IN THE SUPREME COURT OF FLORIDA

TERRI LYNN CONLEY,

Petitioner,

vs. CASE NO. 67,626

BOYLE DRUG COMPANY, etc., et al,

Respondents.

ON CERTIFICATION FROM THE DISTRICT COURT OF APPEAL OF FLORIDA
FOURTH DISTRICT

ANSWER BRIEF OF RESPONDENT THE UPJOHN COMPANY

TED R. MANRY, III, of
MACFARLANE, FERGUSON, ALLISON & KELLY
Post Office Box 1531
Tampa, Florida 33601
Telephone: (813) 223-2411

ATTORNEYS FOR RESPONDENT,
THE UPJOHN COMPANY

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INTRODUCTION

This Answer Brief is respectfully submitted by Respondent, THE UPJOHN COMPANY. The parties will generally be referred to as Plaintiffs and Defendants. The symbol (R.) will designate the Record on Appeal. "Amici" will refer to the arguments advanced by The Association of Trial Laywers of America (ATLA), and The Academy of Florida Trial Lawyers (AFTL) in support of Petitioner, Terri Lynn Conley.

STATEMENT OF THE CASE AND FACTS

Plaintiff's statement of the case and facts requires supplementation. Plaintiff has alleged that she was injured because her mother ingested Diethlstibestrol (a/k/a "DES" or "Stilbestrol"), while pregnant with Plaintiff in 1955-56. Eleven pharmaceutical companies, including UPJOHN, were named as Defendants in the Second Amended Complaint ("Complaint"). (R. 369-392). Certain Defendants, including UPJOHN, filed motions to dismiss. (R. 420-424, 411-412, 455-460, 482-483, 498-499, 415-419, 425, 429). Others, including UPJOHN, answered the Complaint (R. 461, 440, 434, 396, 455), and also moved for summary judgment. (R. 4, 84, 468, 407, 393, 477, 473, 430). The Trial Court granted the motions to dismiss of SQUIBB, BOYLE, SANDOSE, MERCK amd ORTHO, and deferred ruling on all motions for summary judgment. (R. 658).

Following motions for clarification and modification by the remaining Defendants (R. 703, 706, 709, 717), and motions for judgment on the pleadings by ELI LILLY, REXALL, UPJOHN and ABBOTT

(R. 797, 800, 804, 831), the Trial Court entered judgment on the pleadings for those Defendants. (R. 809-829, 833). PARKE DAVIS had been previously dismissed by stipulation. (R. 803). Consolidated appeals followed, and ORTHO and BOYLE cross-appealed. The twelve count Complaint alleged theories of enterprise or industry wide liability (I); concerted action (11); market share liability (111); alternative liability (IV); negligence (V); strict liability (VI); lack of consent (VII); breach of express warranty (VIII); breach of implied warranty (IX); fraud (X); negligence per se (XI); and conspiracy (XII).

The Complaint alleges that the Plaintiff is unable to identify the specific manufacturer of DES ingested by her mother. (R. 370). The drug was allegedly ingested in Broward County, Florida, between June 1955 and March 27, 1956. (R. 371). The Complaint contains a conclusionary charge that these Defendants "...are the manufacturers, promoters, marketers, sellers of a substantial share of the product sold for the purpose of which it was used...". (R. 372). The Complaint generally alleges insufficient testing and warning and that each of the Defendants knew or should have known that DES was carcinogenic.

The Complaint alleges that the Food & Drug Administration (FDA) authorized DES for certain purposes which did not include the prevention of miscarriages, and in 1947 authorized DES for use by pregnant women to prevent miscarriage "...solely on an experimental basis, and with only express warnings to that effect

on the drug's labelling". (R. 373). Plaintiff alleges development of precancerous and cancerous legions and tumors as a result of her mother having ingested DES. (R. 375-376).

Count I conclusionarily alleges that absence of proof is due to the Defendant's conduct, and of an insufficient industry wide standard of safety. (R. 376). This Count alleged, again as a conclusion, that the joined Defendants "...accounted for a high percentage of the DES on the market at the time the Plaintiff's mother ingested it..." (R. 376-377). It alleges that all Defendants, "jointly controlled the risk of harm", although acting independently, by adhering to an industry wide standard regarding the safety of the product, delegating functions of investigation and design such as labelling, selling DES to each other to market under trade names, and engaged in industry wide cooperation in themanufacturingof DES. (R. 377).

Count II alleged that the Defendants' acts, although independent, had the "effect" of encouraging and assisting wrongful conduct of others. There were conclusionary allegations of assistance and encouragement to inadequately test DES and conscious paralleling of "each other" in not fully testing. (R. 377-378).

Count III was a compendium of prior allegations including that the Defendants were "...the manufacturers of the substantial share of DES which Plaintiff's mother might have ingested", and each Defendant should be liable for the proportion of the injury sustained by the Plaintiff represented by its market share. (R. 378-379).

Count IV alleged that each of the Defendants acted independently of each other but, although independent, "were tortious", and that Plaintiff could not prove which Defendant caused her injury, "...but is substantially certain that one of the Defendants named herein caused her injury". (R. *379).*

The Fourth District Court of Appeal, recognizing that it did not have the power to change the established law of Florida, has certifiedthe following question to this Court:

> DOES FLORIDA RECOGNIZE A CAUSE OF ACTION AGAINST A DEFENDANT FOR MARKETING DEFECTIVE DES WHEN THE PLAINTIFF ADMITTEDLY CANNOT ESTABLISH THAT A PARTICULAR DEFENDANT WAS RESPONSIBLE FOR THE INJURY?

The History Of DES.

The effect of the Trial Court's action in deferring ruling on the motions for summary judgment, and dismissing the Complaint or granting judgment on the pleadings, leaves this Court in a factual vacuum. Nevertheless, the history of the development, FDA approval and marketing of DES has been uniformly established in other cases, and utilized by other courts in assessing claims of joint and collaborative conduct and attempts to impose vicarious industry wide liability. E.g., Morton V. Abbott Laboratories, 538 F.Supp. 593 (M.D. Fla. 1982) ("Morton"); Ryan V. Eli Lilly & Co., 514 F.Supp. 1004 (D.S.C. 1981) ("Ryan"); Payton V. Abbott Labs., 512 F.Supp. 1031 (D.Mass. 1981) ("Payton, 512 F.Supp."), Lyons v. Permo Pharmaceutical Labs., Inc., 170 N.J.Super. 183, 406 A.2d 185 (App.Div. 1979), certif. denied, 82 N.J. 267,

412 A.2d **774 (1979)** ("Lyons"); Namm v. Charles E. Frosst & Co., **198** N.J.Super. 19, **427** A.2d **1121** (App.Div. **1981)** ("Namm"); Pipon V. Burroughs-Wellcome Company, **532** F.Supp. **637** (D.N.J. **1982),** aff'd., **696** F.2d **984** (3d Cir. **1982)** ("Pipon"); Tidler v. Eli Lilly & Company, **95** FRD 332 (D.D.C. **1982)** ("Tidler"); ~~see also~~ Sindell v. Abbott Laboratories, **26** Cal.3d **588, 163** Cal.Rptr. **132, 607** P.2d **924 (1980)** ("Sindell"); Mizell V. Eli Lilly & Company, **526** F.Supp. **589 (D.S.C. 1981)** ("Mizell"); Zafft V. Eli Lilly & Co., **676 S.W.2d 241 (Mo. 1984)** ("Zafft").

The history was also set forth in and corroborated by the exhaustive unruled upon evidence in support of the various summary judgment motions (e.g., **R. 138-139,** 139A-139B, **407-410, 473-476, 496-642, 838-376, 837-2254),** which Plaintiff has never refuted.

The developmental history recounted in these decisions shows the following basic facts. DES is a synthetic estrogen developed by independent doctors and researchers in Britain during the **1930's.** Contrary to natural estrogens, DES was found to be effective when administered orally and made estrogen therapy available for the first time to all women because it did not require injection. It was not patented, and marketing in the United States required application and approval of the FDA.

By the close of **1940,** a number **of** separate New Drug Applications had been filed with the FDA for DES use in a variety of conditions unrelated to and inconsistent with pregnancy. F ~ , post menopausal symptoms; senile vaginitis; gonorrheal vaginitis; and suppression of lactation. In order to expedite evaluation of

DES for these problems, the FDA requested the individual companies to withdraw their pending NDA's and to assemble their independently accumulated clinical data into a single file.

The so-called "small committee" was formed (LILLY, SQUIBB, UPJOHN, and WINTHROP CHEMICAL COMPANY) for the sole purpose of collating and assembling the independently collected data into a master file. This submission did not constitute an application by any company for permission to market DES. Each company still had to file its own separate NDA for permission to market DES for the "1941 uses." The FDA required adherence to the United States Pharmacopoeia (USP) standards as essential to the evaluation of the clinical data. These procedures were not met with enthusiasm by the companies, but were generally accepted when the FDA pointed out that individually submitted data would delay approving individual applications.

