocompatibility of these devices." General and Plastic Surgery Devices, 53 Fed. Reg. 23856, 23862 (June 24, 1988).

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[1] Ethicon's premarket notification for Prolift listed a fourth predicate, the Ultrapro Mesh, but it used that device only to clear the Prolift +M Pelvic Floor Repair System, a different device than the Prolift at issue here.

Due to "insufficient evidence of safety and effectiveness," the FDA assigned these surgical meshes to Class II. *Id.*

Because the FDA did not specify the predicate device it used for Prolift's § 510(k) clearance, the chain connecting the 1988 surgical meshes to Prolift is not clear. We do know that Prolift used the piggybacking method to achieve clearance; that is, each of Prolift's three proposed predicates received FDA clearance through a substantial-equivalence determination. The manufacturers of those three predicates collectively proposed 17 predicates. And again, the FDA did not indicate which of the 17 predicates it used to clear these three devices. Because the FDA's records for the 17 second-order predicates are incomplete, we cannot make out a clear picture of the next layer. But the available records reveal an additional degree of piggybacking—all received FDA clearance through a substantial-equivalence determination.

Based on Ethicon's 2007 § 510(k) premarket notification, the FDA cleared Prolift as a Class II device after finding that it was substantially equivalent to existing Class II devices. But in 2011 the FDA ordered Ethicon and other transvaginal mesh manufacturers to submit plans for postmarket studies of the devices. When the FDA rejected Ethicon's plan for Prolift in 2012, Ethicon discontinued the device. In 2016 the FDA reclassified all transvaginal mesh into Class III. *See* 21 C.F.R. § 884.5980.

D. Kaiser's Surgery and Lawsuit

Kaiser suffered from a severe anterior pelvic-organ prolapse. Her doctor referred her to Dr. Gregory Bales, a pelvic-floor surgeon in her home state of Indiana. In January 2009 Dr. Bales surgically implanted Prolift to treat Kaiser's condi-

tion. She was then 60 years old. The parties agree that Dr. Bales properly implanted Prolift and otherwise met the appropriate standard of care.

In September 2011 Kaiser reported pelvic pain to her physician, who attributed the problem to Prolift "bunching." Kaiser's complications gradually worsened. In October 2013 she complained of severe pelvic pain and bladder spasms. After determining that the Prolift was the likely source of these problems, Kaiser's physician recommended surgery to remove the device. In November Dr. Bales performed a corrective procedure by using clamps and scissors to remove the vaginal tissue surrounding the mesh. But he was only able to remove part of the device. He informed Kaiser that her pain was likely permanent.

Kaiser sued Ethicon in the Southern District of West Virginia, the venue of a 28,000-case multidistrict litigation ("MDL") against Ethicon. Kaiser and Ethicon agreed that Indiana law applied, and the MDL judge construed two counts in Kaiser's complaint as alleging design-defect and failure-to-warn claims under the Indiana Product Liability Act ("IPLA" or "the Act"). The judge rejected Ethicon's argument that the federal regulatory scheme preempted Indiana law. He then dismissed Kaiser's other claims as non-cognizable under the Act and transferred the case to the Northern District of Indiana.

Two of Kaiser's posttransfer motions are relevant here. First, the Indiana district judge granted Kaiser's motion to exclude evidence related to the FDA's clearance of Prolift, reasoning that the § 510(k) process was only minimally probative of safety and that introducing evidence about the regulatory process posed a significant risk of jury confusion.

Second, the judge ruled that Prolift did not qualify as "state of the art" under Indiana law, which blocked Ethicon from relying on a rebuttable presumption that the device was not defective. *See* IND. CODE § 34-20-5-1.

The case proceeded to trial. The jury returned a verdict for Kaiser on both the design-defect and failure-to-warn theories of liability and awarded $10 million in compensatory damages and $25 million in punitive damages.[2]

Ethicon moved for judgment as a matter of law under Rule 50 of the Federal Rules of Civil Procedure, reiterating the argument it raised in the MDL court that the § 510(k) process preempts a design-defect claim under state law. Ethicon also argued that the IPLA required Kaiser to present evidence of a reasonable alternative design for the device (she had none), and that the evidence otherwise failed to establish that Prolift was defective and unreasonably dangerous as required for liability. Regarding the failure-to-warn theory, Ethicon argued that Prolift's warnings were adequate as a matter of law and that Kaiser's evidence of causation was insufficient. Ethicon also moved for a new trial based on the judge's exclusion of evidence of Prolift's § 510(k) clearance and his refusal to instruct the jury on a pair of rebuttable presumptions under the IPLA, including the "state of the art" presumption. Finally, Ethicon challenged the jury's award of compensatory damages and attacked the award of punitive damages as both substantively unwarranted and excessive.

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[2] Kaiser's husband, Anton, brought a derivative claim for loss of consortium, but the jury found in favor of Ethicon. He did not appeal.

The judge denied the posttrial motions in all respects except one: he agreed that the jury's award of punitive damages was excessive and granted a remittitur to $10 million, which Kaiser accepted. The judge then entered final judgment, setting up this multifaceted appeal.

II. Discussion

Ethicon's first attack on the judgment rests on federal preemption. Alternatively, Ethicon argues that Kaiser's claims fall short under Indiana law in multiple respects, or at the very least a new trial is warranted based on evidentiary and instructional errors by the district judge. Lastly, Ethicon challenges the compensatory and punitive damages.

Before addressing this flurry of arguments, we pause to sketch the law of product liability in Indiana. The Indiana Products Liability Act governs all claims brought by a consumer against a manufacturer for physical harm caused by its product, regardless of legal theory. IND. CODE § 34-20-1-1. Under the Act a manufacturer who places "into the stream of commerce any product in a defective condition unreasonably dangerous to any user or consumer … is subject to liability for physical harm caused by that product." *Id.* § 34-20-2-1.

Ethicon's state-law challenges to the judgment center on whether Prolift was "defective" and "unreasonably dangerous." Defectiveness "focuses on the product itself." *Gresser v. Dow Chem. Co.*, 989 N.E.2d 339, 345 (Ind. Ct. App. 2013). A product is defective if it is in a condition "not contemplated by reasonable persons among those considered expected users or consumers of the product" and "will be unreasonably dangerous … when used in reasonably expectable

ways." IND. CODE § 34-20-4-1. "A product may be defective under the IPLA if it is defectively designed, if it has a manufacturing flaw, or if it lacks adequate warnings about dangers associated with its use." *Brewer v. PACCAR, Inc.*, 124 N.E.3d 616, 621 (Ind. 2019).

