OA 6-20-88

IN THE SUPREME COURT OF FLORIDA

CASE NO. 71,633

YOLANDA FELIX, as personal representative of the ESTATE OF KEVIN FELIX-BAPTISTE,

Petitioner,

vs.

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

Respondents,

****

INITIAL BRIEF OF PETITIONER

ON THE MERITS

****

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STATEMENT OF THE CASE AND FACTS

INTRODUCTION:

Petitioner, Yolanda Felix, as Personal Representative of the estate of Kevin Felix-Baptiste, was Plaintiff in the Circuit Court of the 11th Judicial Circuit in and for Dade County, Florida and Appellant in the Third District Court of Appeal. Respondents, Hoffmann-LaRoche, Inc., Roche Biomedical Laboratories, Bindley-Western Industries, Gray Drug Stores, Inc., Gray Drug Stores Inc. of Miami, The Sherwin Williams Company, and Lester M. Wachman, were Defendants in the Circuit Court and Appellees in the Third District Court of Appeal.

Decedent, Kevin Felix-Baptiste, died on November 24, 1983, having been born June 26, 1983 with multiple, severe birth defects, as a proximate result of a prescription drug prescribed to his mother for acne in October 1982 when she was pregnant. 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."

A wrongful death action against Hoffmann-LaRoche was filed September 4, 1984, in Dade County Circuit Court by the personal representative of the decedent's estate.

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 May 13, 1986. (R.A. 3814).

The Summary Judgment was appealed to the Third District Court of Appeal via timely Notice of Appeal filed July 14, 1986. (R.A. 3538-3539).

The Third District Court of Appeal issued a written opinion on September 29, 1987, affirming the Summary Judgment. Felix v. Hoffmann-LaRoche, Inc., (R.A. 4913-4915). The Third District's written opinion addressed only one point of several raised before it in the appeal.

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 on October 14, 1987. The Third District entered an Order denying that motion on November 17, 1987. (R.A. 4916).

Petitioner 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 Petitioner's request to extend time for filing her initial brief, ordering that same be served by May 2, 1988.

Petitioner concurrently seeks review of the denial of her motion for rehearing and/or clarification of the final summary judgment (R.A. 3817-3818) and the denial of her motion to strike notice of hearing and/or to continue hearing on the motion for summary judgment (R.A. 3821-3823).

The record on appeal for this case was consolidated by the Third District Court of Appeal with the record for Case No. 71,634 for purposes of appeal by Order of the Third District Court entered September 26, 1986. On July 10, 1985, discovery proceedings at the trial level were consolidated (R.A. 3242-3244), and therefore a single record exists as to the two cases.

Petitioner 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), 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 cystic acne (R.A. 3451, 4100). There are other cystic acne treatments available (R.A. 4106, 2396). Petitioner also seeks damages for negligence, breach of warranty, misbranded drugs and for fraudulent concealment (R.A. 936-937).

In 1982, Yolanda Felix became pregnant just before undergoing Accutane treatment for acne (R.A. 4100, 934). As a result of the Accutane in her body (R.A. 1405), her infant, Kevin Felix-Baptiste, was born with numerous, severe malformations (R.A. 934, 3428-3438, 3875-3879), on June 26, 1983 (R.A. 934), and died November 24, 1983 (R.A. 1405, 2396-2400). 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

Petitioner initially commenced this litigation on September 4, 1984 against only one of the Respondents, Hoffmann-LaRoche, Inc., manufacturer of Accutane (R.A. 1-14). Respondents Roche Lester M. Wachman, Bindley-Western Industries, Inc., Gray Drug Stores, Inc., of Miami, and Gray Drug Stores Inc., became parties by the Interim Amended Complaint (R.A. 839-887), following two Orders allowing the amendment of the Complaint (R.A. 405, R.A. 813), delayed because of the difficulty Petitioner had in identifying these parties through discovery (R.A. 930-994). It was not until Petitioner filed the Third Amended Complaint on November 25, 1985 (R.A. 930-994) that Respondent The Sherwin Williams Company (hereinafter Sherwin-Williams), owner of Respondent Gray Drug Stores, Inc., of Miami, and Gray Drug Stores Inc., (hereinafter Gray Drug Stores), was named as a party defendant (R.A. 974-977).

