



A Division of The Society of The Plastics Industry, Inc.

RECEIVED

AUG 29 1987

Sherry M. Carr

Roy T. Gottesman  
Executive Director

August 26, 1987

TO: The Vinyl Institute Legal Committee

RE: New York State PVC Tort Revival Provision

Please refer to my memorandum to you of August 12th in which I forwarded the letter and complaint received by BFGoodrich Company in the Mary Lampo et al The BFGoodrich action.

I have now received the enclosed letter from Peter de la Cruz with a status report on this provision which is self-explanatory. I particularly call your attention to the "peculiar" provision in New York State procedural rules which allows an additional 60 days for service to a defendant meaning that we will not know until late September if there are any additional PVC-related cases.

As before, if any of you have received complaints under this provision, please let me know.

Roy

RTG/pmb  
enclosure

CTL028821

LAW OFFICES  
**KELLER AND HECKMAN**

1150 17<sup>TH</sup> STREET, N.W.  
SUITE 1000  
WASHINGTON, D.C. 20036  
—  
(202) 956-5600

August 25, 1987

**RECEIVED**

AUG 26 1987

DR. R. T. GOTTESMAN

SCIENTIFIC STAFF  
DANIEL S. DIXLER  
DURWARD F. DODGEN  
CHARLES V. BREDER

TELEX  
48 95531

TELECOPIER  
(202) 296-7662

CABLE ADDRESS "KELMAN"  
WRITER'S DIRECT DIAL NUMBER

JOSEPH E. KELLER  
JEROME H. HECKMAN  
CHARLES M. HECKMAN  
WILLIAM M. BORGHESE, JR.  
MALCOLM D. MACARTHUR  
WAYNE V. BLACK  
MARTIN W. BERGOVICI  
JOHN S. ELDRED  
CAROLE C. HARRIS  
MICHAEL F. MORRONE  
MARK FOX EVENS  
JOHN B. DUBECK  
PETER L. DELACRUZ  
CHRISTINE A. NEAGHER  
SHIRLEY S. FUJIMOTO  
LAWRENCE P. HALPRIN  
RALPH A. SIMMONS  
PETER A. SUSSER  
EDWARD L. KORWEK

TERRENCE D. JONES  
MARY MARTHA MCNAMARA  
JOHN B. RICHARDS\*  
C. DOUGLAS JARRETT  
SHEILA A. MILLAR  
RUSSELL H. FOX  
JAN M. WAMSTED  
ILENE RINGEL KELLER  
SUSAN T. CONTI  
SUSAN J. BLUM  
PATRICK J. MURDO\*\*  
S. CRAIG TAUTFEST  
DAVID M. JETT  
MAUREEN A. O'CONNELL\*\*  
KAREN E. EDELBERG\*  
NINA M. BINSTEIN\*\*\*  
BRIAN O. RONDON\*\*\*  
MARK A. SIEVERS\*\*\*

\*ADMITTED IN PENNSYLVANIA ONLY  
\*\*ADMITTED IN VIRGINIA ONLY  
\*\*\*ADMITTED IN MARYLAND ONLY

(202) 956-5641

Mr. Roy T. Gottesman  
Executive Director  
The Vinyl Institute  
Wayne Interchange Plaza II  
155 Route 46 West  
Wayne, New Jersey 07470

Re: Mary Lampo and David Lampo v.  
The B.F. Goodrich Company

Dear Roy:

To provide you with a status report on the New York State Toxic Tort Revival Provision, we contacted the attorneys representing the asbestos defendants as well as the DES manufacturers. We learned that there are 1200 to 1500 asbestos cases that have been brought under this revival revision. Frankly, they told us that they were expecting more cases and, therefore, they are not sure if they are going to take the same hard-nosed legal position that they originally anticipated. The DES manufacturers estimate that there are 500 to 600 cases that have been brought against them under this provision.

In late July, the DES defendants presented their "un-constitutionality argument" before Judge Gammerman who is a New York State trial court judge. After approximately 20 minutes of argument the judge found the statute constitutional. As soon as the order of judgement is entered, they will have 30 days within which to appeal. It is the opinion of their lawyer that the case will be appealed, however, the companies are evaluating the opinion very closely.

Both lawyers warned me that we could have suits pending and not know about them because of a peculiar provision in the New York procedural rules. Apparently, if a plaintiff has dif-

CTL028822

KELLER AND HECKMAN

Mr. Roy T. Gottesman  
August 24, 1987  
Page 2

ficulty in serving a defendant, the plaintiff can serve the summons on the sheriff (which will toll the running of the statute of limitations) and then have an additional sixty days to serve the party. Accordingly, we will not know if we are completely out of the danger zone until late in September when that 60 days runs.

