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UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

PAUL DECKER; KAREN DECKER,
Plaintiffs-Appellees,

v.

GE HEALTHCARE INC.; GE HEALTHCARE AS,
Defendants-Appellants.

No. 13-4002

Appeal from the United States District Court
for the Northern District of Ohio at Cleveland.
Nos. 1:08-gd-50000; 1:12-gd-50004—Dan A. Polster, District Judge.

Argued: August 7, 2014

Decided and Filed: October 20, 2014

Before: GIBBONS and McKEAGUE, Circuit Judges; LAWSON, District Judge.*

COUNSEL

ARGUED: Pierre H. Bergeron, SQUIRE SANDERS (US) LLP, Cincinnati, Ohio, for Appellants. Christopher V. Tisi, ASHCRAFT & GEREL, LLP, Alexandria, Virginia, for Appellees. **ON BRIEF:** Pierre H. Bergeron, SQUIRE SANDERS (US) LLP, Cincinnati, Ohio, J. Philip Calabrese, SQUIRE SANDERS (US) LLP, Cleveland, Ohio, Rebecca K. Wood, SIDLEY AUSTIN LLP, Washington, D.C., for Appellants. Christopher V. Tisi, Michelle A. Parfitt, Peter T. Anderson, Stephanie L. Gardner, ASHCRAFT & GEREL, LLP, Alexandria, Virginia, William Hawal, Peter J. Brodhead, Peter H. Weinberger, SPANGENBERG SHIBLEY & LIBER LLP, Cleveland, Ohio, for Appellees.

*The Honorable David M. Lawson, United States District Judge for the Eastern District of Michigan, sitting by designation.

OPINION

JULIA SMITH GIBBONS, Circuit Judge. In 2005, in connection with a magnetic resonance imaging procedure ("MRI"), Paul Decker received a dose of Omniscan, a gadolinium-based contrast agent manufactured by GE Healthcare Inc. and GE Healthcare AS ("GEHC"). After taking Omniscan, Mr. Decker developed Nephrogenic Systemic Fibrosis ("NSF"). In 2012, Karen and Paul Decker sued GEHC in the Northern District of Ohio, lodging a host of Ohio products liability claims and other tort claims. The Deckers' case forms a part of a multidistrict litigation ("MDL"), managed by Judge Polster. Prior to the Deckers' case, hundreds of similar cases in the MDL involving GEHC had been settled. This case did not settle and was the first case in the MDL to go to trial. The jury returned a verdict in favor of the Deckers on their failure-to-warn claim, awarding $5 million in damages. GEHC moved for a new trial, which the district court denied. On appeal, GEHC makes a number of disparate arguments against rulings that the district court made applicable to all MDL cases as well as rulings specific to the instant case. GEHC alleges that a new trial is warranted because the district court judge (1) should have recused himself from the trial and its motion for a new trial, (2) made several erroneous evidentiary rulings, which were applicable to all MDL cases, (3) erroneously denied GEHC's motion for a new trial because insufficient evidence supported the jury's verdict regarding the causation element of the Deckers' failure-to-warn claim, and (4) erroneously failed to issue two proposed jury instructions. We affirm.

I.

Gadolinium-based contrast agents ("GBCA") are one type of contrast agent used to enhance the quality of images generated in MRIs. There are currently five different GBCAs approved by the FDA for use in MRI procedures in the United States. Omniscan, which is manufactured by GEHC, is one such GBCA. GBCAs, however, can be toxic to patients with impaired kidney function. The district court aptly summarized the background of GBCAs, their potentially adverse health effects, and the FDA's efforts to eradicate those adverse effects:

> Gadolinium is a lanthanide element (rare earth metal) which exhibits high paramagnetism, a form of magnetism occurring only in the presence of an externally applied magnetic field. It is this characteristic that led research scientists to explore its use as a contrast agent in magnetic resonance scans.
>
> It is undisputed that gadolinium, in its free state, is highly toxic to humans. In order to develop a safe gadolinium-based contrast agent for use in humans, researchers found it necessary to chelate the gadolinium (*i.e.*, bind it to a ligand) in order to render it inert during its passage through the body prior to elimination. Of particular concern was its use in renally impaired patients, whose ability to quickly excrete toxic substances is inherently compromised. Because renally-impaired persons might retain the GBCA for longer periods of time than non-renally impaired persons, the chelate's stability was considered crucial since retained GBCA might well dechelate, exposing the kidney patient to the toxic effects of gadolinium. Research shows that renally impaired persons do in fact retain GBCAs for a significantly longer period of time than non-renally impaired persons, renally impaired persons retain a significant portion of the gadolinium that is injected into them, and dialysis is not very effective in ridding the body of the unrecovered gadolinium.
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> Nephrogenic systemic fibrosis, or NSF, was first described in the medical literature in 2000, with the first reported cases going back to 1997. NSF causes fibrosis of the skin, connective tissue and organs throughout the body. It is a painful, progressive and debilitating disease. While the precise pathogenesis of NSF is unknown, it has been reported only in patients who have severe kidney disease and, with the exception of a few reported cases with inconclusive medical histories, has been found exclusively in kidney patients who have had one or more exposures to GBCAs.
>
> In June 2006, the FDA issued a Public Health Advisory notifying healthcare professionals and the public about the risk of NSF following the administration of GBCAs; and in May 2007, the FDA asked GBCA license holders to issue a boxed warning about the risk of NSF in patients with renal failure. The issuance of the "blackbox warning," along with policies and procedures adopted by healthcare facilities and notice to healthcare providers, have all but led to the eradication of new NSF cases.

In September 2005, Paul Decker, a patient with end-stage renal disease ("ESRD"), underwent an MRI at Riverside Radiology Associates. In connection with the procedure, Mr. Decker received a single dose of Omniscan. Mr. Decker's kidneys were impaired when he received the dose of Omniscan, and sometime thereafter he developed NSF.

In February 2012, Paul and Karen Decker sued GEHC in the United States District Court for the Northern District of Ohio, alleging claims under the Ohio Products Liability Act, section

2307.71 *et seq.* of the Ohio Revised Code, for manufacturing defect, design defect, failure to warn, nonconformance with representations, negligence, breach of express warranty, breach of implied warranty, misrepresentation, fraud, and loss of consortium. The Deckers' case forms part of an MDL established in 2008—*In re Gadolinium Based Contrast Agents Product Liability Litigation*, (MDL No. 1909) (N.D. Ohio)—which was assigned to Judge Dan Polster, who has managed the MDL since 2008. Hundreds of similar cases in the MDL involving GEHC had been settled, including a block of 25 cases involving the same attorneys as in the instant case. Despite multiple attempts at mediation and the active involvement of Judge Polster, the parties in this case did not reach a settlement.

