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## DES AND THE IDENTIFICATION PROBLEM

by

BARRY S. ROBERTS\* and CHARLES F. ROYSTER\*\*

**D**IETHYLSTILBESTROL (DES), a synthetic estrogen, was developed in 1937<sup>1</sup> and was widely prescribed in the 1940's, 1950's and 1960's for pregnant women to prevent miscarriages.<sup>2</sup> The drug has caused a number of maladies to daughters who were exposed *in utero* to the drug, the most serious of which is clear cell adenocarcinoma, a rare form of vaginal cancer. The Food and Drug Administration (FDA) withdrew its approval of DES as a miscarriage preventative in 1971,<sup>3</sup> and since then the focus has shifted to products liability actions filed against the drug manufacturers. The plaintiffs have been largely unsuccessful in these actions, although some innovative judicial theories have recently been advanced in allowing recovery.

This article will examine the history of this drug, how it was used and regulated as well as the subsequent legal turmoil and the proffered resolutions to the quandary. The impact of these theories and of proposals to "further strengthen product liability laws as a substitute for direct government intervention"<sup>4</sup> will also be studied.

### I. DISCOVERY OF DES

Diethylstilbestrol was first synthesized in 1937 by Dr. E. C. Dodds at Oxford and Middlesex Hospital in England.<sup>5</sup> The abbreviation "DES" is used to designate diethylstilbestrol (which is also known as stilbestrol) and sometimes for the related synthetic estrogen, dienestrol, also discovered by Dr. Dodds.<sup>6</sup>

Diethylstilbestrol represented a tremendous improvement over the use of natural estrogens. Natural estrogens were very expensive due to the extensive

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<sup>1</sup>See *Ferrigno v. Eli Lilly & Co.*, 175 N.J. Super. 551, 562, 420 A.2d 1305, 1310 (1980); N. SWEIG, *DES: A Comprehensive Perspective* (1980) [hereinafter cited as SWEIG].

<sup>2</sup>Note, *Industry-Wide Liability*, 13 SUFFOLK L. REV. 980, 998 (1979).

<sup>3</sup>36 Fed. Reg. 21, 537-38 (1971). See Note, *Market Share Liability: An Answer to the DES Causation Problem*, 94 HARV. L. REV. 668, 668 n.6 (1981).

<sup>4</sup>Helms, *FDA, in Weidenbaum, On Saving the Kingdom*, REGULATION, Nov.-Dec. 1980, at 14, 28.

<sup>5</sup>*Ferrigno*, 175 N.J. Super. at 562, 420 A.2d at 1310. See also SWEIG, *supra* note 1, at 2.

<sup>6</sup>*Ferrigno*, 175 N.J. Super. at 562, 420 A.2d at 1310. Dienestrol suits should be kept separate from diethylstilbestrol suits. The term DES when used in this article should be read as diethylstilbestrol unless otherwise indicated.

hormone isolation process and had to be injected into the buttocks with the frequent side effect of abscesses.<sup>7</sup> DES was much less expensive and it could be administered orally.<sup>8</sup>

Dr. Dodds was not connected with any drug manufacture but rather was working under a grant from the Medical Research Council of Great Britain. Most significantly, Dr. Dodds never patented DES<sup>9</sup> which led to the manufacture of DES by many drug companies and to the tendency for doctors to prescribe the drug by its generic name (diethylstilbestrol).

## II. REGULATORY AND LEGAL STANDARDS

Drug regulation began in the United States in 1890 with limitations on the importation of adulterated or unwholesome food, drugs, or liquors.<sup>10</sup> This was followed by the Food and Drug Act of 1906 ("Wiley Act") which provided the first direct regulation of drug manufacturers.<sup>11</sup> However, the FDA was not created until passage of the first comprehensive statute in this area, the Federal Food, Drug, and Cosmetic Act of 1938, which remains the basis of United States drug law.<sup>12</sup>

The next major change in United States drug laws was passage of the Kefauver-Harris Amendment of 1962. This, most importantly, amended Section 505 of the 1938 Act to require drugs be effective as well as safe.<sup>13</sup> DES was originally approved and marketed under the 1938 Act.

Obviously, fulfilling the requirements of the FDA is a major concern of drug manufacturers. Compliance does not, however, fully end their legal responsibilities.<sup>14</sup> The products liability laws of the various states become applicable when anyone is harmed by a drug. Evidence of compliance with FDA requirements may be presented to the jury to show proper care and adequate testing, but such compliance is not conclusive on this issue.<sup>15</sup>

The law has made great strides to allow consumers legal redress against sellers and manufacturers. The law of products liability can be traced to the English case of *Winterbottom v. Wright*.<sup>16</sup> This case led the way for the elimina-

<sup>7</sup>Payton v. Abbott Labs, 512 F. Supp. 1031, 1032 (D. Mass. 1981).

<sup>8</sup>Ryan v. Eli Lilly & Co., 514 F. Supp. 1004, 1009 (D.S.C. 1981). DES costs approximately 1/300 as much as natural estrogens.

<sup>9</sup>*Id.* at 1009.

<sup>10</sup>See 26 Stat. 415 (1890).

<sup>11</sup>See 34 Stat. 768 (1906). See generally Janssen, *Outline of the History of U.S. Drug Regulation and Labeling*, 36 FOOD DRUG COSM. L.J. 420, 429-927 (1981) [hereinafter cited as Janssen].

<sup>12</sup>Food, Drug and Cosmetic Act of 1938, Pub. L. No. 75-717, § 505, 52 Stat. 1040, *as amended*, 21 U.S.C. §§ 301-91 (1976).

<sup>13</sup>76 Stat. 781, *as amended*, 21 U.S.C. § 355(b) (1976).

<sup>14</sup>See, e.g., *Ferrigno*, 175 N.J. Super. at 579, 420 A.2d at 1320.

<sup>15</sup>*Id.* at 579, 420 A.2d at 1320. Note, however, that if a violation of regulations is shown, a manufacturer is almost *per se* liable. Safir, *FDA Regulations and Product Liability*, 36 FOOD DRUG COSM. L.J. 478, 479 (1981) (citing RESTATEMENT (SECOND) OF TORTS § 826).

tion of the privity requirement in tort actions.<sup>17</sup> In 1963, in *Greenman v. Yuba Power Products, Inc.*,<sup>18</sup> a manufacturer was held strictly liable in tort for injuries sustained due to a defective product.<sup>19</sup> This case led the way toward the adoption of strict liability in tort.

