Supreme Court of Florida

NO. 71,633

YOLANDA FELIX, ETC.,
Petitioner,

vs.

HOFFMANN-LaROCHE, INC.,
ET AL., Respondents.

[February 23, 1989]

GRIMES, J.

We review Felix v. Hoffmann-LaRoche, Inc., 513 So.2d 1319 (Fla. 3d DCA 1987), because of apparent conflict with Tampa Drug Co. v. Wait, 103 So.2d 603 (Fla. 1958); Ricci v. Parke Davis & Co., 491 So.2d 1182 (Fla. 4th DCA), review denied, 501 So.2d 1283 (1986); MacMurdo v. Upjohn Co., 444 So.2d 449 (Fla. 4th DCA 1983); and Lake v. Konstantinu, 189 So.2d 171 (Fla. 2d DCA 1966). Jurisdiction is based on article V, section 3(b)(3), of the Florida Constitution.

This was a suit for the wrongful death of a child attributed to the ingestion of Accutane by his mother during pregnancy. Accutane is a drug prescribed for serious and disfiguring cases of acne which was approved for marketing in the United States by the Food and Drug Administration in 1982. The mother took the drug late in 1982 while she was pregnant upon the prescription of her physician. The child was born with severe birth defects which led to his early demise.

A critical issue in the case was whether the manufacturer of the drug furnished adequate warnings of the dangers of using the drug during pregnancy. The relevant text of the package insert at that time stated:

> CONTRAINDICATIONS: Teratogenicity was observed in rats at a dose of isotretinoin of 150 mg/kg/day. In rabbits a dose of 10 mg/kg/day was teratogenic and embryotoxic, and induced abortion. There are no adequate and well-controlled studies in pregnant women.
>
> Because teratogenicity has been observed in animals given isotretinoin, patients who are pregnant or intend to become pregnant while undergoing treatment should not receive Accutane. Women of childbearing potential should not be given Accutane unless an effective form of contraception is used, and they should be fully counseled on the potential risks to the fetus should they become pregnant while undergoing treatment. Should pregnancy occur during treatment, the physician and patient should discuss the desirability of continuing the pregnancy.
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> . . . .
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> WARNINGS: Although no abnormalities of the human fetus have been reported thus far, animal studies with retinoids suggest that teratogenic effects may occur. It is recommended that contraception be continued for one month or until a normal menstrual period has occurred following discontinuation of Accutane therapy.
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> . . . .
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> PRECAUTIONS: INFORMATION FOR PATIENTS:
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> . . . .
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> Women of childbearing potential should be instructed to use an effective form of contraception when Accutane therapy is required. (See CONTRAINDICATIONS AND WARNINGS.)
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> . . . .
>
> PREGNANCY: Category X. See "CONTRAINDICATIONS" section.

Dr. Greenwald prescribed Accutane to the mother for a cystic acne condition of her face and shoulders which had persisted for many years. He characterized Accutane as a miracle

drug for people with acne. Dr. Greenwald testified that he understood the warnings which accompanied the drug and said that "category X" meant that the drug should not be used during pregnancy. He also stated that he had prior knowledge of the teratogenic propensities of Accutane from independent research and reading and from seminars he had attended. He defined "teratogenicity" as "the ability of something to turn out a teratogen" and the term "teratogen" as "a mutant, deformed something--a deformed part, a deformed being, a deformed person, a monster, if you will, something very abnormal." Dr. Greenwald testified that he warned the mother against the use of Accutane if she were to become pregnant. The mother denied having received such a warning.

The trial judge entered summary judgment in favor of those defendants which were involved in the manufacture and distribution of Accutane. The Third District Court of Appeal affirmed and gave two reasons for its decision. First, the court held that the warning provided by the drug manufacturer was adequate as a matter of law. Second, the court reasoned that any inadequacy in the warning could not have been the proximate cause of the damages because the mother's physician knew of the drug's inherent dangers and when it should not be taken.

At the outset, it is clear that the manufacturer's duty to warn of Accutane's dangerous side effects was directed to the physician rather than the patient. Buckner v. Allergan Pharmaceuticals, Inc., 400 So.2d 820 (Fla. 5th DCA), review denied, 407 So.2d 1102 (1981). This is so because the prescribing physician, acting as a "learned intermediary" between the manufacturer and the consumer, weighs the potential benefits against the dangers in deciding whether to recommend the drug to meet the patient's needs. Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1276 (5th Cir.), cert. denied, 419 U.S. 1096 (1974). Furthermore, there is no contention that the warning given in this case contained any misstatements. While there have been subsequent incidents of children born with birth defects after

their mothers ingested Accutane, there had been no Accutane related teratogenicity in human infants prior to the ingestion of the drug in this case.

