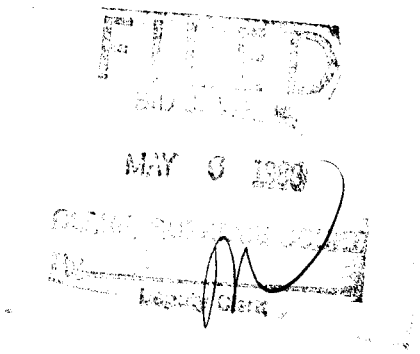
IN THE SUPREME COURT OF FLORIDA

CASE NO. 71,634

WILLIAM F. CHILDERS and HOLLY CHILDERS, as joint Personal Representatives of the Estate of WILLIAM GILES CHILDERS,	:
Petitioners,	:
vs.	:
HOFFMANN-LaROCHE, INC.; LAWRENCE SCHACHNER, M.D.; SAPAC, Ltd.; F. HOFFMANN-LaROCHE & CO. Ltd.; ROCHE BIOMEDICAL LABORATORIES, INC.; BINDLEY WESTERN INDUSTRIES, INC.; THE KROGER COMPANY; SUPER-X DRUG STORES OF FLORIDA, INC.; SUPER X DRUGS CORPORATION;	:
Respondents,	:



****

INITIAL BRIEF OF PETITIONERS

ON THE MERITS

****

LAW OFFICES OF JEFFREY P. KAISER
15476 N.W. 77th Court - Suite 315
Hialeah, Florida 33012
Phone: (305) 822-8484

TABLE OF CONTENTS

APPENDIX

TABLE OF CITATIONS

Federal Cases

Out of State Cases

Florida Cases

CITATIONS TO AUTHORITIES
Florida Cases continued

OTHER AUTHORITIES

STATEMENT OF THE CASE AND FACTS

INTRODUCTION:

Petitioners, William F. Childers and Holly Childers, as Personal Representatives of the Estate of William Giles Childers, were Plaintiffs in the Circuit Court of the 11th Judicial Circuit in and for Dade County, Florida and Appellants in the Third District Court of Appeal. Respondents, Hoffmann-LaRoche, Inc., Roche Biomedical Laboratories, Inc., Bindley-Western Industries, Inc., The Kroger Company, Super-X Drug Stores of Florida, Inc., and Super-X Drugs Corporation, were Defendants in the Circuit Court and Appellees in the Third District Court of Appeal.

Decedent, William Giles Childers, died on October 12, 1983, having been born August 19, 1983 with multiple, severe birth defects, as a proximate result of a prescription drug prescribed to his mother for her skin condition in the first trimester of her pregnancy. The drug, Accutane, had been placed on the market in September 1982 by Hoffmann-LaRoche, Inc. Hoffmann-LaRoche disseminated printed advertisements, warnings and product information about the product aimed at physicians, including wording which it referred to as its "package insert." It also provided directly to Holly Childers, through its contracting agent, the University of Miami, typewritten printed materials purporting to be full warnings of all adverse side effects of isotretinoin.

A wrongful death action against Hoffmann-LaRoche was filed March 20 1985, in Dade County Circuit Court by the personal representatives of the decedent's estate.

The Circuit Court entered a partial order of consolidation of the Petitioners' wrongful death action with the substantially identical wrongful death action filed by the petitioner in the Felix v. Hoffmann-LaRoche, Inc. case which is presently pending review before this Honorable Court, Case No. 71,633. (R.A. 3243-3244).

A Summary Judgment was entered in Circuit Court on all counts in favor of the product's manufacturer, distributors, retailers and the manufacturer's detailman (promotional salesman), on August 13, 1986. (R.A. 3824).

The Summary Judgment was appealed to the Third District Court of Appeal via timely Notice of Appeal filed September 12, 1986. (R.A. 3672-3673).

The District Court granted appellants' motion to share a single record on appeal with the Felix v. Hoffmann-LaRoche, Inc., companion case in an order dated September 26, 1986.

The Third District Court of Appeal issued its opinion on October 6, 1987, affirming the Summary Judgment. Childers v. Hoffmann-LaRoche, Inc., (R.A. 4917). The Childers decision consisted of a per curiam affirmation based upon the authority of its companion case, Felix v. Hoffmann-LaRoche, Inc., 513 So.2d 1319 (Fla. 3d DCA 1987), Third District Case No. 86-1844, filed

six days before. (R.A. 4913-4915). The Felix opinion was timely appealed to this Supreme Court and is under review at present. (Appendix Exhibit "E").

A Motion for Re-Hearing or Clarification of the Third District's decision was timely filed pursuant to Rule 9.330 of the Florida Rules of Appellate Procedure. The Third District entered an Order denying that motion on November 24, 1987. (R.A. 4918).

Petitioners herein timely filed a notice to invoke the discretionary jurisdiction of this court in accordance with Rule 9.120(b) of the Florida Rules of Appellate Procedure.

On March 18, 1988, this Supreme Court entered its Order Accepting Jurisdiction and Setting Oral Argument. On April 12, 1988, this Court granted Petitioners' request to extend time for filing their initial brief, ordering that same be served by May 2, 1988.

Petitioners concurrently seek review of the denial of their motion to strike notices of hearing and/or to continue hearing on the motion for summary judgment (R.A. 3821-3823).

Petitioners will hereafter refer to Respondent, Hoffmann-LaRoche, Inc., as "Hoffmann," and Respondent, Roche Biomedical Laboratories, Inc., as "Roche."

NATURE OF THE CASE

This is a wrongful death action (R.A. 934) alleging as to Respondents strict liability for their admitted manufacturing (R.A. 4100, 3906) and marketing (R.A. 3450, 3902) of a defective product, which is a prescription drug known as Accutane (R.A.

3906), having the generic name of Isotretinoin, a chemical derivative of 13-cis-retinoic acid, and a synthetic analog of Vitamin A (R.A. 3902), conceded to be teratogenic and dangerous (R.A. 3236-3237),the use of which had resulted in fetal abnormality, and about which there was positive evidence of fetal risk (R.A. 932, 3912, 4103, 2396-2400, 3945-3953, 3432-3497) prior to the within incident (R.A. 3433-3438, 3507-3511), and which was distributed and sold by Respondents, or some of them, as a treatment for acne (R.A. 3451, 4100). There are other acne treatments available (R.A. 4106, 2396). Petitioner also seeks damages for negligence, and as to Respondents, Hoffmann and Roche, for fraudulent concealment (R.A. 2743-2744); and breach of warranty, claims for misbranded drugs are alleged against the retailing Respondent. (R.A. 936-937).

In 1982, Holly Childers was in the first trimester of pregnancy while undergoing an Accutane treatment program for ichthyosis (R.A. 4100, 934). As a result of the Accutane in her body (R.A. 1405), her infant, William Giles Childers, was born with numerous, severe malformations (R.A. 2741, 3428-3438, 3875-3879), on August 19, 1983 (R.A. 2741), and died October 12, 1983 (R.A. 2734). In August, 1983, the wording of package inserts published by Respondent Hoffmann, changed from those published in 1982 (R.A. 1432, 3483-3498). These facts are not in dispute (R.A. 1405, 1427, 1432, 4100).

The Case and Facts

A. Pleadings

Petitioners commenced this litigation on March 20, 1985 (R.A. 2498-2511), naming as Defendants Hoffmann-LaRoche, Inc., manufacturer of Accutane (R.A. 1-14) and the treating physician who is not involved in this appeal. Respondents Roche Biomedical Laboratories, Inc., Bindley-Western Industries, Inc., The Kroger Company, Super-X Drug Stores of Florida, Inc., and Super-X Drugs Corporation became parties by the Amended Complaint for Wrongful Death dated October 15, 1985 (R.A. 2736-2796), following an Order allowing the amendment of the Complaint entered October 31, 1985 (R.A. 2797).

On August 14, 1986, the Order of Final Summary Judgment for all six Respondents was entered (R.A. 3824). None had filed an Answer to Appellants' Complaint or Amended Complaint.

B. Material Facts and Issues

In or about June, 1982, Respondent Hoffmann published a four-page package insert (R.A. 3915) which should have complied with Federal Food and Drug Administration labeling requirements[1] (R.A. 3904) for distribution of the drug Accutane. From said package insert Respondent Hoffmann quoted in its Response to Request for Admissions #49 served April 3, 1984 (R.A. 3913). Said package insert is the primary subject of the Affidavit (R.A. 3482-3498) and Supplemental Affidavit (R.A. 3516-3519) of David Ziskind, Petitioner's expert witness; and attached to his Affidavit is a copy of the text of said package insert as it appeared in 1982 (R.A. 3491) and as it appeared subsequent to

[1] FDA labeling requirements appear in 21 CFR §201.57(F)(6)(e). The 1982 package insert does not comply with its mandatory language.