The FDA required development of uniform labeling, and required that each company place a provision in their NDA's authorizing the FDA to use the materials gathered by each firm in considering any other NDA's that might be filed. Not all companies agreed to this latter provision. The FDA was not a "passive receptor" of information, but conducted its own independent investigation. It required additional clinical information to rebut concerns expressed by a small number of physicians, and reviewed medical literature. After the submission of the joint data in May of 1941, the "small committee" was permanently dissolved. Thereafter the FDA reviewed and

approved the individual NDA's.

The "1941" approvals were not sought for marketing purposes related to pregnancy. The importance of estrogen in human pregnancies was independently studied in the 1930's and 1940's, and experimental use of **DES** as a miscarriage preventive began in the early 1940's by independent researchers. Among the pioneers in this research were Drs. George and Olive Smith. By 1947, independent researchers had authored a number of reports on the use of **DES** to treat problem pregnancies.

FDA filings for permission to market DES to treat problems of pregnancy began in 1947. These filings were made independently by each company. The supporting clinical data was totally different from the "1941" data. New data was required because **DES** was considered a "new drug" when permission was sought to market it for pregnancy indications.[1/]

Approval by the **FDA** was a prerequisite to any company indicating DES for problems of pregnancy. No two companies relied upon the same research or medical literature. There was no "small committee" or any coordination of communications between the FDA and the companies with respect to the 1947 applications.

A few years later, when the **FDA** was satisfied that **DES** was "generally recognized . . . as safe" by "experts in the field" it declared that **DES** was no longer considered a "new drug". Ryan at 1011, n. 3; see 21 U.S.C. §321(p)(1). This action allows any

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1/ A "new drug" is a term of art explained in Ryan at 1011, n. 3.

company following approved manufacturing processes to market DES, legally, for any previously approved use without filing an NDA. Some 300 companies marketed DES and its congeners, at different times, to various retailers or wholesalers, through different and varied channels, some for pregnancy related problems and some not. In **1955,** there were at least **149** active manufacturers. Morton at **595, 598.**

In **1971** a statistical correlation was discovered between clear cell adenocarcinoma and DES. As recently as **1970** DES was still being prescribed, although rarely, for pregnant women. In that year a report was published which attempted to document observations of the previously rare malignancy in girls ranging from 14 to 22.[2/] In November of **1971** the FDA required that statement be included on all labels stating that DES was contraindicated for use in prevention of miscarriages.

The drug is still prescribed today for non-pregnancy associated conditions.

RESTATEMENT OF THE ISSUE

SHOULD FLORIDA ABANDON A PLAINTIFF'S TRADITIONAL BURDEN OF PROOF THAT THE DEFENDANT'S ACTS AND PRODUCTS CAUSED HER INJURY, BASED SOLELY UPON ALLEGATIONS OF A COMPLAINT THAT SHE CANNOT IDENTIFY THE PARTICULAR MANUFACTURER OF THE PRODUCT CAUSING INJURY?

2/ Herbst, Vifelder & Pskanzer, Adenocarcinoma of the Vagina, 284 N. Eng. J. Med 878 (1971).

SUMMARY OF ARGUMENT

Florida has always required that a Plaintiff identify the manufacturer who is responsible for the product allegedly to have caused injury. Plaintiff's inability to identify the manufacturer of the DES her mother ingested is not due to any tortious self-concealing conduct of the Defendants.

Plaintiff's various burden shifting theories of concerted, joint, or collective liability are totally inapplicable to the facts of a DES case, and are at odds with Florida's established "more likely than not" standard of proof of causation. The theories of concerted action, alternative liability, and enterprise liability had been properly rejected by the Courts as inapplicable, and inequitable in DES cases.

"Market Share" liability, in practice, results in nothing more than abandonment of fundamental prerequisites of law without a resulting balance of equities. Plaintiff's and the Fourth District's suggested modification of market share liability to allow a plaintiff to pursue but one manufacturer, under a joint and several liability theory, is nothing more than a return to the recognized inequities of alternative liability when applied to DES cases. The Plaintiff's proposed modified market share theory results in nothing more than a form of vicarious liability without even any theoretical rational basis. Due process standards are not satisfied if the probability is such that all of the Defendants held liable in Court are innocent.

This Court should not embark upon a radical change in tort law theory without a complete record. Any form of representative or industry wide liability will undoubtedly have effects upon society as a whole. Especially in DES cases, the policy considerations which should be examined under a full record militate against adoption of any of Plaintiff's theories. Policy considerations advanced by the Plaintiff in support of adopting their far-reaching theories are without merit in the real world.

ARGUMENT

I.

IN FLORIDA THE PLAINTIFF HAS THE BURDEN OF PROVING THAT THE DEFENDANT'S ACTS OR PRODUCTS CAUSED HER INJURY.

Plaintiff's and Amici's attempt to argue that their burden shifting theories involve only "identity" and not "causation" is without merit. As recognized in this Court's decision in Celotex Corporation v. Copeland, 471 So.2d 533, 538 (Fla. 1985), Plaintiff's theories of market share liability would wholly eliminate the tort law requirement of establishing causation. In Florida, the plaintiff has always had the burden of proof on all elements of an asserted cause of action. Included in causation is the identity of the manufacturer who is responsible for the product allegedly to have caused injury. E.g., Matthews V. GSP Corp., 368 So.2d 391, 392 (Fla. 1st DCA 1979); West v. Caterpillar Tractor Co., 336 So.2d 80, 87 (Fla. 1976); Sansing v. Firestone Tire & Rubber Co., 354 So.2d 895, 895 (Fla. 4th DCA 1978), cert.

denied, 360 So.2d 1250 (Fla. 1958); Linder v. Combustion Engineering, Inc., 315 So.2d 199, 200 (Fla. 1st DCA 1975), aff'd, 342 So.2d 474 (Fla. 1977); Smith's Bakery, Incorporated v. Jernigan, 134 So.2d 519 (Fla. 1st DCA 1961).[3/]

Plaintiff alleges she cannot identify the manufacturer of the DES taken by her mother. Plaintiff cannot carry her burden of proof by attempting an ad hoc joinder of a miniscule number of DES manufacturers among the 149 in the 1955-1956 period (Morton at 598) who might possibly have manufactured the DES taken by her mother. Plaintiff must establish the defendant(s) who actually supplied the tablets taken. Morton; West v. Caterpillar Co., supra; Ryan at 1006-1007; Matthews v. GSP Corp., at 392. Mere possibilities are not enough in any circumstance:

> A mere possibility of such causation is not enough; and when the matter remains one of pure speculation and conjecture, or the probabilities are at best evenly balanced, plaintiff cannot recover.
>
> [Restatement, Torts (2d), §433B(1), Comment a; 1

The burden is the same whether strict liability or negligence standards apply. West, supra; Matthews v. GSP Corp., supra; McNamara v. American Motors Corp., 247 F.2d 445 (5th Cir. 1957); Smith v. General Motors Corp., 227 F.2d 210 (5th Cir. 1955); Asgrow-Kilgore Co. v. Mulford Hickerson Corp., 301 So.2d 441, 444-445 (Fla. 1974). See also Prosser, The

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3/ This is in accordance with traditional tort doctrine throughout the United States. E.g., Coggins, Industry-Wide Liability, 13 Suffolk Univ.L.Rev.980, 982 (1979); 1 Hursh & Bailey, American Law of Products Liability 2d, §1:41 (1974); Gray v. United States, 445 F.Supp. 337 (S.D.Tex. 1978).

Fall of The Citadel (Strict Liability to the Consumer), 50 Minn.L.Rev. 791, 840 (1966); Prosser, Law of Torts, §41 at 241 (4th ed. 1971). The law of other states is in accord.[4/]

In Gooding v. University Hospital Building, Inc., 445 So.2d 1015 (Fla. 1984), this Court reaffirmed the basic common law standards of proof of causation in Florida by retaining the "more likely than not" standard of proof of causation in medical malpractice actions, and rejecting a theory of recovery for loss of a possible "chance to survive."

Reliance upon West by Amici, as evidence of this Court's alleged willingness to "relax" traditional burdens of proof, is unfounded. In adopting Restatement, Torts (2d), §402A, West specifically held that it was the plaintiff's burden to prove the defendant's identification to the injury causing product. 336 So.2d at 87. Accord, Morton at 595.

4/ As stated in Daniels v. Smith, 471 S.W.2d 508, 512-513 (Mo.App. 1971):

> Rules as to the burden of proof constitute a substantial right of the party on whose adversary the burden rests; such rules are indispensable in the administration of justice and should, therefore, be jealously guarded and rigidly enforced by the courts . . . Neither difficulty nor impossibility of proof of a material element in a case, though unfortunate, will alter the rules of evidence, and the one having the burden of proof who cannot bear it is simply left with an unenforceable claim.

Also, Zafft at 246-247.

In Matthews v. GSP Corp., supra, the Court affirmed a directed verdict in favor of all defendants, other than the owner of a scaffold which failed because of a parted cable, because plaintiff had failed to prove the source of the cable.

