

SERNA V. ROCHE LABS., 1984-NMCA-078, 101 N.M. 522, 684 P.2d 1187 (Ct. App. 1984)

**MANUEL SERNA, Plaintiff-Appellee,
vs.
ROCHE LABORATORIES, DIVISION OF HOFFMAN-LaROCHE, INC.,
SILVER REXALL DRUG, and PIERSON DEMING, M.D.,
Defendants-Appellants.**

No. 7718

COURT OF APPEALS OF NEW MEXICO

1984-NMCA-078, 101 N.M. 522, 684 P.2d 1187

July 17, 1984

Appeal from the District Court of Luna County, Ray Hughes, District Judge

COUNSEL

Jeffrey R. Fredricks, Alice Tomlinson Lorenz, Miller, Stratvert, Torgerson & Brandt, P.A., Albuquerque, New Mexico, Attorneys for Defendant-Appellant Roche Laboratories.

Anthony F. Avallone, Law Systems of Las Cruces, P.A., Las Cruces, New Mexico, Attorneys for Plaintiff-Appellee.

JUDGES

Hendley, J., wrote the opinion. WE CONCUR: THOMAS A. DONNELLY, Chief Judge, A. JOSEPH ALARID, Judge

AUTHOR: HENDLEY

OPINION

HENDLEY, Judge.

{1} This court granted defendant Roche Laboratories' application for an interlocutory appeal from the district court's denial of its motion for summary judgment. The issue is whether **Richards v. Upjohn Co.**, 95 N.M. 675, 625 P.2d 1192 (Ct. App.1980), precludes summary judgment as a matter of law, in favor of a manufacturer, in a products liability case when the theory of liability is the inadequacy of prescription drug warnings. The trial court found that **Richards** controlled to prohibit summary judgment. We reverse and remand with directions to the trial court to grant Roche Laboratories'

motion for summary judgment. Plaintiff's claims against the remaining defendants are not involved in this appeal.

{2} The following facts are from the depositions, exhibits, and affidavits filed in the district court.

{3} In December 1979 and January 1980, Dr. Deming treated plaintiff for prostatitis (prostate infection). The doctor initially {523} prescribed tetracycline. After finishing two prescriptions of tetracycline, plaintiff returned to Dr. Deming on January 17, 1980, and complained of burning during urination and slight lower back pain. The doctor prescribed Bactrim. After approximately five days on the Bactrim, plaintiff alleges that he experienced nausea and that blisters appeared on his penis. Later these symptoms grew worse and he had a high temperature, dizziness, red eyes, pain on the bottom of his feet, splotches over his body, and he was depressed and unable to sleep.

{4} Plaintiff claims that he reported nausea and the splotches on his penis to Dr. Deming at his appointment on January 25, 1980. Dr. Deming's chart for that visit shows that plaintiff was feeling better except for some skin irritation and an inflammation of the penis. Dr. Deming made a diagnosis of nonspecific balanitis and prescribed an ointment and continuation of the Bactrim.

{5} After the January 25, 1980, visit, plaintiff did not return to Dr. Deming's office, although Dr. Deming claims that plaintiff was instructed to return as needed or in a week. Plaintiff admits he had not been released from care. Instead, plaintiff finished the Bactrim prescription and, less than a week after finishing it, he admitted himself to the hospital emergency room. In his deposition plaintiff testified that "[t]he decision to take me to the hospital was made, I would say, in an instant when I instructed her [his wife] that my throat and my mouth were swelling so much that if I didn't get in the hospital, I might choke to death."

{6} Defendants' experts who have filed affidavits in this case, including defendant, Dr. Deming, identify plaintiff's symptoms at the time of hospitalization as a reaction to Bactrim called Stevens-Johnson Syndrome. **Dorland's Illustrated Medical Dictionary** 1298 (26th ed.1981) defines the syndrome:

[T]he severe form of erythema multiforme [lesions on the skin] in which, in addition to other symptoms * * * there is involvement of the oronasal and anogenital mucosa [mucous membrane], the eyes, and viscera [large interior organs]; constitutional symptoms include malaise, prostration, headache, fever, and arthralgia [pain in a joint]. It may be fatal.

{7} The only allegations in plaintiff's complaint which go to Roche Laboratories' liability are those in count I.

3. Roche Laboratories, Division of Hoffman-LaRoche, Inc. manufactured the drug under its brand name Bactrim.

4. Plaintiff took the prescribed drug as directed by the doctor.
5. The defendants knew or should have known of the dangers involved with use of the drug and each could foresee that harm may result to plaintiff as the user of the drug.
6. None of the defendants provided any warnings to plaintiff of the dangers involved and plaintiff was unaware of the dangers involved in the taking of the prescribed drugs.
7. As a proximate result of the failure to warn, the plaintiff suffered serious injury and attendant pain and suffering all to his damage in an amount deemed reasonable by the fact finder.

{8} New Mexico has adopted the basis for products liability found in **Restatement (Second) of Torts** § 402A (1965). **Stang v. Hertz Corporation**, 83 N.M. 730, 497 P.2d 732 (1972).