Enclosed for your review is a copy of Judge Gammerman's decision. Should you have any questions or desire further information, please do not hesitate to contact me.

Sincerely yours,



Peter L. de la Cruz

Enclosure

CTL028823

**HYMOWITZ v. ELL LILLY & CO.**—In this pharmaceutical product liability action, plaintiff Mindy Hymowitz alleges that she developed cancer as a result of prenatal exposure to diethylstilbestrol ("DES"), a synthetic estrogen taken by her mother in 1954 during pregnancy to prevent possible miscarriage.

Plaintiff was born on Dec. 11, 1954. The cancerous condition for which plaintiff seeks damages allegedly appeared in 1979. Under the statute of limitations then applicable (CPLR 208, 214) plaintiff was barred from commencing suit in December, 1975 (three years after reaching the age of majority). Plaintiff brings this action, however, under the provisions of the 1986 revival statute (L. 1986 ch. 682 §4). Plaintiff moves pursuant to CPLR 3212 to strike affirmative defenses raised by some defendants challenging the constitutionality of the revival statute and alleging that the action is time barred under the statute of limitations otherwise applicable.

Defendants Ell Lilly and Co. ("Lilly") (Abbott Laboratories ("Abbott") and The Upjohn Company ("Upjohn") seek summary judgment and dismissal of the complaint as barred by the statute of limitations absent the availability of the allegedly unconstitutional revival statute.

Defendant E. R. Squibb & Sons ("Squibb") opposes the relief sought by plaintiff and contends that before the issue of the constitutionality of the revival statute is determined further discovery is required on the issue of whether such extraordinary circumstances exist in this case to justify invocation of the statute which Squibb also contends is unconstitutional. (Squibb further urges that discovery is needed to determine whether plaintiff can identify the manufacturer of the DES actually taken by her mother.)

The revival portion of the 1986 tort reform legislation provides that actions seeking damages for personal injury, property damage or death caused by the latent effects of exposure to five substances (DES, asbestos, tungsten-carbide, chlordane and polyvinyl-chloride) that were time barred or dismissed, as of the effective date of the statute, may be instituted "... within one year from the effective date of this act." The statute was passed on July 1, 1986 and was signed by the Governor on July 30, 1986.

In addition to the revival provision for the five specified substances (§4), the new tort reform legislation adopted a general discovery based statute of limitations for injuries caused by latent effects of exposure to any substance (CPLR 214-c(2)). Under subsection 2, a victim may assert a cause of action within three years from the date of the injury was or should have been discovered.

The provision for revival of claims (§4) and the discovery based statute of limitations (§2) were intended by the Legislature to remedy the perceived injustice caused by the application of CPLR §214, 208 (the exposure based statute of limitations), and to provide legal recourse for injuries caused by latent effects of toxic substances. Both provisions were enacted to remedy the failure of the old statute to recognize that such injuries may not appear until years after exposure, long after the expiration of the period within which actions may be instituted.

Legislative history indicates that the five named substances were distinguished from other toxic substances (§2) as a result of compromise between the Assembly (which had voted to permit revival for all toxic substances) and the Senate which wanted to limit revival. The Legislature ultimately limited revival based upon the

by the resulting ability to predict the future costs of such revival. The Legislature was apparently concerned that under a broader revival statute, the large number of unknown victims would create unpredictable risks and costs.

Defendants challenge the revival statute on equal protection and due process grounds, arguing that the statute is the result of an arbitrary and irrational political arrangement arrived at without rational guidelines of scientific certainty or public necessity. Defendant further argue that the legislative effort for limiting the number of potential claimants and costs is not related to the ostensible objective of the legislation, i.e. to allow victims of latent injuries to maintain actions. Defendants contend that the revival provision must be stricken on equal protection grounds, as an underinclusive random penalty without scientific basis, on five arbitrarily chosen substances and their manufacturers. It is contended that the prior exposure statute of limitations would be more than adequate for victims of the five specified substances.

Defendant Lilly urges that generally, chemical injury claims accrue at the time of exposure (here, in utero). Under the three year exposure based statute of limitations (tolled to the age of majority) claimants could bring suit until age 21. Lilly contends that the most DES patients develop cancer by the age of 19, and therefore, their claims would not be time barred before coming aware of their injuries.

Defendants also claim a violation of the due process clause, in that the statute constitutes an arbitrary deprivation of the substantive property right to rely upon the absence of the claims. Defendants assert that dismissal (or the passage of the applicable time bar) gives rise to substantive property rights which as a general rule, may not be abrogated and that the

exceptional circumstances to permit revival are not present (see *Gallewski v. H. Hertz & Co.*, 301 N.Y. 164).