1982 (R.A. 3497). A copy of the language used in August, 1983, which is the same language attached to the Affidavit of Dr. Ziskind, was part of Deposition Exhibit 21 (R.A. 2269-2270).

On February 19, 1986, Respondents took the deposition of Fred O. Pasternack, M.D., (R.A. 2211-2320), who had worked for a drug manufacturing firm as a new product investigator and research/marketing liaison. (R.A. 2220). On March 23, 1986, Petitioner served notice of filing two Affidavits of Paul Benke, M.D., who had authored medical journal articles on Accutane, and of Fred O. Pasternack, M.D., (R.A. 3428-3438), along with the deposition transcript of Dr. Pasternack (R.A. 2211-2320).

On March 28, 1986, Respondents moved to exclude the Affidavit and deposition transcript of Dr. Pasternack (R.A. 1227-1230). The written Order entered May 8, 1986 (R.A. 1332-134) did not exclude same, but ruled that the testimony would not be considered expert testimony for any purpose.

On May 8, 1986, the Trial Court stated it would consider the affidavit of Petitioner's Expert Witness David Ziskind (R.A. 1438, R.A. 3483-3498). Respondents' Motion to Strike the Supplemental Affidavits of David Ziskind served May 13, 1986 (R.A. 3516-3519, together with those of Paul Benke, M.D., (R.A. 3503-3505, May, 1986) and of Fred O. Pasternack, M.D., (R.A. 3512-3515) was denied by Order entered June 13, 1986 (R.A. 1362-1364), and they were therefore before the Court at the time of both Summary Judgment hearings in addition to those previously filed (R.A. 3428-3438, 3481-3498, 3507-3511).

On July 23, 1986, Petitioners filed the Affidavit of James O'Donnell, D. Phar., Ph.D., (R.A. 3556-3559, 4881-4882), who testified regarding the forseeability of Accutane causing the within incident, and this affidavit was considered by the Court in ruling on Respondents' Motion for Summary Judgment (R.A. 3233).

On July 9, 1986, counsel for Petitioners filed Notice of Filing Depositions of Paul Benke, M.D. (R.A. 3027-3029) together with the deposition transcript (R.A. 4528-5691), filed specifically for purposes of consideration by the Court in connection with summary judgment motions of Respondents in this cause. Dr. Benke is board certified in three areas, including "clinical genetics" (R.A. 4533). Of the fifteen or sixteen clinical articles he has authored, at least two deal with teratology (R.A. 4542), and effect on fetuses (R.A. 4545-4546). Dr. Benke stated there was "no safe dose to be given pregnant women." (R.A. 4684). He questioned the adequacy of the printed package inserts of Respondent Hoffmann in the use of the work "should" (R.A. 4586),[2] and as a means of warning a dermatologist (R.A. 4685-4686). However, he defferred to the qualifications of those who actually write the warnings as to adequacy (R.A. 4661). He stated that the warnings were not adequate for at least one dermatologist (R.A. 4685-4686). He stated "Category X"[3] meant,

---

[2] Also in Affidavit dated May 13, 1986, R.A. 3503-3505.

[3] Category X is an FDA designation appearing in the CFR section dealing with labeling requirements of prescription drugs.

"not to be taken when pregnant" (R.A. 4665). Dr. Benke knew of the after-the-fact changes of warnings in the labeling of the product by Appellee Hoffmann (R.A. 4669).

There is evidence of record that Respondent Hoffmann and/or other Respondents failed to comply with FDA labeling requirements in marketing the drug (R.A. 3945-3953), and that Respondent Hoffmann knew and had reason to know of the shortcomings and risks (R.A. 3429-3433, 3507-3511; and R.A. 2261, Deposition Exhibit 8 contained in small box in record). as well as the likelihood of its being administered to pregnant women (R.A. 4587). There is considerable evidence of record that the drug should not have even been on the market (R.A. 3556-3559; 4875-4882, 3429-3432).

Prescribing physician Lawrence Schchner, M.D., a dermatologist, claimed by Affidavit that he warned Petitioner Holly Childers of the hazard involved in the use of Accutane, and that the warnings were oral and written (R.A. 2993-2994). Petitioner denied that Dr. Schachner warned her orally as to the hazard (R.A. 4141, 4180, 4197), and denied she knew anything about it prior to the birth of William Giles Childers (R.A. 4160). Although Appellant Holly Childers acknowledged receiving some type of brochure (R.A. 4223-4351-4351A) she stated she did not recall what it said (R.A. 4222). Petitioner, William F. Childers stated it was some time after the death of the child before he knew that Accutane had anything to do with the child being born deformed (R.A. 4376-4377, 4379-4380, 4381-4382, 4383-4384). The father of Petitioner Holly Childers stated

several times, i.e., (R.A. 4441, 4444-4445, 4487-44448 4458), that he was not warned of the risks and hazards to unborn children of pregnant women. The mother of Holly Childers, Suzanne Giles, swore that the only warnings ever received by her and her family members about Accutane were totally silent on the hazard to a pregnant woman. These defficient warnings were given by the University of Miami while testing the new drug for Hoffmann. Petitioner Holly Childers, then a minor, was involved in the testing (R.A. 3523-3530), but it had discontinued the program because isotretinoin cased her dangerously high triglyceride levels. She subsequently consulted Dr. Schakner after Hoffmann released the drug on the market and was given the prescription that she was on when she conceived.

C. Incomplete Discovery

With reference to written discovery requests to Respondents, at the time of entry of Final Summary Judgment for Respondents, on July 24, 1987, Petitioner's Request to Produce to Respondent Wachman filed May 2, 1986 (R.A. 3469-2471) had not been responded to, the deposition of a knowledgeable corporate representative of Respondent Hoffmann had not been taken, and production requests dating back to early 1984 in the consolidated case, directed to Respondents Hoffmann (R.A. 3463-3465) and Wachman (R.A. 3466-3468), set for hearing May 28, 1986, but not heard until June 27, 1986 (R.A. 1507), were not completed by the time of final summary judgment.

On March 22, 1985, Petiitioners' Request to Produce to Respondent Hoffmann (R.A. 2512) was served with the original complaint in this case. Immediately thereafter, Petitioners moved to consolidate this and the companion case for purposes of discovery (R.A. 293-294). The Order of consolidation was entered July 10, 1985. (R.A. 3243-3244).

On July 26, 1985, Respondent Hoffmann moved to recuse the Special Master who had been ordered to conduct all discovery hearings (R.A. 3271-3272). On July 29, 1985, in his Interim Report, he included a voluntary recusal (R.A. 3304-3305). This was approved by an Order dated September 11, 1985 (R.A. 3303). Although Petitioner moved for the appointment of another Special Master on August 13, 1985 (R.A. 3277-3278), and noticed it for hearing August 28, 1985 (R.A. 3286-3287), the new Special Master was not appointed until December 5, 1985 (R.A. 3366-3367). This caused additional delay in discovery proceedings.

On August 19, 1985, Petitioner filed a Memorandum of Law regarding Hoffmann's moving for summary judgment during pending discovery proceedings, and also discussed Respondent Hoffmann's motions for protective orders (R.A. 3288-3292). Prior to hearing, another one-month delay in discovery proceedings, and diversion of effort from discovery, resulted from Respondent Hoffmann filing a mandatory Petition for Removal to the Federal Court (R.A. 827-836) pursuant to U.S. Code Title 28 §1441 on September 16, 1985. Petitioner's Motion for Remand was granted, and the Order of Remand was filed October 18, 1985 (R.A. 893-894).

On November 25, 1985, Hoffmann again filed a Motion for Protective Order (R.A. 3345-3352). On December 5, 1985, the Court entered a nunc pro tunc order on Hoffmann's Motions for Protective Order on written discovery (R.A. 3360-3365), and another Order December 10, 1985 on Hoffmann's Motion for Protective Order as to the deposition of its corporate executive (R.A. 3393-3395), the same day that Hoffmann filed a further Motion for Protective Order (R.A. 3368-3390).

On May 2, 1986, six days prior to hearing on summary judgment in the companion case, Petitioner filed a Motion to Compel Hoffmann to produce a corporate representative (R.A. 3463-3465). Discovery motions as to Hoffmann continued into June and July (R.A. 1368-1371, 3815-3816), and an Order on various discovery motions as to Hoffmann was entered July 24, 1986 (R.A. 3568-3572) the day before Final Summary Judgment for Appellees was entered.

