O/a 6-20-84 orig.

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,

****

CORRECTED REPLY BRIEF OF PETITIONER

****

LAW OFFICES OF JEFFREY P. KAISER
Palm Springs Center - Suite 514
1840 West 49th Street
Hialeah, Florida 33012
Phone: (305) 822-8484

TABLE OF CONTENTS

Page

CITATIONS OF AUTHORITIES

PAGE

General Cases

Florida Cases

Other Authorities

STATEMENT OF THE CASE AND OF THE FACTS

The Petitioner adheres to and adopts by reference in this Reply Brief the Statement of the Case and Facts contained in her initial brief in this cause. The parties will be referred to in this brief as they were in the Petitioner's initial brief (i.e., Respondent, Hoffmann LaRoche, Inc., as "Hoffmann", and Respondent, Roche Biomedical Laboratories, Inc., as "Roche". The symbols for reference used in Appellant's initial brief will also be used in this Reply Brief (i.e., "R.A." for record on appeal, followed by the page number). Additional symbols will be "IX" for Appendix to the initial brief; "AX", for the Appendix to the answer brief; and "RX" for the Appendix to this reply brief.

Petitioner does not accept the Statement of the Facts submitted by Respondents, as same is misleading and omits in important part reference to the record. Respondents exaggerate the intensity and significance of their product warnings by omitting the surrounding text. Respondents mischaracterize Dr. Greenwald's testimony rather than quoting it in context where its inconclusive and ambiguous nature is apparent. Respondents misstate the holding of the trial court concerning Dr. Pasternack's testimony which clearly was limited to a ruling on his expertise (R.A. 4098-4115; 1332-1334), and did not strike his testimony altogether. Respondents' derogatory references to Mr. Ziskind are conclusory and out of place in a statement of facts (and if true indicate that trial judge erroneously weighed the

evidence at the summary judgment hearing just as Petitioner argues). The reference to Dr. O'Donnell in Petitioner's Statement Of The Case And Facts (Page 11) was properly made to support the portion of Petitioner's argument indicating that prejudicial error resulted from the trial court's refusal to grant more time to file additional evidence opposing the summary judgment motion after the announcement that the Court would not consider Dr. Pasternack's expert opinions (Pages 47-48). Hoffmann's answers to interrogatories (R.A. 3945-3953) were cited by Petitioner's Initial Brief as indicia of the form of Hoffmann's package insert; the insert's variance from the requirements of 21 CFR §201.57(f)(6)(e) is manifest (IX, item 3), and it does not have the boxed, bold warnings required by 21 CFR §201.57(e) (IX item 3). Petitioner's reference to Dr. Benke's first affidavit (R.A. 3507-3511) is cited in conjunction with his second affidavit (R.A. 3503-3505) which demonstrate that certainty or likelihood of human fetal monstrosities was known to Hoffmann but was concealed in the body of its FDA submissions.

As to Respondents' Statement of the Case, Petitioner does not accept same as it is misleading, argumentative and without supporting references to the record on appeal. Gratuitous statements that Petitioner made no attempts to obtain hearings, or to obtain production and other discovery, are incorrect and misrepresent the record which evidences nearly two years of constant effort to obtain discovery, thwarted at every step by Respondents.

ISSUES PRESENTED

The Petitioner adheres to her original statement of the issues presented, which are restated here for convenience:

POINT I

WAS SUMMARY JUDGMENT ERROR BECAUSE MATERIAL ISSUES OF FACT EXITED 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?

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?

ARGUMENT

INTRODUCTION: Reply to Jurisdictional Challenge In Introduction to Respondents' Argument.

This Court has accepted jurisdiction based on conflict[1]. Once jurisdiction is accepted, it should review the entire case on the merits as though the decision was by direct appeal. Bankers Multiple Line Ins. Co. v. Farish, 464 So.2d 530 (Fla. 1985); Tyrus v. Apalachicola Northern Railroad Co., 130 So.2d 580 (Fla. 1961). It is unimportant as to jurisdiction whether the Third District's opinion appealed from discussed issues that this Court finds demonstrate error in the Circuit Court.

I. Reply to Respondents' Argument on Petitioner's Point I

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

a. Florida should recognize cause of action for marketing of unreasonably dangerous per se pharmaceutical product.

