O/a 6-20-88.

IN THE SUPREME COURT OF FLORIDA

CASE NO. 71,633



On Discretionary Review
from the District Court of Appeal
of Florida, Third District

YOLANDA FELIX, as Personal Representative
of the ESTATE OF KEVIN FELIX-BAPTISTE,

Petitioner,

- versus -

HOFFMANN-LaROCHE INC., ROCHE BIOMEDICAL
LABORATORIES, INC., BINDLEY-WESTERN
INDUSTRIES, INC., GRAY DRUG STORES, INC.
OF MIAMI, GRAY DRUG STORES, INC.,
THE SHERWIN WILLIAMS COMPANY, and LESTER M. WACHMAN,

Respondents.

# ANSWER BRIEF OF RESPONDENTS

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## STATEMENT OF THE FACTS

Respondents, Hoffmann-LaRoche Inc., Roche Biomedical Laboratories, Lester M. Wachman, Bindley Western Industries, Inc., Gray Drug Stores, Inc. of Miami, Gray Drug Stores, Inc. and the Sherwin Williams Company (hereinafter referred to collectively as "respondents" or "Roche") believe the statements of the facts and the case as presented by petitioner (hereinafter "petitioner" or "Felix") are misleading and incomplete and therefore present the following statements. References to the record on appeal will be designated R ___ and to Respondent's appendix will be designated A ___.

Roche is the manufacturer of a prescription drug distributed under the registered trademark and brand name "Accutane." (R 1318-1325). Accutane, known generically as isotretinoin or 13-*cis*-retinoic acid, was developed by Roche for treatment of severe, recalcitrant, cystic acne. During clinical tests on humans it was successful in curing the most severe, disfiguring types of acne which were not responsive to any other type of therapy.[1/] Accutane was approved for marketing in the United States by the Food and Drug Administration (FDA) in 1982. (R 787-793). It had been extensively tested on laboratory animals as well as humans prior to being marketed and was known to be teratogenic, i.e., capable of causing birth defects, in laboratory animals. Because teratogenicity had been observed in animals, the initial package insert issued by Roche in June of 1982 to prescribing physicians contained four different warnings that the drug could cause

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1/ Peck, et al., Prolonged Remissions of Cystic and Conglobate Acne with 13-*cis*-Retinoic Acid, *The New England Journal of Medicine*, February 15, 1979, pp. 329-333.

birth defects if ingested during pregnancy. The relevant text of the June 1982 package inserts states as follows:

> 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 child-bearing 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 desirability of continuing the pregnancy.
>
> 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.
>
> PRECAUTIONS: INFORMATION FOR PATIENTS:
>
> Women of child-bearing potential should be instructed to use an effective form of contraception when Accutane therapy is required. (See CONTRAINDICATIONS AND WARNINGS).
>
> PREGNANCY: Category X. See "CONTRAINDICATIONS" section."

(A 4).

Dr. Greenwald, the prescribing physician in this case, first prescribed Accutane to Felix on November 6, 1982, for a cystic acne condition of her face and shoulders which had persisted for more than fifteen years. (R 2356, 2456, 2461, 2466-2467, 2469-2470). He last saw her on December 16, 1982. As of that date there had been no reported cases of human birth defects resulting from the

ingestion of Accutane. (Betof Affidavit, R 787-793; A 1-7). Felix became pregnant during or before Accutane therapy and in June 1983 gave birth to a child with multiple congenital malformations. (R 50). The child died five months later on November 24, 1983. (R 51). For the purposes of the summary judgment and this proceeding only, Roche assumes that Accutane caused the fetal deformities.

Prior to prescribing the drug to Felix, Dr. Greenwald had read the information in the Accutane package insert several times and was aware of the seriousness and significance of the warnings. (R 2494). He knew that the "Category X" designation in the package insert denotes a medication that may not be administered during pregnancy. (R 2384). He also knew that teratogenicity was the ability of a substance to cause birth defects. (R 2391). Dr. Greenwald understood that, based on Roche's warnings, if a patient became pregnant while taking Accutane, she should strongly consider an abortion. (R 2453, 3978).

Independent of the warnings contained in the Accutane package insert and Physician's Desk Reference, Dr. Greenwald was familiar with the teratogenic potential of Accutane before Roche began manufacturing it because of his prior knowledge of the teratogenic effects of high doses of vitamin A and the close chemical relationship between Accutane and vitamin A as well as his extensive reading about the development of isotretinoin. (R 2495, 2472, 2432-2434). He also knew about the teratogenic potential of Accutane as a result of attending a seminar conducted by a panel of distinguished dermatologists who discussed the fact that isotretinoin was teratogenic based on tests which had been performed on laboratory animals.[2/] (R 2413-2415). Thus, it is factually undisputed that Dr.

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2/ Dr. Greenwald also testified that he warned Felix about the teratogenetic potential of Accutane and provided her with an information sheet and brochure furnished by Roche which disclosed the danger and the necessity of an effective form of contraception during treatment. (R 2447, 2450, 2453, 2469, 2474, 2475, 2481 and 3978). Felix denies that she was warned and that she received any information linking Accutane to birth defects.

Greenwald was fully cognizant of Accutane's teratogenic potential from sources independent of Roche.

There are numerous inaccuracies, misstatements and erroneous record citations in Felix's statement of facts. The most glaring are briefly discussed below.

On page eight Felix falsely states that the order excluding Fred Pasternack as an expert did not strike his affidavit and deposition from the record and on page nine that Roche's motion to exclude the deposition "was not granted." The order, however, plainly states that Roche's motion to strike the affidavit and deposition of Fred O. Pasternack from the record is *granted.* The order also states that Pasternack would not be permitted to testify as an expert on any issue. (R 1332, A 8).

Felix's additional statement on page eight that Dr. Benke's article "made reference to studies of fetal deformity published in 1972" is misleading. The article mentions the potential teratogenicity of isotretinoin based on malformations seen in newborn *animals.* There is nothing in the article, nor in this record, which even suggests that isotretinoin caused "fetal deformity" in human infants prior to the Felix infant.

On pages seven and eight Felix asserts that Judge Knight indicated at page 1438 of the record that he would consider the affidavit of David Ziskind. While it is true that Judge Knight did consider the affidavit and refused to strike it, his remarks about Mr. Ziskind's qualifications make it clear that he disregarded without striking the affidavit and supplemental affidavit in reaching his decision to grant summary judgment and to deny rehearing:

> It is my ruling, my feeling that the gentlemen is not competent to give an expressed expert opinion on drugs,

> the effects of drugs, the testing of drugs. His expertise was in fields outside of the drug industry.

(R 3634).

On page eleven Felix states, "There is evidence of record that the drug should not have been on the market (RA 3429-3432)." The record reference, however, is to the Pasternack affidavit which was stricken by order of May 7 because Dr. Pasternack was found unqualified to give that or any other expert opinion. Felix also cites to pages 3565 through 3567 of the record which comprised the affidavit of James O'Donnell. This affidavit, however, was filed *after* the summary judgment hearing and rehearing. Thus, it was not considered by the circuit court and not even referenced in Felix's brief submitted to the District Court of Appeal.

In support of Felix's statement that there is record evidence that Roche failed to comply with FDA labeling requirements she cites to pages 3945 through 3953 which are Roche's responses to plaintiff's third set of interrogatories. Nothing in the questions or answers have anything to do with labeling.

