In the

United States Court of Appeals

For the Seventh Circuit

No. 22-2610

NATALIE JOHNSON,

Plaintiff-Appellee,

v.

C. R. BARD, INC., and BARD PERIPHERAL VASCULAR, INC.,

Defendants-Appellants.

Appeal from the United States District Court for the
Western District of Wisconsin.
No. 19-cv-760-wmc — **William M. Conley**, *Judge*.

ARGUED JUNE 1, 2023 — DECIDED AUGUST 11, 2023

Before EASTERBROOK, WOOD, and PRYOR, *Circuit Judges*.

WOOD, *Circuit Judge*. Hoping to minimize her risk of suffering serious complications from future blood clots, plaintiff Natalie Johnson underwent surgery to implant a retrievable intravascular filter. Intravascular filters are medical devices that are placed in the inferior vena cava (the major lower vein that carries blood to the heart) to prevent blood clots that develop in the lower body from flowing into the heart and lungs. Johnson's doctor selected the Meridian filter, which was

supposed to be temporary and easily removeable. It was not. Instead, Johnson's filter migrated and fractured, leaving shards embedded in the wall of her heart and elsewhere. Her surgeon was unable to remove the device safely and fully. She now faces an ongoing risk of infection, pain, and other complications as a result of the broken filter.

Johnson sued the manufacturers of the Meridian filter—C.R. Bard, Inc., and Bard Peripheral, Inc. (together, "Bard")—claiming that they defectively designed the Meridian filter and failed to warn medical providers about the device's risks, in violation of Wisconsin law. A jury cleared Bard on most of Johnson's theories, but it returned a $3.3 million verdict in her favor on her strict liability failure-to-warn count. Bard moved for a new trial on a host of issues, but the district court denied the motion. We affirm.

I

Johnson's case is one of several that were remanded for further proceedings following the conclusion of multidistrict litigation related to alleged defects in Bard's intravascular filters. See *In re Bard IVC Filters Prod. Liab. Litig.*, No. MDL 15-02641, 2019 WL 3928657 (D. Ariz. Aug. 20, 2019). At trial, she argued that Bard was liable for her injuries under several Wisconsin-law theories: negligent defective-design, strict liability defective-design, negligent failure-to-warn, and strict liability failure-to-warn. Johnson's main contention was that Bard's Meridian filter was defectively designed because it had an unacceptably high risk of migration or fracture, or both, and that Bard failed properly to warn users about these risks. Bard's central defense (as relevant to this appeal) was that Johnson's problems came about because her surgeon, Dr. Irina Goncharova, had placed the filter too high (*i.e.* toward the heart) in

the wall of the vein. Bard contended that Johnson's injuries were caused by that improper placement, not any problem with the device.

Among Johnson's witnesses was Dr. Darren Hurst, a vascular and interventional radiologist. In his expert report and deposition testimony, Hurst stated that CT scans taken a few days after Goncharova implanted Johnson's filter showed that the filter had migrated *down* by 3 *millimeters*. At trial, however, he testified that the scans showed that the filter had migrated *upward* by 2.5 or 2.3 *centimeters*. This led Bard to object at various times on nondisclosure grounds, an issue that we discuss in more depth in Part II.A, *infra*.

Johnson also called Goncharova to testify, but securing her appearance turned out to be difficult. On day one of the trial, Johnson informed the court that she was "concerned that the two physicians that have been subpoenaed have not responded." The district court replied that the trial would proceed, but that it might be possible "to take them out of turn" or "have them appear by videoconferencing." The district court also stated that "if you want some relief in an effort to get them to appear in some way … you need to let me know and I'll do what I can."

As Johnson suspected, Goncharova failed to appear as required by the subpoena at the scheduled time on day two of the trial. On day four, Johnson rested her case. But on the morning of day five of the trial, Johnson informed the court that she intended to file a motion to request that the marshals escort Goncharova to court on Monday, day six of the trial. The motion turned out to be unnecessary. That same day, the court e-mailed the attorney representing the hospital group that employed Goncharova in an effort to enforce the

subpoena. So prompted, Goncharova agreed to testify on day six. Bard objected to the court's decision to re-open the plaintiff's case-in-chief to permit Goncharova to testify, but the court overruled the objection. It made clear, however, that Bard would have an opportunity to respond to her testimony: "If there's something else or other testimony you wanted to submit, you could do that."

