DA 9-5-89

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IN THE SUPREME COURT OF FLORIDA

THE UPJOHN COMPANY,

Petitioner,

vs.

ANNE MARIE MACMURDO, a/k/a
ANNE MARIE STAFFORD,

Respondent.

PETITIONER'S INITIAL BRIEF ON THE MERITS

Case No. **73,596**

District Court of Appeal
Fourth District
Case No. **87-0671**

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(A separately bound appendix accompanies this brief.)

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ABBREVIATIONS

Petitioner, The Upjohn Company, was the appellant/cross appellee in the District Court of Appeal and the defendant in the trial court. Petitioner will be referred to in this brief as "Upjohn" or "defendant." Respondent, Anne Marie MacMurdo, a/k/a Anne Marie Stafford, was the appellee/cross appellant in the District Court of Appeal and the plaintiff in the trial court. She will be referred to in this brief as "MacMurdo" or "plaintiff."

Throughout the brief, citations to the record will be abbreviated "R." Citations to the trial transcript will be abbreviated "T" followed by the appropriate page and line designations. Some of the testimony was presented to the jury through depositions which are filed in the record. References to deposition excerpts in evidence will be identified by the name of the deponent, "D" (indicating Deposition), and the appropriate page of the deposition with a line designation, if one is available. Thus, a reference to the deposition of Dr. Levy will appear "(Levy, D. 22/2)." References to the Appendix to this brief will use the abbreviation "App."

STATEMENT OF THE CASE

The defendant, Upjohn, manufactures a prescription drug under the registered trademark "Depo-Provera." In 1974, the United States Food and Drug Administration (FDA) had approved Depo-Provera for only one indication (use) -- the treatment of inoperable, recurrent and metastatic endometrial carcinoma (Fletcher, D. 14; Plaintiff's Ex. 8; Defendant's Ex. 1; App. 1). Although that was the drug's only FDA-approved use, the plaintiff, Anne MacMurdo, was given two injections of Depo-Provera for the purpose of contraception, a use neither indicated by the manufacturer nor approved by the FDA. These injections were given by medical doctors certified by the American College of Obstetrics and Gynecology.

As a prescription drug that only licensed physicians can prescribe, Depo-Provera is subject to the Food, Drug and Cosmetic Act's strict labeling requirements and the pertinent regulations established thereunder (App. 3 and 4). Under federal law applicable in 1974, a package insert drawn in accordance with the FDA's labeling regulations was required to accompany every vial of Depo-Provera shipped in interstate commerce. The package inserts for Depo-Provera from October 1972 through April 1976 were in evidence as Plaintiff's Ex. 8 and Defendant's Ex. 1, respectively **(App.** 1 and 2).

Following the second injection of Depo-Provera by Dr. Arthur Shapiro in Miami, Florida, MacMurdo allegedly experienced excessive vaginal bleeding. In late 1974 she returned to Dr. Donald Levy who, at the Ochsner clinic in New Orleans, had pre-

scribed MacMurdo's first dose of Depo-Provera for contraceptive purposes. Dr. Levy, in January 1975, performed an elective hysterectomy on MacMurdo.

Over three years later MacMurdo, perceiving that Depo-Provera had some causal connection to the hysterectomy, filed a complaint on 19 May 1978 in the Circuit Court for Broward County, Florida. An amended complaint was filed on 17 January 1979. The complaint essentially charged Upjohn with an inadequate warning as to the side effects of Depo-Provera.

After two trips to the Fourth District Court of Appeal, in one of which a summary judgment for Upjohn was reversed[1], the case came on for trial before the Circuit Court in Broward County, Florida, in December 1986.

At the close of the plaintiff's case in chief (T. 660 et seq.) and again at the close of all the evidence and before the verdict was returned (T. 1043), Upjohn moved for a directed verdict. The case was submitted to the jury on two theories of liability. One was Upjohn's alleged negligence in marketing Depo-Provera and the other was Upjohn's alleged failure to provide an adequate warning with respect to the product (T. 1030-32). The jury found for Upjohn on the first issue and for MacMurdo on the second. It assessed the plaintiff's total damages in the amount of $370,000 but found plaintiff 49% comparatively negligent (App. 6). A judgment was entered on 17

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[1] MacMurdo v. Upjohn Co., 388 So.2d 1103 (Fla. 4th DCA 1980); MacMurdo v. Upjohn Co., 444 So.2d 449 (Fla. 4th DCA 1983, reh. denied 1984).

December 1986 (R. 2574), following which Upjohn timely filed motions for judgment notwithstanding the verdict (R. 2575-2576) and for new trial (R. 2578). MacMurdo moved for judgment notwithstanding the verdict on the jury's finding of comparative negligence. The trial court denied these motions (R. 2731, 2735).

Upjohn appealed to the Fourth District Court of Appeal and MacMurdo filed a cross appeal. The District Court, in a decision rendered 21 December 1988 (App. 7), affirmed the trial court's judgment on the issue of Upjohn's liability but reversed the judgment with respect to plaintiff's comparative negligence. The Upjohn Company v. MacMurdo, 536 So.2d 337 (Fla. 4th DCA 1988). Upjohn filed a timely notice to invoke this Court's discretionary jurisdiction. By order dated 1 May 1989, this Court accepted jurisdiction.

STATEMENT OF THE FACTS

Plaintiff, Anne MacMurdo, appeared in the New Orleans office of Dr. Donald Levy on 27 May 1974. Dr. Levy, a board-certified gynecologist at the Ochsner Clinic in New Orleans, authorized a 250 mg. injection of Depo-Provera for the plaintiff for purposes of controlling abnormal bleeding and contraception (Levy, D. 22/2).

Dr. Levy had at some time read the package insert for Depo-Provera, although exactly when in reference to the injection is uncertain (Levy, D. 28/12). Dr. Levy nevertheless knew the only approved use of the drug as shown by the package insert was for the treatment of endometrial carcinoma (Levy, D. 28/7; 38/22). He had been aware of this for several years prior to his deposition which was taken on 15 August 1978 (Levy, D. 28/16).

MacMurdo testified that after her first injection of Depo-Provera in May 1974, she had no menstrual period for approximately 90 days (T. 553/1). She testified, however, that before she began to use Depo-Provera for contraceptive purposes, her menstrual period was "pretty regular" when she was not utilizing either an IUD or birth control pills (T. 572/10).

MacMurdo visited the offices of Dr. Arthur Shapiro for the first time in August 1974. She saw Dr. Shapiro, a board-certified gynecologist, at the University Family Services Clinic at the University of Miami Hospital on 6 August 1974 (T.472/19). MacMurdo came in requesting an abortion (T. 474/12), only to discover that she was not pregnant. She saw Dr. Shapiro again on 15 August 1974. At that time she provided a history of

irregular menstrual cycle length and heavy and painful menstrual flow (T. 478/15). On that date, on Dr. Shapiro's prescription, a second Depo-Provera injection was administered for contraceptive purposes because, as Dr. Shapiro testified, other forms of birth control had not been satisfactory (T. 479/10-20).