Contrary to Respondents' argument that would immunize them from strict liability, U.S. Courts which have fully analyzed the issue generally are in accord with the scholars who state:

---

[1] Respondents' attempt to reopen the jurisdictional issue in the Answer Brief (p. 12-13) raises points both incorrect and immaterial. Incorrect; because the Third District's alternate basis for its ruling (legal cause) conflicted directly with Ricci v. Parke-Davis & Co., 491 So.2d 1182 (Fla. 4th DCA 1986) as noted at pages 7-8 of the Brief of Petitioner on Jurisdiction where case conflict about the existence of proximate (legal) cause under similar facts is highlighted. Respondents argument is immaterial to this Court's jurisdiction, as any conflict in opinions, even a conflict based on obiter dictum, establishes jurisdiction. Garcia v. Cedars of Lebanon Hosp. Corp., 444 So.2d 538, n. 3 (Fla. 3d DCA 1984); Sweet v. Josephson, 173 So.2d 444 (Fla. 1965); State v. Moore's Estate, 153 So.2d 819 (Fla. 1963); Sunad, Inc. v. City of Sarasota, 122 So.2d 611 (Fla. 1960).

> Since most drugs possess both utility and risk of danger, a two-step analysis has been utilized by the courts. Initially, the court should determine whether the product is unsafe to such a degree that placing the product on the market, alone, is unreasonably dangerous per se. The court should further examine whether the product has been placed in the stream of commerce without adequate safeguards and is thereby rendered unreasonably dangerous as marketed. In either case, the Restatement defines an unreasonably dangerous product, in terms of the user's interest, as being a product that is dangerous to a degree beyond that contemplated by an ordinary consumer. In terms of the seller's responsibility, an unreasonably dangerous product is one that is "so dangerous that a reasonable man would not sell the product if he knew the risk involved. The reasonable man standard set forth in the Restatement becomes the key to a balancing test whereby the utility of the product is weighed against any dangers of harm that may be caused by the product's introduction into commerce.

Maedgen, "A Survey of Law Regarding The Liability of Manufacturers and Sellers of Drug Products and Medical Devices", 18 St. Mary's L.J. 395, at 400 (1986); See Kinney v. Hutchinson, 468 So.2d 714 (La. Ct. App. 1985).

A leading case is Feldman v. Lederle Laboratories, 479 A. 2nd 374 (N.J. 1984). The drug manufacturer made the same arguments in Feldman that they have attempted here in Florida. New Jersey reasoned that drug manufacturers have no claim to immunity from strict liability law; and that the Restatement's comment k immunizes from strict liability the manufacturers of some products, including certain drugs, but that there is no reason to hold as a matter of law and policy that all prescription drugs that are unsafe are unavoidably so. Feldman, Supra; at 382, 383[2]. Brown v. Superior Court, 245 Cal. Rptr. 412, 751 P.2d 470

[2] "Drugs, like any other products, may contain defects that could

(Cal. 1988) and Collins v. Karoll, 231 Cal. Rptr. 396 (Cal. App. 1986) are poorly reasoned. It is clear that the Collins holding that FDA approval conclusively determines factual issues as to risk/benefit, ect., is not logically valid as the FDA process of self-reporting by manufacturers is anathema to principles of jurisprudence if seriously proposed as an alternative to redress of grievances through the Courts. It is also clear the the Brown court, analyzing a life-saving drug, never considered a case involving a minimally beneficial drug like Accutane. Given the instant facts, this Court should not make the logical error of the Brown court and should accept the fully reasoned analysis of Feldman and legal scholars[3] .

The issue of risk/benefit analysis is evidentiary, and should be decided in the trial court, just as it is for a jury to determine whether warnings are sufficient should it be found that

---

have been avoided by better manufacturing or design. Whether a drug is unavoidably unsafe [and thus entitled to treatment under comment k] should be decided on a case-by-case basis." Feldman, Supra, at 383. "The emphasis of the strict liability doctrine is upon the safety of the product, rather than the reasonableness of the manufacturer's conduct... the doctrine of strict liability assumes that enterprises should be responsible for damages to consumers resulting from defective products regardless of fault". Feldman, Supra; at 385. The Court then goes on to set forth criteria for determination of liability in the courtroom, including burden of proof, ect.