In support of her contention that Roche knew of shortcomings and risks concealed in the wording of its 1982 package insert, Felix cites to the first affidavit of Paul Benke (R 3507) which has nothing to do with the wording of Roche's package insert, and an article authored by Dr. Benke which also makes no mention of the wording of the insert.

## STATEMENT OF THE CASE

Plaintiff filed the lawsuit on September 4, 1984 (R 1-14). The action proceeded on the third amended complaint which demanded twenty-five million dollars in damages and alleged seven counts against Roche: fraud; strict liability for product defects and for failure to warn of inherent danger; negligence; gross negligence; express and implied warranties; attorneys' fees against Roche; and punitive damages. (R 930-994).

On August 9, 1985, Roche filed its motion for summary judgment and supporting memorandum on the following grounds:

> 1. That the record clearly established that the warnings given by Roche to the prescribing physician (Greenwald) regarding Accutane were adequate as a matter of law; and
>
> 2. Notwithstanding the warnings given by Roche, Dr. Greenwald was aware of the teratogenic effects of isotretinoin so that no act nor omission of Roche was a legal cause of Felix's injuries.

(R 782-793, 801-812). A motion for summary judgment on behalf of the other respondents was filed on April 21, 1986. (R 3449). Roche's motion for summary judgment was originally scheduled for August 30, 1985, (R 781) but for various reasons it was not heard and granted until May 8, 1986. (R 1389-1434).

Felix appealed the summary judgment. The Third District Court of Appeal affirmed on two grounds: first, that the warnings given to physicians in the package inserts accompanying Accutane, quoted at page 2, *supra*, were adequate as a matter of law; second, Dr. Greenwald's uncontroverted knowledge and understanding of Accutane's teratogenic potential from sources other than Roche established as a matter of law that any inadequacy in the warnings was not a proximate cause of his decision to prescribe Accutane and the subsequent injuries to Felix's child.

Felix complains in the section on "Incomplete Discovery" (petitioner's brief, pp. 11-18) as well as throughout the brief that Roche deprived her of legitimate discovery and that the trial court committed error in not continuing the summary judgment hearing until her discovery was complete. Felix's recitation of events relative to discovery contains glaring omissions which seriously distort the procedural history and the posture of the parties at the time summary judgment was granted. First, the deposition notices so repeatedly filed were the subject of a protective order relieving Roche of any responsibility for producing a witness because of the oppressiveness of the notice. (R 3393, A 9-10)[3/]. Second, a specific document production procedure was ordered by the court (R 3360, A 11-16) which plaintiff never implemented. Third, special master Herbert Stettin submitted a report, requested by the trial judge, in which he absolved Roche of any fault in connection with plaintiff's alleged inability to complete discovery. (R 3535, A 17). A description of the events resulting in those orders and the court's refusal to continue the May 8, 1986, hearing on Roche's motion for summary judgment follows.

As to the documents, the parties litigated over the wording of a protective order regarding Roche documents because they were competitively sensitive and comprised in the neighborhood of 300,000 pages. On December 5, 1985, the court entered an order on Roche's motion for protective order which set out a procedure for document production. (R 3360, A 11-16). The court on that date also appointed Herbert Stettin special master to hear discovery disputes.

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3/ Plaintiff was entitled to certain of the information described in the notice by written response, but Roche was in all respects protected from producing a witness. (R 3393, A 9, 10).

(R 3366). By agreement among counsel plaintiff's counsel was to begin his document inspection and production during the week of December 16, 1986. (R 3759). Shortly before document production was to commence, plaintiff's counsel cancelled it unilaterally without explanation. (R 1483, 1484).

Meanwhile, Roche's motion for summary judgment had been pending since August 9, 1985. On January 28, 1986, Roche noticed the motion for hearing on May 8. On that same day Roche's counsel wrote to Felix's counsel advising him that the documents had been available for inspection since December 16 and would remain in their place of assembly for sixty more days after which they would be returned to storage. (R 3661, A 18-19). No further word was received from plaintiff's counsel concerning document production until April 29, 1986, when counsel served a motion to strike notices of hearing and motions for summary judgment in which he complained that he had been denied access to documents. (R 3453).

The April 29 motion was heard on on May 2 at which time Judge Knight refused to continue the hearing on the 8th unless, in the interim, plaintiff's counsel obtained a hearing before the special master which resulted in a finding that he had not had a reasonable opportunity to complete discovery. (R 3479, A 20-21, R 3812). Counsel made no attempt whatsoever to obtain a hearing before the special master prior to the summary judgment hearing. The court granted the summary judgment at the May 8 hearing. Plaintiff filed a motion for rehearing which was scheduled for June 11 but made no attempt in the interim to obtain a hearing before the special master. On June 12 Judge Knight denied the motion for rehearing (R 3633) subject to reconsidering that ruling on receipt of a report from special master Stettin as to whether there were discovery abuses prior to the

original hearing on May 8. (R 3596, 3597). After a hearing on June 19 that lasted one hour and twenty-five minutes (R 1431-1501), special master Stettin submitted his report which found as follows:

> Hoffmann-LaRoche Inc., did not unreasonably impede plaintiffs from obtaining discovery to which they were entitled and consequently is not at fault to the extent that they have not obtained any such discovery through and including the date of this report.

(R 3535, A 17).

As to the deposition discovery, plaintiff's counsel's statement that he noticed the deposition of the Roche corporate representative fifteen times is of no significance without explanation. Many of the notices are in fact re-notices filed by plaintiff's counsel for no reason other than his own convenience. Moreover, the notice of taking corporate deposition which counsel filed fifteen times was so oppressive because of the volume and detail of information about which the deponent would be required to testify that Roche sought and obtained relief. The notice served on October 25, 1985, (R 3320)[4/] was the subject of a motion for protective order which was heard by special master Stettin. His report (R 3391, A 26-27) and the resulting protective order signed by Judge Knight on December 10 (R 3393, A 9-10) granted the motion to the extent that it sought relief from producing a witness but offered limited relief to plaintiff with which Roche did

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4/ The notice is two full legal pages including six paragraphs of narrative, too voluminous and detailed to cite in full herein. It appears in the appendix at A 22-25.

not disagree.[5/] The October 25 notice is not identical to, but is exemplary of, all the other notices served by plaintiff. (A 22-25).

Significantly, not one of the notices ever served by plaintiff named as the deponent a corporate representative with substantive knowledge about the research, testing, development, application for FDA approval or manufacturing of Accutane. Further, plaintiff made no meaningful attempt to notice the deposition of a Roche corporate representative between October 25, 1985, and the summary judgment hearing on May 8, 1986.[6/] The special master's report, rendered after a hearing which lasted one hour and thirty minutes (R 3674-3741), and Judge Knight's subsequent order (A 9-10) substantiate Roche's position that the notice was oppressive, burdensome and for the most part sought information which had no relevance to the disputed issues. Moreover, plaintiff does not specifically contend that the ruling and order constituted an abuse of discretion or other error.

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5/ As to the information sought in paragraphs 1 and 2 of the deposition notice plaintiff would be allowed to serve an interrogatory within five days after which Roche would be required to file answers by December 31. As to the information sought in paragraph 4 Roche could either furnish plaintiff a list containing the names and addresses of chief supervisors and managers of Roche from January 1, 1978, to the present or furnish an individual for deposition at its option. The protective order was granted in all other respects. Plaintiff never served the interrogatories permitted by the order.