This case was the first in the MDL to go to trial. Before the Deckers filed this action, however, the district court made certain rulings that were applicable to all MDL cases, some of which are the subject to GEHC's appeal in this case. One set of rulings concerned the admissibility of the testimony of certain "generic" experts—that is, testimony that did not relate specifically to an individual plaintiff. The plaintiffs' steering committee ("PSC") and GEHC designated nineteen generic experts to testify about three issues: (1) the likely causal mechanism of NSF; (2) the existence of gadolinium-naïve cases, meaning purported cases of NSF occurring without GBCA exposure; and (3) the presence of gadolinium toxicity signals and whether additional warnings should have been added to the Omniscan label in light of those putative signals. The parties argued over the admissibility of expert testimony on these issues, and the district court addressed those arguments for all MDL cases in two extensive rulings.

First, it was undisputed that Omniscan triggered NSF in ESRD patients; however, the causal mechanism by which Omniscan triggered NSF was disputed. The PSC sought to introduce expert testimony "that Omniscan most likely causes NSF in renally impaired patients when, due to various processes (for example, transmetalation), the gadolinium becomes dechelated, dissociated, released or freed from the ligand to which it is bound . . . [and that t]his dechelation exposes tissue to labile, toxic gadolinium which rapidly bonds elsewhere in the body and begins the fibrotic process leading to NSF." In short, the PSC proffered expert testimony on the "free gadolinium theory" of the likely causal mechanism of NSF, which is the prevailing theory of NSF causation in the scientific community. By contrast, GEHC sought to introduce the

testimony of Benjamin Newton that chelated GBCAs may trigger the fibrotic process leading to NSF. The implication of Newton's hypothesis was that the chelated gadolinium in Omniscan and other GBCAs causes NSF and, thus, Omniscan was no more likely to cause NSF than any other GBCA. Proof of the causal mechanism was disputed because, while adverse health effects from "free gadolinium" were foreseeable, adverse health effects from chelated gadolinium were not.

The district court denied GEHC's motion to exclude the PSC's experts who advanced the "free gadolinium theory" of the likely causal mechanism of NSF. The district court also reaffirmed this ruling after GEHC's motion for reconsideration, explaining that "it would allow Plaintiffs' experts to testify regarding the free (or dechelated) gadolinium theory, a theory that reasonably attempts to explain what happens to the not-insignificant amount of chelated gadolinium (here, Omniscan) that is injected into severely renally impaired persons, is never excreted, and is later found in one form or another in the biopsies of NSF patients." The district court noted that "most researchers (including research scientists employed or retained by GEHC) believe that the gadolinium becomes unbound from its ligand during its prolonged retention time in renal patients where it, either alone or newly bound to other substances, may trigger the process leading to NSF." The district court also allowed Newton to testify about his alternative hypothesis that NSF is caused by chelated gadolinium. The district court concluded that since there was no definitively proven mechanism for NSF causation, both parties could present their respective theories to the jury.

Second, the district court did not permit GEHC experts, including Newton, Sushrut Waikar, and Anthony Gaspari to testify about reports of gadolinium-naïve cases of NSF—*i.e.*, cases of NSF that allegedly occurred in the absence of GBCA exposure. The district court found that proffered expert testimony about gadolinium-naïve cases was based on methodologically flawed studies that did not sufficiently demonstrate the subjects' lack of gadolinium exposure. For example, the "Collidge study"[1] "did not examine whether the one NSF patient who had not received a GBCA while undergoing an MRI had undergone any non-MRI procedures in which a

[1]Collidge, TA, Thomson, PC, Mark PB, et al., *Gadolinium-Enhanced MR Imaging and Nephrogenic Systemic Fibrosis: Retrospective Study of a Renal Replacement Therapy Cohort*, 245 RADIOLOGY 168-175 (2007).

GBCA was used." And the "Wahba study,"[2] "which concluded that two patients developed NSF without exposure to a GBCA, did not confirm its findings by testing these patients' tissue for the presence of gadolinium." For the same reason, the district court barred expert testimony as to gadolinium-naïve cases of NSF based on the "Deng study."[3]

Third, the district court made several evidentiary rulings on proffered expert testimony concerning pharmacovigilance, the science relating to the collection, detection, and prevention of adverse effects of pharmaceutical products. For example, GEHC moved to exclude the testimony of the PSC's generic experts—including the testimony of Cheryl Blume—who testified regarding the significance of four adverse event reports (AERs) concerning Omniscan. AERs are reports sent to drug companies that inform the company that a patient experienced a harmful event after taking the company's drug. Specifically, GEHC argued that Blume's opinion that four specific AERs constituted a "safety signal" was inadmissible. The district court denied that motion.

The district court also reviewed the PSC's motion to exclude testimony of Gaspari concerning his medical analysis of the four AERs. Gaspari submitted an expert report, "the primary purpose of which was to review the four AERs and determine whether there was any consistency in [these] reports to suggest that exposures to gadolinium based contrast agents (GBCA) resulted in NFD/NSF." The report included preliminary information about the history of NSF and the difficulties associated with diagnosing it, and "[t]his information formed the basis for his conclusion that the AERs did not support a clinical diagnosis of NSF." The district court excluded Gaspari's testimony because his "conclusions are based on incomplete information and therefore do not satisfy the . . . requirement that expert testimony be based on sufficient facts or data." Upon GEHC's motion for reconsideration, the district court reaffirmed this ruling because (1) whether the four AERs supported a clinical diagnosis of NSF was irrelevant to the question of whether the AERs constituted a safety signal; (2) Gaspari was not an

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[2]Wahba IM, Simpson EL, White K., *Gadolinium Is Not The Only Trigger For Nephrogenic Systemic Fibrosis: Insights From Two Cases And Review Of The Recent Literature*, 7 AM. J. OF TRANS., 1-8 (2007).