Four of the Respondents filed Answers and Affirmative Defenses to the Third Amended Complaint, (R.A. 1175-1180) Sherwin Williams; (R.A. 1288-1292). Roche; (R.A. 1293-1298) Hoffmann; and (R.A. 1299-1303) Wachman. In March and April, 1986, Petitioner filed her Replies to Respondents' Affirmative Defenses (R.A. 1225-1226) Sherwin Williams; (R.A. 1304-1306) Wachman; (R.A. 1307-1309) Hoffmann; and (R.A. 1310-1312) Roche. The other three Respondents relied on Motions to Dismiss filed in 1985 (R.A. 1111-1113) Bindley Western Industries, Inc., (hereinafter Bindley Western); (R.A. 3316-3317) Gray Drug Stores, as of May 8, 1986 (R.A. 1389), the date of the hearing on Respondents' Motions for Summary Judgment (R.A. 782-786; R.A. 3449-3452).

On August 9, 1985, Respondent Hoffmann filed its Motion for Summary Judgment (R.A. 782-786), accompanied with an Affidavit (787-793) and Memorandum of Law (R.A. 801-812). On April 21, 1986, Counsel for Respondent Hoffmann filed one Motion for Summary Judgment for the remaining Respondents, adopting the Motion, Affidavit, and Memorandum of Law of Hoffmann on the stated basis of "contingent liability" (R.A. 3449-3450). These motions were heard May 8, 1986 (R.A. 1389-1484); and the Final Summary Judgment for Respondents(R.A. 3814) was not re-heard or clarified (R.A. 3817-3818), nor was Petitioner's Motion to Continue granted (R.A. 3821-3823).

B. Material Facts and Issues

In or about June, 1982, Respondent Hoffmann published a four-page package insert (R.A. 3915) which allegedly complied with Federal Food and Drug Administration labeling requirements (R.A. 3904) for wholesale distribution of the drug Accutane. A

copy of this publication is attached to Hoffmann's undated Answers to Plaintiff's Third Set of Interrogatories (R.A. 3945-3953). This same brochure is Exhibit "A" to the deposition of treating physician Gerald Greenwald, M.D., (R.A. 2489; and Deposition Exhibit 3 referred to between R.A. 3511 and R.A. 3512, [copy in portion of record contained in small box identified in index of record]). A similarly worded publication dated December, 1982 was also referred to as an Exhibit, Exhibit "B" to the deposition of Dr. Greenwald (R.A. 2489; and Deposition Exhibit 4 contained in boxed exhibits). From said package insert 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 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, also appears boxed exhibits as Deposition Exhibit 21 (R.A. 2269-2270), and is referred to between R.A. 3511 and R.A. 3512. The wording in the "contraindications" portions of the 1982 package inserts differs markedly from the wording in the August, 1983 package insert. In August, 1983, the following phrase first appears:

> **"Women of childbearing potential should not be given Accutane until pregnancy is excluded." Deposition Exhibit 21, (R.A. 2269-2270)**

This wording does not appear in the package inserts available to treating physician Gerald Greenwald, M.D., at the time he was treating Petitioner. Instead, the wording in the June and December, 1982 brochures, being without three paragraphs of specific directives, merely suggested:

> "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." Deposition Exhibit 4, R.A. 3589, referred to between R.A. 3511 and R.A. 3512,

By August, 1983, the "should" was changed to a bold "must". (R.A. 2269-2270).

On February 19, 1986, Respondents took the deposition of Fred O. Pasternack (R.A. 2211-2320), who had worked for a drug manufacturing firm as a liaison. On March 23, 1986, Petitioner served notice of filing the Affidavits of Paul Benke, M.D., who had authored at least one article on Accutane, and of Fred O. Pasternack, who discussed the marketing of Accutane (R.A. 3428-3438), along with the deposition transcript of Fred O. Pasternack (R.A. 2211-2320). On March 28, 1986, Respondents moved to exclude the Affidavit and deposition transcript of Fred O. Pasternack (R.A. 1227-1230). Hearing was scheduled May 2, 1986, re-scheduled before a different judge and heard May 6, 1986, and the Order was entered on May 7, 1986 (R.A. 1332-1334), the date before the hearing on Appellees' Motions for Summary Judgment.