Based upon the impact which they allege the substantive or property rights of defendants urge the applicability of strict scrutiny or an intermediate standard of review rather than a rational basis examination.

As a general rule, state statutes of limitation reviving time barred actions are not violative of due process. Statutes of limitation represent a public policy statement with respect to the privilege to litigate. "The history of pleas of limitations shows them to be good only by legislative grace and to subject to a relatively large degree of legislative control" (*Chase Securities Corp. v. Donaldson*, 325 U.S. 304, 314). The expiration of the applicable time period does not eliminate a cause of action but rather, suspends the court's power to grant a remedy (*Hulbert v. Clark*, 125 N.Y. 295). In other words, statutes of limitations relate to the availability of a remedy and not to the destruction of any fundamental right.

In the past, New York courts have upheld the power of the state legislature to extend or revise time barred claims. In *Gallewski v. H. Hertz & Co.* (301 N.Y. 164), the court found that a revival statute is not necessarily void as a taking of property without due process. The court stated that "The legislature may constitutionally revive a personal cause of action where the circumstances are exceptional and are such as to satisfy the court that serious injustice would result to plaintiffs not guilty of any fault if the intention of the legislature were not effected."

(262 A.D. 444, aff'd, 306 N.Y. 906) the court found that the legislature acted within the limits of the Constitution in extending the time period within which the victims of callosities disease could seek redress. The legislature sought to remedy the injustice caused to victims of a disease which in many cases did not produce symptoms until after the period for filing Workmen's Compensation claims has passed. The court found that under the circumstances, the legislature, by extending the time within which to institute a claim, was merely complying with the simple demands of justice.

A similar due process challenge was raised by manufacturers of Agent Orange regarding the constitutionality of the recent statute extending the time within which victims of dioxin could sue in New York (CPLR 214-b). There, as here, defendants challenged the law on the ground that it permitted commencement of actions already time barred under the New York statute of limitations otherwise applicable for injuries caused by toxic chemicals. In approving the proposed settlement of the Agent Orange litigation, the court (Weinstein, J.), rejected defendants' federal and state constitutional challenges to revival of otherwise time barred claims by the New York legislature (In re Agent Orange Product Liability Litigation, 597 F. Supp. 740 [E.D.N.Y. 1984]).

Here, as in *Gallewski v. McCann* and the Agent Orange case, the legislature, in reviving time barred causes of action, expressed the public policy of giving preference to plaintiffs' privilege to litigate over defendants' protection from stale or time barred claims. The issue raised is whether there is a reasonable connection between the revival statute and the promotion of a legitimate state interest, here, health, safety and welfare (*Nettleton Co. v. Diamond*, 27 N.Y. 2d 182, 193). In examining the constitutionality of statutes generally, the court must bear in mind the strong presumption that the legislature investigated the problem it addressed and discovered the need for the legislation passed (*Matter of Taylor v. Sae*, 33 N.Y. 2d 357). The court must determine: (1) whether the legislature was acting in pursuit of permissible state objectives and, if

so: (2) were the means adopted reasonably related to the accomplishment of those objectives (*Montgomery v. Daniels*, 38 N.Y. 2d 41, 84).

Here, the legislature acted within permissible objectives relating to health, safety and welfare by reviving causes of action based on latent effects of exposure to toxic substances.

Where a question of what the limits established is raised, the court should accept the opinion of the legislature (*Lincoln Bldg. Assoc. v. Barr*, 1 N.Y. 2d 413, 415, app. dism. 355 U.S. 12, citing *Old Dearborne Co. v. Seagram Corp.*, 299 U.S. 183, 196). In enacting the challenged statute, the legislature expressed the view that victims of the latent effects of certain toxic substances were being denied legal recourse by the automatic application of the exposure based statute of limitations often enough to justify an exception to its general application. A reasonable relationship exists between the reform and the objective of remedying the defects or inequities under the prior statute of limitations. There is considerable support for the position upon which the legislature acted: the need to provide a forum for innocent victims who might otherwise be time barred before becoming aware of their injuries. Indeed, this case is illustrative of that need. That studies or data may refute the legislative conclusions is not dispositive. As the Court of Appeals stated.

If the judiciary, however, is not called on to weigh the relative worth of data on to weigh the relative worth of data or arguments which may be marshaled on either side as to the wisdom of determination made by the Legislature in the realm of policy. Whether the enactment is wise or unwise, whether it is based on sound economic theory, whether it is the best means to achieve the desired result, whether, in short, the legislative discretion within its prescribed limits should be exercised in a particular manner, are matters for the judgment of the legislature, and the earnest conflict of serious opinion does not suffice to bring them within the range of judicial cognizance' (*Montgomery v. Daniels*, 38 N.Y. 2d 41, 52, quoting *Chicago, Burlington & Quincy R.R. Co. v. McGuire*, 219 U.S. 549, 569).