When asked whether in 1974 he was aware that Depo-Provera had the effect of causing excessive bleeding, Dr. Shapiro replied, "I would say that it was if it had been a side-effect, it would be a very rare side-effect" (T. 502/24-503/4). Dr. Shapiro testified that he probably had read the 1974 package insert and knew in 1974 that the drug

> "... would usually cause prolonged, irregular staining usually not heavy bleeding. In other words, the word 'prolonged' is fair to say. Usually the side-effect of the drug was to have no menstrual periods at all.... The other type of reaction that one would have a side effect would be irregular prolonged light type of staining, but usually not excessive bleeding" (T. 504/6).

Dr. Shapiro then indicated in response to a leading question that he did not think a woman would have excessive bleeding for 30 days a month (T. 504/19).

According to MacMurdo, after her second injection of Depo-Provera she returned to New Orleans where she entered a hospital in December 1974 and had her breast implants redone. [Her breast implant was performed in 1969 or 1970 (T.557/15).] She testified that after the second injection of Depo-Provera she had a period which continued for three months or until her hysterectomy (T. 553/17). In describing her bleeding, the plaintiff stated that her blood would go from bright red to brown as though her period

were about to end and then would turn bright red again (T. 554/21).

With regard to the performance of the hysterectomy, the plaintiff testified she returned to the office of Dr. Levy who told her that he could eliminate the bleeding through a hysterectomy (T. 607/16). When asked what her understanding was as to the necessity for the hysterectomy, she obliquely replied, "That it would stop the bleeding and at that point if they hung me from a tree, if that would stop the bleeding, fine" (T. 560/11).

While MacMurdo herself testified she did not request sterilization as a means of birth control (T. 560/6), she carefully avoided testifying that she in good faith believed, on the basis of medical advice, that a hysterectomy was reasonably necessary to resolve her bleeding problem. (T. 560/11; 607/14). The record reflects that in 1973 MacMurdo had an episode of prolonged bleeding attributable to using an IUD. The bleeding was cured by a D&C following removal of the IUD (T. 586/2-24).

According to her own testimony, MacMurdo signed two voluntary consent forms and consented to the hysterectomy with knowledge of its sterilizing effect (T.616/3-19), and, insofar as the record is concerned, without a word of inquiry as to alternatives. She admitted her decision to opt for a hysterectomy was a snap decision. (T. 615/2). Moreover, substantial evidence in the record indicated MacMurdo actually was interested in a hysterectomy as a means of sterilization. She had a strong motivation for avoiding pregnancy. In 1970 she became pregnant (T. 572/8).

Tragically, her child was born with a fatal birth defect (T. 574/22-575/3). Following the birth of the child, MacMurdo attempted suicide (T. 575/18). Thereafter, she sought counseling from a genetic clinic (T. 575/4) and was advised that the problem giving rise to the birth defect in her first child may have been genetic and she had perhaps a one in twenty chance of reoccurrence. (T. 575/15).

Substantial evidence of MacMurdo's own illicit drug usage was presented (T. 582/13; T. 582/19; T. 583/14-23; T. 584/1; T. 587/14 - 588/19; T. 606/10-607/4). While the timeframe of her drug usage was not established with pinpoint accuracy, it was clear from MacMurdo's testimony she extensively used illicit drugs before her hysterectomy in January 1975. At one point in her testimony she recounted that in March 1973, while in the hospital, she took a Quaalude and "probably Librium, too" and then made an aside that a friend brought these items "rather than bringing flowers" (T. 587/8 - 588/21).

Dr. Levy testified that in January 1975 MacMurdo presented herself complaining of painful menstruation and dysfunctional bleeding (Levy, D. 41/23). The precise question asked of Dr. Levy was, "Did she present herself with any of the adverse reactions that are listed on the reverse side of this insert consistent with your examination and history of that visit?" To this he replied, "I have at that time that she was complaining of dysmenorrhea, which is painful menstruation, and dysfunctional bleeding, which is abnormal bleeding. I don't see either one of these listed as an adverse reaction" (Levy, D. 41/23).

Because this testimony was placed before the jury by reading from Dr. Levy's deposition, it is not apparent whether during the questioning he was examining the package insert. However, a fair assumption is that if he examined the insert at all, his examination was somewhat cursory because the package insert specifically lists "breakthrough bleeding" and "change in menstrual flow" as adverse reactions. Breakthrough bleeding is dysfunctional or abnormal bleeding outside the normal menstrual period, and change in the menstrual flow refers to changes from a norm (see Plaintiff's Ex. 8, App. 2 and Defendant's Ex. 1, App. 1; Taber's Cyclopedic Medical Dictionary (1987), p. 206, App. 8). Neither Dr. Levy nor Dr. Shapiro testified that the package insert, when read as a whole and considered in light of their medical education and experience, was inadequate to put them on notice that Depo-Provera when used as a contraceptive involved the risk of prolonged bleeding. Furthermore, Dr. Levy and Dr. Shapiro testified they knew Depo-Provera was not recommended by Upjohn for contraceptive purposes (Levy, D. 28/7-19; T. 473-25; T. 513/6).

The Depo-Provera package insert should be examined in its entirety; however, pertinent portions of the 1974 package insert read as follows:

> DESCRIPTION
> Medroxyprogesterone acetate, U.S.P. is a derivative of progesterone and is active by the parenteral and oral routes of administration....
>
> ACTIONS
> Depo-Provera (medroxyprogesterone acetate) administered parenterally in the recommended doses to women with adequate endogenous estrogen transforms proliferative

endometrium into secretory endometrium.,..

Because of its prolonged action and the resulting difficulty in predicting the time of withdrawal bleeding following injection, Depo-Provera is not recommended in secondary amenorrhea or dysfunctional uterine bleeding....

INDICATIONS
Adjunctive therapy and palliative treatment of inoperable, recurrent, and metastatic endometrial carcinoma.

CONTRAINDICATIONS
...
4. Undiagnosed vaginal bleeding....
...

WARNINGS
...
3. The use of Depo-Provera (medroxyprogesterone acetate) for contraception is investigational since there are unresolved questions relating to its safety for this indication. Therefore, this is not an approved indication for this use....

PRECAUTIONS
...
3. In cases of breakthrough bleeding, as in all cases of irregular bleeding per vaginum, nonfunctional causes should be borne in mind. In cases of undiagnosed vaginal bleeding, adequate diagnostic measures are indicated....
...

ADVERSE REACTIONS
... The following adverse reactions have been associated with the use of Depo-Provera (medroxyprogesterone acetate).

