IN THE UNITED STATES DISTRICT COURT

FOR THE WESTERN DISTRICT OF WISCONSIN

DENISE CHLOPEK
and JARON CHLOPEK,

Plaintiffs,

v.

MEMORANDUM AND ORDER
05-C-545-S

FEDERAL INSURANCE COMPANY
and BREG, INC.,

Defendants.

Plaintiffs Denise and Jaron Chlopek commenced this products liability action in the Circuit Court for Eau Claire County, Wisconsin, alleging that Denise Chlopek suffered a thermal burn injury to her great toe because of a defect in a Polar Care unit manufactured and sold by defendant Breg, Inc. Defendants removed the matter to this Court based on diversity of citizenship, 28 U.S.C. § 1332. The matter is presently before the Court on defendants' motion for summary judgment. The following is a summary of relevant, undisputed facts.

FACTS

Defendant Breg manufactures and sells a medical cooling device called Polar Care 300. The Polar Care 300 consists of a small beverage cooler which is filled with ice water, and a hose and pump which circulates the chilled water to a connected pad which is

wrapped around the area to be treated. The Polar Care 300 is sometimes used to control post-operative swelling. The following warnings were affixed to the Polar Care 300 cooler provided to plaintiffs:

! WARNING

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE FOR SALE BY OR ON THE ORDER OF A LICENSED HEALTH CARE PRACTITIONER.

WARNING: CAREFULLY READ USE INSTRUCTIONS AND WARNINGS BEFORE OPERATION.

WARNING: ALWAYS APPLY A DRESSING OR OTHER MOISTURE BARRIER BETWEEN THE PAD AND THE PATIENT'S SKIN.

WARNING: A LICENSED HEALTH CARE PRACTITIONER MUST CONSIDER EACH PATIENT'S SENSITIVITY TO COLD. A PERIODIC INSPECTION OF THE PATIENT'S SKIN UNDER THE PAD IS RECOMMENDED. IF A NOTICEABLE CHANGE IN SKIN APPEARANCE IN THE AREA OF THE COLD APPLICATION IS OBSERVED SUCH AS BURNING, ITCHING, BLISTERING, DISCOLORATION, OR INCREASED SWELLING MORE THAN AN HOUR AFTER USE, DISCONTINUE USE OF THIS PRODUCT AND CONSULT PHYSICIAN IMMEDIATELY. ALWAYS APPLY SKIN BARRIER OR DRESSING BETWEEN THE PAD AND THE PATIENT'S SKIN. CAUTION SHOULD BE TAKEN DURING PROLONGED USE FOR CHILDREN, DIABETICS INCAPACITATED PATIENTS, AND THOSE WITH DECREASED SKIN SENSITIVITY OR POOR CIRCULATION.

On May 31, 2002 podiatrist Andrew Pankratz performed fusion surgery on plaintiff Denise Chlopek's great right toe. Following surgery Pankratz prescribed the use of a Polar Care 300. A barrier was placed between the Polar Care pad and the plaintiff's skin and the foot was wrapped with the pad inside. Pankratz' nurse instructed plaintiff to leave the unit on until she returned to see Pankratz. Plaintiff used the Polar Care unit continuously for 240 hours, except when it was disconnected to eat or use the bathroom.

When she returned on June 10, 2002 her right great toe had become ischemic and developed eschar. The toe was amputated on July 18, 2002.

MEMORANDUM

Defendants move for summary judgment asserting that plaintiffs lack sufficient evidence, particularly expert testimony, of negligence or causation to support a claim. Plaintiffs contend that the evidence and expert testimony is sufficient to support a claim that the defendants' product was defective, and that defendants were negligent because they failed to warn users that prolonged continuous use of the Polar Care 300 was dangerous.

Summary judgment is appropriate when, after both parties have the opportunity to submit evidence in support of their respective positions and the Court has reviewed such evidence in the light most favorable to the nonmovant, there remains no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. Rule 56(c), Fed. R. Civ. P. A fact is material only if it might affect the outcome of the suit under the governing law. Disputes over unnecessary or irrelevant facts will not preclude summary judgment. A factual issue is genuine only if the evidence is such that a reasonable factfinder, applying the appropriate evidentiary standard of proof, could return a verdict for the nonmoving party. Anderson v. Liberty Lobby, Inc., 477 U.S.