Given the substantial degree of legislative consideration to the need for the challenged tort reform, it would be inappropriate to express an opinion regarding the factual predicate for the statute, its philosophical justification or the wisdom of its enactment (see *Montgomery v. Daniels*, *id.* at 53). In addition, staleness of claims based on the loss of evidence over time is not of significance. Defendants have been litigating similar non-time barred DES cases for years.

Many of the same concepts relevant to the due process analysis are applicable to defendants' equal protection challenge. Defendants argue that the revival statute is underinclusive; it arbitrarily, without scientific basis singles out five substances for the additional burden of revival while excluding other toxic chemicals which cause latent injuries; it discriminates against out-of-state manufacturers; and it denies to defendant the protection of new Article 16 and the §2 discovery based statute of limitations.

Equal protection essentially requires that all persons similarly situated should be treated alike (*Plyer v. Doe*, 457 U.S. 202). As with the due process argument, the court must determine the appropriate standard to review. When social legislation relating to the public health is challenged, as here, the standard of review is rather narrow. The revival statute, contrary to defendants' contentions, does not classify on the basis of a suspect (or quasi-suspect) class or impair a fundamental right and therefore a strict scrutiny standard is not applicable. The legislation must be upheld if the challenged classification (targeting the five substances for the exclusion of other toxic chemicals causing latent injuries) is rationally related to a legitimate state purpose (*Western & S. Ins. Co. v. Board of Equalization*, 451 U.S. 648, 657; *Trump v. Chu*, 65 N.Y. 2d 20, 25).

Under the rational basis analysis, if any conceivable facts support the classification, there is no violation of the equal protection clause. A law may not be arbitrary or irrational and must be reasonably related to some "manifest evil" which need only be "reasonably apprehended." It is only as a last resort that courts will invalidate legislation as unconstitutional (*Maresca v. Cuomo*, 64 N.Y. 2d 242, 250). Further, the stated purpose justifying the statute need not be its primary purpose (*McGuinness v. Royster*, 410 U.S. 263, 276) and the court may even hypothesize the motives of the legislature to discern any conceivable legitimate goal furthered by the provision being attacked (*Maresca v. Cuomo*, *supra*, at 251, quoting *Weinberger v. Salft*, 422 U.S. 749, 790).

Defendants' objection to the distinctions drawn by the legislature between the five materials and other toxic substances is based partly upon the different treatment accorded the two groups under the 1984 tort reform bill. Defendants point to the additional burden of revival and the apparent inapplicability of Article 16 to the revival section. Examination of the provision (as it relates to DES cases) and the legislative history, reveals significant reasons to justify those distinctions, based upon the perceived realities of the latent effects of exposure to the five substances, the ability to ascertain a finite group of potential claimants and consequently to litigate their claims, and the economic costs of revival. Given the reasonable basis for the distinction drawn by the legislature, the alleged lack of scientific precision involved in drawing the line for revival may be disregarded. Here, the statutory classification does not result in such disparate treatment as to be arbitrary, irrational or invidiously discriminatory (see *Dandridge v. Williams*, 397 U.S. 471; see also *Parker 86th Associates v. City of New York*, 93 A.D.2d 388, 394, *aff'd* 59 N.Y.2d 888).

The legislation and the challenged classification, passes constitutional muster under a rational basis test or even under the more demanding intermediate standard ("somewhere along the sliding scale between strict scrutiny . . . and rational basis") (*Montgomery v. Daniels*, 38 N.Y.2d 41, 61). It cannot be said that the legislature acted unreasonably in selecting the five substances for special treatment. The constitution is not offended merely because the classification is not made with mathematical or scientific exactitude or because in practice it results in some inequity (*Dandridge v. Williams*, *supra* at 485; *Montgomery v. Daniels*, *supra*, at 63). In enacting reform legislation, the legislature is permitted to proceed one step at a time and to address the part of the problem that appears most serious (*Williamson v. Lee Optical Co.*, 348 U.S. 483, 489; *Montgomery v. Daniels*, *supra*, at 62).

Seen in its most fundamental light, defendants object to the fact that the line drawn by the legislature in enacting tort reform includes them. Whenever the legislature draws such a line some must be included, some excluded. As long as the line drawn is reasonable, the decision as to where to draw it is left to the legislature and not the judiciary (*Village of Belle Terre v. Boraas*, 416 U.S. 1, 8; *Montgomery v. Daniels*, 38 N.Y.2d 41).