Miscellaneous -- Rare cases of headache and hyperpyrexia have been reported.

The following adverse reactions have been observed in women taking progestin including Depo-Provera:

breakthrouqh bleeding
spotting
change in menstrual flow....

In view of these observations, patients on progestin therapy should be carefully observed.

(Emphasis added)

Dr. Levy testified that the plaintiff requested steriliza-

tion (Levy, D. 42/19). He further testified that her complaints (with respect to bleeding) did not necessarily indicate a need for a hysterectomy (Levy, D. 86/6). He testified that he did not recommend a hysterectomy to the plaintiff (Levy, D. 47/10) but agreed to do one at her request (Levy, D. 47/10). Dr. Levy admitted that MacMurdo's complaints with respect to bleeding could have been treated otherwise than by a hysterectomy. Those complaints, he stated, could have been treated through "hormonial [sic] control" and possibly a D&C (Levy, D. 86/22-87/5).

The plaintiff introduced an article written by Dr. Paul M. Schwallie published in a recognized medical journal in May 1973 (Plaintiff's Ex. 7, App. 5). Dr. Schwallie joined Upjohn after 10 years in private practice and was in its fertility research unit with duties limited to the study of Depo-Provera as an injectable contraceptive (T. 460/17). An excerpt from the article states:

> Medroxyprogesterone acetate usage results in changes in the normal menstrual cycle. The resultant bleeding is irregular and unpredictable both from individual to individual and within the same individual. It is more frequently in the nature of spotting or light bleeding than heavy menstrual flow. For the purposes of this study, spotting was considered to be present if no protection was required to prevent clothing soilage. (Emphasis added.) (at 334).

The plaintiff also introduced portions of Dr. Schwallie's deposition. Dr. Schwallie testified with respect to his terminology in the article, that a woman was considered to have bleeding if she required sanitary protection to prevent clothing spoilage; otherwise her bleeding was classified as "spotting" (Schwallie, D. 48). He testified his studies showed that after

the first injection of Depo-Provera, 32-33% of the women studied experienced bleeding or spotting, but the majority of women with that reaction experienced spotting rather than bleeding (Schwallie, D. 49-54). A bar graph appearing in Dr. Schwallie's article was introduced in evidence as Plaintiff's Ex. 9. It illustrates the incidence of bleeding or spotting in the study group decreased markedly after the second and subsequent injections.

The plaintiff called David Benjamin, a Ph.D. in pharmacology, to comment on Dr. Schwallie's studies and on Upjohn's package insert. When asked if he thought there was more effective language that could have been used in the package insert to convey the message that Depo-Provera should not be used for contraception, Dr. Benjamin stated that Upjohn's language could have been highlighted by a black box or could have been changed to read "not recommended'' for contraceptive purposes (T. 313/2-10). Dr. Benjamin admitted, of course, that he cannot prescribe medication (T.380/9) and that the FDA approved the Depo-Provera package insert (T. 384/7-19). He also admitted that in examining a package insert for approval, the FDA has the benefit of experts in academic medicine (T. 385/2). Dr. Benjamin specifically denied claiming Upjohn did or did not do something wrong or negligent in connection with the phraseology of its package insert (T. 385/2-16). He further conceded that the package insert has four separate warnings with respect to bleeding and the warning related to change in menstrual flow could refer to heavy or light bleeding (T. 398/12-399/14). He

also stated that warning no, 3 on the package insert was clear to him.

Dr. Benjamin interpreted the statistics in the Schwallie article as indicating that 27% of the women in the study experienced 11-30 days bleeding after the first injection of Depo-Provera with the percentage decreasing to 15% after subsequent injections (T. 326-327). The publication of the Schwallie article, he said, was one means of informing the medical community. He testified it is common knowledge that physicians have a right to prescribe drugs for unapproved uses if they make the judgment that such is in the patient's best interest (T. 414/24-415/3).

Dr. Benjamin, when examined on the package insert, testified the package insert contraindicates the drug for women with a history of undiagnosed vaginal bleeding (T. 424/7) and stated that "breakthrough bleeding" listed on the package insert as an adverse reaction is bleeding beyond the normal menstrual period (T. 425/23-426/2).

Dr. Arthur Shapiro, who gave the plaintiff her second injection of Depo-Provera, when asked about the causal connection between the vaginal bleeding complaint reported to Dr. Levy in January 1975 and the hysterectomy, testified that the vaginal bleeding did not necessarily lead to the hysterectomy. When asked whether or not the removal of the uterus solved the problem, Dr. Shapiro made the colorful response: "Yes. You can always sink a rowboat with a torpedo" (T. 492/7-24).

The plaintiff's own medical expert, Dr. Sorosh Roshan, a

board-certified gynecologist from New Jersey and New York, although testifying that in her opinion the Depo-Provera caused the plaintiff's bleeding (Roshan, D. 57/25), stated that there was no justification for the hysterectomy (Roshan, D. 51/22; 70/21-71/13). Its performance was a deviation from acceptable standards (Roshan, D. 51/22-52/8). Dr. Roshan testified that the appropriate treatment for plaintiff's bleeding was iron and bed-rest initially, then the use of estrogen, and finally a D&C, if the other procedures were unsuccessful (Roshan, D/ 51/9-21).

With regard to the package insert, Dr. Roshan testified that she understood the package insert to contain a warning against the use of Depo-Provera for contraceptive purposes (Roshan, D/54/25-55/8) and was of the opinion that it was malpractice to prescribe Depo-Provera as a contraceptive (Roshan, D. 27/12-28/6).

Two expert witnesses testified for Upjohn. The first was Elizabeth Connell, a full professor at Emory and a board-certified gynecologist. Dr. Connell, in addition to testifying that in her opinion the bleeding MacMurdo experienced did not result from Depo-Provera (T. 706/16), testified that the warning on the package insert was adequate to warn the medical profession against the use of Depo-Provera for contraceptive purposes. With regard to the package insert, she testified that breakthrough bleeding is understood to be bleeding outside the normal menstrual cycle (T. 725/1) and that the reference in the package insert to change in menstrual flow refers to either an increase or a decrease in the flow from a person's norm (T. 725/10-18).

Upjohn's other expert, Dr. Donald Levitt, a board-certified gynecologist who had worked five years with the FDA, testified that the adverse reaction section of the package insert tells the physician that Depo-Provera can change the menstrual flow (T. 835/18). He added that the indications section in the package insert states quite clearly that Depo-Provera was not approved for use as a contraceptive (T. 831/10). He pointed out, however, that the FDA does not control the physicians' use of a drug for unapproved indications (T. 839/23-840/10).