[3]Deng, A., et al., *Nephrogenic Systemic Fibrosis with a Spectrum of Clinical and Histopathological Presentation: A Disorder of Aberrant Dermal Remodeling*, J CUTAN. PATHOL. (2009).

expert in pharmacovigilance; and (3) Gaspari arrived at his safety-signal conclusion without reviewing all of the information GEHC had available to it at the time.

Consistent with its free gadolinium theory of NSF causation, the PSC focused its early discovery efforts on demonstrating that GEHC knew that Omniscan was capable of releasing free gadolinium once ingested. The PSC deposed Robert Muller, a Belgian chemist and GEHC consultant. At his 2010 deposition, Muller produced a copy of an unpublished 1995 GEHC study that suggested that Omniscan did release significant amounts of free gadolinium. The PSC subsequently learned that GEHC had this 1995 study but did not disclose it. The PSC filed a motion for sanctions under Federal Rule of Civil Procedure 37(b) and (c). After a sanctions proceeding, it was revealed that GEHC lost or destroyed some documents relating to Muller. The district court did not impose punitive sanctions or allow an "adverse inference and spoliation instruction." The district court, however, imposed the following remedies: (1) Muller's deposition was admitted in any MDL trial; (2) Muller's 1995 study report, along with other documents in the Haldorsen file in which the Muller report was located, was admitted in any MDL trial; (3) PSC experts were permitted to rely on and testify about the contents of the Muller report and the Haldorsen file; and (4) testimony from the sanctions hearing was admissible at trial.

GEHC moved for clarification of the order and requested that the district court reconsider its determination that testimony from the sanctions hearing was admissible at trial. In that motion, GEHC sought to exclude the deposition testimony of Patrick Murphy, GEHC's Rule 30(b)(6) witness. The district court provided that testimony from the sanctions hearing was admissible at trial only if relevant to proving a plaintiff's case. It further suggested during a January 14, 2011 teleconference that counsel work out a stipulation to the operative facts of the destroyed and missing documents. The district court subsequently stated that if the parties could not reach an agreement over a stipulation, the court would permit introduction of the excerpts of Murphy's deposition testimony proposed by the plaintiffs, and should GEHC believe that these excerpts would not present an accurate picture of what occurred regarding the documents, GEHC could introduce additional evidence. Accordingly, the district court denied GEHC's motion to strike plaintiffs' designation of Murphy as a testifying witness.

With respect to the instant case, on August 15, 2012, the district court ordered that "[a]ll prior rulings by the Court in this MDL relating to expert witnesses will remain in effect." Despite the district court's evidentiary rulings, GEHC filed a notice in this case identifying Gaspari as one of the generic experts it intended to call to testify "consistent with" his initial and supplemental generic expert reports. Plaintiffs responded by filing a motion to strike Gaspari's supplemental report in its entirety. The district court barred Gaspari's testimony regarding the occurrence of NSF in the absence of GBCA exposure because Gaspari disregarded the previous rulings on the issue and because he cited and adopted his prior report including every article the district court specifically and unambiguously excluded as unreliable. The district court also excluded Gaspari's testimony about pharmacovigilance matters because he was not an expert on pharmacovigilance.

Prior to trial, GEHC also sought to revisit the district court's previous rulings on testimony concerning gadolinium-naïve cases. In response, the district court noted that unlike the methodologically flawed studies it reviewed in its evidentiary rulings, one purported case of gadolinium-naïve NSF did not suffer from the same defects. This was "Patient 5" in the 2010 "Lemy study." However, the district court held that this patient's seeming contraction of NSF without a known GBCA exposure was not relevant unless GEHC produced an expert who analyzed both Mr. Decker and Patient 5 in the Lemy study and determined that the conditions of the two of them were so similar that it was probable that Mr. Decker's NSF was not caused by his 2005 Omniscan.

At the final pretrial conference, the Deckers sought to introduce excerpts from Murphy's deposition concerning missing or destroyed documents. Over GEHC's objection, the district court ruled that those excerpts were admissible but "deliberately stay[ed] away from letting this jury know that we had this whole sanctions issue because it is not relevant." At trial, Murphy's testimony was straightforward. Murphy testified to the following: (1) the Muller report was produced late; (2) a "four to five inch" stack of documents segregated from a file cabinet by a GEHC scientist, Saebo, was missing; and (3) three additional documents, also dealing with Muller, were missing and destroyed.

During trial, the significance of the AERs was hotly disputed. GEHC had sought a special jury instruction with respect to AERs:

> You have also heard testimony and seen exhibits relating to "adverse event reports" (also known as "AERs") . . . . AERs only provide notice to a manufacturer that a negative reaction occurred around the time that a drug was administered; they do not prove that the reaction was actually a side effect or caused by the drug administration.

Although the district court initially planned to give this instruction, upon further review and consideration, the court deleted the instruction from the final jury charge because "the instruction singles out one type of evidence, and adds, rather than minimizes, confusion." The district court reasoned that "there has been plenty of testimony about what they are and how they are used . . . [and] no witness has testified that you can use an AER to show that Omniscan caused any illness or medical condition described in those AERs and besides, it doesn't matter because those patients are not, are not the plaintiffs."

GEHC also requested that the court instruct the jury on the facts the district court found at the conclusion of the sanctions proceedings in 2010 and January 2011. Specifically, GEHC requested that the court instruct the jury:

> You have heard testimony that some documents relating to gadolinium or Omniscan were lost or discarded. While the specific contents of these documents remain unknown, it is unlikely that the documents are essential to proving any of Plaintiffs' claims, or that their absence prejudices Plaintiffs.

Although the district court previously had held that excerpts of Murphy's deposition testimony that certain documents were produced and destroyed were admissible, the court declined to issue GEHC's proposed instruction because an instruction "would be giving [the issue of the lost or discarded documents] a lot more importance than it has had in this trial."

On March 22, 2013, after twelve days of testimony and two days of deliberation, a jury returned a verdict in favor of the Deckers. Although the jury found for GEHC on the design defect and nonconformance to representation claims, the jury found for plaintiffs on the failure-to-warn claim, unanimously determining that GEHC knew or should have known about the risks that Omniscan presented to patients with renal impairment but failed to warn adequately the medical community—including Mr. Decker's radiologist, Phillip Shaffer, who administered the

contrast dye—about those risks. The jury awarded Mr. Decker $4,500,000 in compensatory damages—$1,000,000 for economic loss and $3,500,000 for noneconomic loss—and Mrs. Decker $500,000 for loss of consortium. The district court entered judgment on March 28, 2013.

