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IN THE SUPREME COURT OF FLORIDA

CASE NO. 71,634

On Petition for Discretionary Review

WILLIAM F. CHILDERS and HOLLY CHILDERS,
as Joint Personal Representatives
of the ESTATE OF WILLIAM GILES CHILDERS,

Petitioner,

- versus -

HOFFMANN-LaROCHE INC., ROCHE BIOMEDICAL LABORATORIES, INC., BINDLEY-WESTERN INDUSTRIES, INC., THE KROGER COMPANY, SUPER-X DRUG STORES OF FLORIDA, INC., and SUPER-X DRUGS CORPORATION,

Respondents.

RESPONDENTS' BRIEF ON JURISDICTION

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STATEMENT OF THE CASE AND FACTS

Respondents, Hoffmann-La Roche Inc., Roche Biomedical Laboratories, Inc., Bindley-Western Industries, Inc., The Kroger Company, Super-X Drug Stores of Florida, Inc. and Super-X Drugs Corporation (hereafter "Roche" or "respondents") adopt the statement of the case and facts presented by petitioner.

SUMMARY OF THE ARGUMENT

The "conflicts" jurisdiction conferred on the Supreme Court under Article V, § 3(b)(3) of the Florida Constitution and Rule 9.030(a)(2)(A)(iv) is invoked when announcement of a rule of law expressly and directly conflicts with a rule previously announced by the Supreme Court or another district court or the application of a rule of law produces a different result in a case which involves substantially the same facts. The instant case does not conflict with the four cases cited at page 1 of petitioner's brief under either test. First, the district court's decision was a per curiam affirmance with a citation to a final decision of the same court. No express conflict can be stated in this situation by definition. In addition, the rule of law announced in the cited case, *Felix v. Hoffman-La Roche Inc.*, 513 So.2d 1319 (Fla. 3d DCA 1987), is that adequacy of the warning in a strict liability case involving pharmaceutical drugs is *usually* a jury question, but summary judgment is appropriate where the warning is clear and unambiguous and the injuries sustained are the ones described in the warning.

There is no conflict with *Tampa Drug Company v. Wait* and *Lake v. Konstantinu* because those cases simply held that the adequacy of the particular warnings under review was a jury issue. There is no conflict with *Lake v.*

Konstantinu because the reversal of summary judgment was based on the appellate conclusion that a fact issue existed with respect to the adequacy of the particular warning in question. There is no conflict with *Macmurdo v. Upjohn Co.* because the warning there did not describe the injurious side effects suffered by the plaintiff, and the court concluded that a fact issue existed with respect to the intensity and explicitness of that particular warning. There is no conflict with *Ricci v. Parke-Davis & Co.* because the holding that adequacy of a warning is a jury issue is made without a recitation of the warning so that whether the injury suffered by the plaintiff was described in the warning is not discernible. Petitioner's characterization of the holdings in these cases that adequacy of the warning is *always* a fact issue is false. None of these cases contain that statement.

Petitioner further contends that *Felix* held that a prescribing physician's testimony that he is aware of a drug's dangers is conclusive as to the lack of the manufacturer's liability and that this holding conflicts with *Ricci*. This position is without merit because the *Felix* case does not contain such a holding.

The *Felix* decision is not in conflict with the cases cited by petitioner for the further reason that the court affirmed the summary judgment on the alternative ground that, even if the warning were inadequate, it was not the proximate cause of the prescribing physician's decision to prescribe Accutane because it was uncontroverted that "he had prior knowledge of the teratogenic propensities of Accutane from independent research and reading, and from seminars he had attended." *Felix v. Hoffmann-La Roche Inc.*, 513 So.2d 1319, 1321 (Fla. 3d DCA 1987). Only conflicts in decisions, not opinions, will confer jurisdiction under Rule 9.030.

ARGUMENT

An express and direct conflict with a decision of another district court of appeal or of the Supreme Court on the same question of law as contemplated by Fla. R. App. P. 9.030(a)(2)(A)(iv) can occur in two circumstances: first, where the rule of law conflicts with a rule previously announced by the Supreme Court or another district court; second, where the rule of law is applied to produce a different result in a case which involves substantially the same facts as a prior case. *Mancini v. State*, 312 So.2d 733 (Fla. 1975). The instant case does not conflict with any of the cases[1/] cited by petitioner under either test.

First, Childers argues that an express and direct conflict may be stated in this case because of an exception to the general rule that the court will not re-examine the case referenced in a "citation PCA" which was first stated in *Jollie v. State*, 405 So.2d 418 (Fla. 1981). This case does not conflict with the holding in *Jollie*, however, and reliance upon that decision is unwarranted.