The exposure of drug manufacturers can best be understood by analyzing Section 402A of the *Restatement (Second) of Torts*:

402A Special Liability of Seller of Product for Physical Harm to User or Consumer.

- (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate use or consumer, or to his property, if
  - (a) the seller is engaged in the business of selling such a product, and
  - (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.
- (2) The rule stated in Subsection (1) applies although
  - (a) the seller has exercised all possible care in the preparation and sale of his product, and
  - (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.<sup>20</sup>

The Restatement, moreover, is accompanied by a number of comments and guidelines. Most important for purposes of this article is Comment K entitled "Unavoidably Unsafe Products," which provides in pertinent part:

There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended or ordinary use. These are especially common in the field of drugs . . . Such a product, properly prepared, and accompanied by proper directions and warnings is not defective . . . It is . . . true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically

<sup>17</sup>Note, *supra* note 2, at 992. See W. PROSSER, HANDBOOK OF THE LAW OF TORTS § 96, at 641 (4th Ed. 1971). See *infra* note 20 and accompanying text.

<sup>18</sup>59 Cal.2d 57, 377 P.2d 897, 27 Cal. Rptr. 697 (1963).

<sup>19</sup>In *Greenman*, the plaintiff was injured when struck by a piece of wood thrown from a power tool manufactured by the defendant. The Supreme Court of California held the defendant strictly liable in tort, thereby avoiding obstacles under a warranty theory. See W. PROSSER, *supra* note 17, § 98, at 657.

<sup>20</sup>RESTATEMENT (SECOND) OF TORTS § 402A (1965).

recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situations call for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attendant with a known but apparently unreasonable risk.<sup>21</sup>

This exception recognizes the fact that drugs (and especially prescription drugs) cannot be made completely safe. This is in essence a decision that frequently the benefit and utility of the drug outweighs its risk, at least if proper warnings are given.<sup>22</sup> Therefore, drug manufacturers are held to the duties of adequately testing their products and of adequately warning of known dangers.<sup>23</sup> Some courts nevertheless have ruled that Comment K's insulation is lost and strict liability applies "(1) where the drug could not reasonably have appeared to be useful and desirable at the time of manufacture or (2) where, despite some apparent efficacy, the medically recognizable risk feasibly outweighed its utility."<sup>24</sup>

Regardless of the result of a Comment K analysis, three essential requirements remain under traditional products liability doctrine in order for the plaintiff to recover. "In order to recover, a plaintiff must show a product is defective, that the defective product is attributable to the party to be held responsible, and that the defect in the product caused the plaintiff's injury."<sup>25</sup> The second requirement has been articulated as the identification requirement. This is where the DES plaintiffs have the most problem. Due to the long time lapse since ingestion by their mothers, and poor recordkeeping by pharmacies and doctors, most plaintiffs "cannot identify the manufacturer of the drug ingested by their mothers."<sup>26</sup> The identification requirement has clearly been a crucial element. "It is a fundamental principle of products liability law that a plaintiff must prove, as an essential element of his case, that a defendant manufacturer actually made the particular product which caused injury."<sup>27</sup>

DES plaintiffs face many problems, both legal and practical. Among the legal problems are: class action certification; the possible running of the statute

<sup>21</sup>*Id.* at Comment k. See Safir, *supra* note 15, at 484.

<sup>22</sup>See W. PROSSER, *supra* note 17, § 99, at 661. Thus, even under products liability standards, plaintiffs frequently must show negligence in drug cases. Note, *Market Share Liability: An Answer to the DES Causation Problem*, 94 HARV. L. REV. 668, 669 n.12 (1981).

<sup>23</sup>Manufacturers must also warn of dangers they should have known.

<sup>24</sup>See, e.g., *Ferrigno*, 175 N.J. Super. at 577, 420 A.2d at 1319. This case indicated that DES did not appear to be reasonably efficacious at the time manufactured and therefore lost Comment k protection. The case then went on to create market share liability. See *infra* note 111 and accompanying text.

<sup>25</sup>Note, *Industry-Wide Liability*, 13 SUFFOLK L. REV. 980, 997 (1979).

<sup>26</sup>Comment, *DES and a Proposed Theory of Enterprise Liability*, 46 FORDHAM L. REV. 963, 972 (1978) [hereinafter cited as FORDHAM Comment].

<sup>27</sup>*Gray v. United States*, 445 F. Supp. 337, 338 (S.D. Tex. 1978) (citing HURSH & BAILEY, AMERICAN LAW OF PRODUCTS LIABILITY 2d § 1:41 (1974)). Note that the same requirement must also be met under a

of limitations; and denial of a cause of action because the injury was prior to birth or viability.<sup>28</sup> The biggest obstacle, however, as already indicated, is the identification requirement. This is the area in which courts have created new doctrine and is the principle focus of this article.

### III. MEDICAL AND REGULATORY HISTORY

As previously noted, DES was developed in 1937 by Dr. Dodds. Since it was not patented, many drug companies were interested in marketing it in the United States. In order to do so, a drug company had to file a New Drug Application (NDA) pursuant to § 505 of the Federal Food, Drug, and Cosmetic Act.<sup>29</sup> The NDA had to state proposed uses (indications), clinical data and studies establishing the safety of the drug, chemical composition, manufacturing method, and proposed labeling.<sup>30</sup>

The first NDA for DES was filed in 1939. Ten firms had made separate NDA filings by the end of 1940. These NDA's were for the following indications: "the treatment of post-menopausal symptoms, senile vaginitis, gonorrheal vaginitis, and suppression of lactation."<sup>31</sup>

The FDA then decided to ask the drug companies to pool their clinical data. According to Dr. Theodore Klumpp, the Chief of the Drug Division of the FDA at that time:

It was feared that to consider each [NDA] separately would present "an overwhelming problem" and so it was decided, "in the public interest," to request that the drug companies pool all their clinical materials and present them together. The companies apparently received this suggestion with little enthusiasm, but accepted it when it was pointed out that consideration of individually submitted data would mean delay in approving the applications. As a result, a committee, whose members represented the drug companies, was formed which put together and summarized all clinical data supplied by the individual pharmaceutical companies eventually presenting this data to the FDA.<sup>32</sup>

<sup>28</sup>FORDHAM Comment, *supra* note 26, at 968-71.

<sup>29</sup>52 Stat. 1040, *as amended*, 21 U.S.C. § 355(b) (1976).