With respect to Motions for Protective Orders, the first was filed by Hoffmann March 13, 1985 (R.A. 222-225), and the second six days later (R.A. 226-227); and by the time these causes were consolidated, three hearings and three more Motions for Protective Orders were held or filed. Discovery hearings A further hearing were held September 23, 1985 (R.A. 3108-3138), and December 2, 1985 (R.A. 3674-3742), and another on December 23, 1985 (R.A. 3743-3761).

The subject of the December 23, 1985 hearing was primarily requests for production propounded over a year earlier. This production had still not been supplied despite orders upon motions to compel, when summary judgment was entered.

Respondent Hoffmann had filed Motions for Protective Orders on November 25, 1985 (R.A. 3345-3352) and on December 10, 1985 (R.A. 3368-3390).

With reference to discovery by deposition, Petitioner served the following Notices of Taking Deposition of Corporate Representative(s) Respondent Hoffmann in July 1985, during the fourth re-noticing of the depositions. Petitioners re-noticed this deposition as follows:

07/24/85 (R.A. 3267-3270)
07/24/85 (R.A. 4794-4797)
09/30/85 (R.A. 3309-3312)
10/03/85 (R.A. 1113-3315)
10/03/85 (R.A. 4810-4812)

On October 7, 1985, one of the issues at the hearing was the deposition of a corporate representative of Respondent Hoffmann (R.A. 4085-4097). On October 8, 1985, a deposition was taken in New Jersey of Respondent's designated representative, who was grossly unqualified to testify on the subjects duly noticed for the deposition. (R.A. 2033-2053). Petitioner tried to re-set meaningful depositions:

10/25/85 (R.A. 3320-3323)
10/25/85 (R.A. 4813-4816)

On December 2, 1985, the foremost subject of the 1-1/4 hour hearing before the Special Master was the deposition of a corporate representative of Respondent Hoffmann. Petitioners again re-noticed the depositions:

03/13/86 (R.A. 3411-3419)
03/26/86 (R.A. 3420-3427)
04/01/86 (R.A. 3439-3411A)

On May 2, 1986, Petitioner filed another Motion to Compel Respondent Hoffmann to arrange the taking of the deposition of a corporate representative of Hoffmann (R.A. 3463-3465), set for hearing before the Special Master on May 28, 1986, (R.A. 3475-3475A). The Motion was heard June 19, 1986 (R.A. 1459, 1467-1468), and again on June 27, 1986 (R.A. 1533-1544).

From May 1985 to July 1986, counsel for Petitioners made multiple attempts to arrange for the photocopying of the records of Respondent Hoffmann, but these efforts were frustrated for example by Respondent not revealing how many papers there were to copy (in hundreds of thousands) or where they were to be copied.

On February 18, 1986 two discovery motions were heard (R.A. 4038-4084). Reference was made also to difficulties Petitioners were having because of non-production of Respondent Hoffmann of documents required to be produced (R.A. 4077-4078).

On April 3, 1986, the deposition of Petitioner Holly Childers was taken. The deposition of Petitioner William F. Childers, was taken April 4, 1986. On April 11th the deposition of Dolores Marshall was taken. On April 25, 1988 the deposition of Lester Wachman was stopped incomplete due to Respondent's

refusals to answer many questions. (R.A. 2097-2210). On May 1st, Petitioners served both Notice of Hearing and Motion for Specific Prodution Procedures.

Petitioners filed two Motions to Compel discovery from Respondent Hoffmann (deposition of its corporate represenative) (R.A. 3463-3465), and from Lester M. Wachman (answers to questions objected to at deposition (R.A. 3466-3468)

On June 16, 1986 the Order on Petitioners' Motion to Strike and Continue was entered requesting the Special Master to determine whether "discovery by Plaintiffs have been delayed by Defendant" (R.A 3815-3816). On June 18, 1986, Petitioners filed a Request for Report Re: Ongoing Discovery (R.A. 3531-3532), and set an emergency hearing before the Special Master on June 19th.

On June 23rd the deposition of Benroe Blount was taken in Belvoir, Virginia (R.A. 4692-4777). On June 25th the Report of the Special Master was filed (R.A. 3535-3537) in response to the Trial Court's query on discovery, containing findings from the June 19th hearing (R.A. 1496-1500). On June 25th Petitioners served Notice of Intent to Commence Photocopying of Production (R.A. 3533-3534). On June 27th, Respondents filed a Motion to to Quash Notice of Intent to Commence Photocopying of Production (R.A. 1372-1375)

On July 10, 1986 summary judgment hearing commenced at but was continued because of incomplete discovery (R.A. 3159-3160). The primary item of incomplete discovery was the production of documents by Respondent Hoffmann (R.A. 3139-3161).

On July 23, 1986, Petitioners filed the Affidavit of Jeffrey P. Kaiser as to both completed and yet incompleted discovery (R.A. 3560-3564).[4] On July 24, 1986, during the re-set hearing on Respondent's Motions for Summary Judgment, counsel for Petitioners raised the question of incomplete discovery (R.A. 3197), which objection was overruled by the Court (R.A. 3198).

[4] After months of Respondent' unsustained objections and last minute motions for protective orders which would be denied or essentially refused once they could be heard (but after disrupting appearance of Petitioners counsel and photocopying personnel in New Jersey), the Special Master's finding specifying detailed procedures and ultimate dates of Hoffmann's compliance were formalized (R.A. 1507-1533). The documents Respondent Hoffmann assembled to be produced about 200,000 pages (R.A. 3560-3561) were first seen by counsel July 7, 1986, and ten days later, with copiers placed on Respondent's premises, copying commenced July 17, 1986. Less than five percent (5%) of the assembled materials could be copied, even working full time, prior to the summary judgment hearing July 24, 1986, after which copying stopped.

POINTS ON APPEAL

POINT I

WAS SUMMARY JUDGMENT ERROR BECAUSE MATERIAL ISSUES OF FACT EXITED SUPPORTING ALLEGAITONS THAT (A) ACCUTANE IS SO UNSAFE THAT MARKETING IT AT ALL IS UNREASONABLY DANGEROUS, (B) ALTERNATIVELY, ACCUTANE WAS UNREASONABLY DANGEROUS AS MARKETED WITH INADEQUATE WARNINGS, INSTRUCTIONS AND SAFEGUARDS, AND (C) RESPONDENTS FRAUDULENTLY CONCEALED ACCUTANE'S TRUE DEGREE OF DANGER?

POINT II

WHETHER RECORD SUPPORTED CONCLUSION THAT HOFFMANN-LaROCHE BREACHED A DUTY TO WARN HOLLY CHILDERS OF TERATOGENIC DANGERS?

POINT III

WAS THERE SUFFICIENT EVIDENCE OF LEGAL CAUSE IN THE RECORD TO PREVENT SUMMARY JUDGMENT?

POINT IV

DID THE RULINGS OF THE TRIAL COURT AND STATUS OF DISCOVERY MADE ENTRY OF SUMMARY JUDGMENT ERROR?

SUMMARY OF ARGUMENT

Petitioners argue that entry of final summary judgment for Respondents was error as there existed material issues of fact in the record which supported her allegations that Accutane was dangerous to have been marketed, was marketed with inadequate instructions and warnings, and was fraudulently misrepresented as safe as marketed; and that Respondent's acts were the legal cause of deceased's birth defects and death. Petitioners argue that a duty to adequately warn Holly Childers was breached after being undertaken by Hoffmann. Petitioners argue that evidentiary exclusions by the circuit court were erroneous and require reversal of the summary judgment. Finally, Petitioners argue that consideration of the summary judgment motion was untimely and that a meaningful continuance should have been granted.

POINT I

I. Summary Judgment Was Error Because Material Issues of Fact Existed Supporting Allegations that (A) Accutane Is So Unsafe That Marketing It At All Is Unreasonably Dangerous, (B) Alternatively, Accutane Was Unreasonably Dangerous As Marketed With Inadequate Warnings, Instructions and Safeguards, (C) Respondents Fraudulently Concealed Accutane's True Degree of Danger.

The Final Judgment in this case was via summary judgment.

> The law is well settled in Florida that a party moving for summary judgment must show conclusively the absence of any genuine issue of material fact and the court must draw every possible inference in favor of the party against whom a summary judgment is sought. [citations omitted]. A summary judgment should not be granted unless the facts are so crystallized that nothing remains but questions of law. [citations omitted]. If the evidence raises any issue of material fact, if it is conflicting, if it will permit different reasonable inferences, or if it tends to prove the issues, it should be submitted to the jury as a question of fact to be determined by it. [citations omitted].
> Moore v. Morris, 475 So.2d 666 (Fla. 1985); at 668.

Petitioners had requested a jury trial of their case (R.A. 993) and the summary judgment was error unless no factual issues remained for jury resolution.