Following the verdict, plaintiffs sought prejudgment interest. Under Ohio law plaintiffs that prevail at trial are entitled to prejudgment interest if they made a good faith effort to settle the case before trial and defendant, by contrast, did not do so. *See* Ohio Rev. Code § 1343.03(C)(1). This decision is usually made by the trial judge following the verdict. *See Singer v. Celina Group*, No. 94-CA-0333, 1995 WL 495427 (Ohio Ct. App. May 30, 1995). In this case, however, Judge Polster *sua sponte* recused himself from ruling on plaintiffs' motion. Judge Polster explained that he "was so heavily involved in mediating a resolution of this case that [he] would likely [have been] a witness to a litigated dispute involving the parties' settlement efforts" and that he was "not allowed to act as both a judge and a witness." Judge Polster emphasized that his recusal applied only to the discrete issue of plaintiffs' motion for prejudgment interest "and nothing more." Plaintiffs' motion for prejudgment interest was reassigned to Judge Donald Nugent, who held a hearing on the motion on October 3, 2013. On November 21, 2013, Judge Nugent denied the motion, finding that counsel for both parties carefully and rationally evaluated the case and followed the recommendations of the court and that neither party failed to act in good faith during settlement negotiations.

GEHC moved for a new trial, to alter or amend the judgment, and for remittitur. GEHC argued, *inter alia*, that (1) the Deckers failed to prove the element of causation on their failure-to-warn claim, (2) the court's decision not to give a jury instruction about AERs unfairly prejudiced GEHC, and (3) because Judge Polster recused himself from ruling on the Deckers' post-trial motion for prejudgment interest, he should never have presided over the trial. The district court rejected those arguments in separate opinions and denied the motion on July 25, 2013. On August 23, 2013, GEHC timely appealed the March 28, 2013 judgment entry, including all interlocutory orders rendered final by the final judgment, and the district court's post-judgment orders, including the orders regarding recusal, the May 7, 2013 order awarding plaintiffs 50% of the amount they billed, and the July 25, 2013 order denying GEHC's motion for a new trial and to alter or amend the judgment. After the Deckers' motion for prejudgment

interest was denied on November 21, 2013, GEHC's notice of appeal became effective. *See* Fed. R. App. P. 4(a)(4)(B)(i).

II.

On appeal, GEHC makes various arguments in support of its contention that the district court erred in denying its motion for a new trial. Each argument fails.

A.

First, GEHC argues that Judge Polster's *sua sponte* recusal from ruling on the Deckers' motion for prejudgment interest requires vacatur of the judgment and a new trial. Relatedly, GEHC suggests that since Judge Polster recused himself from ruling on the prejudgment-interest motion, he should have also recused himself from ruling on GEHC's Rule 59 motion. The district court rejected these arguments in two opinions and orders denying GEHC's motion for a new trial. We review a district court's denial of a motion for a new trial for abuse of discretion. *Nolan v. Memphis City Schs.*, 589 F.3d 257, 264 (6th Cir. 2009) (citing *Morgan v. N.Y. Life Ins. Co.*, 559 F.3d 425, 434 (6th Cir. 2009)). "Reversal is only warranted if the Court has a 'definite and firm conviction that the trial court committed a clear error of judgment.'" *Id.* (quoting *Barnes v. Owens–Corning Fiberglas Corp.*, 201 F.3d 815, 820 (6th Cir. 2000)). Furthermore, "[t]his court will affirm a district judge's decision not to recuse himself pursuant to 28 U.S.C. § 455(a) unless it constitutes an abuse of discretion." *United States v. Howard*, 218 F.3d 556, 566 (6th Cir. 2000) (citing *Union Planters Bank v. L & J Dev. Co.*, 115 F.3d 378, 382 (6th Cir. 1997)).

GEHC contends that 28 U.S.C. § 455 prohibits piecemeal recusal and, therefore, the district court's recusal with respect to plaintiffs' motion for prejudgment interest entailed recusal from all other rulings in the case, including GEHC's motion for a new trial. Under § 455(a), "[a]ny justice, judge, or magistrate judge of the United States shall disqualify himself in any proceeding in which his impartiality might reasonably be questioned." 28 U.S.C. § 455(a). Section 455(d)(1) states that a "'proceeding' includes pretrial, trial, appellate review, or other stages of litigation." This court has yet to interpret these provisions to determine whether § 455 permits partial recusals.

GEHC cites *In re Aetna Casualty and Surety Co.*, 919 F.2d 1136 (6th Cir. 1990) (en banc), as support for its favored position. *Aetna*, however, did not hold that § 455 prohibits partial recusals. In *Aetna*, a chief district court judge had recused himself from seven cases, which had been consolidated, because his daughter worked for a firm that participated in four of the cases. *See id.* at 1137. Upon knowing that the cases would not be tried together, the judge reentered the remaining three cases. *Id.* at 1137−38. Aetna moved for disqualification, the district court denied that motion, and Aetna petitioned for a writ of *mandamus* from the Sixth Circuit. *See id.* at 1137. This court granted that petition, holding that the judge should have recused himself "from making decisions in any of the consolidated FDIC-Aetna cases." *Id.* at 1145. Even if his daughter's firm were not of counsel in the three cases the district judge assigned to himself, this court explained, because a decision on the merits might have constituted law of the case, involved collateral estoppel, or served as persuasive precedent, § 455(b) warranted his disqualification. *See id.* at 1143, 1146. This court also vacated the judge's grant of partial summary judgment because "the risk of undermining the public's confidence in the judicial process [was] significant." *See id.* at 1145−46 (citing *Liljeberg v. Health Servs. Acquisition Corp.*, 486 U.S. 847, 864 (1988)). *Aetna* straightforwardly addressed a disqualification motion under § 455(b). It did not concern the instant, specific issue of whether § 455 permits a limited, partial *sua sponte* recusal in an appropriate case.

