In the

United States Court of Appeals

For the Seventh Circuit

No. 21-2028

DIANNE M. DONALDSON and
DALE A. DONALDSON,

Plaintiffs-Appellants,

v.

JOHNSON & JOHNSON and
ETHICON, INC.,

Defendants-Appellees.

Appeal from the United States District Court for the
Southern District of Illinois.
No. 3:15-cv-00014 — **Staci M. Yandle**, *Judge.*

ARGUED DECEMBER 3, 2021 — DECIDED JUNE 15, 2022

Before ROVNER, HAMILTON, and JACKSON-AKIWUMI, *Circuit Judges*.

ROVNER, *Circuit Judge.* Dianne M. Donaldson and her husband appeal from the grant of summary judgment entered in favor of the makers of surgically implanted medical devices

that she contended injured her due to non-specific defects. Although there is no doubt that Donaldson suffered severe and painful complications after these devices were implanted, she failed to produce sufficient evidence to avoid summary judgment in her case for non-specific defects under Illinois product liability law, and we therefore affirm.

I.

Diane M. Donaldson ("Donaldson") sought treatment for stress urinary incontinence and anterior pelvic organ prolapse.[1] On May 24, 2010, in an attempt to remedy these conditions, Dr. Michael Schultheis surgically implanted in Donaldson two transvaginal polypropylene mesh medical devices—a TVT-Secur to treat her incontinence, and a Prosima to treat the prolapse. Both devices were manufactured by Ethicon, Inc., a subsidiary of Johnson & Johnson. In 2014, Donaldson sought treatment for injuries resulting from erosion of the mesh into her bladder, vagina and adjacent tissues, causing scarring, bladder stones and abdominal pain, among other problems.[2]

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[1] We will refer to Dianne M. Donaldson, the primary plaintiff here, as "Donaldson." The loss of consortium claim of her husband, Dale A. Donaldson, is derivative of Donaldson's claims. We will refer to the defendants jointly as "Ethicon."

[2] Vaginal mesh erosion "is the most common complication following the use of surgical mesh devices to repair pelvic organ prolapse and stress urinary incontinence. Non-absorbable synthetic surgical mesh, such as that made of polypropylene or polyester, can break down or wear away over time. Part of the mesh may become exposed or protrude through the vagina. … Less commonly, the mesh may erode into the urethra, bladder or

(continued...)

Information sheets packaged with the devices warned of the risks of erosion but Donaldson never saw the warnings and contends that Dr. Schultheis did not inform her of these risks. At his deposition, Dr. Schultheis testified that he was aware of the possible complications, and that at the time of the operation, he believed that the benefits of the devices outweighed the risks. He also testified that, in implanting the devices, he followed all of the instructions that the manufacturer presented in writing and in a course that he attended. He opined that the devices were both safe and effective at the time of the surgery. He had placed hundreds of the devices in other patients and stood by his decision to recommend the devices to Donaldson.

Donaldson presented an affidavit and testimony from one of her treating physicians, Dr. Pernankel Nayak, a urologist whom Donaldson began seeing in 2014 for evaluation and treatment of complications that she suffered after the implantation of the mesh devices. In his affidavit, Dr. Nayak asserted that, within a reasonable degree of medical certainty, the devices were defectively designed and unreasonably dangerous. He averred that the devices failed to perform as expected in light of their nature and intended function in that the products had eroded into Donaldson's internal tissues, including her vagina and bladder, causing bladder stones and pelvic pain. He also stated that, based on his own care of Donaldson and on his review of the records of her other treating physicians, there was no abnormal use of the products

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[2] (...continued)
rectum." *See* https://my.clevelandclinic.org/health/articles/16298-surgical-mesh-use-and-complications-in-women (last visited May 20, 2022).

and no reasonable secondary cause of the failures of the products or the injuries sustained. R. 40-1.