Squibb maintains that a theory of liability under which a claimant may maintain an action without identifying the particular manufacturer of the DES taken by her mother is unconstitutional. Squibb contends that under the separation of powers doctrine such a radical restructuring of

traditional tort law must be left to the legislature. Based upon a mistaken belief that causation need not be shown under the challenged theories, it argues that absent causation plaintiff lacks standing and this court is powerless to provide a remedy.

Defendants' contention lack merit and wholly fail to meet the stringent burden to establish unconstitutionality.

Accordingly, plaintiff's motion to strike the affirmative defenses challenging the revival statute as unconstitutional and alleging that this action is time barred, is granted.

Defendants' cross motions for summary judgment and for dismissal of the action as barred by the statute of limitations are denied.

This constitutes the decision and order of the court.

**ELIZABETH TIGUE v. E.R. SQUIBB & SONS, INC.**—Defendants: Rexall Drug Company ("Rexall"), The Upjohn Company ("Upjohn") and Abbott Laboratories. ("Abbott") move pursuant to CPLR 3212 for summary judgment dismissing the complaint based upon the conceded inability of plaintiffs to identify the particular manufacturer of the drug, diethylstilbestrol, ("DES") to which they were allegedly exposed. Defendants contend that the right of recover on collective, non-identification or concerted action theories of liability has not been established in New York and urge the court to reject adoption of such theories. Defendants further contend that if concerted action is a viable basis of liability, it should not be applicable in a DES case. The motions are consolidated for disposition.

Plaintiffs seek to recover for injuries allegedly sustained by Elizabeth Tigue and Myrna Margolies (now deceased) as a result of the ingestion of DES by their mothers. Sayre Margolies proceeds on behalf of her daughter Myrna who died in 1977 at age 23, from clear cell-adenocarcinoma of the cervix and vagina, a rare form of cancer in young women, associated with prenatal exposure to DES. Plaintiff Elizabeth Tigue was diagnosed as having vaginal adenocarcinoma, a pre-cancerous condition associated with DES exposure, in which glandular tissue normally found in the cervix is found in the vagina. Plaintiffs' complaints allege breach of warranty, negligence, strict liability, *res ipsa loquitur*, concerted action and aiding and abetting-strict liability.

#### Historical Background:

DES is a synthetic hormone that duplicates the function of estrogen, a female sex hormone naturally present in women and, in lesser amounts, in men. Estrogen is essential for female sexual development and reproduction. DES was first synthesized in 1937 by British medical researchers. The drug was never patented, and thus, could be produced and marketed in the United States by any company obtaining Food and Drug Administration ("FDA") approval of a New Drug Application ("NDA").

By 1940 ten drug companies had filed NDAs requesting approval to produce and market DES for treatment of menopause, sterile vaginitis, gonorrheal vaginitis and suppression of lactation. None of the conditions for which this initial approval was sought related to pregnancy. These filings were rejected by the FDA, it determining that the review process would be facilitated by the pooling of clinical data produced by the drug companies into a master file which would form the data base for the FDA decision. In 1941, twelve pharmaceutical companies formed the "Small Committee" to pool this clinical data for submission to the FDA. The joint clinical data was incorporated in each company's resubmitted NDA and in September 1941, FDA approval was obtained for the use of DES. The Small Committee was thereafter disbanded.

In 1947 and 1948 a number of drug manufacturers filed supplemental NDAs for authorization to market DES, now for the treatment of certain pregnancy disorders relating to spontaneous abortion or fetal death. The dosage proposed for this treatment was many times stronger than the dosage previously approved in 1941. The

supplemental applications were primarily based upon studies by two independent researchers reported that the administration of additional estrogen in certain high risk pregnancies appeared to reduce the risk of miscarriage. FDA approval for use of the drug in pregnancy was then given. Lack of Product Identification:

The fundamental issue raised here (and the major problem facing these and many other plaintiffs in these DES cases) is their inability to identify the manufacturer of the DES taken by the mothers of the injured women and, thus, to directly connect the injury to a particular defendant.

The DES taken by pregnant women was produced under a chemically identical formula and usually manufactured and prescribed generically. Apparently, many drug companies cannot locate or have failed to keep records of their DES market activity. Although that market was dominated by a small number of companies, entry and exit from the market was fluid and it is estimated that between 94 and 300 pharmaceutical companies manufactured or marketed DES from 1947 to 1971.