On May 8, 1986, the Trial Court stated it would consider the Affidavit of Petitioner's Expert Witness David Ziskind (R.A. 1428, R.A. 3483-3498). Respondents' Motion to Strike the

Supplemental Affidavit of David Ziskind served May 13, 1986 (R.A. 3516-3519, of Paul Benke, M.D., R.A. 3503-3505, 3507-3511), and of Fred O. Pasternack (R.A. 3512-3515) was denied by Order entered June 13, 1986 (R.A. 1362-1364).

With reference to Petitioner's witness Fred O. Pasternack, during the May 2, 1986 hearing on Respondents' Motion, the Trial Judge (R.A. 3788-3790) asked that the Motion be scheduled before the Honorable John Gale to determine whether Fred O. Pasternack was qualified to testify as an expert in this case (R.A. 4098-4113). At the (non-evidentary) hearing May 6, 1986 (R.A. 4098-4115), counsel for Respondents argued both sides of the issue of whether expert testimony was or was not needed on the issue of adequacy of warnings (R.A. 4103-4104), just as Respondents had been self-contradictory in the Motion on the subject (R.A. 1227-1228). At the hearing, counsel for Respondents stated on the one hand:

> "There is nothing magical about the language in the package insert. It is plain English and it simply isn't subject to expert evaluation." (R.A. 4103).

and on the other hand:

> "...it is impossible to seriously contend that simply getting a medical degree entitles a person to render an expert opinion on any medical issue." (R.A. 4105).

The outcome was an Order which did not exclude the Affidavit and deposition transcript, but struck them as testimony of an expert (R.A. 1332-1334, 4111), and this determination was read into the record at summary judgment hearing by the Trial Judge (R.A. 1392).

On Motion for Rehearing of the granting of summary judgment for Respondents, Petitioner reminded the Court that an additional period had been granted to Petitioner to file additional Affidavits, and the period did not expire until May 13, 1986, five days after the summary judgment hearing (R.A. 1340-1344). These Affidavits were therefore before the Court in considering the Motion of Petitioner to rehear the summary judgment hearing (R.A. 3503-3522), in addition to those previously filed (R.A. 3428-3498).

Attached and incorporated into the Affidavit of Paul Benke, M.D. (R.A. 3435-3438, 3507-3511) was a copy of the medical article written by Dr. Benke on the relationship of Accutane to the malformations suffered by Petitioner's infant son as well as the infant who is the subject of the companion case herein. The article made reference to studies of fetal deformity published in 1972 (R.A. 3438, 3511). Respondent Hoffmann admits a causal relationship between the use of Accutane during pregnancy and fetal defects (R.A. 3912, 1432). The written acknowledgement of this knowledge as it appears in the package insert published by Respondent Hoffmann in August, 1983 came after the Petitioner's first discovery that anything of this nature was wrong with her child (R.A. 1710), but preceded the infant's death by approximately three months (R.A. 1919).

Counsel for Petitioner, during the hearing on summary judgment, read to the Court portions of an article published November 19, 1984 (R.A. 1418-1419). This was a warning published by Appellee Hoffmann regarding the use of Accutane, and included was the requirement of a negative pregnancy test two weeks prior

to initiating therapy (R.A. 1418). This article was actually deposition Exhibit 16, contained in the record in the boxed exhibits, and filed with the Circuit Court May 6, 1986. Counsel for Respondents argued that this evidence would be precluded under Florida Statutes §90.704, "Subsequent Remedial Measures" claiming as such evidence would not be "admissible [at trial] to prove ... strict liability," and therefore should not be considered at the time of hearing on a motion for summary judgment (R.A. 1432-1434). Shortly after hearing this argument, the Court entered Final Summary Judgment for Respondents. (R.A. 1433). The article or publication quoted by counsel for Petitioner was already in the record, inasmuch as it was Deposition Exhibit 16, and is referred to in the Record on Appeal between R.A. 3511 and R.A. 3512. Although counsel for Respondents did move to exclude the entire deposition of Dr. Pasternack (R.A. 1227-1230) that request was not heard until May 6, 1986, and was not granted. (R.A. 1332-1334). Neither the Motion nor the Memorandum of Law in Support of the Motion (R.A. 1227-1230, 1233-1245) refer to Florida Statutes §90.704.