3 See the detailed analysis of precedent, logic and policy contained in the two appended articles. Selke, "An Escape from Strict Liability: Pharmaceutical Manufacturers' Responsibility for Drug-Related Injuries under Comment k to Section 402A of the Restatement (Second) of Torts", 23 Duq. L.R. 199 (1984); Kelly, "Prescription Drugs and Strict Liability: The Flaw in the Ointment", 19 Pacific L.J. 193 (1987).

the pharmaceutical product qualifies under comment k for marketing. Toner v. Lederle Laboratories, 112 Idaho 328, 732 P.2d 297 (Idaho 1987).

In Florida, such questions of fact are constitutionally required to be resolved via jury trial, as is discussed further as to factual determination of warning adequacy, infra.

b. Facts in this case supported allegations that accutane was unreasonably dangerous per se.

For lack of space, Petitioner cannot state here her disapproval of every factual assertion of Respondents, but would point out that the facts in opposition to the motion for summary judgment are spelled out in more detail in the initial brief and elsewhere herein.

Contrary to Respondent's contention, deposition Exhibit 17 (quoted in the initial brief) is in the record[4].

Dr. Benke's testimony and affidavits also clearly raises the issue of risk versus benefit, as do the authorities contained in the deposition exhibits. The incidence of the horrible side effects suffered by the deceased, and their predictability, also demonstrate an issue only suitable for a trier of fact.

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.

a. Florida must continue to recognize that adequacy of instructions and warnings is a jury issue. Facts in this case supported allegation that instructions and warnings were inadequate.

---

[4] See boxed exhibits accompanying documentary record, described in Clerk's Index. A copy is appended for reference. (RX 5).

This Court has already accepted conflict jurisdiction based upon the conflicts asserted in Petitioner's juridictional brief[5].

Respondents argument that the adequacy of pharmaceutical warnings should be determined as a matter of law by judges is wrong. Arguing that judges have the intellectual abilities to make such a factual finding misses the point. Florida's law is constitutionally governed, and guarantees litigants a right to jury determination of factual disputes. Art 1, § 22, Fla. Const. This Court is not free to disregard this principle in favor of convenience, "flattering" appeals to judicial intelligence, or policy arguments for industry favortism[6].

Respondents' argument on this issue is especially inappropriate in this case, where the evidence before the Circuit Court[7] certainly established an issue which could not be resolved

---

5 Petitioner's jurisdictional brief contains an adequate response to Respondents argument on pages 20-23 concerning existence of conflict. The purpose of conflict jurisdiction, of course, is to remedy both actual and apparent conflict. The four cases establishing jurisdiction present an actual conflict with the Third District's Felix decision.

6 See Drahota v. Taylor Construction Company, 89 So.2d 16, at 18 (Fla. 1956).

7 For example, see Mr. Ziskind's Supplemental Affidavit, which the trial court found admissible and purportedly considered in arriving at its ruling at the hearing. Ziskind's competent expert analysis found Hoffmann's package insert inadequate, misleading and unreasonably insufficient by standards applicable to FDA regulated warnings (RA 3517-3519). A copy of said affidavit is attached to the appendix to this Reply Brief for this Court's convenience. (RX 1-4). Allowing judges to subjectively interpret medical warnings would make judges ultimate arbiters of their adequacy without benefit of medical or industrial expertise.

merely by a judicial reading, i.e., whether pharmaceutical industry standards were met by HOFFMANN'S original package insert.

Petitioner takes issue with the unsupported assertion in the Answer Brief alleging it to be too great a burden on the pharmaceutical industry to defend its product warnings in court. This argument cannot evade the constitutional issues, but aside from that, numerous courts[8] and legal scholars[9] have found such argument questionable and rejected it. There is hardly any commercial industry which could not couch an argument for favored treatment in the same language. Recent experience in Florida with the insurance industry points to the error of special interests obtaining judicial favortism.