6/ With one legally irrelevant exception that on March 31 plaintiff's counsel noticed the deposition of a Roche corporate representative with the most knowledge of the statements made in the Betof and DelVeccio affidavits for April 17, 1986, at counsel's office in Miami. (R 3439). He was advised for approximately the twentieth time that Roche would not produce the witness in Miami, and he made no further attempts to arrange for that deposition. The record contains two other notices of the same depositions (R 3411 and R 3420), but, as with numerous pleadings filed by plaintiff's counsel, Roche's counsel received no copy.

## SUMMARY OF THE ARGUMENT

Accutane is not and cannot be unreasonably dangerous per se under a strict liability/design defect/risk benefit analysis because public policy dictates that prescription drug manufacturers be excepted from the doctrine of strict liability and, instead, be governed by the principles contained in Comment k. to §402 A of the Restatement (Second) of Torts. Moreover, FDA approval of Accutane conclusively establishes that the benefit outweighs the risk.

There is no issue of material fact concerning the adequacy of the warning accompanying Accutane because it described the exact side effect, that is, birth defects, which plaintiff experienced.

There is no fact issue concerning fraudulent misrepresentations to the Food Drug Administration because the information in the Accutane package insert in effect at the time that Felix was prescribed Accutane was complete and accurate based on existing scientific knowledge.

Any inadequacy of Roche's warning was not a legal cause of plaintiff's injury because the prescribing doctor knew all about the teratogenic potential of Accutane from research sources independent of Roche. Consequently, his decision to prescribe was not affected by the Roche warning.

Felix's contention that Roche package inserts revised subsequent to the discovery of birth defects in the Felix infant should be admitted as proof of negligence or inadequacy of the warning is fallacious because of the applicability of the subsequent remedial measures rule which renders such evidence inadmissible. Inadmissible evidence cannot be considered by a trial judge in opposition to a motion for summary judgment.

The court did not abuse its discretion in striking the affidavit and deposition of Fred O. Pasternack and excluding him as an expert because he was not qualified as an expert in the field in which he was asked to give expert testimony and he was not employed in that field at the time his opinions were given.

Entry of summary judgment was not improper on account of plaintiff's claimed lack of discovery because any such lack of discovery was the result of plaintiff's counsel's inexcusable inaction. The special master appointed specifically to hear discovery matters so found.

## ARGUMENT

### SUMMARY JUDGMENT WAS PROPER BECAUSE NO ISSUE OF MATERIAL FACT REMAINED TO BE DECIDED.

Introduction.

Felix contended in her jurisdictional brief that the decision below conflicted with holdings in *Tampa Drug Co. v. Wait*, 103 So.2d 603 (Fla. 1958), *Lake v. Konstantinu*, 189 So.2d 171 (Fla. 2d DCA 1966), *MacMurdo v. Upjohn Co.*, 444 So.2d 449 (Fla. 4th DCA 1983) and *Ricci v. Parke-Davis & Co.*, 491 So.2d 1182 (Fla. 4th DCA 1986). Roche continues to maintain that this Court is without jurisdiction because, as argued in Roche's brief on jurisdiction, the facts of those cases were materially distinquishable and, in all events, the holdings related to the particular warnings in question, that is, none of the cases expressly held that adequacy of a warning in a prescription drug case is always a fact issue. Moreover, the Court of Appeal affirmed the summary judgment on an additional ground as to which no conflict was asserted, that is, that any alleged inadequacy

in the Accutane warning was not a legal cause of the decision to prescribe and the injuries complained of. Accordingly, there is no conflict between the decision of the Court of Appeal and the cited cases even if there is conflict in parts of the opinions.

All of the arguments presented to this court in Felix's brief on the merits were presented to the District Court of Appeal. The Court of Appeal found only two worthy of consideration, that is, whether the warnings about Accutane's teratogenic potential in the June 1982 package insert and physician's desk reference could be and were adequate as a matter of law and whether, in any event, the warning had any causal connection with the physician's decision to prescribe the drug.

One of the arguments advanced by Felix is that Accutane was defective because its risks of harm outweighed its benefit to the public at large. Roche contends, as discussed, *infra*, that a prescription drug manufacturer's liability is governed by Comment k. to § 402 A of the Restatement (Second) of Torts which excludes a design defect/risk-benefit analysis. By focusing on and applying principles of law derived from Comment k., the Court of Appeal implicitly adopted this view although the design defect issue was not discussed in the opinion.

The other points of error advanced by Felix here and in the Court of Appeal are, as follows: (1) a fact issue existed concerning Roche's misrepresentations to the FDA; (2) error in refusing to consider as evidence subsequent revisions to Roche's package insert; (3) error in excluding Mr. Pasternack as an expert; (4) incomplete discovery. If the Court of Appeal was correct in affirming based on adequacy of the warning, no legal cause and implicit rejection of the design defect/risk-benefit analysis, then any error with respect to the remaining arguments is irrelevant because the result would not change.

Principles Applicable to Prescription Drug Product Liability.

The seminal issues in a products liability suit are product defectiveness and legal cause. *West v. Caterpiller Tractor Company, Inc.*, 336 So.2d 80, 86 (Fla. 1976); *Royal v. Black & Decker Mfg., Co.*, 205 So.2d 307, 309 (Fla. 3d DCA 1967). Prescriptions drugs such as Accutane are among those "unavoidably unsafe" products whose utility and benefits outweigh their risks. Restatement (Second) of Torts, Section 402A, Comment k. (adopted as the law in Florida in *West, supra.*). This determination is made initially by the FDA which is empowered, through delegation of authority from the Secretary of the Department of Health and Human Services, to approve an application for a new drug to be made available for prescription by physicians to the public at large. 21 U.S.C. § 355; 21 C.F.R. §5.10(a). An unavoidably unsafe prescription drug whose benefits have been determined by the FDA to outweigh its risks is not defective nor unreasonably dangerous if it is accompanied by proper directions and warnings of risks attendant to its use. Comment k.

Unlike over-the-counter drugs and other consumer items, prescription drugs are dispensed pursuant to prescriptions from physicians. The decision to prescribe a particular drug is within the medical judgment of the doctor; accordingly, it is the doctor who needs to know about the characteristics of the drug. *Buckner v. Allergan Pharmaceuticals, Inc.*, 400 So.2d 820 (Fla 5th DCA 1981), adopted in Florida the widely recognized principle that, in the case of prescription drugs, the manufacturer's duty to give proper directions and warning is to the prescribing physician, not the consuming patient.

> Pharmaceutical companies then . . . in selling prescription drugs are required to warn only the prescribing physician, who acts as a "learned intermediary" between manufacturer and consumer.

440 So.2d at 822.

No Fact Issue as to Whether Accutane Should Have Been Marketed.