At his deposition, however, Dr. Nayak contradicted most of the key statements in his affidavit. First, he indicated in his deposition that his opinions related only to the Prosima mesh and not to the TVT-Secur device. The erosion that he found in the bladder occurred far from the TVT-Secur and he attributed the mesh he found in Donaldson's bladder to the Prosima alone. He agreed that, after the surgery implanting the devices, Donaldson's prolapse was repaired and her stress incontinence did not return. He inferred that the Prosima had been defectively designed based on the erosion of the mesh into Donaldson's internal organs. Asked to clarify his opinion, he stated that the Prosima "possibly caused the mesh to be eroded into the bladder and caused stones." R. 56-4, at 68–69. Contrary to his affidavit, he declined to give an opinion to a reasonable degree of medical certainty that the Prosima was defectively designed, remarking that he did not know how the device was designed, and that he had inferred the injuries were related to the Prosima implantation because they occurred after the surgery. He opined that the complication would not have occurred but for the implantation. He characterized the product as unreasonably dangerous because it caused complications that are not reasonable when compared with other types of surgery such as "sling" surgery.[3] Because of the

[3] Dr. Nayak testified that he uses a smaller mesh device, a midurethral sling or "Lynx," to treat urinary stress incontinence. He does not treat pelvic prolapse. Like the devices at issue here, the sling is composed of (continued...)

presence of a large amount of material with mesh devices that can erode into the bladder and vagina, he thought these devices were dangerous and never chose to implant them. He declined to give an opinion that there was something wrong with the mesh in the Prosima, stating only that mesh can cause complications of erosion into the bladder or vagina, "no matter who makes it." R. 56-4, at 75–76. He could not say whether Donaldson would still have had these complications if a different mesh had been used or if the Prosima had been designed differently.

Dr. Nayak also testified that he did not evaluate whether Dr. Schultheis incorrectly implanted the Prosima in too deep of a plane, which can lead to bladder erosion.[4] Dr. Nayak confirmed that he did not consider "abnormal use" of the Prosima

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[3] (...continued)
polypropylene. Dr. Nayak testified that he preferred the smaller sling device because "the larger the mesh, of course the more chance of erosion." R. 56-4, at 133–34.

[4] The phrases "abnormal use" and "secondary causes" refer to elements of proof under a products liability doctrine in Illinois known as the *Tweedy* doctrine, which we discuss below. In relation to abnormal use, the defendants presented the affidavit of Dr. Douglas Grier. He opined that the erosion of the Prosima into Donaldson's bladder was, "more likely than not, due to surgical technique – likely implanting the mesh in too deep a plane." R. 56-3, at 18. Because Dr. Schultheis testified that he correctly followed the instructions and training provided, there is a classic genuine issue of material fact on "abnormal use" due to surgical technique. Donaldson's claim nevertheless fails because, as we discuss below, she did not present evidence creating a genuine issue of material fact on the absence of secondary causes or whether the products failed to perform as expected, two other *Tweedy* factors.

device at all, and could not offer any opinion regarding whether the device was implanted correctly. Contrary to his affidavit, Dr. Nayak also testified that he had not considered potential secondary causes for the failure of the products or the injuries that Donaldson suffered. He agreed that vaginal atrophy increases a patient's risk for vaginal erosion of the mesh but was unaware that Donaldson had been diagnosed with atrophy. When shown her medical records from another treating physician who diagnosed atrophy, Dr. Nayak agreed that her atrophy could be one of the causes for vaginal erosion of the mesh and could not say whether the mesh itself or the atrophy was the cause of the erosion. Dr. Nayak also confirmed that a posterior colporrhaphy, a surgical procedure that a physician at the Mayo Clinic performed on Donaldson in 2014, could contribute to pelvic pain and pain during sexual intercourse, two of her symptoms that she sought to attribute to the Prosima and TVT-Secur. Dr. Nayak had not considered and offered no opinion as to whether Donaldson's pain was a result of that surgery as opposed to either of the implanted mesh products.

By the time the defendants moved for summary judgment, Donaldson and her husband had narrowed their claims to strict liability for a defective product predicated on a design defect with the mesh devices, and loss of consortium. To establish the existence of a non-specific defect in the products, Donaldson relied exclusively on the *Tweedy* doctrine, named for an Illinois case setting forth a manner of proof that resembles the common law doctrine of *res ipsa loquitor* in products liability cases. *Tweedy v. Wright Ford Sales, Inc.*, 357 N.E.2d 449 (Ill. 1976). When Donaldson submitted the affidavit of Dr.