ISSUES PRESENTED FOR REVIEW

FIRST ISSUE

WHETHER THE DISTRICT COURT ERRED IN CONCLUDING THAT THE EVIDENCE AT TRIAL PRESENTED A JURY QUESTION AS TO THE ADEQUACY OF DEFENDANT UPJOHN'S WARNING CONCERNING DEPO-PROVERA.

SECOND ISSUE

WHETHER THE DISTRICT COURT ERRED IN HOLDING IMPLICITLY THAT THE EVIDENCE PRESENTED A JURY QUESTION AS TO THE CAUSAL CONNECTION BETWEEN THE ALLEGEDLY INADEQUATE WARNING AND THE PLAINTIFF'S INJURY.

THIRD ISSUE

WHETHER THE DISTRICT COURT ERRED IN HOLDING THAT THE EVIDENCE PRESENTED A JURY QUESTION AS TO THE FORESEEABILITY OF PLAINTIFF'S INJURY BASED ON THE ALLEGEDLY INADEQUATE WARNING.

FOURTH ISSUE

WHETHER THE DISTRICT COURT ERRED IN HOLDING THAT THE JURY'S VERDICT WAS NOT CONTRARY TO THE MANIFEST WEIGHT OF THE EVIDENCE.

FIFTH ISSUE

WHETHER THE DISTRICT COURT ERRED IN HOLDING THAT THE EVIDENCE DID NOT PRESENT A JURY QUESTION ON THE ISSUE OF PLAINTIFF'S COMPARATIVE NEGLIGENCE.

SUMMARY OF ARGUMENT

This appeal involves Upjohn's liability for injuries that Anne MacMurdo claims were the proximate result of an inadequate warning. The warning was contained in a package insert delivered with every vial of Depo-Provera, a drug that only licensed physicians can prescribe. The appeal presents five issues. The first deals with the adequacy of the warning. Upjohn's first contention is simple. The plaintiff did not produce sufficient evidence to permit the jury to lawfully conclude that the warning was inadequate.

A warning provided in a package insert has a function. That is to inform the prescribing physician of the intended use of the drug and its adverse effects so that the physician, utilizing that information and his own store of knowledge, can make a reasoned decision whether to prescribe the drug for a particular patient. The ethical manufacturer has the right to assume that a physician will read and heed the warning.

In this case, two physicians prescribed Depo-Provera for the plaintiff for a use not indicated by the manufacturer nor approved by the FDA. Neither physician testified that the warning, when combined with his knowledge gained through formal education and experience, was insufficient to permit him to make an enlightened decision whether to use the drug. No testimony of any other medical doctor was presented to the jury stating that the package insert did not contain an adequate warning. On the contrary, the plaintiff's own medical expert testified the warning was clear to her and clearly warned against the use of

Depo-Provera as a contraceptive!

The second issue presented is whether any inadequacy in the warning had a causal relation to the alleged injury. There was no evidence presented that any other warning would have altered the conduct of the physicians in prescribing the drug and later treating the plaintiff. For this reason, as a matter of law the plaintiff failed to prove the essential causation-in-fact element of proximate cause.

The third issue also relates to the question of proximate cause, but it relates to the foreseeability aspect of proximate cause. For reasons amplified hereafter, a reasonable drug manufacturer simply could not have foreseen the events that befell MacMurdo, and as a matter of sound policy the consequences of the events should not be visited upon Upjohn.

The fourth issue presents the question of whether the verdict is contrary to the manifest weight of the evidence. The only real loss MacMurdo suffered derived from the hysterectomy performed in 1975 that was unrelated to Depo-Provera. MacMurdo simply elected to have a hysterectomy even though every physician on record testified that a hysterectomy was not necessary to treat the bleeding she experienced after her second Depo-Provera injection. The fourth point is an alternative to the first three.

Finally, Upjohn appeals the district court's reversal of that portion of the jury's verdict finding the plaintiff 49% comparatively negligent. The evidence supported a finding that MacMurdo chose to have a hysterectomy with full knowledge of the

risks and consequences. The district court's refusal to pass on the adequacy of the drug manufacturer's warning as a matter of law stands in stark contrast to the ease with which the district court removed the finding of plaintiff's comparative negligence from the province of the jury. This final issue need only be reached if the Court finds the jury's verdict otherwise lawful.

While this case is presented to this Court on the basis of five separate issues, there is but one underlying theme. The manufacturer satisfied its legal duty by providing physicians with a warning concerning its prescription drug that was accurate, clear and unambiguous. The verdict against the manufacturer is therefore unlawful and places the manufacturer in the position of an insurer with respect to the safety of a prescription drug that was used for a purpose not indicated by the manufacturer or approved by the FDA.

ARGUMENT ON ISSUES PRESENTED FOR REVIEW

Introduction

This case comes before the Court because the opinion of the Fourth District Court of Appeal below was based on a faulty premise -- its conclusion in an earlier appeal that "in all events, the adequacy of the warning is for the jury to decide...." MacMurdo v. Upjohn Company, 444 So.2d 449, 451 (Fla. 4th DCA 1983). The Court now has expressly rejected the Fourth District's premise in Felix v. Hoffmann-LaRoche, Inc., 540 So.2d 102 (Fla. 1989), holding in Felix that the adequacy of a pharmaceutical manufacturer's warning becomes a question of law where the warning is accurate, clear and unambiguous. Felix at 105.

As the Court reviews the issue of the adequacy of the Upjohn warning, it will notice that only two theories of liability were presented to the jury. The first related to the allegation that Upjohn was negligent in its marketing of Depo-Provera. The second related to the adequacy of the warnings Upjohn provided to the medical community (T. 1030/21). The jury found in favor of Upjohn on the first issue, exonerating it from the negligent marketing claim.

A prescription drug cannot lawfully be marketed until the drug is found both safe and effective for a use approved by the Secretary of Health, Education and Welfare or his delegate and its labeling found not false or misleading in any particular. 21 U.S.C.A. Sections 331(d) and 355. Furthermore, the approval accorded a prescription drug by the Secretary may be withdrawn on

a finding that the "labeling" (which includes the package insert) of the drug is false or misleading in any particular. 21 U.S.C.A. Section 355(e)(5).

Federal law governing ethical manufacturers provides, in addition to the administrative control by the Secretary, stringent criminal sanctions if the manufacturer's labeling is false or misleading in any particular. 21 U.S.C.A. Section 352(a), 352(n) and 321(m).

Volume 21 C.F.R. § 1.100 et seq. contained the federal labeling regulations in effect in 1974 (App. 4 at p. 52). The regulations required the label to bear

> ... adequate information for its use including indications, effects, dosages, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the drug can use the drug safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented....

