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PATRICK FISHER
Clerk

PUBLISH

UNITED STATES COURT OF APPEALS
TENTH CIRCUIT

ERIC J. WRIGHT, a disabled minor, by
and through The Trust Company of
Kansas, Conservator of the Estate of Eric
J. Wright,

Plaintiff - Appellant,

v.

ABBOTT LABORATORIES, INC.,

Defendant - Appellee.

No. 99-3331

**Appeal from the United States District Court
for the District of Kansas
(D.C. No. 97-CV-1333-JTM)**

Lynn R. Johnson, Shamberg, Johnson & Bergman, Chartered, Overland Park, Kansas for
Plaintiff-Appellant.

June K. Ghezzi, Jones, Day, Reavis & Pogue, Chicago, Illinois, (Tina M. Tabacchi, Jones,
Day, Reavis & Pogue, Chicago, Illinois; Richard C. Hite, Hite, Fanning & Honeyman,
L.L.P., Wichita, Kansas, with her on the brief), for Defendant-Appellee.

Before **HENRY** and **MURPHY**, Circuit Judges, and **MILLS**, District Judge.¹

¹ The Honorable Richard Mills, United States District Judge for the Central
District of Illinois, sitting by designation.

MILLS, District Judge.

I. BACKGROUND

Eric Wright was born on November 10, 1992, at Wesley Medical Center in Wichita, Kansas. Shortly after birth, his doctor prescribed intravenous treatments of unconcentrated sodium chloride because Wright suffered from low blood pressure. The hospital stocked its unconcentrated sodium chloride solutions in close proximity to its concentrated solutions and, tragically, a nurse mistakenly gave Wright two doses of concentrated sodium chloride. The concentrated doses caused Wright to sustain severe brain damage.

The Wright family claims that Abbott Laboratories knew that stocking the solutions together could result in the sort of inadvertent administration of concentrated sodium chloride that debilitated their son. The Wrights argue that Abbott had a duty to warn the hospital about the risk of inadvertent administration and that Abbott's failure to do so was the proximate cause of Eric's brain damage.

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Abbott was the sole supplier of concentrated sodium chloride solution to Wesley Medical Center ("the hospital") from 1990 to 1992. On April 10, 1990, the United States Department of Health and Human Services, Food and Drug Administration ("the FDA") alerted manufacturers of concentrated sodium chloride about recent reports of serious adverse reactions following the inadvertent administration of concentrated sodium

chloride solution. The letter was signed by Philip G. Walters, M.D. on behalf of John F. Palmer, M.D., and sent to three concentrated sodium chloride manufacturers:

International Medication Systems, LTD. (IMS), Lyphomed, and American Regent.² Of the three manufacturers, IMS produced and marketed concentrated sodium chloride solutions with concentrations of 14.6% and 23.4%; Lyphomed and American Regent only produced and marketed solutions with a 23.4% concentration.

The so-called "Palmer Letter" recommended that the manufacturers change the labeling and package inserts for their sodium chloride products and immediately notify their hospital customers about the reports and risks of inadvertent administration of concentrated sodium chloride. The letter also recommended that the manufacturers advise hospitals to institute the additional safety precaution of restricting the storage of hypertonic sodium chloride to the hospital pharmacies in order to eliminate the possibility of medication errors. The three manufacturers promptly sent "Important Drug Warning" letters to their hospital customers in April, May and June, 1990. Each of the "Important Drug Warning" letters sent by these manufacturers complied with all of the warnings and instructions recommended in the Palmer Letter. In particular, the letters warned that the storage of hypertonic sodium chloride should be restricted to hospital pharmacies in order to eliminate or reduce the possibility of inadvertently substituting one sodium chloride

² Although the parties have not indicated what positions Dr. Walters and Dr. Palmer held, both men were medical doctors employed by the FDA.

solution for another.