Nayak in response to the defendants' motion for summary judgment, the defendants moved to strike portions of the affidavit as inconsistent with the testimony that Dr. Nayak gave at his deposition. In particular, they asked the court to strike paragraphs six through eight, where Dr. Nayak presented the core of his opinions. After noting the inconsistencies between the declarations made in those three paragraphs and Dr. Nayak's subsequent deposition testimony, the court granted the motion to strike. Although the defendants asked the court to disregard only the three designated paragraphs, the court more generally ruled that it would "not consider Dr. Nayak's Declaration in ruling on Defendants' motion for summary judgment," suggesting that the court was striking the entire Declaration and its attached exhibits.[5] *Donaldson v. Johnson & Johnson*, 2021 WL 1754605, *3 (S.D. Ill. May 4, 2021).

The court also granted the defendants' motion for summary judgment. The court first concluded that the *Tweedy* doctrine could not be applied in a complex medical device case because the issues involved were beyond a jury's common knowledge, experience and understanding. The court found that expert testimony was necessary in this case to assist the jury's understanding of whether the products were unreasonably dangerous. In the alternative, the court concluded that Donaldson failed to produce sufficient evidence to create a genuine issue of material fact on two of the *Tweedy* factors, namely, the absence of reasonable secondary causes or whether the devices failed to perform as reasonably expected. Because

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[5] Dr. Nayak's affidavit was titled, "Declaration." We will refer to it as his affidavit.

the loss of consortium claim was derivative of the product liability claims, the court granted summary judgment in favor of the defendants on all claims. The plaintiffs appeal.

II.

On appeal, Donaldson contends that the district court abused its discretion in striking the entire affidavit of Dr. Nayak rather than limiting the ruling to the parts of the three offending paragraphs that directly contradict his deposition testimony. Donaldson also maintains that the court erred in granting summary judgment because she has raised genuine disputes of material facts relevant to the elements of a strict liability claim under the *Tweedy* doctrine. A district court's ruling on a motion to strike an affidavit is reviewed for an abuse of discretion. *Magyar v. St. Joseph Regional Medical Center*, 544 F.3d 766, 770 (7th Cir. 2008). We review the district court's grant of summary judgment *de novo*, and we examine the record in the light most favorable to the plaintiffs, construing all reasonable inferences from the evidence in their favor. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986); *Horne v. Electric Eel Mfg. Co.*, 987 F.3d 704, 713 (7th Cir. 2021). Summary judgment is appropriate when there are no genuine disputes of material fact and the movant is entitled to judgment as a matter of law. Fed.R.Civ.P. 56(a); *Anderson*, 477 U.S. at 247–48; *Horne*, 987 F.3d at 713. "Although federal law governs procedure in a case in which federal court jurisdiction is premised on diversity of citizenship, state law applies to substantive issues." *Skyrise Constr. Group, LLC v. Annex Constr., LLC*, 956 F.3d 950, 956 (7th Cir. 2020). When neither party raises a conflict of law issue in a diversity case, the applicable law is that of the state

in which the federal court sits, in this case, Illinois. *RLI Ins. Co. v. Conseco, Inc.*, 543 F.3d 384, 390 (7th Cir. 2008). No party raised a conflict of law issue here, and Illinois law therefore applies to the substantive issues. *Id*.

A.

Donaldson first contends that the court abused its discretion in striking the entirety of Dr. Nayak's affidavit. She asserts that paragraphs one through three, together with Exhibit A, are consistent with his deposition testimony. These portions of the affidavit identify Dr. Nayak and set forth his credentials. She also maintains that paragraph four and Exhibit B, which identify the medical records that Dr. Nayak maintained in his treatment of Donaldson, are also consistent with his deposition testimony. Finally, she argues that certain parts of paragraph seven, which set forth Dr. Nayak's opinion that the products were defectively designed and unreasonably dangerous, were consistent with his deposition. She contends that, on summary judgment, the court should have credited any parts of the affidavit that were consistent with Dr. Nayak's deposition testimony because the court is obligated in summary judgment proceedings to construe the record in the light most favorable to the non-moving party.

