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In the
Indiana Supreme Court

No. 49S04-0902-CV-88

JIM KOVACH AND JILL KOVACH,

INDIVIDUALLY AND ON BEHALF OF
DECEASED MINOR CHILD,
MATTHEW KOVACH,

Appellants (Plaintiffs below),

v.

CALIGOR MIDWEST, ET AL.,

Appellees (Defendants below).

Appeal from the Marion Superior Court, No. 49D11-0407-PL-001227
The Honorable John F. Hanley, Judge

On Petition To Transfer from the Indiana Court of Appeals, No. 49A04-0707-CV-406

September 8, 2009

Boehm, Justice.

The plaintiffs allege their son was given a fatal overdose of pain medication by a nurse after a surgical procedure. The plaintiffs sued the manufacturers and distributors of the medicine cup used to administer the medication, alleging defects in design of the cup and failure to warn that the cup was not suitable for precision measurement. We affirm summary judgment in favor of these defendants because these claimed defects did not cause the death. The undisputed facts establish that if an overdose caused the death it was due to a quantity of drug essentially double the prescribed amount. None of the claimed defects in the cup would have caused an overdose of that magnitude.

Facts and Procedural History

Nine-year-old Matthew Kovach was diagnosed with an enlargement of nasal tissue causing congestion, mouth-breathing, and impaired dental development. In August 2002 Matthew underwent surgery and was prescribed 15 milliliters (mL) of acetaminophen with codeine for pain following the procedure. In the post-anesthesia care unit of the surgical center, a nurse administered a dosage of the medication, a light red liquid, using a medicine cup made of

flexible, translucent plastic with a volume of just over 30 mL. The interior of the cup bore translucent markings to measure its contents, and graduations delineated both 15 and 30 mL. The nurse had used that type of cup frequently both at this surgical center and at other hospitals, and she had no difficulty reading its markings. The nurse testified she filled the cup approximately half-way and administered 15 mL of medication to Matthew. According to Matthew's father, who was present when the drug was administered, the nurse gave Matthew a full cup of medicine.

Matthew was discharged from the recovery unit and sent home with his mother. He took no additional medication after leaving the surgical center. That afternoon Matthew went into respiratory arrest and was brought to Bloomington Hospital where he was later pronounced dead of asphyxia. An autopsy identified the cause of death as an opiate overdose, and revealed that Matthew had between 280 and 344 nanograms/mL of codeine in his bloodstream, more than twice the recommended therapeutic level.

Matthew's parents sued, among others, the manufacturers[1] and a distributor of the medicine cup (collectively the "Cup Defendants"). Their complaint set forth several causes of action against the Cup Defendants including strict liability and negligence under the Products Liability Act, breach of implied warranty of fitness for a particular purpose, and breach of implied warranty of merchantability. The thrust of these counts was that Matthew's overdose was caused by an imprecise measurement of codeine resulting from defects in the medicine cup. The Cup Defendants moved for summary judgment on all claims, arguing among other things that the undisputed facts revealed no causal connection between the cup's alleged defects and Matthew's overdose.

The Kovachs responded to the Cup Defendants' motion for summary judgment by designating the affidavit of Dr. James O'Donnell, a pharmacist and associate professor of pharmacology. Dr. O'Donnell analyzed the physical characteristics of the medicine cup, found it was not suitable for precision measurement, and concluded that the cup should have provided a

[1] The manufacturer defendants argue that they are entitled to summary judgment because the Kovachs cannot identify the manufacturer of the cup at issue in this case. The Kovachs respond that their complaint alleged these defendants were "manufacturers" under the Product Liability Act, and that the defendants failed to designate any evidence to refute the allegations. In light or our resolution of this case in favor of the defendants, we need not address this issue.

corresponding warning. For purposes of his affidavit, Dr. O'Donnell assumed that the cup "was full when [the nurse] administered Capital with Codeine to Matthew." He opined that Matthew's overdose was "a medication error caused by Codeine being administered at a wrong dose" and the overdose "[r]esulted from using the [c]up as a volume measuring device for [p]recision [m]easurement." The Cup Defendants deposed Dr. O'Donnell after receiving his affidavit. He elaborated on the contents of his affidavit and also estimated that measurements performed using the medicine cup posed a 20% to 30% margin of error.