Jollie's very clear holding is that when the case referenced in a citation PCA is either pending review in or has been reversed by the supreme court, a prima facie express conflict is stated. *Id.* at 420. *Jollie* involved a situation where the court had already accepted jurisdiction over the case referenced in the citation PCA - and in fact had already quashed it - at the time it accepted jurisdiction of the case presenting the citation PCA. *Id.* at 419. The court carefully distinguished that situation from the one presented in *Robles Del Mar, Inc. v. Town of Indian River Shores*, 385 So.2d 1371 (Fla. 1980). *Id. Robles Del*

1/ *Tampa Drug Company v. Wait*, 103 So.2d 603 (Fla. 1958); *Ricci v. Parke-Davis & Co.*, 491 So.2d 1182 (Fla. 4th DCA 1986); *Macmurdo v. Upjohn Co.*, 444 So.2d 449 (Fla. 4th DCA 1983); *Lake v. Konstantinu*, 189 So.2d 171 (Fla. 2d DCA 1966).

Mar involved companion cases decided on the same day. *Id.* The second decision, which was the subject of the petition for review, was a per curiam affirmance citing the first. *Id.* Because the first case was a final decision of the district court which was not pending review in the supreme court and had not been reversed, the petition for review was dismissed upon the strength of the general rule stated in *Dodi Publishing Co. v. Editorial America, S.A.*, 385 So.2d 1369 (Fla. 1980). *Id.*

This case is identical to *Robles Del Mar*. The case cited by the *Childers* court, *Felix v. Hoffmann-La Roche Inc.*, 513 So.2d 1319 (Fla. 3d DCA 1987), was a final decision which was not pending review in the supreme court and had not been reversed. The district court did not withhold its mandate pending disposition of the petition for review, if any, in *Felix* and Childers did not ask the court to stay its mandate. This procedure would have "pair[ed]" the cases for the purposes of discretionary review as outlined in *Jollie*, 405 So.2d at 421. Childers having failed to avail herself of this procedure, this case is indistinguishable from *Robles Del Mar* and the petition should be dismissed.

Next, Childers misstates in her summary of the argument that the four cases as to which conflict is asserted hold that adequacy of the warning is *always* a jury issue. None of the cases contain such a statement. An inferential broadening of these holdings is essential to petitioner's contention that there is an express and direct conflict because the statements, "adequacy of a warning is a fact issue" (the holdings in *Ricci* and *Macmurdo*) and "adequacy of a warning is usually a fact issue" (the holding in *Felix*) do not expressly and directly conflict, whereas the statements, "adequacy of a warning is *always* a fact issue" and "adequacy of a warning is usually but not always a fact issue" may. Moreover, a

careful reading of the cases cited by petitioner shows that no general rule of law relating to adequacy of warnings was established. Instead, the courts in effect held that a fact issue existed with respect to the adequacy of the particular warnings in question. Thus, there was no rule of law announced in *Felix* which conflicted with a rule established in a prior case, and, since the warnings in each of those cases were different from the warning in the *Felix* case, there was no application of a rule of law to substantially the same facts which produced a different result. Thus, there is no conflict under either of the criteria set out in *Mancini v. State, supra.*

In *Macmurdo v. Upjohn Co.*, 444 So.2d 449 (Fla. 4th DCA 1983), the court stated that it was error for the trial judge to read the warning in question subjectively and to determine that it was adequate as a matter of law. "It is not for judges but it is for the jury to determine if a particular warning is adequate under the circumstances." 444 So.2d at 451. The warning, 2/ however, did not describe the injurious side effect suffered by the plaintiff. In discussing the warning in that case, the court concluded that a jury question existed concerning its intensity and explicitness. Had the warning been couched in terms so intense and explicit that reasonable men could not differ on the effectiveness of the warning to communicate the danger, the court presumably would have ruled, as the *Felix* court did, that adequacy of the warning is usually but not always a fact issue. From the appellate court's explanation of why the adequacy of that particular warning was a fact issue it can be presumed that, had the warning not contained the arguable inadequacies, no jury issue would have existed. Thus,

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2/ "The use of Depo Provera . . . for contraception is investigational since there are unresolved questions relating to safety for this indication. Therefore, this is not an approved indication for this use." 444 So.2d at 450.

absent an express statement to that effect *Macmurdo* cannot be read broadly enough to hold that adequacy of a warning is *always* a fact issue. In the factual context of the case, the court simply ruled that the particular warning was not sufficently explicit to warrant a disposition in favor of the manufacturer by summary judgment.

Rules to which there are and can be no exceptions rarely evolve in the law. Even if *Macmurdo* could be read to establish a general rule that the adequacy of a warning must be a fact issue, the *Felix* case does nothing more than create an exception to that rule which is that, where the precise injurious side effect warned about in unambiguous terms is experienced by the plaintiff, the warning's adequacy may be decided as a matter of law. Although we have found no Florida case law squarely on point, it stands to reason that creation of an exception to a rule does not result in an express and direct conflict with that rule in the jurisdictional sense under Rule 9.030.