There was no abuse of discretion in the court's decision granting the motion to strike the affidavit. During the deposition, it became clear that Dr. Nayak did not agree with significant parts of the key paragraphs (six through eight) setting forth his purported opinions. Among other things, Dr. Nayak testified in his deposition that he had no opinion at all about the TVT-Secur device; that he was not offering an opinion to a

reasonable degree of medical certainty that the Prosima was defectively designed, remarking that he did not know how the device was designed; and critically, that he had not evaluated whether there was abnormal use of the device or any reasonable secondary cause for Donaldson's injuries. A court is well within its discretion to strike an affidavit that contradicts deposition testimony unless the affiant has offered a plausible explanation for the discrepancy. *Beckel v. Wal-Mart Associates, Inc.*, 301 F.3d 621, 623 (7th Cir. 2002). Affidavits offered to contradict the affiant's deposition testimony can be "so lacking in credibility as to be entitled to zero weight in summary judgment proceedings" unless there is a plausible explanation for the discrepancy from the affiant. *Beckel*, 301 F.3d at 623. *See also Russell v. Acme-Evans Co.*, 51 F.3d 64, 67–68 (7th Cir. 1995) ("Where deposition and affidavit are in conflict, the affidavit is to be disregarded unless it is demonstrable that the statement in the deposition was mistaken, perhaps because the question was phrased in a confusing manner or because a lapse of memory is in the circumstances a plausible explanation for the discrepancy."). Dr. Nayak offered no explanation for the discrepancies that we described above. It is not unusual for affidavits, which are signed under oath by the affiant, to have been drafted by a lawyer for a party or for the affiant, and that is the case here. R. 40-1, at 3 (indicating that the affidavit had been prepared by the plaintiffs' lawyer). We decline to speculate why Dr. Nayak signed under penalty of perjury a document with which he substantially disagreed, or why counsel was not prepared at Dr. Nayak's deposition to address the significant discrepancies between Dr. Nayak's written and oral

evidence.[6] Given the substantial inconsistencies between the affidavit and the deposition testimony, and the complete absence of any explanation for the discrepancies, the court acted well within its discretion in striking the affidavit. As for paragraphs one through four, the defendants did not specifically ask the court to strike those paragraphs, but as will become clear in the summary judgment analysis, neither those portions of the affidavit nor the attached exhibits and medical records were sufficient to avoid summary judgment. Any error in striking the additional paragraphs was therefore harmless.

B.

Donaldson relies exclusively on the *Tweedy* doctrine in seeking to prove the existence of a non-specific design defect in the mesh devices. We very recently had occasion to explore in depth Illinois law on strict liability claims for defective products:

> A strict liability claim is premised on a defect that renders a product dangerous because the product fails to perform in the manner one reasonably expects it to in light of its nature and intended function. To prevail on such a claim, a plaintiff must establish each of the following elements: (1) a condi-

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[6] Plaintiffs' counsel remarked at oral argument that Dr. Nayak gave a "horrible deposition on behalf of the plaintiff." Oral Argument, at 3:15—3:25. But what rendered it "horrible" was that it conflicted with the Declaration that counsel drafted for Dr. Nayak's signature, and that Dr. Nayak provided no explanation for the marked inconsistencies. This left the plaintiffs with a gaping hole in the evidence they needed to provide to survive summary judgment under the *Tweedy* doctrine.

> tion of the product resulting from its manufacture or design, (2) that made the product unreasonably dangerous, (3) and that existed at the time the product left the defendant's control, and (4) an injury to the plaintiff, (5) that was proximately caused by the condition. A product may be unreasonably dangerous as a result of (1) a manufacturing defect—that is, a physical defect in the individual product itself, (2) a defect in the product's design, or (3) the manufacturer's failure to warn of a known danger associated with the product or to instruct the consumer on the proper use of the product. A "manufacturing defect occurs when one unit in a product line is defective, whereas a design defect occurs when the specific unit conforms to the intended design but the intended design itself renders the product unreasonably dangerous."
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> Illinois courts employ two different approaches to determining whether a product is unreasonably dangerous: the consumer expectations test and the risk-utility test. The consumer expectations test asks whether the product is "dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics." The risk-utility test balances the magnitude of the danger against the utility of the product, as designed.

Bensenberg v. FCA US LLC, 31 F.4th 529, 535 (7th Cir. 2022) (citations omitted).

