In the

United States Court of Appeals

For the Seventh Circuit

No. 17-2068

CHARLOTTE ROBINSON and
BOBBY DON BOWERSOCK as co-personal
representatives of the Estate of
Georgia J. Bowersock, deceased, and
MARK BOWERSOCK, individually,

Plaintiffs-Appellants,

v.

DAVOL INC. and C.R. BARD, INC.,

Defendants-Appellees.

Appeal from the United States District Court for the
Southern District of Indiana, Indianapolis Division.
No. 1:08-cv-01313-LJM-TAB — **Larry J. McKinney**, *Judge*.

ARGUED FEBRUARY 13, 2018 — DECIDED JANUARY 22, 2019

Before SYKES and BARRETT, *Circuit Judges*, and GRIESBACH, *Chief District Judge*.*

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* Of the Eastern District of Wisconsin, sitting by designation.

SYKES, *Circuit Judge*. C.R. Bard, Inc., manufactures a surgical mesh patch used to repair hernias by implantation. The patch consists of two pieces of mesh that surround a flexible plastic ring. During a hernia repair, the patch is folded to fit through a small incision, then the plastic ring springs back into its original shape and flattens the mesh against the abdominal wall.

Bard recalled several versions of the patch in late 2005 and early 2006 following reports that the plastic ring was defective. Sometimes the ring broke, exposing a sharp edge that could perforate the patient's intestines. Other times the ring caused the patch to bend and warp, exposing the patch's adhesive to a patient's viscera.

Prior to the recall, Georgia Bowersock underwent surgery to repair a hernia, and her surgeon implanted a Bard patch. Roughly one year later, on October 31, 2006, she died of complications arising from an abdominal-wall abscess. Her estate and family members sued Bard and Davol Inc., the patent holder for the patch, alleging that a defect in the patch caused her death. To establish medical causation, the plaintiffs retained three experts to opine on the defect and the likely cause of Mrs. Bowersock's death.

But the experts had trouble establishing causation. Unlike defective patches in other injured patients, Mrs. Bowersock's patch did not adhere to her bowel or perforate her organs with a broken, sharp edge. One expert tried to present a new theory of causation: the patch had "buckled," forming a stiff edge that rubbed against and imperceptibly perforated her internal organs.

The defendants moved to exclude the expert testimony. The judge granted the motion, finding that the "buckling" theory was not sufficiently reliable. Lacking expert testimony to establish causation, the plaintiffs could not prove their case, and the judge entered summary judgment for Bard and Davol.

We affirm. The novel theory of causation was not peer reviewed, professionally presented, consistent with Mrs. Bowersock's medical records or autopsy, or substantiated by other cases. The judge therefore did not abuse his discretion in excluding the expert testimony. Summary judgment for the defendants necessarily followed.

I. Background

The Composix® Kugel Patch is a prescription medical device designed to repair hernias. Bard manufactures the patch and Davol owns the patent. (We refer to them collectively as "Bard.") The patch consists of two layers of mesh that surround one or two flexible plastic rings called memory rings. The top layer is made of polypropylene; it adheres to the abdominal wall under the hernia and facilitates healing. The bottom layer is made of smooth expanded polytetrafluorethylene; it faces the bowel to prevent the patch from attaching to the viscera. To implant the patch, a physician folds the device and then inserts it into the patient via a small incision. After insertion the memory ring springs back and flattens the patch against the abdominal wall. The patch remains in the body after the hernia heals.

The patch hit the market in 2001. Users soon began reporting problems with the plastic ring. Sometimes it would altogether fail. Other times the ring would experience "buck-

ling"—that is, the mesh components of the patch would contract, causing the ring to resist and bend, kink, break, or buckle. Although the patch came with instructions for use that contained user warnings, none of the warnings mentioned any of these problems with the plastic ring. On December 22, 2005, Bard recalled all extra-large models. Several months later Bard expanded the recall to include other models.

On May 25, 2005, Mrs. Bowersock sought medical treatment for an abdominal-wall hernia. On July 22 Dr. Mark O. Lynch performed surgery and implanted a Bard patch, using a model that was included in the second recall. Dr. Lynch testified that he would not have implanted the patch if he had known about the defective memory rings.

