APPENDIX A

PUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 15-1950

HOWARD E. NEASE; NANCY NEASE,

Plaintiffs – Appellees,

v.

FORD MOTOR COMPANY, a
Delaware Corporation,

Defendant – Appellant.

Appeal from the United States
District Court for the Southern District
of West Virginia, at Huntington.

Robert C. Chambers, Chief District Judge.
(3:13-cv-29840)

Argued: September 21, 2016
Decided: February 1, 2017

Before MOTZ, TRAXLER, and AGEE,
Circuit Judges.

Reversed and remanded with instructions by published opinion. Judge Traxler wrote the opinion, in which Judge Motz and Judge Agee joined.

ARGUED: Jonathan D. Hacker, O'MELVENY & MYERS LLP, Washington, D.C., for Appellant. Larry Lee Javins, II, BAILEY, JAVINS & CARTER, L.C., Charleston, West Virginia, for Appellees.

ON BRIEF: Andrew B. Cooke, FLAHERTY, SENSABAUGH & BONASSO, PLLC, Charleston, West Virginia; Bradley N. Garcia, O'MELVENY & MYERS LLP, Washington, D.C., for Appellant. Tony L. O'Dell, TIANO O'DELL, PLLC, Charleston, West Virginia, for Appellees.

TRAXLER, Circuit Judge:

Howard and Nancy Nease commenced this product liability action against Ford Motor Company, alleging that Howard suffered serious injuries in an accident caused by a design defect in the speed control system of his 2001 Ford Ranger pickup truck. Over Ford's objection, the Neases offered the expert testimony of Samuel Sero that the speed control cable in the 2001 Ranger is susceptible to getting stuck or "bound" while the throttle to which it is linked is in the open position, thus preventing the driver from slowing down the vehicle. The Neases claim that this is precisely what

happened while Howard was driving his 2001 Ranger. A West Virginia jury awarded the Neases $3,012, 828.35 in damages. Ford made several post-trial motions, including a motion for judgment as a matter of law under Rule 50(b) of the Federal Rules of Civil Procedure. In its motion, Ford renewed its pre-trial argument that Sero's testimony was inadmissible under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and should have been excluded. In the alternative, Ford sought a new trial on the basis that the district court erroneously instructed the jury on strict liability under West Virginia law and erroneously admitted evidence of prior incidents involving Ford vehicles.

The district court denied Ford's post-trial motions. Ford now appeals. For the reasons that follow, we conclude that Sero's testimony should not have been admitted. And, without any other expert testimony to establish that the 2001 Ford Ranger was defectively designed and that there were safer alternative designs available that a reasonably prudent manufacturer would have adopted, the Neases cannot prove their case under West Virginia law. Accordingly, we must reverse and remand for entry of judgment in Ford's favor.

I.

On November 20, 2012, Howard was driving his recently purchased, used 2001 Ford Ranger pickup truck on U.S. Route 60 in St. Albans, West Virginia. According to Howard, he was traveling 45-50 mph when he discovered his vehicle would not slow down when he released the accelerator pedal. He tried to slow the pickup truck by applying the brakes, but to no

avail. In order to avoid running into pedestrians or other cars, Howard turned the Ranger off the road, drove over a curb, and crashed into a brick car wash building. For about 25-30 seconds after the pickup truck hit the brick wall, the tires reportedly continued spinning until the engine shut down. Howard's Ranger had approximately 116,000 miles on it at the time of the accident, and there is no indication in the record that the vehicle had ever manifested problems with the accelerator, cruise control or throttle. The Neases thereafter filed this action against Ford Motor Company, alleging that Ford defectively designed the accelerator pedal-to-throttle assembly of the 2001 Ranger pickup truck. The complaint asserted causes of action for strict liability, negligence, and breach of warranty.

A.

The general design and function of the throttle control system in the 2001 Ford Ranger is typical of any modern passenger vehicle. The driver controls engine speed by depressing the accelerator pedal, which is linked to the throttle, which, in turn, regulates the amount of air flowing into the engine. When the accelerator pedal is depressed, the throttle opens and engine speed increases; when the accelerator pedal is released, the throttle closes, airflow is restricted and engine speed decreases.

In the 2001 Ford Ranger, the accelerator pedal is linked to the throttle body by a steel accelerator cable. The accelerator cable is attached to a lever on the throttle body; the lever operates the throttle valve and the throttle valve controls the engine's air intake. As "the accelerator pedal is depressed, the accelerator

cable [which is attached to the throttle lever] is pulled to open the throttle [valve] and increase the engine speed." J.A. 83. In essence, the accelerator pedal, the accelerator cable and the throttle lever form a pulley system that opens the throttle. As a safety feature, the throttle lever is equipped with return springs that exert 7.2 pounds of continuous force to pull the throttle closed when the driver takes his foot off of the accelerator.