The Act grounds design-defect and failure-to-warn liability in negligence: a plaintiff must "establish that the manufacturer or seller failed to exercise reasonable care under the circumstances in designing the product or in providing the warnings or instructions." IND. CODE § 34-20-2-2. Under either theory, a plaintiff must prove that the defendant breached the duty of reasonable care owed to him—whether in the product's design or in its warnings—and the breach proximately caused his injury. *See Brewer*, 124 N.E.3d at 621. (In cases involving a manufacturing defect, the statute imposes strict liability; a showing of negligence is not required. *See* IND. CODE § 34-20-2-2.)

The "unreasonably dangerous" standard incorporates the "consumer expectations" test set forth in the *Restatement* (*Second*) *of Torts*: A product is unreasonably dangerous when it "exposes the user or consumer to a risk of physical harm to an extent beyond that contemplated by the ordinary consumer who purchases the product with the ordinary knowledge about the product's characteristics common to the community of consumers." IND. CODE § 34-6-2-146; *accord* RESTATEMENT (SECOND) OF TORTS § 402A cmt. i (AM. LAW INST. 1965). To decide whether a product is unreasonably dangerous, the fact-finder may consider several factors, including "the reasonably anticipated knowledge, perception, appreciation, circumstances, and behavior of expected users." *Koske v. Townsend Eng'g Co.*, 551 N.E.2d 437, 440–41

(Ind. 1990). Whether a product is unreasonably dangerous is a distinct inquiry and must be established whether the claim is based on a manufacturing defect, a design defect, or a defective warning.

A. Design-Defect Liability

Ethicon reprises several of its arguments for judgment as a matter of law on Kaiser's design-defect claim. Our review is de novo; judgment as a matter of law is warranted "only if on the basis of the admissible evidence, no rational jury could have found for the prevailing party." *Stragapede v. City of Evanston*, 865 F.3d 861, 865 (7th Cir. 2017) (quotation marks omitted). A threshold legal issue, however, is federal preemption.

1. *Preemption*

Under the Supremacy Clause, federal law is "the supreme Law of the Land … , any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. CONST. art. VI cl. 2. When "state and federal law 'directly conflict,' state law must give way." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 617 (2011). A direct conflict exists where "it is impossible for a private party to comply with both state and federal requirements." *Id.* at 618 (quotation marks omitted). Ethicon maintains that it is impossible for it to comply with both the federal regulatory scheme for medical devices—here, the § 510(k) clearance process—and the requirements of the IPLA.

We begin by recapping Ethicon's duties under state and federal law. As relevant here, under Indiana tort law, Ethicon was required to "exercise reasonable care under the circumstances in designing" Prolift. § 34-20-2-2. That is,

Ethicon had a state-law duty to ensure that Prolift's design made the device "reasonably fit and safe for the purpose for which [it was] intended." *Brewer*, 124 N.E.3d at 623 (quotation marks omitted). Meanwhile, federal law required Ethicon to obtain FDA clearance before marketing or substantially modifying Prolift. § 360c(f)(2)(A); 21 C.F.R. § 807.81(a)(3)(ii). To obtain FDA clearance under the § 510(k) process, it had to file a premarket notification establishing that Prolift was substantially equivalent to an already-cleared device or otherwise met the requirements for a Class I or II device.

Ethicon argues that these state and federal duties directly conflict: it could not independently redesign Prolift to satisfy its duties under the IPLA because the § 510(k) regulatory scheme required it to seek FDA clearance before making any substantive changes to the device.

This argument does not come to us on a blank slate. In *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), the Supreme Court addressed the § 510(k) clearance process in relation to the MDA's express preemption provision, which preempts state regulations that are "different from, or in addition to, any [MDA] requirement applicable … to the device." 21 U.S.C. § 360k(a)(1). The Court held that the § 510(k) regulatory regime does not preempt state tort liability through this provision. *Lohr*, 518 U.S. at 501. The Court explained that the § 510(k) substantial-equivalence standard does not impose any requirements on a medical device but is simply an exception to the premarket approval process. *Id.* at 492–94; *cf. Riegel*, 552 U.S. at 323 (holding that the MDA premarket approval process does preempt state law under the express-preemption provision).

Kaiser argues that *Lohr* forecloses Ethicon's preemption defense without further inquiry. We disagree. *Lohr* addressed a question of express preemption; Ethicon argues here for implied preemption. An express-preemption provision "supports a reasonable inference[] that Congress did not intend to pre-empt other matters," but it does not "entirely foreclose[] any possibility of implied pre-emption." *Freightliner Corp. v. Myrick*, 514 U.S. 280, 288 (1995); *see also PLIVA*, 564 U.S. at 618 n.5 ("[T]he absence of express pre-emption is not a reason to find no *conflict* pre-emption."). The Court's decision in *Lohr* turned on the particular language of the MDA's preemption provision—more specifically, whether the § 510(k) process imposes "any requirement[s] applicable … to the device." 518 U.S. at 486 (quoting § 360k(a)(1)). *Lohr*'s reasoning is certainly instructive, but it does not tell us whether it was impossible for Ethicon to comply with its duties under both federal and state law.

Still, implied preemption does not arise here. "The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." *PLIVA*, 564 U.S. at 620. "[W]hen a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes." *Id.* at 623–24.

Nothing in the § 510(k) regulatory scheme prevented Ethicon from complying with the IPLA's standard of care before seeking § 510(k) clearance for Prolift. Indeed, the § 510(k) process did not require Prolift "to take any particu-

lar form for any particular reason." *Lohr*, 518 U.S. at 493. As we've explained, the § 510(k) process simply asks whether a device is substantially equivalent to an approved device or otherwise meets the MDA's broad standards for Class I or II devices. *See* § 360c(f). Federal law did not stop Ethicon from satisfying its state-law duties regarding Prolift's design *before* it filed its premarket notification seeking substantial-equivalence clearance. It lost independent control over Prolift's design only after it received § 510(k) clearance from the FDA.