Respondents argument that wherever a package insert mentions the exact side effect suffered it must be found adequate as a matter of law cites to foreign cases but misses the significant issue recognized by this Court in Tampa Drug Co. v. Wait, 103 So.2d 603 (Fla. 1958), that it is not only the content but the degree of intensity of the warning which allows a jury to draw varied inferences. Here it might be added that a jury's comparative review of a specialized medical warning like Accutane's with those used on similar medications (here, the record showed drugs like Valium with far less serious teratogenic

---

8 Feldman v. Lederle Laboratories, Supra; Toner v. Lederle Laboratories, Supra;

9 Selker, Supra; 215-219. Also see Kelley, Supra at 201, n. 72.

effects had much more intense and prominent package insert language), and evaluation of expert testimony should play an important function.

Johnson v. American Cyanamid Co., 718 P.2d 1318 (Kan. 1986) relied on in the Answer Brief, is immediately distinguishable as to the policy considerations before that Court, and as the side effect (contact polio) is statisticly small and unpredictable, whereas the adverse effects of Accutane might be avoided by precautions which the package insert reasonably should have mandated, and were certain to occur if pregnancy occurs during the ingestion period. The inadequacy of Accutane warnings is further evidenced by the number of physicians who did not appreciate the dangers and by the reports of adverse effects which came in from its use during the period the particular package insert was in use. (See initial Brief, page 40, note 1)

The record does not support the unreferenced contention at page 25 of Respondents' Brief that Accutane's warning had been approved by the FDA, which is not conceded by Petitioner. It is neither conceded that the warning accurately reflected existing knowledge as to the drug's dangerous potential. See discussion of evidence of fraudulent concealment, infra. Furthermore, the actual language of Accutane's package insert varied significantly from FDA regulation minimum teratogenicity warnings, as described in the Initial Brief, and was on its face in conflict therewith. Lastly, it is the duty of a manufacturer under FDA regulations to without agency action put out stronger warnings than those

originally submitted or approved as soon as it is apparent that the existing warnings may not be sufficient. See 21 CFR § 130.9; Feldman v. Lederle Laboratories, Supra; at 389-391.

Respondents falsely assert in their Answer Brief that Mr. Ziskind's affidavit was not accepted by the Circuit Court when the opposite is true (see cite infra.) Mr. Ziskind specifically raised the issue as to inadequacy of Respondents' warnings in his affidavits. A copy of his supplemental affidavit (RA 3517-3519) is appended to this Brief (RX 1-4) for convenience.

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.

There is no dispute as to Florida's requirement that the party moving for summary judgment must first bring forward facts establishing a negative, i.e., the lack of disputed issues of fact, before the burden shifts to the motion's opponent to bring forward factual support for his allegations. See Moore v. Morris, 475 So.2d 666 (Fla. 1985); and cases cited therein. With reference to the allegations of fraud, the record is devoid of evidence supporting Respondents' contention that no such issue existed and Respondents' Answer Brief makes no showing thereof.

Petitioner's ongoing attempts to obtain discovery when the summary judgment was entered underscore the error of such ruling given the state of the record. Summary judgment as to fraud is rarely appropriate under any circumstances. Nessim v. DeLoache, 384 So.2d 1341 (Fla. 3d DCA 1986).

It is incorrect that the package insert language evidenced the requisite negative as Respondent's Answer Brief suggests. Nor does Edward Betoff's affidavit concern the issue of whether significant or misleading reports and analysis of the drug's risks versus its benefits were furnished to the FDA (RA 787, AX 1-2). Said affidavit does not discuss the issue of fraud. The existence of the unanswered fraud allegations should alone have prevented summary judgment.

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

a. No dispute that evidence of per se unreasonably dangerous product was evidence of legal cause of damage.

Petitioner has already set forth the reasoning and facts supporting her contention that Respondents should be subject to liability for marketing a per se unreasonably dangerous product with inherent dangers and evil consequences outweighing its (primarily cosmetic) benefits, particularly in light of the reasonable alternative treatment available. Respondents make no attempt to dispute the conclusion that if Accutane can be found unreasonably dangerous per se, its marketing by Respondents was a legal cause of the damages claimed by Petitioner. This point is therefore conceded by Respondents.

b. Conflicts in evidence and inconclusive evidence of Respondents allow inference that inadequate instructions and warnings were legal cause of damages.