Reliance upon Cassisi v. Maytag Company, 396 So.2d 1140 (Fla. 1st DCA 1981), by Amici, similarly does not aid their argument. Cassisi did not eliminate or shift the plaintiff's burden of proving the defendant was responsible for the product. It, in fact, continued to recognize the burden that the plaintiff show that the defect existed at the time it left the defendant's control. There is no Florida authority imputing liability for a defective product in the absence of proof of the manufacturer's identity.

Nothing in the doctrine of res ipsa loquitur supports Plaintiff's burden shifting arguments. This Court has, in fact, condemned the attempted expansive applications of the doctrine of res ipsa loquitur to cases in which the existence of a causal relationship between the accident and the defendant's alleged negligence was wholly speculative. Goodyear Tire & Rubber Co. v. Hughes Supply, Inc., 358 So.2d 1339, 1342 (Fla. 1978). As Dean Prosser states:

> Certainly it is not the general rule that plaintiff may place the burden of proof of an issue upon his adversary merely by showing that he himself was ignorant of the facts and that defendant knows or should know, all about them. If it were, pure ignorance might be the most powerful weapon in the law.
>
> [Prosser, Res Ipsa Loquitur, (A Reply to Professor Carpenter), 10 Southern California Law Review 459, 464 (1937)].

Neither is the concept of concurrent negligence of aid to the Plaintiff in this case. Plaintiff must still prove that the conduct of each defendant, considered separately, concurred to cause her harm, in such a way to make it not possible to determine the extent of damage for which each defendant is responsible. Hudson v. Weiland, 150 Fla. 523, 8 So.2d 37 (Fla. 1942); Feinstone v. Allison Hospital, 106 Fla. 302, 143 So. 251 (1932). An allegation that several defendants were negligent toward a diverse group of individuals, and possibly toward Plaintiff, does not carry the burden of showing the breach of a legal duty to the plaintiff. Only the company whose product was actually consumed has caused damage to the Plaintiff.

11.

PLAINTIFF'S THEORIES OF CONCERTED, JOINT OR COLLECTIVE LIABILITY DO NOT AND SHOULD NOT REPRESENT THE LAW OF FLORIDA AND WERE PROPERLY DISMISSED.

It has been said that the Courts "...cannot [and should not] pluck negligence out of thin air". Memorial Park, Inc. v. Spinelli, 342 So.2d 829 (Fla. 2d DCA 1977), cert. denied, 354 So. 2d 986 (Fla. 1978). Neither should they do so with respect to liability theories on the basis of allegations of complaints, totally unsupported factual statements, and bald rhetoric. Nevertheless, this Court is now being called upon to do just that, and to address the issue bypassed in Celotex, supra. As

this Court has already noted in Celotex at 538-539, even with **DES** cases, many of which this Court cited, the clear majority of courts have refused to abandon the traditional safeguards of tort law by placing the burden of proof of causation on the defendants.

In Celotex, this Court was not directly involved with **DES.** Unfortunately, the present case is, technically, only a case involving the dismissal of a complaint and/or judgment on the pleadings without a fully developed record concerning the Plaintiff in particular, or **DES.** Plaintiff and Amici make many statements which are completely unfounded concerning the manufacturing and marketing of **DES,** as well **as** its alleged effects. Accordingly, in examining the various theories advanced by Plaintiff and Amici, this brief must, necessarily, draw on established sources beyond the Record at least to attempt to give the Court a balanced picture should it determine to make a major policy shift without a complete Record.

A. Concert Of Action.

In standing on the conclusionary allegations of her Complaint, Plaintiff simply asks this Court to ignore that virtually every court which has considered the issue has rejected concert of action theories in **DES** cases. **E.g.**, Lyons; Morton;, Ryan; Payton, 512 F.Supp.; Tidler; Sindell; Zafft. Contra Able v. Eli Lilly and Co., 418 Mich. 311, 343 N.W.2d 164, 175-177 (1984), on basis of pleadings only.

Concert of action stems from criminal law concepts of conspiracy and aiding and abetting, and renders jointly and severally liable all who intentionally combine in an unlawful activity proximately causing injury. The concert of action theory does not eliminate Plaintiff's burden of identifying the party directly responsible for the harm.

As Plaintiff readily admits (Initial Brief, p. 24), concert of action as applied in Florida has been on "different facts". The elements necessary to establish concert of action were established in two early Florida cases. Symmes v. Prairie Pebble Phosphate Co., 66 Fla. 27, 63 So. 1 (1913), and Standard Phosphate Co. v. Lunn, 66 Fla. 220, 63 So. 429 (1913). Both cases involved phosphate plants discharging into a stream, damaging the plaintiff's land. Joint recovery was not allowed because the tortious activities were separate and independent. No defendant had control or direction over the acts of any other defendant and there was no intention to act together. Symmes at 3; Standard at 432.

Concert of action has well defined limits. A defendant is liable only if he: (1) intentionally and actively encourages or participates in a wrongful activity; (2) with knowledge of the wrongful nature of the conduct; and (3) the joint wrongful activity is the proximate cause of the injury. See Skroh v. Newby, 237 So.2d 548 (Fla. 1st DCA 1970) (cited by Plaintiff), and Jacobs v. State, 184 So.2d 711 (Fla. 1st DCA 1966) (both involving illegal highway drag racing); Insurance Field Services, Inc. v. White & White Inspection & Audit Service, Inc., 384 So.2d

303 (Fla. 5th DCA 1980), and Bermil Corporation v. Sawyer, 353 So.2d 579 (Fla. 3d DCA 1977) (both involving tortious interference with business relationships). These common law limitations on joint liability are consistent with rules in other juridictions.[5/]

Restatement, Torts (2d), §876, cited by the Plaintiff, retains these same limits. Clauses (a) and (b) announce essentially the common law theories of conspiracy and aiding and abetting, where the defendant agrees with another to perform a wrongful act, or provides knowing and substantial assistance or encouragement of a tort that causes injury. Thus, the Restatement would require pleading (of relevant facts) and proof of a knowing participation, as well as proximate cause, scienter and substantial assistance to a third party. See Payton, 512 F. Supp. at 1035.

The Comment to Clause (a) emphasizes another point dispositive of Plaintiff's allegations of joint conduct, and which has been found lacking in the vast majority of courts which have considered DES cases:

> [I]t is essential that the conduct of the actor be in itself tortious. One who innocently, rightfully and carefully does an act

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5/ E.g., Bierczynski v. Rogers, 239 A.2d 218 (Del. Sup. 1968); Day v. Walton, 199 Tenn. 10, 281 S.W.2d 685 (1955); Knight v. Western Auto Supply Co., 239 Mo.App. 643, 193 S.W.2d 771 (1946).

> that has the effect of furthering the tortious conduct or cooperation in the tortious design of another is not for that reason subject to liability.

See Payton, **512** F.Supp. at **1035**; Ryan at **17**; Lyons at **190-191.** The only type of "concert" ever discovered in DES cases was the joint pooling of information at the request of the FDA for the 1941 non-pregnancy uses of DES, for which it is still recognized as safe by the FDA. Such action was obviously not tortious. Payton, **512** F. Supp. at **1038.**

Clause (c) of **§876** states a variant on the rule of joint and several liability, where independent but concurrent torts cause a single injury. This constitutes a damages rule, not one of collective liability. It applies where two or more unrelated tort feasors proximately caused injury. It does not dispense with the requirement of product/manufacturer identification in products liability cases. See Payton, **512** F. Supp. at **1036,** n. 4.

As stated in Morton at **596-597:**

> This Court agrees with the vast majority of courts that have considered the question: The DES manufacturers simply did not act in concert as that concept is defined in tort law. Their filings with the Food and Drug Administration (FDA) did not represent concertedtortious conduct.

Accord Ryan at 1014; Payton **512** F. Supp. at **1037-1039**; Lyons at **190-191**; Sindell, 607 P.2d at **935**; Zafft at 245.

Even Plaintiff's allegations, if allowed to stand in a vacuum, notwithstanding the wealth of case law establishing the development and marketing of DES, do not state sufficient facts.

The gravamen of Plaintiff's allegation is a so-called "conscious parallelism". However, there are no allegations of fact showing any "conscious parallelism" outside of that required by law and the FDA, regardless of the fact that the **1947** wholly independent submissions for pregnancy did not relate at all to the **1941** submissions and approvals. As stated in Morton at **597,** it is ridiculous to equate independent marketing of a generic product with some unlawful conspiracy:

> DES, it can be said, is DES; the defendants could not market the active ingredient in DES in any formula other than that prescribed in the United States Pharmacopoeia. **21** U.S.C., **§351 (1956).**

These and similar allegations have been repeatedly found wanting. Their legal insufficiency has been summarized well in Sindell, **607** P.2d at **932-933.** Accord Payton, **512** F. Supp. at **1037-1039;** Ryan at **1017-1018;** Lyons at **190-191;** Zafft at **245;** see Note, Market Share Liability and DES - Sindell v. Abbott Laboratories: Square Pegs In Round Holes, **13** Conn. L. Rev. **777, 794-795 (1981).**

In recognizing, as she must, that the lawful approval and marketing of DES did not involve a conspiracy or concert of action, Plaintiff chooses to rely upon the New York Appellate Division decision in Bichler v. Eli Lilly & Co., **79** A.D. 2d **317, 436** N.Y.S **2d 625** (App. Div. **1981),** aff'd, **55** N.Y.2d **571, 436** N.E.2d **182, (1982** . The Bichler Court affirmed a verdict for the plaintiff on the basis of a "modified version" **(436** N.Y.2d at **630-631)** of concert of action. The trial court had charged the jury on "conscious parallel" behavior stemming from the fact that

each made the same drug, knowing that other manufacturers were also making that drug. That charge represented an unprecedented and unsupportable expansion of the theory of concert of action. Tidler at 335-336; Morton at 597; see also Sindell, 607 P.2d at 933.