Felix first argues that this record presents a fact issue as to whether Accutane was so dangerous that it should not have been marketed at all. Felix contends that support for her position is found in Comment i to Section 402A, Restatement (Second) of Torts, and in *Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (5th Cir. 1974). Comment i, however, merely defines the concept of "unreasonably dangerous." It clearly applies to products, unlike prescription drugs, which are *avoidably* unsafe. Comment k, relating to *unavoidably* unsafe products, is applicable to the analysis of a prescription drug as indicated in the text of Comment k. itself. 7/

Felix's statement on page 22 that one of the factors in determining the "degree of danger" of a prescription drug is a reasonable man's ordinary expectations is false because it is the expectation of the prescribing physician, trained in the uses of drugs to treat physical ailments, which is relevant, not the expectation of a "reasonable man" who could not possibly be "expected" to comprehend the pharmacological process of a drug without guidance and explanation from his

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7/ Comment k. provides in pertinent part:

> There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are specially common in the field of drugs. * * * Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason, cannot legally be sold except to physicians, or under the prescription of a physician. (Emphasis added).

prescribing physician. *See, Brown v. Superior Court (Abbott Laboratories)*, 751 P.2d 470 (Cal. 1988) in which the California Supreme Court expressly rejected Felix's premise, 751 P.2d at 477. *See also, Buckner v. Allergan Pharmaceuticals, Inc.*, 400 So.2d 820 (Fla. 5th DCA 1981). Felix further compounds the error by mis-citing *Buckner* for the proposition that both a patient ("ultimate consumer") and prescribing physician must be made aware of the dangerous propensities of the drug. Brief of petitioner, n. 2, p. 22. *Buckner* plainly holds that the manufacturer's obligation is to warn the medical community *not* the ultimate consumer. 440 So.2d at 822.

*Reyes v. Wyeth Laboratories* is a thirty page opinion in which the manufacturer of a polio vaccine was found liable to the plaintiff who contracted polio from the vaccine itself. The vaccine had been administered by a clinic through a non-physician. At 498 F.2d 1294 the court discusses "per se" liability based on a risk/benefit analysis. The court then disposes of the issue by simply taking notice of the fact that the benefit of polio vaccine outweighs its potential for harm. Thus, per se liability was *not* a basis for affirming the jury verdict against the manufacturer.

The risk/benefit analysis mentioned in dicta in *Reyes* has been expressly rejected in the case of prescription drugs in two recent cases from the state of California. In *Brown v. Superior Court (Abbott Laboratories)*, 751 P.2d 470 (Cal. 1988), the court determined that prescription drug manufacturers should not be subjected to the traditional concepts of strict liability on the basis of the argument that a particular drug is defectively designed because the risk of harm in individual cases outweighs the benefit to the public at large. Instead, the court concluded that prescription drugs should be analyzed under Comment k. to Section

402 A of the Restatement (Second) of Torts which assumes that, although prescription drugs are unavoidably unsafe, their benefits outweigh their risks so that a manufacturer's liability will depend only on whether the warning accompanying the drug is adequate to convey the danger. The court reasoned that exposing drug manufacturers to strict liability based on a jury finding that the risks attendant to a drug outweighed its benefits under a design defect analysis would cause reluctance on the part of manufacturers to engage in research and development of new pharmaceuticals. Moreover, such a policy would drive up the cost of insurance, if available at all, and of additional research necessary to try to discover every possible risk associated with a potentially beneficial drug and could place the cost of the drug beyond the reach of those who most need it. 751 P.2d at 479. For these reasons the court adopted Comment k. as applicable to all prescription drugs to the exclusion of a design defect analysis under strict liability.

> In conclusion and in accord with almost all our sister states that have considered the issue, we hold that a manufacturer is not strictly liable for injuries caused by a prescription drug so long as the drug was properly prepared and accompanied by warnings of its dangerous propensities that were either known or reasonably scientifically knowable at the time of distribution.

*Collins v. Karoll*, 231 Cal. Rptr. 396 (Cal. App. 1986), reached the same result and cited the same policy factors but concluded that the design defect/risk-benefit analysis is conclusively decided in favor of the manufacturer when the FDA approves a new drug application after completing its thorough analysis.

> When the FDA then determines, based on such testing, that a prescription drug or device is 'generally' safe *if* accompanied by warnings of the risks and side effects identified in the product testing, this determination logically equates to a finding that the product is unavoidably unsafe, i.e., it is as safe as it can be made, given present knowledge and capability, but retains a risk which cannot be avoided but can be warned against.

231 Cal. Rptr. at 404. The court's ultimate conclusion was that:

> ["W]hether the interest in availability (again measured as of the time of distribution) outweighs the interest in promoting enhanced accountability through strict liability design defect review" [citation omitted] has been answered by the FDA's approval of the prescription product in favor of availability.

231 Cal. Rptr. at 406. The court emphasized that the holding was limited to instances where, as here, the plaintiff is injured "in precisely the manner about which the manufacturer had warned . . . ."

These cases stand for the proposition that a prescription drug manufacturer's liability will be measured by the Comment k. standard, not a design defect/risk-benefit analysis which is not contemplated by Comment k. The California courts view Comment k. as an exception to strict liability. Whether it is an exception to or an extension of the doctrine, the well-reasoned policy considerations set out in *Brown* and *Collins* for limiting prescription drug manufacturer's liability to the parameters of Comment k. are compelling.

Notwithstanding the non-applicability of the design defect argument, none of the recitations to evidence in the record set out in footnotes 1 through 3 on page 24 of petitioner's brief bring into question whether Accutane's risks outweighed its benefits. The quoted article in footnote 1 by Dr. Benke merely states that Accutane's "*potential* teratogenicity [in humans] was well known" based on birth defects in newborn animals. Roche fully agrees, and the applicable warning so states. There is no opinion or even suggestion by Dr. Benke that the risk of birth defects was so great that Accutane should not be marketed. Felix's reference to the affidavit of James O'Donnell is totally inappropriate and should be stricken from her brief because O'Donnell's affidavit was filed after the hearing and rehearing on Roche's motion for summary judgment and, presumably

for that reason, was not raised or argued as a basis for reversal in the District Court of Appeal. [8/] The affidavit and deposition of Mr. Pasternack were stricken from the record by order dated May 7, 1986. (R 1332.) The correctness of that order is discussed *infra*.

On page 25 Felix then suggests that FDA approval of Accutane was based only on "limited data" supplied by Roche and refers to deposition exhibit 17 which is quoted in footnote 15 at page 44. Deposition exhibit 17, however, was never filed in this record, was never raised as a basis for denial of summary judgment to the trial judge and, presumably because it is not in the record, was never brought to the attention of the appellate court. It is axiomatic that matters and things not in the record before the reviewing court cannot be argued as a basis for reversal of an inferior court decision. *Williams v. Albritton*, 190 So. 423, 139 Fla. 195 (Fla. 1939); *Altchiler v. State Dept. of Professional Regulation, Div. of Professions, Bd. of Dentistry*, 442 So.2d 349 (Fla. 1st DCA 1983) ("That an appellate court may not consider matters outside the record is so fundamental that there is no excuse for any attorney to attempt to bring such matters before the court." 442 So.2d at 350). Felix, the party seeking review, had the obligation to insure proper preparation and submission of the record to the appellate court and to this Court. *Cameron v. Sconiers*, 393 So.2d 11 (Fla. 5th DCA 1980); *Tesher & Tesher v. Rothfield*, 387 So.2d 499 (Fla. 4th DCA 1980).