Other circuit courts have expressed contrary views on the matter of partial recusals. The majority view approves partial recusals as an important case-management device. *See, e.g.*, *Ellis v. United States*, 313 F.3d 636, 642 (1st Cir. 2002) ("Today, we make that approval explicit: we hold that a judge may, in an appropriate case, decide certain issues and recuse himself or herself as to others."); *Pashaian v. Eccelston Props., Ltd.*, 88 F.3d 77, 84–85 (2d Cir. 1996) (holding that district court did not err in deciding a motion before effecting recusal and that such was "a practical and appropriate resolution"); *United States v. Kimberlin*, 781 F.2d 1247, 1258–59 (7th Cir. 1985) (finding no abuse of discretion where the trial judge issued a limited recusal order); *but see United States v. Feldman*, 983 F.2d 144, 145 (9th Cir. 1992) ("[W]hen a judge determines that recusal is appropriate it is not within his discretion to recuse by subject matter or only as to certain issues and not others.").

We join the majority view that 28 U.S.C. § 455(a) does not categorically prohibit partial recusal. Construing § 455(a), we find that the reasons for questioning judicial impartiality in one "proceeding" of a case do not necessarily obtain in every "proceeding" of that case. *See* 28 U.S.C. § 455(d)(1). Rather, in the appropriate instance, partial recusal serves the interests of case management and judicial economy. *See, e.g.*, *Ellis*, 313 F.3d at 642 (finding that the judge's partial recusal "was a valid exercise of judicial authority" and "constituted a sound method of dealing with the prickly problem of balancing the demands of section 2255—a statute that evinces a strong preference for post-conviction review by the judge who presided at the defendant's trial—with the demands of the recusal statute, 28 U.S.C. § 455(a)").

In this case, Judge Polster declined to rule on the Deckers' motion for prejudgment interest, which requires a showing of the prevailing party's good faith effort to settle and the non-prevailing party's lack of such an effort. *See* O.R.C. § 1343.03(C)(1). Because Judge Polster "was so heavily involved in mediating a resolution of this case that [he] likely [would have been] a witness to a litigated dispute involving the parties' settlement efforts," and because Judge Polster was not allowed to act as both a judge and a witness, *see* Fed. R. Evid. 605, he held that any ruling on the Deckers' motion would have been improper. Judge Polster also explained that from the beginning of the MDL in 2008 he had been extensively involved in mediating resolutions and that over six hundred cases had been resolved, a majority with his direct assistance. Because cases remained in the MDL, including several cases in which GEHC was a party, Judge Polster was concerned that a ruling on GEHC's good faith in pursuing pre-trial settlement might have impaired his ability to assist in settling the remaining MDL cases. Unlike the district court judge in *Aetna*, Judge Polster's limited recusal avowedly was not based on any financial conflict, any other conflict, or any actual or perceived bias or prejudice to either party, and had no bearing on his impartiality as a trial judge. The specific reasons for Judge Polster's delimited recusal, especially his first-hand knowledge of the parties' settlement efforts, simply are not implicated in his subsequent rulings, including his denial of GEHC's motion for a new trial. Accordingly, we hold that Judge Polster's decision not to recuse himself from ruling on GEHC's Rule 59 motion was not an abuse of discretion.

Nor does Judge Polster's recusal from ruling on the Deckers' motion for prejudgment interest require vacatur and a new trial. GEHC argues that the recusal indicated an appearance of partiality and argues that vacatur of the judgment and a new trial are necessary to maintain public confidence in the judiciary. GEHC suggests that because recusal is warranted where a judge acquires "a deep-seated favoritism or antagonism that would make a fair judgment impossible," *Liteky v. United States*, 510 U.S. 540, 555 (1994), an impartial observer could conclude that Judge Polster's recusal arose from such an antagonism, and, therefore, vacatur and a new trial are necessary to maintain the appearance of impartiality and the public confidence in the judiciary. GEHC also suggests that Judge Polster's concern over his impartiality as to the Deckers' motion for prejudgment interest demonstrates a lack of impartiality that arose before trial.

GEHC overstates the case. First, Judge Polster's recusal was not from the entire case but only from the Deckers' motion for prejudgment interest. Second, he gave motion-specific reasons for recusal, citing his firsthand knowledge of the parties' settlement efforts and his concern that ruling on the Deckers' motion would undermine his ability to mediate other settlements in the MDL. Third, he avowed that his limited recusal was not due to any financial conflict or to any actual or perceived bias toward either party. GEHC has not shown otherwise. Therefore, the reasons for Judge Polster's recusal from the Deckers' prejudgment interest motion are specific to that motion, do not impugn his impartiality or the appearance thereof with respect to the jury trial or any other proceeding, and simply do not count in favor of his disqualification from the entire case. Vacatur and a new trial are not required to ensure the appearance of impartiality and public confidence in the judiciary. Accordingly, Judge Polster did not abuse his discretion in holding that recusal from the Deckers' motion for prejudgment interest does not require a new trial.

B.

Next, GEHC argues that the district court erred in several evidentiary rulings and that these errors warrant a new trial. We review a district court's decision to deny a motion for a new trial for an abuse of discretion, and "[t]o the extent the motion for new trial was based on an erroneous evidentiary ruling, the evidentiary ruling, too, is evaluated under the abuse-of-discretion standard." *Cummins v. BIC USA, Inc.*, 727 F.3d 506, 510 (6th Cir. 2013) (citing

United States v. Morales, 687 F.3d 697, 701–02 (6th Cir. 2012)). "The district court has broad discretion to determine questions of admissibility; an evidentiary ruling is not to be lightly overturned." *Id.* (citing *Nolan*, 589 F.3d at 265). "An erroneous evidentiary ruling amounts to reversible error, justifying a new trial, only if it was not harmless; that is, only if it affected the outcome of the trial." *Id.* (internal citation omitted).

GEHC asserts several challenges to the district court's evidentiary rulings. In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999), the Supreme Court set forth the standard for admissibility of expert testimony under Federal Rule of Evidence 702. The Court's "requirement that 'any and all scientific testimony or evidence admitted [be] not only relevant, but reliable,' . . . 'entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.'" *Champion v. Outlook Nashville, Inc.*, 380 F.3d 893, 907 (6th Cir. 2004) (alteration in original) (quoting *Daubert*, 509 U.S. at 589, 592–93). "In short, under *Daubert* and its progeny, a party proffering expert testimony must show by a 'preponderance of proof' that the expert whose testimony is being offered is qualified and will testify to scientific knowledge that will assist the trier of fact in understanding and disposing of relevant issues." *Sigler v. Am. Honda Motor Co.*, 532 F.3d 469, 478 (6th Cir. 2008) (internal citation omitted).