242, 254 (1986). Under Rule 56(e) it is the obligation of the nonmoving party to set forth specific facts showing that there is a genuine issue for trial.

For purposes of the present motion, the issues are whether there is sufficient evidence to support a finding that the Polar Care 300 was defective because it failed to warn against long term continuous use and whether there is evidence that the absence of a warning caused plaintiffs' injuries. The evidence is sufficient on both elements to survive this summary judgment challenge.

As an initial matter defendants seek to preclude consideration of certain proffered expert opinions on the basis that they are untimely. In accordance with Rule 26(a)(2) plaintiffs' disclosures were due on January 24, 2006. Defendants now vigorously object to supplemental affidavits offered on February 10, 2006. Apart from hyperbole concerning the evils of failing to comply with a deadline, defendants make no suggestion that the minor delay had any adverse effect on either their preparation of the case or their ability to pursue the summary judgment motion. Accordingly, to the extent that the presentation of expert testimony was outside the deadline, such delay was harmless and does not justify exclusion of the evidence from consideration on summary judgment.

Plaintiffs assert that defendant Breg was negligent in failing to warn that continuous, prolonged use of the Polar Care 300 was potentially dangerous. In support of their position plaintiffs

offer the affidavit of expert Lee Sapetta who opines that omitting such a warning is negligent and renders the product unreasonably dangerous, particularly in light of the fact that the user will be anesthetized by the cold in the area of use and therefore will be unlikely to become aware of tissue damage. Sappetta also bases his opinion on the fact that a contemporaneous product manufactured by defendant Breg at the time, the Polar Care 500, expressly warned against prolonged use at cold temperatures. This evidence is sufficient to create a fact issue on the sufficiency of the product warnings and precludes summary judgment.

Two discrete causation issues have been advanced by defendants. First, whether the evidence is sufficient to prove that prolonged use of the Polar Care 300 caused damage to plaintiff's toe. Second, whether there is sufficient evidence that the presence of a warning against prolonged use would have caused plaintiffs to alter their behavior. Concerning the first issue, plaintiffs' treating physician, Dr. Pankratz, opines to a reasonable degree of probability that the continuous cold therapy was a substantial factor in causing thermal injury to the toe and the subsequent amputation. This opinion is consistent with medical records prepared by Pankratz contemporaneously with his observation of the toe. Combined with plaintiffs' testimony concerning the long term continuous application of the Polar Care 300, there is sufficient evidence to create a fact issue concerning whether the

use of the device was a substantial factor in causing the amputation. Although there is evidence of other possible causative factors which may allow defendants to prevail on the causation issue at trial, the evidence is not sufficient to entitle defendants to prevail as a matter of law on summary judgment.

Concerning the second causation issue, defendants argue that plaintiffs, having conceded that they relied exclusively on the advice of their medical providers and did not consider the existing warnings, would not have heeded a warning against continuous use. Plaintiffs bear the burden to prove that had they been properly warned they would have altered their behavior. Kurer v. Parke, Davis & Co., 2004 WI App 74, ¶ 25, 272 Wis.2d 390, 679 N.W.2d 867. However, defendants' characterization of Jaron Chlopek's testimony in support of plaintiffs' motion does not withstand scrutiny. Jaron Chlopek's testimony is consistent with, and in fact assumes, that he had read the product label. Jaron Chlopek's subsequent affidavit stating that he read and followed the use instructions on the cooler is consistent with his deposition testimony.

He testified that the label warning suggesting that the skin be inspected was not applicable because he had been expressly instructed not to remove the dressing on the foot. However, such testimony does not conclusively prove that he would have disregarded a warning against continuous use, particularly because the discharge instruction not to remove the dressing was clear,

while the instruction to use the device continuously was ambiguous. Furthermore, the language of the inspection warning is a mere recommendation ("A PERIODIC INSPECTION OF THE PATIENT'S SKIN UNDER THE PAD IS RECOMMENDED") which a user would be expected to ignore where it directly conflicted with instructions from the medical care provider. In contrast, it seems probable that he would have asked the nurse about continuous use had he been confronted with an express warning against it. Defendants' contention that plaintiffs would have ignored a warning against continuous use may persuade the jury, but it does not entitle them to summary judgment.

ORDER

IT IS ORDERED that defendants' motion for summary judgment is DENIED.

Entered this 1st day of March, 2006.

BY THE COURT:
S/

JOHN C. SHABAZ
District Judge