Ethicon's situation is loosely analogous to that of a brand-name drug manufacturer faced with state-law tort duties regarding the adequacy of its warnings. A brand-name manufacturer can strengthen a warning label without waiting for FDA approval. *See* 21 C.F.R. § 314.70(c)(6)(iii). The FDA requires brand-name manufacturers to file a supplement explaining a change in warnings and reserves the right to reject a labeling change after it is made. *Id.* § 314.70(c)(7).

In *Wyeth v. Levine*, 555 U.S. 555 (2009), the Supreme Court considered whether it was impossible for a brand-name drug manufacturer to comply with this federal labeling regime and its duties under state tort law. The Court rejected the manufacturer's claim of impossibility preemption, noting that the FDA permitted a manufacturer "to unilaterally strengthen its warning" to comply with state law. *Id.* at 573. The Court recognized that the FDA could veto such a change, but "absent clear evidence that the FDA would not have approved a [warning] change," no direct conflict between federal and state duties could be said to exist. *Id.* at 571.

The same reasoning applies here. The federal regulatory regime did not make it impossible for Ethicon to comply with its state-law duties before it sought § 510(k) clearance for Prolift in 2007. Ethicon does not claim that the FDA would have rejected a different design, so on a straightforward application of *Wyeth*, Ethicon hasn't established a direct conflict between its duties under federal and state law. *See id.* at 573 ("[T]he mere fact that the FDA approved [a different] label does not establish that it would have prohibited such a change.").

Ethicon's response rests largely on an analogy to the FDA's framework for generic drugs, which the Supreme Court has held preempts failure-to-warn liability under state tort law. *See Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 486–87 (2013); *PLIVA*, 564 U.S. at 618. There is some similarity between the § 510(k) process for clearing a medical device and the FDA's clearance of generic drugs. A manufacturer can receive FDA clearance for a generic drug "by showing equivalence to a reference listed drug that has already been approved by the FDA." *PLIVA*, 564 U.S. at 612 (citing 21 U.S.C. § 355(j)(2)(A)).

But there is a crucial difference: A manufacturer of generic drugs has no flexibility when it initially creates a warning label. Instead, federal law imposes the "duty of sameness," which requires a generic drug manufacturer to "ensur[e] that its warning label is the same as the brand name's" label. *Id.* at 613. So if a brand-name warning is insufficient under state law, it's impossible for a generic drug manufacturer to simultaneously comply with federal and state law. *See Bartlett*, 570 U.S. at 490 ("Federal law requires a very specific label … , and state law forbids the use of that label.").

Because of this inflexibility, the Court's generic-drug rulings turn on whether a "generic manufacturer[] may change [its] label[] *after* initial FDA approval." *PLIVA*, 564 U.S. at 613. The important point for this case, however, is that Ethicon had complete and independent control over Prolift's design before it sought § 510(k) clearance for the device. It was not impossible to simultaneously comply with federal and state law.

Ethicon also relies on the Supreme Court's rejection of the "stop selling" theory in *Bartlett*. The plaintiffs in *Bartlett* resisted federal preemption by asserting that the manufacturer could comply with both federal and state law by simply ceasing to manufacture the generic drug at issue. The Court explained that this argument would make "impossibility pre-emption … all but meaningless." *Bartlett*, 570 U.S. at 488 (quotation marks omitted). The Court held that "an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability." *Id.* At least one circuit has relied on *Bartlett* to reject an "exit the market" argument in a case raising a preemption defense against a design-defect claim involving a pharmaceutical product. *Yates v. Ortho-McNeil-Janssen Pharm., Inc.*, 808 F.3d 281, 300 (6th Cir. 2015).

Ethicon's reliance on this aspect of *Bartlett* is misplaced. *Bartlett*, 570 U.S. at 490 ("[F]ederal law establishes no safe-harbor for drug companies … ."); *see also Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1678 (2019) ("[W]e have refused to find clear evidence of … impossibility where the laws of one sovereign permit an activity that the laws of the other sovereign restrict or even prohibit."). The Court held only that a plaintiff cannot use the stop-selling rationale

to harmonize otherwise conflicting federal and state laws. *Bartlett*, 570 U.S. at 488. That holding is of little help where, as here, no direct conflict between federal and state law exists. As we've explained, the requirements of the § 510(k) premarket-notification process do not directly conflict with Indiana law under the principles announced in *Wyeth*. The design-defect claim is not preempted.

2. *Reasonable Alternative Design*

Moving on to state-law arguments, Ethicon contends that the IPLA requires a plaintiff to produce evidence of a reasonable alternative design for the product in order to prevail on a design-defect claim. If this reading of Indiana law is correct, Ethicon is entitled to judgment as a matter of law. Kaiser did not present evidence of a reasonable alternative design for transvaginal mesh.

As we've noted, a product is defective within the meaning of the IPLA if it is sold "in a condition: (1) not contemplated by reasonable persons among those considered expected users or consumers of the product; and (2) that will be unreasonably dangerous to the expected user or consumer when used in reasonably expectable ways of handling or consumption." IND. CODE § 34-20-4-1. Put in terms of the Act's negligence standard for design-defect claims, Ethicon had a duty to ensure that Prolift's design made the device "reasonably fit and safe for the purpose for which [it was] intended." *Brewer*, 124 N.E.3d at 623 (quotation marks omitted).

Nothing in the IPLA expressly requires a plaintiff to prove that an alternative product design would have prevented his injury; indeed, the Act is silent on the subject.

Nevertheless, we have long held that "[t]o demonstrate a design defect under Indiana law, the plaintiff must … show that another design not only could have prevented the injury but also was cost-effective under general negligence principles." *Aregood v. Givaudan Flavors Corp.*, 904 F.3d 475, 488 (7th Cir. 2018) (quotation marks omitted). Ethicon invokes this line of circuit precedent. Kaiser, in turn, points to the Indiana Supreme Court's decision in *TRW Vehicle Safety Systems, Inc. v. Moore*, 936 N.E.2d 201, 209 (Ind. 2010), which specifically rejected an alternative-design requirement as inconsistent with the IPLA standards for design-defect liability.