<sup>30</sup>*Payton*, 512 F. Supp. at 1032-33. More specifically, the statute provides in § 505(b):

Any person may file with the Administrator an application with respect to any drug subject to the provisions of subsection (a). Such person shall submit to the Administrator as part of the application (1) full reports of investigations which have been made to show whether or not such drug is safe for use; (2) a full list of articles used as components of such drug; (3) a full statement of the composition of such drug; (4) a full description of the methods used in, and the facilities and controls used for, the manufacturer, processing, and packing of such drug; (5) such samples of such drug and of the articles used as components thereof as the Administrator may require; and (6) specimens of the labeling proposed to be used for such drug.

52 Stat. 1052 (1938). The 1962 Amendments added the requirement that the drug must be shown to be effective as well as safe. See 76 Stat. 781 (1962).

<sup>31</sup>See *Payton*, 512 F. Supp. at 1033.

<sup>32</sup>*Lyons v. Premo Pharmaceutical Labs, Inc.*, 170 N.J. Super. 183, 190-91, 406 A.2d 185, 189 (1979). Another case presented the possibility that at least some drug companies sought this pooling of data

The drug companies complied with this request and the “small committee” was formed in early 1941.<sup>33</sup>

The FDA, nevertheless, made further requests of uniformity. The companies were required to use the same *United States Pharmacopeia* standard so that the active ingredients of all DES products were the same.<sup>34</sup> The FDA also requested that uniform labeling (warnings and dosages) be used.<sup>35</sup> Finally, the FDA requested that the companies include a “permissions clause” in their NDA’s. This clause allowed any company to refer to the “master file” of clinical studies in their NDA’s.<sup>36</sup> In 1941, the FDA began approving the NDA’s for the four indications previously noted.<sup>37</sup>

Meanwhile, research was begun in the 1940’s into the use of DES in the treatment of problems of pregnancy. Apparently, all research was originally done by independent medical researchers,<sup>38</sup> although the drug companies later cooperated by supplying DES to the researchers.<sup>39</sup>

In 1947, several drug companies submitted supplemental NDA’s in order to market DES as a miscarriage preventative.<sup>40</sup> These applications referred to the independent research done, particularly that of Drs. O. Smith and George Smith of Boston.<sup>41</sup> The companies did not, however, conduct laboratory tests on pregnant laboratory animals.<sup>42</sup> This later became a claim of inadequate testing in several DES cases.

The FDA began approving these NDA’s in 1947 based upon all available information. Eventually approximately 300 companies marketed DES<sup>43</sup> in various dosages and for various indications.

In 1952 the FDA declared that DES was no longer a “New Drug” but

<sup>33</sup>See *Payton*, 512 F. Supp. at 1033.

<sup>34</sup>*Ferrigno*, 175 N.J. Super. at 563, 420 A.2d at 1311. See 21 U.S.C. §§ 321(j), 351(b) (1976).

<sup>35</sup>See *Payton*, 512 F. Supp. at 1033. This was largely achieved.

<sup>36</sup>See *Ferrigno*, 175 N.J. Super. at 563, 420 A.2d at 1311.

<sup>37</sup>*Id.* at 563, 420 A.2d at 1311. See *supra* note 2 and accompanying text.

<sup>38</sup>See *Lyons*, 120 N.J. Super. at 191, 406 A.2d at 189.

<sup>39</sup>See *Payton*, 512 F. Supp. at 1034.

<sup>40</sup>A supplemental NDA is required whenever the drug is recommended for a new indication, or a change in dosages or sizes. Any such change makes it a “new drug” within the definition of § 201(p) of the 1938 Act. 52 Stat. 1040 (1938).

<sup>41</sup>Reports of this research abounded in the medical literature starting around 1945. *Ryan*, 514 F. Supp. at 1010. Two key sources were later questioned: Karnky, *The Use of Stilbestrol for the Treatment of Threatened and Habitual Abortion and Premature Labor: A Preliminary Report*, 34 S. MED. J. 838 (1942); Smith, *Diethylstilbestrol in the Prevention and Treatment of Complications of Pregnancy*, 56 AM. J. OBSTETRICS & GYNECOLOGY 821 (1948). See generally FORDHAM Comment, *supra* note 26, at 963 n.2.

<sup>42</sup>See *Payton*, 512 F. Supp. at 1034; *Bichler v. Eli Lilly & Co.*, 79 A.D.2d 317, 322-23, 436 N.Y.S.2d 625, 629 (1981).

<sup>43</sup>See *Ryan*, 514 F. Supp. at 1011. The estimates vary considerably and the 300 figure may include distributors or packagers, see FORDHAM Comment, *supra* note 26, at 964, n.3. For other estimates see SWIG, *supra* note 1, at 2 (200 Firms); *Payton*, 512 F. Supp. at 1034 (a high of 151 firms); *Ferrigno*, 175 N.J. Super. at 565, 420 A.2d at 1312 (287 firms).

was instead “generally recognized as safe” under § 201(p) of the 1938 Act.<sup>44</sup> This meant that a drug company could now enter the DES market without submitting an NDA, thus prompting a great number of manufactures to enter the market.<sup>45</sup> The new companies had only to meet the manufacturing standards and to market the drug for the previously approved indications.<sup>46</sup>

During the period 1947-1971 DES was widely prescribed as a miscarriage preventative. It was estimated that between 500,000 and 2,000,000 pregnant women used the drug.<sup>47</sup> High dosages were needed when DES was used as a miscarriage preventative. The most popular tablet for this indication was the 25 mg. size. Multiple tablets of lower dosages, primarily 5 mg. and 10 mg., were also probably prescribed.<sup>48</sup>

In 1967, the National Academy of Sciences-National Research Council (NAS-NRC) completed its review, required by the 1962 Drug Amendments,<sup>49</sup> of the efficacy of DES. The NAS-NRC rated DES as “possibly effective” as a miscarriage preventative.<sup>50</sup> The FDA, however, delayed further action until 1971.<sup>51</sup>

By 1971, the link between DES used in pregnancy and the development of vaginal cancer in DES exposed daughters was well demonstrated.<sup>52</sup> This form of cancer, adenocarcinoma, is rare, and in fact the incidence rate in DES exposed daughters is still fairly low.<sup>53</sup> There have been approximately 250 reported cases of adenocarcinoma in DES exposed daughters.<sup>54</sup> Further, although the disease

<sup>44</sup>See 52 Stat. 1040 (1938), as amended, 21 U.S.C. § 321(p)(1) (1976).

<sup>45</sup>See *Ferrigno*, 175 N.J. Super. at 565, 420 A.2d at 1312.

<sup>46</sup>See *Ryan*, 514 F. Supp. at 1011.