One final aspect of the trial requires a word. Bard sought a jury instruction stating that it was entitled to a rebuttable presumption that the Meridian filter was not defective. Under Wisconsin law, manufacturers are entitled to such a presumption if the product "complied in material respects with relevant standards, conditions, or specifications adopted or approved by a federal or state law or agency." Wis. Stat. § 895.047(3)(b). Bard argued that it qualified for the presumption because its filter received "510(k) clearance" from the federal Food and Drug Administration (FDA). As we explain at greater length in Part II.C, 510(k) clearance authorizes a manufacturer to sell a medical device without undergoing the FDA's rigorous premarket review process. See *Kaiser v. Johnson & Johnson*, 947 F.3d 996, 1003–04 (7th Cir. 2020). The district court refused to give the jury instruction, holding that Bard's 510(k) clearance did not qualify as a relevant safety standard for purposes of the statutory presumption.

The jury returned a verdict for Bard on both of the defective-design theories and on the negligent failure-to-warn theory, but it returned a $3.3 million verdict for Johnson on the strict liability failure-to-warn theory. For the latter, it concluded that the "foreseeable risks of harm posed by the [Meridian filter] could have been reduced or avoided by the provision of reasonable instructions or warnings by [Bard] and

the omission of the instructions or warnings render[ed] the [Meridian filter] not reasonably safe." Wis. Stat. § 895.047(a).

Bard moved for a new trial on a host of issues, but the district court denied the motion in its entirety. On appeal, Bard renews three of its post-trial arguments. First, it asserts that Hurst's flip-flop violated the expert witness disclosure requirements of Federal Rule of Civil Procedure 26. Second, Bard argues that the district court erred by permitting Goncharova to testify belatedly and without submitting an expert report. Third, Bard contends that the court should have instructed the jury on the presumption of non-defectiveness. We examine the first two points only for abuse of discretion; to the extent the third involves issues of law, our review is *de novo*.

II

A

1

Bard asserts that we must grant a new trial "because of Dr. Hurst's undisclosed and contradictory expert opinions offered for the first time at trial." Although Hurst's expert report and deposition testimony stated that the filter migrated down by 3 millimeters, he testified at trial that the filter migrated upward by 2.5 centimeters or so. This change in opinion was significant, according to Bard, because one of its defenses was that Johnson's injuries were caused by Goncharova's placement of the filter in a spot that was too high. It would have needed an entirely different defense if the evidence showed that the placement was at the right spot and the device drifted up. On the stand, Hurst admitted that he had arrived at his new opinion only after Johnson asked him

to reevaluate her CT scans. On appeal, Johnson does not dispute that Hurst changed his opinion regarding the filter's migration, that she knew of the change, and that she failed to disclose the change to Bard.

Before we delve into this part of the appeal, we need to assure ourselves that Bard's objections to Hurst's testimony have something to do with Johnson's failure-to-warn theory. If they pertain only to her defective-design theories, there is nothing left to say—Bard prevailed on all of those theories before the jury, and Johnson did not file a cross-appeal. Hurst's testimony addressed the flaws in the device rather than any warnings that went along with it, and so at first glance one might think that any errors in admitting or denying it were harmless for purposes of the failure-to-warn theory. On the other hand, the Supreme Court of Wisconsin has held that "the likelihood of an accident's taking place and the seriousness of the consequences are always pertinent matters to be considered with respect to the duty to provide a sufficient warning label, and … there is a particular need for a sufficient warning where there is a representation that the product in question is not dangerous." *Schuh v. Fox River Tractor Co.*, 63 Wis. 2d 728, 739 (1974); *Tanner v. Shoupe*, 228 Wis. 2d 357, 368 (Wis. Ct. App. 1999). The jury might well have relied on Hurst's testimony in its consideration of the seriousness of the consequences that attended the alleged failure to warn. That is enough, we think, to support the continued relevance of Bard's arguments about him.

