

MICHAEL V. WARNER/CHILCOTT, 1978-NMCA-043, 91 N.M. 651, 579 P.2d 183 (Ct. App. 1978)

**Kaiser MICHAEL, Jr., Plaintiff-Appellee,
vs.**

WARNER/CHILCOTT, a Division of Warner Lambert Company, a Foreign Corporation, Davis Brothers Drug Company, Amfac Drug Supply, Ted Sanderson, a Representative of Warner/Chilcott, Defendants, and Skaggs Drug Centers, Inc., a Foreign Corporation, Byrne Cates, a Representative of Skaggs Drug Centers, Inc., Defendants-Appellants; McKesson ROBBINS, a Foreign Corporation, and Foremost-McKesson, a Foreign Corporation, Defendants and Third-Party Plaintiffs-Appellants, v. REVLON, INC., a Foreign Corporation, successor corporation to Nysco Laboratories, Inc., a Foreign Corporation, Third-Party Defendant, and U.S. Nuclear, Inc., a Foreign Corporation, successor corporation to Strong, Cobb, Arner, Inc., a Foreign Corporation, Third-Party Defendant-Appellant.

No. 3133

COURT OF APPEALS OF NEW MEXICO

1978-NMCA-043, 91 N.M. 651, 579 P.2d 183

April 18, 1978

Petition for Writ of Certiorari Denied May 11, 1978

COUNSEL

William Booker Kelly, White, Koch, Kelly & McCarthy, Santa Fe, for appellants.

William E. Snead, Ortega & Snead, Steven P. Michael, Albuquerque, for appellee.

JUDGES

SUTIN, J., wrote the opinion. HERNANDEZ, J., specially concurring. LOPEZ, J., concurs.

AUTHOR: SUTIN

OPINION

{*652} SUTIN, Judge.

{1} This is an interlocutory appeal granted defendant McKesson-Robbins, Foremost-McKesson, Skaggs Drug Centers, and third party defendant, U.S. Nuclear, Inc. These parties will be designated as defendants. The trial court denied defendants' motion for summary judgment and defendants' appeal. We affirm.

A. Facts.

{2} Plaintiff suffered with sinus congestion symptoms since about 1952. Over the years, he took a variety of medicines as initially prescribed by physicians. Around 1965, his physician prescribed "Sinutab" in writing to be ingested four a day on a daily basis. Plaintiff purchased this over-the-counter drug at Skaggs. He read the dosage requirements, the precautions and the printed literature on the label. He saw his doctor intermittently until 1970.

{3} In 1970, plaintiff went to Skaggs to make another purchase of "Sinutabs" and was informed by the cashier that Skaggs had their own house brand called "Sinus Congestion Tablets." Plaintiff compared the ingredients on the label with those of "Sinutab" and determined that they were identical and purchased the bottle of "Sinus Congestion Tablets." On the front of the label is the name of Skaggs, Sinus Congestion Tablets, and the ingredients. One of the ingredients is phenacetin, a dangerous drug. The left side of the label is titled "SOLD WITH MONEY BACK GUARANTEE" and contains the "DOSAGE." On the right side, are "CAUTION" and "WARNING," the contents of which appear in small letters. A copy of the label is attached as Appendix "A".

{4} The "WARNING" reads:

This medication may damage the kidneys when used in large amounts or for a long period of time. Do not take more than the recommended dosage, nor take regularly for longer than 10 days without consulting your physician. KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN. IN CASE OF ACCIDENTAL OVERDOSE, CONTACT A PHYSICIAN IMMEDIATELY. [Emphasis added.]

{5} Plaintiff read the label. He did not recall reading either side of the label **while he was taking the drug**. He thought that if he had noted that kind of warning he would have consulted a doctor. He saw his personal physician intermittently with reference to his sinus and allergy problems and thought his doctor knew of his dosage of Sinus Congestion Tablets. {*653} He did not rely on the warning. He did not think an over-the-counter drug was harmful.

{6} Plaintiff continued ingestion of this over-the-counter drug, four a day, on a regular daily basis, until April, 1973, when his kidney failure was first diagnosed. Plaintiff's physician ordered him to stop all medication.