<sup>47</sup>Comment, *Market Share Liability and DES — Sindell v. Abbott Laboratories: Square Pegs in Round Holes*, 13 CONN. L. REV. 373, 781 (1981). Another source estimated the exposure to be six million B. SEAMON & G. SEAMON, WOMEN AND THE CRISIS IN SEX HORMONES (1977) [hereinafter cited as SEAMON].

<sup>48</sup>SWEIG *supra* note 1, at 5.

<sup>49</sup>Kefauver-Harris Amendments, 76 Stat. 681 (1912), Pub. L. No. 37-781 (current version contained within 21 U.S.C. § 355(b) (1976)).

<sup>50</sup>“Possibly effective” was defined as having “little evidence of effectiveness under any of the criteria stated.” SEAMON, *supra* note 47, at 15. See generally 4 FOOD DRUG COSM. L. REP. (CCH) ¶71,068 (NAS-NCR review). The possible ratings are: “effective, probably effective, possibly effective, effective but (some countervailing consideration was named), or lacking substantial evidence of effectiveness for each label indication.” 4 FOOD DRUG COSM. L. REP. (CCH) ¶71,071 (DESI). Under the DESI (Drug Efficacy Study Implementations) program approval for a drug classified as less than effective will be withdrawn unless the manufacturer can submit sufficient evidence of effectiveness. *Id.* at ¶71,071.

<sup>51</sup>See SEAMON, *supra* note 47, at 14 (includes report of Rep. L. H. Fountain’s hearings on the delay).

<sup>52</sup>See *FERRIGNO*, 175 N.J. Super. at 565, 420 A.2d at 1312; Herbst, Ulfeder & Paskanzer, *Adenocarcinoma of the Vagina: Association of Maternal Stilbestrol Therapy with Tumor Appearance in Young Women*, 284 NEW ENGLAND J. OF MEDICINE 878 (1971); R. PATTERSON, MALPRACTICE AND PRODUCT LIABILITY ACTIONS INVOLVING DRUGS at 86 (1976).

<sup>53</sup>Div. of Cancer Control & Rehabilitation, National Cancer Institute, Department of Health and Human Services, DESAD Project, *Questions and Answers About DES Exposure During Pregnancy and Before Birth*, NIH Pub. No. 80-1118 at 7 (1980) [hereinafter cited as *DES Questions*], (incidence rate of approximately 1.4 out of 10,000).

<sup>54</sup>*Id.* at 9. Other estimates are as high as 350 to 400 cases. See Hecht, *DES: The Drug With Unsuspected Legacies*, FDA CONS. MAY 1979, at 14, 15 (350 cases). The number of adenocarcinoma cases being discovered should be declining since the peak discovery period is between 17 and 21 years of age and use



is serious, its treatment is extremely effective if it is detected in its early stages.<sup>55</sup>

DES daughters, nevertheless, suffer from other health problems as well. The most common is adenosis, which is the abnormal presence of glandular tissue in the vagina.<sup>56</sup> Current research indicates that adenosis is not a pre-cancerous condition<sup>57</sup> and that it may tend to disappear over time.<sup>58</sup> Apparently, daughters exposed earlier in pregnancy have a higher incidence of adenosis.<sup>59</sup> DES daughters have also developed structural abnormalities other than adenosis.<sup>60</sup> Furthermore, there is a slightly increased risk of an unfavorable pregnancy (for DES exposed daughters) according to the National Cooperative Diethylstilbestrol Adenosis Project (DESAD Project).<sup>61</sup> There does not, however, appear to be any carryover to the children of DES daughters as of yet, although research is continuing.<sup>62</sup> There have been some reports of non-cancerous abnormalities of DES exposed sons, but, it does not appear that there is any cancer risk.<sup>63</sup>

In 1971, the FDA issued a warning which required a labeling change which contraindicated the use of DES during pregnancy.<sup>64</sup> By contraindicating the use

of DES as a miscarriage preventative declined greatly after 1962 (NAS/NRC review). The 25 mg. dosage was not, of course, removed from the market until 1971 See *id.* at 15; *DES Questions, supra* note 53, at 3.

<sup>55</sup>*DES Questions, supra* note 53, at 7.

<sup>56</sup>Comment, *supra* note 47, at 782 (30-90% of exposed daughters developed adenosis). But see SWEIG, *supra* note 1, at 5 (contending that 39-40% develop adenosis).

<sup>57</sup>Hecht, *supra* note 54, at 15. See also Antonioli, Burke & Freidman, *Natural History of Diethylstilbestrol-Associated Genital Tract Lesions: Cervical Ectopy and Cervicovaginal Hood*, 137 AM. J. OBSTETRICS & GYNECOLOGY 841, 852-53 (1980).

<sup>58</sup>*DES Questions, supra* note 53, at 13.

<sup>59</sup>*Id.* at 10; Comment *supra* note 47, at 782 n.32.

<sup>60</sup>*DES Questions, supra* note 53, at 3.

<sup>61</sup>Barnes, Colton, Gundersen, Noller, Tilley, Strama, Townsend, Hatab & O'Brien, *Fertility and Outcome of Pregnancy in Women Exposed in Utero to Diethylstilbestrol*, 302 NEW ENGLAND J. OF MEDICINE 609 (1980). The DESAD Project studied 618 DES exposed daughters and compared them to a control group of 618. The DES daughters experienced a 38% rate of unfavorable outcome of pregnancy (miscarriage, premature birth, pregnancy outside the uterus, or still-birth). One observer analyzed the data as follows:

On a specific breakdown of these cases, we find that DES exposed daughters appear to have had a substantially higher pregnancy risk of the following problems:

- 1) a 69% higher risk of 'any unfavorable outcome';
- 2) a 61% increase in miscarriage;
- 3) a 177% increase in the chances of having a stillbirth or ectopic [outside uterus] pregnancy;
- 4) a 71% high level of premature births; and
- 5) an almost threefold increase of not having a full-term live birth.

SWEIG, *supra* note 1, at 4.

<sup>62</sup>See *DES Questions, supra* note 53, at 3.

<sup>63</sup>*Id.* at 4.

<sup>64</sup>36 Fed. Reg. 21, 537-38 (1971). The warning acknowledged the link with acenocarcinoma, and listed pregnancy as a contraindication. The required warning stated:

A statistically significant association has been reported between maternal ingestion during pregnancy of diethylstilbestrol and the occurrence of vaginal carcinoma developing years later in the offspring.

Whether such an association is applicable to all estrogens is not known at this time. In any event, estrogens are not indicated for use during pregnancy.