To understand this split in authority, it's helpful to trace its origin. The story begins with the Indiana Supreme Court's decision in *Miller v. Todd*, 551 N.E.2d 1139 (Ind. 1990), which considered the appropriate standard for crashworthiness cases, also known as "enhanced injury" cases. These claims seek to hold manufacturers liable "for injuries sustained in a motor vehicle accident where a manufacturing or design defect, though not the cause of the accident, caused or enhanced the injuries." *Id.* at 1140. *Miller* held that to prove "'[d]efectiveness' from a crashworthiness standpoint," a plaintiff must "demonstrate that a feasible, safer, more practicable product design would have afforded better protection." *Id.* at 1143.

Following *Miller*'s instructions, we have applied an alternative-design requirement in crashworthiness cases under Indiana law. *See Piltch v. Ford Motor Co.*, 778 F.3d 628, 632 (7th Cir. 2015); *Whitted v. Gen. Motors Corp.*, 58 F.3d 1200, 1204–05 (7th Cir. 1995); *Pries v. Honda Motor Co.*, 31 F.3d 543, 545 (7th Cir. 1994); *Bammerlin v. Navistar Int'l Transp. Corp.*,

30 F.3d 898, 902 (7th Cir. 1994). But we limited *Miller* to that specific context—at least initially. *See Anderson v. P.A. Radocy & Sons, Inc.*, 67 F.3d 619, 625 n.5 (7th Cir. 1995) ("[T]he requirement that the plaintiff, in order to establish a defective condition, must offer a more cost-effective design applies to enhanced injury cases only."); *see also Welch v. Scripto-Tokai Corp.*, 651 N.E.2d 810, 815 n.5 (Ind. Ct. App. 1995) ("Although the feasibility of a safer design of a product may be relevant to the ordinary consumer's expectations about that product, such feasibility is not controlling.").

We later applied an alternative-design requirement in a design-defect case outside the crashworthiness context, albeit through the IPLA's negligence provision. *See* § 34-20-2-2. In *McMahon v. Bunn-O-Matic Corp.*, we cited *Miller* for the proposition that "a design-defect claim in Indiana is a negligence claim, subject to the understanding that negligence means failure to take precautions that are less expensive than the net costs of accidents." 150 F.3d 651, 657 (7th Cir. 1998). In the design-defect context, the "failure to take [cost-effective] precautions" is another way of saying that the manufacturer did not adopt a reasonable alternative design. *Id.*; *see* 1 DAVID G. OWEN & MARY J. DAVIS, OWEN & DAVIS ON PRODUCTS LIABILITY § 8:11, at 746 (4th ed. 2014). *McMahon* involved burn injuries from hot coffee; the plaintiffs sued the manufacturer of the coffee maker alleging that the device was unreasonably dangerous because it held the coffee temperature too high. 150 F.3d at 653. Based on the foregoing understanding of the requirements of Indiana law, we affirmed a summary judgment for the manufacturer.

Since *McMahon* we have generally read the IPLA to require evidence of a reasonable alternative design in all

design-defect cases. *See, e.g.*, *Aregood*, 904 F.3d at 489; *see also Mesman v. Crane Pro Servs.*, 409 F.3d 846, 849 (7th Cir. 2005) (holding that a product is negligently designed "only if the product could have been redesigned at a reasonable cost to avoid the risk of injury").

The Indiana Supreme Court rejected that interpretation of the Act in its 2010 decision in *TRW Vehicle Safety Systems*. The plaintiff in *TRW* brought a crashworthiness claim against several vehicle and component-part manufacturers, including a seat belt manufacturer. Applying *Miller*, the Indiana Court of Appeals held that because the claim "proceeded in negligence … , [the plaintiff] was required to provide proof of an alternative design." *Ford Motor Co. v. Moore*, 905 N.E.2d 418, 427 (Ind. Ct. App. 2009). The manufacturers defended this conclusion in the state supreme court, contending that the plaintiff had to provide evidence of "a safer, more practicable product design" and "rebut evidence that its proposed alternative design … presented safety concerns." *TRW*, 936 N.E.2d at 209.

The Indiana Supreme Court disagreed, explaining that although the *Restatement* (*Third*) *of Torts* proposes an alternative-design requirement, the 1998 version of the IPLA "did not adopt this analytical framework." *Id.* at 209 n.2. The Indiana legislature "instead enacted … a negligence standard for product liability claims based on defective design." *Id.* And because the Act "prescribes the applicable standard of care," the court explicitly declined "to require proof of any additional or more particular standard of care in product liability actions alleging a design defect." *Id.* at 209.

Our circuit caselaw cannot be reconciled with *TRW*. Our view that Indiana law imposes an alternative-design re-

quirement rests on an understanding that "negligence means failure to take precautions that are less expensive than the net cost[] of accidents." *McMahon*, 150 F.3d at 657; *see also Bammerlin*, 30 F.3d at 902 (endorsing this approach and stating that there is "no reason to think that [Indiana] would see things otherwise"). The Indiana Supreme Court has unambiguously rejected that reading of state law, clarifying that the IPLA's negligence provision does not incorporate the standard proposed by the American Law Institute in the *Restatement* (*Third*) *of Torts* and thus does not "require proof of any additional or more particular standard of care." *TRW*, 936 N.E.2d at 209. Requiring a design-defect plaintiff to produce evidence of a cost-effective, safer design imposes a "more particular standard of care" and is therefore inconsistent with the IPLA as authoritatively construed by the state's highest court.

"A decision by a state's supreme court terminates the authoritative force of our decisions interpreting state law, for under *Erie* our task in diversity litigation is to predict what the state's highest court will do. Once the state's highest court acts, the need for prediction is past." *Reiser v. Residential Funding Corp.*, 380 F.3d 1027, 1029 (7th Cir. 2004). The Indiana Supreme Court has spoken clearly and unequivocally: the IPLA does *not* require evidence of a reasonable alternative design to establish design-defect liability. *TRW*, 936 N.E.2d at 209. Sitting in diversity, we are required to follow *TRW* rather than our own cases to the contrary, which are not accurate interpretations of state law.[3]

[3] This opinion declines to follow circuit precedent, which must give way to an authoritative decision of the Indiana Supreme Court on a matter of

Of course, a plaintiff proceeding under Indiana law remains free to establish design-defect liability through evidence of a reasonable alternative design. *TRW* left this method of proof open to plaintiffs, while not requiring it as an element of the claim. *Id.* at 210; *accord FMC Corp. v. Brown*, 551 N.E.2d 444, 446 (Ind. 1990). Reasonable alternative designs are also "relevant to the issue of whether the design in question is unreasonably dangerous." *Marshall v. Clark Equip. Co.*, 680 N.E.2d 1102, 1106 (Ind. Ct. App. 1997) (quotation marks and emphasis omitted); *see also Gilbert v. Stone City Constr. Co.*, 357 N.E.2d 738, 744 (Ind. Ct. App. 1976) ("Those who come into contact with a product may reasonably expect its supplier to provide feasible safety devices in order to protect them from dangers created by its design."). Although evidence of a cost-effective alternative design can be relevant to design-defect liability, *TRW* holds that the IPLA does not *require* such evidence to prevail on a design-defect claim.

