OA 9-5-89

IN THE SUPREME COURT OF FLORIDA

THE UPJOHN COMPANY,

Petitioner,

v.

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

Respondent.

CASE NO. 73,596

RESPONDENT'S BRIEF ON THE MERITS
On "Conflict Jurisdiction" From The
Fourth District Court of Appeal

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TABLE OF CONTENTS

TABLE OF CONTENTS (Cont'd)

TABLE OF CITATIONS

TABLE OF CITATIONS (Cont'd)

TABLE OF CITATIONS (Cont'd)

ISSUES PRESENTED FOR REVIEW

Point I	WHETHER THE FOURTH DCA SHOULD BE QUASHED FOR AGREEING WITH THE TRIAL COURT THAT THE EVIDENCE PRESENTED A JURY QUESTION AS TO THE ADEQUACY OF UPJOHN'S WARNING CONTAINED IN THE PACKAGE INSERT?
Point II	WHETHER THE FOURTH DCA SHOULD BE QUASHED FOR IMPLYING (WITHOUT STATING) THAT THE EVIDENCE PRESENTED A JURY QUESTION ON THE CAUSAL CONNECTION BETWEEN THE INADEQUATE WARNING AND THE PLAINTIFF'S INJURIES?
Point III	WHETHER THE FOURTH DCA SHOULD BE QUASHED FOR IMPLYING (WITHOUT STATING) THAT THE ISSUE OF FORE-SEEABILITY OF PLAINTIFF'S INJURIES WAS FOR THE JURY?
Point IV	WHETHER THE FOURTH DCA SHOULD BE QUASHED FOR IMPLYING (WITHOUT STATING) THAT THE JURY'S FINDINGS WERE NOT CONTRARY TO THE MANIFEST WEIGHT OF THE EVIDENCE?
Point V	WHETHER THE FOURTH DCA SHOULD BE QUASHED FOR HOLDING THERE WAS NO EVIDENCE OF COMPARATIVE NEGLIGENCE ON THE PART OF THE PLAINTIFF TO JUSTIFY A REDUCTION OF HER DAMAGES?

STATEMENT OF THE CASE AND FACTS

Upjohn's statement of facts must be supplemented because certain important facts have been omitted and because Upjohn in arguing entitlement to a directed verdict, is still not presenting the facts in a light most favorable to the plaintiff (as they were considered by the Fourth DCA). First, it is necessary for this court to understand more about the nature of the drug, Depo-Provera, and its history.

Depo-Provera is classified as a steroid type drug (T. 252) and acts as a synthetic form of progesterone (App. 1; T. 282). In the normal woman the hypothalamus and pituitary gland control the process of ovulation and menstrual bleedin (R. 2502-2503; Roshan Depo. at pp. 24-25; T. 284). Depo-Provera inhibits the secretion of pituitary gonadotropin which, in turn, inhibits ovulation. (App. 1; R. 1090, Levy Depo at p. 34; T. 460-461, 536). Most frequently it causes women to become amenorrheac, meaning they do not ovulate or have any menstrual bleeding. (T. 461, 288, 291, 521). This usually lasts for about three months after each injection of the drug. (R. 1076, Levy Depo p. 20).

Unlike some other forms of contraception, this drug usually causes the woman not to have any menstrual periods for as long as she is on the drug. When the drug therapy is taken away, normal cycle typically returns. In extreme case it may take up to 18 months for menstruation and fertility to return. (App. 2, p. 2).

Depo-Provera was originally marketed by Upjohn in 1960 t treat multiple different gynecological problems including habitual abortions. (Fletcher Depo at p. 12; T. 454, 292). Although it has not been approved by the FDA in this country to be used as a means of contraception, it has been approved in at least 20 to 30 other countries for purposes of contraception and that fact has been published widely in foreign and American medical literature. (T. 852, 138, 714). It is known by most American doctors. (T. 833). Although Depo-Provera has not yet been a major money maker in this country Upjohn admitted it has been trying for years to get FDA approval of the drug to be used for contraception. (T. 111, 130; See also R. 2501-2520; Roshan Depo. at pp. 23-24). Upj n admitted at trial it was aware that a number of American doctors were using the drug for contraceptive purposes. (T. 138, 71, 80). The OB/GYN Advisory Committee of the FDA recommended to the FDA in 1973 that Depo-Provera should be approved for use as a contraceptive as long as appropriate warnings accompanied it (T. 728; R. 2242). The widespread use of Depo-Provera for contraception in the United States became a matter of such concern that in 1973 there were hearings initiated by Congress to investigate it. (T. 739, 850).

When the plaintiff, Anne Macmurdo, first went to Dr. Levy in May of 1974 she was twenty-three years old and unmarried. (T. 120, 550). She had no children of her own. She was bleeding from an IUD (intra-uterine contraceptive

device) which had to be removed and alternative forms of contraception had to be explored. (R. 1096). Since she had als previously experienced other types of adverse physiological reactions to birth control pills, Dr. Levy (a board certified OB/GYN with ten years experience) prescribed an injection of 250 Mg. of Depo-Provera for contraception. (R. 1136-1137; Levy Depo. p. 80-81; T. 479).

Contrary to the statements in Upjohn's brief, Dr. Levy did not testify he was aware that Depo-Provera was not "recommended" by the manufacturer for contraception. He testified he has read the package insert and he knows the drug is "indicated" for use as palliative treatment for inoperable endometrial cancer.' (R. 1084, Levy Depo. p. 28; R. 2883-2884, 2286). The package insert does not state that the manufacturer does not recommend the use of the drug for contraception, it merely advises the doctor that it is still being investigated for that use and has not received FDA approval for that indication. (App. 1). Use for contraception is not listed as a "contraindication" on the package insert, nor does Upjohn specifically recommend against that use. (App. 1). Although its use for "undiagnosed vaginal bleeding" is contraindicated, Dr. Levy explained that plaintiff's bleeding was diagnosed by him as being secondary to her IUD, so his prescription of Depo-Provera as an alternatiive contraception was not contra-

1. The word "indicated" on a package insert is understood to mean a use approved by the FDA; not what the drug manufacturer recommends. (T. 314). Thus when Upjohn says the drug was not "indicated" by the manufacturer for a certain use, that is a non-sequitur.

indicated on the package insert. (R. 1096; Levy Depo. p. 40)

Dr. Levy testified he was trained as a first-year resider to use Depo-Provera for contraception and used it frequently. (R. 1081-1082, Levy Depo. pp. 25-26; R. 1137, Levy Depo. p. 81). He does not consider the package insert to be a direction to him from Upjohn not to use the drug for contraceptior (R. 1083; Levy Depo. p. 27). When he gave it to plaintiff he told her she would probably go for a while without having menstrual periods. (R. 1076: Levy Depo. p. 20).

Another expert agreed that the package insert was not a direction by the manufacturer to the doctor not to use the drug for contraception. Dr. Benjamin is a Ph.D. in clinical pharmacology (T. 239-240) who has worked over the years for several major pharmaceutical companies (eg., Pfizer; Hoffman-LaRoche; Rorer; Revlon Health Care) and has vast experience in working on investigational new drugs and preparing applica tions to the FDA for approval of new drugs. (T. 245, 250-25: 255). He has substantial experience in writing package inse: s. (T. 299, 309). Dr. Benjamin testified there is terminology customary in the industry for getting certain messages across with different degrees of force, and if Upjohn really intend to discourage doctors from using Depo-Provera as a contraceptive it could have simply stated on the package insert thi it was not recommended for that use. T. 312-313).