FORDHAM Comment, *supra* note 26, at 966 n.11. These FDA actions in effect removed the 25 mg. DES from the market since that size was only approved for use as a miscarriage preventative.

of DES as a miscarriage preventative, the FDA removed its approval of the drug for that use.

Thus, after 1971 DES was no longer used as a miscarriage preventative. It is very hard not to sympathize with the DES plaintiffs, especially those who have developed adenocarcinoma.<sup>65</sup> Yet, DES should not be viewed as a total mistake. It is still an approved drug for many indications, and several companies still produce it, although in lower dosages.<sup>66</sup>

#### IV. DES LITIGATION

The number of pending DES suits is tremendous. There are over 1,000 suits pending today.<sup>67</sup> As one writer observed, "given the magnitude of the potential liabilities, these DES cases in the aggregate appear to this writer very much like a tidal wave, still miles out to sea, but sweeping inexorably toward shore."<sup>68</sup>

Further, these products liability actions appear to be an inefficient method of compensating the plaintiffs. In a general drug products liability suit, one observer estimated that the plaintiff receives only thirty cents out of a dollar after attorney fees and costs are deducted.<sup>69</sup> As we have seen, DES cases are even more complicated than the average drug case. The defendant drug manufacturers obviously do not fare well either. The minimum defense costs of a "simple" DES case has been estimated at \$50,000.<sup>70</sup> The national total in claims alone could reach \$40 billion.<sup>71</sup>

Defendants have prevailed in the vast majority of DES cases decided to date;<sup>72</sup> the usual reason being the plaintiffs' failure to identify the manufac-

<sup>65</sup>There is much popular literature supporting the plight of the DES daughters. See e.g., SEAMAN, *supra* note 47; M. MERKIN, PREGNANCY AS A DISEASE (1977); J. BICHLER, DES DAUGHTER (1981).

<sup>66</sup>See Approved Drug List, 4 FOOD DRUG COSM. REP. (CCH) ¶ 71,247.04 (current manufacturers include Lilly, Squibb, Westward, Tablicaps, and Dome/Miles Labs); PHYSICIANS' DESK REFERENCE 1055 (35th Ed. 1981) [hereinafter cited as PDR]. Only Lilly is listed in the current PDR. The "boxed warning" required to appear on the labeling states: "1. PROLONGED USE OF ESTROGENS HAS BEEN REPORTED TO INCREASE THE RISK OF ENDOMETRIAL CARCINOMA. 2. ESTROGENS SHOULD NOT BE USED DURING PREGNANCY" *Id.* at 1055. Approved uses include severe menopausal symptoms, atrophic vaginitis, Kraurosis vulvae, female hypogonadism, female castration, primary ovarian failure, breast cancer, and prostate cancer *Id.* at 1055-56. Apparently, DES has also been used as a "morning-after pill" (post-coital contraceptive) despite lack of FDA approval and strong warning in the current PDR. See *id.* at 1055; R. PATTERSON, *supra* note 52, at 87.

<sup>67</sup>Podgers, *DES Ruling Shakes Products Liability Field*, 66 A.B.A.J. 827. See Comment, *Sindell v. Abbott Laboratories — A High Water Mark in Tort Law?*, 1981 UTAH L. REV. 655, 656.

<sup>68</sup>Henderson, *DES Litigation: The Tidal Wave Approaches Shire*, 3 CORP. L. REV. 143, 143 (1980).

<sup>69</sup>See P. MUNCH, COSTS AND BENEFITS OF THE TORT SYSTEM IF VIEWED AS A COMPENSATION SYSTEM (June 1977) (published thesis as part of Rand Paper Series) 29.

<sup>70</sup>See, Comment, *supra* note 47, at 802 n.137. Another scholar put the estimate closer to \$100,000. See SWEIG, *supra* note 1, at 7.

<sup>71</sup>See Henderson, *Products Liability*, 3 CORP. L. REV. 143, 148 (1980).

<sup>72</sup>*Sindell v. Abbott Laboratories*, 26 Cal. 3d 588, 597, 607 P.2d 924, 927, 163 Cal. Rptr. 132, 135-36, cert. denied. 449 U.S. 912 (1980). One large verdict for the plaintiff was recently overturned. *Needham v. White Laboratories*, 639 F.2d 934 (7th Cir. 1981) (dienestrol case). As of late 1980 one observer noted that no DES plaintiff has actually collected any damage payments due to appeals. See SWEIG, *supra* note

turer. The plaintiffs have attempted to overcome this obstacle by asserting two traditional theories, alternative liability and concert of action, as well as proffering two novel theories. The first of these novel theories was initially presented in a 1978 law review comment entitled "DES and a Proposed Theory of Enterprise Liability."<sup>73</sup> This excellent and often-cited article began the trend toward enterprise or market share liability. The second development was the California case of *Sindell v. Abbott Laboratories*.<sup>74</sup> *Sindell* proposed a market share approach to the DES identification problem. *Sindell* will first be discussed since it contains a discussion of all of the proposed theories.

### A. *Sindell*

In *Sindell* the Supreme Court of California held four-to-three that the plaintiff's action should not have been dismissed solely because the plaintiff could not identify the manufacturer of the DES they had been exposed to *in utero*. Instead of requiring specific identification, the Court said that upon a showing that the manufacturers joined as defendants<sup>75</sup> produced a "substantial percentage of the drug in question"<sup>76</sup> each manufacturer would be held liable for his share of the market.

In dissent, Judge Richardson noted practical and theoretical deficiencies in the majority's reasoning. The dissent felt that such a drastic change in products liability law should have a legislative rather than judicial source.<sup>77</sup> By obviating the required proof of cause-in-fact, the dissent observed that *Sindell* was indeed "a new high watermark in tort law."<sup>78</sup>

Plaintiff Judith Sindell brought suit against eleven drug companies and 100 "Does." She sued on behalf of herself and on behalf of all similarly situated women of California.<sup>79</sup> She developed a malignant bladder tumor which was surgically removed, and suffers from adenosis. Sindell stated that she was unable to identify the manufacturer, and her case was therefore dismissed at trial.<sup>80</sup>

1, at 12. Since that time a plaintiff has won an appeal although not at the highest level. See Bichler v. Eli Lilly & Co., 79 A.D.2d 317, 436 N.Y.S.2d 625 (1981) (verdict for \$500,000).

<sup>73</sup>FORDHAM Comment, *supra* note 26.

<sup>74</sup>*Sindell v. Abbott Laboratories*, 26 Cal. 3d 588, 607 P.2d 924, 163 Cal Rptr. 132, *cert denied*, 449 U.S. 912 (1980). Justice Mosk wrote the majority opinion, joined by Chief Justice Bird and Justices Newman and White.