On appeal, New York's highest court did not reach the question of "conscious parallel" behavior. The Court of Appeal simply affirmed the jury's verdict on procedural grounds, finding that the defendant had not preserved its objections to the jury charge.[6/]

Although not openly argued in her Brief, Plaintiff also alleged a "conspiracy" based upon the fact that DES was a generic drug. (R. 389-390). Civil conspiracy is generally not a separate tort. It is a method for joining defendants who act together, illegally, in a common plan which causes harm. It is similar to concert of action, and it does not relieve the plaintiff of the burden of identifying the responsible party.[7/]

6/ The Appellate Division had relied upon the events leading to the approval of the 1941 NDA's to base its "concert of action" charge. The Court of Appeals, however, recognized that these facts had "no bearing on the concerted action which plaintiff must establish" regarding the marketing of DES for problems of pregnancy. 55 N.Y.2d at 585, n. 7; Zafft at 245. Bichler has been expressly rejected in Tidler at 335-336 and Morton at 597. It has also been severely criticized by a number of commentators. E.g., Birnbaum, DES Concert-of-Action Theory: New Cases Bring New Confusion, Nat'l L.J. May 4, 1982, at 31; Hoenig, Products Liability Recent Developments, N.Y.L.J., March 27, 1982.

7/ See Liappas v. Agoustis, 47 So.2d 582 (Fla. 1950). There must be an agreement among alleged co-conspirators, Reagan v. Davis, 97 So.2d 324, 328 (Fla. 2d DCA 1957), to accomplish an

(footnote continued next page)

B. Alternative Liability.

Plaintiff's attempt to invoke "alternative liability" does not represent the law of Florida, and it has been almost uniformly held not to apply to DES cases, nor has Plaintiff met the requirements. Plaintiff relies upon Restatement, Torts (2d), §433B(3), Summers v. Tice, 33 Cal.2d 80, 199 P.2d 1 (1948), and Ybarra v. Spangard, 25 Cal.2d 486, 154 P.2d 687 (1944). §433B(3) provides:

> Where the conduct of two or more actors is tortious, and it is proved that the harm has been caused to the plaintiff by only one of them, but there is uncertainty as to which one of them has caused it, the burden is upon each such actor to prove that he has not caused the harm.

As recognized in Bowman v. Redding & Co., 449 F.2d 956, 967-968 (D.C.Cir. 1971), this exception to the primary doctrine of proving all elements of proximate cause, is ". . . so limited and structured that it is evidence that [it does] not represent a disguised overturning or undermining of the main doctrine." However, Plaintiff would have it do just that in the present case. Only Abel v. Eli Lilly, 343 N.W.2d supra, on pleadings alone, has recognized possible application of alternative liability in a DES case.

(continuation of footnote 7)

unlawful purpose or a lawful purpose by an unlawful means. Bond v. Koscot Interplantary, Inc., 246 So.2d 631, 635 (Fla. 4th DCA 1971), cert. denied, 283 So.2d 866 (Fla. 1973); 4 Fla. Law and Practice, Conspiracy, §13; Prosser, Law of Torts, 0291-292, (4th ed., 1971). There is no such thing as conspiracy to commit negligence. See Ryan at 1012.

The Restatement concept is based upon Summers. The plaintiff did not know which of the two hunters firing at him had actually caused his injury, and brought suit against both. The Court shifted to defendants the burden of proof, "each to absolve himself if he can,". Summers at 4. This occurred because: (1) both had been negligent with respect to the Plaintiff, and (2) each, under the circumstances, was in a better position than the plaintiff to offer evidence about the role he had played in causing the plaintiff's injury. Upon failure to absolve themselves, both were held jointly and severally liable.

Alternative liability requires plaintiff show four key factors: (1) there are a small number of possibly responsible negligent tort feasors; (2) all of them are joined as defendants; (3) the defendants are in a superior position to offer evidence of identification of the responsible party; and (4) all defendants were tortiously responsible for the plaintiff's inability to identify the actual tort feasor. Morton at 598-599; Ryan at 1017; Payton v. Abbott Labs, 386 Mass. 540, 437 N.E.2d 171, 189 (1982) (Payton, 437 N.E.2d); Namm at 1128; Sindell at 936-937; Ybarra, supra; Spannaus v. Otolaryngology Clinic, 308 Minn. 334, 242 N.W.2d 594 (1976).

Holman v. Ford Motor Company, 239 So.2d 40 (Fla. 1st DCA 1970) does not aid Plaintiff. Plaintiffs' and Amici's attempt to once again expand res ipsa loquitur has been previously addressed. Supra, p. 13. Likewise, the limited acceptance of Ybarra in Marrero v. Goldsmith, 11 F.L.W. 35 (Fla. January 23, 1986) is of no aid to Plaintiff where, as here, the Defendants do not have

superior access to identification evidence, and the possible tort feasors are not fully known, are not limited in number, and all are not capable of being joined.

Plaintiff has studiously avoided alleging that all possible tort feasors (in this case, at a minimum, all possible suppliers of the medication) have been joined.[8/] Neither does she plead facts which would establish that any tortious conduct of the Defendants led to her inability to identify the source of her injury.

Quite obviously, all possible Defendants have not been joined. Plaintiff's mother's ingestion of DES occurred in the same time frame covered by Morton where the Court found that there were **149** possible suppliers. The reliance upon Comment h to **§433B(3)** is nothing but an attempt to expand that section beyond its intended parameters. Copeland V. Celotex Corporation, **447** So.2d **908, 919** (Fla. 3d DCA **1984)** (dissent) ("Copeland"). As noted in Ryan at **1016-1017:**

> Comment 'h' to **§433B(3)** indicates further that '[t]he cases thus far decided in which

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8/ This initially would require proof that her injuries were caused by DES before she could limit the group to possible suppliers of that medication. Dr. Herbst, in **1971** (see, Payton, 512 F.Supp. at **1034),** found only a statistical association. Herbst, et al, Age, Incidents and Risk of Diethylstilbestrol Related Clear Cell Adenocarcinoma of the Vagina and Cervix, 128 Am.J.Obstl Gyn. **43 (1977).** Medical literature shows that the cancer occurs naturally in women, and at least 43 per cent have had no exposure to DES. Herbst & Bern, Developmental Effects of Diethylstilbestrol in Pregnancy, Ch. **5** (Thieme-Stratton, Inc. **1981);** Morrow & Townsend, Synopsis of Gynecologic Oncology, at 55 (2 ed. **1981).** One group of physicians candidly noted, after reviewing all of the DES data, "the fact remains we still have no idea what causes any cancer of the lower genital tract". Wharton, et al, Invasive Tumors of the Vagina: Clinical Features and Management, 1 Gynecologic Oncology **345** (Churchill & Livingston **(1981)).**

> the rule stated in Subsection (3) has been applied all have been cases in which all of the actors involved have been joined as defendants'. (Emphasis added). While Comment 'h' notes the modification of the rule is conceivable where 'one of the actors is not or cannot be joined', the comment does not go so far as to suggest the wholesale abandonment of the requirement that all or substantially all of the allegedly tortious defendants be present before the court. Specifically, plaintiff must produce evidence that one of the defendant's products was taken by her mother and caused her injury; a suit against 7 of 118 manufacturers must fail on this theory.

The same result obtained in Sindell where only 5 out of a possible 200 suppliers were before the court. 607 P.2d at 936-937. See also Namm at 1124 (44 out of 300); Morton at 598-599 (8 out of 149).

Plaintiff alleges no facts that would, if proved, show either that the Defendants have greater access to identification information, or that any or all of the Defendants are tortiously responsible for Plaintiff's inability to identify the actual tort feasor. The superior access requirement is a principal underpinning of the Summers rationale, and is demonstrated by Ybarra. Compare Spannaus, supra.

In McCreery v. Eli Lilly & Co., 87 Cal.App.3d 77, 85, 150 Cal. Rptr. 730 (3d Dist. 1978), the Court presented with a similar case involving DES, concluded that the evidence compelled the conclusion that evidence of the identity of the manufacturer was in fact more accessible to the plaintiff. 87 Cal.App.3d at 83. See also Namm at 1127; Zafft at 244-245; Fischer, Products

Liability-An Analysis of Market Share Liability, 34 Vanderbilt L. Rev. 1623, 1636-1637 (1981); Note, 13 Conn. L. Rev. at 789-790.