Respondents' contended at the summary judgment hearing that the deposition of the treating physician, former party defendant Gerald Greenwald, M.D. (R.A. 2321-2497), disposed of the issue of adequacy of and need for instructions or warnings regarding the use of Accutane in this case (R.A. 1397-1405), and therefore shifted any possible blame for what occurred away from Respondents. Respondents contended that the doctor's self assessed but disputed level of knowledge with reference to Accutane or products with similar components (R.A. 2432-2434,

2461, 2471-2472, 2494) rendered warnings irrelevant (R.A. 1409-1410). Petitioner's position was that what the treating physician may have known generally about the drug, first introduced into the market a few months prior to its ingestion by Petitioner (R.A. 3902, 2430) is one thing; what he was or was not advised would be required because of hazards involved in the use of it is another thing. In addition, under the facts and circumstances existing in this case, including primarily cosmetic benefit weighed against risks, Petitioner contended she was entitled to a jury trial on whether the drug should have been marketed at all.

There is evidence of record that the drug should not have even been on the market (R.A. 3429-3432; 3565-3567; various deposition exhibits stressing the extreme dangers of the drug). There is also evidence of record that Respondents failed to comply with FDA labeling requirements in distributing the drug (R.A. 3945-3953), and that Respondent Hoffmann knew and had reason to know of these shortcomings and risks which it concealed in the wording used in its package inserts in 1982 (R.A. 3508-3511; the various Exhibits evidencing pre-marketing, conclusive proof of the teratagenicity of isotretinoin, the human metabolism studies described in Exhibit 21 demonstrating the body's transformation of the cis-isomer to the tranz isomer [100% teratagenic test results after human ingestion; 3514; 2241-2246).

C. Incomplete Discovery

With reference to written discovery requests to Respondents, at the time of entry of Final Summary Judgment for Respondents, Petitioner's Request to Produce to Appellee Wachman filed May 2,

1986 (R.A. 3469-2471) had not been responded to, and Petitioner's Motions to Compel directed to Respondents Hoffmann (R.A. 3463-3465) and Wachman (R.A. 3466-3468) as to prior discovery had not been heard.

The following exemplifies time and effort devoted by counsel for the Court to preliminary discovery covering a period of more than a year and a half. Also included are explanations of some factors which seriously impeded discovery proceedings for Petitioner.

Between September, 1984 and October 26, 1984, counsel for Petitioner propounded four Requests to Produce to Respondent Hoffmann. Three initial Requests to Produce (R.A. 15-17, 18-21, and 22-24) were served just after the original complaint and the fourth separately (R.A. 40-41).

Between September, 1984 and February 27, 1985, counsel for Petitioner propounded four sets of Interrogatories to Respondent Hoffmann.

Respondent Hoffmann's objections to discovery were first filed October 18, 1984 (R.A. 32-33), and thereafter Hoffmann filed a Motion to Extend Time to Respond (R.A. 63-64). On February 12, 1985, Petitioner filed two Motions to Compel Hoffmann to Answer the First Set of Interrogatories (R.A. 108-121) and the Second Set of Interrogatories (R.A. 97-107) served October 22, 1984, the subject of which included basic corporate information and information regarding testing, reporting and marketing Accutane. On February 22, 1985, Petitioner noted that amending the complaint to add party defendants was being delayed by overdue discovery from Hoffmann

(R.A. 205-206). On March 4, 1985, the Court entered an Order requiring Answers to Interrogatories and Responses to Requests to Produce within a time certain (R.A. 1203-1205). On March 14, 1985, Petitioner filed a Motion to Compel answers to the Third Set of Interrogatories (R.A. 230-259), the subject of which included New Drug Applications, Safety and Effectiveness. On April 9, 1985, two Orders were entered requiring responses by Hoffmann within a time certain (R.A. 392-394, 395-397). Six days later, Petitioner filed a Motion to Compel Better Answers to Interrogatories (R.A. 402-403). On May 3, 1985, Hoffmann filed a Memorandum in Opposition to Petitioner's Motion to Compel (R.A. 414-421). A non-evidentiary hearing was held May 6, 1985 (R.A. 471-522), (see specifically pages 497-498), and thereafter Petitioner filed a Memorandum regarding discovery on the subject of warnings (R.A. 535-539). On May 29, 1985, Hoffmann was ordered to produce better Answers (R.A. 593-596), and the next day Petitioner agreed to an Order allowing Hoffmann time to May 28, 1985, to respond to discovery (R.A. 588). On June 5, 1985, Petitioner filed a Motion to Strike Objections and to Determine Sufficiency of Hoffmann's Responses to Requests for Admissions (R.A. 635-637). On June 13, 1985, the Court entered a nunc pro tunc Order as to Motions for Protective Order (R.A. 664-667), and another Order requiring a Special Master to deal with discovery matters (R.A. 668-672). On June 18, 1985, Hoffmann served notice of serving Supplemental Answers to Interrogatories (R.A. 679-694).