Injuries caused by prenatal exposure to DES appear many years later. Over time, the ability of a plaintiff to identify the manufacturer is, obviously reduced. The memories or records of those who could assist in identifying the manufacturer (parents, physicians, pharmacists and drug companies) fade or disappear.

#### Prior Holdings:

In this state, the general rule is that a plaintiff has the burden of proof on product identification (*Morrissey v. Conservative Gas Corp.*, 235 A.D. 625 [1953], *aff'd* 1 N.Y.2d 741 [1956]). However, several non-identification or collective liability theories have been proposed and in some cases signed, to deal with cases in which the manufacturer of a product cannot be identified.

In *Bichler v. Lilly & Co.*, (79 A.D.2d 317 [1st Dept. 1981], *aff'd* 55 N.Y.2d 571 [1982]), a theory of concerted action liability was the basis of recovery even though the defendant was not identified as the manufacturer of the particular DES taken by the plaintiffs mother. Indeed in *Bichler*, the jury found that the plaintiff had not established that Lilly manufactured the DES taken by her mother.

Two theories of concerted action were submitted to the jury: concerted action by implied agreement and concerted action by substantial assistance. The jury was instructed that concerted action by agreement could be inferred from evidence of consciously parallel actions, that such consciously parallel action could be the basis of a finding that the drug companies had impliedly agreed to market DES for pregnancy use without first testing the drug on pregnant mice. The trial court's charge with respect to concerted action by substantial assistance permitted the jury to find that the failure to test DES on pregnant mice by defendant Lilly substantially aided or encouraged other companies (including, presumably, the company that marketed the DES taken by plaintiff's mother) to market without appropriate testing.

The jury found that Lilly had acted in concert, that the failure to test was wrongful and that the injurious effects of DES were foreseeable. On appeal to the Appellate Division, defendant argued that the trial court's concerted action charge was erroneous, and argument that the court addressed on its merits.

The Appellate Division found sufficient evidence to support the jury's findings and, in effect, adopted the concerted action theory of liability charged by the trial court. When *Bichler* reached the Court of Appeals, a determination was made that Lilly had failed to properly except to the trial court's charge on concerted action and concerted action liability was applicable only as the law of the case. The Court concluded that there was adequate evidence to support concerted action liability by conscious parallelism or substantial assistance. The Court of Appeals (unlike the trial court and the Appellate Division) based its finding solely by events beginning in 1947 (formation of identical chemical standards, marketing DES without testing on pregnant mice, reliance upon the same studies to support supplemental NDAs) and indicated that the 1941 collaboration to secure approval for non-pregnancy use, had no bearing upon concerted action relating to the 1947 supplemental NDA for pregnancy use (*Bichler v. Lilly & Co.*, 55 N.Y.2d 571, 583, n.7).

In *Kaufman v. Lilly & Co.*, (65 N.Y.2d 449, 456, the court stated: "...we expressed no view in *Bichler* and, express none now, on which of the proposed theories - concerted action, alternative liability, enterprise liability or market share liability - if any, should be adopted in this or similar DES cases (see, *Bichler v. Lilly & Co.*, supra, at p. 550, n.5). The question is still an open one in New York."

#### Discussion:

Defendants correctly contend that the applicability of the various "collective liability" theories (including concerted action) to DES fact patterns has not been finally ruled upon by the Court of Appeals. Nevertheless, the First Department clearly recognized and expressly adopted the concerted action theory for DES cases (*Bichler v. Lilly & Co.*, 79 A.D.2d 317; *Kaufman v. Lilly & Co.*, 99 A.D.2d 695; see, *Carrao v. Heitler*, 117 A.D.2d 308, 313).

Since plaintiffs, at least in this Department, may proceed on a collective or concerted action liability theory, the inability to identify the actual manufacturer of the DES taken by Mrs. Tigue and Mrs. Margolies is not fatal. Plaintiffs' factual allegations to support a finding of concerted action are substantially the same as those pleaded in *Bichler* and clearly state a viable cause of action for concert by agreement or substantial assistance.

As in *Bichler*, plaintiffs contend that a finding of concert by conscious parallelism or substantial assistance may be supported based upon the formation of identical chemical standards for DES in pregnancy, the marketing of the drug without prior testing on pregnant mice and the drug companies' reliance upon the same studies in supplemental NDAs. Plaintiffs also rely on defendants' activities leading to the FDA approval for non-pregnancy use based upon the contention that their supplemental NDAs relied upon the earlier filings. Whether the requests for approval of DES for use in pregnancy relied upon the earlier filings presents an issue of fact which cannot be determined on a motion for summary judgment. Similarly, defendant's claim that the actions by the drug companies in gaining FDA approval of DES (whether for non-pregnancy or pregnancy use) and their actions with regard to the manufacture, marketing and distribution of DES for use in pregnancy constitute concerted action sufficient to impose liability are questions for the trier of fact.