B. Only claim on appeal is ordinary negligence.

{7} Plaintiff filed a second amended complaint in which he sought damages from these defendants and other arising out of the manufacture and sale of "Sinutabs" and "Sinus Congestion Tablets." The complaint was fashioned in the alternative, strict liability and ordinary negligence.

{8} On the issue of strict liability, plaintiff claimed that he ingested various quantities of these tablets that were in a defective condition and unreasonably dangerous when ingested; that this defective condition was a proximate cause of damage to his kidneys.

{9} In the alternative, plaintiff claimed defendants were jointly and severally negligent in the manufacture and sale of the products and breached their duty to plaintiff.

{10} Defendant filed a motion for summary judgment. A hearing was held. No record of the hearing was made. We are without assistance of oral arguments made below, the briefs filed with the court, or any comments made by the hearing judge.

{11} Plaintiff says that defendants' contention on this appeal ignores plaintiff's claims. One claim is **failure to adequately warn plaintiff**, as an ordinary consumer of this over-the-counter drug product, of the danger that long term ingestion of the drug, (as compounded to include phenacetin), will cause permanent, severe, life shortening kidney disease. The other claim is that defendants are liable to plaintiff under both negligence and strict liability **irrespective of any warnings provided**.

{12} The trial court found "that it **cannot** conclude as a matter of law that the warnings furnished by defendants on 'Sinus Congestion Tablets'... **did constitute as a matter of law adequate warnings as to the use of Sinus Congestion Tablets to preclude liability of these defendants** and that therefore the motion should be denied."
[Emphasis added.]

{13} With respect to plaintiff's claim on strict liability, the finding of the trial court on lack of adequate warning is not applicable. This means that defendants' motion for summary judgment was denied on plaintiff's claim of negligence, and not on the claim of strict liability, and this latter claim is not an issue on this appeal.

{14} We feel obliged to accept plaintiff's contention. In a complex, complicated case in which summary judgment is granted or denied, the burden is on the losing party to delineate the proceedings in the court below, preserve a record of the hearing, the comments of the court and seek a clear ruling on the issues involved and determined. Otherwise, on appeal, we shall use any reasonable basis disclosed by the record to uphold the order of the trial court.

C. A genuine issue of material fact exists on adequacy of warning.

{15} This matter is before us on denial of defendants' motion for summary judgment. The finding of the trial court is limited in scope and poorly worded. We read it to mean:

In the negligence claim, the warning given did not, as a matter of law, contain sufficient information "as to the use of Sinus Congestion Tablets" to preclude liability of defendants; that a genuine issue of material fact exists as to the adequacy of the warning.

{16} Defendants added a new section to the Brief-in-Chief entitled "Statement of Facts." Here defendants argue that plaintiff didn't bother to read the full label on Sinutabs; that if there was a warning, he did not rely on it; that when suit was filed, plaintiff was under the impression there was no warning on the label of "Sinus Congestion Tablets"; {654} that if he had read the warning he would have quit using the tablets or asked the doctor about it. These are matters that relate to the conduct of plaintiff and bear upon his contributory negligence. They may test the credibility of plaintiff. These facts, however, do not relate to the issue of the adequacy of the warning given.

{17} Defendants argue that the serious abuse of the product "is so extreme as to be almost beyond belief." Upon what basis this exaggeration is stated, we do not know. Defendants do not point to any evidence that plaintiff ingested more than the recommended dosage. Perhaps defendants mean that plaintiff took these tablets regularly for more than 10 days without consulting a physician. This fact, if true, does not bear upon the adequacy of the warning. It may constitute a factor relative to contributory negligence of the plaintiff.

{18} The burden is on the defendants, not the plaintiff, to show an absence of a genuine issue of material fact, or that they were entitled as a matter of law, for some other reason, to a summary judgment in their favor. **Goodman v. Brock**, 83 N.M. 789, 498 P.2d 676 (1972).

{19} The only evidence presented by defendants is a regulation adopted under the Federal Food and Drug and Cosmetic Act of 1938, the contents of which appear on the label, and that there has never been a change in the label on the Skaggs Sinus Congestion Tablets. Apart from the regulation, we can find nothing that bears upon the adequacy of the warning. Neither do we find a discussion of the meaning of an adequate warning.