Petitioners' pleadings alleged facts which could establish liability under alternate portions of Restatement (Second) of Torts, §402 A, concerning strict liability for unavoidably unsafe products (Fraud, Negligence, Breach of Warranty, and Statutory Misbranding of Drugs were also alleged). (R.A. 930-934).

Florida has adopted strict liability for products manufacture as stated by the Restatement (Second) of Torts, §402A. West v. Caterpillar Tractor Company, Inc., 336 So.2nd 80 (Fla. 1976), at 87.

> The obligation of the manufacturer must become what in justice it ought to be - an enterprise liability, and one which should not depend upon the intricacies of the law of sales. The cost of injuries or damages, either to persons or property, resulting from defective products, should be borne by the makers of the products who put them into the channels of trade, rather than by the injured or damaged persons who are ordinarily powerless to protect themselves. We therefore hold that a manufacturer is strictly liable in tort when an article he places on the market, knowing that it is to be used without inspection for defects, proves to have a defect that causes injury to a human being.
> West v. Caterpillar Tractor Company, Inc., Supra; at 92.

A. Facts Existed To Support Allegations That Accutane Is So Unsafe That Marketing It At All Was Unreasonably Dangerous.

Petitioners' Third Amended Complaint alleged:

> 37. Defendant, Hoffmann-LaRoche, Inc., developed, manufactured, marketed, sold and/or distributed a drug, Accutane, which Holly Childers purchased and consumed pursuant to the prescription of a duly licensed medical doctor. Accutane was and is a defective product. (R.A. 937).
> 12. Accutane was and is defective and/or unreasonably dangerous to human beings, especially women of child bearing age, as it is likely and/or virtually certain to cause pregnant women to conceive and/or bear malformed children, amongst other dangers. Accutane's dangers outweigh its benefits. (R.A. 932).

The record before the trial court certainly demonstrated that Accutane was, as termed by the Restatement, an "unavoidably unsafe product,"i.e., one inherently incapable of being "safe" no matter how carefully manufactured.

The question of whether Accutane was "unreasonably dangerous," thus "defective," must be answered with the analysis set forth in comment i to Section 402 A, Restatement (Second) of Torts.[5]

Determination whether a product reaches this degree of danger requires at least three factual determinations; (1) the amount of danger posed by the product, (2) what a reasonable man's[6] ordinary knowledge and expectations of danger would be, and (3) determination of the degree of benefit offered by the product versus the dangers it poses. A leading case stated the issue this way:

> In determining whether placing a commodity on the market is "unreasonably dangerous per se," the reasonable man standard of the Restatement becomes the fulcrum for a balancing process in which the utility of the product properly used is weighed against whatever dangers of harm inhere in its introduction into commerce. Obviously, use of an unavoidably unsafe product

---

5 "i. Unreasonably Dangerous. The rule stated in [402A] applies only where the defective condition of the product makes it unreasonably dangerous to the user or consumer. Many products cannot possibly be made entirely safe for all consumption, and any food or drug necessarily involves some risk of harm, if only from over consumption... The article sold must be dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics." Restatement (Second) of Torts, §402A, comment i.

6 This analysis of Accutane must be from the perspective of the prescribing physician as well as the ultimate consumer. See Buckner v. Allergan Pharmaceuticals, Inc., 400 So.2d 820 (Fla. 4th DCA 1981).

> always presents at least a minimal danger of harm, but only if the potential harmful effects of the product - both qualitative and quantitative - outweigh the legitimate public interest in its availability will it be declared unreasonably dangerous per se and the person placing it on the market held liable. Reyes v. Wyeth Laboratories, 498 F. 2d 1264 (5th Cir. 1974); at 1274.[7]

Accutane, the pleadings and proof of Petitioners would show, was unreasonably dangerous because of its inherent qualities and potential harm, and should never have been marketed (or, minimally, never should have been marketed for distribution to women of childbearing age). The law of strict liability will hold Respondents responsible for the damage resulting from Accutane's placement on the market if the jury accepts these facts. Stated another way, it is a question of fact, which should have been left for a jury, whether Accutane's harmful effects so outweighed its benefits that it should never have been placed on the market, irrespective of warnings, because it was inevitable or foreseeable that that Accutane would cause unreasonable harm.

---

[7] In Reyes there was no serious factual support to permit a finding that the product, a polio vaccine protecting the public against terrible disease, was too dangerous to market given the great benefit balanced against what the Court stated was a statistically miniscule risk of dangerous reaction to the vaccine. The court therefore found the vaccine not "unreasonably dangerous per se." This is markedly different than the facts concerning Accutane, which is primarily prescribed for temporary, cosmetic purposes, is "virtually certain" to cause horrible birth deformaties whenever pregnancy accompanies its use, has multiple other serious side effects requiring its use to be limited to a few months, and is responsible for over a thousand deformed babies and estimated thousands more miscarriages and abortions by exposed pregnant women. Accutane poses serious questions of fact which a jury must determine in considering whether it was too dangerous to be marketed. (R.A. 3503-3505, 3507-3511; 3428-3438; 3565-3567; 4692-4777; 4528-4691; Appendix Exhibits)

The evidence of record supports exactly this holding[8]. Some of the opposing affidavits expressly concluded Accutane was too dangerous even to have been marketed, with the birth defects of Petitioners' children the predictably sad results.[9][10] The Food and Drug Administration's approval was based on only "limited

---

[8] "Isotretinoin (Accutane), a retinoic acid - vitamin A analog, has been marketed in the United States since September 1982 for acne, ichthyosis and other skin conditions. Its potential teratogenicity was well known, based on malformations seen in newborn animals following exposure in early gestation to retinoic acid or retinoic acid analogs. Isotretinoin has been promoted by many physicians as a "cure" for acne, so it was inevitable that infants would be born after being exposed in the first trimester of pregnancy. An initial report noted the risk of spontaneous abortions when pregnant women were exposed to isotretinoin early in gestation. Hydrocephaly was found in four of four infants, microtia and ear anomalies in two of four infants, and microphalmia and transposition of the great vessels in one of four infants in retrospective studies. Isotretinoin was therefore listed as a severe hazard during pregnancy by the Food and Drug Administration [In the 1983 FDA Drug Bulletin]. Warnings were intensified and placed on the bottle, and the manufacturer wrote to practicing physicians in the United States (Pediatric News 1983; 17:13)." "The Isotretinoin Teratogen Syndrome," Paul J. Benke, M.D., Ph.D., Journal of the American Medical Association, June 22, 1984, Vol. 251, No.24, incorporated into Dr. Benke's affidavit opposing summary judgment (R.A. 3507-3511). Dr. Benke is a practicing medical specialist and Professor at the University of Miami School of Medicine with extensive knowledge and experience with Accutane and birth defects. (R.A. 4528-4691).

[9] "Based upon my review of the facts and circumstances relating to the release of Accutane upon the United States market for prescription pharmaceuticals in 1982, and the research results and the lack of certain research at the time of the release of Accutane upon the market, I can state within a reasonable probability that Accutane was not known to be reasonably safe and was capable of causing birth defects and other serious harmful effects, and should not have been released upon the market by its manufacturer. It was reasonably forseeable that the birth defects suffered by William Giles Childers and Kevin Felix-Baptiste would be caused by Accutane to infants in their position as a result of the release of Accutane upon the U.S. market by Hoffmann-LaRoche, Inc." Affidavit of James O'Donnell, Pharm.D.,M.S. (R.A. 3505-3507)

[10] Affidavit and deposition of Fred O. Pasternack, M.D., quoted and referenced in Point III, part 2 of this brief.

data" supplied by Hoffmann (R.A. deposition exhibit 17, quoted in Point III, part 2 of this brief), and Hoffmann's pre-marketing research and/or reporting was inadequate[11] (R.A. 3514). Noting the thousands of miscarriages and the babies that survive gestation with these congenital defects, and Petitioner's expert testified, "I think this is a very unrealistic amount of risk... balanced against the basic intent and purpose of this medication." (R.A. 2307; see also the recent newspaper articles in the appendix of this brief). The quantity of other evidence in the record from which reasonable inference can be taken that Accutane was too dangerous to be marketed is too extensive to be set forth in this brief.

B. Facts Existed To Support Allegations That Accutane Was Marketed With Inadequate Instructions and Warnings; and It Could Not Be Said As A Matter of Law That The Warnings Were Adequate.