The Cup Defendants moved to exclude Dr. O'Donnell's testimony as unfounded and irrelevant. They also submitted a joint reply brief in support of summary judgment in which they cited portions of Dr. O'Donnell's deposition. The trial court denied the motion to exclude but nonetheless granted summary judgment in favor of the Cup Defendants.

The Kovachs appealed the summary judgment ruling, and the Cup Defendants cross-appealed the denial of their motion to exclude. The Court of Appeals reversed in part, holding that (1) the trial court did not abuse its discretion in admitting Dr. O'Donnell's affidavit, and (2) genuine issues of fact precluded summary judgment on the Kovach's claims against the Cup Defendants. Kovach v. Alpharma, Inc., 890 N.E.2d 55, 72 (Ind. Ct. App. 2008). On the issue of proximate cause relevant to all theories of liability, the Court of Appeals held that "the missing warning is in essence a presumption of causation." Id. at 71 (citing Ortho Pharm. Corp. v. Chapman, 180 Ind. App. 33, 55, 388 N.E.2d 541, 555 (1979)). In addition, the court expressly refused to consider Dr. O'Donnell's deposition testimony in connection with the summary judgment motion, stating that the evidence was never designated to the trial court during the summary judgment proceedings. Id. at 65. Chief Judge Baker dissented, finding that the Kovachs had failed to establish that the cup's alleged defects were the proximate cause of Matthew's death. Id. at 72. We granted transfer.

Standard of Review

We review a summary judgment order de novo. Atterholt v. Herbst, 902 N.E.2d 220, 222 (Ind. 2009), clarified on reh'g, 907 N.E.2d 528 (Ind. 2009). Considering only those facts supported by evidence that the parties designated to the trial court, we must determine whether there is a "genuine issue as to any material fact" and whether "the moving party is entitled to a

judgment as a matter of law." Ind. Trial Rule 56(C); Dreaded, Inc. v. St. Paul Guardian Ins. Co., 904 N.E.2d 1267, 1269–70 (Ind. 2009). We construe all factual inferences in the non-moving party's favor and resolve all doubts as to the existence of a material issue against the moving party. Id.

Discussion

The Kovachs assert four claims against the Cup Defendants, described as strict products liability and negligent products liability under the Indiana Product Liability Act ("PLA"), and breach of implied warranty of merchantability and breach of implied warranty of fitness for a particular purpose under the Uniform Commercial Code ("UCC"). The Court of Appeals concluded that the UCC and PLA provide "alternative remedies," and it therefore entertained all four of the Kovachs' claims as separate theories. Kovach v. Alpharma, Inc., 890 N.E.2d at 67. This Court has never addressed whether the PLA preempts warranty-based theories of recovery for physical harm, but several federal district courts and other panels of the Court of Appeals have held that tort-based breach-of-warranty claims have been subsumed into the PLA. See, e.g., Cincinnati Ins. Cos. v. Hamilton Beach/Proctor-Silex, Inc., No. 4:05 CV 49, 2006 WL 299064, at *3 (N.D. Ind. Feb. 7, 2006); N.H. Ins. Co. v. Farmer Boy AG, Inc., No. IP 98-0031-C-T/G, 2000 WL 33125128, at *3 (S.D. Ind. Dec. 19, 2000); Condon v. Carl J. Reinke & Sons, Inc., 575 N.E.2d 17, 18 (Ind. Ct. App. 1991). To the extent they are separate theories, the plaintiffs' claims all require proof that the injury sustained was proximately caused by the alleged product defect. Ford Motor Co. v. Rushford, 868 N.E.2d 806, 810 (Ind. 2007) (as to strict liability and negligence in products liability); James J. White & Robert S. Summers, Uniform Commercial Code § 9-7 (5th ed. 2000) (as to breach of implied warranty of merchantability); 63 Am. Jur. 2d Products Liability § 724 (1997) (as to implied warranty of fitness for a particular purpose). We find the causation issue in this case dispositive as to all causes of action. We therefore do not resolve the relationship between the PLA and the UCC today, as that issue is directly raised only by amici, and presented obliquely, if at all, by the

parties. We also do not address several collateral issues that the parties have raised in this appeal.[2]