If the requirement of superior access to identification evidence is ignored, the burden upon the Defendants is unfair. It is not unduly cynical to suggest that the application of alternative liability under such circumstances would encourage the memories to "fade." See Prosser, Res Ipsa Loquitur, quoted supra, p. 13. This is especially true if the manufacturer has gone out of business or is not subject to jurisdiction where the plaintiff would like to sue.9/

Contrary to the rhetoric of Plaintiff's Brief, and to rebut any possible misconception of this Court in its opinion in Celotex at 537, the generic nature of DES, as decreed by the provisions of the USP, did not result in mass "generic" marketing. Zafft at 246. As many of the cases and authorities note, the separate manufacturers marketed their tablets in distinctive trade names, colors, size, shapes and dosages. E.g., McCormack v. Abbott Laboratories, 617 F. Supp. 1521, 1530 (D. Mass. 1985); Coggins, 13 Suff. Univ. L.Rev. at 999.

Manufacturers variously supplied products to wholesalers, drug stores or pharmacies. Pharmacists purchasing from wholesalers have complete freedom of choice on whose product to select

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9/ For example, in Abel v. Eli Lilly, 94 Mich.App. 59, 289 N.W.2d 20, 23 (App. 1979), mod., 343 N.W.2d 164 (Mich. 1984) many plaintiffs initially alleged that they could not identify the manufacturers of the drug taken. After suffering summary judgment on that ground, many plaintiffs suddenly were able to identify the particular manufacturer of their drug. Fischer, 34 Vand. L. Rev. at 1650.

and could simultaneously select a range of products to stock. The physician had the same freedom to select among brands when prescribing. No records relating to individual prescriptions or patients were kept by, or even sent to the drug companies, and they had no ready access to such information. See, Payton, 512 F.Supp. at 1039. In the main, only a plaintiff's mother can reveal the name of the physician who described the drug. Only she can, if she remembers, describe the color of the drug, dosage size and the form, i.e., pill, tablet, etc. Only she, generally, can identify the pharmacist. In other words, every piece of relevant information lies primarily with the Plaintiff. Liability should not be predicated upon failed or faded memories of third parties, nor, in this situation, should the drug companies be held to be insurers of those memories and information sources over which they have no control. Zafft at 244-245.

Plaintiff's claims of "mass marketing" are nothing more than claims that because DES was not patented by its discoverer any company complying with FDA requirements can market it. Marketing of generic drugs provides no basis for finding tortious conduct by defendants to prevent identification of their product.[10/]

To apply alternative liability to the present circumstances would, in effect, impose absolute liability on a small number of

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10/ It is a matter of public policy favored by federal and state law. See Brand Names and Generic Drugs, 1974, Hearings before Subcommittee on Labor and Public Welfare, 93rd Cong. 2d sess. (July 22, 1974); Maximum Allowable Health Costs for Drugs, Office of Secretary, Dept. of Health, Education and Welfare (July 25, 1976); §465.025(2) and (7), Fla.Stat. (1985).

defendants who cannot be shown to have, more likely than not, played any part in bringing about the Plaintiff's injuries. McCreery, supra. As pleaded and presented, Plaintiff's argument of alternative liability theory has a built-in assumption that all the manufacturers were negligent. This fails to "separate tort feasors from innocent actors" and "would practically ensure that Defendants innocent of any wrongdoing" would be held liable to the Plaintiff. Payton v. Abbott Labs., 437 N.E.2d at 189. For example, the Plaintiff ignores the fact that a company which did not sell DES for use in treating accidents of pregnancy cannot be negligent with respect to an injury which arose out of an unauthorized use. See, e.g., Standback V. Parke-Davis & Co., 657 F.2d 642, 645-646 (4th Cir. 1981). Yet the product of that company may have been supplied to the Plaintiff beyond any ability of that company to object.

Plaintiff's reliance upon the trial court decision in Ferrigno v. Eli Lilly & Co., 175 N.J.Super. 551, 420 A.2d 1305 (Law Div. 1980), as stating the law of New Jersey, is misplaced. The Appellate Division in Namm at 1127, n. 3, rejected Ferrigno. See also Pipon at 639; Lyons; Aarnes v. Merck & Co., 532 F.Supp. 148 (D.N.J. 1980), aff'd, 672 F.2d 903 (3rd Cir. 1981).

McElhaney v. Eli Lilly & Co., 564 F.Supp. 265 (D.S.D. 1983), is clearly wrong in fact and principle, and out of step with the weight of authority. The Federal District Courts' "Erie" guess that South Dakota would approve alternative liability has yet to come true.

C. Enterprise Liability.

The theory of enterprise liability, only postulated in dicta in Hall v. E. I. DuPont deNemours & Co., 345 F.Supp. 353 (E.D.N.Y. 1972), has not been applied outside of its own peculiar factual circumstances. It has been been rejected in DES cases by every court to consider it. E.g., Sindell, 607 P.2d at 933-935; Namm at 1128-1129; Morton at 598; Ryan at 1017; Zafft at 245; see also Aarnes v. Merck & Co., supra; Note, 13 Conn. L. Rev. at 795-799.

In Hall there were 12 separate accidents in 10 different states. The defendants were 6 blasting cap manufacturers, comprising virtually the entire blasting cap industry, and the industry's trade association. Plaintiffs could not identify the manufacturer of the product. Plaintiffs therefore alleged an "industry-wide" failure in blasting cap safety, caused by the defendants' delegation of safety issues to the trade association, and thereafter adhering to the "tortious policies" set by that association.

The District Court in Hall outlined a form of industry-wide liability that might possibly apply if a plaintiff could allege and prove: (1) the product was manufactured by a small number of defendants in an industry; (2) the defendants had a joint capacity to "reduce'' the risks of the product; and (3) each of them failed to take steps to reduce the risk at a substantially concurrent time by delegating the responsibility to an association. In the absence of any of these factors (e.g., where there is a large number of producers, or the industry was decentralized, or

the safety function was not delegated), the Court recognized that it would be unreasonable to apply such a theory. The Court specifically noted that the prescription drug industry did not fit this category.

> The expansive notion of vicarious liability represented by the enterprise concept --which would render every manufacturer and insurer not only of the safety of its products but of all generically similar products made by others -- is repugnant to the most basic tenets of tort law.
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> [Ryan, at 1017].

D. Market Share Liability.

The so-called "Sindell market share liability" theory finds no support in prior Florida law, and has found little support outside of California. Zafft at 245-246. It was created by a bare majority of the Supreme Court of California in Sindell. The Sindell Court admitted that it was adopting a total departure from all previous rules of causation and liability.

While Plaintiff has alleged that ". . . the joined Defendants accounted for a high percentage of the DES on the market at the time Plaintiff's mother ingested it" (R. 378), she offers no facts to support that assertion. The dissenting opinion in Sindell clearly points out that the majority's unprecedented enlargement of liability permits recovery

> . . . from a handful of defendants each of whom individually may account for a comparatively small share of the relevant market . . . In other words, a particular defendant may be held proportionately liable even though mathematically it is much more

likely than not that it played no role what ever in causing plaintiff's injury.

[607 P.2d at 939].

As noted by the Sindell dissent, neither the Sindell majority, nor the Plaintiff here, define the words "substantial" and "market". See also Celotex at 538.

The theory has been rejected in Morton at 599, Mizell at 596, Ryan at 939, Tidler at 334, and by the Supreme Judicial Court of Massachusetts in Payton, 436 N.E.2d at 188-190, and the Supreme Court of Missouri in Zafft at 245-247. See also Pipon at 639. As held by the Tidler Court, even if 90 per cent of the market were joined, the adoption of market share liability, because of the number of variables present in the distribution process, would always create substantial doubt as to which product the plaintiff's mother had actually taken and would impose liability on the basis of rank speculation. Rejection of market share liability is in accord with the decisions rejecting the application of alternative liability where all possible tort feasors are not joined as defendants. The underpinnings of the Sindell theory are irrational when considered in light of the Plaintiff's arguments which concede the lack of an adequate system of retail records over the last 29 some odd years from which to formulate a proper "market" of any type.

The Sindell majority justified its decision in a "rough justice" sort of way on the theory that each manufacturer's liability for injury would be approximately equivalent to that

caused by the DES it manufactured. 607 P.2d at **938.** Its conclusion was not premised on any likelihood that a given defendant caused plaintiff's injury, but upon erroneous assumptions that: (1) each defendant caused harm to someone else, and (2) in a hypothetical case brought by that other, unidentified person, each defendant would be held liable. The premise that liability would "even out" in a number of cases, while having some surface appeal, ignored reality. See Note, **13** Conn. L. Rev. at 801-802.