Petitioners' Amended Complaint alleges:

> 47. Alternatively, Accutane was and/or is defective and unreasonably dangerous for human consumption, both inherently and as manufactured, sold, distributed, advertised, published, marketed and/or packaged by Hoffmann-LaRoche, Inc.; without adequate instructions and/or warnings and/or descriptive literature and/or package inserts and/or

[11] Paul Benke, M.D., Ph.D., in a second affidavit noted how important clues to the potent human teratogenicity were buried in the information given by Hoffmann to the FDA, specifically, how the cis compound, Accutane's chemical formula, was without teratogenic effect except in high doses in some lower animal studies, while the trans compound was a potent teratogen in animals even at low doses. Little or no cis was convered to trans in the rats tested by Roche, but human blood testing showed that human bodies convert the cis into the trans compound! (R.A. 3503-3505). The FDA materials referred to by Dr. Benke are Deposition Exhibit 21, boxed in the record, and reveal that Hoffmann never bothered to point out the significance of this to the FDA reviewers. This is not in keeping with the reporting requirements of 21 CFR concerning new drug applications.

> information and warnings in periodicals, newspapers and medical journals, pamphlets and circulars, and/or through sales representatives or detailmen; and through said Defendant's advertising, publicizing or dissemination of information, so that Hoffmann-LaRoche, Inc. failed to properly and reasonably warn the class of reasonably foreseeable users and/or the class of health care practitioners who foreseeably might prescribe Accutane and/or the distributors, promoters and sellers of Accutane of said dangers and defects in the drug, including the parties in this action. (R.A. 2745).
>
> 49. The lack or absence of such precautions and warnings by Hoffmann-LaRoche, Inc. imbued in said drug defective properties which posed an unreasonable danger of harm to the class of reasonably forseeable users and affected persons of which William Giles Childers and his parents were members. (R.A. 2746)
>
> 50. ....Hoffmann-LaRoche, Inc. breached its duties to warn, as previously pled, and as a proximate result thereof, Holly Childers ingested said drug prescribed by a medical doctor and gave birth to a malformed child, William Giles Childers, who died after his birth as a result of the malformation caused by Accutane. (R.A. 2746).

The Restatement sets forth standards of liability for failure to adequately give directions for use or adequately warn of inherent danger regarding unavoidably unsafe products as follows:

> 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 especially common in the field of drugs. An example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and even permanently injurious consequences when it is injected. Since the disease itself invariably results in a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidably high degree of risk which they involve. Such a product, properly prepared and accompanied by proper directions and warning, is not defective, nor

> directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other vaccines, drugs and the like, many of which for this very reason cannot be legally sold except to physicians, or under the prescription of a physician. It is also true, in particular, of many new or experimental drugs as to which, because of lack to time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable danger. Restatement (Second) of Torts, §402 A, comment k.[1]

Applying the Restatement comment k rule to the present case, the issue of fact becomes whether Accutane, if it had the right to be on the market at all, was properly on the market with reasonably adequate directions and warnings.

Florida has always said trial by jury is an organic right and should under no circumstances be denied. Orr v. Avon Florida Citrus Corporation, 130 Fla. 306, 177 So. 612 (1938); Tesher & Tesher, P.A. v. Rothfield, 392 So.2d 1000 (Fla. 4th DCA 1981).

1

> It might well be argued that this restriction of the strict liability doctrine is unwarranted, and unjustly places the risk of unforseeable harm upon the powerless individual rather than on the enterprising manufacturer, contrary to the public policy asserted in West v. Caterpillar Tractor Company, quoted Supra. However, this court does not need to reject comment k for resolution of the present case in Petitioners' favor on the issues of inadequate instruction and warning.

The constitutional right to jury trial demands that particular care be accorded in ruling on motions for summary judgment to the end that controverted issues of fact be resolved not upon pleadings and depositions but by a jury functioning under proper instructions. Drahota v. Taylor Construction Company, 89 So.2d 16 (Fla. 1956); Gartner v. Atlantic National Bank of Jacksonville, 350 So.2d 495 (Fla. 1st DCA 1977); Art. 1, §22, Fla. Const.

This Supreme Court, in Tampa Drug Company v. Wait, 103 So.2d 603 (Fla. 1958), ruled that a manufacturer or distributor of an inherently dangerous commodity has a duty to convey to those using the product a fair and adequate warning of its dangerous potentialities to the end that the user by the exercise of reasonable care on his own part shall have a fair and adequate notice of the possible consequences of use or even misuse. The manufacturer and distributor argued its duty had been discharged by labels on the container which gave notice of the dangers involved, and urged the Court to hold as a matter of law that the label was adequate to give notice to the decedent that use of the chemical could result in his death. The Court responded;

> While some might conclude that the notice on the label quoted in the forepart of this opinion would meet the requirements of adequacy, we do not feel that such a conclusion can be reached as a matter of law. The differences in the various labels in evidence of themselves demonstrate that reasonable minds might well differ on the sufficiency of the notice furnished by this label. We think that the sufficiency of the warning to place a reasonable man on notice of the potentially fatal consequences of the commodity here involved and under the conflicting evidence in

> this record justified submitting the problem to the jury for determination. Tampa Drug Company v. Wait, Supra., at 609.

The Supreme Court went on to say:

> Implicit in the duty to warn is the duty to warn with a degree of intensity that would cause a reasonable man to exercise for his own safety the caution commensurate with the potential danger. ....We do not agree that in a case such as this where the jury may draw varied inferences from the evidence properly before it that the trial judge should enter into the jury box and become an arbiter of the facts. Tampa Drug Company v. Wait, Supra., at 609.

In Lake v. Konstantineu, 189 So.2d 171 (Fla. 2nd DCA 1966), a Florida Court reversed a summary judgment for Parke, Davis & Company in a wrongful death case arising from the administration of the prescription drug Chloromycetin. The pleadings alleged Parke, Davis negligently failed to advise the medical profession of the inherent dangers in the drug, negligently lacked safety instructions to pharmacists and negligently failed to test the drug. The record indicated that the 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. The Second District said; "This issue above all others must certainly be submitted to a jury." Lake v. Konstantinu, Supra., at 174. After quoting from Tampa Drug Company, it further said:

> A movant for a summary judgment has the burden of demonstrating that there is no genuine issue on any material fact. All doubts regarding the existence of an issue are resolved against the movant and the evidence presented at the hearing plus favorable inferences reasonably justified thereby are liberally construed in favor of the opponent. [citation omitted]. A motion for summary judgment must be denied if the facts revealed by the depositions, ect.,

> failed to overcome every theory on which, under the pleadings, plaintiff's position might be sustained. [citation omitted]. Florida is committed to the "slightest doubt" rule and even though there is no conflict in the evidence, a motion for summary judgment should be denied where inferences are reasonably deductible therefrom casting doubt upon the issue of negligence. [citation omitted]. Lake v. Konstantinu, Supra., at 175.

In MacMurdo v. Upjohn Co., 444 So.2d 449 (Fla. 4th DCA 1983), a Florida Court reversed a summary judgment for the Upjohn Company, finding that there were genuine issues of material fact. Regarding the issue as to the adequacy and sufficiency of the warning given by Upjohn to the medical community, the Fourth District said:

> The trial court specifically found as a basis for the summary judgment:
>
> > The the warnings contained in the package insert which are contained in the Court file were sufficient and adequate warnings to the medical community lawfully authorized to prescribe, dispense and administer prescription drugs.
>
> Thus, it is clear that the trial court read the warning subjectively and determined as a matter of law that same was sufficient and adequate. This was error under the law of this state. It is not for judges but it is for the jury to determine if a particular warning is adequate under the circumstances. MacMurdo v. Upjohn Co., Supra., at 450, 451.

The MacMurdo Court went on to find "unsound" Upjohn's argument that summary judgment was proper because there was no conflicting testimony on the adequacy of the warning, saying that:

> Here, the jury could have considered the dangerous propensities of Depo - Provera and decided that the warning given was insufficient

> because it was not sufficiently intense or was not sufficiently explicit and detailed or was not sufficiently alarming or was not sufficiently prohibitive or for other reasons. Of course, it would have decided oppositely. But, in all events, the adequacy of the warning is for the jury to decide and may not be disposed of by summary judgment. MacMurdo v. Upjohn Co., Supra., at 451.

In Ricci v. Parke-Davis & Co., 491 So.2d 1182 (Fla. 4th DCA 1986), Pet. for rev. denied, 501 So.2d 1283 (Fla. 1986), a Florida Court reversed a summary judgment for a prescription drug manufacturer who had been sued for alleged failure to adequately warn. The Court said it was undisputed that the manufacturer had a duty to warn the medical community with respect to any potential side effects from the use of its product, citing Buckner v. Allergan Pharmaceuticals, Inc., 400 So.2d 820 (Fla. 5th DCA 1981), pet. for rev. denied, 407 So.2d 1102 (Fla. 1981).