Apparently, the FDA only sent the Palmer Letter to manufacturers who produced 23.4% concentrated sodium chloride solution in April 1990. Since Abbott did not produce a 23.4% solution at that time, the FDA never sent Abbott a copy of the letter. Abbott did not learn about the Palmer Letter until August 1991, when Frederick Gustafson, its Director of Regulatory Affairs for the Hospital Products Division, received a copy during a deposition in another case involving injuries which resulted from an inadvertent administration of concentrated sodium chloride. At the time of this other deposition, Abbott was not aware of the facts surrounding the issuance of the Palmer Letter, but was led to believe that the letter had been sent to all manufacturers, regardless of the type of solution they produced. In response to this information, Abbott notified the FDA that it never received a copy of the Palmer Letter and submitted a label change for its 14.6% solution to the FDA. The FDA reviewed and approved Abbott's proposed label change, but it never requested or required Abbott to do anything else with respect to the Palmer Letter. Accordingly, Abbott did not send an "Important Drug Warning" letter to its hospital customers to warn them about the dangers of inadvertent administration, or instruct them to store concentrated sodium chloride in a pharmacy to minimize the risk of inadvertently administering concentrated sodium chloride. Gustafson and one of Abbott's staff attorneys decided that it "would not be of any major benefit" and would have been "confusing" if Abbott sent such a letter.

Since Abbott was Wesley Medical Center's sole provider of sodium solutions, and Abbott did not send a warning letter, the hospital never received written warning about the dangers of storing concentrated solutions with unconcentrated solutions. The hospital continued to stock Abbott's 14.6% sodium chloride solution in the same NSCU medication cart it stocked the normal saline solution throughout 1992.

* *

Shortly after Eric Wright's birth on November 10, 1992, the hospital transferred him to its Neonatal Special Care Unit (NSCU) because he had low blood pressure that required correction with intravenously administered fluids. Dr. Barry Bloom instructed NSCU Nurse Benjamin to "Piggyback normal saline, 20ccs over 30 minutes" in order to raise Wright's blood pressure. Nurse Diltz overheard Nurse Benjamin repeating Dr. Bloom's order, asked if she could help, and was told to prepare the solution.

Contrary to the hospital's nursing policies and her own nursing school training, Nurse Diltz did not read Dr. Bloom's order or the label on the sodium chloride vial she took from the NSCU cart before preparing the solution. The concentrated sodium chloride that Nurse Diltz took from the cart vial bore a large red legend that read "CONCENTRATE" and "CAUTION: MUST BE DILUTED FOR I.V. USE." It also warned in large red ink that the vial contained 14.6% solution. Nurse Diltz went to select a normal strength sodium solution for Nurse Benjamin to administer to Eric Wright, but she mistakenly picked up a concentrated sodium solution and gave it to Nurse Benjamin

who administered it to Wright. Nurse Diltz repeated this mistake 30 minutes later when helping Nurse Benjamin to administer a second dose. Eric Wright suffered brain damage as a result of these two doses.

During the litigation which followed Wright's injury, his family contended that Abbott knew about the risk of storing concentrated sodium chloride next to vials of normal saline solution and that it had a duty to warn the hospital. They claimed that Eric's brain damage could have been avoided if Abbott informed the hospital of the dangers of storing concentrated and unconcentrated sodium chloride together.

However, testimony by hospital personnel indicated otherwise. The hospital's Director of Pharmacy Services, Mike Hurst, stated in his deposition that if he had received a copy of the Palmer Letter in 1990 it would have been used to determine "what actually would be required for patient safety." He may have "determined that no action [was] necessary at that point." He would have exercised his own judgment on the FDA's recommendations. In his opinion, recommendations from the FDA and manufacturers were not always useful or helpful; thus, the hospital did not always follow them.

Dr. Bloom testified in his deposition that he did not need the FDA to tell him about the risk of inadvertent administration of concentrated sodium chloride because that information was not new. He stated that immediate access to concentrated sodium chloride was sometimes necessary and it would have been irrational to remove electrolytes from the floor stock without having an alternative source that was at least as

expedient. It was not until late 1993 or early 1994 that an alternative was available at the hospital, and even then nurses had access to concentrated electrolytes so they could be immediately administered to patients. The hospital knew at that time, as it did in 1992 and the years before, that there was a risk that nurses might administer the wrong solutions and that the practice of floor stocking medications increased that risk.