Dr. Benjamin explained the difference that would be commonly understood in the industry between using certain terms in the package insert:

A. 'Not indicated' meant that it wasn't approved for that indication by the FDA. 'Not recommended' would mean regardless of what its status was, that the manufacturer didn't think you should use it for that.

Q. Does that language appear in the package insert, 'not recommended'?

A. . . . my best recollection is that it does not. (T. 314).

* * *

A. . . . you cou d basically put whatever you want to in the package-insert as long as the FDA finally approves the wording. So how you phrase it is really up to you to decide as the manufacturer of the medication. (T. 373).

Even Upjohn's own OB/GYN expert, Dr. Levitt, agreed on cross examination that the package insert does not say that Depo-Provera is not recommended by the manufacturer for contraceptive purposes. (T. 848). There are other uses that are expressly "not recommended" but contraception is not one of them. (T. 848-849). (For ex., usage in pregnancy or wher a woman is already experiencing amenorrhea or dysfunctional bleeding is "not recommended." See App. 1, p. 1. Compare that language with ¶3 on the package insert regarding use for contraception.)

Another one of Upjohn's experts, Dr. Connell (a professor of OB/GYN at Emory University) testified that it is not illegal or even unusual for a physician to use a drug for an indication not approved by the FDA, provided there is support for such use in the medical community and in the literature. (T. 727). She stated:

> . . . so many drugs actually are used for indications that are not FDA approved, but provided it's done within the context of good medical practice. [If] it's a practice used by physicians in a comparable clinic situation and there is no contra-indication to the use of that drug, then it's clearly acceptable and it is no case illegal. (T. 727).

The first injection of Depo-Provera given to the plaintif by Dr. Levy in May, 1974, acted as expected and caused amenorrhea (lack of menstrual period) for three months (T. 552-553). On August 6, 1974, plaintiff received a second injection of Depo-Provera from Dr. Shapiro in Miami, for contraception. He testified he was aware that it was being routinely used by family planning centers as a contraceptive (T. 501-502). However, the second injection had a totally different reaction on the plaintiff. Instead of becoming amenorrheac she had heavy menstrual bleeding continuously without let up. (T. 553). At first she tried to control it through nutrician and eventually, when that did not help and she had been bleeding non-stop for four months, she returned to see Dr. Levy in New Orleans in December, 1974 (T. 553). When Dr. Levy performed the hysterectomy a month later in January, 1975, she still had not stopped bleeding (making it five months) and at this point she was "boarder-line anemic." (R. 2535-2536, 2565; T. 488, 799).

Before being injected with Depo-Provera the plaintiff had no prior medical history of having such prolonged inter-menstrual bleeding. Her prior problems with bleeding were related to the IUDs she attempted to use and she did not

otherwise have such a problem. (R. 2516; T. 485, 487, 556, 567-568). She did have irregular menstrual periods when she was a teenager (R. 2514), but Dr. Roshan testified that is not uncommon for a young woman during her first several years of menstruation. (R. 2515). Irregular periods is not what she was suffering from after she was injected with Depo-Prove a.

When plaintiff returned to Dr. Levy in December 1974, with symptoms of having been bleeding nonstop for four months Dr. Levy was at a disadvantage because Upjohn knew something that he did not. It is undisputed Upjohn was aware that prior test results with Depo-Provera showed that in women who had been injected for the first time about 33% experienced severe prolonged menstrual bleeding and in women who had been injected twice the figure was around 23% to 27% (R. 2489-2490; Schwallie Depo at 54; T. 458, 326, 462). There was expert testimony from Dr. Roshan, a board certified OB/GYN who teaches in medical school (R. 2481, 2483) and who has had substantial experience with the use of Depo-Provera (R. 2485), that plaintiff's heavy prolonged bleeding after the second injection of Depo-Provera was directly related to the drug. (R. 2494, 2522; 2387-2388).

Dr. Levy testified that when plaintiff returned to his office in December, 1974, and January, 1975, she was suffering from a condition (dysmenorrhea which is painful and dysfunctional bleeding) which, in his opinion, was <u>not</u> listed as a possible adverse reaction on the package insert to Depo-Provera. (R. 1097-1098, Levy Depo. pp. 41-42). For that

eason, Dr. Levy testified he did not consider at that time hat Depo-Provera might have been causing her dysfunctional leeding because it is supposed to have the opposite effect i.e., it is supposed to cause amenorrhea). (R. 1113-1114; evy Depo, pp. 57-58). Dr. Levy stated, "If I thought her hief complaints were directly related to the drug, I obviously ould have suggested she not take it any more." (R. 1143; epo Levy, p. 87).

Dr. Shapiro agreed these symptoms were not listed by pjohn on its package insert as possible adverse reactions o the drug. The only adverse reactions listed on the package nsert which are even remotely applicable are "breakthrough leeding," "spotting" and "change in menstrual flow." (App.). Dr. Shapiro stated that "prolonged bleeding" is a separate ondition from "irregular bleeding" or even "heavy bleeding." (T. 486). He testified that nothing in the package insert would have put him on notice that the drug could cause such excessive bleeding. The only thing it put him on notice of was that it could cause prolonged irregular staining, but not prolonged heavy bleeding. (T. 503-505). He stated at trial:

> Q. Nothing that you've seen in writing including package insert has told you differently; is that correct?
>
> A. About reference to heavy bleeding?
>
> Q. Excessive bleeding.
>
> A. Correct. (T. 503).
>
> * * *
>
> Q. Certainly didn't think that a woman

could have excessive bleeding for 30 days a month?

A. No.

Q. Nobody from Upjohn.

A. Excessive bleeding prolonged?

Q. Nobody from Upjohn told you any differently?

A. No. (T. 504-505).

Accordingly, Upjohn is in error when it states in its brief that neither Dr. Levy nor Dr. Shapiro testified that th package insert was insufficient to place them on notice that Depo-Provera involved the possibility of prolonged bleeding. In actuality they both testified to that effect.

Dr. Benjamin (the Ph.D. in clinical pharmacology) also agreed with this. He testified that he read all the medical records as well as the depositions of Drs. Levy and Shapiro and apparently netiher one of them were aware that Depo-Provera can cause excessive bleeding from 11 to 30 days a month. (T. 423). He then testified:

Q. Dr. Benjamin, do you have an opinion to a reasonable degree of probability within your profession as to whether or not a package insert, in effect, for Depo-Provera in 1974 was effective to warn doctors about the incidence of excessive bleeding as we defined it, namely, from 11 to 30 days?

A. I don't think it accomplished that goal. No.[2] (T. 332-333; 971).

2. This testimony was originally proffered outside the jury's presence (T. 332-333), however, later in the trial it was read to the jury during plaintiff's presentation of rebuttal evidence. (See T, 930, 952, 962-963, 971, 973).

Upjohn asserts several times in its brief that the package insert was a sufficient warning because it listed "breakthrough bleeding" as an adverse reaction. Upjohn states that "breakthrough bleeding" encompasses all bleeding beyond the normal menstrual period (initial brief at p. 12, 13) which was "the very problem encountered by the plaintiff" (initial brief at p. 25). That is not correct. The evidence at trial was that "breakthrough bleeding" (usually associated with oral contraceptives) means there is some continued irregular spotting after the normal five day bleeding period has ended. (T. 425-426). It is a completely different condition than excessive and prolonged heavy inter-menstrual bleeding. (T. 426).