Finally, *Felix* does not conflict with *Macmurdo* because of the material difference in the facts. In *Macmurdo* no injurious side effect is described in the warning. In *Felix* the risk of fetal deformity is plainly and unambiguously explained in the information furnished to physicians by Roche. *Felix* at 513 So.2d 1320, 1321. Thus, the rule of law applied in *Felix* produced a different result than *Macmurdo* but did not involve substantially the same facts. *Mancini v. State, supra.*

Ricci v. Parke-Davis & Co., 491 So.2d 1182 (Fla. 4th DCA 1986) does not conflict with *Felix* for the same and other reasons. Unlike *Macmurdo* the disputed warning is not quoted in the opinion. The statement assertedly raising the conflict is, "The adequacy and sufficiency of these warnings [undescribed but

contained in information furnished by a birth control manufacturer to physicians] is clearly a jury issue in Florida." Again, there is no statement that the adequacy of "these warnings" is always a jury issue. Thus, the rule of law stated in *Felix* does not expressly and directly conflict with *Ricci*, and, since *Ricci* does not describe the warning or the plaintiff's injury, it cannot be ascertained whether substantially the same facts as in *Felix* were involved. *Mancini v. State, supra.*

Tampa Drug Company v. Wait, 103 So.2d 603 (Fla. 1958), did not involve pharmaceutical drugs. Plaintiff was injured by inhaling carbon tetrachloride fumes. The appeal was from a jury verdict and judgment after trial during which warning labels from other carbon tetrachloride products were introduced which conflicted with the label in issue. Under these facts the court held, "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." 103 So.2d at 609. Thus, the case was decided on its particular facts. Nothing about this case even suggests that adequacy of a warning in a pharmaceutical drug case is always a fact issue.

Lake v. Konstantinu, 189 So.2d 171 (Fla. 2d DCA 1966) is asserted by petitioner to hold that adequacy of the warning "must certainly be submitted to a jury . . . ." (Petitioner's brief, p.6). In *Lake* the court observed that the warnings published by Parke-Davis varied from time to time as the company became more and more aware of the drug's extremely dangerous potentiality. In that factual context the court observed, "This issue above all others must certainly be submitted to a jury." 189 So.2d at 174. In the *Felix* opinion there is no mention of evolution of changes in the warnings about Accutane. Once again, *Lake* was

decided on its facts as they related to the particular warning in question, all of which differed from the facts in *Felix*. No general rule of law was announced in *Lake* that adequacy of the warning in a pharmaceutical drug case is always a fact issue. Consequently, there is no conflict between rules of law announced in *Lake* and *Felix*, and in all events there are material facts described in the *Lake* opinion which are absent from the *Felix* opinion. Application of a different, although not conflicting, rule of law is therefore appropriate. *Mancini v. State, supra.*

Petitioner's final point is that additional grounds for conflict exist between *Felix* and *Ricci* relating to the knowledge of the prescribing physician. In *Ricci* the defendant manufacturer contended that there was overwhelming evidence that the doctors received and understood the warnings which were furnished by the manufacturer. Plaintiff introduced an affidavit, the content of which is not disclosed, which somehow raised a fact issue on this point. The court held in effect that proof that the prescribing doctors understood the warning given did not establish conclusively that the warning was adequate to communicate the danger. In *Felix* the uncontroverted evidence was that Dr. Greenwald (the prescribing physician) had acquired extensive knowledge about Accutane's propensity to cause birth defects from his own research and sources other than information furnished by the manufacturer. Since Dr. Greenwald had actual knowledge of the teratogenic dangers of Accutane from independent sources, the *Felix* court held that any inadequacy in Roche's warning was not causally related to Dr. Greenwald's decision to prescribe Accutane to Ms. Felix. The physician's knowledge in *Ricci* was relevant to the legal issue of adequacy of the warning while the physician's knowledge in *Felix* was relevant to the legal issue of proximate cause. Thus, the holdings do not conflict.

Conflicts jurisdiction cannot lie in this Court for the additional reason that the summary judgment in *Felix* was affirmed on the alternative ground, as just discussed, that there was absence of proximate cause as a matter of law. Absence of proximate cause was not an issue in any of the cases cited by petitioner; consequently, there is no demonstrated conflict on this legal issue. Conflicts jurisdiction under Rule 9.030 is founded on conflicts between decisions, not opinions. *Niemann v. Niemann*, 312 So.2d 733 (Fla. 1975); *Gibson v. Maloney*, 231 So.2d 823 (Fla. 1970). Even if the opinion in *Felix* conflicts somewhat with the opinions in the cases cited by petitioner, the decision does not. Since *Felix* was affirmed in the alternative on the basis of another legal rule as to which no conflict is asserted, there is no jurisdiction under Rule 9.030.

CONCLUSION

For the foregoing reasons, respondents contend that there is no express and direct conflict between the instant case and the cases relied on by petitioner; accordingly, jurisdiction in this Court is not conferred under Rule 9.030 of the Florida Rules of Appellate Procedure. The petition for discretionary review should be denied.

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CERTIFICATE OF SERVICE

WE HEREBY CERTIFY that a true and correct copy of the foregoing Respondents' Brief on Jurisdiction was mailed to Jeffrey P. Kaiser, Esq., Attorney for Petitioner, Palm Springs Center, 1840 West 49th Street, Hialeah, Florida 33018 this 22nd day of January, 1988.

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