21 C.F.R. Section 1.106(b)(3)(i) (1974). (Emphasis added.) A label or package insert that suggests that a drug is intended by the manufacturer to be used for an unapproved use is misleading and false and the introduction of the drug into interstate commerce is a federal offense. This was the position of the FDA as early as August of 1972 as shown by the notice of Proposed Rule Making published by the Food and Drug Administration in the Federal Register on August 15, 1972 (App. 9). The notice states in part at page 16504:

> Section 1.106 of the regulations (21 CFR 1.106) requires the labeling to contain appropriate information with respect to all intended uses of

the drugs. Thus, where a manufacturer or his representative, or any person in the chain of distribution, does anything that directly or indirectly suggests to the physician or to the patient that an approved drug may properly be used for unapproved uses for which it is neither labeled nor advertised, that action constitutes a direct violation of the Act and is punishable accordingly.

ISSUE 1:

WHETHER THE DISTRICT COURT ERRED IN CONCLUDING THAT THE EVIDENCE AT TRIAL PRESENTED A JURY QUESTION AS TO THE ADEQUACY OF DFFENDANT UPJOHN'S WARNING CONCERNING DEPO-PROVERA.

Recognizing that prescription drugs can be prescribed only by physicians, the courts have consistently limited ethical drug manufacturers' liability for such drugs' adverse effects to cases where the manufacturer has failed to provide the prescribing physician with an "adequate warning." This position was first adopted in Florida in Buckner v. Allergan Pharmaceuticals, Inc., 400 So.2d 820 (Fla. 5th DCA 1981) review denied, 407 So.2d 1102 (Fla. 1981), and followed by this Court in Felix, supra, p. 19. In prescribing a prescription drug, the physician acts as a "learned intermediary" between the manufacturer and the patient recipient.[2] The physician is expected to use independent judgment, taking into account his knowledge of the patient and the product. Buckner at 823.

Since the decision to use the drug rests with the physician, the adequacy of the warning depends on its capacity to inform the physician of the approved use of the drug and the risk of any side effects associated with the normal use of the

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[2] Other cases discussing the "learned intermediary" rule include Stanback v. Parke Davis and Company, 657 F.2d 642 (4th Cir. 1981) applying Virginia law; Swayze v. McNeil Laboratories, Inc., 807 F.2d 464 (5th Cir. 1987) applying Mississippi law; Terhune v. A. H. Robins Co., 577 P.2d 975 (Wash. 1978); Plummer v. Lederle Laboratories, Div. of American Cyanamid Company, 819 F.2d 349 (2d Cir. 1987) applying California law; Kinney v. Hutchinson, 468 So.2d 714 (La. App. 5th Cir. 1985) applying Louisiana law.

product, to the end that the physician, with his medical education and unique knowledge of the patient and the product, can make an informed decision to use or not to use the product. Rhoto v. Ribando, 504 So.2d 1119, 1124 (La. App. 5th Cir. 1987); Swayze v. McNeil Laboratories, Inc., 807 F.2d 464, 472 (5th Cir. 1987); Kinney v. Hutchinson, 468 So.2d 714, 717 (La. App. 5th Cir. 1985); Wooten v. Johnson & Johnson Products, Inc., 635 F.Supp. 799 (N.D. Ill. 1986); Stanback v. Parke Davis and Company, 657 F.2d 642, 644 (4th Cir. 1981); Eiser v. Feldman, 507 N.Y.S.2d 386 (N.Y., S.Ct. App. Div. 1986); Terhune v. A. H. Robins Company, 577 P.2d 975, 978 (Wash. 1978). The Supreme Court of Washington aptly stated the rule in Terhune:

> ... if the product is properly labeled and carries the necessary instructions and warnings to fully apprise the physicians of the proper procedures for use and the dangers involved, the manufacturer may reasonably assume that the physician will exercise the informed judgment thereby gained in conjunction with his own independent learning, in the best interest of the patient....

Terhune at 978. As mentioned above, this Court has recently declared that a clear, accurate and unambiguous label is adequate as a matter of law. ~~See Felix~~, supra, p. 19, and authorities cited therein.

Since the manufacturer's warnings are directed to physicians, the adequacy of the warning to inform a particular physician must, except in the most obvious situations, be proved by expert testimony of a physician or a person having similar qualifications concerning pharmaceuticals. Dion v. Graduate Hosp. of Univ. of Pa., 520 A.2d 876, 880 (Pa. Super. 1987); Hill v. Squibb & Sons, E.R., 592 P.2d 1383 (Mont. 1979); Wyeth

Laboratories, Inc. v. Fortenberry, 530 So.2d 688, 692 (Miss. 1988); Williams v. Ciba-Geigy Corporation, 686 F.Supp. 573 (W.D. La. 1988). Hence, to determine whether a particular prescription drug warning is adequate as a matter of law, a court must analyze the expert testimony concerning the information imparted by the warning label as well as the testimony of the prescribing physicians.

MacMurdo's physicians who prescribed the Depo-Provera, Drs. Levy and Shapiro, at the time were board-certified specialists in obstetrics and gynecology. Neither testified that Upjohn's package insert, when considered in light of his knowledge as an experienced professional, was inadequate to provide sufficient information to permit him to make an informed decision whether or not to prescribe Depo-Provera.

The plaintiff called two other expert witnesses. One was David Benjamin, a pharmacologist. Dr. Benjamin was not a physician and never qualified as an expert to testify as to the capacity of the Depo-Provera label to enlighten the judgment of board-certified OB/GYNs. He suggested that Upjohn could have placed a box around the approved use of the drug as shown in the package insert. His other suggestion was that Upjohn change the wording on the package insert to state that Depo-Provera's use as a contraceptive was "not recommended'' as opposed to not approved. Neither of these suggestions was of consequence insasmuch as both Dr. Levy and Dr. Shapiro testified they knew the drug was not recommended for contraceptive purposes. Furthermore, Dr. Benjamin specifically disclaimed any opinion as

to whether or not Upjohn did "anything wrong" or was negligent in connection with the phraseology on the package insert. Dr. Benjamin conceded that warning no. 3 on the package insert was clear to him.

The plaintiff's other expert, Dr. Roshan, a board-certified OB/GYN, testified that she understood the package insert to contain a warning against the use of Depo-Provera for contraceptive purposes. She volunteered an opinion that it was malpractice to prescribe Depo-Provera as a contraceptive. Thus, to her the warning was clear, accurate and unambiguous.

The evidence revealed that the very problem encountered by the plaintiff was specifically adverted to in the package insert reference to breakthrough bleeding and to change in menstrual flow. It is clear from the plaintiff's own testimony that her problem was either breakthrough bleeding, which is bleeding outside the normal menstrual period, or a change in menstrual flow, which refers to a prolongation of the menstrual period. No witness, expert or lay, suggested what more Upjohn could have done consistent with the requirements of federal law and the FDA regulations to enlighten the choices of Drs. Levy and Shapiro.