But Illinois law also sets forth an alternate means for proving a strict liability claim for a defective product, a form of the common law doctrine of *res ipsa loquitor*:

> Illinois recognizes a claim for non-specific defect, which, in the appropriate case, relieves the plaintiff of the obligation to identify a particular defect in the product in order to make a prima facie case of product liability. *Tweedy*, 2 Ill.Dec. 282, 357 N.E.2d at 452; *Horne v. Elec. Eel Mfg. Co.*, 987 F.3d 704, 726 (7th Cir. 2021) (citing *DiCosolo v. Janssen Pharm., Inc.*, 351 Ill.Dec. 574, 951 N.E.2d 1238, 1244 (Ill. App. Ct. 2011)); *McKenzie v. S K Hand Tool Corp.*, 272 Ill.App.3d 1, 208 Ill.Dec. 918, 650 N.E.2d 612, 616 (1995); *Varady v. Guardian Co.*, 153 Ill.App.3d 1062, 106 Ill.Dec. 908, 506 N.E.2d 708, 711–12 (1987). The plaintiff may instead resort to circumstantial evidence that supports an inference that the product was defective, by showing that the product failed to perform as expected, in light of its nature and intended function, and that the product was not being used abnormally and that there were no reasonable secondary causes of failure. *Tweedy*, 2 Ill.Dec. 282, 357 N.E.2d at 452; *Horne*, 987 F.3d at 726.

Bensenberg, 31 F.4th at 535–36. *See also Tweedy*, 357 N.E.2d at 452 (a prima facie case that a product was defective and that the defect existed when it left the manufacturer's control is made by proof that, in the absence of abnormal use or reasonable secondary causes, the product failed to perform in the

manner reasonably to be expected in light of its nature and intended function).

In assessing the defendants' summary judgment motion, the district court first remarked:

> This Court does not believe that the *Tweedy* doctrine can appropriately be applied in complex medical device cases. These devices are not simple products that lay jurors commonly use or see and their functions are, therefore, beyond a jury's common knowledge, experience or understanding. That is why expert testimony is needed to assist the jury's understanding of whether a product is unreasonably dangerous. Without the aid of expert testimony, the jury can only speculate as to what inferences to draw. … Thus, the question of whether the devices in question were defective and caused Donaldson's injuries is a complex issue that requires expert interpretation and proof.

Donaldson, 2021 WL 1754605, *5. But Illinois courts have applied the *Tweedy* doctrine to medical devices that are arguably as complex as the mesh products at issue here. *See, e.g.*, *DiCosolo v. Janssen Pharmaceuticals, Inc.*, 951 N.E.2d 1238 (Ill. App. Ct. 2011) (affirming jury verdict in favor of plaintiff who proceeded under the *Tweedy* doctrine to prove that a transdermal Duragesic skin patch defectively delivered more fentanyl through its rate-controlled membrane than it was designed to do, resulting in the plaintiff's death due to overdose); *Weedon v. Pfizer, Inc.*, 773 N.E.2d 720 (Ill. App. Ct. 2002) (reversing summary judgment in favor of defendant manufac-

turer of a venous access device implanted in plaintiff's body to deliver chemotherapy because, although plaintiff produced no experts in the manufacture or design of the device, under the *Tweedy* doctrine, the plaintiff's treating physicians and nurse provided sufficient evidence that the device did not perform as expected when it likely leaked chemotherapy drugs into surrounding tissues, and also testified to the absence of abnormal use and secondary causes).

Although Illinois courts appear to approve the use of the *Tweedy* doctrine in cases involving medical devices, the application of that doctrine does not automatically eliminate the need for any sort of expert testimony.[7] Under *Tweedy*, the plaintiff must present evidence that, in the absence of abnormal use or reasonable secondary causes, the product failed to perform in the manner reasonably to be expected in light of its nature and intended function. *Tweedy*, 357 N.E.2d at 452; *Bensenberg*, 31 F.4th at 535–36. In a case involving a medical device that is implanted in the body, proving the absence of abnormal use or reasonable secondary causes will likely require evidence from healthcare providers who have experience in the use of the device, in other words, expert testimony. For an implanted device, for example, a plaintiff will likely need medical testimony on the appropriate installation of the device in the body in order to rule out abnormal use, or

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[7] Donaldson argues that *Tweedy* obviates the necessity of expert testimony to prove a specific defect, citing *DiCosolo*, 951 N.E.2d at 1243 ("[a] plaintiff is not required to present expert testimony that the product contained a specific defect."). Although that is true, expert testimony may be necessary to establish the *Tweedy* factors.

evidence from a medical professional demonstrating the absence of infection or other medical conditions that could have caused the injury. This sort of evidence is outside the knowledge, experience and understanding of jurors.