In addition to the accelerator pedal-to-throttle assembly, another means by which the driver of a 2001 Ranger can open the throttle is the cruise control system. This system is operated by a "speed control actuator and [a] speed control cable." J.A. 85. The cruise control system incorporates an electric motor that operates a steel cable – the speed control cable – to open and close the throttle. The speed control cable and the accelerator cable are attached to the same throttle lever/pulley system that operates the throttle valve. When the speed control actuator receives input from the cruise control switch on the steering column, the motor manipulates the speed control cable to pull the throttle lever independently of the main accelerator cable.

The throttle control design takes into account that both cables are attached to the same throttle lever/pulley-system. In order to prevent significant stress to the speed control cable that could potentially occur when the cruise control is not engaged and the throttle lever is being controlled by the accelerator pedal and cable, Ford incorporated a "'lost motion' configuration" for the speed control cable assembly. J.A. 85. In this design, the steel speed control cable runs from the motor in the speed control actuator through a plastic "guide tube," and is attached to the

throttle lever by a plastic "connector." *Id.* The connector and the guide tube move with the throttle lever when it is being operated by the accelerator cable. The speed control cable itself stays stationary while the guide tube moves up and down the cable and in and out of a stationary plastic casing tube, called a "casing cap," which is attached to the motor. *Id.* The gap between the moving guide tube and the stationary casing cap is approximately 0.04 inches.

B.

Following the accident, plaintiffs hired Samuel Sero, an electrical engineer, to examine the engine and the throttle assembly in Howard's 2001 Ford Ranger. Sero approached his examination with the view that in failure-to-decelerate cases, the issue is often one of "mechanical binding" and that a post-accident investigation should "look at the accelerator cable, [to] see if there's anything on it that bound up and prevented it from closing the throttle when the accelerator pedal was released, looking for . . . any kind of grime, grit, or anything that could bind that one." J.A. 613.[1] Sero indicated that a post-accident investigation should therefore look for the presence of contaminants and particles that could lodge between the speed control guide tube and the casing cap and create a "wedging effect." J.A. 628. Sero used a borescope to inspect the speed control assembly.

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[1] Contaminants that typically build up on automobile engine parts over time include carbon, substances accumulating from "vapors off of gasoline, brake fluid, hydraulic fluids, battery acids, steel, copper, aluminum, [and] magnesium," J.A. 644, as well as the dirt and grime that washes up into the engine from the surface of the road.

A borescope is essentially a fiber-optic tube equipped with a light that a mechanic or an engineer can insert into an inaccessible area of the engine and view a given component without having to disassemble the engine. When he examined the speed control cable in the Neases' pickup, Sero did not find any materials wedged between the guide tube and the cap. In fact, he noted that the speed control cable moved freely. Nevertheless, Sero concluded that contaminants had entered and built up in the casing cap over time, causing the guide tube to stick and, therefore, the throttle plate to remain open. Sero testified that he was able to identify "a lot of contaminant . . . deposited" in the casing cap, J.A. 636, and "along the guide tube," J.A. 631. Sero also noticed "gouges or striations" on the guide tube. J.A. 645. From this observation, Sero believed that there had been "a rough, abrasive material between the . . . interior of the [casing] cap tube and the surface of the guide tube," indicative of binding. J.A. 645. Sero surmised that sufficient debris had accumulated to create the "wedging effect" needed to keep the throttle open after the accelerator pedal was released. However, Sero had no way of knowing precisely how much contaminant was present in the casing cap or whether it was enough to lodge in the 0.04 inch-gap between the cap and the guide tube such that the throttle would be stuck in the open position. The borescope is simply a viewing tool; it does not afford a means for determining the amount of the contaminant that can be seen with the device.

To bolster his opinion, Sero pointed to a document Ford had prepared in 1987 identifying potential risks Ford engineers should consider addressing in the design of particular vehicles in the future. This document is called a Failure Mode and Effects Analysis ("FMEA"). According to Ford's "Potential Failure Mode and Effects Analysis" Handbook, "[a]n FMEA can be described as a systemized group of activities intended to: (a) recognize and evaluate the potential failure of a product/process and its effects, (b) identify actions which could eliminate or reduce the chance of the potential failure occurring, and (c) document the process." J.A. 968. The primary purposes of an FMEA include "identify[ing] potential failure modes and rat[ing] the severity of their effects" and "help[ing] engineers focus on eliminating product and process concerns and help[ing] prevent problems from occurring." *Id.* An FMEA "is meant to be a 'before-the-event' action, not an 'after-the-fact' exercise." *Id.*

Sero testified that the 1987 FMEA "directly addresse[d] the fact [that] dirt, grease or ice has formed between cable and cable sheath" and therefore demonstrated that "Ford [was] well aware of the problem of binding in the lost motion device/cruise cable." J.A. 52. Sero asserted therefore that the 1987 FMEA proved the speed control assembly in the 2001 Ford Ranger was susceptible to binding. Sero was apparently unaware, however, that the 1987 FMEA did not even apply to the 2001 Ford Ranger. The 1987 FMEA "dealt with a vacuum-actuated speed control system" that was not present in the 2001 Ranger. J.A. 1260.