Abbott moved for summary judgment on the Wright's claim. In the course of allowing Abbott's motion, the district court struck Wright's Statement of Uncontroverted Facts because it contained irrelevant and inadmissible facts. The court entered summary judgment for Abbott on four separate grounds: 1) Abbott's warnings to the hospital were adequate as a matter of Kansas law; 2) Abbott had no duty to warn a sophisticated user like the hospital about any storage dangers since the hospital should have already known about the dangers; 3) that *Restatement (Second) of Torts* §402A Comment j barred Wright's suit; and 4) that Abbott did not proximately cause Wright's injury. Wright's family moved for reconsideration, but the district court denied their motion.

Wright's family appeals each of the district court's findings as well as its decision to strike their Statement of Uncontroverted Facts and deny their Motion for Reconsideration.

We exercise jurisdiction over this matter pursuant to 28 U.S.C. § 1291, and we AFFIRM the district court's granting of summary judgment for Abbott.

II. STANDARD OF REVIEW

The Court reviews a district court's decision to grant summary judgment *de novo*, applying the standard set forth in Fed.R.Civ.P. 56(c). See Adler v. Wal-Mart Stores, Inc., 144 F.3d 664, 670 (10th Cir. 1998). If upon reviewing the record the Court determines that there were no genuine issues of material fact, it need only decide whether the district court correctly applied the substantive law. See Osgood v. State Farm Mut. Auto. Ins. Co., 848 F.2d 141, 143 (10th Cir. 1988). A fact is "'material' if under the substantive law it is essential to the proper disposition of the claim." See Adler, 144 F.3d at 670.

Timeliness of Appeal

The district court entered summary judgment for Abbott on August 17, 1999. In the course of doing so, the court denied a motion for leave to file a surreply and a supplemental appendix that the Wrights had filed. On August 25, the Wrights moved the court to reconsider its refusal to allow the surreply and appendix. They filed the motion “in order to ensure that the record reflects all the evidence reviewed by the [district court]” and to ensure that they “would be able to have a full hearing before the Tenth Circuit”. The district court treated the Wrights’ motion as if it had been filed pursuant to Federal Rule of Civil Procedure 59(e) when it denied the motion on September 17, 1999.³ The Wrights filed a notice of appeal on October 15, 1999—within 30 days of the denial of their Motion for Reconsideration but almost 60 days after the district court entered

³ The district court signed the order on September 17, 1999, but it was not docketed until September 20. Regardless of the date used, the jurisdictional result is the same.

summary judgment. Abbott argues that the notice of appeal was untimely under Federal Rule of Appellate Procedure Rule 4 and should be dismissed for lack of appellate jurisdiction.

We disagree.

While Rule 4(a)(1)(A) requires that a notice of appeal be filed “within 30 days after the judgment or order appealed from is entered”, Rule 4(a)(4) provides that:

(A) If a party timely files in the district court any of the following motions under the Federal Rules of Civil Procedure, the time to file an appeal runs for all parties from the entry of the order disposing of the last such remaining motion:

- (i) for judgment under Rule 50(b);
- (ii) to amend or make additional factual findings under Rule 52(b), whether or not granting the motion would alter the judgment;
- (iii) for attorney's fees under Rule 54 if the district court extends the time to appeal under Rule 58;
- (iv) to alter or amend the judgment under Rule 59;
- (v) for a new trial under Rule 59; or
- (vi) for relief under Rule 60 if the motion is filed no later than 10 days (computed using Federal Rule of Civil Procedure 6(a)) after the judgment is entered.

See Fed.R.App.P. 4(a)(4).

Because the Wrights’ Motion for Reconsideration asked the district court to review its decision to deny their surreply and supplemental appendix, and did not address the merits of the summary judgment order, Abbott contends that the Motion for Reconsideration cannot be deemed a Rule 59(e) motion and does not toll Rule 4(a)(1)’s 30 day filing period.