3. *Unreasonably Dangerous*

As we've explained, the Act's "unreasonably dangerous" standard "focuses on the reasonable expectations of the consumer." *Gresser*, 989 N.E.2d at 345. The parties agree that the relevant consumers here are pelvic-floor surgeons. Ethicon contends that the jury based its verdict on an improper understanding of consumer expectations in this context. Quoting our decision in *Bourne v. Marty Gilman, Inc.*, Ethicon argues that "a user's knowledge of a general risk precludes recovery even if he did not know the extent or

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state law. Accordingly, we circulated the opinion under Circuit Rule 40(e) to all judges in active service. No judge wished to hear this case en banc.

specific degree of that risk." 452 F.3d 632, 636 (7th Cir. 2006); *see also Moss v. Crosman Corp.*, 136 F.3d 1169, 1173 (7th Cir. 1998) (rejecting a claim that a BB gun was unreasonably dangerous in a case involving a fatal injury when ordinary consumers would know the device could cause serious injury). By the same logic, Ethicon reasons that Prolift wasn't unreasonably dangerous if an ordinary pelvic-floor surgeon would be aware of the *possibility* of all relevant risks, even if he would be unaware of the precise *likelihood* or *severity* of those risks. As Ethicon sees it, that describes this case.

This argument overreads our decision in *Bourne*. We did not hold that "a user's knowledge of a general risk precludes recovery"; that statement came from our description of the district court's decision. *Bourne*, 452 F.3d at 636. *Bourne* explained that under the consumer-expectations test, some cases involving obvious risks are "so one-sided that there is no possibility of the plaintiff's recovery." *Id.* at 637. Even so, "a product may be designed with a feature that, although obvious, is nonetheless unreasonably prone to cause accidents." *Id*. at 636. *Bourne* does not help Ethicon.

Nor does *Moss* advance Ethicon's position. As we later explained in *McMahon*, our decision in *Moss* rejected a claim that a consumer's "failure to appreciate the gravity of the damage a product could do" could satisfy the consumer-expectations test under Indiana law when ordinary consumers "understood that the product could cause a serious injury." *McMahon*, 150 F.3d at 657. *Moss* does not, however, stand for the proposition that the severity or frequency of a product's risks are irrelevant. Indeed, Ethicon's argument on this point actually contradicts the IPLA, which contemplates an inquiry into probability and severity of risk. *See* IND.

CODE § 34-6-2-146 (mandating that a product is unreasonably dangerous when it "exposes the user or consumer to a risk of physical harm *to an extent* beyond that contemplated by the ordinary consumer") (emphasis added). It was entirely proper for the jury to consider evidence of the frequency and severity of Prolift's complications when applying the consumer-expectations test.

And on this understanding of Indiana law, a reasonable jury could conclude that Prolift created risks beyond the expectations of ordinary pelvic-floor surgeons. Dr. Bales testified that "none of the surgeons originally implanting the Prolift probably were quite as appraised of all the possible risks and some of the subsequent problems" associated with the device. For example, he testified that he was not aware that Prolift was impossible to remove safely in some patients, making its complications permanent. Similarly, Dr. Bruce Rosenzweig, an expert witness for Kaiser, testified that he "did not know of [the] risks that were associated with the Prolift device[,] and once [he] found out about them, [he] stopped using it." Finally, Dr. Daniel Elliott, another plaintiff's expert, testified that it would be "impossible" for every surgeon to know about all of Prolift's risks.

To be sure, the evidence wasn't one-sided. Dr. Bales testified that he was aware of many of Prolift's risks. The jury also heard testimony that surgeons could have learned more about Prolift's risks from medical literature. But "whether a product is unreasonably dangerous is usually a question of fact that must be resolved by the jury." *Baker v. Heye-Am.*, 799 N.E.2d 1135, 1140 (Ind. Ct. App. 2003). That some evidence favored Ethicon establishes only that the case presented factual disputes for the jury to resolve. The jury was free

to infer, for example, that an ordinary pelvic-floor surgeon does not have exhaustive knowledge of medical literature. On this record a reasonable jury could conclude that Prolift was unreasonably dangerous.

B. Failure-to-Warn Liability

A product is also defective under the IPLA if a seller does not "properly package or label the product to give reasonable warnings of danger about the product … when the seller, by exercising reasonable diligence, could have made such warnings or instructions available to the user or consumer." IND. CODE § 34-20-4-2. Put another way, Ethicon had "a duty to warn with respect to latent dangerous characteristics of the product, even though there is no 'defect' in the product itself." *Nat. Gas Odorizing, Inc. v. Downs*, 685 N.E.2d 155, 161 (Ind. Ct. App. 1997). Under Indiana's learned-intermediary doctrine, a medical-device manufacturer can discharge this duty by providing adequate warnings to physicians. *See id.* at 162 n.10; *Phelps v. Sherwood Med. Indus.*, 836 F.2d 296, 303 (7th Cir. 1987).[4]

Ethicon argues that Kaiser's failure-to-warn claim was deficient as a matter of law. More specifically, Ethicon contends that no reasonable jury could have found that it breached its duty or that any failure to warn caused Kaiser's

[4] Kaiser asserts that the learned-intermediary doctrine applies only when an intermediary has equal knowledge and sophistication as the manufacturer. That's true only of the "sophisticated intermediary" defense, a "related but distinct" doctrine. *Nat. Gas Odorizing, Inc. v. Downs*, 685 N.E.2d 155, 162 n.10 (Ind. Ct. App. 1997). Both doctrines permit a manufacturer to warn an intermediary instead of the end consumer, but the learned-intermediary doctrine, which "is limited to prescription drugs and medical devices," applies without this qualification. *Id.*

injuries. It faces an uphill battle on both fronts. Looking first to breach, whether a warning is "reasonable" is "generally a question of fact for the trier of fact to resolve." *Cook v. Ford Motor Co.*, 913 N.E.2d 311, 319 (Ind. Ct. App. 2009). It only becomes "a question of law when the facts are undisputed and only a single inference can be drawn from those facts." *Id.* at 327.