The Ricci Court said that despite strong deposition testimony by the medical witnesses in favor of the defense, the Plaintiff was entitled to have the adequacy and sufficiency of warnings and information furnished by Parke-Davis to the doctors and health care providers prescribing and administering its pills determined by a jury and not as a matter of law, being, "clearly a jury issue in Florida." Ricci v. Parke-Davis & Co., Supra at 1182.

David Ziskind, technical writer with expertise and experience in composition, review and design of FDA regulated product descriptions and warnings for new products; with educational, clinical research, professional authorship and lecture experience; who's work involves composition and layout of

product warnings very similar to that used in the PDR by Hoffmann for Accutane; who reviewed various materials including medical literature on Accutane, comparative warnings used with other pharmaceutical products including those of Hoffmann itself; and who was qualified to express expert opinions on the standards applicable to package insert materials; gave opinions in two affidavits timely filed in opposition to the summary judgment motion, that the Respondents' package insert was inadequate, due to its lack of instructions and inadequate, deceptive warnings. (R.A. 3482-3498); 3516-3519).[2] Dr. Pasternack (See Point III of this brief) and Dr. O'Donnell (R.A. 3565-3567) also found the warnings inadequate, as did the FDA (R.A. 3507-3511). Significantly Respondent's package insert did not comply with federally required language for catagory X drugs despite Accutane's placement in such catagory, but markedly de-emphasized the teratogenic properties, was closer to the catagory C warning language used for drugs which are allowed to be prescribed in pregnancy in a physician's discretion, and the insert lacked the bold, boxed warnings federally required. 21 CFR §201.57(f)(6)(e)[1982]. As to the other evidence on record that the predictable effects of the drug allow inferences that the Respondent's warnings and instructions to physicians were inadequate, it is too extensive to list it all here.

[2] Paragraphs 11 through 20 of Ziskind's Supplemental Affidavit (R.A. 3517-3519) are so important they would be reproduced in whole here if space permitted.

C. The Record Fails To Support The Trial Court's Entry Of A Summary Judgment On The Allegations Of Fraudulent Representation To The Food and Drug Administration In Hoffmann's Efforts to Seek Federal Approval For Accutane's Market Release.

> Fraud is not ordinarily a proper subject for summary judgment because, being a subtle matter, fraud requires a full explanation of the facts and circumstances of the alleged wrong to permit a determination whether they collectively constitute fraud [citations omitted] and for that reason such determination is seldom one that can be made in a legally sufficient manner, without a trial. Nessim v. DeLoache, 384 So.2d 1341 (Fla. 3d DCA 1980), at 1344.

Petitioners allege that Hoffmann and/or Roche applied for Food and Drug Administration approval and falsely represented through communications with official agencies and physicians relying upon their communications that Accutane would be reasonably safe and beneficial beyond its inherent dangers. (R.A. 2738, 2739; 2743, 2744). Petitioners allege:

> 14. These Defendants misrepresentations concealed the defective nature of Accutane and/or the dangers inherent in such drug from the public, the parents of Kevin Felix-Baptiste, and from physicians, including Gerald Greenwald, M.D., who were likely to prescribe Accutane to their patients; as the Defendants were in a greatly superior position to that of said persons to know the falsity of said misrepresentations, and/or Defendants' acts tended affirmatively to be a supression of the truth, and/or withdrawal or distraction of said persons' attention from the real facts. (R.A. 2739).

There was record evidence that Hoffmann had not fully investigated or analyzed Accutane for the FDA or not reported its findings, described more fully elsewhere in this brief. There was record evidence indicating that Respondents had not utilized

language mandated by 21 CFR §201.50 for catagory X pregnancy drugs as its package insert (R.A. 3915). Furthermore, discovery material to the fraud allegations was still pending at the time of summary judgment hearing. Summary Judgment on this issue was improper.

POINT II

Record Supported Conclusion That Hoffmann Breached A Duty To Warn Holly Childers of Teratogenic Dangers

"The law imposes an obligation on everyone who attempts to do anything, even gratuitously, for another, to exercise some degree of care and skill in the performance of what he has undertaken." Padgett v. School Board of Escambia County, 395 So.2d 584 (Fla. 1st DCA 1981). The Padgett case determined that when warnings are undertaken, even by one who had no duty otherwise to warn, one has a duty to warn properly.

Wheareas ordinarily the "learned intermediary" described in Buckner v. Allergan Pharmaceuticals, Supra., is the only one to whom prescription drug manufacturers would owe a duty, if the record reflects they undertook to warn the ultimate consumer, then the duty to properly warn, as described in Restatement comment k, extends to that consumer. Padgett, Supra.

Petitioners alleged precisely such a duty was undertaken by Respondents in the Complaint. (R.A. 2743-2748; 2764-2769).

The record reveals factual support for such allegation in that Holly Childers was supplied a written, explicit warning advising her of the purported side effects of Accutane by the University of Miami; (R.A. 3523-3530) alleged in the Complaint to

be then acting as the agent and pursuant to contractual arrangement with Hoffmann, (R.A. 2740) which allegations were never refuted by Respondents in pleadings or by evidence supporting their claims that no material facts existed. Summary Judgment should never have been granted, as the record contains said written warning, and it reveals that Holly Childers was told absolutely nothing about Accutane having any teratogenic dangers whatsoever! (R.A. 3525-3530). With this grossly inadequate warning, which expressly stated the risks of Accutane were minimal and represented itself to be a full warning, Holly Childers could hardly have been expected to appreciate or shield herself from the teratogenic dangers of Accutane when she recommenced its use presumably believing she already knew everything necessary to reasonably ingest the drug.

POINT III

There Was Sufficient Evidence Of Legal Cause In The Record To Prevent Summary Judgment.

Legal cause, a/k/a proximate cause, must be demonstrated or be inferable from the record to support a jury verdict for a plaintiff on strict liability claims as well as on claims for negligence, fraud, and breach of warranty. As Respondents had only moved for summary judgment upon all issues, however, and not for individualized partial summary judgment rulings on specified portions of Petitioner's case, Petitioner had only to demonstrate that the record supported a finding of legal cause due to a defect, negligence, fraud or breach on any of her theories of

liability to prevail against the motion. See Cheshire v. Magnacard, Inc., 510 So.2d 1231 (Fla. 2nd DCA 1987); Fla. R. Civ. P. 1.510(c).

As to Petitioners' claims that Accutane was too unsafe to have been marketed at all, which have been discussed at some length in part A of Point I of this brief, obviously the record supported such allegation that Accutane, as "unreasonably dangerous per se," was the legal cause of the damages and death. Had Respondents never placed Accutane on the market, it would not have been prescribed or ingested by Holly Childers, who testified in her deposition that it was news of the drug's FDA approval which prompted her to contact Dr. Schackner and schedule an appointment to obtain an Accutane prescription. (R.A. 4176, 4177), and William Giles Childers would never have suffered the birth defects which the record demonstrates were the cause of his death.[3]

The foregoing alone should have disposed of the legal cause argument of Respondents.

However, the record showed further support for Petitioners regarding their allegations that, alternatively, the Respondent's failure to adequately instruct and warn were the legal cause of the birth defects and death.

Specifically, Holly Childers' deposition indicated that until she delivered her child (R.A. 4205) she had no knowledge about the teratogenic properties of Accutane Without any

[3] Respondents did not attempt to argue at the summary judgment hearing nor before the Third District that Accutane was not the physical cause of the birth defects or death.

instructions or warnings about birth control or pregnancy, Dr. Schackner gave her a prescription for Accutane (R.A. 4180),which her father filled at Super X Drugs (R.A. 4183, 4184). Dr. Schackner did not treat her in any fashion other than to give her a prescription for Accutane. (R.A. 4183). He did not inquire about birth control (R.A. 4180).

That Respondent's promotion and warnings had not adequately put the medical community on notice is reflected in the fact that when Holly Childers advised the obstetrical doctor providing with prenatal care that she had taken Accutane, he discussed nothing with her about any dangers or advice regarding terminating the pregnancy. (R.A. 4204, 4205). Holly Childers did not find out about the fetal abnormalities until after the ceasarian delivery. (R.A. 4205). No pregnancy testing, no wait for completion of a menstrual cycle, no confirmation or prescription of birth control was ever undertaken by Dr. Schackner.

Dr. Schackner supplied Respondents with an Affidavit. He is a co-defendant in this action and faced with claims for medical malpractice. (R.A. 2770-2771).

Dr. Schackner's testimony contradicted Holly Childers' testimony as to whether he warned her about side effects.

There is a presumption that had Respondents provided reasonably adequate instructions and warnings, that the prescribing physician would have read and followed them.