For the statement on page 25 that Roche's premarketing research was inadequate, Felix cites to page 3514 of the record which is a supplemental affi-

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[8/] The hearing occurred on May 8, 1986. R 1389. The rehearing began on June 11 and concluded on June 12, 1986. R 3579, 3594. O'Donnell's affidavit was filed on July 23, 1986. R 3565.

davit of Fred O. Pasternack. Again, Mr. Pasternack was disallowed as an expert witness in the case because of his lack of competence. The opinion of "Petitioner's expert" quoted on page 25 also belongs to Mr. Pasternack. Finally, petitioner takes the outrageous position that "recent newspaper articles" which are not and never have been part of the record in this cause, but comprise petitioner's entire appendix, should cause this Court to conclude that the trial and appellate courts erred in granting and affirming summary judgment. The impropriety of including such materials in an appendix in an effort to influence this Court's ruling is manifest. *Gulf Oil Corp. v. Poole*, 426 So.2d 1254 (Fla. 1st DCA 1983); *Hillsborough County Bd. of County Com'rs. v. Public Employees Relations Com'n.*, 424 So.2d 132 (Fla. 1st DCA 1982). Roche's motion to strike Felix's appendix accompanies this brief.

The Warning Was Adequate.

Felix's primary position in its jurisdictional brief is that the conclusion of the District Court of Appeal that adequacy of the warning in a pharmaceutical drug case is usually a fact issue but was not under the circumstances of this case conflicted with holdings in *Tampa Drug Company v. Wait*, 103 So.2d 603 (Fla. 1958), *Lake v. Konstantinu*, 189 So.2d 171 (Fla. 2d DCA 1966), *MacMurdo v. Upjohn Co.*, 444 So.2d 449 (Fla. 4th DCA 1983) and *Ricci v. Parke-Davis & Co.*, 491 So.2d 1182 (Fla. 4th DCA 1986). Felix contends that these cases stand for the proposition that the adequacy of the warning in a products liability case involving a pharmaceutical drug is always a fact issue so that summary judgment may never be granted regardless of the accuracy and clarity of the warning. As indicated in Roche's jurisdictional brief none of the cases cited above expressly so hold; rather, the wording of the particular warnings in each case was found to be susceptible to

a jury conclusion that they did not adequately communicate the danger of the product. Thus, in *Tampa Drug Company*, which involved carbon tetrachloride, not a pharmaceutical, warning labels from other carbon tetrachloride products were introduced which conflicted with the label in issue. The conflicting evidence made adequacy of that warning a fact issue. In *Lake* the court was confronted with a number of subsequent warnings which had been admitted into evidence, apparently without objection, and contained stronger warnings.[9/] In that fact context the court concluded that the adequacy of the initial warning must be submitted to a jury.

On close analysis it also appears that *MacMurdo* and *Ricci* were decided on the basis of the particular facts relative to the warnings in question, not on a rigid rule of law that adequacy of a warning is always a fact issue. The *MacMurdo* warning did not identify any particular side effect or adverse reaction which could be expected from use of the drug Depo-Provera as a contraceptive. Had the warning described the side effect, the court easily could have found it to be "explicit" enough to be adequate as a matter of law. As pointed out by the Court of Appeal, Roche's warning clearly described the precise adverse reaction which Felix experienced.

The holding in *Ricci* that the adequacy of "these warnings is clearly a jury issue in Florida" is unaccompanied by any recitation of the warning or other facts. Again, had the warning at issue described the exact adverse reaction and the risk of its occurrence, there is nothing in the *Ricci* opinion that suggests that

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[9/] Felix attempted to introduce subsequent revisions of Roche's warning which the trial judge excluded under the subsequent remedial measures rule as discussed, *infra*.

the court would not have found it adequate as a matter of law. Thus, these decisions do not conflict with the Third District Court of Appeal holding either as to the rule of law announced (adequacy of a warning is *usually* a fact issue but not in this case) or in the application of the rule on substantially the same facts since the facts, at least in *MacMurdo*, are materially distinguishable. *Mancini v. State*, 312 So.2d 732 (Fla. 1975).

If conflict does exists, then the cases cited by Felix must be read to hold that adequacy of a warning to communicate the danger of adverse side effects to prescribing physicians in a pharmaceutical drug product liability case is always a jury issue. Such an inflexible rule makes absolutely no jurisprudential or practical sense and flies in the face of the overwhelming weight of authority. In *Dunkin v. Syntex Laboratories, Inc.*, 443 F. Supp. 121, 124 (W.D. Tenn. 1977), the court observed:

> With regard to the adequacy of the warnings given, it is difficult to see how they could have been more precise or more accessible to the medical profession. The package inserts and the Physician's Desk Reference entry warned specifically of the possibility of the adverse side effect which Gail Dunkin allegedly suffered.

*See also, Weinberger v. Bristol-Meyers Co.*, 652 F.Supp. 187 (D.Md. 1986); *Hurley v. Lederle Lab., Div. of American Cyanamid*, 651 F.Supp. 993 (E.D. Tex. 1986); *Wooten v. Johnson & Johnson Products, Inc.*, 635 F.2d 799 (N.D. Ill. 1986); *Goodson v. Searle Laboratories*, 471 F. Supp. 546 (D. Conn. 1978), *Brick v. Barnes-Hines Pharmaceutical Co., Inc.*, 428 F. Supp. 496 (D. D.C. 1977), *aff'd*, 567 F.2d 269 (4th Cir. 1977), *Kinney v. Hutchinson*, 468 So.2d 714 (La. App. 1985), *Wolfgruber v. Upjohn Co.*, 423 N.Y.S. 2d 95 (N.Y. App. 1979), in which the courts entered summary judgments because plaintiff's injury was of the type warned against in the package insert, and *see Chambers v. G.D. Searle & Co.*, 441 F. Supp. 377 (D. Md.

1975), *aff'd.* on the opinion of the district court, 567 F.2d 269 (4th Cir. 1977), and *Nolan v. Dillon*, 276 A.2d 36 (Md. App. 1971), in which directed verdicts in favor of the pharmaceutical manufacturer on adequacy of the warning were affirmed for the same reason and *Johnson v. American Cyanamid Co.*, 718 P.2d 1318 (Kan. 1986), in which the Kansas Supreme Court reversed without remand a judgment against American Cyanamid because the warning was adequate as a matter of law to convey the danger of the adverse reaction which plaintiff suffered.

It is inconsistent with rational analysis to hold that the adequacy of the warning accompanying a prescription drug is always a fact issue and can never be the subject of a summary judgment. The implication is that trial judges, who are charged with the obligation of deciding in the first instance whether contracts and other legal instruments are ambiguous or unambiguous, [10/] are intellectually incapable of making that same initial determination with respect to a prescription drug warning. We have found no case which has so held, and Felix cites none except *Lake*, *MacMurdo* and *Ricci* which, as previously discussed, do not contain that express holding. The cased cited above hold directly to the contrary.

No pharmaceutical manufacturer could be expected to make the capital investment in research, development, 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. *See, e.g.*,

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[10/] American Medical Intern. v. Scheller, 462 So.2d 1 (Fla. 4th DCA 1984); Boat Town U.S.A., Inc. v. Mercury Marine Div. of Brunswick Corp., 364 So.2d 15 (Fla. 4th DCA 1978); Innkeepers International, Inc. v. McCoy Motels, Ltd., 324 So.2d 676 (Fla. 4th DCA 1976); Russell & Axon v. Handshoe, 176 So.2d 909 (Fla. 1st DCA 1965); Paddock v. Bay Concrete Indus., Inc., 154 So.2d 313 (Fla. 2nd DCA 1963).