We review the district court's decision to admit or exclude the testimony of a party's expert witness for abuse of discretion. *Kumho Tire*, 526 U.S. at 152; *Sigler*, 532 F.3d at 478. As the Supreme Court explained in *Kumho Tire*, "[t]he trial court must have the same kind of latitude in deciding *how* to test an expert's reliability, and to decide whether or when special briefing or other proceedings are needed to investigate reliability, as it enjoys when it decides *whether or not* that expert's relevant testimony is reliable." 526 U.S. at 152. The abuse of discretion standard "applies as much to the trial court's decisions about how to determine reliability as to its ultimate conclusion." *Id.* Accordingly, the district court has "broad latitude" to determine "whether *Daubert*'s specific factors are, or are not, reasonable measures of reliability in a particular case." *Id.* at 153.

1.

First, GEHC argues that the district court erred because "it refused to exclude Plaintiffs' experts' speculation that 'free' gadolinium is to blame." The district court rejected GEHC's argument that plaintiffs' experts must be prohibited from giving testimony about the free gadolinium theory of NSF causation because the precise pathogenesis of NSF is unknown. The district court found:

> Published studies, and GEHC's own studies, show that the recovery of GBCAs from kidney patients takes significantly longer than non-kidney patients and is far from complete. Numerous techniques (e.g., radio-labeling in rats and mice, SEM/EDS, ICP-MS, SIMS and SXFRS in human NSF tissue samples) employed by a multitude of research scientists unrelated to this litigation have demonstrated the *in vitro* and *in vivo* dechelation of GBCAs. Many studies show that Omniscan is more prone to dechelation than other GBCAs. When dechelated, gadolinium is available to bond with other endogenous substances in blood and tissue. Gadolinium is found in the biopsied tissue of NSF patients.
>
> The dominant theory is that dechelation occurs through transmetalation (simply, a chemical reaction involving the exchange of ligands between two metal centers), although there are other theories including that dechelated (or, free) gadolinium has a proliferative effect on human dermal fibrosis and gadolinium's propensities as a calcium blocker triggers the fibrotic process. In any event, given the wealth of evidence on causation – that is, the rapid emergence and decline of NSF associated with the rise and fall of its use in renally impaired persons, the presence of gadolinium in the tissue of NSF patients, the known toxicity of gadolinium, and the majority view in the published and peer reviewed studies and articles [is] that dechelated gadolinium causes NSF.

Therefore, the district court concluded:

> The free gadolinium theory passes reliability muster under *Daubert* because it is based on research conducted by scientists and doctors performing animal studies, *in vitro* studies, *in vivo* studies, human clinical studies and retrospective case studies along with review of the relevant published scientific and medical studies; the theory has been subjected to publication and peer review; the theory has been generally accepted in the relevant scientific and medical community; the Plaintiffs' experts have adequately accounted for obvious alternative explanations; and the research of Plaintiffs' experts relates not only to their review of the literature but to matters growing naturally or necessarily out of research they have conducted independent of this litigation.

Reviewing GEHC's motion for reconsideration, the district court again found that plaintiffs' experts could testify regarding the "free (or dechelated) gadolinium theory" because it was "a

theory that reasonably attempts to explain what happens to the not insignificant amount of chelated gadolinium (here, Omniscan) that is injected into severely renally impaired persons, is never excreted, and is later found in one form or another in the biopsies of NSF patients." The district court found that "[s]ince it is beyond dispute that gadolinium is not a trace element normally found in the body, and that gadolinium is highly toxic to humans, most researchers (including research scientists employed or retained by GEHC) believe that the gadolinium becomes unbound from its ligand during its prolonged retention time in renal patients where it, either alone or newly bound to other substances, may trigger the process leading to NSF." Reviewing GEHC's motion to exclude testimony pertaining to the free gadolinium theory in the *Decker* trial, the district court found that the passage of time had "not diminished that theory, but strengthened it." The district court cited the 2012 American College of Radiology Manual's statement that "it is now generally accepted that GBCA exposure is a *necessary* factor in the development of NSF."

For the reasons articulated by the district court, testimony about the free gadolinium theory of NSF was admissible under *Daubert* and its progeny. Accordingly, the district court did not abuse its discretion when it refused to exclude plaintiffs' experts' testimony that free (dechelated) gadolinium is a cause of NSF.

2.

Second, GEHC states that the district court erred by excluding the opinion testimony of Gaspari about AERs and the difficulty of diagnosing NSF. The district court concluded in several rulings that because Gaspari was not a pharmacovigilance expert, he was not qualified to testify reliably as to the significance of the AERs. The district court found that Gaspari's deposition testimony made clear that he is not an expert in pharmacovigilance, noting that Gaspari "repeatedly testified that this sole assignment was to review, as a dermatologist, the four AERs . . . and to determine whether there were any consistencies or inconsistencies between those AERs, and whether they supported a clinical diagnosis of NSF," not whether they constituted a safety signal. Furthermore, the district court found Gaspari's testimony regarding the significance of the AERs unreliable because AERs are only useful when assessed in the

context of available data and Gaspari reached his conclusion "without reviewing all the information GEHC had available to it at the time."

GEHC also contends that the district court violated *Daubert* by permitting plaintiffs' pharmacovigilance expert, Blume, to testify about AERs and safety signals. The district court held that Blume's opinion that four AERs constituted a safety signal was admissible. It noted that Blume received her Ph.D. in Pharmacology and Toxicology, is the president of Pharmaceutical Development Group, Inc., a consulting firm specializing in pharmaceutical development and registration, has held executive positions in pharmaceutical companies over a twenty-year period, and "has designed, executed, and interpreted preclinical and clinical studies associated with pharmaceutical product development." The district court also noted that another federal court addressing Blume's ability to testify on AERs as a safety signal declined to exclude her methodology. *See In re Viagra Prods. Liab. Litig.*, 658 F. Supp. 2d 950, 961−62 (D. Minn. 2009).

GEHC argues that "[b]ecause Blume is not a medical doctor, she is not qualified to assess the clinical significance of these AERs, and the court should have limited her testimony [that four AERs were signals for NSF]." The district court rejected the converse argument when it excluded the testimony of Gaspari, a board-certified dermatologist, that the four disputed AERs did not constitute a safety signal. The district court reasoned:

> The question of whether these AERs constituted a safety signal requires someone with expertise in pharmacovigilance. The expert must determine whether, given all the information available to GEHC at the time, the AERs gave rise to a safety signal alerting GEHC to the risks associated with administering Omniscan, particularly to the renally impaired. Hence, whether the four AERs supported a clinical diagnosis of NSF is irrelevant to the question of whether the AERs constituted a safety signal.