Based on his borescope exam and the 1987 FMEA, Sero opined that the 2001 Ford Ranger's design was not reasonably safe and that there were several alternative designs that Ford could have utilized in the design of the speed control assembly:

It is my opinion, . . . within a reasonable degree of engineering certainty that . . .

1. Mr. Nease's 2001 Ranger experienced a failure to decelerate by reason of the binding of the lost motion portion of the cruise . . . cable while the throttle was substantially open;

2. The cable design employed by Ford in the subject 2001 Ranger permits dirt, grease and grime to enter the conduit through which the cable passes and is known to cause sticking or binding of the cable;

3. The subject cable is defectively designed;

4. The binding of the cable . . . was caused by particles of dirt and/or debris typically found under the hood of motor vehicles;

5. The open-throttle condition . . . almost immediately deplete[d] the vacuum assist to the brakes;

6. The open-throttle condition, accompanied by loss of vacuum assist, required the application of brake pedal forces beyond the physical capabilities of Mr. Nease;

7. The binding of the defectively-designed cable was the proximate cause of the crash of the Nease vehicle;

8. Safer, feasible alternative designs were available and known to Ford Motor Company at the time the 2001 Ranger was manufactured.

J.A. 53-54.

Prior to trial, Ford moved to exclude Sero's opinions under *Daubert* on the grounds that Sero's opinions were not based on any reliable methodology

and that Sero had not established through testing or other means, such as scientific literature, that the binding of the speed control assembly could actually occur. *See Daubert,* 509 U.S. at 597 (explaining that the district court must "ensur[e] that an expert's testimony . . . rests on a *reliable* foundation" (emphasis added)). Ford also argued that Sero, as an electrical engineer, was unqualified to render an expert opinion on matters of automotive design. The district court denied Ford's motion to exclude Sero's testimony, concluding that Sero was sufficiently qualified by means of his experience "design[ing] and operat[ing] . . . mechanical systems in a variety of settings." J.A. 525. The court also determined that in arriving at his opinion, Sero employed "standard engineering methodology to conduct his physical inspection and reach his opinions." *Id.* This methodology included "physically inspecting the vehicle's parts, understanding how they are designed to operate, observing evidence of whether some material interfered with the operation of the cable, and opining how that could and did occur here." *Id.* at 526.

The case proceeded to trial and Sero offered his opinions. Ford attacked Sero's opinions on cross examination and offered its own expert testimony. Sero acknowledged that when he performed his inspection of the speed control cable in the Neases' Ranger, he did not find any materials *actually* wedged between the guide tube and cap, and he noted that the speed control cable moved freely. Sero further admitted that he had never actually found a bound speed cable assembly *in any vehicle* that he had inspected.

In contrast to Sero's professed inability to determine how much debris was present in the casing

cap (because the borescope does not provide a way to determine the scale of the contaminants), Ford's experts performed tests on the Neases' vehicle and were able to quantify the size of the contaminants found on the Ranger's guide tube. Dr. Steven MacLean, an expert in the field of mechanical engineering, used a scanning electron microscope to determine that "the thickest region . . . [found] on Mr. Nease's guide tube . . . was approximately 50 microns in thickness," J.A. 2438. For perspective, Dr. MacLean explained that a piece of paper is about 60 microns thick, making it 10 microns thicker than the contaminants found on the guide tube in the speed control assembly. Either one is far smaller than the .04 inch gap between the casing cap and guide tube. And, with respect to the gouge marks Sero noticed during the borescope exam that he believed were indicative of binding, Dr. MacLean testified that his analysis indicated that these marks "are from the manufacturing process, the molding process of these parts," not "a binding event." J.A. 2419.

Sero agreed that he had never conducted any testing to determine whether enough debris could accumulate in the casing cap during normal operation to resist the 7.2 pounds of force exerted by the return spring and to cause the throttle to stick open. Sero simply relied upon his observations during the borescope exam, which was videotaped. At trial, however, Sero was unable to distinguish between the video of the Nease borescope and a borescope exam for a previous case in which Sero had testified that the speed control cable did *not* bind. He could not tell the borescope of the cable that he said did bind from the borescope of the cable that he said did *not* bind. In other words, he could not tell one from the other.