<sup>75</sup>The defendants in *Sindell* were Abbott Laboratories, Eli Lilly & Co., E.R. Squibb & Son, the Upjohn Co., and Rexall Drug Co.

<sup>76</sup>*Sindell* 26 Cal. 3d at 612, 607 P.2d at 937, 163 Cal. Rptr. at 145.

<sup>77</sup>*Id.* at 614-22, 607 P.2d at 938-42, 164 Cal. Rptr. at 146-51. Joining Justice Richardson in dissent were Justices Clark and Manuel.

<sup>78</sup>*Id.* at 641, 607 P.2d at 938, 163 Cal. Rptr. at 146 (Richardson, J., dissenting).

<sup>79</sup>The proposed class consisted of "girls and women who are residents of California and who have been exposed to DES before birth and who may or may not have known that fact or the danger to which they were exposed." *Id.* at 593, 607 P.2d at 925, 163 Cal. Rptr. at 133 n.1.

<sup>80</sup>*Id.* at 595-96, 607 P.2d at 926, 163 Cal. Rptr. at 134. Plaintiff Maureen Rogers filed a similar suit. After the dismissal below, however, she amended her complaint to allege that Eli Lilly & Co. was the manufacturer of the DES taken by her mother. The *Sindell* opinion allows consolidation, but the reasoning applies to Rogers only if she later fails to adequately identify Eli Lilly as the manufacturer. *Id.* at 596-97, 607 P.2d

The *Sindell* opinion recognizes the plight of the plaintiff who cannot meet the identification requirement. It must be remembered that the identification problem in DES cases is due to the long latency period before the adverse reactions develop, the delay before the cancer relationship was established, and the fact that DES tended to have been marketed generically.<sup>81</sup>

*Sindell* then analyzed the case under several theories. It rejected the following: alternative liability;<sup>82</sup> concert of action;<sup>83</sup> and enterprise liability.<sup>84</sup> Each of these theories will be examined in later sections of this article.

After finding existing theories inapplicable, *Sindell* fashioned a new theory, market share liability. The Court, nevertheless, stated that the theory is merely a modification of the alternative liability theory of *Summers v. Tice*.<sup>85</sup> The *Sindell* majority boldly based its market share theory on the policy grounds that "as between an innocent plaintiff and negligent defendants, the latter should bear the cost of injury."<sup>86</sup> Justice Mosk observed:

In our contemporary complex industrialized society, advances in science and technology create fungible goods which may harm consumers and which cannot be traced to any specific producer. The response of the courts can be either to adhere rigidly to prior doctrine, denying recovery to those injured by such products, or to fashion remedies to meet these changing needs.<sup>87</sup>

Fashion a remedy they did. Under the market share liability theory, plaintiffs are required to join a "substantial share"<sup>88</sup> of DES manufacturers and prove that each was negligent. Each defendant is then allowed to show that his product could not have caused the plaintiff's harm. If not absolved, each defendant will be liable "by the percentage which the DES sold by each of them for the purpose of preventing miscarriage bears to the entire production of the drug by all for that purpose."<sup>89</sup>

The dissent too felt sorry for the plaintiffs, but felt that the majority's

<sup>81</sup>See *id.* at 601, 607 P.2d at 930, 163 Cal. Rptr. at 138; Comment, *supra* note 47, at 783.

<sup>82</sup>*Sindell* 26 Cal. 3d at 602-03, 607 P.2d at 930-31, 163 Cal. Rptr. at 138-39.

<sup>83</sup>*Id.* at 603-06, 607 P.2d at 931-33, 163 Cal. Rptr. at 139-41.

<sup>84</sup>*Id.* at 609, 607 P.2d at 935, 163 Cal. Rptr. at 143. The enterprise theory was as previously noted, proposed in the FORDHAM Comment, *supra* note 26.

<sup>85</sup>33 Cal. 2d 80, 199 P.2d 1 (1948). In *Summers*, the court shifted the burden of proof on causation from the plaintiff, who was struck by one bullet, to the two defendants, who had each negligently fired their guns while hunting. The defendants would face joint and several liability if neither could absolve themselves.

<sup>86</sup>*Sindell* 26 Cal. 3d at 610-11, 607 P.2d at 936, 163 Cal. Rptr. at 144. The *Sindell* court said that Comment h to RESTATEMENT (SECOND) OF TORTS § 433B(3) (the *Summers* rule) invited such a modification of the *Summers* rule if future conditions warranted.

<sup>87</sup>*Sindell*, 26 Cal. 3d at 610, 607 P.2d at 936, 163 Cal. Rptr. at 144.

<sup>88</sup>*Id.* at 612, 607 P.2d at 937, 163 Cal. Rptr. at 145. The FORDHAM Comment, *supra* note 26, states that this should be 75-80%, but *Sindell* leaves it open.

<sup>89</sup>*Sindell* 26 Cal. 3d at 612, 607 P.2d at 937, 163 Cal. Rptr. at 145. Defendants are also allowed to cross-complaint other manufacturers not originally joined.

solution was too large a break from prior doctrine. Justice Richardson stated:

The majority adopts a wholly new theory which contains these ingredients: The plaintiffs were not alive at the time of the commission of the tortious acts. They sue a generation later. They are permitted to receive substantial damages from multiple defendants without any proof that any defendant caused or even probably caused plaintiffs' injuries.<sup>90</sup>

The dissent would abide by prior case law which required identification unless the case fell within one of the exceptions that California recognizes, which even the majority dismissed as inapplicable.<sup>91</sup>

Since the plaintiff joined only five drug manufacturers, the dissent observed that it was far from certain that the manufacturer who actually caused the injuries was joined.<sup>92</sup> The majority countered this by their "substantial percentage" requirement and by noting that the plaintiff claimed that Eli Lilly and five or six other producers accounted for 90 percent of the DES market.<sup>93</sup> The dissent further argued that by having only 5 of 200 manufacturers, the alternative liability theory or its derivatives should be inapplicable.<sup>94</sup>

The dissent would adhere to the requirement that causation in fact be proven. Justice Richardson felt courts should resist the "deep pocket theory of liability" and further observed that plaintiffs who could not make a specific identification would be rewarded by "being offered both a wider selection of potential defendants and a greater opportunity for recovery."<sup>95</sup> In addition, Justice Richardson continued his assault by asserting:

<sup>90</sup>*Id.* at 614, 607 P.2d at 938, 163 Cal. Rptr. at 146 (Richardson, J., dissenting).