The warnings in Prolift's Instructions for Use were brief, so we'll repeat them in full: "Potential adverse reactions are those typically associated with surgically implantable materials, including infection potentiation, inflammation, adhesion formation, fistula formation, erosion, extrusion and scarring that results in implant contraction." The Instructions also warned that "[t]ransient leg pain may occur and can usually be managed with mild analgesics." Much of the evidence at trial supported the jury's finding that this warning was inadequate. For example, Dr. Bales pointed to the absence of any warning about Prolift's potential for permanent pelvic pain and sexual dysfunction. Similarly, Dr. Elliott testified that the Instructions did not provide warnings about the frequency, severity, or permanence of Prolift's side effects. Given the limited scope of the warnings in Prolift's Instructions for Use, a reasonable jury could conclude that Ethicon breached its duty to warn surgeons of its risks.

Ethicon challenges this conclusion on two grounds. It first contends that the "Surgeons' Resource Monograph"—a document it distributed to surgeons only at training events—contained more comprehensive warnings about Prolift's risks. But even if we assume that Ethicon can satisfy its duty to warn through a limited-distribution monograph

(an open question), Kaiser successfully undermined this evidence through effective cross-examination. For example, Dr. Salil Khandwala, one of Ethicon's experts, conceded that Ethicon failed to update the monograph when it received information regarding heightened complication rates. A reasonable jury could conclude that the monograph did not tip the scales in Ethicon's favor.

Ethicon also argues that its duty to warn did not extend to providing information about the frequency, severity, or permanence of Prolift's side effects. This argument relies on a different aspect of *McMahon*. Recall that the claims in *McMahon* arose out of burn injuries from hot coffee; in addition to a design-defect claim, the plaintiff argued that the manufacturer of the coffee maker failed to warn consumers about the severity of burns that hot coffee can produce. 150 F.3d at 654. We affirmed the summary judgment for the manufacturer, reasoning that the IPLA "expects consumers to educate themselves about the hazards of daily life … by general reading and experience." *Id.* at 656.

This case is far removed from "the hazards of daily life." Ethicon asks us to rule as a matter of law on the contents of a reasonable warning for a specialized medical device. The question raises technical and highly fact-bound inquiries. We have held in the related context of "sophisticated intermediaries" that "[w]hether a manufacturer has discharged its duty … is almost always a question for the trier of fact." *Id.* (quotation marks omitted). That principle applies with equal force to the learned-intermediary doctrine. Whether Ethicon breached its duty to warn was a question for the jury, and we see no reason to disturb its determination on this element of the claim.

Ethicon's causation argument is a closer question. As with breach, "[c]ausation-in-fact is ordinarily a factual question reserved for determination by the jury." *Kovach v. Caligor Midwest*, 913 N.E.2d 193, 198 (Ind. 2009). But "where reasonable minds cannot disagree as to causation-in-fact, the issue may become a question of law for the court." *Id.*

The causation question here is relatively straightforward: Would Dr. Bales have used the Prolift device to treat Kaiser's condition if Ethicon had provided additional warnings? The answer is more complicated. When asked: "Is there anything you would have done differently with respect to Ms. Kaiser's January 2009[] surgery?" Dr. Bales responded: "No, not looking back, I don't think I would have done anything differently." He also admitted that the "medicolegal climate" surrounding Prolift "probably was a factor" in his ultimate decision to discontinue using it. And he conceded that after discontinuing Prolift, he returned to a procedure he felt had "virtually the same complication risks, except for … extrusion and erosion." But when asked if he would "have wanted to use Prolift if told about [its] risks," Dr. Bales offered a different response: "My sense is that had I had all the subsequent information about how some patients fared and how some complications occurred, it's probably safe to say that I may not have started using the Prolift."

Reasonable minds could read Dr. Bales's mixed testimony and disagree about causation. Again, however, that just means the question was one for the jury—and a reasonable jury could credit Dr. Bales's assertion that additional warnings about complications would have led him to choose a different treatment plan.

C. Motion for a New Trial

As a fallback, Ethicon asks us to reverse for a new trial, arguing that the judge failed to instruct the jury on two of the IPLA's evidentiary presumptions and improperly excluded evidence of Prolift's § 510(k) clearance. Different standards of review apply. "We review jury instructions de novo to determine whether, taken as a whole, they correctly and completely informed the jury of the applicable law." *Javier v. City of Milwaukee*, 670 F.3d 823, 828 (7th Cir. 2012) (quotation marks omitted). We review the district court's evidentiary decisions for abuse of discretion. *Smith v. Hunt*, 707 F.3d 803, 807 (7th Cir. 2013). Under either standard, an error warrants a new trial only if it is prejudicial. *See id.* at 808; *Javier*, 670 F.3d at 828.

1. *State-of-the-Art Presumption*

The IPLA provides a rebuttable presumption that "the product that caused the physical harm was not defective" and "the manufacturer … was not negligent" if the product "was in conformity with the generally recognized state of the art applicable to the safety of the product at the time the product was designed, manufactured, packaged, and labeled." § 34-20-5-1. The judge declined to instruct the jury on this presumption. Ethicon challenged this ruling in its posttrial motions and does so again on appeal.

To justify the instruction, Ethicon needed a "legally sufficient evidentiary basis" to support the state-of-the-art presumption. FED. R. CIV. P. 50(a)(1). The presumption requires evidence that the product used "the best technology reasonably feasible at the time the defendant designed" it. *Wade v. Terex-Telelect, Inc.*, 966 N.E.2d 186, 192 (Ind. Ct. App. 2012)

(quotation marks omitted). Ethicon could satisfy this standard by providing "[e]vidence of the existing level of technology, industry standards, the lack of other advanced technology, the product's safety record, and the lack of prior accidents." *Id.*

Ethicon's evidence in support of the presumption was thin at best. It presented no expert testimony on the issue, nor did it produce evidence of existing industry standards. Ethicon conceded that it hadn't conducted any human trials before releasing Prolift, so it couldn't present a safety record. Instead, it offered testimony that Prolift was generally an improvement over its predecessor. It also provided a lay witness's statement that those who designed Prolift were "working to get something out there that's better … than anything that has been out there before."