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).

Much of the discovery in the early months of 1986 pertained to other parties not involved in this appeal. On May 2, 1986, six days prior to hearing on summary judgment, 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).

With respect solely 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 a Memorandum of Law and Affidavit in Support followed on April 1, 1985 (R.A. 297-325, 326-333). Petitioner filed a Memorandum in Opposition on April 9, 1985 (R.A. 358-388). The hearing held March 20, 1985 (R.A. 262-292, 348-379), was continued April 4, 1985 (R.A. 4833-4874). On May 29, 1985, Hoffmann filed a Motion to Strike or for Protective Order (R.A. 577-578), and a Motion for Protective Order as to the deposition of a corporate representative on June 6, 1985 (R.A. 642-649). A hearing on these motions was held June 23, 1985 (R.A. 698-734). A further hearing was held September 23, 1985 (R.A. 3108-3138), and December 2, 1985 (R.A. 3674-3742), and yet a further hearing on December 23, 1985 (R.A. 3743-3761). The subject of the 1-1/2 hour hearing December 2, 1985 before a Special Master was discovery, and specifically Respondent Hoffmann's corporate representative's deposition; and on December

23, 1985 a primary subject was Petitioner's Requests to Produce propounded over a year before. With trial already set for December, 1985, (R.A. 723, 751-752) it did not appear that meaningful discovery proceedings could possibly be concluded prior to trial. Respondent Hoffmann had also filed Motions for Protective Order on November 25, 1985 (R.A. 3345-3352), and on December 10, 1985 (R.A. 3368-3390). In December, 1985, the Special Master reported (R.A. 3391-3392), and the Court entered two Orders (R.A. 3360-3365, 3393-3395).

With reference to discovery by deposition, Petitioner served the following Notices of Taking Deposition of Corporate Representative of Hoffmann:

03/12/85 (R.A. 219-221)
05/13/85 (R.A. 526-527)
05/13/85 (R.A. 528-530)
05/31/85 (R.A. 611-612)
05/31/85 (R.A. 611-615)
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. 3313-3315)
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 Hoffmann (R.A. 4085-4097). On October 8, 1985, a deposition was taken in New Jersey (R.A. 2033-2053), at which the corporate representative produced proved totally unknowledgeable in the areas for which the deposition had been noticed (R.A. 2033-2053). Thereafter, Petitioner tried to again notice a meaningful deposition.

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 Special Master Herbert Stettin was the deposition of a corporate representative of Appellee Hoffmann. Thereafter, notices were again attempted.

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 Hoffmann to arrange the taking of the deposition of a corporate representative of Hoffmann (R.A. 3463-3465). On May 8, 1986, six days later, Final Summary Judgment for Hoffmann was entered (R.A. 1433).

During the May 2, 1986 hearing (R.A. 3807-3811) and again May 8, 1986 (R.A. 1413), counsel for Petitioner raised with the Trial Judge the matter of incomplete discovery with reference to pending Motions for Summary Judgment of the Appellees. The Court's response was:

> "...if [the master] says discovery, you were dilatory, it's your fault, not their fault, the it's going to be denied. If he says yes, you've done everything you can, you need more time to complete discovery, then I certainly will defer my opinion." (R.A. 3811).

This ruling was placed in the form of written Order on June 16, 1986 (R.A. 3815-3816). On June 25, 1986, however, instead of a ruling on dilatoriness of Petitioner, the Special Master found that Hoffmann "did not unreasonably impede" Petitioner in seeking discovery (R.A. 3535-3537); although at hearing the master noted that "of course" Respondents had delayed their discovery responses (R.A. 1431-1506), and also on June 25, 1986,

the Trial Court entered an Order finally denying Appellant's Motion to Continue the Summary Judgment hearing (R.A. 3821-3823).

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

POINT III

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

SUMMARY OF ARGUMENT

Petitioner argues 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. Petitioner argues that evidentiary exclusions by the circuit court were erroneous and require reversal of the summary judgment. Finally, Petitioner argues 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, And (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.