On October 4, 2006, Mrs. Bowersock went to the emergency room with an abdominal-wall abscess. The hospital cultured the abscess, and the lab results returned positive for staphylococcus aureus. Doctors administered antibiotics, drained the abscess, and released her from the hospital. She returned several days later with a large wound infection. While hospitalized she suffered a cardiac arrest. She was resuscitated and placed on a ventilator. The hospital took a second culture that indicated the presence of staphylococcus epidermidis and enterococcus faecalis, or fecal bacteria. A third culture returned positive for pseudomonas aeruginosa and yeast. Her condition deteriorated until her death on October 31, 2006.

Dr. Roland Kohr, the county coroner, performed an autopsy that same day and determined that pneumonia and complications of that disease ultimately caused Mrs. Bowersock's death. In his report Dr. Kohr noted

"abdominal adhesions" and an "abdominal wall fistula." He also noted that the "small bowel and colon [were] intact without perforation, diverticula or palpable tumors." Dr. Kohr later exhumed Mrs. Bowersock's body and retrieved the implanted patch for further study.

Bobby and Mark Bowersock (Mrs. Bowersock's sons) and Charlotte Robinson (her sister) sued Bard in federal court raising claims of negligence, failure to warn, breach of implied warranty, fraud, and intentional infliction of emotional distress. They also asserted a statutory claim for violation of the Indiana Deceptive Consumer Sales Act, IND. CODE § 24-5-5. Bobby and Charlotte are co-representatives of Mrs. Bowersock's estate; Mark also asserted an individual claim under the Indiana Wrongful Death Act, *id.* § 34-23-1-1. All of the claims rested on the same essential allegations: the patch implanted in Mrs. Bowersock was defective and ultimately caused her death. The district court consolidated the claims under the Indiana Products Liability Act, *id.* §§ 34-20-1-1 *et seq.*, which "govern[s] all product liability actions, whether the theory of liability is negligence or strict liability in tort," *Dague v. Piper Aircraft Corp.*, 418 N.E.2d 207, 212 (Ind. 1981).

The plaintiffs retained Dr. Stephen Ferzoco to opine on the cause of death. Dr. Ferzoco has experience treating patients who had problems with the patches. He also has testified in cases where the memory ring broke or the polypropylene side of the patch adhered to the intestines. After examining the patch that was retrieved from Mrs. Bowersock, however, Dr. Ferzoco conceded that neither of those problems had occurred here. He instead developed a new theory to account for her injury: the ring had buckled

but stayed intact, and the raised portion of the mesh "rubb[ed] up against the bowel causing a fistula or break and then seal[ed] up prior to explantation or discovery of the mesh in the bowel." The parties and the district judge referred to this as the "nidus" theory (meaning the location or focus of an infection), so we do the same; here it describes the location where Dr. Ferzoco theorized that the buckled ring rubbed against the bowel. Dr. Ferzoco also testified that he could rule out several other possible causes of death, including cross-contamination of fecal matter, fecal matter entering through the skin, obesity, diabetes, and chronic obstructive pulmonary disease.

Dr. Ferzoco's theory was novel: he had never before presented it in a formal or professional setting and could not identify published medical literature discussing it. Though he claimed to have seen this particular malfunction occur in other patients, he declined to identify the patients or produce their medical records. Crucially, he admitted that there was no evidence in the medical records or autopsy report of bowel erosion or perforation.

The plaintiffs also retained Dr. William Hyman, a professor of biomedical engineering. He opined that the memory ring's design was inherently dangerous, that Bard failed to adequately test the patch, and that feasible alternative designs were available. He also speculated that based on the defective design and Dr. Ferzoco's medical testimony, the ring buckling likely caused the bowel injury. He identified two important limitations in his testimony, however. First, he admitted that he never examined or viewed images of Mrs. Bowersock's patch. Second, he is "not a microbiologist

and [was] not offering an independent opinion on the microbiology of her infection."