The plaintiff's reaction to the drug (excessive and prolonged dysfunctional bleeding lasting for several months without stop) was not listed on the package insert as a possible adverse reaction to Depo-Provera. Because Dr. Levy did not understand (since he was not warned) that in roughly one fourth of the cases Depo-Provera produces such prolonged inter-menstrual bleeding, he misinterpreted plaintiff's symptoms and he recommended a hysterectomy, to which plaintiff consented. We now know the hysterectomy was not necessary since plaintiff's symptoms would have probably subsided gradually on their own after the effect of the Depo-Provera wears off.

FACTS PERTINENT TO POINT IV

As a result of the hysterectomy, plaintiff will never be

able to bear children. (T. 158; R. 2548). In its alternative argument (not addressed by the Fourth DCA below), Upjoh asserts that even if it is liable for negligent failure to warn the damages should not include the hysterectomy because plaintiff wanted to become sterile and she freely elected th hysterectomy although it was not medically necessary. While Upjohn attempted to construct this theory at trial, there was substantial evidence to the contrary which the jury was justified in believing.

Plaintiff testified she went to Dr. Levy to stop the bleeding and by that time she was so desperate she would hav agreed to anything the doctor recommended to stop it. (T. 607, 560). She was almost anemic by that time. (T. 799). Dr. Levy told her it could be stopped with a hysterectomy. (T. 607, 613). She was adament in testifying she did not request sterilization (T. 560, 608), she only requested relief from the bleeding. (T. 609). The trial judge expressly noted there was credible evidence plaintiff was frantic about the bleeding by the time she had the hysterectomy. (T. 664).

Dr. Levy testified that when plaintiff first came to him in May, 1974, she did not tell him she wanted to become sterile but only that she was not ready yet to become pregnant. (R. 1153-1154; Levy Depo. pp. 97-98; T. 619). Sh was twenty-three years old and unmarried. Dr. Levy admitted he did not give plaintiff any alternatives to alleviate her bleeding other than a hysterectomy. (R. 1112; Levy Depo. p.

56). At another point in his deposition Dr. Levy said he di not actually recommend sterilization to the plaintiff but th she later requested it, and he gave her more than one alternative. (R. 1102–1103; Levy Depo. pp. 46–47).

Plaintiff's mother testified that plaintiff never indicated she did not desire to ever have children (T. 147) or that she wanted a hysterectomy (T. 148).

There was evidence presented that if plaintiff only wanted to become sterile she could have had a tubal ligation (had her fallopian tubes tied) which is much less invasive than a hysterectomy. (T. 490–491). However, that would not have alleviated her bleeding problem. (R. 2548; Roshan Depo p. 70).

Upjohn's brief mentions (at pp. 6–7) the unfortunate episode in 1970 when plaintiff became pregnant and gave birt to a stillborn fetus. Upjohn believes that episode demonstrates that plaintiff had a strong motivation for avoiding pregnancy (even to the point of electing to become sterile). However, there was only a 5% chance that such a condition could recur in another child. (T. 575; R. 1133, Levy Depo. p. 77).

The jury rejected this theory constructed by Upjohn and returned a verdict finding that Upjohn's negligent failure t warn was the legal cause of plaintiff's injuries. (R. 2570)

FACTS PERTINENT TO POINT V

Upjohn raised comparative negligence as an affirmative defense without alleging any ultimate facts as to how plain-

tiff may have been negligent. (R. 1689). At the close of Upjohn's case Plaintiff moved for a directed verdict on the defense of comparative negligence. At first the lower court stated it was inclined to grant the motion:

> The Court: I don't think that there is an issue of contributory or comparative negligence.
>
> * * *
>
> [Plaintiff's Counsel]: I was going to move on the directed verdict on comparative.
>
> The Court: I just can't see - -
>
> [Defense Counsel]: My theory of the case is as follows so the court knows where I'm going.
>
> She requested it [the hysterectomy], we are not liable for it.
>
> The Court: That's not comparative negligence, that's a denial of the claim.
>
> [Defense Counsel]: I'm not arguing with the court on that. (T. 881).

However, a few minutes later the court, sua sponte, raise the question again and considered a basis for comparative negligence which Upjohn had not previously articulated:

> The Court: Are we gonna cross out the contributory negligence? There is no way this lady could have --- wait a minute. That's -- you're getting into recreational drug use. That could be --
>
> * * *

It's not she may have intended to be negligent but perhaps the injection or some type of marijuana or --

[Defense Counsel]: Caused or contributed or exacerbated or aggravated. She did testify.

[Plaintiff's Counsel]: . . . should I make my motion for directed verdict on that now? I know what the ruling will be.

The Court: To tell you the truth, two seconds ago, I would have granted. Now I can't. I keep thinking it's true. There was quite an issue made over the fact that she had taken marijuana and that Dr. Connell said it could have contributed. That could be an issue for comparative negligence.

* * *

We'll leave in then the contributory negligence.

[Plaintiff's Counsel]: Just for the record, would that be a denial of my motion for directed verdict?

The Court: Yeah. (T. 887-888).

Plaintiff renewed her motion for directed verdict on the comparative negligence defense at the close of all the evidence. (T. 1042). In its closing argument, Upjohn did not present any argument to the jury regarding comparative negligence; in fact, it did not even mention the words "comparative negligence." Nothing was said in closing argument about any drug use as constituting negligence on the part of the plaintiff.

After the jury's verdict (R. 2570), plaintiff timely

servedher motion for judgment for the full amount of the verdict ($370,000) notwithstanding the jury's finding of 49% comparative negligence, on grounds that there was no evidence offered at trial that could support a finding of comparative negligence in this case. (R. 2575, 2577, 2591-2598). There was no evidence linking plaintiff's use of any drugs (years before she was injected with Depo-Provera) with the prolonged bleeding she experienced from August, 1974, to January, 1975. The use of drugs was **brought** into the trial just to prejudice the jury against the plaintiff over irrelevant matters.

Upjohn conceded at oral argument before the Fourth DCA that there was no evidence at trial to support any connectio between plaintiff's drug use when she was a teenager and her excessive bleeding years later after she was injected with Depo-Provera. The Fourth DCA commented on this admission in its opinion below. The Upjohn Co. v MacMurdo, 536 So.2d 337 340 (Fla. 4th DCA 1988).[3] However, Upjohn relied on plaintiff's "decision to have a hysterectomy" as being an alternative ground to justify a finding of comparative negligence Id. at 340. The Fourth DCA disagreed that there was any evidence to support such an alternative ground and reversed the finding of 49% comparative negligence since there was no

3. For this reason we will omit the discussion in our DCA brief concerning the lack of evidence on this ground; which was the trial court's actual basis for allowing comparative negligence to go to the jury. The "marijuana theory" of comparative negligence was abandoned by Upjohn on appeal.

basis to allow comparative negligence to go to the jury in this case.

SUMMARY OF ARGUMENT

POINT I

The basic premise for Upjohn's reason for invoking this court's jurisdiction is flawed. The Fourth DCA below did not hold that the adequacy of a drug manufacturer's warning is always for the jury to decide. There is no conflict between this case and the Felix case on that point, or any other point. For that reason, we believe this court has improvidently accepted jurisdiction in this case.