Respondents' Answer Brief at pages 27 to 29 wrongly asserts that Petitioner does not dispute Respondents' characterizations of the facts relating to Dr. Greenwald's knowledge, understanding

or appreciation of the dangerous side effects of Accutane. Petitioner believes the Third District "swallowed" such characterizations[10] contained in the Appellees' Brief rather than fully investigating what Dr. Greenwald actually said (quoted at length in the Initial Brief) because consideration of the actual testimony yields at least the reasonable inference that the doctor was not really certain what a category X drug was, could not identify any of the supposed independent sources of his alleged prior knowledge about Accutane, and was oversold on Accutane by Hoffmann's promotions believing it a "wonder drug". See page 36 to 37 of the Initial Brief. His actual behavior, as described by Yolanda Felix, certainly did not display an appreciation of the product's deadly potential (see pages 35 and 36, Initial Brief). Dr. Greenwald did not say he knew about the dangers and made a mistake, or forgot, or deliberately disregarded them. He claimed his acts were completely in accordance with his appreciation of the product's dangers and the information he obtained from Hoffmann. (RA 2471, 2472). His testimony as a whole, contradicted as it was by his patient's, is consistent with that of an interested party misrepresenting himself to have had greater knowledge and to have taken greater precautions than he did, a conclusion which is certainly

---

[10] These incorrect characterizations of Dr. Greenwald's knowledge are again made by Respondents, without record citations, on pages 27 to 29; and in Respondents' Statement of Facts such characterizations are made, accompanied by citations to the record which when received indicate serious doubt as to the doctor's knowledge and appreciation.

available to a jury upon the record facts. Respondents failed to instruct physicians to obtain conclusive proof to rule out pregnancy, both in the written materials and in the verbal information supplied by Hoffmann's detailman, Mr. Wachman. This is precisely the necessary procedure Greenwald failed to follow, which certainly creates a fact issue as to inadequate instructions and warnings being the legal cause of the resulting damages.

Respondents' attempted distinction from the holding in Ricci v. Parke-Davis & Company, 491 So.2d 1182 (Fla. 4th DCA 1986), based on purported independent sources of information, fails because of the valid inference that Dr. Greenwald's information was inadequate or even wrong, which underlines the reasonable conclusion that adequate instructions and warnings would have prevented the tragic deformaties and death.

Respondents do not dispute that a jury is free to infer that had reasonably adequate instructions and warnings been given, they would have been followed.

There is sufficient record evidence to support the allegations of legal cause so that summary judgment was error.

III. The Rulings Of The Trial Court And Status Of Discovery Made Entry Of Summary Judgment Error

1. Revised Package Inserts.

Petitioner again argues that the decision in Jeep Corp. v. Murray, 708 P. 2d 297 (Nevada 1985), is a better determination of the applicability of an evidentiary statute identical to Fla.

Stat. §90.407 than recent decisions of the district courts of Florida. The language of §90.407 is couched in terms of negligence, and policy considerations strongly suggest it should be inapplicable to strict liability products litigation. See Jeep Corp., supra. Although not strictly necessary for Petitioner to prevail on this evidentiary issue, this Court should consider adoption of the better rule.

In response to Respondents' comments on the significance of Lake v. Konstantinu, 189 So.2d 171 (Fla. 2nd DCA 1966), Petitioner would contend that Lake, in addition to its aforementioned holding that adequacy of warnings is a fact issue to be decided by a jury, decided that in summary judgment proceedings material subsequent changes in warning language evidences a factual dispute, which is to be left for resolution at trial.

Stricter rulings on evidentiary matters should apply at trial than in summary judgment hearings. See Holl v. Talcott, 191 So.2d 40 (Fla. 1966). Petitioner does not mean to imply that the revisions will not be admissible at trial in the present case. They should be admissible as set forth in Point III of the Initial Brief.

Contrary to the suggestion in Respondent's Answer Brief, at page 30, it is HOFFMANN'S pleadings and not the evidence of its package insert language which define what the issues in the case are. The issues raised by the pleadings and evidence offered by HOFFMANN to support its claim that its warnings were reasonably

safe bring into play the exceptions to the subsequent change evidence rule, as described in Murray v. Almaden Vineyards, 429 So.2d 24 (Fla. 2nd DCA 1983). Therefore the altered product inserts were clearly admissible for the purpose relied on by Petitioner.[11]

This evidence, which directly established a factual issue contrary to the motion for summary judgment, should have been considered by the Circuit Court.