2

Several provisions of the Federal Rules of Civil Procedure govern the pretrial disclosure of expert opinions. Under Rule 26(a)(2)(B), witnesses who are "retained or specially

employed to provide expert testimony in the case" must provide a written report that includes, among other disclosures, "a complete statement of all opinions the witness will express and the basis and reasons for them." Rule 26(e)(2) imposes on parties a "duty to supplement" their initial disclosures: "Any additions or changes to [information in an expert's report or deposition] must be disclosed by the time the party's pretrial disclosures under Rule 26(a)(3) are due." The consequences for violating these rules can be dire. Under Rule 37(c)(1), "[i]f a party fails to provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness … at a trial, unless the failure was substantially justified or is harmless."

We have held in the context of Rule 26(a)—which governs initial disclosures, not the duty to supplement—that Rule 37(c)(1)'s "sanction of exclusion is automatic and mandatory unless the sanctioned party can show that its violation of Rule 26(a) was either justified or harmless." *David v. Caterpillar, Inc.*, 324 F.3d 851, 857 (7th Cir. 2003) (quoting *Salgado v. Gen. Motors Corp.*, 150 F.3d 735, 742 (7th Cir. 1998)). At the same time, we have emphasized that "[t]he determination of whether a Rule 26(a) violation is justified or harmless is entrusted to the broad discretion of the district court." *Id.* (quoting *Mid-America Tablewares, Inc. v. Mogi Trading Co., Ltd.*, 100 F.3d 1353, 1363 (7th Cir. 1996)). Given that the text of Rule 37(c)(1) treats violations of 26(a) and 26(e) equally, we apply the same standards to a party's failure to supplement.

We agree with Bard that Johnson's failure to disclose Hurst's new opinion regarding the direction and magnitude of the filter's migration appears to violate Rule 26(e). From Bard's standpoint, that is the end of the discussion: a new trial

should be automatic. But Bard is trying to sweep a critical problem under the rug: It did not raise in the trial court the broader argument it presses here. Its objections to Hurst's testimony were narrow, and the court addressed and ruled in its favor each time. That raises the specter of waiver; we normally do not criticize a district judge for refraining from more drastic measures when no one asked for them.

Hurst initially testified at some length about the placement of the filter, with no objection from Bard regarding nondisclosure. Bard's first objection came when Johnson's lawyer, James Johnson, attempted to present a demonstrative aid that Bard had not received in advance and that Bard believed was inconsistent with Hurst's previous disclosures. The court sustained Bard's objection, admonishing Attorney Johnson that "you should have cleared this in advance. And you've put yourself in this position, so he'll have to testify without it, Counsel." The demonstrative was not shown to the jury, and Bard did not request any further remedial action from the court.

Bard's next objection was also sustained. When Attorney Johnson attempted to show an exhibit to Hurst (though not to the jury), Bard objected. A lengthy sidebar ensued, during which the parties disputed whether Hurst's intended testimony about the filter's location and its upward movement was consistent with his expert report and deposition. Given the uncertainty about whether Hurst's intended testimony had previously been disclosed, the court told Attorney Johnson that he was "going to have to lay a foundation then, before you ask him about any movement, as to the placement of the apex of the filter after three days in relation to the inferior cortical margin." Counsel's questioning immediately

following the sidebar respected that limitation. And when Attorney Johnson requested permission to publish the exhibit at issue, the court refused: "No. You didn't disclose it in advance. There's problems with it and you're not going to be showing it to the jury."

Bard's last nondisclosure objection during Hurst's testimony came shortly thereafter, when Hurst stated that the filter had moved 2.3 centimeters. Bard objected, citing Hurst's deposition testimony that the filter had moved only 3 millimeters. The district court asked Hurst about the discrepancy, and Hurst replied that he "was asked to reevaluate" one of the images by the plaintiff. At that point, the following exchange took place:

> **Court:** There's a procedure for someone to correct their deposition transcript. Did you do that, did you review your transcript and change it?
> **Hurst:** I did not review my transcript, but I did not make the change because this change—I was asked to review the IVC venacavogram later.
> **Court:** And was this change ever disclosed to the defendants?
> **Attorney Johnson:** No, sir.
> **Court:** I'm sorry?
> **Attorney Johnson:** No, sir.
> **Court:** Then we are where we are, Counsel.
> **Attorney Johnson:** I'll ask about other features that were disclosed.
> **Court:** Fine.