*Collins v. Karoll*, 231 Cal. Rptr. 396 (Cal. App. 1986), discussed in more detail, *infra*. The Accutane warning has the same feature as those involved in the cited cases where summary judgment was granted, that is, it describes the precise side effect which Felix experienced. The holding of the Court of Appeal that adequacy of a prescription drug warning is usually but not always a fact issue comports with the only legal authority on the point and should be affirmed. To the extent that the cases cited by Felix conflict, which Roche contends is not the case, they should be disapproved.

The underlying issue remains concerning the correctness of the Court of Appeal's conclusion that this warning (see p. 2 *supra*.) was adequate as a matter of law. The reasoning of the Court of Appeal set out at 513 So.2d 1320 needs little editorialization except to point out that Roche's warning described the precise adverse reaction which Felix experienced. In this respect the facts of this case differ materially from *MacMurdo* and possibly even *Ricci* since the warning involved there is not disclosed in the opinion.

In *Weinberger v. Bristol-Meyers Co.*, 652 F.Supp. 187 (Dist. Md. 1986) the court analyzed the warning in a fashion similar to the Court of Appeal as follows:

> The warning clearly alerted Dr. Chang that skin (integument) toxicity was a danger in a significant number of patients (4 out of 100). That plaintiff was one of those four is unfortunate, but Dr. Chang was adequately warned.

In *Johnson v. American Cyanamid Co.*, 718 P.2d 1318 (Kan. 1986), the plaintiff contracted polio from contact with his infant daughter who had been vaccinated. The warning stated that paralytic disease following ingestion of polio virus vaccines had been reported in persons receiving the vaccine and in some instances in persons who were in close contact with those who received the vaccine. These occurrences were characterized as "rare." The court noted:

> The . . . warning clearly states the scientific fact that some persons in close contact with the vaccinees may develop a paralytic disease from such contact. It is unnecessary to describe to a physician what paralytic disease is and the seriousness of it.

718 P.2d at 1325. It is equally unnecessary to describe to a physician what teratogenic means or the seriousness of it.

In *Johnson* plaintiff contended that the warning was inadequate because it failed to disclose that people not immune were at greater risk than those who were immune. The court observed, "It hardly takes a medical degree to know that a person immune to a virus cannot acquire the disease. Later warnings spelled this out, but this is not evidence of negligence." 718 P.2d at 1326. The appellate court here made an observation similar to those of the Kansas Court:

> It 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.

513 So. 2d at 1320. In other words, it is clear from the warning that Accutane is dangerous to pregnant women.

Finally, the *Johnson* court observed, "The warning given herein has been approved by the Federal Drug Administration and was consistent with an overwhelming bulk of the current medical opinion." 718 P.2d at 1326. It is undisputed that the Accutane warning had been approved by the FDA and that it was consistent with current medical knowledge concerning its teratogenic effects. (Betof affidavit, R 787, A 1-7).

As the Court of Appeal stated, the warning quoted in the opinion and at page 2 *infra*, was clear and unambiguous on its face. The self-serving affidavits of Messrs. Pasternack and Ziskind cited as evidence of inadequacy on page 32 of Felix's brief were disregarded by the trial judge because the affiants were not

qualified to give opinions.[11/] Ordinarily, where a writing is clear and unambiguous, no opinion testimony, expert or otherwise, is permitted to interpret the writing. See cases at n. 10 *supra*. The Court of Appeal's holding that the warning in question was adequate as a matter of law should be affirmed.

No Issue of Fact as to Fraud.

Felix asserts at page 33 that her bare bones allegations of misrepresentations accompanied by a recitation of "record evidence . . . described more fully elsewhere in this brief" raises a fact issue concerning fraud. Roche's response is that the June 1982 package insert and PDR reference in effect at the time Felix was prescribed Accutane, quoted in full at page 2 *infra*, contained no concealment. The uncontroverted affidavit of Edward Betof (R 787, A 1-7) states that there had been no reported cases of Accutane-related teratogenicity in human infants prior to Felix's use of the drug, and that is exactly what the package insert says. The insert makes clear reference to the *potential* teratogenicity of Accutane in human infants based on *known* teratogenicity in laboratory animals. As soon as the Felix infant was born, the insert was changed to reflect known teratogenicity in human infants. There is no competent evidence in this record to refute Roche's submission that the June 1982 package insert was accurate and complete based on existing scientific knowledge. Significantly, the Court of Appeal did not view the fraud issue as worthy of discussion.

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[11/] Felix again makes reference to the O'Donnell affidavit which was filed in this record subsequent to the summary judgment hearing and rehearing. Such fundamentally improper tactics should not be tolerated. Altchiler v. State Dept. of Professional Regulation, Div. of Professions Bd. of Dentistry, *supra* p. 17. At footnote 1 on page 32 Felix suggests that Ziskind's supplemental affidavit is so important that she would have reproduced it in her brief if space permitted. Yet Felix inexplicably did not include the affidavit in her appendix.

No Legal Cause.

Felix's first argues that Accutane is unreasonably dangerous per se; accordingly, it should not have been placed on the market. Therefore, placing it on the market was "per se" the legal cause of Felix's infants injuries. The per se liability issue has been addressed previously and will not be further discussed here. The remainder of Felix's argument on this point focuses on the comprehension of the prescribing physician, Dr. Greenwald, and an ill-advised observation in the *Ricci* case which, in any event, is not applicable to these facts.

Felix does not dispute the finding by the Court of Appeal that Dr. Greenwald testified "not only that he understood the warnings but that he had prior knowledge of the teratogenic propensities of Accutane from independent research and reading and from seminars he had attended." 513 So.2d at 1321. Because of his knowledge from other sources, the Accutane warning, adequate or not, did not affect his decision to prescribe or what he told or did not tell Ms. Felix about the danger of birth defects. 12/

Notwithstanding Dr. Greenwald's uncontroverted testimony, Felix argues that other evidence in the record could cause a jury to infer that Dr. Greenwald did not really understand Accutane's teratogenic potential. The only case cited by Felix in support of her contention that a jury should be allowed to draw such an inference is *Ricci*. Brief of Petitioner pp. 38 and 39. In *Ricci*,

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12/ If a physician prescribes a drug under circumstances in which he should not have or, apropos of the instant case, fails to warn the patient of the dangers, he would be liable for professional negligence. Dr. Greenwald was sued for professional negligence, and, although he denied that he failed to warn Felix (R 2453), he and his insurance company settled with her for $100,000 and were dropped as parties. *See* Stipulation and Motion for Approval of Settlement (R 824).

however, the testimony from the prescribing physicians was that they received and understood the *manufacturer's* warning and that they considered that warning to be adequate. Here, as pointed out by the appellate court, Dr. Greenwald not only received the Roche warning but also knew about Accutane's teratogenic potential from learned sources independent of Roche. In such a case the authorities are uniform that disposition in favor of the manufacturer is proper on the issue of proximate cause. *Lindsay v. Ortho Pharmaceutical Corp.*, 637 F.2d 87, 92 (2d Cir. 1980) ("[N]o one needs notice of that which he already knows."); *Borowicz v. Chicago Mastic Company*, 367 F.2d 751 (7th Cir. 1966); *Wooten v. Johnson & Johnson Products, Inc.*, 635 F.2d. 799 (N.D. Ill. 1986) ("He [the prescribing physician] testified that, on the basis of his training, experience, and through various sources, he had all of the data necessary to make an informed decision . . ."); *Dunkin v. Syntex Laboratories, Inc.*, 443 F.Supp. 121 (W.D. Tenn. 1977). (Doctor's knowledge eliminated adequacy of warning as proximate cause of injury); *Douglas v. Bussabarger*, 438 P.2d 829 (Wash. 1968) (Doctor relied on his own knowledge of anesthetics in administering the drug. "Thus, if defendant-drug company was negligent in not labeling its container so as to warn of dangers, this negligence was not a proximate cause of plaintiff's disability."); *Mulder v. Parke-Davis & Company*, 181 N.W. 2d 882 (Minn. 1970) (In pharmaceutical drug cases, "the manufacturer is not liable if the doctor was fully aware of the facts which were the subject of the warning. . . ." Directed verdict affirmed); *Oppenheimer v. Sterling Drug, Inc.*, 219 N.E.2d 54 (O. 1964) (Manufacturer exonerated where prescribing physician relied on his own knowledge and not the manufacturer's warnings).