The facts developed at trial clearly presented a jury question on the adequacy of the warnings to alert the medical community to expect such prolonged heavy bleeding as a possible side effect of the drug. Neither of the plaintiff's prescribing doctors knew that Depo-Provera could cause prolonged heavy bleeding for five months. They both thought it was not listed as a possible adverse reaction on the package insert, and Dr. Benjamin agreed with them.

Upjohn did not recommend against or contraindicate the use of Depo-Provera for contraceptive purposes, and it had self-serving reasons not to do so.

The evidence at trial was that the only adverse side effects listed by Upjohn in the package insert ("spotting," "breakthrough bleeding" and "change in menstrual flow") do

not describe the plaintiff's reaction to the drug. The fact that the package insert was approved by the FDA does not foreclose common-law liability for negligent failure to warn The FDA is not alleged to have been aware of this undisclose side effect of Depo-Provera. Upjohn was aware of it. The trial court did not err by submitting this issue to the jury and the Fourth DCA did not err by declining to reverse the trial court on this issue.

POINT II

The Fourth DCA's opinion does not address this issue and this point is not individually reviewable based on any express and direct conflict.

There was more than ample evidence for the jury to find a causal connection between the inadequate warnings and plaintiff's injuries. If Dr. Levy had been warned that Depo Provera can cause prolonged heavy bleeding in a high percentage of women he would have allowed the effects of the drug to wear off instead of performing a hysterectomy. There was expert testimony offered about the cause of plaintiff's prolonged heavy bleeding being directly related to her second injection of Depo-Provera.

POINT III

The Fourth DCA's opinion does not address this issue. That is possibly because it was not properly preserved when Upjohn first moved for a directed verdict at trial.

Besides, Upjohn admittedly had knowledge of the widespread use of Depo-Provera for contraceptive purposes in thi

country and abroad. The use of the drug in this case as a contraceptive was hardly unforeseeable to Upjohn. The duty to warn extends not only to the manufacturer's intended use of a product but to all foreseeable uses, and even foreseeable misuses.

If Dr. Levy had prescribed Depo-Provera to a uterine cancer patient who reacted with prolonged heavy bleeding, he still would not have known it was a side effect of the drug since there is no warning. Foreseeability is almost invariably a jury question, and it was certainly one in this case.

Even if Dr. Levy's conduct was negligent, as a matter of law in Florida a doctor's malpractice in treating a tort victim is held to be foreseeable to the initial tortfeasor.

POINT IV

This is another issue Upjohn raises which was not addressed in the Fourth DCA's opinion and cannot create any conflict.

The lower court did not abuse its discretion by determining that the jury's verdict was not contrary to the manifest weight of the evidence and denying the motion for new trial. There was credible evidence presented to the jury that plaintiff did not want to become sterile and voluntaril elect the hysterectomy for permanent contraception. The jur was justified in believing the evidence that plaintiff only consented to the hysterectomy as a means to stop her uncontrollable bleeding.

The specific type of relief Upjohn asks for under this point is not the same thing Upjohn asked for in its motion

for new trial filed in the trial court.

POINT V

This issue was addressed by the Fourth DCA but it has nothing to do with the alleged basis for jurisdiction in this court.

After abandoning its "marijuana theory" of comparative negligence (which was the theory that persuaded the trial court to submit the comparative negligence issue to the jury Upjohn now relies exclusively on plaintiff's "snap decision" to have a hysterectomy as being an alternative ground to support a finding of comparative negligence.

Plaintiff's "snap decision" was made after bleeding heavily for five months to the point of anemia, and after he doctor told her a hysterectomy would stop the bleeding. It was not comparative negligence for plaintiff to take her doctor's advice without seeking further medical alternatives Although Upjohn professes not to be taking the position that plaintiff should have sought another medical opinion, that is exactly what their position was before the Fourth DCA, and what it still boils down to even now. Upjohn admitted to the trial court that this position of theirs is not really a comparative negligence issue but a denial of the plaintiff claim based on proximate cause grounds. However now Upjohn relies on this as its sole basis to justify the jury's finding of comparative negligence.

There was no theory of comparative negligence that was suggested to the jury by Upjohn during its closing argument.

Nor do the pleadings suggest the basis for such an affirmative defense. The fact that all the evidence of plaintiff's prior drug use as a teenager (years before she went to Dr. Levy with a bleeding problem) was admitted at trial (under the guize of comparative negligence) along with plaintiff's prior suicide attempt, and was never tied later on to any relevant issue in this case, caused improper prejudice to the plaintiff before the eyes of the jury. That is the only explanation for the jury's finding of 49% comparative negligence. There is no legal basis in the record to find the plaintiff comparatively negligent and the Fourth DCA acted correctly in directing the trial court to reinstate the complete verdict.

ARGUMENT

POINT I

WHETHER THE FOURTH DCA SHOULD BE QUASHED FOR AGREEING WITH THE TRIAL COURT THAT THE EVIDENCE PRESENTED A JURY QUESTION AS TO THE ADEQUACY OF UPJOHN'S WARNING CONTAINED IN THE PACKAGE INSERT?

Upjohn begins its argument by incorrectly stating that the basic premise of the Fourth DCA's decision in this case is that "in all events" the adequacy of a warning is always for the jury to decide; and that this conflicts with this court's recent decision in Felix v Hoffmann-LaRoche, Inc., 540 So.2d 102 (Fla. 1989), which held that such an issue can sometimes be a question of law. In actuality that is not what the Fourth DCA held in this case and there is no con-

flict at all with the Felix case. We believe this court has improvidently accepted jurisdiction in this case because there is no conflict with Felix.

Upjohn cites language from an earlier appeal in this case, in 1983, where the Fourth DCA stated that "in all events" the adequacy of a warning is for a jury to decide. MacMurdo v The Upjohn Co., 444 So.2d 449, 451 (Fla. 4th DCA 1983). In context, the Fourth DCA was not saying, even in that old 1983 appeal, that such an issue can never be determined by the court as a matter of law. In fact even Upjohn took this position in the latest appeal before the Fourth DCA. We are filing, as an appendix to this brief, an excerpt from Upjohn Fourth DCA brief where Upjohn discusses the 1983 opinion in this case and states:

> In an earlier appeal in this case, the Court reversed a summary judgment which had been entered in favor of the Upjohn Company. Writing for the Court, Judge Walden concluded the opinion by stating: 'But, in all events, the adequacy of the warning is for the jury to decide and may not be disposed of by summary judgment.' [citation omitted]. . . The Appellant [Upjohn] respectfully submits that the opinion was not intended as an expression by the Court that in no instance may the adequacy of a warning label be disposed of as a matter of law. . .
>
> (See Appendix attached to this brief.)

However, now Upjohn is saying the exact opposite to this court, in order to make it appear that there is a conflict with Felix. Now Upjohn is saying that Judge Walden's 1983 opinion did hold that an issue over the adequacy of warnings

can never be determined by the court as a matter of law. It is well-settled that a litigant is estopped from taking a position on appeal which is inconsistent with the position taken by the litigant at an earlier point in the same litigation. MacKay v Fla. Power and Light Co., 524 So.2d 1068 (Fla. 4th DCA 1988). Obviously Upjohn can't have it both ways and, in fact, they were correct the first time.