The *Weedon* case illustrates well that expert testimony is sometimes necessary in *Tweedy* cases. Weedon sought to prove that his implanted venous access device injured him by leaking chemotherapy drugs into the tissues surrounding the device, a process called extravasation:

> Although there was no witness produced by the plaintiff to testify as an expert regarding any specific defect in the venous access device, Sarah Coveny, the oncology nurse who administered the chemotherapy, testified that she used a specially designed "Port–A–Cath needle" and that she did not remember having any problems with Weedon's chemotherapy injections. Dr. Talamanti testified that he inspected the device prior to and immediately after implantation and testified that there was no indication of any defects. Although Dr. Dumanian, the plastic surgeon, did not see the Port–A–Cath through which the chemotherapy was given, he testified to the difference between an infection and an IV infiltration injury and, although he did not know exactly what happened, he testified that Weedon had an infiltration injury. The defendants' expert, Mr. James Hagar, testified that a venous access device should not leak absent external forces, such as a medical mistake or use of an improper needle.

Weedon, 773 N.E.2d at 731. Weedon methodically countered each secondary cause that the defendant presented, demonstrating that his injuries were not due to infection, a medical mistake such as improper implantation of the device, or the use of an improper needle by the person administering the drugs. Although "the doctors that treated Weedon all testified that his injury could have resulted from infection, malpositioning of the device or extravasation … each doctor testified that it was more likely that plaintiff had an extravasation injury than an injury due to infection or malpositioning of the device." 773 N.E.2d at 722. The court therefore concluded that the plaintiff's evidence was sufficient to preclude summary judgment under *Tweedy*.

Unfortunately for Donaldson, this is a case that required expert evidence. On the question of abnormal use, there was conflicting medical evidence in the record on whether the implanting surgeon placed the Prosima device in too deep a plane. The implanting physician testified that he installed the devices correctly, following all of the manufacturer's instructions and his training. That testimony countered the claim by the defendants' expert that the Prosima device was likely implanted in too deep of a plane, leading to the bladder erosion. If that were the only *Tweedy* factor in dispute, summary judgment would have been inappropriate as to the Prosima device.

But on the issue of reasonable secondary causes, the record was entirely one-sided. The defendants presented expert opinion regarding several possible secondary causes for Donaldson's injuries, factors independent of the design of the devices. In particular, the defendants presented an affidavit

from Dr. Douglas Grier, who examined Donaldson's extensive medical records and concluded that there were several causes of mesh erosion and pelvic pain in Donaldson's case that had nothing to do with the design of the mesh products. Among these secondary causes, Dr. Grier cited vaginal atrophy as a cause of vaginal erosion, and noted the posterior surgical repair and pelvic floor muscle dysfunction as the causes of her pelvic pain. R. 59-3, at 16. Donaldson's own treating physician, Dr. Nayak, agreed that vaginal atrophy could be a cause of her vaginal erosion injury. Dr. Nayak also agreed that Donaldson's pelvic pain could have been caused by the surgical procedure she had undergone at the Mayo Clinic. Donaldson did not counter this evidence with any direct or circumstantial evidence that would negate any of the reasonable secondary causes that are supported by the record.

Instead, Dr. Nayak opined only that the Prosima "possibly caused the mesh to be eroded into the bladder and caused stones." R. 56-4, at 68–69. Where "[t]he evidence presented by plaintiff only raised possibilities for the cause of the accident, not a probability," the evidence is insufficient to make out a *Tweedy* claim. *Saieve v. Budget Rent-A-Car of Rockford*, 591 N.E.2d 507, 515 (Ill. App. Ct. 1992). Dr. Nayak inferred that the injuries were related to the Prosima implantation because they occurred after the surgery. But as we noted recently in a case involving another Ethicon mesh product:

> The FDA had approved the use of mesh implants knowing that they are not 100 percent effective. The fact that a known complication or failure occurs could reasonably be interpreted as a sign that such

> product or procedure-related failures could occur without anyone acting wrongfully.