Since there is no requirement that a motion seek substantive alteration or amendment in order for it to be deemed a Rule 59(e) motion, Abbott’s contention is incorrect. See, i.e., Grantham v. Ohio Casualty Co., 97 F.3d 434, 435 (10th Cir. 1996) (citations omitted); see also Dalton v. First Interstate Bank of Denver, 863 F.2d 702, 703-04 (10th Cir. 1998) (stating that “post-judgment motions filed within ten days of the final judgment should, where possible, be construed as 59(e) motions to avoid otherwise endless hassles over proper characterization.”) (quotations omitted), *superseded by statute on other grounds as stated in Grantham*, 97 F.3d 434. As such, the district court properly characterized the Wrights’ August 25, 1999, Motion For Reconsideration as a Rule 59(e) motion. The Wrights, therefore, had 30 days from September 17—the date the district court denied the Motion for Reconsideration—to file a notice of appeal. By filing their notice of appeal on October 15, the Wrights ensured the timeliness of their appeal.

Statement of Uncontroverted Facts

The Wrights contend that the district court made an errant evidentiary ruling when it found that their 149 uncontroverted facts were inadmissible or irrelevant. The Court reviews a district court's evidentiary rulings for an abuse of discretion. See Wright-Simmons v. City of Oklahoma, 155 F.3d 1264, 1268 (10th Cir. 1998). An abuse of discretion occurs where the district court clearly erred or ventured beyond the limits of permissible choice under the circumstances. See Deters v. Equifax Credit, 202 F.3d 1262, 1268 (10th Cir. 2000).

In their brief, the Wrights decry the district court's decision to deny their 149 paragraphs of uncontroverted facts as “not relevant, based on inadmissible evidence, or both.” Having reviewed the Wrights’ uncontroverted facts, we find numerous grounds (ranging from hearsay to relevance) which support the district court’s decision to strike the Wrights’ uncontroverted facts. However, we need not detail these reasons since—as the rest of this opinion makes clear—summary judgment would have been in order even if the Wrights’ uncontroverted facts had been admitted into evidence.

The “Learned Intermediary” Doctrine

The “learned intermediary doctrine” states that once a manufacturer warns a doctor about a drug's inherent dangers, it has fulfilled its legal duty to provide a warning. See Hall v. Merck, Sharp & Dohme, 774 F.Supp. 604, 605-06 (D.Kan. 1991) (granting summary judgment to a drug manufacturer because it discharged its legal duty to plaintiff by warning prescribing physician of drug's inherent risks); Phelps v. Sherwood Med. Indus., 836 F.2d 296, 301-03 (7th Cir. 1987). Under Kansas law, a plaintiff cannot prevail against a prescription drug manufacturer in a failure to warn case where the manufacturer warned the “learned intermediary” of the drug's inherent risks. See, e.g., Humes v. Clinton, 792 P.2d 1032, 1039 (1990) (affirming summary judgment for manufacturer based on the “learned intermediary” doctrine).

The Wrights attempt to avoid the learned intermediary doctrine’s crushing effect by citing to Wooderson v. Ortho Pharmaceutical Corp., 235 Kan. 386, 681 P.2d 1038

(1984), a case which held that a drug manufacturer has a duty to warn of “all potential dangers which it knew, or in the exercise of reasonable care, should have known to exist.” In reaching this conclusion, however, the Kansas Supreme Court discussed only those dangers caused by drug use. It did not consider storage-related problems. See Id. Given that the court limited its discussion to dangers posed by actual drug use (*i.e.* side effects)—not extrinsic dangers such as floor stocking—we do not read Wooderson to thwart the learned intermediary doctrine.