Bard did not make any further relevant objections during Hurst's testimony. At the conclusion of the testimony, Bard filed a motion "seeking the exclusion of plaintiff's expert Dr. Hurst's undisclosed opinions." On appeal, Bard claims that "the district court never ruled on that request." True enough,

but a closer look at the motion and subsequent developments during the trial explains why.

Bard's motion did not focus on the damage that had already been done by Hurst's trial testimony during the plaintiff's case-in-chief. Instead, the motion requested that the court exclude Hurst's prospective testimony as a *rebuttal* witness. For example, Bard explained:

> [T]he Court, *sua sponte*, stated that Dr. Hurst could return as a rebuttal witness to testify about his new opinion … . If Dr. Hurst was allowed to offer his entirely new opinion about where the filter was placed and how far and in what direction it moved following the placement, he would not be rebutting anyone except himself … . Furthermore, Plaintiff did not offer a rebuttal expert report for Dr. Hurst by the Court mandated August 11, 2020 deadline.

After Bard filed its motion, the court asked Attorney Johnson if he intended to call any rebuttal witnesses. He expressly declined: "We are not planning on calling Dr. Hurst in rebuttal, and, therefore, we have no rebuttal expected, Your Honor." Thus, Bard's motion to exclude Hurst's rebuttal testimony was moot and there was no need for a ruling by the court.

Nowhere in the motion did Bard ask the court to reconsider rulings it had made on Bard's objections during Hurst's testimony. Never did Bard suggest that it was seeking additional curative measures to remedy the harm done by Hurst's testimony in the case-in-chief. To the contrary, the motion stated that "[f]ollowing Bard's objection, the Court sustained

Bard's objection to the introduction of this new opinion and excluded it," and that this "refusal to allow" the testimony was "proper." This stands in stark contrast to Bard's position on appeal to the effect that the district court "did not squarely address Bard's myriad objections." We decline to accept this revisionist account.

The record shows that the nondisclosure-related objections Bard made to Hurst's testimony were all addressed to its satisfaction by the district court. We appreciate the challenges that parties face when attempting to respond to unanticipated issues arising in the heat of trial. For this reason, we have explained that "an objection [need not] be perfectly contemporaneous with the challenged testimony in order to … be considered 'timely.'" *Jones v. Lincoln Elec. Co.*, 188 F.3d 709, 727 (7th Cir. 1999). But objections still must be "raised within a sufficient time after the proffer of testimony so as to allow the district court an adequate opportunity to correct any error." *Id.* Although Bard could have asked the court for a stronger sanction, such as striking Hurst's testimony from the record, a curative instruction, or even a mistrial, it chose not to do so. Bard cannot, only after losing a jury verdict, repackage its earlier acquiescence as a bid for much stronger measures.

B

Bard also argues that it is entitled to a new trial because the district court mishandled Dr. Goncharova's appearance. It accuses the court of abusing its discretion by "sua sponte" reopening the plaintiff's case-in-chief to allow Goncharova to testify, and of similarly erring by permitting her to opine on matters outside her role as Johnson's treating physician without providing an expert report. Once again, we can see the

potential relevance of this testimony to the failure-to-warn theory of liability. As the treating physician, Goncharova was just the person who needed to see an adequate warning, and her testimony was capable of shedding light on this issue.

The biggest problem we see with Bard's current arguments is that they do not reflect what happened at the trial. We begin with Bard's contention that Goncharova should not have been allowed to testify at all, because Johnson rested her case without securing Goncharova's appearance. We review a district court's decision to reopen a party's case-in-chief for abuse of discretion. See *Nanda v. Ford Motor Co.*, 509 F.2d 213, 223 (7th Cir. 1974). Federal Rule of Evidence 611(a)(1) instructs that courts "should exercise reasonable control over the mode and order of examining witnesses and presenting evidence so as to[ ] … make those procedures effective for determining the truth." This authority includes the discretion to permit (or deny) a party's request to reopen its case after it has rested. See *United States v. Green*, 757 F.2d 116, 119 (7th Cir. 1985) ("[T]he district court is invested with broad, discretionary powers in allowing a party to reopen its case.").