Florida courts have not hesitated to exonerate manufacturers, notwith-

standing alleged inadequacy of product warnings, where the user (by appropriate analogy, the treating physician) had actual knowledge of the danger. *Talquin Elec. Co-op. v. Amchem Products, Inc.*, 427 So.2d 1032 (Fla. 1st DCA 1983) ("Summary judgment is appropriate where the uncontroverted evidence is that a plaintiff is aware of the danger." Distinguishing *Tampa Drug Co. v. Wait); Wickham v. Baltimore Copper Paint Co.*, 327 So.2d 826 (Fla. 3d DCA 1976) (also distinguishing *Tampa Drug Company*); *May v. Allied Chlorine & Chemical Products, Inc.*, 168 So.2d 784 (Fla. 3d DCA 1964) (also distinguishing *Tampa Drug Company.*) It is uncontroverted that Dr. Greenwald was fully cognizant of the dangers of Accutane independent of information supplied to him by Roche. Accordingly, any inadequacy in Roche's written warning could not have affected his decision to prescribe Accutane or what he told Ms. Felix and could not be a legal cause of any resulting injury. *Fraley v. American Cyanimid Co.*, 589 F. Supp. 826 (D. Colo. 1984); *Chambers v. G.D. Searle & Co.*, 441 F. Supp. 377 (D. Md. 1975), *aff'd*, 567 F.2d 269 (4th Cir. 1977). The appellate court was correct in so holding.

No Error Regarding Application of Subsequent Remedial Measures Rule to Revised Package Inserts.

The subsequent remedial measures rule, § 90.407 of the Florida Evidence Code, states:

> Evidence of measures taken after an event, which measures if taken before it occurred would have made the event less likely to occur, is not admissible to prove negligence or culpable conduct in connection with the event.

At page 40 Felix asserts that in *Lake v. Konstantinu*, 189 So.2d 171 (Fla. 2d DCA 1966), evidence of revisions in a package insert relating to a prescription drug were admitted to prove negligence or culpable conduct. While the opinion does

seem to indicate that the trial and appellate courts were aware of subsequent revisions, [13/] there is no indication in the opinion that objection was made to the introduction of this evidence. Thus, *Lake* does not hold that subsequent revisions of a package insert are admissible notwithstanding the subsequent remedial measures rule. As pointed out in Felix's brief, Roche objected and the court ruled that subsequent revisions would be inadmissible. Felix's brief at 41.

Felix then states that § 90.407 does not apply because Roche disclaimed knowledge of the dangerous nature of Accutane citing to answers and affirmative defenses of Roche and two other defendants. This contention is absurd. Roche's package insert fully acknowledged the dangerous nature of Accutane. Felix then contends that Roche attempted to argue through the affidavit of Dr. Del Vecchio (R 1222) that its warnings were "reasonably safe." Since a warning is nothing more than words on a piece of paper, it is neither safe nor dangerous. The only argument Roche has made with respect to the warning is that it was adequate to communicate the danger of birth defects to the medical community. Roche has never argued that Accutane was "safe" as was the case in *Murray v. Almaden Vineyards*, 429 So.2d 24 (Fla. 2d DCA 1983) cited at page 41. On the contrary, Roche concedes that Accutane is an unavoidably unsafe product, but it is not "defective" because it is accompanied by an adequate warning as contemplated by Comment k.

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[13/] This conclusion can be reached from the following language:

> Especially important in the ultimate disposal of this suit is the question of sufficiency of the warnings attempted to be made by Parke,Davis in merchandising the drug and in persuading physicians to use it, *which warnings varied from time to time as Parke,Davis became more and more aware of the drug's extremely dangerous potentiality* and the danger inherent in its use. (Emphasis added.)

180 So.2d at 174.

Felix's citation to *Johns-Manville Sales Corp. v. Janssens*, 463 So.2d 242 (Fla. 1st DCA 1984), is of no assistance because the holding there simply is that evidence of subsequent remedial measures may be admitted to impeach the testimony of a witness. Nothing in the subsequently revised package inserts impeaches the statements in Dr. Del Vecchio's or Dr. Betof's affidavits concerning the fact that there had been no reported cases of teratogenicity in human infants prior to Felix's ingestion of Accutane.

Felix then suggests that the firmly established rule in Florida that the subsequent remedial measures rule applies in strict liability cases should be discarded in favor of the minority view set out in *Jeep Corp. v. Murray*, 708 P.2d 297 (Nev. 1985). The First, Fourth and Fifth District Courts of Appeal have expressly rejected this position. *Alderman v. Wysong & Miles Co.*, 486 So.2d 673 (Fla. 1st DCA 1986); *Thursby v. Reynolds Metols Co.*, 466 So.2d 245 (Fla. 1st DCA 1984); *Voynar v. Butler Mfg. Co.*, 463 So.2d 409 (Fla. 4th DCA 1985); *American Motors Corp. v. Ellis*, 403 So.2d 459 (Fla. 5th DCA 1981). The soundness of the reasoning in these opinions need not be elaborated here, and of course no conflict is asserted as to this rule because, again, the Court of Appeal did not consider Felix's argument on this issue worthy of comment.

No Error in Disqualifying Pasternack as an Expert Witness.

Felix argues that the trial judge committed error in disqualifying Fred O. Pasternack as an expert witness to give opinions concerning the adequacy of Roche's warning and the advisability of marketing Accutane. The Court of Appeal apparently concluded that Felix's argument on this issue was so lacking in merit as to not warrant comment.

Section 90.702 of the Florida Evidence Code defines an expert as one who is "qualified as an expert by knowledge, skill, experience, training or education. . . ." Rule 1.390 of the Florida Rules of Civil Procedure, relating to depositions of experts, further defines an expert witness as a person who is not only specially trained, but is also "duly and regularly engaged in the practice of his profession. . . ." Mr. Pasternack clearly was unqualified. Felix devotes page 43 of her brief to an explanation of Mr. Pasternack's "qualifications." Apparent from although not emphasized by that recitation is the fact that, although Mr. Pasternack graduated from medical school, he never practiced medicine as a profession and was associated with a pharmaceutical manufacturer only from 1957 through 1961, more than twenty five years ago.