Finally, the plaintiffs retained Dr. Kohr, the coroner. He reiterated in his deposition that the autopsy did not reveal any visible breaches of the small bowel or colon. He clarified, however, that "there could have been superficial breaches scarred over with additional inflammation" and that "extensive adhesions in the suprapubic area [and] lower abdomen" suggested the "possibility" of a breach. He also testified that at the time of the autopsy, he wasn't aware of the problems with the patch or Bard's recalls. Dr. Kohr concluded that there was a "reasonable medical probability" that the patch caused Mrs. Bowersock's death.

Bard moved to exclude the causation opinions offered by each of these experts, arguing that (1) Dr. Ferzoco's nidus theory was not reliable; (2) Dr. Hyman's opinion was unsupported by the medical records; and (3) the plaintiffs failed to timely disclose Dr. Kohr as an expert under Rule 26 of the Federal Rules of Civil Procedure. Bard also sought summary judgment, arguing the plaintiffs could not prove that the patch or its warnings were defective or caused Mrs. Bowersock's death.

The judge granted the motion to exclude the experts. He ruled that Dr. Ferzoco's nidus theory failed to meet the reliability threshold under Rule 702 of the Federal Rules of Evidence. He also held that Dr. Hyman was not qualified to offer an opinion about medical causation and that the plaintiffs' failure to disclose Dr. Kohr as an expert precluded them from calling him to testify in that capacity. That left the plaintiffs without a causation expert—a requirement to

prove the element of medical causation under Indiana law—so the judge entered summary judgment for Bard.

II. Discussion

We normally review a summary judgment de novo, but our review is "slightly more nuanced" when summary judgment follows from a decision to exclude expert testimony. *Higgins v. Koch Dev. Corp.*, 794 F.3d 697, 701 (7th Cir. 2015). Our first question is whether the judge properly applied the *Daubert* framework for evaluating the admissibility of expert testimony. *Id.* (citing *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993)). We then review for abuse of discretion the judge's decision to exclude the expert witness. *Id.*

The plaintiffs must establish causation to prove a violation of the Indiana Products Liability Act. IND. CODE § 34-20-1-1. Under Indiana law "questions of medical causation of a particular injury are questions of science necessarily dependent on the testimony of physicians and surgeons learned in such matters." *Higgins*, 794 F.3d at 703 (quoting *Armstrong v. Cerestar USA, Inc.*, 775 N.E.2d 360, 366 (Ind. Ct. App. 2002)). "[W]hen there is no obvious origin to an injury and it has multiple potential etiologies, expert testimony is necessary to establish causation." *Id.* (quotation marks omitted).

The key expert testimony is that of Dr. Ferzoco; without it the plaintiffs cannot establish medical causation. They concede as much. They do not challenge the exclusion of Dr. Kohr as an expert based on their procedural violation, and they acknowledge that Dr. Hyman's opinion "does not, in and of itself, establish medical causation." We therefore

focus our attention on the exclusion of Dr. Ferzoco's testimony under Rule 702.

An expert's opinion is permitted if:

> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
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> (b) the testimony is based on sufficient facts or data;
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> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert has reliably applied the principles and methods to the facts of the case.

FED. R. EVID. 702.

The familiar *Daubert* two-step framework applies to determine whether the requirements of Rule 702 have been satisfied. 509 U.S. at 593–94. The proponent of the expert testimony must first establish that "the proposed witness would testify to valid scientific, technical, or other specialized knowledge." *Ammons v. Aramark Unif. Servs., Inc.*, 368 F.3d 809, 816 (7th Cir. 2004) (internal quotation marks omitted). The proponent must then show that the expert testimony will assist the trier of fact. *Id.* At step one the judge evaluates whether the expert's theory has been "(1) tested, (2) subjected to peer review and publication, (3) analyzed for known or potential error rate, and/or is (4) generally accepted within the specific scientific field." *Lapsley v. Xtek, Inc.*, 689 F.3d 802, 810 (7th Cir. 2012). At step two the judge evaluates "whether the proposed scientific

testimony fits the issue to which the expert is testifying." *United States v. Hall*, 165 F.3d 1095, 1102 (7th Cir. 1999).