"Proximate cause" has two components: causation-in-fact and scope of liability. City of Gary ex rel. King v. Smith & Wesson Corp., 801 N.E.2d 1222, 1243–44 (Ind. 2003). To establish factual causation, the plaintiff must show that but for the defendant's allegedly tortious act or omission, the injury at issue would not have occurred. Id. The scope of liability doctrine asks whether the injury was a natural and probable consequence of the defendant's conduct, which in the light of the circumstances, should have been foreseen or anticipated. Id. at 1244. Liability is not imposed on the defendant if the ultimate injury was not reasonably foreseeable as a consequence of the act or omission. Id. Causation-in-fact is ordinarily a factual question reserved for determination by the jury. Id. at 1243–44. However, where reasonable minds cannot disagree as to causation-in-fact, the issue may become a question of law for the court. Peters v. Forster, 804 N.E.2d 736, 743 (Ind. 2004).

The plaintiffs argue that if the medicine cup had been better suited as a precision measuring device or had contained a warning that it was not suitable for precision measurement, Matthew would not have received an overdose. We agree with Chief Judge Baker that the undisputed facts establish that there is no such causal connection. There is a dispute as to whether the 30-mL cup was full or half-full, but the following facts are not contested. Matthew was prescribed 15 mL of codeine after surgery. The nurse used a medicine cup to dispense the medication. She had extensive experience with the cup and had no difficulty in identifying its markings. A half-cup of medication would have contained approximately 15 mL. A full cup

[2] There are several collateral issues in connection with Dr. O'Donnell's affidavit and deposition testimony. The defendants moved to exclude Dr. O'Donnell's testimony as unreliable, unspecialized, speculative, and irrelevant. At the same time, they apparently cited several portions of Dr. O'Donnell's deposition in various subsequent filings. The Kovachs purport to stand by their expert and the competence of his opinions, yet they insist that Dr. O'Donnell's deposition testimony was not properly designated to the trial court and is off limits for purposes of summary judgment. Our analysis of the proximate cause issue in this case moots the defendants' motion to exclude. As for the O'Donnell deposition, we are unable to evaluate the sufficiency of the defendants' designation, as no party has included the pertinent summary judgment materials in the appellate appendix. In any event, we are able to decide this case on the basis of evidence that was undisputedly designated, and we reach the same result whether or not the O'Donnell deposition is considered as well.

would have contained approximately 30 mL or slightly more. The cup was translucent, and acetaminophen with codeine is a red liquid. The nurse knew that she was supposed to administer a half-cup of medication, and anyone observing her could see whether the cup was half full or completely full. Matthew's father asserts that he was present and saw that it was in fact full. The Kovachs contend Matthew's death was caused by a full, 30-mL cup of codeine. The results of the autopsy revealed that Matthew had more than twice the recommended therapeutic level of codeine in his blood stream. The undisputed evidence thus demonstrates that if there was an overdose in this case, it was not caused by an imprecise measurement of medication attributable to less than readily discernible marks. Rather, if the codeine was the cause of Matthew's death, it was due to an erroneous double dosage of 30 mL of codeine when Matthew was supposed to receive 15 mL. The accident therefore cannot be attributed to any alleged defects in the cup itself.

For the foregoing reasons, we need not consider Dr. O'Donnell's deposition to resolve this case. We note, however, that our conclusion is further supported by Dr. O'Donnell's testimony. Dr. O'Donnell estimated that the cup's imprecision could result in up to a 20% to 30% margin of error. But Matthew had over twice the recommended level of codeine in his bloodstream when he died. So even if we assume the nurse administered the correct 15-mL dosage of codeine, the cup's imprecision would at most result in an overdose of only 30% and could not account for the 100% excess level of codeine discovered in the autopsy.