The asserted basis for conflict in this case is the district court's conclusion that the warning given was adequate as a matter of law. In Tampa Drug Co. v. Wait, a man had died as the result of using carbon tetrachloride to clean the floors of his home. The main issue before the Court was the adequacy of the warning to consumers on the jug which contained the carbon tetrachloride. The Court held that the conflicting evidence in the record concerning the adequacy of the warning justified submitting that issue to the jury for determination. Citing Wait as authority, several subsequent district courts of appeal decisions have employed language which can be read to say that the adequacy of drug warnings is invariably a jury question. Ricci; MacMurdo; Lake.

Thus, petitioner argues that the adequacy of a drug warning can never be decided as a matter of law. Respondents suggest that a pharmaceutical manufacturer would be much less likely to make the capital investment in research, development, obtaining FDA approval, and marketing of a potentially beneficial drug which is accompanied by serious side effects if faced with the knowledge that, no matter how accurate and well-phrased the warning, a jury could decide its adequacy every time the side effect occurred.

While in many instances the adequacy of warnings concerning drugs is a question of fact, we hold that it can become a question of law where the warning is accurate, clear, and unambiguous. The courts of many other jurisdictions have reached the same conclusion. See Hurley v. Lederle Laboratories, Div. of American Cyanamid Co., 651 F.Supp. 993 (E.D. Tex. 1986), rev'd on other grounds, 851 F.2d 1536 (5th Cir. 1988); Weinberger v. Bristol-Myers Co., 652 F.Supp. 187 (D. Md. 1986); Wooten v. Johnson & Johnson Products, Inc., 635 F.Supp. 799 (N.D. Ill. 1986); Goodson v. Searle Laboratories, 471 F.Supp. 546

(D. Conn. 1978); Brick v. Barnes-Hines Pharmaceutical Co., 428 F.Supp. 496 (D. D.C. 1977); Chambers v. G. D. Searle & Co., 441 F.Supp. 377 (D. Md. 1975), aff'd, 567 F.2d 269 (4th Cir. 1977); Johnson v. American Cyanamid Co., 239 Kan. 279, 718 P.2d 1318 (1986), aff'd, 243 Kan. 291, 758 P.2d 206 (1988); Kinney v. Hutchinson, 468 So.2d 714 (La. Ct. App. 1985), writ denied, 472 So.2d 35 (La. 1985); Nolan v. Dillon, 261 Md. 516, 276 A.2d 36 (1971); Wolfgruber v. Upjohn Co., 72 A.D.2d 59, 423 N.Y.S.2d 95 (1979), aff'd, 52 N.Y.2d 768, 417 N.E.2d 1002, 436 N.Y.S.2d 614 (App. Div. 1980).

In the instant case, the district court of appeal acknowledged that whether a warning is adequate is usually a jury question. However, in this case the court held that "[i]t is inconceivable that reasonable persons could disagree as to the adequacy of the warnings in conveying to physicians that the prescription drug, Accutane, is dangerous to pregnant women and should not have been prescribed." Felix, 513 So.2d at 1320. We agree. While the word "teratogenicity" is not one with which all consumers might be familiar, we are convinced that, as to physicians, the warning concerning the dangerous side effects of Accutane was quite clear.

The district court of appeal also held that even if it could be said that there was a factual dispute concerning the adequacy of the warning, any breach of the duty to warn in this case could not have been the proximate cause of the damage. The court reached this conclusion because the prescribing physician testified that he fully understood the warnings and also had prior knowledge of the teratogenic propensity of Accutane. Therefore, we agree that any inadequacy in the Accutane warning could not have been the proximate cause of the birth defects in this case. Insofar as the liability of the manufacturer is concerned, it makes no difference that the mother testified that Dr. Greenwald did not warn her of the danger of taking Accutane while she was pregnant. While this would present a factual issue in a claim against the doctor, the drug manufacturer could not be

penalized for the failure of the doctor to impart knowledge concerning the dangers of the drug of which the doctor had been warned and was aware.

We approve the opinion of the district court of appeal. We recede from Wait and disapprove Ricci, MacMurdo, and Lake to the extent that those cases may be construed to be inconsistent with this opinion.

It is so ordered.

EHRLICH, C.J., and OVERTON, McDONALD, SHAW, BARKETT and KOGAN, JJ., Concur

NOT FINAL UNTIL TIME EXPIRES TO FILE REHEARING MOTION AND, IF FILED, DETERMINED.

Application for Review of the Decision of the District Court of Appeal - Direct Conflict of Decisions

Third District - Case No. 86-1844
(Dade County)

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