The learned intermediary doctrine applies so long as Abbott warned the hospital of concentrated saline’s inherent risks. Abbott did this. It clearly warned the hospital of concentrated saline’s inherent risks by including a package insert that explicitly stated that hypernatremia and resulting injuries could occur if concentrated saline solution was administered in undiluted form. This was the inherent danger the Palmer Letter warned about and Abbott’s packaging brought the risk to the hospital’s attention. Abbott was required to do no more under the “learned intermediary” doctrine. Thus, the district court appropriately entered summary judgment on this basis. See, e.g., Humes v. Clinton, 792 P.2d 1032, 1039 (1990).

Kansas Product Liability Act

Section 60-3305 of the Kansas Product Liability Act requires drug manufacturers to warn about dangers or hazards which could or did arise in the use or misuse of such product to reasonable users or consumers of the product. See K.S.A. § 60-3305.

However, the duty to warn “shall not extend”:

(a) To warnings, protecting against or instructing with regard to those safeguards, precautions and actions which a reasonable user or consumer of the product, with the training, experience, education and any special knowledge the user or consumer did, should or was required to possess, could and should have taken for such user or consumer or others, under all the facts and circumstances;

(c) To warnings, protecting against or instructing with regard to dangers, hazards or risks which are patent, open or obvious and which should have been realized by a reasonable user or consumer of the product.

Id.

The Wrights contend that § 60-3305(a) and (c) are inapplicable to this case because, while the hospital and its staff knew about the dangers of actually giving a patient a concentrated dose of saline solution, the hospital and staff did not know that floor stocking different saline solutions together increased the risk of inadvertent administration.

There are two problems with the Wrights’ argument. First, the hospital and its staff knew that floor stocking the different saline solutions together increased the risk of inadvertent administration. Dr. Barry Bloom, the physician who prescribed Wright’s saline treatments, testified in his deposition that he knew about this risk. Second, even if the hospital and its staff did not know about the risk of floor stocking the different strength solutions together, they should have known about the risk. They were sophisticated medical practitioners and the risk should have been obvious to them. Because the hospital’s floor stocking method made inadvertent administration such an

apparent risk, Abbott had no duty under Kansas law to warn the hospital and its staff about the danger. See K.S.A. § 60-3305(a) and (c); See also Duffee v. Murray Ohio Mfg. Co., 879 F.Supp. 1078, 1082 (D.Kan. 1995) (“Kansas law does not impose a duty to warn of dangers actually known to the product user, or of obvious common dangers or generally known risks connected with the use of the product”) (citations omitted), aff’d, 91 F.3d 1410 (10th Cir. 1996); Miller v. Lee Apparel Co., 881 P.2d 576, 588 (Kan. Ct. App. 1994) (if a danger is obvious, its obviousness constitutes a warning and that a manufacturer is “not an insurer of the safety of persons who use the product”). Thus, Abbott was entitled to summary judgment on this basis alone.⁴

Proximate Cause

Under Kansas law, “[t]he proximate or legal cause of an injury is that cause which in natural and continuous sequence, unbroken by an efficient intervening cause, produces the injury and without which the injury would not have occurred, the injury being the natural and probable consequence of the wrongful act.” See Wilcheck v. Doonan Truck & Equip., Inc., 220 Kan. 230, 235, 552 P.2d 938, 942-43 (Kan. 1976) (citing Campbell Sixty-Six Express, Inc. v. Adventure Line Mfg. Co. Inc., 209 Kan. 357, 496 P.2d 1351 (Kan. 1972); and Elliott v. Chicago, Rock Island & Pac. Rld. Co., 203 Kan. 273, 454 P.2d

⁴ In addition to finding that Abbott was entitled to summary judgment pursuant to K.S.A. § 60-3305(a) and (c), the district court relied on *Restatement (Second) on Torts*, § 402(A) Comment j as a separate, independent ground for entering summary judgment. Because § 60-3305 (a) and (c) were proper grounds for summary judgment, we need not consider Comment j.

124 (Kan. 1969); see also Duffee, 879 F.Supp. at 1083. An “efficient intervening cause” is a “new and independent act, itself a proximate cause of an injury, which breaks the causal connection between the original wrong and injury.” See Budden v. United States, 15 F.3d 1444, 1449 (8th Cir. 1994) (internal quotations omitted).