402 A. Special Liability of Seller of Product for Physical Harm to User or Consumer

(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if

(a) the seller is engaged in the business of selling such a product, and

(b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

(2) The rule stated in Subsection (1) applies although

{*524} (a) the seller has exercised all possible care in the preparation and sale of his product, and

(b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

{9} Plaintiff does not allege that Roche Laboratories is liable because of a physical defect in the drug Bactrim, but because no warnings about the possible dangers of the drug were given. This allegation states a theory of liability because, where dangers from use can be anticipated, the manufacturer must provide adequate warnings or the product is defective. **Restatement**, § 402A comment h. **See also Perfetti v. McGhan Medical**, 99 N.M. 645, 662 P.2d 646 (Ct. App.1983); **First National Bank, Albuquerque v. Nor-Am Agricultural Products, Inc.**, 88 N.M. 74, 537 P.2d 682 (Ct. App.1975). Where the product is a prescription drug, the manufacturer's duty to warn is fulfilled if it warns the physician, not the patient. **Perfetti**. In **Richard v. Upjohn Co.**, this court adopted the five criteria originally given in **Nor-Am** for determination of the adequacy of a warning to a physician. These criteria are:

1. the warning must adequately indicate the scope of the danger; 2. the warning must reasonably communicate the extent or seriousness of the harm that could result from misuse of the drug; 3. the physical aspects of the warning must be adequate to alert a reasonably prudent person to the danger; 4. a simple directive warning may be inadequate when it fails to indicate the consequences that might result from failure to follow it and, most importantly, in the context of the present case; 5. the means to convey the warning must be adequate.

In evidence, as the warnings provided by Roche Laboratories to physicians, were the package insert and the excerpt on Bactrim from the **Physicians' Desk Reference** (PDR).

{10} In support of its motion for summary judgment, defendant Roche Laboratories filed affidavits of four doctors, including that of defendant Dr. Deming. Although Roche Laboratories claims that the affidavits of Drs. Kolosseus and Friedman go to the adequacy of the warning, they do not. Their affidavits go instead to the safety of the product and its proper prescription in this case. However, the affidavits of Drs. Lackner and Deming do go to the adequacy of the warning and establish a prima facie case that the warning was adequate based on the five factor test in **Richards**.

{11} Factors 1 & 2 - the warning "must adequately indicate the scope of the danger * * * [and] reasonably communicate the extent or seriousness of the harm that could result from misuse of the drug".

{12} Drs. Lackner and Deming stated in their affidavits:

The warnings provided by Roche Laboratories of the risks potentially associated with Bactrim or with any trimethoprim or sulfamethoxazole were adequate and sufficiently indicated the scope of any associated dangers. The warnings reasonably communicated the extent or seriousness of any possible harm that could result from misuse of the drug.

{13} Factors 3, 4, & 5 - "physical aspects of the warning must be adequate to alert a reasonably prudent person to the danger * * * [the] warning * * * [should] indicate the consequences that might result from failure to follow it and * * * the means to convey the warning must be adequate."

{14} Drs. Lackner and Deming stated in their affidavits:

The Roche warnings provided through the package insert and the literature were also sufficiently adequate to alert a reasonably prudent person to the associated dangers of the use of Bactrim. They were also adequate to indicate the consequences that might result from failing to follow the warnings provided.

Although the affidavits of Drs. Lackner and Deming mechanically track the test for adequate warnings in **Richards** without explanation as to why the warnings were

adequate under the five factors, they are {525} evidence by qualified experts, and there is nothing in the record to show that plaintiff objected to them as being conclusory and unable to support a summary judgment motion. **See Smith v. Klebanoff**, 84 N.M. 50, 499 P.2d 368 (Ct. App.1972). Further, plaintiff does not raise this on appeal. Accordingly, we do not consider the conclusory aspect of the affidavits.

{15} In addition to the foregoing, the documents themselves support a prima facie showing of adequacy. The package insert and PDR list "Stevens-Johnson Syndrome" in the section on allergic reactions. Defendant Roche Laboratories points out that the single symptoms plaintiff complained of were also listed separately under adverse reactions.

{16} The above evidence is sufficient to support a prima facie case of summary judgment for defendant Roche Laboratories on the adequacy of the warnings provided to physicians. **Goodman v. Brock**, 83 N.M. 789, 498 P.2d 676 (1972). Plaintiff introduced no evidence which would support a factual question as to the adequacy of the warnings. Plaintiff's evidence went only to the malpractice claim.

{17} The trial court read **Richards** to mean that as a matter of law the adequacy of prescription drug warnings is always a jury question which may not be resolved without trial through summary judgment proceedings. This is incorrect. **Richards** did not change the law on summary judgment. The holding in **Richards** was that when the nonmovant presents evidence of the inadequacy of the warnings, it is improper for the court to grant summary judgment for the drug manufacturer. Here, plaintiff presented no evidence of the inadequacy of the warnings and summary judgment is proper.

{18} Reversed and remanded. Defendant Roche Laboratories is awarded appellate costs.

{19} IT IS SO ORDERED.

WE CONCUR: DONNELLY, Chief Judge, ALARID, Judge.