Bard first accuses the district court of abusing its discretion because (according to Bard) it acted on its own initiative to secure Goncharova's attendance. But that is a misleading portrayal of what happened. Johnson informed the court during the trial that she was attempting to secure Goncharova's testimony after Goncharova disregarded a trial subpoena and failed to appear on day two of the trial. On the morning of day five of the trial, Johnson stated that she intended to file a motion to request that the U.S. marshals escort Goncharova to testify on the next trial date. At that point, the court e-mailed the hospital group's attorney in an attempt to enforce its

subpoena. This effort was successful; Goncharova indicated that same afternoon that she would appear to testify on day six. The most one could say is that the court anticipated Johnson's motion and sought to avoid dispatching U.S. marshals by sending a warning first. That does not amount to unprompted or inappropriate activism.

Bard also argues that the district court abused its discretion in permitting Goncharova's belated testimony because Johnson did not act "diligently" to secure her presence. The court was willing to say that Johnson "should have done a better job of pursuing [Goncharova]." But it nevertheless concluded that the "various steps" Johnson had taken were sufficient, and so it declined to exclude Goncharova's testimony for lack of diligence. The district court was well-situated to make this determination, and Bard has not shown that the court's conclusion amounted to an abuse of discretion.

Bard also argues that allowing Goncharova to testify "on the last day of all evidence" was prejudicial because it upset Bard's case strategy and gave "her testimony out-sized importance … without any meaningful ability to respond." This too is a matter that lies squarely within the district court's discretion, and we see nothing amiss here. The court was satisfied that Bard was not unfairly prejudiced by the timing of Goncharova's testimony. Bard was on notice from the outset that Johnson intended to call Goncharova as a witness. Johnson attempted to depose Goncharova (albeit unsuccessfully) and listed her as a witness on her pretrial submissions. In addition, Bard knew that the court had expressed a willingness to permit Goncharova to testify "out of turn" after Johnson shared concerns about Goncharova's responsiveness. If Bard decided to rest its trial strategy on the hope that a key witness

would successfully ignore a subpoena, that was a risk it accepted voluntarily.

We reject Bard's argument that the timing of Goncharova's testimony deprived it of a meaningful opportunity to respond to her. The trial court stated that it would accommodate Bard's needs in response to Goncharova's testimony: "If there's something else or other testimony you wanted to submit, you could do that." Nor did Goncharova get the last word before the case was sent to the jury; Bard called its own witness after her testimony and before deliberations began. In sum, the court's decision to permit Goncharova's belated testimony was not an abuse of discretion.

Alternatively, Bard argues that Goncharova's testimony should have been excluded because she impermissibly offered "opinions on a variety of issues that went far beyond describing her care and treatment of Plaintiff." Typically, "[a]n expert witness must submit a written report 'if the witness is one retained or specially employed to provide expert testimony in the case or one whose duties as the party's employee regularly involve giving expert testimony.'" *E.E.O.C. v. AutoZone, Inc.*, 707 F.3d 824, 833 (7th Cir. 2013) (quoting Fed. R. Civ. P. 26(a)(2)(B)). "However, a treating physician can provide an expert opinion without submitting a written report if the physician's opinion was formed during the course of the physician's treatment, and not in preparation for litigation." *Id.*; see also 1993 Committee Note to Fed. R. Civ. P. 26 ("A treating physician, for example, can be deposed or called to testify at trial without any requirement for a written report.").

As we discussed above with respect to Hurst, we review a district court's decision to admit or exclude expert testimony

after a nondisclosure violation for abuse of discretion. See *David*, 324 F.3d at 857. Here, however, the underlying question is whether Goncharova's testimony was within the scope of her role as Johnson's treating physician. We have treated similar issues as legal questions that are evaluated *de novo*. See, *e.g.*, *Echo, Inc. v. Timberland Machs. & Irrigation, Inc.*, 661 F.3d 959, 963 (7th Cir. 2011) ("We review the district court's classification of a witness as lay or expert de novo.").

Bard highlights three exchanges during Attorney Johnson's examination of Goncharova as impermissibly veering outside the scope of her treatment of Johnson and into the realm of an expert retained for litigation purposes. It failed to lodge relevant objections to Attorney Johnson's questions during two of these exchanges. But in any event, counsel's questions to Goncharova appropriately focused on her treatment of Johnson.