Sindell would compel the court, and perhaps the jury, to try to reconstruct a diverse and dynamic "product market" of possibly 149 manufacturers, 30 years after the fact. Morton at 595, 598. The passage of time has rendered this task difficult, if not impossible, especially if the "market" is the state or local level. It would require the impossible calculation of what percentage of actual retail sales were devoted to uses for prevention of accidents of pregnancy, the only use involved here. The reformulation of the active ingredient by others alone would render this difficult if not impossible, even assuming all companies were still in business. This absence of evidence would make it all the more probable that speculative and arbitrary "market shares" will be assigned with larger shares being imposed on those manufacturers that are currently solvent, have maintained the best records, and are well known, all of which is unrelated to actual causation. As stated by the dissent in

Sindell, 607 P.2d at 940-941, good record keeping and name recognition are not proper grounds for judicial determination of liability.[11/]

Under market share, any defendant who can demonstrate that his product could not have been used is "exonerated" and entitled to dismissal. Celotex, supra. The effect of the passage of time on records, not controlled by defendants, alone will work an inequality and a lack of equitable distribution of the ultimate loss. In effect, the market share theory would only work where there was complete absence of identification evidence in every case. Even in California, in practice, the basic assumption that matters will "even out" has not been true, and has been the source of continued criticism by commentators. E.g., Note, 13 Conn. L. Rev. at 801-802. The inevitable result will be that a limited number of manufacturers will pay for more damage than their products possibly could have caused, or incur more litigation expense, because of current name recognition and solvency. These companies are doubly exposed, paying their "market share" in every case where the Plaintiff's mother cannot remember whose

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11/ Even defining a relevant "geographic market" presents inherently unrealistic problems of proof. Again, defendants should not be made insurers of fading memories and happenstance of record keeping. The lack of proof becomes an advantage and plaintiff has little incentive to attempt to identify the actual prescription drug manufacturer, making Dean Prosser's prediction a reality. Supra, p. 14; supra p. 25, n. 9.

product she took, and 100 percent of a Plaintiff's damages in those cases where facts exist that result in their identification.12/

Under Sindell, low profile defendants fare far better. An obscure manufacturer whom a druggist may not remember after 30 years, but who accounted for a large percentage within a particular "market", may escape liability altogether. Consumers may not recall the names of such manufacturers or have never heard of them; they may use shape or size pills which are not readily distinctive. In practice, only those high profile companies which are solvent and amenable to suit are sued and they become sued over and over again. The same manufacturers are accordingly forced to defend a disportionate number of suits and are exposed to paying a disportionate amount of any settlements or judgments.

12/ See, e.g., Comment, Refining Market Share Liability: Sindell v. Abbott Laboratories, 33 Stan.L.Rev. 937 (1981); Comment, Sindell v. Abbott Laboratories: A Market Share Approach to DES Causation, 69 Cal.L.Rev. 1179 (1981); Comment, Market Share Liability for Defective Products: An Ill-Advised Remedy for the Problem of Identification, 76 N.W.Univ.L.Rev. 300 (1981); Note, California Expands Tort Liability Under the Novel "Market Share" Theory: Sindell v. Abbott Laboratories, 8 Pepperdine L.Rev. 1011 (1981).

As an example, if X produced a white pill accounting for the 5 per cent of the market, it will always be included in cases where the plaintiff's mother remembers only taking a white pill and in all cases where the color is unknown. It will also pay 100 per cent of the damages in any case where it is identified. The same will be true where the manufacturers are isolated because a pharmacist or doctor remembers only specified brands or colors, or dosages, as opposed to cases where information is absent. See Note, 13 Conn.L. Rev. at 777, 806, n. 148.

Ultimately, the Sindell Court's bottom principle that "things will even out" assumed, impermissibly, that all courts and jurisdictions: (1) would adopt "market share liability", and (2) would and even could identically define "market" (product and/or geographic) or "substantial share". This, of course, has not happened and is not likely to happen. Zafft at 245-246.

In the absence of uniform acceptance and application and national market definitions, and the truth of its basic assumptions, a description of market share as a "lottery" is correct. See Fischer, 34 Vand. L. Rev. at 1643, 1646.[13/]

The adoption of market share liability in the practical world, based upon erroneous facts and assumptions, does nothing more than throw away fundamental prerequisites of the law, the proof of causation, and the identification of the tort feasor to the product, without resulting in any balance of equities. See, Copeland at 920, (dissent).

E. Modified Market Share

Plaintiff's, Amici's, and The Fourth District's suggested modification of Sindell, and of even Martin V. Abbott Laboratories, 102 Wash. 2d 581, 689 P. 2d 368 (1984), to allow Plaintiff

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13/ As an example, if defendant A is sued in four different cases, and each court defines the market differently, the selection of different geographic markets and definitions can result in a wide disparity of A's total liability. An arbitrary or differing selection of particular time periods can create the same type of disparity. Similarly, if in one court Defendant A is liable only for a percentage of the judgment equivalent to its share of relevant market, but in another court it is required to pay one hundred percent of the judgment, then defendant A will be required to pay much more than its share of the relevant market, and any due process rationale of market share is destroyed.

to sue only one or two manufacturers, regardless of their standing in whatever relevant market might be decipherable, and to place upon them joint and several liability, recognizes the inherently erroneous assumptions of Sindell. However, they amazingly avoid recognition that because of the invalidity of those assumptions any legal and equitable justification of market share liability, as a basis for placing the burden of exoneration on defendants, does not exist. See Note, 13 Conn. L. Rev. at 801-802.

By allowing joint and several liability, against one or a small number of defendants, any possible working of the "rough justice" trade off underlying pure market share liability is totally destroyed. It is amazing that Amici's Brief, at p. 10, can state that the very nature of market share theory is logical only where liability is actually apportionable on a market share percentage formula in each case, but on page 11, seeks to dispense with even that questionable logic and eliminate any possible due process rationale to change established tort law to shift the burden of proving causation to the Defendants.

Rather than seeking to protect Defendants from paying for more harm than they have actually caused, the proposed modified theory insures an inequitable distribution of any liability. The "lottery" will have become "fixed." Fischer, supra. Even the one other court which has accepted Martin has recognized that acceptance of market share liability at least precludes all

theories of joint and several liability, or alternative liability.[14/]

The assertion that Sindell market share liability should be "modified" to allow for joint and several liability, rather than liability based upon the "market share", is nothing more than a return to pure enterprise or alternative liability without the due process requirement that plaintiff join all possible tort feasors. The implication that this comports with the concept of contribution among joint tort feasors, and is justified on a spreading of the costs rationale, is absolutely specious. As Amici correctly points out, many manufacturers are now insolvent, defunct or beyond the jurisdiction chosen by the Plaintiff. To shift the burden to Defendants, through third party actions or subsequent suits in other jurisdictions for contribution, would require a uniformity of recognition and application of market share liability in every jurisdiction. This situation just does not exist. Zafft at 245-246. Thus, even any theoretical concept of fundamental fairness which must underlie any shift of the burden of proof of causation is eliminated. See Copeland at 920-921. (dissent).

Amicus' suggested "modified" joint and several liability/ market share theory results in nothing but a form of vicarious

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14/ See, McCormack, supra at 1524. The Federal District Court in McCormack, a split off of the original action in Payton, 512 F.Supp., not feeling bound by the Supreme Judicial Court of Massachusetts misgivings on adoption of any burden shifting theory in a DES case absent a full and complete record, as expressed in Payton v. Abbott Labs, 437 N.E. 2d, nevertheless adopted Martin.

liability without even the pretext of a rational basis. As stated in the dissent in Abel v. Eli Lilly & Co., 289 N.W.2d at 33:

> The naked application of the collective liability theory would result in a taking of the property of all of the Defendants in order to pay for harm which may have been caused by conduct of only one of the Defendants, or even one who is not a party to this lawsuit, over whom the Defendants have no control or with whom they have no meaningful contact. Due process requires that a state action which deprives a person of his property must have a rational basis, it must not be arbitrary.

Plaintiff's theories rest "on pure and undisguised speculation, with serious questions of due process of law involved". Pipon at 639; see also Namm at 1127; Tidler at 334.

As The Supreme Court of California pointed out in a recent case, Murphy v. E.R. Squibb & Sons, Inc., No. L.A. 31970 (Cal. December 30, 1985), any claim that under market share the Plaintiff's burden of joining a substantial share of the market is unrelated to the doctrines designed to accomplish a fair approximation of the damages which each DES manufacturer will be required to pay, "lacks merit". In Murphy, The Supreme Court of California rejected the Plaintiff's contention that the single Defendant's ten percent of the national market was sufficient. As stated by the Court in Murphy:

> We declined to apply an unmodified Summers rational to the facts in Sindell, because only five of the two hundred manufacturers of the DES which could have harmed Plaintiff were before the Court, and therefore there was "no reasonable basis upon which to infer that any Defendant in this action caused Plaintiff's injuries, nor even a reasonable

> possibility that they were responsible." *** We held that if the Plaintiff joined in the action the manufacturers of a substantial share of the DES which her mother might have taken, the injustice of shifting the burden of proof to Defendants to exonerate themselves would be significantly diminished. (Emphasis added) (Slip Op. 20-21).

As the Murphy Court concluded, since Squibb had only a ten percent national share of the DES market, there is only a ten percent chance that it produced the drug causing Plaintiff's injury and a ninety percent chance that another manufacturer was the producer.