{20} The warning on the label was adopted verbatim from the warning promulgated by FFDC in 1964. The regulation is still in effect. 21 C.F.R. § 201.309 (1977). Defendants cite no authority to support a contention that this warning is adequate as a matter of law. In fact, it is not.

{21} The Federal Act does not purport to change the common-law duty to warn. It is evidence on the issue of negligence, but it does not mean that the defendant is free of negligence. **Rumsey v. Freeway Manor Minimax**, 423 S.W.2d 387 (Tex. Civ. App.1968). "The Defendant still owes a duty to warn of dangers of which it knew or

should have known in the exercise of reasonable care." **Stromsodt v. Parke-Davis and Company**, 257 F. Supp. 991, 997 (D.N.D.1966), aff'd 411 F.2d 1390 (8th Cir. 1969); **Love v. Wolf**, 226 Cal. App.2d 378, 38 Cal. Rptr. 183 (1964).

{22} Statutes and regulations of these agencies merely set minimum standards. **Rumsey**, supra; **Whitley v. Cubberly**, 24 N.C. App. 204, 210 S.E.2d 289 (1974); **Stevens v. Parke, Davis & Company**, 9 Cal.3d 51, 107 Cal. Rptr. 45, 507 P.2d 653 (1973); **Incollingo v. Ewing**, 444 Pa. 263, 282 A.2d 206 (1971).

{23} We hold that a warning adopted verbatim from a regulation promulgated by a federal or state agency does not constitute an adequate warning as a matter of law.

{24} Defendants rely on **Garrett v. Nissen Corporation**, 84 N.M. 16, 498 P.2d 1359 (1972); **Hines v. St. Joseph's Hospital**, 86 N.M. 763, 527 P.2d 1075 (Ct. App.1974); and **Skyhook Corporation v. Jasper**, 90 N.M. 143, 560 P.2d 934 (1977). These cases are product liability cases related to plaintiff's claim of strict liability.

{25} Defendants have not met the burden placed upon them by the Order that denied them summary judgment on plaintiff's claim of ordinary negligence.

{26} What is an adequate warning on a drug label? "Adequate" is defined as "sufficient for a specific requirement." **Nissen v. Miller**, 44 N.M. 487, 490, 105 P.2d 324, 326 (1940) says:

The word "sufficient" is defined to mean adequate, enough, equal to the end proposed, and that which may be necessary to accomplish an object; it embraces no more than that which furnishes a plenitude, which, when done, suffices to accomplish the purpose intended in light of present conditions and viewed through the eyes of practical and cautious men.

{*655} {27} "Warning" is defined to mean previous notice; caution against danger. **Antonian v. Southern Pac. Co.**, 9 Cal. App. 718, 100 P. 877 (1909). The purpose of a "warning" is to apprise a party of the existence of danger of which he is not aware to enable him to protect himself against it, and where the party is aware of the danger, the warning will serve no useful purpose and is unnecessary, and there is no duty to warn against risks which are open and obvious. **Wiseman v. Northern Pac. Ry. Co.**, 214 Minn. 101, 7 N.W.2d 672 (1943).

{28} An "ample warning" has been stated as a warning that would discharge the duty of reasonable care or fully sufficient to apprise those entitled thereto. **City Ice & Fuel Co. v. Center**, 54 Ohio App. 116, 6 N.E.2d 580 (1936).

{29} A "reasonable warning" is one which is reasonable under the circumstances, by one exercising ordinary care under the circumstances. **Olney v. Kansas City Public Service Co.**, 19 S.W.2d 534 (Mo. App.1929).

{30} In **First Nat. Bk., Albuquerque v Nor-Am Agr. Prod., Inc.**, 88 N.M. 74, 537 P.2d 682 (Ct. App.1975) summary judgment was granted. Two theories of recovery were sought by plaintiff against defendant:

(1) Negligence as to the warning, provided by the seller, of dangers associated with the use of the seller's product;

(2) Special liability of the seller of a product for physical harm to a user or consumer, pursuant to Restatement, Torts, 2d § 402A, v. 2 (1965), at 347-348. [88 N.M. at 79, 537 P.2d at 687.]

{31} In reversing the case, we held that adequacy of the warning given by a manufacturer in a negligence action presents an issue of fact for the jury. In making this determination, we said:

The warning must adequately indicate the scope of the danger.