The three exchanges that Bard now criticizes follow a similar pattern. First, Attorney Johnson asked Goncharova whether she knew certain information regarding Meridian filters at the time she chose a Meridian filter for Johnson's surgery. Next, counsel asked Goncharova whether that information "would … have been important" to her. Finally, he asked why the information would have been important, or what she would "likely have done had [she] been made aware of that information[.]"

These questions were directed at what Goncharova knew about the Meridian filter at the time she decided to implant that device in one particular patient—Johnson—and how that knowledge (or lack thereof) affected the doctor's decisions with respect to her treatment of that patient. This is not a case where the plaintiff attempted to back-door undisclosed

expert testimony through the testimony of the plaintiff's treating physician. Goncharova did not, for example, offer a general opinion on industry standards, what other surgeons might do, or conclusions based on studies or research she conducted after Johnson's surgery. Nor did she engage in special preparation leading up to the litigation. To the contrary, the events leading up to her testimony show that Goncharova was an uncooperative witness. Goncharova testified about her personal knowledge and decision-making process with respect to a particular patient at the time she treated that patient. This is precisely the type of testimony that the treating-physician exception to the expert-report requirement permits.

C

Finally, Bard argues that the district court should have instructed the jury that Bard was entitled to a rebuttable presumption that the Meridian filter was not defective. Again, we need to ensure that these arguments continue to be relevant to the appeal. It appears to us that they are. Wisconsin law considers a manufacturer to be strictly liable for a product that "is defective because of inadequate instructions or warnings." Wis. Stat. § 895.047(1)(a). "A product is defective because of inadequate instructions or warnings only if the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the manufacturer and the omission of the instructions or warnings renders the product not reasonably safe." Wis. Stat. § 895.047(1)(a). If, however, there is "evidence that the product, at the time of sale, complied in material respects with relevant standards, conditions, or specifications adopted or approved by a federal or state law or agency," then the manufacturer is entitled to "a rebuttable

presumption that the product is not defective." Wis. Stat. § 895.047(3)(b). This presumption applies not only to alleged defects in a product's design, but also to alleged defects that flow from inadequate instructions or warnings.

Bard argues that the fact that the Meridian filter received "510(k) clearance" from the FDA means that it "complied in material respects with relevant standards, conditions, or specifications adopted or approved by a federal … agency," Wis. Stat. § 895.047(3)(b), and thus as a matter of state law it is presumed not to be defective. But Bard overstates the impact of 510(k) clearance for present purposes.

To see why, a brief look at that process is in order. We described it in detail in *Kaiser v. Johnson & Johnson*, 947 F.3d 996, 1003–05 (7th Cir. 2020), a case dealing with an analogous Indiana presumption of non-defectiveness. The FDA categorizes medical devices as Class I, Class II, or Class III. See 21 U.S.C. § 360c(a). New devices are considered Class III devices by default and therefore must go through "a rigorous regime of premarket approval." *Kaiser*, 947 F.3d at 1003 (quoting *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317 (2008)). One exception, however, is key. A new device need not undergo premarket approval if it is "substantially equivalent" to a Class I or Class II device already on the market or a device that is otherwise exempt from premarket review. *Id.* at 1004 (citing § 360c(f)(1)(A)).

There are two ways to show substantial equivalence, if the new device has the same intended use as the predicate device: the new device may "(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.'" *Id.* (quoting § 360c(i)(1)(A)). Critically for

our purposes, this means that a device can receive 510(k) clearance based on its technological similarity to another device without an inquiry into the safety of the new device. In addition, the statutory scheme authorizes "piggybacking"—*i.e.*, "clearing a device based on its substantial equivalence to a predicate device that itself received clearance through substantial equivalence." *Id.* at 1005.

In lay terms, this means that 510(k) clearance is possible without any examination of the safety of a particular medical device if the company uses the first path. The FDA has admitted as much, noting that 510(k) clearance "does not in any way denote official approval of the device" and "it's unlawful for a device manufacturer to make such a representation." *Id.* (quoting 21 C.F.R. § 807.97).