In conclusion, given the conflict between the interested doctor's claims he "was concerned" about the dangers of birth defects and warned Holly Childers of them, versus Holly Childers'

contradicting testimony coupled with the uncontroverted lack of any meaningful exclusion of the possibility of pregnancy prior to the doctor's prescription, it is well within a jury's ability to find that Dr. Schackner was not adequately informed about the danger of birth defects when he prescribed the drug and that his lack of information resulted from the Respondents' inadequate and/or missing instructions and warnings concerning Accutane.

Also supporting the allegation of legal cause is the deposition of Hoffmann's detailman, Lester M. Wachman. Wachman testified that it was his job to make office visits to promote Accutane and instruct physicians, regarding its use. (R.A. 2111, 2112, 2122-2124, 2174). He never specified any procedures to be followed by physicians prescribing Accutane to their female patients other than not to prescribe it to a pregnant female or one considering pregnancy. (R.A. 2186). He never advised any physicians to prescribe birth control to Accutane patients before placing them on an Accutane prescription. (R.A. 2188). He never advised any physicians to delay prescribing Accutane to a female patient until after she has demonstrated that she has had her period. (R.A. 2188). Until the package insert changed (In late 1983) he never advised any physicians to take a pregnancy test from a female patient prior to prescribing Accutane. (R.A. 2189).

Detail men for Hoffmann compete for cash bonuses which are based, at least partly, upon the gross sales of the products within their assigned territories measured by independent companies monitoring market shares. (R.A. 2195-2200, 2203-2205).

In conclusion, it appears from the record that a jury could infer that, had the instructions and warnings provided by Respondents been adequate, Dr. Schackner would have abided by them and that but for the inadequate instructions and warnings, the birth defects and death of William Giles Childers would not have occurred.

Florida law on this is best stated by Ricci v. Parke-Davis & Co., Supra., where the Fourth District said that even though there was, "overwhelming evidence that the doctors in this case all received and understood the warnings which they were furnished, and that they considered the warnings and information provided by [Parke-Davis & Co.] to be adequate.... plaintiff has raised a genuine issue of material fact, which was supported by the affidavit of at least one non-treating physician, placing in issue the adequacy of the warning...[Plaintiff] is entitled to have these disputed fact issues determined by a jury and not as a matter of law." Ricci, Supra., at 1182, 1183.

POINT IV

The Rulings Of The Trial Court and Status of Discovery Made Entry of Summary Judgment Error.

A. Disallowing Evidence at the Summary Judgment Hearings.

Florida has carefully narrowed discretionary limits of a trial court to disallow evidence, affidavits and requests for rehearings presented by a party opposing summary judgment; in

recognition of the summary judgment procedure being in derogation of the constitutionally protected right to trial. Holl v. Talcott, 191 So.2d 40 (Fla. 1966).

Nevertheless, the various rulings of the circuit court excluding Petitioner's evidence severely prejudiced defense of Respondents' motions, and suggest arbitrary or erroneous evidentiary rulings not proper in a summary judgment hearing.

The issues raised in the pleadings included allegations that Respondents' fraudulently misrepresented the degree of danger and relative utility of Accutane when seeking FDA approval and initially marketing the drug (R.A. 936, 937); strict liability for inadequate instructions and learnings (R.A. 938, 939; 957; 959); and also allegations that the Respondents' negligently developed and tested Accutane prior to or while marketing and promoting it (R.A. 941, 942; 962).

1. Revisions in Package Inserts and Promotional Materials

Certainly relevant to these allegations was the fact that Accutane's "package insert" had been significantly revised several times[4] greatly intensifying the warnings to prescribing

---

4

Note too the article entitled; "More Cautionary Labeling Appears on Isotretinoin," which appeared in the Journal of the American Medical Association on June 22, 1984, Volume 251, No. 24, at page 3208, which notes, "The labeling contains two boxed warnings that were not in the earlier version. These emphasized in boldface type that the drug should not be used by women who are pregnant... the FDA has advised the blood banking community that patients receiving isotretinoin should not donate blood for a transfusion for 30 days after the use of the drug. The director of the Division of Blood and Blood Products... pointed out that the biological effects of the drug appear to last a long time, even though its presence in the blood may not be measurable after a week. The new labeling was developed after reports last year of birth defects and spontaneous abortions in women who were

physicians and so as to include instructions to doctors (for example, to test for pregnancy before prescribing, to wait for conclusion of a menstrual cycle, to prescribe only in conjunction with effective birth control, ect.). (R.A. 2267). Such modified pharmaceutical labeling has been found admissable in Florida concerning summary judgment hearings where it was ruled to create an issue requiring submission to a jury. Lake v. Konstantinue, Supra.

Rather than accept the revised warnings as evidence demonstrating a conflict on what reasonable instructions or warnings might have been, the circuit court ruled at the summary judgment hearing that it would not consider the revised language on the basis that Florida Statute §90.402[5] made it inadmissable.

It is noteable that the changes in wording were required by the FDA and not freely undertaken by Respondents, and that in prescription pharmaceutical cases the policy considerations for the subsequent remedial evidence exclusion are inapplicable. It is further noteable that the pleadings of Hoffmann, Wachman and Roche disclaimed knowledge of the dangerous nature of Accutane; (R.A. 1293-1298; 1299-1303; 1288-1292); and that Respondents submitted an Affidavit (R.A. 1222) which attempted to argue by

---

being treated with isotretinoin...the initial labeling warned against prescribing the drug in pregnant women...the problem is that there seems to be "quite a contrast between these striking defects reported retrospectively in association with Accutane." [quote of Franz W. Rosa, M.D., Ph.D., an epidemiologist with the FDA's Division of Drug Experiment]."

[5] Florida Statute 90.407; "Subsequent remedial measures. 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 admissable to prove negligence or culpable conduct in connection with the event.

inference that its warnings were reasonably safe. Murray v. Almaden Vineyards, 429 So.2d 24 (Fla. 2nd DCA 1983) indicates that there is an exception to §90.407 inadmissability where the defendant offers evidence that a product was safe and there was no reason to change it, which is precisely what respondents argued their warnings were as a matter of law at the summary judgment hearing.

Petitioner's allegations of fraud are analogous to those in Johns-Manville Sales Corp. v. Janssens, 463 So.2d 242 (Fla. 1st DCA 1984), pet. for rev. denied 467 So.2d 999, where another exception to §90.407 was carved out where the changes showed Defendant's continuation of an intentional course of conduct decided upon prior to exposure to the product.

It might also be considered appropriate, as to the interpretation of Florida Statute §90.407 is now before this Court in a strict liability setting, to consider whether it is better for Florida to follow the reasoning of Jeep Corp. v. Murray, 708 P.2d 297 (Nevada 1985), where the state construed an identical statute inapplicable to strict liability products cases on weighing the policy considerations and the statutory language's own restricted application to negligent or culpable conduct. This would be a judicially wise move, and would correct the misapplication of §90.407 evidenced by recent district court opinions[6].

---

[6] Alderman v. Wysong & Miles Co., 486 So.2d 673 (Fla. 1st DCA 1986); Voynar v. Butler Mfg. Co., 463 So.2d 409 (Fla. 4th DCA 1985).

Rather than accept the revised warnings as evidence demonstrating a conflict on what reasonable instructions or warnings might have been, the circuit court ruled at the summary judgment hearing that it would not consider the revised language on the basis that Florida Statute §90.407[12] made it inadmissable.

It is noteable that the changes in wording were required by the FDA and not freely undertaken by Respondents, and that in prescription pharmaceutical cases the policy considerations for the subsequent remedial evidence exclusion are inapplicable. It is further noteable that the pleadings of Hoffmann, Wachman and Roche disclaimed knowledge of the dangerous nature of Accutane; (R.A. 1293-1298; 1299-1303; 1288-1292); and that Respondents submitted an Affidavit (R.A. 1222) which attempted to argue by inference that its warnings were reasonably safe. Murray v. Almaden Vineyards, 429 So.2d 24 (Fla. 2nd DCA 1983) indicates that there is an exception to §90.407 inadmissability where the defendant offers evidence that a product was safe and there was no reason to change it, which is precisely what respondents argued their warnings were as a matter of law at the summary judgment hearing.

Petitioner's allegations of fraud are analogous to those in Johns-Manville Sales Corp. v. Janssens, 463 So.2d 242 (Fla. 1st DCA 1984), pet. for rev. denied 467 So.2d 999, where another

---

12 Florida Statute 90.407; Subsequent remedial measures. "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 admissable to prove negligence or culpable conduct in connection with the event."

exception to §90.407 was carved out where the changes showed Defendant's continuation of an intentional course of conduct decided upon prior to exposure to the product.