This Court is now reviewing the Fourth DCA's 1988 opinion; not the 1983 opinion. In the 1988 opinion Judge Anstead wrote for the court:

> We are convinced by a review of the record in this case that substantially more evidence on the issue of liability was presented at trial than existed at the time this court reviewed and reversed the summary judgment entered in favor of Upjohn. . . Even if not bound by [the 1983 appeal], our review of the evidence presented at trial compels us to conclude that the case was properly submitted to the jury. . . . While there was considerable evidence 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 of this risk, and that her hysterectomy was performed to treat the bleeding condition.
> 536 So.2d at 339-340.

Dr. Levy, who prescribed the drug for MacMurdo to be used as a contraceptive, later misdiagnosed her prolonged and excessive bleeding and performed a hysterectomy because he was given no warning from Upjohn that this drug can produce such side effects. If he had been warned of this then all he would have had to do was discontinue MacMurdo's use of

this drug and the bleeding would have gradually subsided. The Fourth DCA noted in its 1988 opinion:

> [Dr.] Levy also testified that Upjohn's warnings about the side effects of the drug did not alert him to the possibility that MacMurdo's bleeding condition was related to the use of the drug. 536 So.2d at 341.

The Fourth DCA did not state, nor imply, that an issue concerning the sufficiency of warnings must always go to the jury in every case. In fact the court noted Upjohn's concession that "the adequacy of a particular warning is generally [not always] a question of fact for jury determination." [e.s.] 536 So.2d at 339.

Felix v Hoffmann-LaRoche, Inc., 540 So.2d 102 (Fla. 1989 is easily distinguishable from this case. In Felix the doctor who prescribed the drug (accutane) to a pregnant woman testified that he understood the written warnings (not to prescribe it to such a patient) and he had prior knowledg of the drug's dangerous side effect. That is at odds with the testimony of Dr. Levy in the present case. This Court i Felix expressly "recognize[d] that whether a warning is adequate is usually a jury question." Id. at 1321. However this Court also noted that there may be some cases where reasonable persons could not possibly differ on that issue and those cases could be determined as a matter of law.

The Fourth DCA in the present case did not disagree with that and its opinion does no violence to that principle since, even if some cases could be determined as a matter of law, this obviously is not such a case. In fact, the Fourth

DCA did not even mention the Felix case in its opinion because it does not apply to a case like this one where there was substantial evidence presented to support a jury determination that the warning was inadequate. Not only did the jury find the existence of such evidence in this case but so did the trial judge and three separate appellate panels after three separate appeals.

We agree with Upjohn that in a prescription drug case the manufacturer has a duty to warn the medical community and the prescribing physician of any known dangers, adverse side effects, contraindications, etc.; rather than a duty to directly warn the ultimate consumer. Buckner v Allergan Pharmaceuticals, Inc., 400 So.2d 820 (Fla. 5th DCA 1981). One of the purposes of warning the medical community is to alert the doctor to recognize known side effects of the drug so they are not later misdiagnosed as being something else. The failure of a drug manufacturer to warn the physician of all known side effects creates a cause of action running directly to the ultimate consumer of the drug. Albertson v Richardson-Merrell, Inc., 441 So.2d 1146 (Fla. 4th DCA 1983)

In this case neither of the plaintiff's prescribing doctors knew that Depo-Provera can cause prolonged heavy bleeding for five months. Dr. Levy, Dr. Shapiro and Dr. Benjamin all testified that the side effect plaintiff experienced from the drug (prolonged dysfunctional bleeding, or "dysmenorrhea," lasting for several months) was not listed a a possible adverse reaction on the package insert. (R. 1097

1098; T. 332-333, 423, 486, 503-505, 971).

Concerning the use of Depo-Provera for contraception; the package insert does not state that the manufacturer recommends against the use of the drug for contraception nor is such a use listed as a "contraindication." Dr. Levy, Dr. Benjamin and Dr. Levitt all noted this during their testimony. (R. 1083; T. 312-314, 848-849).

There was also evidence that Upjohn had an obvious motive not to specifically recommend against the use of Depo-Provera as a contraceptive. As plaintiff argued to the jury in closing argument (T. 984), Upjohn had been trying for years to get the FDA to approve the use of Depo-Provera for contraception, so they naturally would not choose to be too aggressive about telling doctors that such a use was not recommended and contraindicated. Such a logical inference could certainly be drawn by the jury.

Upjohn relies in its brief on three adverse reactions listed in the package insert: "spotting," "breakthrough bleeding" and "change in menstrual flow." What the plaintif experienced for five months could hardly be classified as "spotting," and it was also a completely different condition than "breakthrough bleeding," which is merely continued irregular spotting after the end of the normal menstrual period. (T. 425-426). Upjohn argues that if plaintiff's problem was not breakthrough bleeding then it was at least encompassed in the term "change in menstrual flow" which can include a prolonged period.

If Upjohn had meant that term ("change in menstrual flow" to warn about the possibility of non-stop heavy dysfunctional bleeding for five months, they could hardly have chosen a more understated phrase to alert the medical community. If (hypothetically) the plaintiff had begun bleeding out of her rectum, would Upjohn still argue that such a condition is also encompassed in the phrase "change in menstrual flow?" If (hypo-

was that the package insert should have quantified the risk of "breakthrough bleeding" or "changes in menstrual flow." That is not accurate. Plaintiff's position was that "they [Upjohn] had a duty to warn the doctors using the drug of any side effects that Upjohn was aware of . . . [and] they failed

Common sense.

> You don't have to put fancy words. Just lay it on the line so doctors will understand it and not react the wrong way to a situation caused by a drug. (T. 1024).

Upjohn, like most drug manufacturers, employs "detail men" on the road who are available to discuss Upjohn's products with doctors. However, Upjohn's own detail man in South Florida, Joseph Paterniti, testified at trial (T. 191, et seq.) he had no knowledge that a high percentage of women using Depo-Provera, for any purpose, could expect to have prolonged bleeding as a side effect. (T. 216). Furthermore he indicated that if a doctor would have asked him any questions along these lines he simply would have provided the doctor with the package insert. (T. 215). Upjohn's own detail men knew as little as Dr. Levy knew about this particular side effect.

Finally under this point, Upjohn mentions several times that the wording it used on the package insert was approved by the FDA. Upjohn admitted in its Fourth DCA brief that "federal law does not conclude the issue which is before this court." (See Appendix attached to this brief.) However, Upjohn repeats several times in its brief how a package insert must be approved by the FDA before a drug is shipped inter-state.