Mr. Pasternack graduated from medical school in 1956 and completed a one year internship at Jackson Memorial Hospital. (R 2210-2214). In 1957 he took a job with Lederle Laboratories for whom he worked until January of 1961 in the area of clinical investigation and product development. (R 2220). In January 1961 he began law school, graduated in 1963 and from 1963 to the date of his deposition had been engaged professionally in the practice of law to the exclusion of the practice of medicine. (R 2214, 2215). He is available, however, as a "medical-legal consultant." (R 2215). His duties as clinical investigator at Lederle from 1957 through 1960 involved consulting with doctors in his region concerning the efficacy of new drugs placed into distribution (R 2220, 2221) and generally assisting in coordinating research and development of new medicines. (R 2217). His duties did not include writing package inserts although he was "cognizant of the problems we had in putting out a competent brochure or package insert. . . ." (R 2126).

According to Florida law, a person must be regularly engaged in his

profession to be designated as an expert. Although he has some medical training, Mr. Pasternack has never practiced medicine. The limited experience he had with research and development of new drugs occurred thirty years ago. The witness's expertise must also be in area in which his opinion is sought. *Husky Industries, Inc. v. Black*, 434 So.2d 988 (Fla. 4th DCA 1983); *Kelly v. Kinsey*, 362 So.2d 402 (Fla. 1st DCA 1978). Even during his employment with Lederle, he was merely "cognizant of the problems" associated with authoring a package insert. (R 2226).

Inadmissible testimony may not be considered in opposition to a motion for summary judgment. Fla. R. Civ. P. 1.510(e). Mr. Pasternack had no qualifications by training or experience which would justify admission into evidence of his opinion on the adequacy of Roche's warning or the desirability of marketing Accutane. Whether a witness is qualified as an expert is within the sound discretion of the trial judge, and his decision will not be disturbed unless an abuse of discretion is shown. *Trustees, etc. v. Indigo Corp.*, 401 So.2d 904 (Fla. 1st DCA 1981); *Troj v. Smith*, 199 So.2d 285 (Fla. 2d DCA 1967); *Central Hardware Co. v. Stampler*, 180 So.2d 205 (Fla. 3d DCA 1965). On this record Roche contends there clearly was no abuse of discretion.[14/]

Felix next claims on page 47 that the order disqualifying Pasternack did not actually strike his affidavit and deposition. The order plainly states, however, that Roche's motion to strike the affidavit and deposition is *granted*. (R 1332, A 8). Felix then makes the incorrect statement at page 47 that, after Pasternack was stricken as an expert, the court denied her request for additional time to file

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14/ For a more detailed analysis of his lack of expertise, see memorandum in support of Hoffmann-LaRoche's motion to strike the affidavit and deposition of Fred O. Pasternack (R 1233) included in the appendix at A 28-38.

opposing affidavits and cites to pages 3479 and 3480 of the record. Those pages of the record comprise Judge Knight's May 6, 1986, order which states as follows in paragraph 2:

> With respect to the *Felix* case, the motion [motion to strike notices of hearing] is denied to the extent that it is based upon lack of notice, although the plaintiff will have 20 days from the date stated on the defendants' last notice of hearing within which to serve and file counter-affidavits.

Once again, in affirming the summary judgment, the Court of Appeal did not believe that the abuse of discretion argument warranted comment.

Incomplete Discovery.

Roche contends that the discovery issue is laid to rest by the finding of the special master that Roche did not impede plaintiff from obtaining discovery to which she was entitled and was not at fault to the extent that she did not obtained any such discovery as of the date of the hearing, June 19, 1986. The reasons for his ruling include the fact that counsel did nothing to arrange for copying documents which were available nor to take meaningful deposition discovery from Roche representatives from December 16, 1985, through the end of April, 1986. There were numerous other arguments made to the special master on which he commented. See the hearing transcript. (R. 1431-1501).

Although Felix filed a motion to continue the hearing so that she could file supplemental affidavits, her counsel never brought the existence of that motion to the attention of the trial judge during the hearing on the motion for summary judgment which occurred on May 8, 1986. See hearing transcript (R 1389 - 1434).

Even if counsel had, a motion to continue a summary judgment hearing based on lack of opportunity to complete discovery is addressed to the sound

discretion of the court and will be denied where it appears that the alleged lack of opportunity was really unexplained inaction. *Howard v. Shirmer*, 334 So.2d 103 (Fla. 3d DCA 1976); *McNutt v. Sherrill*, 141 So.2d 309 (Fla. 3d DCA 1962). Moreover, plaintiff was able to file the Ziskind and Benke affidavits previously referenced in this brief prior to the motion for rehearing which were considered by Judge Knight. Judge Knight found Mr. Ziskind to be unqualified to give an opinion. (R 3634). As previously pointed out, the Benke affidavit contains nothing which even suggests that Roche's warning was inadequate or that Accutane should not have been marketed. (R 3507). These affidavits simply did not raise a material fact issue.

Felix made no significant effort to arrange for depositions or review documents which had been assembled for that purpose for months prior to the summary judgment hearing, and the special master so found.[15/] She had ample opportunity to attempt to raise a material fact issue through affidavits or other competent evidence, but she was unable to do so even though the court considered the Ziskind and Benke affidavits on rehearing. Felix has shown no abuse of discretion by the trial judge in refusing to continue the hearing on the motion for summary judgment.

## CONCLUSION.

Roche's primary position is that there is no conflict between the decision of the District Court of Appeal in this case and the cases cited by Felix in her jurisdictional brief; accordingly, this Court is without jurisdiction to hear this cause. On the merits the better rule of law is that the trial judge has the authority to conclude in the first instance whether a fact issue exists as to the adequacy of a warning to the medical community accompanying a prescription

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[15/] See comments of special master Stettin at R 1496 through 1502.

drug. If he concludes that the warning is clear, unambiguous and plainly conveys the danger of the adverse reaction which the plaintiff experiences, he can decide that the warning is adequate as a matter of law. In the instant case the Court of Appeal properly decided that the warning in question was adequate as a matter of law, but, even if there were a fact issue as to its adequacy, there was no fact issue with respect to legal cause because the prescribing physician was fully informed from sources independent of Roche about Accutane's teratogenic potential.

As to the issues not addressed by the appellate court, there was no demonstrable error, but, even if there were, these issues are moot in light of the demonstrated adequacy of the warning and absence of legal cause. For the foregoing reasons Roche contends that the petition for discretionary review should be dismissed or, alternatively, the decision of the Third District Court of Appeal should be approved, and the opinions in *Tampa Drug Co. v. Wait*, *Lake v. Konstantineu*, *MacMurdo v. Upjohn Company* and *Ricci v. Parke-Davis & Company* should be disapproved to the extent that they conflict.

Respectfully submitted,

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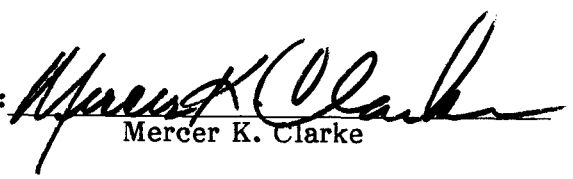
## CERTIFICATE OF SERVICE

**WE HEREBY CERTIFY** that a true and correct copy of the foregoing answer brief of respondents together with the appendix thereto was mailed to Jeffrey P. Kaiser, Esq., Attorney for Petitioner, 15476 N.W. 77th Court, Suite 315, Miami Lakes, Florida 33016 this 6 day of June, 1988.

KELLEY DRYE & WARREN
including
SMATHERS & THOMPSON

By: 
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