The reason for requiring Plaintiff initially to join Defendants having a substantial share of the market is to approximate more of a probability that one of the Defendants in the Court produced the product that caused the Plaintiff's injuries, rather than a probability that he did not. If this Court has any inclination to adopt any "market share" concept, this requirement must be included. This Court has in the past recognized that tort liability must be predicated on probabilities and not possibilities. Gooding, supra; Cone v. Inter County Telephone & Telegraph Co., 40 So.2d 148, 149 (Fla. 1949). Certainly, due process standards are not satisfied if the probability is such that all of the Defendants in court are innocent.

A DES case is not just a question of market share and product identification. It is a complex personal injury trial. The Plaintiff's medical history may be unique and have complex factors bearing upon the issue of defectiveness. Although DES is manufactured pursuant to the USP common formula, dosages, and

recommendations made by manufacturers may vary, and certainly the state of knowledge of the scientific community and each drug company, varied from time to time. A DES trial under market share liability would involve evaluation of the conduct of each manufacturer in the entire industry in any event.

As even the Sindell Court recognized, it is simply unjust to force a single defendant to carry the entire burden of litigating the medical condition of the Plaintiff and bear the expense of defending the conduct of all the members of an entire national industry. As of **1981,** the expenses of simply defending a DES case were estimated to be in the area of $50,000 - $100,000 per case, per defendant. See Note 13 Conn. L. Rev. at 802-803.

If plaintiffs are allowed to pick any manufacturer, they could, if available, pick a small producer lacking the financial resources to bear such a burden. Plaintiff contends here that a whole industry of a national scope erred in producing DES. She must be required to bring into Court enough members of that industry to ensure a fair trial of that allegation, if any form of market share is adopted.

Similarly, as previously demonstrated, if any type of market share is going to work, it must be predicated on a national market, not Florida, and not a city or a particular pharmacy. As Sindell and many other cases point out, the failure of records from which a "market" can be constructed, especially at the local levels, is not the fault of the drug companies. They have no control over local doctors or pharmacies.

Only a uniform national "market share" could possibly begin to afford the rationale underlying the doctrine of market share a chance to work, assuming that all jurisdictions recognize the doctrine, which is, of course, not the case. A uniform national market definition would at least begin to provide a constant measure of liability for each Defendant, making easier resolution of law suits in which a particular defendant cannot produce exoneration evidence. The problems of proof would be simplified in each case where the source of the DES cannot even be identified, and the defendants cannot produce exoneration evidence. Fischer, 34 Vand. L. Rev. at 1643-1644.

Any concept of joint and several liability, hooked to the coat tails of a market share theory, would also be inherently unjust, destroying the only possible equitable theory for shifting the burden of causation and exoneration to the defendants. As the Sindell majority clearly noted, the market share concept was theoretically designed to avoid the adverse moral and due process circumstances that "one manufacturer would be held responsible for the products of another or for those of all other manufacturers if Plaintiff ultimately prevails." Sindell, 607 P.2d at 938. In short, any inherent fairness of the burden shifting of market share depends upon several liability based upon each defendant's market share, rather than joint liability. See, e.g., Note, 8 Pepperdine L. Rev. at 1032; McCauley, Products Liability: Sindell v. Abbott Laboratories: Proportional Unidentifiable Fairness And The Oklahoma Perspective, 34 Okla. L. Rev., 843, 854-855 (1981).

The manufacturers of DES are manifestly not joint tort feasors. Indeed, if several innocent manufacturers are required to pay all of the Plaintiff's damages, because they cannot prove that Plaintiff did not take their drug, their liability is certainly not commensurate with their responsibility for an injury caused by their products. See, Sheffield V. Eli Lilly & Co., 144 Cal. App. 3d **583, 599, 192** Cal. Rptr. **870 (1983).** Joint and several liability would remove any incentive to establish the identity of the actual manufacturer. See Copeland at **921-922** (dissent).

111.

POLICY CONSIDERATIONS DEMAND CAUTION

Attempts to invoke various "industry wide" forms of vicarious liability completely fail to analyze the policy and social implications of such action. Fischer, **34** Vand. L. Rev. at 1650-**1658.** These policy considerations transcend any individual case, and require the balancing of a large number of legitimate interests and concerns. ~~See~~ ~~Zafft~~ at **247;** Copeland at **921-922** (dissent). This is primarily a function of the legislative system, not the courts. Florida has, in the past, recognized that the judicial imposition of liability on the ethical drug industry is to be approached with extreme caution. Buckner V. Allergan Pharmaceuticals, Inc., **400** So.2d **820** (Fla. 5th DCA **1981),** pet. denied, **407** So.2d 1102 (Fla. **1981).**

The problem of the determination of which company caused injury comes from passage of time and the absence of retail

records. Public as well as judicial policy simply cannot operate to shift to a defendant a burden which is recognized cannot be carried because of the actions or inactions, or faded memories, of third parties.

The various theories stem from a presupposition that Defendants are "deep pockets" who are "better able to bear the cost of injury" by insuring risk of loss and distributing the risk among the public as a "cost of doing business". This assumption is both essentially fallacious as a practical matter, and as a judicial policy or a general social policy, cannot be tolerated. Sindell, 907 P.2d at 941 (dissent).

The "cost spreading" argument, applied either in the market place or in the tort arena, directly or through the theory of contribution, is naive. Industry wide or market share liability make losses both unpredictable and to a large degree uninsurable. The pharmaceutical industry is finding product liability insurance extremely expensive and difficult to obtain. E.g., United States Commerce Department, Interagency Task Force on Product Liability: Final Report of the Insurance Study, Ch. I at 1-9, Ch. IV (January 1977) (cost increase 613 per cent between 1971 and 1976). In its report, the Commerce Department attributed much of the cost increases in, and the unavailability of, insurance to far-reaching appellate decisions which have converted product liability iaw from a "means of apportioning liability" to a "compensation system".

Insurers cannot anticipate the scope of vicarious industry wide risks which do not materialize for 10 to 30 years. There is

no method by which an insurer can determine the risk of loss and calculate premiums where the calculations must be based not only on a particular insured's record of safety, research, sales, prior losses, etc., but also the same factors for all other manufacturers of each product. In addition, with such theories as market share, the insurer would be left to guess at the probable location and size of each "relevant market" to the extent uniformity does not exist. The defense costs alone would be tremendous, regardless of success on the merits, especially to those few highly visible and solvent manufacturers who undoubtedly will be sued in virtually every case. Note, 13 Conn. L. Rev. at 803.[15/]

To justify any Sindell, joint, or alternative "vicarious" liability theories on the argument that the industry can equitably pass along the costs to the consumer is not only naive, but irresponsible. The exposure of each company would depend not on its sales, but the sales of some arbitrary selected part of the

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15/ The pharmaceutical industry has already experienced one collapse of insurance coverage in the swine flu vaccine experience. See Ducharme v. Merril-National Laboratories, 574 F.2d 1307, 1310-1311 (5th Cir. 1978), cert. denied, 439 U.S. 1002, 58 L.Ed.2d 677, 99 S.Ct. 612 (1978); Franklin & Mais, Tort Law and Mass Immunization Programs: Lessons From the Polio and Flu Episodes, 64 Cal.L.Rev. 754, 759-772 (1977). The manufacturers, refused liability insurance, rather understandably declined to produce the vaccine at the government's request, without the special legislation which shifted the risk of liability to the government.

entire industry. A particular company could not, under any rational principle, anticipate the risks. Companies who sustain adverse judgments would be forced to raise the prices of their products while having to compete with firms making similar products who have not been sued. This problem is compounded where joint and several liability is imposed upon a system where the Plaintiff is allowed to "select" only one or a small handfull of possible defendants. It presents unjustified obstacles to established public policy, both state and federal, which encourages the marketing of generic drugs in order to keep the costs of medical care at a minimum. Supra, p. 26, n. 10. To impose a new tort standard contrary to anything known in the law of Florida, based solely upon the allegations of the Complaint in this case, will serve to unduly and unnecessarily impinge upon a major objective of established public policy which is to continue to encourage widespread and heavy investment in pharmaceutical research and development. Zafft at 247; McCreery, supra, 87 Cal.App.3d at 86-87; see Note, Product Liability, 13 Seton Hall L. Rev. 625, 641 (1983); Fisher, 34 Vand. L. Rev. at 1629; Note, Strict Liability for Drug Manufacturers: Public Policy Misconceived, 13 Stan. L.Rev. 645, 649-650 (1961).