* * * * *

"The warning must reasonably communicate the extent or seriousness of harm that could result from the danger * *"

* * * * *

The physical aspects of the warning -- conspicuousness, prominence, relative size of print, etc., -- must be adequate to alert the reasonably prudent person. [88 N.M. at 83-84, 537 P.2d at 691.]

{32} From this potpourri, we hold that an "adequate warning" in this case means a notice placed on a label of "Sinus Congestion Tablets," reasonably readable, that appries a consumer exercising reasonable care under the circumstances, of the existence and seriousness of the danger, sufficient to enable the consumer to protect himself against it, and sufficient to accomplish the purpose intended by the seller in the light of present conditions.

{33} The "warning" given by defendants states that "This medication **may** damage the kidneys." [Emphasis added.] It does not apprise the consumer of the fact that it **will** damage the kidneys. It states "when used in **large** amounts." [Emphasis added.] The term "large" is vague and indefinite to a consumer. It does not state that "Phenacetin" is a dangerous drug. The lettering is so tiny it might require a consumer to read the words with a magnifying glass.

{34} As a result, we conclude that a genuine issue of material fact exists on the adequacy of the warning.

{35} Affirmed.

{36} IT IS SO ORDERED.

HERNANDEZ, J., specially concurring.

LOPEZ, J., concurs.

SPECIAL CONCURRENCE

HERNANDEZ, Judge (specially concurring).

{37} I concur in the result only. I consider that plaintiff has not raised an issue of fact concerning the adequacy of the warning, Appendix to follow Judge Sutin's Opinion.

{*656} APPENDIX A

[See Illustration in Bound Volume]

but that he has raised an issue of fact as to defective design.

About 1965, plaintiff began to take Sinutabs for his hay fever, on prescription of a doctor. When he discovered that Sinutabs were sold over the counter, he threw away the prescription; he has no memory of its terms. He read the label on the Sinutab bottle; he does not remember that the label contained any warning about possible kidney damage from extended usage of the drug. He took four tablets almost every day from 1965 on.

About 1970, a clerk at a Skaggs drugstore in Albuquerque suggested to plaintiff that he take Skaggs Sinus Congestion Tablets instead of Sinutabs, because they had the same ingredients and the Skaggs product was cheaper. Plaintiff compared the ingredients on the two products and satisfied himself that the ingredients were the same. He does not recall having read any portion of the Skaggs label except the ingredients, and he did not rely on the warning on the label. He testified at his deposition that if he had read the warning, he would have stopped taking the drug or would have consulted a doctor about continuing to use it. He took the Skaggs product at a rate of about four tablets a day until he developed acute kidney failure in 1973 and was told to stop taking it. Subsequently, two nephrologists determined that the phenacetin and acetaminophen in Sinutabs and Skaggs Sinus Congestion Tablets were responsible for permanent damage to his kidneys.

Plaintiff filed suit against a number of defendants associated with the production, distribution, and sale of Sinutabs and Skaggs Sinus Congestion Tablets, alleging strict liability and negligence in that the products were defectively designed (in that their risks outweighed their benefits) and the warnings provided were inadequate. The defendants who produced, distributed, and sold Skaggs Sinus Congestion Tablets moved for summary judgment. The motion was denied on the ground that the district court "cannot conclude as a matter of law that the warnings furnished by Defendants on 'Sinus

Congestion Tablets'... did constitute as a matter of law adequate warnings as to the use of Sinus Congestion Tablets to preclude liability of these defendants...." This interlocutory appeal followed. The issues, therefore, turn only on plaintiff's use of the Skaggs product, not on the use of Sinutabs.

The label on the Skaggs product has a colored center panel containing the name of the product and, in small print, the ingredients. The left-hand third of the label says, in pertinent part:

"For the symptomatic relief of headaches, facial pain, nasal and sinus congestion often associated with acute and chronic sinusitis, allergic rhinitis and the common cold.

{*657} DOSAGE: Adults: One tablet every 4 hours. Do not exceed 6 tablets in 24 hours."