<sup>91</sup>*See also* McCrerry v. Eli Lilly & Co., 87 Cal. App. 3d 77, 150 Cal. Rptr. 730 (1978). In this case the Court of Appeals affirmed summary judgment for the defendants because the plaintiff admitted she could not identify the specific manufacturer of the DES her mother took. *Accord*, Gray v. United States, 445 F. Supp. 337 (S.D. Tex. 1978).

<sup>92</sup>*Sindell*, 26 Cal. 3d at 616, 607 P.2d at 939, 163 Cal. Rptr. at 147 (Richardson, J., dissenting). Remember that there were at least 200 manufacturers of DES, with some estimates as high as 300. *See supra* note 43 and accompanying text.

<sup>93</sup>*Sindell*, 26 Cal. 3d at 611-12, 607 P.2d at 937, 163 Cal. Rptr. at 145. Obviously developing this market data will be difficult, and estimates vary. The following table is one estimate:

Company	% Share — All Indications	% Share — Miscarriage Preventions
Eli Lilly	46	33
Squibb	9	10
Upjohn	6	7
Schering-Plough	1-2	3-4
American Home Products	1-2	3
Merck	1-2	3
Sterling Drug	1-2	2
Abbott Laboratories	1	1
All Others	32	36
	100%	100%

SWEIG, *supra* note 1, at 13.

<sup>94</sup>*Sindell*, 26 Cal. 3d at 615, 607 P.2d at 939, 163 Cal. Rptr. at 147 (Richardson, J., dissenting).

<sup>95</sup>*Id.* at 618, 607 P.2d at 941, 163 Cal. Rptr. at 149 (Richardson, J., dissenting).

The "market share" thesis may be paraphrased. Plaintiffs have been hurt by someone who made DES. Because of the lapse of time no one can prove who made it. Perhaps it was not the named defendants who made it, but they did make some. Although DES was apparently safe at the time it was used, it was subsequently proven unsafe as to some daughters of some users. Plaintiffs have suffered injury and defendants are wealthy. There should be a remedy. Strict products liability is unavailable because the element of causation is lacking. Strike that requirement and label what remains "alternative" liability; "industry-wide" liability, or "market share" liability, proving thereby that if you hit the square peg hard and often enough the round holes will really become square, although you may splinter the board in the process.<sup>96</sup>

The dissent concluded by observing the "omnious ramifications" of the majority's theory. It questioned whether the pharmaceutical industry should be made an insurer for any and all injuries attributable to drugs.<sup>97</sup> Justice Richardson suggested that a legislative approach would be preferable, in particular a system "which would establish and appropriate funds for the education, identification, and screening of persons exposed to DES, and would prohibit health care and hospital service plans from excluding or limiting coverage to person exposed to DES."<sup>98</sup>

### B. *Alternative Liability*

The case of *Summers v. Tice*<sup>99</sup> created the theory of alternative liability, or double fault and alternative liability.<sup>100</sup> In *Summers*, two hunters simultaneously and negligently fired their guns in the same direction. One bullet hit their companion, the plaintiff Summers. Clearly only one of the defendants actually caused the injury, but identification was not possible. The Court therefore shifted the burden of proof or cause-in-fact to the defendants. If they could not absolve themselves, joint and several liability results.<sup>101</sup>

The "DES Comment" argued that alternative liability could be used to solve the DES identification problem.<sup>102</sup> The author, however, admits that the reasoning must be strained a bit, but concludes that the theory is viable on policy grounds since the plaintiffs are innocent and the defendants were all tortfeasors.<sup>103</sup>

<sup>96</sup>*Id.* at 616, 607 P.2d at 939-40, 164 Cal. Rptr. at 147-48 (Richardson, J., dissenting).

<sup>97</sup>*Id.* at 621, 607 P.2d at 943, 163 Cal. Rptr. at 150-51 (Richardson, J., dissenting).

<sup>98</sup>*Id.* at 621-22, 607 P.2d at 943, 163 Cal. Rptr. at 151 (Richardson, J., dissenting). The legislature responded by enacting a DES Program. This program puts emphasis on finding and treating DES victims. It is funded by the state. CAL. HEALTH AND SAFETY CODE §§ 349.0-.5 (West Supp. 1982).

<sup>99</sup>33 Cal. 2d 80, 199 P.2d 1 (1948) See *supra* note 85.

<sup>100</sup>W. PROSSER, *supra* note 17, § 41, at 243. See RESTATEMENT (SECOND) TORTS § 433(3) (1965).

<sup>101</sup>See FORDHAM Comment, *supra* note 26, at 985; Note, *supra* note 2, at 1007-08.

<sup>102</sup>FORDHAM Comment, *supra* note 26, at 990-91.

<sup>103</sup>*Id.* at 991. The author would obviously prefer courts to use the enterprise liability theory however. In justifying alternative liability, the author analogizes the *res ipsa loquitur* cases and *Ybarra v. Spangard*,

Other commentators have rejected the alternative liability theory for DES cases.<sup>104</sup> The chief reason why *Summers* should not apply is that in *Summers* all the potentially responsible parties were joined, this is clearly not true in the DES cases. Indeed, it is quite possible that the actual defendant would not be before the court.<sup>105</sup> Other distinctions include that in *Summers*, the negligence caused the identification problem, yet in the DES cases the problem was largely caused by the lapse of time,<sup>106</sup> and in *Summers*, the defendants arguably had better access to the information than the plaintiff, although this is more questionable in the DES cases.<sup>107</sup>

The *Sindell* majority rejected the alternative liability theory for many of these same reasons. The key reason was that not all possible responsible parties were joined.<sup>108</sup> The Court also considered, but did not rest its decision on, the fact that the defendants had no greater access to information which might facilitate identification.<sup>109</sup> It must be remembered that this is the Court that decided the key precedents for the alternative liability theory, *Ybarra v. Spangard* and *Summers v. Tice*, and it found the theory inapplicable to DES cases.<sup>110</sup>

It seems clear that alternative liability cannot be the solution to the DES identification problem. The one authority which justified it, the "DES Comment," did so only as an alternative to its main proposed theory. As one author stated:

Applying the theory of alternative liability to DES litigation, wherein an entire industry may be held liable for an unforeseeable reaction to a product arguably produced in the public interest, goes far beyond the circumstances of a nonrecurring hunting accident. In the context of DES litigation, the benefit of alternative liability to the plaintiff's ultimate recovery may strain the very notion of "fairness" upon which the *Summers* decision was based.<sup>111</sup>

Nevertheless, some courts, including the lower court in *Sindell*, have employed

25 Cal. 2d 486, 154 P.2d 687 (1948) to the DES cases and concludes that if the majority of DES manufacturers are joined, then alternative liability can apply even though not all the potentially responsible parties are present. *Id.* at 988-95. In *Ybarra*, the plaintiff became paralyzed in his shoulder following an appendectomy. He sued the doctors and nurses who participated in the operation. The Supreme Court of California shifted the burden of going forward to the plaintiffs based largely upon alternative liability theory. *See id.* at 989-90.