It is well settled in Florida that a defendant's compliance with federal regulations or standards is admissible as evidence but it is not dispositive in a common law action brought for failure to issue an adequate warning or similar

negligence. Tampa Drug Co. v Wait, 103 So.2d 603 (Fla. 1958) disapproved on other grounds, 540 So.2d 102 (Fla. 1989); Duff v Florida Power & Light Co., 449 So.2d 843 (Fla. 4th DCA 1984 Seaboard Coastline RR. Co. v Louallen, 479 So.2d 781 (Fla. 2n DCA 1985); Rubin v Brutus Corp., 487 So.2d 360 (Fla. 1st DCA 1986); Fries v Florida Power & Light Co., 402 So.2d 1229 (Fla 5th DCA 1981). See also Dorsey v Honda Motor Co., Ltd., 655 F.2d 650 (5th Cir. 1981) (applying Florida law); American Cyanamid Co. v Roy, 498 So.2d 859 (Fla. 1986); Palm Beach County Bd. of County Comm. v Salas, 511 So.2d 544 (Fla. 1987) Federal safety standards and regulations do not generally supersede common-law liability for negligence. There is an exception to that when a federal statute clearly indicates an intent to preempt state common law on a subject that gives the federal government constitutional power to do so. See Silkwood v Kerr-McGee Corp., 464 U.S. 238, 104 S.Ct. 615, 78 L.Ed. 443 (1984). Nothing of that nature has ever been alleged by Upjohn in this litigation; nor was this subject addressed by the Fourth DCA below. This Court noted in Felix supra, that even in pharmaceutical drug cases the adequacy of warnings is usually (although not always) a jury question.

Upjohn cites federal statutes and regulations which prohibit drug labels that are false or misleading. It is not our contention that the label was false or misleading, but that it did not warn doctors of an important side effect of the drug which occurred in about 25% of the women tested by

Upjohn after their second injection of Depo-Provera. The FDA is not alleged in this lawsuit to have been aware of this undisclosed side effect of the drug. However there is no question that Upjohn was aware of it, as the jury implicitly found in its verdict.

The jury was properly instructed by the trial court on a drug company's duty to warn the medical community (T. 1032-1033) and the jury found there was a negligent failure to warn (K. 2570). A directed verdict should not be entered for a defendant where there is any evidence to justify a possible verdict for the plaintiff. Hernandez v Motrico Inc., 370 So. 2d 836 (Fla. 3d DCA 1979). The court's entry of a judgment notwithstanding the jury's verdict is governed by these same principles. Stirling v Sapp, 229 So.2d 850 (Fla. 1969). A defendant moving for directed verdict (or judgment N.O.V.) admits every reasonable inference and conclusion favorable to plaintiff. Stirling v Sapp, supra; Napoli v Liberty Mut. Ins Co., 364 So.2d 878 (Fla. 4th DCA 1978).

There was credible evidence presented by plaintiff at trial to justify submitting the issue of the adequacy of the warnings to the jury. Upjohn argues it is inconceivable that reasonable persons could find its warning deficient. However not only did a jury find it deficient but three separate appellate panels have all agreed that the warnings could be viewed as being deficient. Were all these lay persons and judges unreasonable, as well as the trial judge and as well

as Drs. Shapiro, Levy and Benjamin?[4] The Fourth DCA should not be quashed for agreeing with the trial court that this case falls within the general line of cases in which such an issue should be resolved by a jury.

POINT II

WHETHER THE FOURTH DCA SHOULD BE QUASHED FOR IMPLYING (WITHOUT STATING) THAT THE EVIDENCE PRESENTED A JURY QUESTION ON THE CAUSAL CONNECTION BETWEEN THE INADEQUATE WARNING AND THE PLAINTIFF'S INJURIES?

The sole basis for this court's acceptance of jurisdiction in this case was under the previous section (Point I) and the alleged conflict with the Felix case when the trial court allowed the jury to decide whether the warnings were adequate. Upjohn admits under this point (at p. 30 in its brief) that the Fourth DCA's opinion does not actually address this "causal connection" issue (nor, for that matter does it address the issues Upjohn raises under Points III an IV). Thus, this point does not even arguably create an express and direct conflict with any other case and it need

4. Upjohn infers that Dr. Benjamin was not competent t give an opinion on the adequacy and the meaning of the warnings in the package insert because he is not a medical doctor. However, there are numerous cases discussing the competency of a Ph.D. clinical pharmacologist to testify on such matters. See eg. Thompson v Carter, 518 So.2d 609 (Mis 1987); Breit v St. Luke's Memorial Hospital, 49 Wash. App. 461, 743 P.2d 1254 (1987); Holley v Burrough Wellcome Co., 348 S.E. 26 772, 776-777 (N.C. 1986). Cf. Hermes v Pfizer, Inc., 848 F.2d 66, 69, n. 15 (5th Cir. 1988); Executive Car & Truck Leasing, Inc. v DeSerio, 468 So.2d 1027 (Fla. 4th DCA 1985). Besides, Dr. Benjamin was not the only witness whose testimony was damaging to Upjohn on this point.

not be reviewed by this court for that reason alone. Upjohn is simply seeking de novo review over every issue it raised before the Fourth DCA, regardless of whether it was addressed Nevertheless we will respond briefly to the merits of these other issues, in an abundance of caution, however we do not believe they should be addressed by this court.

The causal connection between the inadequate warning of adverse side effects and the plaintiff's injuries is straight forward. The plaintiff, who had been experiencing continuous heavy bleeding for several months, came back to Dr. Levy as a patient in distress and the doctor did not understand (becaus he was not warned) that the drug can cause such prolonged heavy bleeding. Therefore, rather than simply allow the effects of the drug to wear off, the doctor misdiagnosed plaintiff's problem and performed a hysterectomy. (See R. 2880-2881).

Before being injected with Depo-Provera the plaintiff had no prior medical history of having such prolonged inter-menstrual bleeding and Dr. Roshan testified that the heavy prolonged bleeding after the second injection of Depo-Prover; was directly related to the drug.

Upjohn argues under this point that there was no evidenc that any other warning it could have provided in the package insert would have altered Dr. Levy's conduct. We disagree. (So did the jury, the trial judge and, implic tly, the Fourth DCA.) Dr. Levy testified that when plaintiff returned to his office she was suffering from a condition which was not liste

as a possible adverse reaction on the package insert, and for that reason he did not consider that the drug might have been causing her dysfunctional bleeding (since the drug is supposed to have the opposite effect). (R. 1097-1098, 1113-1114, Levy Depo. p. 41-42, 57-58). Dr. Levy stated that if he had thought plaintiff's problem was related to the drug he obviously would have suggested she not take it anymore. (R. 1143, Levy Depo. p. 87).

The jury was certainly entitled to infer that Dr. Levy would not have performed a hysterectomy if he had been clearly warned by Upjohn that Depo-Provera can cause prolonged dysfunctional bleeding in a high percentage of women. Besides, the law recognizes a presumption that if appropriate warnings had been given they would have been read by the user and heeded. Hermes v Pfizer, Inc., 848 F.2d 66, 70, n. 20 (5th Cir. 1988); Reyes v Wyeth Laboratories, 498 F.2d 1264 (5th Cir. 1974) (cited with approval in Felix, supra); Giddens v Denman Rubber Mfg. Co., 440 So.2d 1320 (Fla. 5th DCA 1983).

In Giddens, supra, the product manufacturer argued (just as Upjohn does here) that the court should decide as a matter of law that even if a better warning had been given it would have been useless to the plaintiff and therefore the lack of a better warning was not a proximate cause. The court held that if the evidence is even susceptible to an inference that an adequate warning would have been noticed, then the issue of proximate cause is properly submitted to the jury.

The trial court did not commit error by submitting the

issue of proximate cause to the jury after properly instructing the jury from the standard jury instructions on the law of proximate cause. (T. 1033-1034).

POINT III

WHETHER THE FOURTH DCA SHOULD BE QUASHED FOR IMPLYING (WITHOUT STATING) THAT THE ISSUE OF FORESEEABILITY OF PLAINTIFF'S INJURIES WAS FOR THE JURY?