The right-hand third of the label says:

"CAUTION: Individuals with high blood pressure, heart disease, diabetes, or thyroid disease should use only as directed by physician. This preparation may cause drowsiness. Do not drive or operate machinery while taking this medication. Do not give to children under 6 years of age or exceed the recommended dosage unless directed by physician. If relief of cold symptoms does not occur within 3 days, discontinue use and consult physician.

"WARNING: This medication may damage the kidneys when used in large amounts or for a long period of time. Do not take more than the recommended dosage, nor take regularly for longer than 10 days without consulting your physician. KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN. IN CASE OF ACCIDENTAL OVERDOSE, CONTACT A PHYSICIAN IMMEDIATELY."

I disagree with the majority because I cannot find that plaintiff has raised any issue of fact as to the adequacy of the warning on the label of Skaggs Sinus Congestion Tablets. Plaintiff admits that he never read the warning on the Skaggs product. He makes no claim that the physical aspects of the warning were not adequate to attract his attention. "The physical aspects of the warning -- conspicuousness, prominence, relative size of print, etc., -- must be adequate to alert the reasonably prudent person." **First Nat. Bk., Albuquerque v. Nor-Am Agr. Prod., Inc.**, 88 N.M. 74, 537 P.2d 682 (Ct. App.1975), **cert. denied**, 88 N.M. 29, 536 P.2d 1085 (1975). In **Spruill v. Boyle-Midway, Incorporated**, 308 F.2d 79 (4th Cir. 1962), where the court allowed recovery against a manufacturer of furniture polish despite the fact that the user admitted that she had not read the label, it is clear from the opinion that the plaintiff had raised an issue of fact as to whether the warning was sufficiently conspicuous. In the instant case, the only evidence on the adequacy of the contents of the warning comes from plaintiff himself, who admits that, had he read the warning, he would have discontinued use of the drug or consulted a physician about continuing it. Hence plaintiff admitted, in effect, that the contents of the warning were quite adequate to alert him to danger.

The district judge misconceived the grounds necessary for him to grant summary judgment on this issue. It was not necessary for him to determine **as a matter of law** that the warning was or was not adequate; it was necessary, rather, for him to determine whether plaintiff had raised an **issue of fact** as to the adequacy of the warning. On this issue, defendants met their burden of making a prima facie showing that no genuine material issue of fact existed, and plaintiff did not meet his burden of showing that there was a genuine factual issue requiring trial. N.M.R. Civ.P. 56(c), § 21-1-1(56)(c), N.M.S.A. 1953 (Repl. Vol. 4, 1970); **Smith Const. Co. v. Knights of Columbus, Coun**, 86 N.M. 50, 519 P.2d 286 (1974).

Plaintiff has succeeded, on the other hand, in raising an issue of fact with regard to the claim of "defective design," or risks that outweigh benefits so far that no warning could provide adequate protection for the consumer. The test for defective condition resulting from improper design is whether the product is unreasonably dangerous to the user or consumer or to his property. **Skyhook Corp. v. Jasper**, 90 N.M. 143, 560 P.2d 934 (1977). Defendants rely on testimony from plaintiff's medical experts that the drug causes kidney damage only if it is grossly overconsumed, in disregard of the warning on the label. The following statements of Dr. Barenberg, however, are sufficient to raise a material issue of fact as to whether the drug was so dangerous that no warning could be sufficient and the inclusion of phenacetin and acetaminophen constituted a design defect:

"It is my further medical opinion, as a nephrologist, that products containing phenacetin or acetaminophen [sic] [acetaminophen] are unreasonably dangerous for over-the-counter {*658} sales not controlled by physicians' prescription because any beneficial effect they may have is outweighed by the danger of their use without control by a qualified physician."

"In my mind there is no excuse for allowing a toxic drug such as phenacetin to be available to the public without the benefit of medical supervision. No layman could be expected to medically evaluate the seriousness or the risk of kidney damage, even with specific data."

Summary judgment should therefore have been denied as to plaintiff's "defective design" claim, under the rule that where issues of material fact exist, summary judgment cannot be granted. N.M.R. Civ.P. 56(c) (§ 21-1-1(56)(c), N.M.S.A. 1953 (Repl. Vol. 4, 1970)); **Runyan v. Jaramillo**, 90 N.M. 629, 567 P.2d 478 (1977); **Goodman v. Brock**, 83 N.M. 789, 498 P.2d 676 (1972).