Like the district court, we find that the facts here show that Abbott's failure to warn the hospital was not a proximate cause of Wright's injury. First, for reasons explained in our discussion of the “learned intermediary” doctrine and the Kansas Liability Act, it is apparent that Abbott had no duty to warn the hospital of the potential dangers of floor stocking the different strength sodium chloride solutions together. Second, even if Abbott had a duty to warn, warning the hospital would not have changed the outcome in this case. Hospital personnel testified that doctors and nurses needed to have efficient access to concentrated sodium chloride solutions. Since the hospital did not have a 24-hour pharmacy for I.V. admixtures, or an automated delivery system, it had no alternative other than to use the floor stocking procedure that existed at the time of Wright's injury. Furthermore, Mike Hurst, the hospital's Director of Pharmacy Services, stated in his deposition testimony that if he had received a copy of the Palmer Letter he may have "determined that no action [was] necessary at that point" since recommendations from the FDA and manufacturers were not always useful or helpful. As such, a warning from Abbott would not and could not have been implemented had the

warning been required.⁵

As important as these other facts are, it is most significant that Nurse Diltz—a qualified pediatric attendant—failed to exercise the simple precaution of reading the label on the sodium chloride solution used for Eric Wright’s treatment. As her coworker Nurse Cindy Harmon testified, “regardless of where the drug is located, it's incumbent upon the person that is getting the drug for use to look at the label and make certain that he or she has the right drug.” Had Nurse Diltz read the label on the concentrated sodium chloride solution, she would have realized her mistake and that solution would not have been administered to Eric Wright. Thus, Nurse Diltz's failure to read the label—a basic task which she was trained to perform—was an efficient intervening cause of Wright’s injury. Had Abbott done anything wrong by not sending the hospital a warning, Nurse Diltz's action broke the causal connection between Abbott's original wrong and Wright's injury. See Budden, 15 F.3d at 1449.

Motion for Reconsideration

The Court uses an abuse of discretion standard when it reviews a district court’s decision to deny a motion for reconsideration. See Matosantos Commercial Corp. v. Applebee's Intern., Inc., 245 F.3d 1203, 1213 (10th Cir. 2001) (citation omitted). Under an abuse of discretion standard, “a trial court's decision will not be disturbed unless the

⁵ In fact, the hospital continues to this day to handle and dilute 14.6% sodium chloride solutions in the manner it did prior to the lawsuit.

appellate court has a definite and firm conviction that the lower court made a clear error of judgment or exceeded the bounds of permissible choice in the circumstances.” See Phelps v. Hamilton, 122 F.3d 1309, 1324 (10th Cir. 1997). That is to say, we will not alter a trial court’s decision unless it can be shown that the court’s decision was “an arbitrary, capricious, whimsical, or manifestly unreasonable judgment.” See Brown v. Presbyterian Healthcare Serv., 101 F.3d 1324, 1331 (10th Cir. 1996).

In the instant case, the district court denied the Wrights’ Motion to Supplement Appendix and their Motion for Leave to File Surreply. The Wrights asked the court to reconsider and the court declined. In the one paragraph argument the Wrights makes on appeal, they contend that “[s]ince it is apparent that the district court considered [their] Surreply and Supplemental Appendix in ruling on [Abbott’s] summary judgment motion, the district court erred in failing to grant [their] Motion for Reconsideration.”

Although the district court considered the Wrights’ Surreply and Supplemental Appendix, it found that they did not preclude summary judgment for Abbott. Thus, the court did not include the Wrights’ Surreply or Supplemental Appendix in its record. The Wrights complained about this omission, but the district court found their complaints to be without merit.

We agree with the district court. Failure to add materials to a record cannot rise to an abuse of discretion when the materials in question have no effect on a case's outcome.

CONCLUSION

For the foregoing reasons, we AFFIRM the district court's granting of summary judgment.