With regard to the FMEA process that was so central to Sero's opinion, Ford presented evidence that potential failure modes identified in the FMEA had not occurred during actual vehicle operation. For example, Dr. MacLean explained that a FMEA is a common "engineering tool," J.A. 2475, used before marketing a new product to the public to "proactively try to determine what are all of the possible failure modes for that particular new design." *Id.* According to MacLean, an FMEA is not a record of existing problems but rather "a forward-looking tool for . . . a new product." J.A. 2481. When an FMEA is performed, the manufacturer "bring[s] in design engineers, analysis engineers, manufacturing engineers, people from all different disciplines, and . . . [the group tries] to come up with a very comprehensive and exhaustive list of failure modes. . . . [and seek to determine] how likely it is to occur, and what does my system do to possibly detect it and prevent it from happening." J.A. 2475. Similarly, Karl Stopschinski, a registered professional engineer and member of the Society of Automotive Engineers, testified that the FMEA process is akin to a "brainstorming session" to "identify any *potential* failure modes." J.A. 2157 (emphasis added). Additionally, Ford's engineering experts indicated that the 1987 FMEA on which Sero relied did not even apply to the Neases' 2001 Ranger pickup truck. Rather, James Engle, a design analysis engineer, indicated that it is the 2004 FMEA that applies to the 2001 Ranger because it was "originated in February of '97 and carried forward." J.A. 1265.

Finally, Sero testified that several alternative speed control cable designs were available at the time and that Ford could have made the 2001 Ranger safer by incorporating one of these designs. He admitted,

however, that he had not tested any of these alternative designs to determine whether any of them would have prevented the accident in question. In Sero's opinion, testing of the alternative designs he identified was unnecessary because the designs had been in use in other vehicles for years and were therefore "proven commodit[ies]." J.A. 717.

The district court instructed the jury that on plaintiffs' strict liability claim, plaintiffs had to prove that the design of the 2001 Ford Ranger was not "reasonably safe for its intended use." J.A. 1922. Although the court explained that the "plaintiffs are only entitled to a reasonably safe product, not to an absolutely safe product," the court then instructed, over Ford's objection, that "[i]f a product can be made safer and the danger may be reduced by an alternative design at not substantial increase in price, then the manufacturer has a duty to adopt such a design." *Id.* During closing argument, plaintiffs' counsel highlighted the safer alternative design instruction:

> . . . If a product can be made safer and the danger reduced by an alternative design or device at no substantial increase in cost, then the manufacturer has a duty to adopt such design. All that means is if you find that one of the other designs was safer and it wasn't going to cost very much . . . [t]hen you can find that Ford breached its duty.

J.A. 1960.

The jury returned a verdict for the Neases on the strict liability count and awarded damages of $3,012,828.35. The jury returned defense verdicts on the negligence and breach of warranty counts.

After trial Ford filed a Renewed Motion for Judgment as a Matter of Law pursuant to Rule 50(b). First, Ford argued that "there was insufficient evidence to support the jury's verdict for strict liability because the claim was dependent upon the testimony of Plaintiffs' expert . . . Sero." J.A. 3477. And, Ford argued, as it had prior to trial, that Sero's testimony should not have been admitted because Sero was unqualified to testify as an expert and that Sero's opinions should have been excluded under *Daubert*. Specifically, Ford argued that "Sero never demonstrated unidirectional binding of Mr. Nease's speed control cable, he did not attempt to simulate his theory, he did not conduct any tests that a foreign substance could withstand the seven-pound spring pressure, [and] he did not demonstrate alternative designs were equally or more safe." J.A. 3478. The district court denied the Rule 50 motion, concluding that Sero's methodology was reliable because he used the FMEA methodology used by Ford and that the borescope examination was "consistent and trustworthy and what historically [was] used in failure to decelerate cases." J.A. 3479.

Alternatively, Ford moved for a new trial pursuant to Rule 59(a)(1)(A), arguing that the verdict should be set aside because the district court issued an improper "duty to adopt" jury instruction as to safer alternative designs. Ford also contended that the district court erroneously admitted evidence of other incidents involving Ford vehicles with an allegedly defective speed control assembly unit. The district court denied the motion for a new trial on both grounds. The court did not expressly reject Ford's position that the "duty to adopt" instruction was incorrect under West Virginia law. Instead, the district court concluded that

even if the jury instruction was erroneous, it was harmless because the jury found that the product was defective and not reasonably safe, and thus the jury did not need to reach the question of the duty to adopt a safer alternative design. Additionally, the district court noted that the jury instructions were otherwise correct and informed the jury that the Neases were not entitled to an absolutely safe product. Finally, the district court ruled that even if the admission of evidence regarding other incidents was erroneous, it was harmless in view of court's limiting instruction to the jury that it "only consider the alleged other incidents for the limited purpose of determining whether Ford had notice of the defect" and not "as evidence that the 2001 Ford Ranger was defective." J.A. 3486.

Ford appeals, arguing that the district court incorrectly admitted Sero's expert testimony in contravention of the requirement that such testimony be reliable under *Daubert* and its progeny; that the district court's erroneous "duty to adopt" jury instruction was not harmless in view of the fact that it was the only instruction that counsel for Nease highlighted in his closing argument to the jury; and that the erroneous admission of other incident evidence was not rendered harmless by the district court's limiting instruction because the limiting instruction did not apply to the other incidents at issue. To resolve this appeal, we need only address Ford's *Daubert* argument.

II.