In addition, plaintiffs apparently seek to impose industry wide liability based upon wrongful failure to test and subsequent generic marketing and dispensing of DES. Plaintiffs' basic theory is that "but for the development, manufacture, distribution and sale of DES by the defendants, plaintiffs would not have suffered the injuries which they have suffered."

Plaintiffs contend that under their "but for" analysis, in addition to concert, they would be permitted to recover under various non-identification theories: enterprise liability (Hall v. E. I. DuPont de Nemours & Co., 345 F. Supp. 353 [EDNY] 1972); alternative liability; market share liability (Sindell v. Abbott Laboratories, 163 Cal.

Rptr. 132, 607 P. 2d 924) cert. denied, 449 U.S. 912; risk contribution (Collins v. Eli Lilly & Co., 116, 3423 N.W.2d 37 cert. denied, 469 U.S. 826).

This Court declines to rule at this time on the applicability to DES cases of each of the various theories of liability (in addition to concerted action), which are not specifically pleaded but are raised in response to defendants' motions. The only question raised on the motions before this court is whether defendants may be held liable absent product identification and the answer is yes.

#### Claims of Exculpation:

Defendants Rexall and Upjohn contend that under any collective liability theory, a defendant who can establish that its product could not have caused plaintiffs' injury may exculpate itself from liability. While exculpation may be theoretically possible (certainly under market share liability), even if the product of a particular manufacturer could be excluded a defendant may bear legal responsibility based on joint activity, encouragement or assistance in bringing a harmful product into the stream of commerce.

#### Constitutional Attack:

Rexall further contends that any theory of liability (including judicially established tort doctrines) under which liability may be imposed without "causation-in-fact," presumably product identification, is unconstitutional as an excessive burden on interstate commerce and violative of the due process and equal protection clauses. Further, it argues, that imposing market share and enterprise liability frustrate expressed federal policies regarding the marketing of prescription drugs and thus violate the supremacy clause.

Defendant Rexall's due process challenges are unavailing. Under the various theories discussed above, the requirement of traditional product identification is merely relaxed based on a finding that each defendant by its tortious behavior caused or contributed to plaintiffs' injuries. Under these theories, liability may be premised upon the tortious behavior of each defendant, whose adherence to a cause of conduct resulting in an unsafe standard, perpetuates the standard.

Fundamentally, imposition of liability absent product identification is based on policy grounds. As a matter of equity, the tortfeasor (who is in the best position to absorb the cost and to take the precautions) rather than the innocent victim, should bear the cost of injury. Defendants can be held responsible for wrongful conduct of omissions that result in placing a generic/fungible harmful product on the market.

Rexall's equal protection challenge amounts to no more than a fairness argument which does not rise to constitutional proportions. Equal protection is not synonymous with absolute equality (see *Dandridge v. Williams*, 397 U.S. 471; *People v. Parker*, 41 N.Y.2d 21; *Parker 16th Associates v. City of New York*, 93 A.D.2d 338, aff'd, 59 N.Y.2d 930).

Rexall's federal preemption claim also lacks merit. "The criteria for determining whether there has been federal preemption are (1) the pervasiveness of the federal regulation, (2) the dominance of the federal interest, (3) the federal and state objectives to be obtained, and (4) the existence of actual conflict between the state and federal statutes, including whether the state law is an obstacle to the purposes and objectives of Congress" (*Pharmaceutical Soc. of State of New York v. Lefkowitz*, 546 F.2d 953, 958 [2d Cir., 1978]). Application of these criteria precludes a finding of federal preemption. The primary objectives of the federal law is controlling product safety and efficacy (id., p. 953). The objective of the proposed theories of recovery is basic fairness, to provide a remedy to the innocent victims of wrongdoers.

Rexall contends that the imposition of liability without product identification burdens interstate commerce, by increasing the cost of products, reducing availability and limiting sales by discouraging development of new drugs, and by generally increasing the cost of doing business thereby precluding entry into the pharmaceutical business.

In determining whether there is an undue burden on interstate commerce, the test is whether "... the burden on interstate commerce is clearly excessive in relation to the putative local benefits" (id. at 957, quoting *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142). Here, the local benefit is providing a forum to innocent victims of alleged wrongdoing by relaxing the traditional product identification requirement in tort law. Clearly, a legitimate state interest is furthered. While adoption of a non-identification theory of liability could conceivably burden interstate commerce to the extent that the cost of such increased liability would be passed on to consumers through higher prices, "... [n]ot every exercise of local power is invalid merely because it affects in some way the flow of commerce between the States" (*Great Atlantic & Pacific Tea Co. v. Cottrell*, 424 U.S. 266, 371). Rexall has failed to demonstrate that the burden here would be clearly excessive compared to the benefit. Therefore, the commerce clause challenge also must fail.