The district court concluded that because Blume was a pharmacovigilance expert, irrespective of whether she was a medical doctor, she was qualified to reliably testify as to the significance of the AERs. Conversely, the district court concluded that because Gaspari was not a pharmacovigilance expert, even though he was a medical doctor, he was not qualified to testify reliably regarding the significance of the AERs. The district court did not abuse its discretion in reaching either conclusion.

3.

Lastly, GEHC proposes that the district court violated *Daubert* because it excluded key rebuttal evidence proffered by GEHC's experts about cases of NSF in the absence of GBCA exposure. GEHC contends that the testimony concerning gadolinium-naïve NSF cases is both reliable and relevant, as GEHC sought to introduce it "not to dispute causation, as the court presumed, but to rebut Plaintiffs' theory of foreseeability." "In excluding this evidence," GEHC argues, "the district court unfairly deprived the jury of critical rebuttal explaining why a link between GBCAs and NSF was not foreseeable or as obvious as Plaintiffs suggest." GEHC particularly objects to the district court's ruling regarding the irrelevance of the Lemy study in the instant case.

In excluding GEHC's proffered-expert testimony regarding reports of gadolinium-naïve cases of NSF as unreliable, the district court meticulously analyzed the studies on which the proffered testimony was based. The district court concluded that these studies, particularly the Collidge, Wahba, and Deng studies, were methodologically flawed because they did not definitively confirm the lack of exposure of GBCAs. Accordingly, the district court determined that expert testimony regarding gadolinium-naïve cases of NSF was unreliable. The court also cited the 2012 American College of Radiology Manual, stating that "it is now generally accepted that GBCA exposure is a *necessary* factor in the development of NSF." The district court did not abuse its discretion in its rulings concerning GEHC's proffered expert testimony about gadolinium-naïve cases of NSF.

Nor did the district court abuse its discretion when it refused to admit expert testimony about Patient 5 in the Lemy study unless the expert had examined both the patient and Mr. Decker and had determined that the conditions of the two of them are so similar that it was probable that Mr. Decker's NSF was not caused by his 2005 Omniscan dosage. GEHC suggests that testimony about Patient 5 is relevant to show that the causal link between GBCAs and NSF was not foreseeable. But the Lemy study, which concerned a potential gadolinium-naïve case of NSF, was published in 2010. Hence, it is not clear how the specific case of Patient 5 in the Lemy study was relevant to GEHC's ability to foresee the risk that GBCAs, including Omniscan, presented to renally-impaired patients. The district court did not err in refusing to admit it. In

sum, because the district court did not err in the evidentiary rulings that GEHC challenges, a new trial is not required on that basis.

C.

GEHC next argues that the district court erred in denying a new trial because the Deckers failed to show that an inadequate warning proximately caused Mr. Decker's NSF. "A new trial is appropriate when the jury reaches a 'seriously erroneous result as evidenced by (1) the verdict being against the [clear] weight of the evidence; (2) the damages being excessive; or (3) the trial being unfair to the moving party in some fashion, i.e., the proceedings being influenced by prejudice or bias.'" *Cummins v. BIC USA, Inc.*, 727 F.3d 506, 509 (6th Cir. 2013) (quoting *Static Control Components, Inc. v. Lexmark Int'l, Inc.*, 697 F.3d 387, 414 (6th Cir. 2012)). "[N]ew trials are not to be granted on the grounds that the verdict was against the weight of the evidence 'unless that verdict was unreasonable.'" *Barnes*, 201 F.3d at 820−21 (citing *Holmes v. City of Massillon*, 78 F.3d 1041, 1047 (6th Cir. 1996)). "Thus, if a reasonable juror could reach the challenged verdict, a new trial is improper." *Id.* at 821 (citing *Holmes*, 78 F.3d at 1048). "'[C]ourts are not free to reweigh the evidence and set aside the jury verdict merely because the jury could have drawn different inferences or conclusions or because judges feel that other results are more reasonable.'" *Id.* (alternation in original) (quoting *Duncan v. Duncan*, 377 F.2d 49, 52 (6th Cir. 1967)). Again, "[t]his court reviews a district court's decision to deny a motion for a new trial for an abuse of discretion." *Id.* at 820 (citing *Logan v. Dayton Hudson Corp.*, 865 F.2d 789, 790 (6th Cir. 1989)).

During trial, the Deckers presented evidence of what GEHC knew in September 2005—when Mr. Decker received a dose of Omniscan—indicating the drug was harmful to patients with impaired renal function. This evidence included chemistry, toxicology, and human studies, some of which were conducted by GEHC staff and consultants but left unpublished and undisclosed to regulatory agencies. The evidence also included four AERs.

On appeal, GEHC offers three arguments for its contention that a new trial is warranted on the failure-to-warn claim. Two of these arguments target any "but for" causal relationship between the warning it issued and Mr. Decker's injury. First, GEHC argues that even if it had issued a more informative warning, Mr. Decker's doctors would have nevertheless administered

Omniscan. GEHC points to the testimony of Geoffrey Wiot, a partner in the radiology practice where Mr. Decker received Omniscan. Wiot testified that an improved warning "would have made no difference" without knowing about the relationship between Omniscan and NSF, a relationship that GEHC contends was unknown until 2006. GEHC emphasizes that Wiot "made decisions about which GBCAs to use and what policies to follow on a practice-wide basis."

Yet Phillip Shaffer was the radiologist in charge of Mr. Decker's MRI. Even assuming an improved warning would not have caused Wiot to include a different contrast dye in the dispensary in 2005, Shaffer decided whether to administer a GBCA for Decker's MRI. Shaffer testified that an improved warning would have caused Mr. Decker to receive a different treatment. Regarding Mr. Decker's treatment, Shaffer said that "I probably wouldn't have used the contrast if I knew these things were all true."