Ford contends that the district court erroneously denied its motion to exclude Sero's opinion that Ford's

design of the speed control assembly in the 2001 Ford Ranger was defective and that Ford could have used a different design that would have prevented Nease's accident. We review the district court's application of *Daubert* for abuse of discretion. *See Anderson v. Westinghouse Savannah River Co.*, 406 F.3d 248, 260 (4th Cir. 2005). "If the district court makes an error of law in deciding an evidentiary question, that error is by definition an abuse of discretion." Id. (internal quotation marks omitted). A district court likewise abuses its discretion in deciding a *Daubert* challenge if its conclusion "rests upon a clearly erroneous factual finding." *Bryte ex rel. Bryte v. American Household, Inc.*, 429 F.3d 469, 475 (4th Cir. 2005).

A. *Daubert*'s Applicability

We first must visit the question of whether *Daubert* even applies under these circumstances. The Neases insist that it does not. We disagree; *Daubert* clearly applies here.

In *Daubert*, the Supreme Court addressed an evidentiary issue that had long divided federal courts – whether the admissibility of expert scientific testimony was governed by the "general acceptance" test established in *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923)[2] or the later-adopted standards set forth in Federal Rule of Evidence 702, *see* 509 U.S. at 586–87 & n.5. *Daubert* held that the Federal Rules of Evidence superseded *Frye* and that the admissibility

[2] Under *Frye*, expert scientific testimony was admitted only if the expert opinion was based on principles that were "generally accept[ed]" in "the particular field in which it belongs." 293 F. at 1014.

of scientific evidence no longer was limited to knowledge or evidence "generally accepted" as reliable in the relevant scientific community. *See* 509 U.S. at 588–89.

Thus, *Daubert* made clear that the governing standard for evaluating proposed expert testimony was set forth in Rule 702, which at the time provided: "If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise." *Daubert*, 509 U.S. at 588. Implicit in the text of Rule 702, the *Daubert* Court concluded, is a district court's gatekeeping responsibility to "ensur[e] that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." *Id.* at 597 (emphasis added).

Relevant evidence, of course, is evidence that helps "the trier of fact to understand the evidence or to determine a fact in issue." *Id.* at 591 (internal question marks omitted). To be relevant under *Daubert*, the proposed expert testimony must have "a valid scientific connection to the pertinent inquiry as a precondition to admissibility." *Id.* at 592.

With respect to reliability, the district court must ensure that the proffered expert opinion is "based on scientific, technical, or other specialized *knowledge* and not on belief or speculation, and inferences must be derived using scientific or other valid methods." *Oglesby v. Gen. Motors Corp.*, 190 F.3d 244, 250 (4th Cir. 1999). *Daubert* offered a number of guideposts to help a district court determine if expert testimony is sufficiently reliable to be admissible. First, "a key question to be answered in determining whether a

theory or technique is scientific knowledge that will assist the trier of fact will be whether it can be (and has been) tested." 509 U.S. at 593. A second question to be considered by a district court is "whether the theory or technique has been subjected to peer review and publication." *Id.* Publication regarding the theory bears upon peer review; "[t]he fact of publication (or lack thereof) in a peer reviewed journal will be a relevant, though not dispositive, consideration in assessing the scientific validity of a particular technique or methodology on which an opinion is premised." *Id.* at 594. Third, "in the case of a particular scientific technique, the court ordinarily should consider the known or potential rate of error." *Id.* Fourth, despite the displacement of *Frye*, "'general acceptance'" is nonetheless relevant to the reliability inquiry. *Id.* "Widespread acceptance can be an important factor in ruling particular evidence admissible, and a known technique which has been able to attract only minimal support with the community may properly be viewed with skepticism." *Id.* (citation and internal quotation marks omitted). *Daubert's* list of relevant considerations is not exhaustive; indeed, the Court has cautioned that this "list of specific factors neither necessarily nor exclusively applies to all experts or in every case," *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999), and that a trial court has "broad latitude" to determine whether these factors are "reasonable measures of reliability in a particular case," *id.* At 153.

The Neases contend that we can affirm because the district court was not obliged to perform its *Daubert* gatekeeping function in the first place: "Because the *Daubert* test for assessing the validity of scientific evidence applies only to novel scientific

testimony, it does not apply in the expert field of engineering." Brief of Appellees at 29. This bifurcated argument is dead wrong on both counts.

First, *Daubert* itself makes clear that its application is not limited to newfangled scientific theory, explaining that "we do not read the requirements of Rule 702 to apply specially or exclusively to unconventional evidence." *Daubert*, 509 U.S. at 592 n.11. The Court recognized the common-sense premise that "well-established propositions are less likely to be challenged than those that are novel," *id*., but clearly never suggested that longstanding theories are immune to a *Daubert* analysis.