The prospects of a serious diminution in the creation of cost effective generics are clear. If the public policy favoring generics in fact causes identity problems 20 - 30 years later it should be attacked legislatively through mandatory record preservation. The cost-passing rationale would most certainly discourage the production of new drugs because the added costs would

require a potentially larger market to justify development and selling. The inevitable result would be that more people would suffer to provide a remedy to a handful of plaintiffs. The incentive and ability to research and develop the so-called "orphan" drugs, to combat serious and debilitating maladies which confront a small but nonetheless significant portion of the overall population of the United States, would be seriously discouraged. These drugs already are not cost efficient. Further, the effect of Plaintiff's theories would be to visit the costs upon those who are least able to bear it - the sick and the elderly. See Comment, **69** Cal. L. Rev. at 1201; Note, **13** Seton Hall L.Rev. at **637;** Note, **13** Conn. L. Rev. at **808.**[16/]

Under the Martin approach, and that advocated by the Fourth District and Plaintiff in this case, the "cost passing" rational is totally spurious. To allow suit against one member of the industry as a "representative", and to allow joint and several

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16/ It has been estimated that the risk in women exposed to DES is perhaps .0001. Barnes, Ambulatory Management of the DES - Exposed Patient, Ambulatory Care and Obstetrics and Gynecology, **339, 341-345** (Ryan, ed. **1980).** Herbst & Bern, supra, Ch. **5,** identifies less than **500** cases of clear-cell adenocarcinoma in the world in the 12 years prior to **1980,** including those not exposed to DES. Supra, p. **23,** n. **8,** see also, Fisher, **34** Vand. L. Rev. at **1624.** Thus, even if one assumes a cause-effect relationship is proved by the present Plaintiff for her present alleged condition, and others do so, the imposition of industry-wide liability will have a greater adverse impact upon a far larger percentage of the population than is, or would be, justified by the relaxation of individual plaintiffs' burden of proof.

liability, will probably mean only that large solvent "name" drug companies will be sued, regardless of the fact that they may have occupied a very small portion of the market. To say that they can either bring in other defendants, or seek contribution in other jurisdictions, ignores the fact that many possible defendants may not now be able to be "long armed" into Florida, e.g., Hunter v. The Challenge Machinery Company, 11 F.L.W. 259 (Fla. 1st DCA January 23, 1986), and that the vast majority of jurisdictions have rejected any form of industry wide or vicarious liability, Zafft at 245-246, and that contribution rules between jurisdictions are widely varied.

The Martin approach is clearly a provincial approach to what is, if anything, a nationwide problem. Even if the cost could be spread by contribution actions elsewhere, the Defendants in those cases would not be bound by the Florida action. Other courts could redefine the market in those cases, or refuse any form of contribution under their public policy. In any event, it would spawn a proliferation of law suits, each with extremely high and duplicative litigation costs, thus destroying any practical ability to spread the cost.

The argument that forms of vicarious, industry wide liability would provide greater incentives for safety is also fallacious. One cannot reasonably be responsible for another's product. Sheffield v. Eli Lilly & Co., supra, 144 Cal. App. 3d at 597, 192 Cal. Rptr. at 878; Zafft at 247. As noted in Fischer, 34 Vand. L. Rev. at 1653-1658, the risk of "over

deterrence" is extremely high. If liability can attach because of a speculation based on fluxuating "market shares," regardless of a particular manufacturer's care or testing, because of hind sight developments 20 - 30 years later, where is the incentive for care and safety?

In inviting this Court to create a right of action unknown at common law, Plaintiff's reliance on Article I, 921, Florida Constitution is misplaced. That provision must be read in conjunction with the due process clause, Article I, §9, Florida Constitution. Article I , 921, does not guarantee a "remedy" to a plaintiff who cannot prove causation. The Plaintiff and Amici overlook the fact that the power of the courts of Florida to dispense with common law concepts of causation is quite limited. Under 92.01, Florida Statutes (1985), in force and effect since 1829, the common law as of July 4, 1776, is codified. Where, as here, the common law was clear and there was no doubt as to its force and effect, it has been held that the courts are, in fact, without power to change the common law:

> The court has no more right to abrogate the common law than it has to repeal the statutory law.
>
> * * *
>
> Under our constitutional system of government, however, courts cannot legislate. They cannot abrogate, modify, repeal, or amend rules long established and recognized as parts of the law of the land.
>
> * * *
>
> The courts of this jurisdiction do, and properly so, take into account the changes in our social and economic customs and present day conceptions of right and justice. But the

> fact remains, as this Court said in Ripley v. Ewell, 'when the common law is clear we have no power to change it'.
>
> [State v. Egan, 287 So.2d 1, 6-7 (Fla. 1973)].[17/]

For this Court to adopt any of the Plaintiff's theories, it would be forced into guessing at the extensive, far reaching consequences of such a change in a fundamental policy of the common law. The ramifications of such changes cannot be determined in any single case. Before a court should change a specific rule, and common law policy, it should at least be able to foresee with reasonable clarity the results of its decision and to say that such a change will best serve societal interests as a whole.

To adopt Plaintiff's and Amici's theories of industry wide liability would result in a denial of both substantive and procedural due process to defendants because those theories unfairly

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17/ The fact that Gates v. Foley, 247 So.2d 40, 43 (Fla. 1971), receded from Ripley v. Ewell, 61 So.2d 420, 423 (Fla. 1952), and the common law rule which did not recognize a wife's loss of consortium because of the radical changes in the reasons underlying the common law, does not negate the validity of the approach to the common law under 52.01, supra, recognized in either Ripley or Egan. As noted in Gates, the question of a wife's right to consortium concerned primarily limited judicial concerns, as opposed to consideration of broader social policies and the interrelations between various segments of society, which is the primary function of the Legislature to balance, and not the courts. Moreover, when Gates was decided there had been a substantial constitutional and statutory changes which had effectively negated the reasoning and viability of the common law rule. 247 So.2d at 44.

shift burdens of proof and do nothing more than create a mandatory presumption of liability without proof that it was "more likely than not" that the defendants' product caused the Plaintiff's injury.

Certainly, this Court has not seen fit to impose theories of recovery which do not meet the traditional "more likely than not" standard of an individual defendant's liability. In Gooding V. University Hospital Building, Inc., supra, quoting from Cooper V. Sisters of Charity of Cincinnati, Inc., 27 Ohio St.2d 242, 251-252, 272 N.E.2d 97, 103 (1971), this Court aptly stated:

> Lesser standards of proof are understandably attractive in malpractice cases where physical well being, and life itself, are the subject of litigation. The strong intuitive sense of humanity tends to emotionally direct us toward a conclusion that in an action for wrongful death an injured person should be compensated for the loss of any chance for survival, regardless of its remoteness. However, we have trepidations that such a rule would be so loose that it would provide more injustice than justice.

The Supreme Court of Missouri in Zafft at 247 refused to abandon the fundamental concept of tort law which requires proof of a nexus between wrongdoing and injury because of countervailing policy considerations.

More often than not, juries and courts, in their zeal to compensate an injury to a particular individual plaintiff, fail to consider (from a lack of a proper record or otherwise) the negative effect that a decision will have upon a broader segment of society than the particular individual plaintiff.

The Supreme Judicial Court of Massachusetts in Payton, 437 N.E.2d at 188-190, on certification of questions from the Payton, 512 F.Supp. Court, refused to answer the question of whether Massachusetts recognized market share theories of liability, because of the formulation of the question and the state of the record necessary to make an informed policy decision. Nevertheless, its discussion, which assumed that the defendants will be shown to have been negligent and actively participated in marketing DES (437 N.E.2d at 188), evidences considerable doubt as to the validity and social utility of the theories because of the potential adverse effect upon society as a whole. The Court exercised commendable restraint in refusing to create new theories in a vacuum:

> The posture of the case and consequent state of the record, the magnitude of the ramifications of our decision with respect to this certified question, and our view of the judicial process combines to convince us that such a course of action is imprudent at this time.
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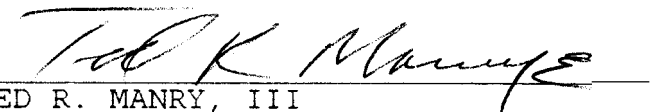
> [437 N.E.2d at 190].

CONCLUSION

For the foregoing reasons, the Dismissal of the Complaint should be affirmed.

Respectfully submitted,



TED R. MANRY, III
MACFARLANE, FERGUSON, ALLISON & KELLY
Post Office Box 1531
Tampa, Florida 33601
(813) 223-2411
ATTORNEYS FOR RESPONDENT
THE UPJOHN COMPANY

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a copy of the foregoing has been furnished by U.S. Mail to the following list of Counsel of Record in this cause this **24th** day of February, 1986.

Dianne J. Weaver, Esq.
P. O. Box 14663
Fort Lauderdale, FL 33302

Diane H. Tutt, Esq.
2400 AmeriFirst Building
One Southeast Third Avenue
Miami, FL 33131

Hugh J. Turner, Jr., Esq.
James L. Armstrong, Esq.
1301 Alfred I. duPont Bldg.
Miami, FL 33131

Lamar D. Oxford, Esq.
P. O. Box 2928
Orlando, FL 32802

Robert Jordan, Esq.
Valerie Shea, Esq.
P. O. Box 14723
Fort Lauderdale, FL 33302

Richard A. Kupfer, Esq.
P. O. Box 3466
West Palm Beach, FL 33402

Jack W. Shaw, Jr., Esq.
1500 American Heritage Life Bldg.
Jacksonville, FL 32202

Peter Perlman, Esq.
388 South Broadway
Lexington, KY 40508

Susan Powell Sistare, Esq.
633 S.E. Third Avenue
Suite 4F
Fort Lauderdale, FL 33302

H. Jackson Dorney, Esq.
Suite 405, Dart Building
2101 North Andrews Avenue
Fort Lauderdale, FL 33311

Ted K Mann
ATTORNEY