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IN THE SUPREME COURT OF FLORIDA

CASE NO. 71,634

FILED
SID J. WHITE
JUN 23 1988
CLERK, SUPREME COURT
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WILLIAM F. CHILDERS and HOLLY CHILDERS, as joint Personal Representatives of the Estate of WILLIAM GILES CHILDERS,

Petitioners,

vs.

HOFFMANN-LaROCHE, INC.; LAWRENCE SCHACHNER, M.D.; SAPAC, Ltd.; F. HOFFMANN-LaROCHE & CO. Ltd.; ROCHE BIOMEDICAL LABORATORIES, INC.; BINDLEY WESTERN INDUSTRIES, INC.; THE KROGER COMPANY; SUPER-X DRUG STORES OF FLORIDA, INC.; SUPER X DRUGS CORPORATION;

Respondents,

****

CORRECTED
REPLY BRIEF OF PETITIONERS

****

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STATEMENT OF THE CASE AND OF THE FACTS

The Petitioners adhere to and adopt by reference in this Reply Brief the Statement of the Case and Facts contained in their initial brief in this cause. The parties will be referred to in this brief as they were in the Petitioners' 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 Appendix to the answer brief; and "RX" for the Appendix to this Reply Brief.

Petitioners do not accept the Statement of the Facts submitted by Respondents, as same is misleading and omits in important part reference to the record. Accutane does not cure acne or icthyosis , it only temporarily puts them into remission, as stated in the Peck article referred to at page 1 of the Answer Brief and the other deposition exhibits make clear, and it can only be taken for a few months because of the gradual worsening of other side effects, like increased blood lipids (fats), whereupon the acne or icthyosis reoccurs. (RA small box of exhibits mentioned in Clerk's Note at Page 30 of Index to Record on Appeal). Respondents exaggerate the intensity and effect of the product warnings by omitting accompanying text. Respondents liberally speculate about Dr. Schackner's knowledge

of Accutane when they say "he knew all about the risks;" and there is no record support for such statement. Respondents misstated 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 the trial judge erroneously weighed the evidence at summary judgment hearing just as Petitioners argue). The Respondents' challenge of Dr. Benke's expertise was never made in Circuit Court nor before the Third District and is by now waived, if it ever had merit. Neither did Respondents challenge Dr. O'Donnell's expertise before the Circuit Court. Hoffmann's answers to interrogatories (R.A. 3945-3953) were cited by Petitioners' Initial Brief as indicia of the form of Hoffmann's package insert; the insert's variance from the FDA's requirements in 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). Petitioners' reference to Dr. Benke's first affidavit (R.A. 3508-3511) is cited in conjunction with his second affidavit (2241-2246) which demonstrate that the certainty or likelihood of human fetal monstrosities was known to Hoffmann but was concealed in the wording of its package inserts.

As to Respondents' Statement of the Case, Petitioners do not accept same as it is misleading, argumentative and without supporting references to the record on appeal. Gratuitous

statements that Petitioners 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 Petitioners adhere to their 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 RECORD SUPPORTED CONCLUSION THAT HOFFMANN-LaROCHE BREACHED A DUTY TO WARN HOLLY CHILDERS OF TERATOGENIC DANGERS?

POINT III

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

POINT IV

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

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 for jurisdictional purposes 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:

> 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

[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).

> 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 manufacturers 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

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

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

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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).

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.

Dr. O'Donnell's affidavit (RA 3565-3567) indisputedly raises a factual issue on the propriety of placing Accutane on the market.

Contrary to Respondents' 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 inadequacy of instructions and warnings is a jury issue. The facts in this case supported allegations that instructions and warnings were inadequate.

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

On this point Petitioners rely upon and adopt the argument which follows the identical headnote on pages 7 through 11 of the Reply Brief filed with this Court in the companion case of Felix v. Hoffmann-LaRoche, Inc., Case No. 71-633.

The technical writer of FDA warnings, Mr. Ziskind, found the warnings and instructions inadequate (RX 1-4). So did the phamaceutical expert, Dr. O'Donnell (R.A. 3565-3567). Dr. Benke, the birth defect specialist, testified the warnings failed to adequately inform (R.A. 4585-4587; 4684-4685). These experts' testimony is evidence of the existence of fact issues as to the Respondent's liability for inadequate instructions and warnings.

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.

Petitioners' 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 F.D.A. (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. The Record Supported Allegations That Hoffmann Breached A Duty To Warn Holly Childers Of Teratogenic Dangers.