Accordingly, defendants' motions for summary judgment dismissing the complaint are denied, and the matter is set down for trial on September 30, 1987.

(1) The twelve companies were: Abbott; Armour Laboratories; Ayerst, McKenna & Harrison, Ltd.; Geo. A. Brion & Co., Inc.; Charles E. Frost & Co.; Eli Lilly & Co.; Merck & Co., Inc.; Sharpe & Dohme, Inc.; E. R. Squibb & Sons; Upjohn Winifredo Chemical Company; and John Wyeth & Brothers, Inc. (Affidavit of Don Charles Hines, M.D., at p. 8).

**HYMOWITZ v. ELI LILLY & CO.**—In this pharmaceutical product liability action, plaintiff Mindy Hymowitz alleges that she developed cancer as a result of prenatal exposure to diethylstilbestrol ("DES"), a synthetic estrogen taken by her mother in 1934 during pregnancy to prevent possible miscarriage.

Plaintiff was born on Dec. 11, 1934. The cancerous condition for which plaintiff seeks damages allegedly appeared in 1979. Under the statute of limitations then applicable (CPLR 208, 214) plaintiff was barred from commencing suit in December, 1973 (three years after reaching the age of majority). Plaintiff brings this action, however, under the provisions of the 1986 revival statute (L. 1986 ch. 42 § 4).

Plaintiff moves pursuant to CPLR 3212 to strike affirmative defenses raised by some defendants challenging the constitutionality of the revival statute and alleging that the action is time barred under the statute of limitations otherwise applicable.

Abbott Laboratories ("Abbott") and The Upjohn Company ("Upjohn") seek summary judgment and dismissal of the complaint as barred by the statute of limitations absent the availability of the allegedly unconstitutional revival statute.

Defendant E. R. Squibb & Sons ("Squibb") opposes the relief sought by plaintiff and contends that before the issue of the constitutionality of the revival statute is determined further discovery is required on the issue of whether such extraordinary circumstances exist in this case to justify invocation of the statute which Squibb also contends is unconstitutional. (Squibb further urges that discovery is needed to determine whether plaintiff can identify the manufacturer of the DES actually taken by her mother.)

The revival portion of the 1986 tort reform legislation provides that actions seeking damages for personal injury, property damage or death caused by the latent effects of exposure to five substances (DES, asbestos, tungsten-carbide, chlordane and polyvinyl-chloride) that were time barred or dismissed, as of the effective date of the statute, may be instituted "... within one year from the effective date of this act." The statute was passed on July 1, 1986 and was signed by the Governor on July 30, 1986.

In addition to the revival provision for the five specified substances (24), the new tort reform legislation adopted a general discovery based statute of limitations for injuries caused by latent effects of exposure to any substance (CPLR 214-a2)). Under subsection 2, a victim may assert a cause of action within three years from the date of the injury was or should have been discovered.

The provisions for revival of claims (24) and the discovery based statute of limitations (32) were intended by the Legislature to remedy the perceived injustice caused by the application of CPLR 214, 208 (the exposure based statute of limitations), and to provide legal recourse for injuries caused by latent effects of toxic substances. Both provisions were enacted to remedy the failure of the old statute to recognize that such injuries may not appear until years after exposure, long after the expiration of the period within which actions may be instituted.

Legislative history indicates that the five named substances were distinguished from other toxic substances (32) as a result of compromise between the Assembly (which had voted to permit revival for all toxic substances) and the Senate which wanted to limit revival. The Legislature ultimately limited revival based upon the existence of an identifiable group affected by the resulting ability to predict the future costs of such revival. The Legislature was apparently concerned that under a broader revival statute, the large number of unknown victims would create unpredictable risks and costs.

Defendants challenge the revival statute on equal protection and due process grounds, arguing that the statute is the result of an arbitrary and irrational political arrangement arrived at without rational guidelines of scientific certainty or public necessity. Defendants further argue that the legislative concern for limiting the number of potential claimants and costs is not related to the ostensible objective of the legislation, i.e. to allow victims of latent injuries to maintain actions. Defendants contend that the revival provision must be stricken on equal protection grounds, as an indiscriminate random penalty without scientific basis, on five arbitrarily chosen substances and their manufacturers. It is contended that the prior exposure statute of limitations would be more than adequate for victims of the five specified substances.