The Kovachs also assert a failure to warn against the cup's use for precision measurement. We do not address whether any such warning is required in this or any other circumstance because, even if given, it would not have prevented the injury here. Any claimed failure to warn that the cup was unsuitable for use in "precise" measurements had no effect on a double dose which was known to be improper. In holding that the cup's missing warning created "a presumption of causation," the Court of Appeals relied primarily on language from Ortho Pharmaceutical Corp. v. Chapman, 180 Ind. App. at 55, 388 N.E.2d at 555. In Ortho, the plaintiff developed thrombophlebitis after taking an oral contraceptive manufactured by the defendant and prescribed by her doctor. Id. at 58, 388 N.E.2d at 557. She sued the manufacturer alleging negligence, strict liability, and breach of warranty. Id. at 35–36, 388 N.E.2d at 544. The plaintiff claimed that the manufacturer published inadequate and misleading warnings about

the relationship between the contraceptive and development of thrombophlebitis. Id. at 52, 388 N.E.2d at 554. In the course of discussing the issue of proximate cause, the Court of Appeals explained that there exists "a presumption that an adequate warning would be heeded. This operates to the benefit of a manufacturer where adequate warnings in fact are given. Where warnings are inadequate, however, the presumption is in essence a presumption of causation." Id. at 55, 388 N.E.2d at 555 (citing Restatement (Second) of Torts § 402A cmt. j (1965)).

Ortho was merely following the prevailing view that in a failure-to-warn case, the plaintiff is not required to establish that he would have read the warning and taken the steps to avoid injury. See Nissen Trampoline Co. v. Terre Haute First Nat'l Bank, 332 N.E.2d 820, 826–27 (Ind. Ct. App. 1975), rev'd on procedural grounds, 265 Ind. 457, 358 N.E.2d 974 (1976); 2 Dan B. Dobbs, The Law of Torts § 367 (2001) ("Perhaps the best ground for invoking the presumption is that the plaintiff could seldom prove convincingly that he would have read a warning, so that the manufacturer's duty to warn would be effectively avoided in almost all cases."). But the "read-and-heed" presumption does not completely dispose of the causation issue in a failure-to-warn case. The most the presumption does is establish that a warning would have been read and obeyed. It does not establish that the defect in fact caused the plaintiff's injury. The plaintiff invoking the presumption must still show that the danger that would have been prevented by an appropriate warning was the danger that materialized in the plaintiff's case. See 2 Dobbs, supra, § 367 ("The plaintiff who is not properly warned that asbestos can cause respiratory disorders must show . . . that she in fact has such a disorder resulting from asbestos exposure. . . . [T]he injury suffered must be within the class of injury that the warning requirement was meant to avoid."); 1 David G. Owen, M. Stuart Madden & Mary J. Davis, Madden & Owen on Products Liability § 9:11 (3d ed. 2000) (even where the read-and-heed presumption applies, "pivotal to the successful maintenance of plaintiff's claim of actionable failure to warn is the demonstration that the seller's failure to warn adequately of the hazard was a cause-in-fact and a proximate cause of the injury").

Here, the Kovachs claim that the medicine cup should have borne a warning that it was not designed for precision measurement. If we apply the read-and-heed presumption, then we must assume the nurse would have read such a warning and chosen a precision applicator to administrate the codeine. But as explained above, Matthew's overdose was not the result of

imprecise measurement. If the overdose was the cause of death, it was due to mistaken dispensation of a full cup, a 30-mL double dosage, by a nurse who knew that a half cup, 15 mL, was the proper dosage. Matthew's death was not factually caused by the danger that a warning against use of the cup for precision measurement would have addressed, and the accident would not have been avoided if any such warning had been given.

Conclusion

For the foregoing reasons, the Cup Defendants have established that Matthew's death was not caused by the alleged defects in their product. The judgment of the trial court granting summary judgment in favor of the Cup Defendants is affirmed.

Shepard, C.J., and Dickson, Sullivan, and Rucker, JJ., concur.