Respondents' Answer Brief falsely argues that Point II in Petitioner's Initial Brief was never raised in the Court of Appeal. It was. The Third District Appellate briefs contain:

> The mother of Holly Childers, Suzanne Giles, swore that the only warnings ever received by her and her family members about Accutane were totally silent on the hazard to a pregnant woman. These deficient warnings were given by the University of Miami while testing the new drug for HOFFMANN. Appellant HOLLY CHILDERS, then a minor, was involved in the testing (R.A. 3523-3530).[5]

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5 Initial Brief of Appellants, Case No. 86-2305, Third District Court of Appeals, page 9.

[T]here are extremely significant factual differences which critically distinguish the within cause from Buckner, supra[6]; and ... those distinctions [are] critical as to whether Appellants are entitled to trial by jury on the issues raised in the Amended Complaint against Appellees.[7]

Argued at the final hearing ...[was] the further contention that inasmuch as Appellee HOFFMANN undertook the warning process to the consumer, it became liable for failing to properly carry it out (R.A. 3227).[8]

Appellant HOLLY CHILDERS had undergone a similar treatment several years prior to the within treatment program. She testified that during the course of the earlier program she was never warned of the hazard to the fetus in the event of pregnancy during treatment (R.A. 4141). The consent forms and authorizations forms attached as exhibits to the Affidavit of Suzanne Giles, her mother (R.A. 3523-3530), although containing warnings of possible side effects, made no mention whatsoever of any hazard to the fetus in the event of pregnancy. Inasmuch as Appellees undertook the duty of warning Appellant directly of side effects, the:

> "law imposes an obligation... to exercise some degree of care and skill in the performance of what he has undertaken".

Padgett v. School Board of Escambia County, 395 So.2d 584 (Fla. 1st DCA 1981), and cases cited. Appellants contend that Appellee HOFFMANN failed to perform its duty to warn Appellants with any degree of care and skill during the earlier program, and is therefore liable to Appellants for their having no knowledge of the real hazard involved...[9]

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6 Buckner v. Allegan Pharmaceuticals, Inc., 400 So.2d 820 (Fla. 4th DCA 1981).

7 Initial Brief of Appellants Case No.86-2305, Third District Court of Appeals, page 36.

8 Initial Brief of Appellants Case No. 86-2305, Third District Court of Appeals, page 44.

9 Reply Brief of Appellants, Case No.86-2305, Third District Court of Appeals, page 15.

Respondents' Answer Brief also falsely argues that Petitioners never raised this same point before the Circuit Court. To the contrary, at the hearing on the summary judgment motions Petitioners' attorney first handed to the Judge the Giles Affidavit and its attached description of side effects;[10] then described the "warning"'s omission of the side effect; counsel then referred to the deposition testimony that no other written nor verbal warnings were given; then referred to the pleadings raising the direct warning issue; then counsel argued that having undertaken to provide Holly Childers with direct information and warnings there was a duty to adequately and properly warn her (RA 3225-3227). This transcript excerpt is included in the appendix to this reply brief for convenience, (RX 59-62). As pointed out in the Initial Brief of Appellant before the Third District Court of Appeal, at page 49, before Holly Childers was handed these "warnings" that were silent about birth defects, Hoffmann's researchers published data which referred to teratogenic effects reported in laboratory animals in chemical analogs as far back as 1972, proving that HOFFMANN was well aware that, as the published article said; "synthetic retinoids should be assumed to be teratogens as well until the contrary is proved. Fertile women treated with 13-cis-RA should

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10 For convenience, the affidavit and attachments are included in the Appendix submitted with this reply brief (R.X. 63-70). The language of the forms provided by HOFFMANN and its researchers has absolutely no reference to teratogenic properties, although its supposed purpose was to inform Holly Childers and her parents of the risks inherent in the product so that they could make an informed choice whether she would consume it.

take contraceptive precautions during therapy and probably for a period of time afterward to ensure complete excretion of 13-cis-RA". (R.A. 2261). Finally, the complaint expressly alleges that HOFFMANN undertook to warn Petitioners directly of the drug's dangers, and failed to do so adequately (R.A. 2743-2748; 2764-2769) and Respondent's contention to the contrary (Answer Brief, page 27) is not true.

It certainly is possible for a jury to conclude from the evidence that the inadequate description of Accutane's dangers supplied to Holly Childers by HOFFMANN would cause her to rely thereon when subsequently prescribed the drug, and that she would have had no reason based on her knowledge to anticipate the extreme danger of becoming pregnant; i.e., that the direct, inadequate warnings were a legal cause of the birth defects and death.