Second, GEHC suggests that because the 2005 label was substantially similar to an improved warning suggested by Blume's testimony, an improved label would not have caused Mr. Decker to receive a different treatment. By contrast, the Deckers offered Blume's testimony, which catalogued the various ways in which an improved label would have departed from the 2005 label. Blume testified that the 2005 Omniscan label failed to capture GEHC's knowledge of the risk of gadolinium toxicity to renally impaired patients. According to Blume, the label did not "reflect the data [GEHC] generated in multiple studies with patients with impaired renal function," which showed that such patients retained high levels of gadolinium weeks after receiving a dose of Omniscan. Blume also testified that the label did not inform doctors that gadolinium had the risk of being retained in an unchelated state, meaning that it was no longer bound to the ligand that helped ensure safe passage through the patient's body. According to Blume, the label should have also mentioned the four AERs and the symptoms suffered by the patients in those reports. Blume also explained that the 2005 label, which contained a precaution for patients with impaired kidney function, served as the label for all contrast dyes, including iodine based contrast agents, and did not reflect the specific, long-term, debilitating effects of gadolinium. Most significantly, Blume testified that GEHC should have placed a contraindication on the label for patients with severe renal impairment, which would have

warned doctors against administering Omniscan to such patients. This testimony is sufficient to support a reasonable juror's verdict as to the Deckers' failure-to-warn claim.

Third, adverting to the jury's verdict on the Deckers' design defect claim, GEHC argues that the jury rejected the conclusion that Omniscan should have been contraindicated in 2005. In its opening brief, GEHC does not sufficiently elaborate on the part the jury's design defect verdict plays in its argument against the failure-to-warn claim. In its reply brief, however, GEHC explains that the jury's design defect conclusion prevents the Deckers from arguing that any warning should have included a contraindication that would have caused Mr. Decker to receive a different treatment. Blume's testimony as to contraindication is only one way in which Blume explained that GEHC could have issued an improved warning that would have caused Mr. Decker to receive a different treatment. And "courts are not free to reweigh the evidence and set aside the jury verdict merely because the jury could have drawn different inferences or conclusions." *Barnes*, 201 F.3d at 821 (internal citation omitted) (quotation marks omitted).

Therefore, the district court correctly concluded that the Deckers produced sufficient evidence to support the jury's verdict and did not abuse its discretion in concluding that a reasonable juror could find that GEHC's failure to warn caused Mr. Decker's NSF.

D.

Next, GEHC contends that a new trial is required because the district court failed to give two proposed jury instructions. "[T]o the extent the motion for new trial was based on the court's refusal to give a requested jury instruction, the refusal is reviewed for abuse of discretion." *Cummins*, 727 F.3d at 510 (citing *Taylor v. TECO Barge Line, Inc.*, 517 F.3d 372, 387 (6th Cir. 2008)). "A district court's refusal to give a jury instruction constitutes reversible error if (1) the omitted instruction is a correct statement of the law, (2) the instruction is not substantially covered by other delivered charges, and (3) the failure to give the instruction impairs the requesting party's theory of the case." *Id.* (quoting *Taylor*, 517 F.3d at 387).

First, GEHC argues that the district court's refusal to give a limiting instruction with respect to the AERs—namely, that the AERs did not "prove that the [negative] reaction [described therein] was actually a side effect or caused by the drug administration"—unfairly

prejudiced its defense. GEHC believes that, absent this limiting instruction, the jury likely considered the AERs for an improper purpose as proof of causation. The district court pointed out, however, that "GEHC presented no evidence challenging the fact that Mr. Decker had NSF, or the fact that his NSF was caused by the single dose of Omniscan administered to him in 2005." Thus, the district court found that a limiting instruction would have been confusing and, for that reason, properly refused to issue it.

It is far from clear that the district court's refusal to give the proposed instruction on the AERs impaired GEHC's theory of the case. The significance of the AERs concerned the notice GEHC had regarding the risks of Omniscan, not the causal relationship between Omniscan and NSF. Hugo Flaten, GEHC's director of global pharmacovigilance, among other experts, explained the context and limits of the AERs. Flaten testified that pharmacovigilance concerns the identification and evaluation of safety signals and that even one, two, or three AERs may represent a safety signal. Further, the Deckers' experts did not rely on the AERs to prove a causal relationship between Omniscan and NSF. Blume relied on the AERs to prove notice of a safety signal. In her testimony, Blume emphasized that she did not state that the AERs proved causation. The Deckers' toxicology expert, Laura Plunkett, did not rely on the AERs to conclude that NSF is gadolinium poisoning. And the Deckers' nephrology expert, Derek Fine, did not rely on the AERs to support his conclusion that gadolinium causes NSF. Because the district court correctly found that GEHC's proposed AER instruction would have been confusing, the district court did not abuse its discretion in refusing to give it. Nor did it abuse its discretion in denying that this refusal constituted the basis for a new trial.

Lastly, GEHC argues that the district court's refusal to issue an instruction regarding the lost or discarded documents warrants a new trial. Relatedly, GEHC contends that the district court erred in admitting evidence and argument of discovery conduct at trial.

Neither argument has merit. First, the district court's evidentiary ruling, which GEHC suggests requires a new trial, is reviewed for abuse of discretion. *See Cummins*, 727 F.3d at 510. The district court did not abuse its discretion in admitting Murphy's limited testimony as to missing or destroyed documents relating to Muller. In ruling this testimony admissible, the

district court noted that it was curtailing Murphy's testimony so as to permit the relevant fact that there were potentially gaps in the evidence without prejudicing GEHC:

> The main discussion is that certain documents were destroyed and when they were destroyed and that's a fact, and [Murphy] is not saying who did it or why, why – why it happened or what. None of that, none of that is simply coming in. Simply that the facts, the facts are correct. So it may be relevant here. So I'm allowing the excerpts.

Murphy's testimony was limited to the fact that the Muller report was produced late, a "four to five inch" stack of documents segregated from a file cabinet by Saebo was missing, and three additional documents, dealing with Muller, were destroyed.

The district court's refusal to issue a limiting instruction that the destroyed or missing documents were unlikely essential to proving any of the Deckers' claims is not an abuse of discretion. The court was careful not to overemphasize the importance of the fact that GEHC lost or destroyed documents relating to Muller's deposition and study, declining to give GEHC's proposed instruction because it "would be giving [the issue of the lost or discarded documents] a lot more importance than it has had in this trial." The district court's failure to issue this instruction did not impair GEHC's theory of the failure-to-warn claim. *See Cummins*, 727 F.3d at 510.

III.

For the foregoing reasons, we affirm the district court's judgment entry and denial of GEHC's motion for a new trial.