Althougn the Fourth DCA's opinion does not address this issue at all, we will respond to the merits. We still submit however, it should not be entertained by this court.[5]

Under this point Upjohn argues that Dr. Levy committed malpractice by prescribing Depo-Provera for contraceptive purposes, and Upjohn could not have reasonably foreseen that Dr. Levy would depart from acceptable medical practice in his treatment of the plaintiff. For this reason, Upjohn asserts it was entitled to a directed verdict.

In Florida a chemical manufacturer has the duty to warn with sufficient intensity that "the user . . . have fair and adequate notice of the possible consequences of use or even misuse." [e.s.] Tampa Drug Co. v Wait, 103 So.2d 603 (Fla. 1958), disapproved on other grounds, 540 So.2d 102 (Fla. 198[illegible] .

5. One of the possible reasons that Upjohn's "foreseeability" argument was not addressed by the Fourth DCA is because it was not preserved for appeal in the trial court. When Upjohn moved for a directed verdict at trial the word "foreseeable" was never uttered. (T. 658-667; 1043-1044). It was not until post-trial motions were filed that Upjohn first raised this issue. (R. 2581).

The duty to warn extends not only to the intended use of the product but to all foreseeable uses, and even a foreseeable misuse of the product. Tampa Drug Co., supra; Noonan v Buick Co., 211 So.2d 54 (Fla. 3d DCA 1968). See also LeBouef v The Goodyear Tire & Rubber Co., 623 F.2d 985 (5th Cir. 1980); General Dynamics Corp. v Adams, 340 F.2d 271 (5th Cir. 1965); Ford Motor Co. v Evancho, 327 So.2d 201 (Fla. 1976) (Held: Florida adopts the crashworthiness doctrine because, even though a collision is not the intended use of a vehicle, it is a reasonably foreseeable contingency which places a duty on the manufacturer to guard against); Advance Chemical Co. v Harter, 478 So.2d 444 (Fla. 1st DCA 1985); Magic Chef, Inc. v Sibley, 546 S.W.2d 851, 856 (Tex. Ct. App. 1977).

Here, Upjohn can hardly claim that Dr. Levy's and Dr. Shapiro's prescription of Depo-Provera for contraception was an unforeseeable use of the drug even though it had not received FDA approval. Depo-Provera has been approved in at least 20 to 30 other countries for contraceptive use and most American gynecologists are aware of that fact. Upjohn has been trying for years to get FDA approval of the drug for contraceptive use and it admitted at trial it was aware that some American doctors used it for such purposes. In fact, this "misuse" was so widespread in this country that in 1973 there were congressional committee hearings to investigate it Dr. Levy was trained as a first-year resident to use Depo-Provera for contraception and Dr. Shapiro testified he was aware that it was routinely being used by family planning

centers as a contraceptive. Even Upjohn's own expert, Dr. Connell, testified it is not unusual for a physician to use an ethical drug for an indication not approved by the FDA so long as it is not expressly contraindicated.

Besides, whether the drug was prescribed for use as a contraceptive or whether it was prescribed for use as palliative treatment for endometrial cancer is not significant in this case. It does not matter why it was prescribed. The point is that Upjohn was aware that a high percentage of women reacted by experiencing prolonged menstrual bleeding (just the opposite of its most usual effect). A cancer patient could have also reacted the way plaintiff reacted but the package insert still does not warn that this is a possible adverse reaction the doctor should expect. A tortfeasor does not have to foresee the precise manner in which his negligence will cause an injury, but merely that his conduct is likely to result in damages to someone. Stevens v Jefferson, 436 So.2d 33 (Fla. 1983); Crislip v Holland, 401 So.2d 1115 (Fla. 4th DCA 1981).

The point is that it is reasonably foreseeable (or so a jury could find) that if Upjohn does not warn of this side effect it can be misdiagnosed and treated incorrectly. The harm resulting to plaintiff was within the "scope of the danger" created by Upjohn's failure to warn. Stevens, supra Foreseeability is almost invariably a question for the jury and not for the court. Stevens, supra; Gibson v Avis Rent-A Car Systems, Inc., 386 So.2d 520 (Fla. 1980); Cole v Leach,

405 So.2d 449 (Fla. 4th DCA 1981); Loranger v State of Fla., D.O.T., 448 So.2d 1036 (Fla. 4th DCA 1983).

Upjohn's attempt to argue that Dr. Levy's "malpractice" was unforeseeable to them is also unavailing for another reason. It is recognized in Florida that if an initial tortfeasor causes an injury to a plaintiff (such as the prolonged heavy bleeding for five months) which is later aggravated by medical malpractice (such as a negligent hysterectomy), the malpractice is deemed to be foreseeable as a matter of law to the initial tortfeasor. Stuart v The Hertz Corp., 351 So.2d 703 (Fla. 1977). If Dr. Levy was negligent in his care of th plaintiff that may give Upjohn a cause of action against Dr. Levy for subrogation; Underwriters of Lloyds v City of Lauderdale Lakes, 382 So.2d 702 (Fla. 1980); but that in no way affects Upjohn's liability to plaintiff for the total damages she suffered. That is particularly true in this case because Upjohn's negligent failure to warn set in motion the chain of events leading to the plaintiff's unnecessary hysterectomy. The doctor's failure to properly treat plaintiff was caused by Upjohn's failure to list her symptoms as a known side effect of the drug.

Upjohn also asserts under this point that the jury's verdict imposes on a drug manufacturer the duty to police the activities of the medical community. That is not the case. The jury's verdict does not say anything about failing to police the medical community; but it does say something about failing to warn the medical community. (R. 2570).

This point on appeal would have no merit even if it had been preserved for review.

POINT IV

WHETHER THE FOURTH DCA SHOULD BE QUASHED FOR IMPLYING (WITHOUT STATING) THAT THE JURY'S FINDINGS WERE NOT CONTRARY TO THE MANIFEST WEIGHT OF THE EVIDENCE?

As Upjohn admits (at p. 36 of its brief), this is another issue the Fourth DCA did not address in its opinion. It has nothing to do with the basis for jurisdiction in this court and should not be entertained. Nevertheless we briefl respond to the merits.

Under this argument for entitlement to a new trial, Upjohn must demonstrate the trial court abused its broad discretion in determining that the jury's verdict was not against the manifest weight of the evidence. A trial court', ruling on a motion for new trial based on the manifest weigh. of the evidence should not be disturbed by an appellate cour· unless reasonable persons could. not differ as to the impropr. ty of the trial court's ruling on the motion. Baptist Memorial Hospital v Bell, 384 So.2d 145 (Fla. 1980); Ford Motor Co. v Kikis, 401 So.2d 1341 (Fla. 1981).

Upjohn asserts that even if it is liable for failure to warn, the damages should not include the hysterectomy because plaintiff wanted to become sterile and voluntarily elected the hysterectomy. To the contrary there was substantial evidence showing that plaintiff only consented to the hyster-

ectomy as a means to stop her uncontrollable bleeding. She did not just elect it like she would a facelift. To avoid repetition, we rely on the statement of the facts set out at pp. 11-13 supra, in this brief, which relate to this issue on appeal.