The plaintiff's attorney argued to the jury that the package insert was inadequate because it did not include the findings of the study reported on by Dr. Schwallie in the article which is in evidence as Plaintiff's Exhibit 7. Specifically, the plaintiff's attorney's contention was that the package insert should have somehow quantified the risk of breakthrough bleeding or changes in the menstrual flow. An examination of the article

itself, however, shows quite clearly the impossibility of meaningfully quantifying the risk. The Schwallie study found that the bleeding that was observed in some women taking Depo-Provera for contraceptive purposes was irregular and unpredictable both from individual to individual and within the same individual. The study also indicated that the resultant bleeding was more frequently in the nature of spotting or light bleeding than heavy menstrual flow. On the basis of these findings, of course, no quantifiable risk could have been suggested in the package insert.

Moreover, had Upjohn published in its package insert the findings from a study of the use of Depo-Provera for contraceptive purposes, such could have rendered the labeling misleading by suggesting that the drug was safe, effective and/or recommended for contraceptive purposes. In that event, the company could have been subjected to criminal penalties under the provisions of 21 U.S.C.A. Section 331(d) and the further sanction of having its drug withdrawn from the market under the provisions of Section 355(e) of Title 21 U.S.C.A., and certainly the plaintiff would have used that theory as a basis for her claim against Upjohn's labeling. FDA regulations in the applicable time frame required the labeling to provide information sufficient to enable practitioners to safely use the drug for its intended purpose -- and that of necessity would not include purposes for which the product was not indicated by the manufacturer nor approved by the FDA (App. 4 at p. 52.).

In Felix, supra, p. 19, this Court held adequate as a matter

of law the warning given by the manufacturer of a drug prescribed for serious and disfiguring cases of acne. The package insert accompanying the prescription drug clearly warned against use of the drug during pregnancy, but plaintiff was given the drug while pregnant and her child was born with severe birth defects. The Court determined that the manufacturer's warning concerning the dangerous side effects of Accutane was quite clear and accurate, and approved the Third District's opinion affirming summary judgment for the manufacturer.

Similarly, in Wyeth Laboratories, Inc. v. Fortenberry, supra, the Mississippi Supreme Court held that a package insert for a non-swine influenza vaccine gave plaintiff's physician an adequate warning as a matter of law. The plaintiff in Wyeth Laboratories had been in good health but contracted Guillaine-Barre Syndrome (GBS) after he received the vaccine at his doctor's direction. The vaccine manufacturer's package insert had stated:

> INDICATIONS AND USAGE * * * * *
>
> Annual routine influenza immunization is NOT recommended for healthy adults, infants, or children but is strongly recommended for all persons, children and adults, who are at increased risk of adverse consequences from infections of the lower respiratory tract.
>
> ADVERSE REACTIONS * * * * *
>
> 3. Guillaine-Barre syndrome (GBS). This is an uncommon illness characterized by ascending paralysis which is usually self-limiting and reversible.... Before 1976, no association of GBS with influenza use was recognized.... A statistically significant excess risk of contracting GBS after receipt of the 1978-79 or 1979-80 Influenza Virus Vaccine could not be

> demonstrated.... Nevertheless, candidates for Influenza Virus Vaccine should be made aware of the benefits and possible risks, including GBS, of administration.

Wyeth Laboratories at 689, n.l.

The court in Wyeth Laboratories determined that the plaintiff was in the group of "healthy adults" for whom the vaccine was not recommended, and that the insert warned of a possible connection between the vaccine and GBS. After a comprehensive analysis of the case law, the court declared the manufacturer's warning reasonable under the circumstances and thus legally adequate.

Upjohn's package insert warned MacMurdo's physicians in even stronger language than the language held adequate as a matter of law in Wyeth Laboratories. Like the warning in Wyeth stating that the vaccine is not recommended for healthy adults, Upjohn's Warnings section stated that contraception is "not an approved indication" for Depo-Provera, explaining that "there are unresolved questions relating to its safety for this indication." Like the package insert in Wyeth noting GBS as an adverse reaction, Upjohn's package insert specifically listed break-through bleeding, spotting and change in menstrual flow as observed adverse reactions to Depo-Provera. It is inconceivable that reasonable persons could disagree as to the adequacy of these warnings to convey to physicians the message that Depo-Provera should not have been prescribed for contraceptive purposes. Under Wyeth and Felix, supra at p. 19, these warnings were adequate as a matter of law. No other result could obtain

in the face of the testimony from plaintiff's only medical expert, Dr. Roshan, who said the warning was clear to her and it was malpractice to prescribe the drug for contraceptive purposes.

Plaintiff adduced no medical expert to testify that Upjohn's package insert did not adequately warn the medical community. In Lindsay v. Ortho Pharmaceutical Corp., 637 F.2d 87 (2d Cir. 1980), the Second Circuit Court of Appeals said:

> If plaintiffs claim that Ortho is liable for a failure to give adequate warning to any or all of Mrs. Lindsay's physicians, they must prove that Ortho failed to give those physicians **a** reasonable warning under all the circumstances..... In this respect, plaintiffs' burden is the same as it would be in an ordinary negligence action.... The failure to give adequate warnings is the 'defect' in the product upon which the plaintiffs base their claim.... The full burden of proving that such a defect existed and that it was a proximate cause of Mrs. Lindsay's injury remains at all times on the plaintiff. With regard to the treating physicians, the burden was not satisfied (Emphasis added)

Lindsay at 92. Plaintiff MacMurdo utterly failed to sustain her burden of proving the inadequacy in the warning label. Neither of the doctors who prescribed the Depo-Provera suggested that the label was inadequate to enable him to make an informed decision. One of the plaintiff's experts, Dr. Benjamin, disclaimed any contention on his part that the company breached its duty to warn. As a pharmacologist, Benjamin was unqualified and in fact did not attempt to assess the effectiveness of the warning label as to board-certified OB/GYNs. The plaintiff's other expert, to the extent she testified with regard to the labeling, simply testified that the label was a clear warning to

her against the use of the drug as a contraceptive. The jury's finding on the labeling issue has no lawful foundation and amounts to nothing more than an arbitrary exaction, based on an asserted loss.

For the foregoing reasons, the district court of appeal erred in concluding that the evidence at trial presented a jury question as to the adequacy of Upjohn's warning concerning Depo-Provera, and in affirming the trial court's denial of defendant's motions for directed verdict and for judgment notwithstanding the verdict.

ISSUE 2:

WHETHER THE DISTRICT COURT ERRED IN HOLDING IMPLICITLY THAT THE EVIDENCE PRESENTED A JURY QUESTION AS TO THE CAUSAL CONNECTION BETWEEN THE ALLEGEDLY INADEQUATE WARNING AND THE PLAINTIFF'S INJURY

The plaintiff failed to carry her burden of proving that Upjohn's warning proximately caused the injury she allegedly experienced as a result of receiving two Depo-Provera injections. Although Upjohn argued this issue to the district court, the district court's opinion did not address the issue, and concluded without explanation

> [W]hile there was cons derable evi(ence presented that may have supported a verdict for Upjohn, there was also substantial evidence presented that the drug in question caused MacMurdo's bleeding problem, that the warnings were insufficient to alert her physicians to this risk, and that her hysterectomy was performed to treat her bleeding condition.