Stark v. Johnson & Johnson, 10 F.4th 823, 830 (7th Cir. 2021). *See also Ralston v. Casanova*, 473 N.E.2d 444, 451 (Ill. App. Ct. 1984) (finding that a *Tweedy* claim failed where the only evidence presented by plaintiff was his testimony that he was wearing a seat belt while operating his vehicle and that he sustained injuries during a collision, because "it cannot legally be presumed from evidence of the mere occurrence of an accident involving a product that the product was defective when it left the manufacturer's control"). Unlike the healthcare providers in *Weedon*, Dr. Nayak declined to say that the design of the Prosima was the likely cause of Donaldson's injuries as opposed to any other cause cited by the defendants' expert.

Donaldson asserts that an examination of her medical records, attached to Dr. Nayak's affidavit, demonstrates the absence of reasonable secondary causes. That is simply not the case. First, there is no indication that these records are a complete account of Donaldson's treatment from her many providers. In his affidavit, Dr. Nayak characterized the thirty pages of attached medical records as "portions of the medical records" that he maintained pertaining to Donaldson's treatment. R. 40-1, at 2. Dr. Grier averred that he reviewed "several thousand pages of Mrs. Donaldson's medical records," and pointed out that Dr. Nayak's records begin in 2014 and contain no record of the operation where the devices were implanted. R. 56-3, at 29–30. Obviously, a statement that there are no secondary causes apparent in a tiny portion of the medical record does not exclude secondary causes. Second, the records that Dr. Nayak attached confirm other conditions from

which Donaldson suffers such as vaginal atrophy and pelvic floor dysfunction, conditions that the defendants' expert opined caused Donaldson's injuries. Nothing in Dr. Nayak's records indicates that any physician considered or excluded secondary causes for the erosion of the devices into either the bladder or vagina, or for her painful pelvic symptoms. And as we noted previously, Dr. Nayak expressly conceded that he had not considered the issue of secondary causes. Third, reviewing and deciphering Donaldson's complex medical records to eliminate secondary causes is simply not a task that a jury is competent to conduct without the aid of a medical expert.

Finally, on the question of whether the Prosima failed to perform in the manner to be expected in light of its nature and intended function, the record is again one-sided. Dr. Nayak conceded that the Prosima repaired Donaldson's prolapse. He characterized the product as unreasonably dangerous because it caused complications that are not reasonable when compared with other types of surgery such as "sling" surgery. But the "sling" to which he referred was a device he employed to treat urinary incontinence, not pelvic prolapse, and that is the purpose of the Prosima device. Dr. Nayak testified that he does not treat pelvic prolapse, and he was not, therefore, in a position to offer an opinion on the risk-benefit profile of using the Prosima for that purpose. Dr. Grier, on the other hand, testified that the Prosima performed as expected, and explained that erosion is a known risk factor for all types of

surgical repairs for prolapse, not only for mesh products such as the Prosima.[8] He stated that the fact of erosion does not necessarily indicate that the product is defective and he agreed with Dr. Schultheis that the benefits of the device outweighed the risks. Donaldson presented no evidence to counter Dr. Grier's expert opinion on the risk profile of the Prosima compared to other surgical options. She argued only that her surgeon did not warn her of the risks. But her surgeon's failure to warn her does not counter Dr. Grier's testimony.

III.

Because Dr. Nayak disclaimed any opinion on the TVT-Secur device, there is no evidence in the record eliminating abnormal use or secondary causes, and no evidence that the device failed to perform as expected. As for the Prosima device, Donaldson presented no medical evidence that the secondary causes offered by the defendants' experts were not the likely source of her injuries, or that the device did not perform as reasonably expected in light of its intended purpose. Summary judgment was therefore appropriate under *Tweedy*.

AFFIRMED.

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[8] According to Dr. Grier, other surgical options include the use of sutures or cadaver parts, both of which present the risk of erosion.