There was a conflict in Dr. Levy's testimony, as pointe out in our statement of facts, supra. At one point he testified he did not give plaintiff any alternatives to alleviate her bleeding other than a hysterectomy. (R. 1112; Levy Depo. p. 56). At another point he testified he did not actually recommend sterilization but the plaintiff later requested it, and he gave her more than one alternative. (R 1102-1103; Levy Depo. pp. 46-47). Dr. Levy obviously has a self-serving reason to say this now that his diagnosis of plaintiff's condition seems to have been in error. The jury was certainly entitled to consider that factor and resolve this conflict in favor of plaintiff.

Upjohn now argues it should get a new trial limited onl to damages, with instructions to the lower court to allow damages only for the episode of bleeding but not for the hysterectomy. In its motion for new trial filed with the trial court, Upjohn did not ask for anything like that. In its motion Upjohn only requested that the trial court "enter an order granting a new trial on liability and damages." (R 2590). Upjohn should not be heard to ask for a new type of legal relief for the first time on appeal.: Cf. Shamel v Schechter, 371 So.2d 109 (Fla. 4th DCA 1978).

The record is such that the damages awarded by the jury cannot be separated into different types of damage. The verdict was not itemized. Although Upjohn argues it is "reasonable to assume" the jury's verdict was almost entirely attributable to the hysterectomy, there really is no way to tell that from the verdict. Appellate review should not be based on what is "reasonable to assume."[6]

Although Upjohn argued the theory at trial that the plaintiff was just interested in getting a hysterectomy as the ultimate means of contraception, the jury was entitled t reject that rather callous theory based on contrary testimon set out in our statement of facts, supra, and also based on plain common sense. If the plaintiff merely wanted to becom permanently sterile then why bother taking Depo-Provera in the first place? Why bother wearing IUDs? The inferences drawn by the jury from the facts and testimony are well within the range of reasonable fact-finding.

Upjohn has failed to demonstrate that the trial court abused its discretion by denying the motion for new trial an refusing to interfere with the jury's findings of fact on conflicting evidence.

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6. It should be noted that if the verdict did properly include all the damages suffered by the plaintiff, including the hysterectomy, Upjohn does not challenge the amount awarded by the jury as being excessive for such damages.

POINT' V

WHETHER THE FOURTH DCA SHOULD BE QUASHED FOR HOLDING THERE WAS NO EVIDENCE OF COMPARATIVE NEGLIGENCE ON THE PART OF THE PLAINTIFF TO JUSTIFY A REDUCTION OF HER DAMAGES?

The facts pertaining to this issue, regarding comparative negligence, are set out at pp. 13-17 supra, in this brief. As mentioned before, Upjohn has now abandoned its "marijuana theory" of comparative negligence (which was the theory relied on by the trial judge for allowing comparative negligence to go to the jury), and now relies exclusively on the theory that plaintiff's "snap decision" to have a hysterectomy (after bleeding heavily for five months to the point of anemia) constitutes comparative negligence.

Upjohn professes not to be taking the position that plaintiff should have sought another medical opinion (since that, as a matter of law, is not comparative negligence that would justify a reduction of plaintiff's verdict against Upjohn[7]) but in actuality that is exactly what Upjohn is saying with its "snap decision" argument.

When, after bleeding heavily for five months and not knowing the cause of it, Dr. Levy suggested (according to both his testimony and MacMurdo's testimony) that a hyster-

7. It is not comparative negligence for a patient to rely on her doctor's recommendation without getting a second medical opinion. Mack v Garcia, 433 So.2d 17 (Fla. 4th DCA 1983); Norman v Mandarin Emergency Care Center, Inc., 490 So.2d 76 (Fla. 1st DCA 1986); Piper v Moore, 410 So.2d 646 (Fla. 3d DCA 1982).

ectomy would cure the problem, Upjohn says plaintiff made a snap decision and agreed to have a hysterectomy. That is the same thing as saying she should have sought other opinions about other medical alternatives. That is not comparative negligence. Even Upjohn's attorney agreed in the trial court that plaintiff's alleged rush to have a hysterectomy was not really a comparative negligence issue but was actually a proximate cause issue and a denial of her claim for damages based on the hysterectomy. (See T. 881). However now Upjohn is arguing this as its sole basis for justifying the jury's finding of comparative negligence.

Upjohn maintains that since plaintiff experienced a bleeding problem in 1973 stemming from her use of an IUD, which was cured by a D & C following remov 1 of the IUD, she should have known that there were means short of a hysterectomy for the treatment of her bleeding problem in 1974-1975 Of course, the prolonged bleeding she experienced after being injected with Depo-Provera in 1974 had nothing to do with an IUD. It is illogical to suggest that plaintiff should have known the same medical procedure could be utilized for two different conditions. This is the same type of argument as when a defendant argues that a plaintiff was comparatively negligent for failing to seek a second opinion from another doctor.

It is axiomatic that a defendant bears the burden of proof of all affirmative defenses, including comparative negligence, and when no evidence exists tending to prove com-

parative negligence the issue should not be submitted to the jury. Cuozzo v Ronan & Kunzl, Inc., 453 So.2d 902, 903 (Fla. 4th DCA 1984); Valdes v Faby Enterprises, Inc., 483 So.2d 65 (Fla. 3d DCA 1986); Nationwide Mut. Fire Ins. Co. v Vosburgh, 480 So.2d 140 (Fla. 4th DCA 1985).

It is more than just interesting that there was no theory of comparative negligence ever argued to the jury during Upjohn's closing argument, and that Upjohn later conceded on appeal there was no evidence linking plaintiff's prior drug use, years before her bleeding problem, with her reaction to Depo-Provera in 1974-75. The fact that all this evidence of prior drug use came into trial but was never tied into any relevant issue in this action caused substantia prejudice to the plaintiff before the eyes of the jury. Defense counsel, in opening statement, mentioned to the jury a long list of controlled drugs which he said the plaintiff had used in the past (without saying exactly when in the past including LSD, mescaline, marijuana, hashish, percodan, seconol, valium, thorazine, nembutal, and antibiotics. (T. 133). The jury was even told of a suicide attempt in 1972. (T. 133). All of this was irrelevant to this lawsuit and it could only have served to prejudice the plaintiff before the jury. It apparently had its intended effect, judging from the jury's 49% reduction for comparative negligence in a case where there was no evidence of any comparative negligenc .

Upjohn failed to present any evidence which, as a matter of law, could possibly support a jury's finding that

plaintiff's own negligence brought about her prolonged heavy bleeding and the resulting hysterectomy. The trial judge should have followed her initial inclination and refused to submit the comparative negligence issue to the jury since there was no evidence to support it. The Fourth DCA should not be quashed for directing the trial court to reinstate the complete verdict.

CONCLUSION

Initially, it is respectfully submitted that jurisdiction in this case has been improvidently granted because there is no express and direct conflict between the Fourth DCA's opinion in this case and this court's opinion in the Felix v Hoffmann-LaRoche, Inc., case, supra. The notice to invoke this court's discretionary jurisdiction should, for that reason, be denied.

If the merits are reached, the opinion of the Fourth DCA should be approved since the district court did not depart from the law nor abuse its discretion in any way in reaching its decision in this appeal.

Respectfully submitted,

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CERTIFICATE OF SERVICE

IT IS HEREBY CERTIFIED that a true copy of the foregoing has been furnished, by mail, this 7th day of August, 1989, to: JOHN REED, ESQ., and R. KIMBARK LEE, ESQ., P. O. Box 2809, Orlando, FL 32802; 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.

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