Upjohn Co. V. MacMurdo, 536 So.2d at **340.**

The rules of causation applicable in drug labeling cases were concisely stated in Stanback v. Parke Davis & Company, 502 F.Supp. 767, 770 (W.D. Va. 1980), aff'd., 657 F.2d 642 (4th Cir. 1981), as follows:

> ... The plaintiff must establish two elements of causation. First, she must prove that the ingestion of the defendant's drug produced her illness. Second, she must prove that had an adequate warning been given a reasonable physician would have treated her in a manner that would have avoided or reduced the severity of her injuries. (Emphasis added)

Another opinion on the subject, Plummer v. Lederle Laboratories Div. of American Cyanamid, supra, p. 22, held that the plaintiff failed to establish a causal connection between an allegedly inadequate warning and his injury where there was no evidence that a different warning would have altered the prescribing physician's conduct.

In this case, as in Stanback and Plummer, the plaintiff has simply failed to present any evidence whatsoever upon which a reasonable jury could have concluded that some other warning would have altered the conduct of Dr. Shapiro in prescribing the second injection of Depo-Provera or the conduct of Dr. Levy in prescribing the first injection and later performing the hysterectomy. Both physicians testified that they knew Depo-Provera was not recommended for use as a contraceptive. When asked why he prescribed the second injection, Dr. Shapiro testified:

> It appeared that she had come in having missed her period for about seven weeks, and I had given a history she had been started on the drug in New Orleans based on the fact that she had been through the basic other forms of medication. The pills, the IUD and had different problems with

> each of those forms of contraception, and for that reason had been started in New Orleans by Dr. Levy on Depo-Provera shots. She was actually about three months now since that first shot was given to her. (T. 479/10-20)

It is facetious to suggest that had the text of the Schwallie article (Plaintiff's Ex. 7) been published or summarized in the package insert, such would have altered the conduct of Dr. Shapiro or Levy in prescribing Depo-Provera. Undoubtedly the Schwallie findings would simply have confirmed their intent to use the drug as a contraceptive. Thus, the hiatus in plaintiff's case is the absence of testimony from Dr. Shapiro or Dr. Levy that either would have altered his conduct in any respect in response to some other warning.

In Felix v. Hoffmann-LaRoche, Inc., supra at p. 19, this Court held that where a physician used a drug with knowledge of the risk, he became the proximate cause of any resulting loss. The logic of Felix compels the conclusion that where board-certified physicians knowingly prescribe a drug for a use not indicated by the manufacturer or approved by the FDA, their prescription of the drug for the nonapproved use is the proximate cause of any resultant loss. Both Shapiro and Levy knew Depo-Provera was not indicated or recommended as a contraceptive. They prescribed it for that purpose in the face of an explicit warning against such use.

Furthermore, Dr. Levy performed the hysterectomy not because it was necessary as a means to stop the bleeding, but because the plaintiff requested it. He knew the hysterectomy was not necessary as a means of eliminating the bleeding and

delineated other methods by which the bleeding could have been treated. Therefore, the proximate cause of the plaintiff's loss is the combined conduct of the plaintiff and her physicians.

For the foregoing reasons, the District Court erred in holding implicitly that the evidence presented a jury question as to the causal connection between the allegedly inadequate warning and the plaintiff's injury.

ISSUE 3:

WHETHER THE DISTRICT COURT ERRED IN HOLDING THAT THE EVIDENCE PRESENTED A JURY QUESTION AS TO THE FORESEEABILITY OF PLAINTIFF'S INJURY BASED ON THE ALLEGEDLY INADEQUATE WARNING.

The concept of proximate cause has two functions. One is to require a causal connection between misconduct of a defendant and injury to a plaintiff. The other is to place a limit on liability for one's misconduct to avoid bizarre applications of the law which impose responsibility for injuries no reasonable person would foresee as a likely result of his conduct. The latter function serves to promote respect for the tort law scheme for compensating injured persons.

The Florida Supreme Court recently noted the dual function of the doctrine of proximate cause in Department of Transp. v. Anglin, 502 So.2d **896, 899** (Fla. **1987)** wherein the Court stated:

> The policy of the law will of course not allow tort liability to attach to all conduct factually "caused" by a defendant:
>
> > Florida courts, in accord with courts throughout the country, have for good reason been most reluctant to attach tort liability for results which, although caused-in-fact by the defendant's negligent act or ommission [sic], seem to the judicial mind highly

> unusual, extraordinary, bizarre, or, stated differently, seem beyond the scope of any fair assessment of the danger created by the defendant's negligence. Plainly, the courts here have found no proximate cause in such cases based solely on fairness and policy consideration rather than actual causation grounds. (Emphasis added)

The evidence in the present case shows that two board-certified gynecologists decided to prescribe Depo-Provera to a young woman as a means of birth control. They did so in the face of clear warnings in the package insert that Depo-Provera was not approved for use as a contraceptive because of unresolved safety questions; they did so despite their own knowledge that Depo-Provera was not recommended as a contraceptive; and they did so in the face of package insert warnings that the use of Depo-Provera could cause changes in the menstrual flow as well as breakthrough bleeding and was indicated only for treatment of inoperable, recurrent, and metastatic endometrial carcinoma. They did so despite the fact that at least in the opinion of the plaintiff's own medical expert, it was malpractice to utilize Depo-Provera for contraceptive purposes. On this record, it is not reasonable to conclude that the defendant should have foreseen and thus become liable for the activities of Drs. Levy and Shapiro.

Penalizing Upjohn for the conduct of Drs. Levy and Shapiro simply transfers to the manufacturer a loss which in good conscience should be borne by the medical practitioners. From a practical standpoint, the jury in this case imposed on an ethical drug manufacturer the duty to police the activities of the

medical community, and that is a duty which is impossible for a manufacturer to perform.

> ... The defendant cannot control the individual practices of the medical community, even if it is the prevailing practice, and we decline to impose such a duty. Drug manufacturers must adequately warn physicians of the potential side effects of their prescription drugs: thereafter, the physician with his special knowledge of the patient's needs assumes the burden of presiding over the patient's best interests. Swayze v. McNeil Laboratories, Inc., 807 F.2d 464, 472 (5th Cir. 1987).

For the foregoing reasons, the courts below should have removed the case from the realm of the jury. Their failure to do so constitutes reversible error.