Second, the Supreme Court made clear more than 17 years ago in *Kumho Tire* that *Daubert* was not limited to the testimony of scientists but also applied "to testimony based on 'technical' and 'other specialized' knowledge." 526 U.S. at 141. Despite having cited *Kumho Tire* in their brief, the Neases are apparently unaware that the very issue there involved the application of *Daubert to the testimony of a mechanical engineer*. *See id.* at 141 ("This case requires us to decide how *Daubert* applies to the testimony *of engineers* and other experts who are not scientists." (emphasis added)). The *Kumho* Court concluded that Rule 702 "applies to all expert testimony" as its "language makes no relevant distinction between 'scientific' knowledge and 'technical' or 'other specialized' knowledge. It makes clear that any such knowledge might become the subject of expert testimony." *Id.* at 147. The *Kumho* Court affirmed the district court's application of *Daubert* and decision to exclude the engineering

expert's testimony as unreliable. *See id.* at 158.[3] And, finally, if *Kumho* were not enough, this court has also sanctioned the application of *Daubert* to assess the reliability of expert engineering testimony. *See Oglesby*, 190 F.3d at 250-51 (affirming district court's application of *Daubert* principles to testimony of a mechanical engineer and concluding that the district court did not abuse its discretion in excluding the engineer's opinion as unreliable).

Accordingly, we conclude that *Daubert* most certainly applies to Sero's testimony. We now turn to consider whether, under *Daubert*, the district court properly admitted Sero's testimony.

B. The District Court's Application of *Daubert* to Sero's Opinions

As we already explained, Rule 702 imposes a special gatekeeping obligation on the trial judge to ensure that an opinion offered by an expert is reliable. And although a trial judge has broad discretion "to determine reliability in light of the particular facts and circumstances of the particular case," *Kumho*, 526 U.S. at 158, such discretion does not include the decision "to abandon the gatekeeping function," *id.* at 158–59 (Scalia, J., concurring).

In ruling on Ford's motion in limine to exclude Sero's testimony as unreliable under *Daubert*, the district court simply dismissed "[e]very argument raised by [Ford]" as "go[ing] to the weight, not

[3] In so holding, the Supreme Court rejected the Eleventh Circuit's view that engineering testimony "[fell] outside the scope of *Daubert*, [and] that the district court erred as a matter of law by applying *Daubert* in this case," *Kumho Tire*, 526 U.S. at 146, which is precisely the same argument the Neases make here.

admissibility, of [Sero's] testimony." J.A. 526. The court did not use *Daubert*'s guideposts or any other factors to assess the reliability of Sero's testimony, and the court did not make any reliability findings. Indeed, the district court referred neither to Rule 702 nor to *Daubert*. We are forced to conclude that the court abandoned its gatekeeping function with respect to Ford's motion in limine.

In denying Ford's post-trial Rule 50(b) motion for judgment as a matter of law (which renewed Ford's argument that Sero's opinion should have been excluded under *Daubert*), the district court again "[found] that Ford's arguments go to the weight the jury should afford Mr. Sero's testimony, not its admissibility." J.A. 3481. Although the district court this time cited *Daubert* and stated that, according to Sero, "the methodology he employed is consistent and trustworthy and what historically is used in failure to decelerate cases," J.A. 3479, the court repeatedly emphasized that Ford effectively raised its objections to Sero's opinion through cross-examination. For the district court to conclude that Ford's reliability arguments simply "go to the weight the jury should afford Mr. Sero's testimony" is to delegate the court's gatekeeping responsibility to the jury. "The main purpose of *Daubert* exclusion is to protect juries from being swayed by dubious scientific testimony." *In re Zurn Pex Plumbing Prods. Liab. Litig.*, 644 F.3d 604, 613 (8th Cir. 2011). The district court's "gatekeeping function" under *Daubert* ensures that expert evidence is sufficiently relevant and reliable *when it is submitted to the jury*. Rather than ensure the reliability of the evidence on the front end, the district court effectively let the jury make this determination after listening to Ford's cross examination of Sero.

In sum, the district court did not perform its gatekeeping duties with respect to Sero's testimony. The fact that an expert witness was "subject to a thorough and extensive examination" does not ensure the reliability of the expert's testimony; such testimony must still be assessed before it is presented to the jury. *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1238 (11th Cir. 2005). Thus, we are of the opinion that the district court abused its discretion here "by failing to act as a gatekeeper." *Id.*; *see Kumho*, 526 U.S. at 158–59 (Scalia, J. concurring) ("[T]rial-court discretion in choosing the manner of testing expert reliability . . . is not discretion to abandon the gatekeeping function . . . [or] to perform the function inadequately.").

C. Sero's testimony should have been excluded under *Daubert*

1. Sero's testimony that the speed control assembly was not reasonably safe because it was susceptible to binding

"[A] plaintiff may not prevail in a products liability case by relying on the opinion of an expert unsupported by any evidence such as test data or relevant literature in the field." *Oglesby*, 190 F.3d at 249 (internal quotation marks omitted). "A reliable expert opinion must [not] be based . . . on belief or speculation." *Id.* at 250. One especially important factor for guiding a court in its reliability determination is whether a given theory has been tested. According to *Daubert,* "a key question to be answered in determining whether a theory or technique is scientific knowledge that will assist the

trier of fact will be whether it can be (and has been) tested." 509 U.S. at 593.