III. 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

Petitioners have already set forth the reasoning and facts supporting their 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 alternatives 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 Petitioners. 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 page 28 wrongly states it is undisputed prescribing doctors in the companion Felix case and in this appeal had total knowledge about the drugs dangers. This is vehemently disputed, and close review of the record does not support any conclusion other than that what the doctors knew about Accutane is controverted. The record references to Dr. Schackner on pages 28 and 29 of the Answer Brief at most show only that he knew the definition of a medical term, and that he had "concern", whatever that signifies, about teratogenic potential.[11]

It is inaccurate for Respondents to contend that Dr. Schackner's testimony was uncontroverted. The testimony of Holly Childers evidenced that Dr. Schackner gave her no warnings or instructions about the drug, did not rule out whether she was pregnant, gave her a prescription at the initial visit, did not inquire about birth control, ect. (R.A. 4141, 4180, 4183, 4197).

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[11] The unsupported assertions on page 28 of the Answer Brief that; "Childers was also affirmed because Dr. Schackner knew all about Accutane's teratogenic potential from sources other than Roche"; and, "Dr. Schackner's level of knowledge about Accutane from sources independent of Roche equalled Dr. Greenwald's level of knowledge in Felix"; are unsupported by evidence in the record and are misrepresentations in the context of an appeal brief. Childers being a per curiam affirmed decision, Respondents should not attribute factual findings to the Third District.

She did not know of its teratogenic properties until after the birth of her child (R.A. 4160). Dr. Blount, who was a medical student and present when Dr. Schackner saw Holly Childers, did not recall any instructions or conversations about birth defects. (R.A. 4708-4710). The issue, 'what did Dr. Schackner know?' is very much debatable from the record and open to the inference by a jury able to judge the witnesses' demeanor that he had inadequate appreciation of the terrible potential inherent in Accutane which would have been greatly aided had HOFFMANN utilized reasonably adequate instructions and warnings.

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.

Dr. Schackner, a co-defendant interested in portraying himself as knowledgeable, and who contradicted Holly Childers about his having provided her with warnings, and who provided an inconclusive affidavit as to the extent of his knowledge; is certainly not to be assumed to have been totally knowledgeable as Respondents represented, particularly in a summary judgment proceeding where credibility issues should result in denial of the motion in favor of jury trial.

There is a lack of evidence of actual knowledge of the degree of danger by the physician, and sufficient evidence that he did not appreciate it or he would have acted upon it, for this matter to have proceeded to jury trial on the inadequate instruction and warning issue.

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

1. Revised Package Inserts.

Petitioners again argue 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 Florida district courts' decisions. 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 Petitioners to prevail on this evidentiary issue, this Court should consider adoption of the better rule now that it has this opportunity.

In response to Respondents' comments on the significance of Lake v. Konstantinu, 189 So.2d 171 (Fla. 2nd DCA 1966), Petitioners 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). Petitioners do 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 IV of the Initial Brief.

Contrary to the suggestion in Respondents' Answer Brief, at page 32, it is the pleadings and not Hoffmann's package insert language which define what the evidentiary issues in the case are. The interrogatory responses, pleadings and Betoff's affidavit offered by Defendant 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 Petitioners.[12]

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

Petitioners' Initial Brief, pages 41 to 46, sufficiently counters nearly all of Respondent's argument concerning the admissability of Dr. Pasternack's testimony. The applicable standard as to admissability of evidence in opposition to summary judgment was ignored by Respondent, but must be consistent with Holl v. Talcott, 191 So.2d 40, (Fla. 1966). The

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[12] 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.

affidavits and other testimony were clearly competent under Holl v. Talcott's standards, and the opinions were consistent with logic and the supporting medical research and data. 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 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, (RA 1332-1334) clarified by the hearing transcript (RA 4098-4115) only referred to the doctor's expertise but did not exclude his testimony altogether. Following Respondent's counsel's argument before Judge Gale that the issue of sufficiency of Accutane's package insert was not a subject for expert testimony (RA 4103), Respondents then contradicted 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 Respondent's 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 Petitioners. In any event, the master's only finding was that Roche had not "unreasonably impeded discovery"[13]. There was never a finding that Petitioners' discovery was incomplete through their own fault, contrary to Respondents' representation. Respondents' argument amounts to a statement that after two years of refusing any 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.

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[13] The mischaracterization of the master's ruling in Respondent's Answer Brief at page 36 is not supported by the transcript cited to.

CONCLUSION

In conclusion, Florida should recognize that a cause of action 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,

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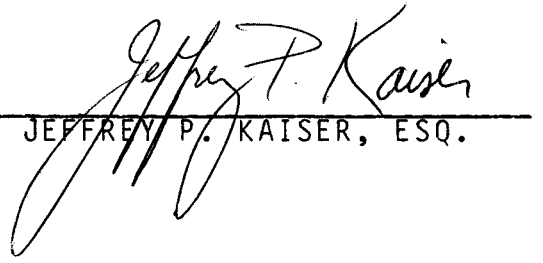
By 
JEFFREY P. KAISER, ESQ.

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.

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