It might also be considered appropriate, as the interpretation of Florida Statute §90.407 is now before this Court the first time in a strict liability setting, to consider whether it is better for Florida to follow the reasoning of Jeep Corp. v. Murray, 708 P.2d 297 (Nevada 1985), where the state construed an identical statute inapplicable to strict liability products cases on weighing the policy considerations and the statutory language's own restricted application to negligent or culpable conduct. This would be a judicially wise move, and would correct the misapplication of §90.407 evidenced by recent district court opinions[13].

2. Dr. Pasternack's Testimony

Two Affidavits[14] and a deposition from Fred O. Pasternack, M.D., were before the Court in the summary judgment deliberations (R.A. 3428-3438; 3512-3515; 2211-2320).

---

13 Alderman v. Wysong & Miles Co., 486 So.2d 673 (Fla. 1st DCA 1986); Voynar v. Butler Mfg. Co., 463 So.2d 409 (Fla. 4th DCA 1985).

14 Although the second affidavit was filed May 13, 1986, and the Summary Judgment hearing was May 8, 1986, the Circuit Court's Order of May 6, 1986 (R.A. 3479-3480) extended the time for filing counter-affidavits to "20 days from the date stated on defendants' last notice of hearing [April 23, 1986]," i.e., to May 13, 1986, so the affidavit was timely filed. It is disturbing to note that although the Circuit Court had extended the time for filing opposing evidence to May 13, 1986, and in fact several opposing affidavits and exhibits were filed that day, the circuit court also signed its Order of Summary Judgment May 13, 1986 and could not have considered these timely filed evidence opposing the motion.

> 13. The detailmen working for Accutane's manufacturer and sellers should have advised physicians who were considering prescription of the drug that proper procedures necessitated: placement of the patient on birth control before the prescription; keeping the patient on birth control medication throughout the prescription period and afterwards until the body was free of the drug; obtaining a negative pregnancy test result before prescribing or administering Accutane; and that a physician should wait for the completion of a menstrual cycle before commencing Accutane administration. Because of the severity of the teratogenic effects of Accutane, not giving such advice through detail men would be improper conduct by a pharmaceutical firm, below industry standards for reasonable behavior. (R.A. 3514).

Dr. Pasternack also found the language in the package insert to be misleading, watered-down, not strong enough, and inadequate. (R.A. 2241-2246). He testified how the mere use of the word teratogenic is itself not an adequate indication of the degree of risk posed by a product, and that the degree of risk was not stated in Accutane's package insert (R.A. 2240 to 2244).

---

track," and the conditions of fewer than 600 patients were evaluated nationwide before its approval. In the past, most FDA approved drugs were used overseas for several years, and, therefore, a vast international data based existed to draw on for human toxicology data. This was not here for this medication. Since this drug, hailed as a "cure for acne," has had such massive media exposure (in television talk shows and popular magazines), the majority of patients with acne are well aware of its benefits. Unfortunately, neither patients nor physicians have been made aware of its potential toxicity..." Journal of the American Medical Association, January 21, 1983, Vol. 249, No. 3, page 350.

Florida Statute §90.702 says a witness qualified as an expert by knowledge, skill, experience, training or education may testify as to this opinion about the evidence or a fact in issue if scientific, technical or other specialized knowledge will assist the trier of fact. The facts or data upon which an expert bases his opinion need not themselves be admissable in evidence if of a type reasonably relied upon by experts in the subject to support the opinion expressed. Fla. Stat. §90.704. Opinion testimony including an ultimate issue to be decided by the trier of fact is not thereby objectionable. Fla. Stat. §90.703. While it has been said that in trial, a judge has the discretionary function of determining qualifications and the range of subjects on which experts may testify, which appellate courts will not disturb absent a clear showing of abuse of discretion, Guy v. Kight, 431 So.2d 653 (Fla. 5th DCA 1983); when considering a motion for summary judgment, the presumptions which favor the party moved against continue and must be applied throughout the entire consideration of the motion, the papers and opposing affidavits should be liberally read and construed (while movant's papers read strictly), receipt of supplementary or corrective affidavits should be liberally allowed, and the opponent of the motion is not obligated to have his expert witness cover all the details and formalities that would be required in offering the same experts' testimony at a trial of the cause. Holl v. Talcott, Supra. As this Court has stated, to hold a plaintiff opposing a motion for summary judgment to the same requirements in his affidavits as will be applied at trial, "would turn the

summary judgment process itself into a trial of, rather than a search for, issues.... The evidentiary matter offered... need not be in the exact form, or cover all the preliminaries, predicates, and details which would be required of a witness, particularly an expert witness, if he were on the stand at trial. Holl v. Talcott, Supra at 45.

Nevertheless, the circuit court granted Respondent's motion (R.A. 1227) to strike Dr. Pasternack as an expert. This was clearly an abuse of discretion. Although the question of expertise should initially be determined by the Court, the weight to be given such testimony is for the jury. Ritter v. Jimenez, 343 So.2d 659 (Fla. 3d DCA 1977). The Respondent's motion to strike Dr. Pasternack's affidavit and exclude his deposition contained an open invitation to weigh the testimony, by arguing that Dr. Greenwald's awareness of the definition of the word "teratogenicity" alone made all evidence of inadequate instructions or warnings irrelevant. (R.A. 1227). The circuit court in error succumbed to this temptation.

The order on Motion to Strike Pasternack's Affidavit and Deposition entered May 7, 1986 (R.A. 1332) did not strike the affidavit or deposition but rather ruled the testimony would not be considered expert testimony. Petitioner filed a motion to continue the hearing set for May 8, 1986 upon the motions for summary judgment, on the grounds that Petitioner had relied upon Dr. Pasternack's affidavit and deposition to defend the summary judgment motions, and now required more time prior to the hearings to file further affidavits in support of her allegations

(R.A. 3472-3474). The Court denied the request for additional days to file opposing affidavits (R.A. 3479-3480) a patently insufficient response to Petitioner's predicament, and violative of this Supreme Court's policy expressed in Holl v. Talcott, Supra., regarding allowing the filing of corrective or supplemental affidavits. That this act by the circuit court was not harmless is evidenced by the fact that Petitioner's counsel was in fact able to file the affidavit of Dr. James O'Donnell prior to the re-set hearing for Summary Judgment on the Childers case on July 23, 1986 (R.A. 3556-3559; 3565-3567) which provided essentially the same expert opinions as to Respondents' liability that Dr. Pasternack's testimony did.

3. Incomplete Discovery

There is no need to reiterate the information contained in the statement of the Case and Facts, which demonstrates that Petitioner had been involved in a frustrating war with Respondents over Respondents repeated refusals to provide meaningful discovery. Without these discovery responses, Petitioner's allegations of fraud and negligence were not demonstrable via record evidence at the summary judgment hearing.[8]

It was error for the Circuit Court to proceed with the summary judgment hearings, over the objections at hearing (R.A. 1389-1434) and motions for continuance (R.A. 3815-3816) of

---

[8] Of course, neither had Respondents provided the requisite affirmative showing which negated such allegations.

Petitioner, given the status of the discovery. Commercial Bank of Kendall v. Heiman, 322 So.2d 564 (Fla. 3d DCA 1975); Lovelace v. Sobrino, 380 So.2d 514 (Fla. 3d DCA 1973).

> A summary judgment should not be granted until the facts have been sufficiently developed to enable the Court to be reasonably certain that there is no genuine issue of material fact. [citation ommitted]. Similarly, a summary judgment is also premature where there has been insufficient time for discovery, [citation ommitted], or where a party through no fault of his own, has not yet completed discovery, [citation ommitted], or where objections to interrogatories and a motion to produce are pending. [citation ommitted]. Singer v. Star, 510 So.2d 637 (Fla. 4th DCA 1987).

CONCLUSION

Based on the foregoing argument, the record of the lower court proceedings, the evidence and the failure of Respondents to demonstrate the lack of material issues of fact concerning the allegations against them, the Summary Judgment should be reversed.

Respectfully submitted,

LAW OFFICES OF JEFFREY P. KAISER
Attorneys for the Petitioners
15476 N.W. 77th Court - Suite 315
Miami Lakes, Florida 33016
Phone: (305) 822-8484

By _____
JEFFREY P. KAISER, ESQ.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing was mailed to Mercer Clarke, Esq., Attorney for Respondents, 100 Chopin Plaza, Suite 2400, Miami, Florida 33131, this 2nd day of May, 1988.

LAW OFFICES OF JEFFREY P. KAISER
Attorneys for the Petitioners
15476 N.W. 77th Court - Suite 315
Miami Lakes, Florida 33016
Phone: (305) 822-8484

By _____
JEFFREY P. KAISER, ESQ.