Sero's opinion had three critical components: that the speed control assembly in the 2001 Ford Ranger was vulnerable to binding because the design allowed for contaminant to lodge between the speed control guide tube and the casing cap; that such binding in fact occurred while Howard was driving his 2001 Ranger, resulting in the accident; and that there were safer alternative speed control assembly designs available to Ford for use in the 2001 Ranger.

Testing was of critical importance in this case as Sero conceded that the speed control cable in the Neases' Ranger was not bound or wedged; the cable "moved freely" when Sero performed a post-accident inspection of the Neases' Ranger. J.A. 676. In fact, Sero admitted he has *never seen any vehicle* with "post-crash binding." J.A. 679. Sero, however, conducted no testing whatsoever to arrive at his opinion. Specifically, he has never tested a 2001 Ford Ranger to determine whether it is actually possible for enough debris to accumulate in the casing cap during normal operation to resist the 7.2 pounds of force exerted by the return springs to pull the throttle closed. Sero conceded that he never ran any tests to confirm his theory:

> Q. Now, as I understand it, . . . you have not demonstrated your unidirectional binding theory on Mr. Nease's speed control cable, have you?
>
> A. No, I have not.

> Q. You have not even attempted to simulate your speed control binding theory on Mr. Nease's speed control cable, have you?
>
> A. No.
>
> Q. You have not demonstrated your unidirectional binding theory [using] another 2001 Ford Ranger, have you?
>
> A. No.
>
> Q. You have not even attempted to simulate your speed control malfunction theory with an exemplar 2001 Ford Ranger, have you?
>
> A. No, I have not.

J.A. 678.

Sero's failure to test his hypothesis renders his opinions on the cause of Howard's accident unreliable. Although Sero's theory is plausible and "may even be right[,] . . . it is no more than a hypothesis, and it thus is not knowledge, nor is it based upon sufficient facts or data or the product of reliable principles and methods applied reliably to the facts of the case." *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 670 (6th Cir. 2010) (internal quotation marks and alterations omitted). Generally, scientific methodology involves "generating hypotheses and testing them to see if they can be falsified." *Daubert,* 509 U.S. at 593. Sero presented a hypothesis only – he failed to validate it with testing.

Daubert is a flexible test and no single factor, even testing, is dispositive. But *Daubert*'s other reliability markers likewise suggest that Sero's testimony should not have been admitted under Rule 702. Sero has not published or otherwise subjected his theory to peer review. Actually, it would hardly be possible to solicit peer review since Sero conducted no tests and used no "methodology" for reaching his opinions other than merely observing dirt on the speed control assembly components. And, for this same reason, we cannot assess the potential rate of error of Sero's methodology – he did not employ a particular methodology to reach his conclusions.

Daubert also suggests that district courts, in performing their gatekeeping functions, consider whether and to what extent an expert's theory has been accepted within the relevant scientific or engineering community. *See Daubert*, 509 U.S. at 593-94. Despite their contention that *Daubert* does not apply, the Neases nonetheless suggest that the internal FMEA performed by Ford in 1987, which Sero relied upon to support his opinion, is widely accepted by engineers – Ford's own engineers in this case – as a method for identifying design defects. The FMEA relied upon by Sero, however, does not establish that Sero's theory is widely accepted in the relevant engineering community.

To begin with, the 1987 FMEA does not even apply to the 2001 Ranger; rather, the 2004 FMEA, which originated in 1997, applied to the 2001 Ranger at issue here. In other words, Sero rests his theory on an FMEA produced for different designs. The 1987 FMEA, therefore, lacks a "valid scientific connection to the pertinent inquiry," *Daubert*, 509 U.S. at 592, and is not "relevant to the task at hand," *id.* at 597.

Moreover, to the extent Nease claims the FMEA performed by Ford in 1987 proves that the speed cable is susceptible to binding, he misconstrues the nature of the FMEA process. FMEA is part of the *design process itself*; design engineers follow this method well before the design is complete to "identify potential failure modes and rate the severity of their effects" and "help engineers focus on eliminating product and process concerns and help prevent problems from occurring." J.A. 968. As Ford engineer James Engle explained, "[t]he purpose [of] the FMEA is to analyze the [current] design . . . [and] give[] the engineer information beforehand . . . to let the engineer know areas where he needs to focus." J.A. 1279. It is a "brainstorming session" performed on the front end of the design process to "identify any potential failure modes." J.A. 2157. And, in this case, because it is "conceivable" that "grime or some sort of debris [could] enter[] into the cable and caus[e] sticking," Ford naturally listed the potential binding of the speed control cable "in a brainstorming session of [potential] failure modes." J.A. 2157. But Ford included numerous "mitigating" features in its final design, such as an engine cover, aimed at eliminating potential problems identified in the FMEA. J.A. 2157. Ford also placed the throttle "high up on the engine" to mitigate the intake of "[b]igger and heavier particles [which] take more force to be . . . moved up . . . to the top of the engine." J.A. 2157-58. Additionally, the components of the speed control assembly were made of nylon that had a slippery quality and "a very low coefficient of friction." J.A. 2433.