The judge properly applied the Rule 702 and *Daubert* standards in addressing Bard's motion. He summarized Dr. Ferzoco's theory that the patch buckled and rubbed against Mrs. Bowersock's colon, causing fecal matter to escape through an opening that either closed prior to discovery or was not visible to the naked eye. He then explained why this novel theory of causation wasn't reliable. To begin, the theory wasn't tested, subjected to peer review, or described in medical literature. *See Lapsley*, 689 F.3d at 810. Moreover, the phenomena that Dr. Ferzoco described were not found in Mrs. Bowersock's medical records or autopsy report. Last, the judge discounted Dr. Ferzoco's contention that he had previously treated patients injured in this manner, explaining that the claim was not substantiated with identified patients or records. *See Olinger v. U.S. Golf Ass'n*, 52 F. Supp. 2d 947, 950 (N.D. Ind. 1999) ("The court cannot evaluate the reliability of the undisclosed methodology or of the principles that support the methodology.").

On appeal the plaintiffs contend that Dr. Ferzoco's method was the equivalent of a differential diagnosis, which is an "accepted and valid methodology." *Myers v. Ill. Cent. R.R. Co.*, 629 F.3d 639, 644 (7th Cir. 2010). Put in simple terms, a differential diagnosis "provides a framework in which all reasonable hypotheses are 'ruled in' as possible causes of a medical problem and some of these possible causes are then 'ruled out' to the extent scientific evidence makes it appropriate to do so." *Ervin v. Johnson & Johnson, Inc.*, 492 F.3d 901, 903 (7th Cir. 2007). The plaintiffs didn't raise this argument at summary judgment, however. They first used the term

"differential diagnosis" in their motion to alter or amend the judgment. That's too late to preserve an argument for appeal. *Cf. Green v. Whiteco Indus., Inc.*, 17 F.3d 199, 201 n.4 (7th Cir. 1994) ("[R]aising [an] argument for the first time in the motion for reconsideration is not adequate to preserve the issue for appeal and definitively waives it.").

The plaintiffs insist that they presented the argument below, just without using the term "differential diagnosis." They point to their argument at summary judgment that Dr. Ferzoco's opinions were "founded on reliable methods, experience[,] and data." That's far too general a statement to situate their expert's opinion in the specific domain of differential-diagnosis methodology. *See Fednav Int'l Ltd. v. Cont'l Ins. Co.*, 624 F.3d 834, 841 (7th Cir. 2010) (explaining that the failure to present a specific argument below results in waiver, even if the argument "may have been before the district court in more general terms").

Even if preserved, the argument fails on the merits. Though differential diagnosis is widely accepted as a general matter, an expert's decision to "rule in" or "rule out" potential causes must itself be "scientifically valid." *Ervin*, 492 F.3d at 904. In other words, Dr. Ferzoco needed to establish the reliability of his nidus theory in order to "rule in" the buckling as a potential cause of Mrs. Bowersock's death. As we've noted, the judge identified several reasons why Dr. Ferzoco's nidus theory is not sufficiently reliable.

The plaintiffs also argue that a scientific theory should not be rejected solely because it lacks peer review. *See Smith v. Ford Motor Co.*, 215 F.3d 713, 720 (7th Cir. 2000). But the judge gave multiple reasons for his decision, including the lack of corroborating evidence in Mrs. Bowersock's medical

records and autopsy report. Along the same lines, the plaintiffs repeatedly assert that the lack of scientific literature supporting the expert's theory goes to the weight, not the admissibility, of his testimony. That's not the correct standard. Rule 702 and *Daubert* require the judge to act as a vigorous gatekeeper to ensure the reliability of expert testimony. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 149 (1999).

In sum, the plaintiffs cannot prove medical causation without Dr. Ferzoco's testimony. The record reflects that the judge properly applied the *Daubert* framework and soundly exercised his discretion to exclude it. It follows that Bard was entitled to summary judgment.

AFFIRMED.