ISSUE 4:

WHETHER THE DISTRICT COURT ERRED IN HOLDING THAT THE JURY'S VERDICT WAS NOT CONTRARY TO THE MANIFEST WEIGHT OF THE EVIDENCE.

The jury verdict found that MacMurdo's loss totaled $370,000. It is beyond belief that the jury could have arrived at this figure without including therein compensation for the hysterectomy. In fact, an examination of the closing argument by the plaintiff reveals virtually no argument suggesting a monetary loss as a result of the prolonged bleeding which preceded the hysterectomy. It is, therefore, reasonable to assume that the jury's award, if not entirely attributable to the hysterectomy, is substantially attributable thereto. Although Upjohn argued in its appeal to the district court that the jury's verdict was contrary to the manifest weight of the evidence, the district court failed to address the issue in its opinion.

The evidence which has been reviewed at length and discussed in connection with the preceding points clearly indicates that the hysterectomy was a needless procedure done only because MacMurdo requested it. Indeed, she executed two consent forms to authorize the procedure. The doctor who performed the hysterectomy acknowledged it was not necessary as a means for treating the bleeding. And there should be no mistake about MacMurdo's testimony on the point. At no time did she put herself on the line with sworn testimony to the effect that she believed the hysterectomy was necessary to eliminate the bleeding problem. She obviously was interested in the procedure as a means of sterilization. As pointed out in the statement of

facts, supra, p. 6-7, MacMurdo had a strong motivation for avoiding pregnancy because of the events surrounding the birth of her child in 1970.

No witness testified the hysterectomy was needed to correct the plaintiff's bleeding. The verdict, to the extent it charged Upjohn with a loss attributable to the hysterectomy, was contrary to the manifest weight of the evidence. For the foregoing reason, the district court erred in holding at least by implication that the jury's verdict was not against the manifest weight of the evidence.

Upjohn contends that the evidence was insufficient to support a verdict in favor of Macmurdo. Only as an alternative does Upjohn present the error of the trial court in failing to grant a new trial because the verdict was contrary to the manifest weight of the evidence. The remedy for this error would be a remand for a new trial on the issue of damages with instructions to the trial court to limit the damages to whatever monetary value is attributable to the bleeding MacMurdo claimed occurred between her second injection of Depo-Provera in August 1974 and the hysterectomy in January 1975. Wackenhut Corp. v. Canty, 359 So.2d 430, 435 (Fla. 1978).

ISSUE 5:

WHETHER THE DISTRICT COURT ERRED IN HOLDING THAT THE EVIDENCE DID NOT PRESENT A JURY QUESTION ON THE ISSUE OF PLAINTIFF'S COMPARATIVE NEGLIGENCE.

The Fourth District Court of Appeal's reversal of the jury's verdict finding plaintiff 49% comparatively negligent is ironic

in view of the court's refusal to remove the determination of the issues of proximate cause and adequacy of the warning from the province of the jury.

Contrary to the district court's holding, the testimony of the plaintiff's drug use, whether it was connected to the bleeding or not, was certainly sufficient to permit a jury to infer that MacMurdo's judgment was severely impaired. The jury could well have inferred that she negligently and carelessly and without consideration of available alternatives known to her - i.e., a D&C -- opted to proceed with a hysterectomy. This is a judgment which the jury could have drawn and indeed should have drawn from the evidence before it and, on such basis, the jury was entirely correct in making a finding of negligence on the plaintiff's part. See Pensacola Electric Garage v. Colley, 348 So.2d 667 (Fla. 1st DCA 1977) and Hoffman v. Jones, 280 So.2d 431 (Fla. 1973).

The district court based its reversal of the judgment with respect to comparative negligence on medical malpractice cases in which the plaintiff's failure to seek a second medical opinion or failure to seek early medical attention was held not to be a legal cause of plaintiff's injury. Norman v. Mandarin Emergency Care Center, Inc., 490 So.2d 76 (Fla. 1st DCA 1986), and Piper v. Moore, 410 So.2d 646 (Fla. 3d DCA 1982). Upjohn does not contend that MacMurdo should have sought other or earlier medical advice; therefore, these cases are inapplicable. Upjohn contends that ample evidence was presented to the jury from which it could reasonably conclude that Anne MacMurdo's snap decision to elect a

hysterectomy was an act of carelessness on her own part because of the knowledge and information that was then available to her. While MacMurdo testified that she did not request sterilization as a means of birth control (T. 560/6), she carefully avoided testifying that she in good faith believed, on the basis of medical advice, that a hysterectomy was reasonably necessary to resolve her bleeding problem (T. 560/11; 607/14). The record reflects that in 1973 the plaintiff had an episode of prolonged bleeding attributable to the use of an IUD. The bleeding was cured by a D&C following removal of the IUD (T. 586/2-24). The plaintiff thus knew there were means short of a hysterectomy for the treatment of bleeding. Furthermore, on the evidence before it, the jury could have found MacMurdo acted not out of a desire to stop the bleeding, if indeed she was experiencing bleeding, but out of a desire to render herself sterile.

For the foregoing reasons, the district court erred in holding that the evidence did not present a jury question on the issue of plaintiff's negligence, and in reversing that portion of the judgment reducing plaintiff's damages.

CONCLUSION

For the reasons stated herein, Petitioner, Upjohn, respectfully requests that the decision herein of the Fourth District Court of Appeal be reversed and that the cause be remanded to the District Court. If reversal is grounded on one or more of the first three issues presented herein, the Court should vacate the mandate of the Fourth District Court of Appeal and direct a remand to the circuit court for Broward County with directions to enter a judgment in favor of Upjohn, with appropriate taxation of costs. Because Upjohn was held liable for a loss resulting from the use of an adequately labeled prescription drug for a purpose which was neither indicated by Upjohn nor approved by the United States Food and Drug Administration, Upjohn urges that these are the appropriate grounds for reversal.

If reversal is grounded on the fourth issue presented, the result should be a remand to the trial court with instructions to provide a new trial on damages, with the damage claim limited to damages accruing from the episode of bleeding plaintiff allegedly experienced between her second injection of Depo-Provera and the hysterectomy. If reversal is grounded solely on the fifth issue presented, the district court should be instructed to vacate that portion of its mandate reversing the trial court's final judgment.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing was furnished by U.S. Mail to DOMINIC L. BRANDY, ESQ., 115 S.E. 13th St., Ft. Lauderdale, FL 33316, and RICHARD A. KUPFER, ESQ., Cone, Wagner, Nugent, et al., P.O. Box 3466, West Palm Beach, FL 33402, Co-counsel for Respondent; DAVID M. COVEY, ESQ., 59 Maiden Lane, 41st floor, New York, NY 10038, and G. WILLIAM BISSETT, ESQ., 501 N.E. First Avenue, Miami, FL 33132, Co-counsel for Petitioner, this 23rd day of June, 1989.

John A. Reed, Jr.