In sum, the FMEA relied upon by Sero cannot be viewed as having established that the binding of the speed control cable was a recurring design problem in

the 2001 Ranger. And it cannot be used as a proxy for the testing that Sero failed to do. Ford's FMEA process merely identifies conceivable design failures; it does not produce them via testing.

2. Sero's testimony that there were safer alternative designs that Ford could have used in the 2001 Ranger

To establish strict liability under West Virginia law, the plaintiff must show that the "product is defective in the sense that it is not reasonably safe for its intended use." *Morningstar v. Black & Decker Mfg. Co.*, 253 S.E.2d 666, 683 (W. Va. 1979). "The standard of reasonable safeness is determined . . . by what a reasonably prudent manufacturer's standards should have been at the time the product was made." *Id.* Significantly, the West Virginia Supreme Court explained that the determination of what a "reasonably prudent manufacturer's standards *should have been* at the time" requires a consideration of "the general state of the art of the manufacturing process, including design." *Id.* (emphasis added).

Ford argues that West Virginia law, as articulated by the *Morningstar* court, therefore requires a products liability plaintiff to prove that a reasonably prudent manufacturer would have adopted a safer design during the relevant time period. The Neases disagree, relying on a couple of district court opinions that suggest the West Virginia Supreme Court "has not stated one way or the other whether a design defect claim requires proof of a safer alternative design of the allegedly defective product." *Mullins v. Ethicon, Inc.*, 117 F. Supp. 3d 810, 821 (S.D.W. Va. 2015)

(internal quotation marks omitted); *Keffer v. Wyeth*, 791 F. Supp. 2d 539, 547 (S.D.W. Va. 2011).

While it is true that West Virginia law on the matter is not crystal clear, we agree with Ford that *Morningstar* "can only be read to require the production of evidence on reasonable alternative design, to gauge what 'should have been.'" Restatement (Third) of Torts: Products Liability § 2, Reporter's Note (1998). Although *Morningstar* does not use the phrase "alternative design," a plaintiff in a design case, for all practical purposes, must identify an alternative design in order to establish the "state of the art." *See Church v. V.R. Wesson*, 385 S.E.2d 393, 396 (W. Va. 1989) (holding plaintiff in a defective design case failed to establish a prima facie case because plaintiff's expert identified an alternative design that was not feasible at the time of manufacture and thus failed to prove that defendant's design was not "state of the art").

Sero testified that safer, proven design alternatives existed during the relevant time period that would have prevented Howard's accident. One preferable alternative, according to Sero, incorporates a "nipple wipe" to clean contaminants off the cable as it moves. Another alternative identified by Sero utilizes a "boot" which blocks debris and grime from accumulating on the cable. And, a third alternative design that Sero believed would have prevented Howard's accident simply had a larger gap between the guide tube and the casing cap. Sero pointed out that Ford had been using all of these alternative design features for many years by the time the 2001 Ranger was produced.

Sero, however, performed no tests or studies to determine whether, in fact, these older, long-standing

designs were involved in fewer binding incidents. According to Sero, such tests were unnecessary because designs such as the nipple wipe had been in use for 50 years and therefore were "proven elements." J.A. 669. Similarly, he offered no data from any other studies or accident records to prove that the older designs were less likely to bind than the one incorporated in the Neases' 2001 Ranger. Sero instead simply proclaimed without any support that the alternative designs he identified were safer than the design of the speed control cable assembly in the 2001 Ranger.

This testimony should have been excluded as it was "unsupported by any evidence such as test data or relevant literature in the field." *Oglesby*, 190 F.3d at 249 (internal question marks omitted). The fact that the alternatives have generally been in use for decades is wholly insufficient to prove that such designs were safer with respect to the alleged binding incident and that reasonably prudent manufacturers would have adopted them.[4]

[4] To the extent that the Neases argue that testing or other comparative analysis of Sero's alternative designs was unnecessary because they were not novel designs, their argument relies upon the same flawed understanding of Daubert that we have already rejected.

III.

Without Sero's testimony, the Neases cannot prove that the design of the speed control assembly in the 2001 Ford Ranger renders the vehicle "not reasonably safe for its intended use." *Morningstar,* 253 S.E.2d at 683. Accordingly, we reverse the district court's denial of Ford's post-trial motion for judgment as a matter of law and remand the case to the district court for entry of judgment in Ford's favor. And, because the granting of judgment as a matter of law effectively ends this litigation, we need not reach Ford's challenges to the jury instruction and the admission of prior incidents evidence.

REVERSED AND REMANDED
WITH INSTRUCTIONS