In *Kaiser*, we held that the defendants were not entitled to the Indiana presumption of non-defectiveness because there was no assurance that product safety had factored into the FDA's clearance decision, which was based on the substantial-equivalence exception. *Id.* at 1018. We also found that the district court did not abuse its discretion in refusing to allow the defendant to present evidence of the product's 510(k) clearance to the jury. *Id.* The Fourth and Eleventh Circuits have come to similar conclusions in cases dealing with 510(k) clearance. See *In re C.R. Bard, Inc., Pelvic Repair Sys. Prod. Liab. Litig.*, 810 F.3d 913 (4th Cir. 2016); *Eghnayem v. Boston Sci. Corp.*, 873 F.3d 1304 (11th Cir. 2017).

The district court in the present case concluded that the line of substantial-equivalence findings that Bard's filter depended on did not demonstrate compliance with relevant federal safety standards. We agree with this reasoning. Bard did not show that the 510(k) clearance of its Meridian filter was

based on the FDA's determination that it complied with any specific safety standards, rather than its similarity to previously approved devices.

Bard finally argues that the district court failed to consider that apart from the substantial-equivalence showing, the FDA requires it to comply with three "special controls." These "special controls," it asserts, are sufficient to invoke the presumption. But it was vague about what these "special controls" actually were, other than referring generically to "three mandatory guidance documents … delineat[ing] the testing, labeling, etc. that must be done when developing a [sic] intravascular filter." This is not good enough. Recall that the Wisconsin presumption applies only if Bard shows that it "complied in *material* respects with *relevant* standards." Wis. Stat. § 895.047(3)(b) (emphasis added). Bard does not explain what within these guidance documents establishes "relevant" standards regarding risks of filter migration or fracture.

Even if we were to overlook Bard's failure to develop this argument fully (and we are not inclined to do so), we are skeptical that the special controls currently applicable to intravascular filters qualify as relevant standards as contemplated by Wisconsin law. The special controls consist of three guidance documents: (1) "Use of International Standards Organization's ISO 10933 'Biological Evaluation of Medical Devices Part I: Evaluation and Testing," (2) "510(k) Sterility Review Guidance and Revision of 2/12/90 (K90-1)," and (3) "Guidance for Cardiovascular Intravascular Filter 510(k) Submissions." 21 C.F.R. § 870.3375.

Bard does not discuss these documents in any detail, probably because they are far too general to qualify as relevant

safety standards. One document enumerates "the criteria for an ideal filter," but only at a high level of generality:

- Nonthrombogenic
- High filter efficiency without impedance of blood flow
- Secure fixation within the vena cava
- Rapid and safe percutaneous insertion
- Low rate of associated morbidity
- Magnetic resonance imaging (MRI) compatibility

U.S. Food & Drug Admin., FDA-2020-D-0957, *Guidance for Cardiovascular Intravascular Filter 510(k) Submissions – Guidance for Industry and FDA Staff* (1999). The guidance does not attempt to measure, quantify, or describe these criteria. What, for example, constitutes "secure" fixation? Or a "low rate" of morbidity? The guidance does not say. Similarly, the guidance provides broad suggestions for categories of tests that manufacturers should conduct, but it does not prescribe any particular methodology, metrics, or criteria regarding how these tests should be performed or what results must be attained. It states, for example, that "an adequate number of samples should be tested," that the "[t]est protocols and acceptance criteria for these tests are the responsibility of the submitter," and that "the objectives, test methodologies, results, and conclusions should be clearly defined for each test performed." *Id.* We are not willing to say that an agency's recommendation that manufacturers conduct tests using the methodologies and criteria of the manufacturer's choosing are enough to establish "relevant standards, conditions, or specifications" regarding the product's safety. See also *In re*

Bard IVC Filters Prod. Liab. Litig., 969 F.3d 1067 (9th Cir. 2020) (holding that the three special controls at issue here did not constitute "specific FDA requirements applicable to a particular device" for preemption purposes).

We conclude that the district court did not err in holding that the evidence that Bard proffered regarding its 510(k) clearance was insufficient to show that it materially complied with relevant federal safety standards. Therefore, the district court did not err by refusing to instruct the jury that there was a rebuttable presumption that the Meridian filter was not defective for failure to warn.

III

Our decision in this appeal should not be misinterpreted as our endorsement of some of Johnson's counsel's trial tactics. But ours is an adversary system, and parties in civil litigation are held to the decisions they make. From that perspective, we find no reversible error, and we AFFIRM the district court's denial of defendants' motion for a new trial.