These highly generalized statements fall far short of satisfying the legal standard for the presumption. "State of the art evidence must be relevant to the risk at issue." *Id.* at 193. In *Wade,* for example, the Indiana Court of Appeals held that the presumption did not apply even when the manufacturer offered "anecdotal evidence that the same technology had been used for almost thirty years and that it … had not heard of a report of anyone" being injured by the design risk. *Id.* at 194. Ethicon's evidence is no more specific to the risks at issue here. The judge was right to decline to instruct the jury on the presumption.

2. *Regulatory-Compliance Presumption*

The IPLA also provides a rebuttable presumption that the product was not defective if the manufacturer can establish that it "complied with applicable codes, standards,

regulations, or specifications established, adopted, promulgated, or approved … by an agency of the United States or Indiana." § 34-20-5-1. Based on Prolift's § 510(k) clearance, Ethicon faults the judge for not instructing the jury on this presumption.

Ethicon did not request this instruction at the close of evidence, *see* FED. R. CIV. P. 51(c)(1), so our review is limited to plain error, *id.* R. 51(d)(2). The regulatory-compliance presumption requires evidence of compliance with governmental standards that "relate to the risk or product defect at issue." *Wade*, 966 N.E.2d at 195; *see also id.* (holding that a regulation wasn't relevant to the presumption because it was "silent" regarding the particular defect at issue, even when it had a "primary objective of … prevent[ing] accidents associated" with the product). We've explained at length that the § 510(k) process does not require a medical device "to take any particular form for any particular reason." *Lohr*, 518 U.S. at 493. Prolift's § 510(k) clearance is insufficient to support the presumption. We find no error.

3. *FDA Evidence*

Ethicon also wanted to present evidence of Prolift's § 510(k) clearance for the more general purpose of inviting the jury to draw an inference that the device was safe. The judge excluded this evidence under Rule 403 of the Federal Rules of Evidence, reasoning that because the § 510(k) process "speaks to equivalency, not safety," the probative value of this evidence was minimal and substantially outweighed by the risk of confusing or misleading the jury and wasting time.

That was not an abuse of discretion. To start, evidence of Prolift's § 510(k) clearance faces the same categorical problem as any device cleared to market through substantial equivalence: The FDA expressly disclaims any intent of "approving" devices through the § 510(k) process. *See* 21 C.F.R. § 807.97. Prolift's clearance also contains several red flags. The FDA warned that Prolift's original predicates—the surgical meshes in the 1988 rulemaking—did not come with a reasonable assurance of safety. While incomplete, the § 510(k) history also shows that Prolift's connection to these meshes is attenuated—both it and its three possible immediate predicates all piggybacked off of other § 510(k)-cleared devices. And importantly, Ethicon's § 510(k) premarket notification never claimed that Prolift was as safe as its proposed predicates. Instead, it asserted that Prolift had the same technological characteristics.

Simply put, Prolift's § 510(k) clearance is remote from FDA safety review. The available records indicate only that Prolift lies at the end of an undefined chain of devices that each received FDA clearance through a process that does not necessarily consider product safety. And at the origin of this chain is a group of devices that raised serious safety concerns at the FDA. It was reasonable to conclude that the probative value of this evidence was minimal at best and that admitting it would precipitate a confusing sideshow over the details of the § 510(k) process.

D. Damages

1. *Compensatory Damages*

Ethicon sought remittitur of the jury's $10 million award of compensatory damages. Applying the federal standard

for reviewing damages awards, the judge denied the motion, reasoning that the damages were rationally connected to the evidence, not "monstrously excessive," and comparable to awards in other personal-injury cases involving vaginal mesh. *Marion Cty. Coroner's Office v. EEOC*, 612 F.3d 924, 930–31 (7th Cir. 2010). Ethicon challenges that ruling, which we review for abuse of discretion. *EEOC v. AutoZone, Inc.*, 707 F.3d 824, 833 (7th Cir. 2013).

We note at the outset that it was a mistake to review the jury's award under the federal standard. The Supreme Court has held that state standards for reviewing damages awards are substantive law for *Erie* purposes. *Gasperini v. Ctr. for Humanities, Inc.*, 518 U.S. 415, 430–31 (1996). Accordingly, "when a federal jury awards compensatory damages in a state-law claim, state law determines whether that award is excessive." *Rainey v. Taylor*, 941 F.3d 243, 253 (7th Cir. 2019); *see also Smart Mktg. Grp., Inc. v. Publ'ns Int'l Ltd.*, 624 F.3d 824, 832 (7th Cir. 2010); *Naeem v. McKesson Drug Co.*, 444 F.3d 593, 611 (7th Cir. 2006). So the judge's use of the federal standard was legal error. In fairness, the judge relied on our suggestion in *Jutzi-Johnson v. United States* that portions of the federal standard remain viable when a court reviews a state-law damages award. 263 F.3d 753, 760 (7th Cir. 2001); *accord Arpin v. United States*, 521 F.3d 769, 777 (7th Cir. 2008). We take this opportunity to clarify that federal law has no place in reviewing a damages award in a state-law claim. *Rainey*, 941 F.3d at 252–53 (acknowledging the lack of clarity in our cases on this point).

That said, the error was harmless. The damages award was not excessive under Indiana law. Indiana courts will not disturb a compensatory-damages award "[i]f there is any

evidence in the record which supports the amount of the award, even if it is variable or conflicting." *Sears Roebuck & Co. v. Manuilov*, 742 N.E.2d 453, 462 (Ind. 2001) (quotation marks omitted). The evidence here satisfies this deferential standard. For example, the jury learned that Kaiser underwent painful corrective surgery that removed large portions of vaginal tissue. And Kaiser suffers from permanent pelvic pain, bladder spasms, and pain during intercourse—all Prolift-related conditions. This evidence was enough to justify the jury's $10 million compensatory award.