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

Petitioner's 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 Yolanda Felix 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.[1]

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[2] 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 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.

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1 "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.

2 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).

Reyes v. Wyeth Laboratories, 498 F. 2d 1264 (5th Cir. 1974); at 1274.[3]

Accutane, the pleadings and proof of Petitioner 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.

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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[1]. 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.[2][3] The Food

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[1] "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).

[2] "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)

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

and Drug Administration's approval was based on only "limited 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[7] (R.A. 3514). Noting the thousands of miscarriages and the babies that survive gestation with these congenital defects, 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 to 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.

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[7] 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.

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.

Petitioner's Third Amended Complaint alleged:

> 40. 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 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. 938)
>
> 42. 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 Kevin Felix-Baptiste and his parents were members. (R.A. 939)
>
> 43. ....Hoffmann-LaRoche, Inc. breached its duties to warn, as previously pled, and as a proximate result thereof, Yolanda Felix ingested said drug prescribed by a medical doctor and gave birth to a malformed child, Kevin Felix-Baptiste, who died after his birth as a result of the malformation caused by Accutane. (R.A. 939).

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 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.[8]

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.

8

> 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 Petitioner's favor on the issues of inadequate instruction and warning.

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). 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 and 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).[1] 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 indicating 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.

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[1] 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.

Petitioner alleged 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. 932, 933). Petitioner alleged:

> 17. 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. 933).

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 §201.57 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

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 Petitioner's 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 obviously

would not have been prescribed or ingested by Yolanda Felix and Kevin Felix-Baptiste would never have suffered the birth defects which the record demonstrates were the cause of his death.[10]

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

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

Specifically, Yolanda Felix's deposition indicated that prior to her first visit to Dr. Greenwald, she had no knowledge about Accutane (R.A. 1671). After seeing Dr. Greenwald's name in the yellow pages (R.A. 1659), she went to his office the first time, when he looked at her face and chest (R.A. 1666). She told him she was having some skin problems and needed his advice on what to use (R.A. 1666), and he gave her a prescription for Accutane (R.A. 1674, 1675) which she filled at Gray Drugs (R.A. 1677). Dr. Greenwald did not tell her that she should not become pregnant while taking Accutane. (R.A. 1670). The only mention of the word, pregnancy, came when Dr. Greenwald said, "You're not planning on getting pregnant, are you?" to which Yolanda Felix responded no. (R.A. 1671). Of course, Kevin Felix-Baptiste was born June 26, 1983, so Yolanda Felix was presumably pregnant when she first saw Dr. Greenwald, although unaware of it. In December, 1982, she last saw Dr. Greenwald, and asked him what she should do if she became pregnant, to which he responded, just

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[10] 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.

stop taking the medication. (R.A. 1700). No pregnancy testing, no wait for completion of a menstrual cycle, no confirmation or prescription of birth control was ever undertaken by Dr. Greenwald. Dr. Greenwald's response, even to the inquiry as to what Yolanda Felix should do if she learned she was pregnant, was "nonchalant." (R.A. 1706).

Dr. Greenwald had his deposition taken as an interested party, a co-defendant faced with claims for medical malpractice. (R.A. 2325). He alleged he knew about Accutane from something received from Hoffmann in the mail, had attended a seminar sponsored by Hoffmann, had read some periodical articles about it, and had read an Accutane package insert. (R.A. 2409, 2412, 2415, 2418). He said, "I felt I had thorough and complete information by the time the drug became publicly available." (R.A. 2417). He came away from Hoffmann's seminar convinced that Accutane was a wonder drug for people with acne. (R.A. 2426).

Dr. Greenwald's testimony contradicted Yolanda Felix's as to whether he warned her about side effects. Although his testimony in 1985 was that he had an understanding of the potential of the drug for birth defects when he prescribed it in November 1982, he admitted that all he did for Yolanda Felix on the first visit was to observe her, make statements to her, take her medical history, then prescribe Accutane. (R.A. 2454, 2455). He did not clearly recall her physical appearance or whether she had any grossly distinguishing marks such as a pierced nose or gold capped tooth. (R.A. 2336, 2337). He believed that everything he did concerning his decision to prescribe Accutane to Yolanda Felix and then to re-prescribe Accutane at the time and in the manner he treated

her was in accordance with the prescribed information that he had obtained from Hoffmann-LaRoche. (R.A. 2470, 2471). He never monitored her blood levels, and never inquired whether she had pregnancy testing before commencing the drug. (R.A. 2472). He never wrote any prescription for any kind of birth control device or medication (R.A. 2473). He did not know what the Food and Drug Administration's category "C" classification denotes, and when asked what the Food and Drug Administration's category "X" denotes, said; "I believe it denotes that you should not use it during pregnancy, medication that you should not use during pregnancy. I may be wrong." (R.A. 2384).