2. Dr. Pasternack's testimony

Appellant's Initial Brief, pages 41 to 46, sufficiently counters nearly all of Respondents' argument concerning the admissability of Dr. Pasternack's testimony. The applicable standard as to admitting evidence in opposition to summary judgment (ignored by Respondents') must be applied consistent with Holl v. Talcott, 191 So.2d 40, (Fla. 1966). The affidavits and other testimony were clearly competent under Holl v. Talcott's standards, and the opinions were reasonable and consistent with the medical research and information on which they were based. Given Dr. Pasternack's qualifications (see page 41 of the Initial Brief) his testimony was at least competent for presentation to the trier of fact, where it could

[11] Also, Johns-Manville Sales Corp. v. Janssens, 463 So.2d 242 (Fla. 1st DCA 1984) is an exception based upon continuing fraud, not impeachment as asserted in Respondent's Answer Brief, and is applicable to the instant facts.

be weighed as might be proper. The judge's role in considering expert testimony admissability is not to determine if he agrees with it himself.

Respondents' misstatement that the record did not include Dr. Pasternack's affidavit has already been countered in the Statement of Facts herein. It is clear that the Court's order, (R.A. 1332-1334) clarified by the transcript (R.A. 4098-4115) only concerned the weight it deemed was proper to give such testimony based upon Respondents' counsel's argument before Judge Gale that the issue of sufficiency of Accutane's package insert was not a subject for expert testimony. (R.A. 4103) Respondents then reversed this position before Judge Knight when at the summary judgment hearing they argued there was insufficient expert testimony of inadequacy of instructions and warnings.

3. Incomplete discovery.

The cases on the need for summary judgment proceedings to wait for completion of relevant discovery were decided for policy reasons directly applicable to this type of complex litigation, where hundreds of thousands of documents must not only be obtained, but then read, analyzed, and provided to expert witnesses.

The record shows incomplete discovery resulted from Respondents' stream of eleventh hour motions for protective orders, requests for reconsideration , challenge of the master on questionable grounds , production of incompetent witnesses and the like. The master's finding that such tactics are not

forbidden by Florida's discovery rules is not conceded by Petitioner. In any event, the master's only finding was that Hoffmann had not "unreasonably impeded discovery"[12]. There was never a finding that Petitioner's discovery was incomplete through her own fault, contrary to Respondents' representation. Respondents' argument amounts to a statement that after two years of frustrating production, Respondents' counsel held up a hoop for Petitioners to jump through, asserting (without any documentation or testimony in this record that the required production would have really been furnished) without the benefit of any court's order, that no production would be provided if the hundreds of thousands of documents could not be copied out of state in the next eight weeks. It is hardly surprising that this first suggestion of Respondents that any document would voluntarily be produced was made at the same moment Respondents re-noticed their motion for summary judgment (AX 22). The time offered by the letter was obviously known to the writer to be insufficient to accommodate production, analysis, motions to compel any obviously deleted items, etc.

---

12 The characterization of the master's ruling in Respondents' Answer Brief at page 35 is not supported by the transcript cited to.

CONCLUSION

In conclusion, Florida should recognize that a cause of action in strict liability exists against the providers of a pharmaceutical product which is unreasonably dangerous per se and the record demonstrates existence of an issue of fact as to such liability of Respondents which should be resolved by a jury. The record also demonstrates existence of an issue of fact concerning the adequacy of instructions and warnings for Accutane which requires resolution by a jury. The record does not indicate an absence of issues as to allegations of fraud. The record further demonstrates that the Circuit Court erred in not considering the evidence of subsequent warning revisions and Dr. Pasternack's expert testimony. The record demonstrates that it was error to consider the motion for summary judgment before Petitioner was provided reasonable opportunity to complete discovery or obtain opposing affidavits.

Based on any of the above, the order appealed should be reversed.

Respectfully submitted,

LAW OFFICES OF JEFFREY P. KAISER
Attorney for the Petitioner
15476 N.W. 77th Court - Suite 315
Miami Lakes, Florida 33016
PH: (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 hand-delivered to Mercer Clark, Attorney for Respondents, 100 Chopin Plaza, Suite 2400, Miami, Florida 33131, this 26th day of June, 1988.

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

By _____
JEFFREY P. KAISER, ESQ.