Ethicon's counterargument largely focuses on comparisons to other damages awards. While these comparisons are relevant to the federal standard, *see, e.g.*, *AutoZone*, 707 F.3d at 834, Indiana courts heavily disfavor "comparative analysis" when reviewing a damages award, *Weinberger v. Boyer*, 956 N.E.2d 1095, 1114 (Ind. Ct. App. 2011). The state courts instead adopt a "historical regard for the uniqueness of every tort claim and … the belief that compensatory damage assessments should be individualized and within the province of the factfinder." *Id.* Because the jury had a reasonable evidentiary basis for its decision, we will not disturb the compensatory award. *See id.* at 1112 ("The jury's damage award will not be deemed the result of improper considerations if the size of the award can be explained on any reasonable ground.").

2. *Punitive Damages*

The judge granted Ethicon's remittitur motion and reduced the punitive award from $25 million to $10 million, which Kaiser accepted. Ethicon argues that an award of punitive damages is unwarranted as a substantive matter

and that the size of this award is excessive even after remittitur.

The parties agree that New Jersey law applies to this issue, so bear with us as we discuss one more statutory regime. New Jersey's Punitive Damages Act establishes a two-step process for awarding punitive damages. First, the jury must decide whether the defendant's conduct warrants punitive damages, which requires the plaintiff to prove "by clear and convincing evidence" that the defendant's acts or omissions caused the harm and were "actuated by actual malice or accompanied by a wanton and willful disregard of persons who foreseeably might be harmed." N.J. STAT. ANN. § 2A:15-5.12(a). When making this determination, the jury must consider four factors:

> (1) The likelihood, at the relevant time, that serious harm would arise from the defendant's conduct;
>
> (2) The defendant's awareness of reckless disregard of the likelihood that the serious harm at issue would arise … ;
>
> (3) The conduct of the defendant upon learning that its initial conduct would likely cause harm; and
>
> (4) The duration of the conduct or any concealment of it by the defendant.

Id. § 2A:15-5.12(b).

If the jury finds that punitive damages are warranted, it next sets the amount of damages. Besides the four factors listed above, the jury must consider "[t]he profitability of the

misconduct to the defendant," "[w]hen the misconduct was terminated," and "[t]he financial condition of the defendant." *Id.* § 2A:15-5.12(c).

Finally, as relevant here, the Punitive Damages Act provides an affirmative "FDA defense" that applies in two situations: (1) when the medical device at issue is "subject to premarket approval or licensure" by the FDA or (2) when the device "is generally recognized as safe and effective pursuant to conditions established" by the FDA. *Id.* § 2A:58C-5.

Ethicon raises three arguments in opposition to the punitive award: the FDA defense precludes punitive damages altogether; the evidence is insufficient to support an award of punitive damages at step one of the New Jersey framework; and the remitted award is excessive under step two. To the first point, the FDA defense does not apply. The § 510(k) process cannot be considered "premarket approval or licensure" when the FDA itself cautions that § 510(k) clearance "does not in any way denote official approval of the device." 21 C.F.R. § 807.97; *see also Lohr*, 518 U.S. at 492–94 (holding that the § 510(k) process is an exception from the MDA licensing process). And we reiterate one last time that the § 510(k) process is not designed to designate devices as "safe and effective."

To the second point, as we've noted, to justify an award of punitive damages under the New Jersey framework, Kaiser had to prove that Ethicon's conduct evinced "wanton and willful disregard" of those who might foreseeably be harmed by its conduct. N.J. STAT. ANN. § 2A:15-5.12(a). That is, Ethicon must have acted or failed to act "with knowledge of a high degree of probability of harm to another and

reckless indifference to the consequences of such act or omission." *Id.* § 2A:15-5.10. Although a plaintiff must prove the required degree of culpability "by clear and convincing evidence," *id.* § 2A:15-5.12(a), the New Jersey Supreme Court has recognized that "determinations about whether there is sufficient evidence of egregiousness to permit or to support a punitive award are necessarily fact-sensitive," *Quinlan v. Curtiss-Wright Corp.*, 8 A.3d 209, 230 (N.J. 2010). Thus, "the appropriate focus" for legal challenges to punitive-damages claims is "whether there was too little evidence of egregiousness presented by plaintiff to get to the jury on the issue at all." *Id.* at 231.

Even under the heightened burden of proof, on this record a reasonable jury could find that Ethicon acted recklessly when releasing Prolift and crafting its warnings. For example, the jury saw e-mails from Prolift's inventors alerting Ethicon that problems could occur from mesh shrinkage, including permanent pain and sexual dysfunction. Dr. Peter Hinoul, one of Ethicon's medical directors, admitted that Ethicon knew from the outset that Prolift had a high risk of these side effects. He also conceded that Ethicon knew that if the device contracted, it could lead to invasive remedial surgeries. Dr. Hinoul also testified that Ethicon understood when Prolift was released that it would eventually need to replace its mesh with a safer material due to these complications.

Notably, an Ethicon medical director proposed updating Prolift's Instructions for Use to account for the risk of sexual dysfunction. The jury heard testimony that Ethicon denied this request in order to reduce printing costs and avoid delaying Prolift's release. The Instructions instead generical-

ly described Prolift's "[p]otential adverse reactions" as those "typically associated with surgically implantable materials." Ethicon did not warn of Prolift's risks of sexual dysfunction, permanent pain, and other complications. Indeed, the Instructions mentioned the risk of postsurgical pain only once, in its warning that "[t]ransient leg pain may occur and can usually be managed with mild analgesics."

A reasonable jury could credit this evidence and conclude that Ethicon knew of the risk of serious complications and acted with reckless indifference by failing to warn surgeons. *See Ripa v. Owens-Corning Fiberglas Corp.*, 660 A.2d 521, 532 (N.J. Super. Ct. App. Div. 1995) (holding that sufficient evidence existed for punitive damages where a manufacturer knew about a serious product risk but failed to warn consumers of the danger). Accordingly, we see no basis to disturb the jury's conclusion that Ethicon's conduct warranted punitive damages.

Finally, Ethicon objects that the punitive award is excessive even after remittitur. But it raised this objection only in its reply brief and even then the argument is undeveloped. That's a waiver. *See Harris v. Warrick Cty. Sheriff's Dep't*, 666 F.3d 444, 448 (7th Cir. 2012).

AFFIRMED