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 knew about the dangers of birth defects and warned Yolanda Felix of them, versus Yolanda Felix's contradicting testimony coupled with the conceded 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. Greenwald 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, including Greenwald, regarding

its use. (R.A. 2111, 2112, 2122-2124, 2174). He had spoken with Dr. Greenwald about Accutane at length in Greenwald's office (R.A. 2182-2184) but 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). He never had any conversations with Gerald Greenwald, M.D., about any of these precautionary procedures. (R.A. 2192).

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. Greenwald would have abided by them and that but for the inadequate instructions and warnings, the birth defects and death of Kevin Felix-Baptiste 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 III

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 warnings (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[1] greatly intensifying the warnings to prescribing 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.

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1 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 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]."

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[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

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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).

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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.

Doctor Pasternack, the record revealed, is a medical doctor licensed in Florida since 1956, who worked for the pharmaceutical industry from 1957 through 1961 in research and development of new prescription medications, had reviewed various materials, records, sworn statements and summaries regarding the Felix-Baptiste and Childers infants, of a type reasonably relied upon by experts in this field to support the opinions he expressed. (R.A. 3429-3431). He had for four years been employed at Lederle Laboratories, Inc., one of the largest manufacturers of prescription drugs on the U.S. market, as regional coordinator for new product clinical research and development, a job involving the areas of expertise he testified upon in his affidavits and deposition, including coordination of clinical research and submission of investigational results for new drug applications to the F.D.A., and was responsible for communication with Lederle's marketing and sales area representatives regarding untoward side effects. (R.A. 3512-3513). Since 1963, he has spent a great deal of his time in forensic medicine and as a medical legal consultant. (R.A. 2215). As one of five physicians with his rank at Lederle, each assigned different national territories (R.A. 2217-2219), he was involved in clinical analysis of new drug products' efficacies and risks following animal testing (R.A. 2220, 2221). He was familiar with the problems in preparing and amending package inserts for FDA approval encountered by Lederle with the new products. (R.A. 2225-2227). The "negligence and errors of Accutane's manufacturer and sellers" to which he testified

involved basic principles of clinical testing and product development which are unchanged from the date of his employment at Lederle, he stated. (R.A. 3513).

Dr. Pasternack stated:

> Accutane should not have been put on the market for general use of the medical profession for child bearing females since the medication was potentially so destructive for in utero infants... I respectfully suggest that one review the horrors Thalidomide caused pregnant women in the 1960's. Lessons are soon forgotten by the drug industry... The Accutane provided by Defendants to the mothers of the two deceased infants was unreasonably dangerous and therefore defective and its defective nature caused the infant's death. (R.A. 3431-3432).

> 12. Based upon my review of the F.D.A. materials [The Summary basis of Approval and other documents received from the F.D.A.], Hoffmann-LaRoche, Inc., did not submit any test results concerning the teratogenicity of Accutane, as tested in guinea pigs and primates, to the F.D.A. when seeking approval of its new drug application. This demonstrates insufficient research and development, or insufficient disclosure if such testing was performed; considering the results of the test on rats and rabbits, the history of Vitamin A and etretinate as human teratogens, and the unavailability of data on human teratogenicity of Isotretinoin (Accutane). (R.A. 3514)[15].

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[15] Note also Exhibit 17 to Dr. Pasternack's deposition, a letter to the editor of the Journal of the American Medical Association written by Frank W. Yoder, M.D., a pioneer int he clinical studies of isotretinoin, and formerly associated with the National Institute of Health, who said, "the potential toxicity of this drug has been seriously underemphasized.... Food and Drug Administration approval for this medication was based on limited data. The F.D.A. put isotretinoin on a "fast 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

> 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 is misstated in Accutane's package insert (R.A. 2240 to 2244).

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

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> 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.

testimony including an ultimate issue ot 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 funciton 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.[16]

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, 3472-3474, 3821-3823) of 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).

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

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,

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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.

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