<sup>104</sup>*See supra* note 47, at 784-91; Note, *supra* note 2, at 1008.

<sup>105</sup>Note, *supra* note 2, at 1008.

<sup>106</sup>*Id.* at 1009. Obviously the plaintiffs could argue that the drug manufacturers were negligent in their record keeping.

<sup>107</sup>Comment, *supra* note 47, at 788-89. Superior access to information may not be a requirement in order to shift the causation burden, but it is a factor to be considered. The drug manufacturers do not have better information since the drugs were distributed through distributors, and due to the passage of time physicians and pharmacy records have been lost or destroyed.

<sup>108</sup>*Sindell*, 26 Cal. 3d at 602, 607 P.2d at 931, 163 Cal. Rptr. at 139.

<sup>109</sup>*Id.* at Cal. 3d at 601-02, 607 P.2d at 930, 163 Cal. Rptr. at 138.

<sup>110</sup>*See supra* notes 99 and 103 and accompanying text.

<sup>111</sup>Comment, *supra* note 47, at 785.

the alternative liability theory in DES cases.<sup>112</sup> One case, *Abel v. Eli Lilly & Co.*,<sup>113</sup> held that the theory stated a sufficient cause of action, and another, *Ferrigno v. Eli Lilly*,<sup>114</sup> used alternative liability in fashioning a market share approach. It must be noted that *Ferrigno* was severely criticized in a subsequent case also before the New Jersey Superior Court, *Namm v. Frosst and Co.*<sup>115</sup> *Namm* flatly rejected the theory of alternative liability.<sup>116</sup>

### C. Concert of Action

The concert of action theory is based upon the requirement of a "common plan or design to commit a tortious act."<sup>117</sup> Actual agreement is not necessary, but the court must find a tacit understanding and tortious acts pursuant to the common plan. As with alternative liability, the defendants under a concert of action theory are held jointly and severally liable.<sup>118</sup>

The classic fact situation for concert of action to be applied is the illegal drag race. The agreement or tacit understanding can be inferred from the parallel conduct of the participants.<sup>119</sup>

This theory was argued in *Sindell*, and the "DES Comment" also argues it as a viable theory for DES cases. The "DES Comment" argued that the case of *Hall v. E. I. DuPont De Nemours & Co.*,<sup>120</sup> supports this position. In *Hall*, thirteen children were injured by the explosion of dynamite blasting caps.<sup>121</sup> The specific manufacturer could not be identified since all markings

<sup>112</sup>149 Cal. Rptr. at 150.

<sup>113</sup>94 Mich. App. 59, 289 N.W.2d 20 (1979).

<sup>114</sup>175 N.J. Super. 551, 420 A.2d 1305 (1980).

<sup>115</sup>178 N.J. Super. 19, 427 A.2d 1121 (1981).

<sup>116</sup>*Id.* at 34, 427 A.2d at 1128. *Namm* also rejected the theory of enterprise liability.

<sup>117</sup>W. PROSSER, *supra* note 17, § 41, at 292. The concert of action theory has very solid and old underpinnings. According to Prosser, the original concept was as follows:

All persons who acted in concert to commit a trespass, in pursuance of a common design, were held liable for the entire result. In such a case there was a common purpose, with mutual aid in carrying it out; in short, there was a joint enterprise, so that "all coming to do an unlawful act, and of one point, the act of one is the act of all of the same party being present."

*Id.*, § 46, at 291 and n.3 (quoting Sir John Heydon's Case, 1613, 11 Co. Rep. 5, 7 Eng. Rep. 1150). A current definition is:

All those who, in pursuance of a common plan or design to commit a tortious act, actively take part in it, or further it by cooperation or request, or who lend aid or encouragement to the wrongdoer, or ratify and adopt his acts done for their benefit, are equally liable with him.

*Id.*, § 46, at 292. The RESTATEMENT (SECOND) OF TORTS § 876 (1965).

For harm resulting to a third person from the tortious conduct of another, one is subject to liability if he (a) does a tortious act in concert with the other or pursuant to a common design with him or (b) knows that the other's conduct constitutes a breach of duty and gives substantial assistance to the other in accomplishing a tortious result and his own conduct, separately considered, constituted a breach of duty to the third person.

<sup>118</sup>W. PROSSER, *supra* note 17, § 46, at 291-92. It differs from alternative liability in that all defendants are jointly and severally liable with no opportunity to absolve themselves.

<sup>119</sup>See FORDHAM Comment, *supra* note 26, at 978-79.

<sup>120</sup>345 F. Supp. 353 (E.D.N.Y. 1972).

<sup>121</sup>*Id.* at 359.



on the caps were destroyed in the explosion.<sup>122</sup> The plaintiffs, therefore, sued the six American manufacturers of blasting caps and their trade association under the concert of action theory.<sup>123</sup> The court held for the plaintiffs upon finding that the manufacturers had known of the dangerous nature of their product but had agreed among themselves not to place warnings on the caps. The effect of this holding was to shift the burden of proof on identification to the defendants.<sup>124</sup> The “DES Comment” author contends that, in the DES situation there is enough conscious parallel behavior involved in the pooling of clinical data and other cooperative activity by the drug manufacturers in 1941 to find concerted action.<sup>125</sup>

The *Sindell* Court nevertheless refused to apply the concert of action theory because they could not find a tacit understanding or a common plan among the drug manufacturers. Most of the activity alleged to be parallel was indeed required by law.<sup>126</sup> Justice Mosk admitted:

Application of the concert of action to this situation would expand the doctrine far beyond its intended scope and would render virtually any manufacturer liable for the defective products of an entire industry, even if it could be demonstrated that the product, which caused the injury was not made by the defendant.<sup>127</sup>

A good reason not to apply the concert of action theory is the pervasive regulation by the FDA. The testing, manufacturing, and marketing of drugs is all highly regulated.<sup>128</sup> Further, *Hall* is clearly distinguishable from the DES situation. In *Hall*, the entire industry was joined as it consisted of small number of firms, and the identification problem in *Hall* was caused by the explosion itself.<sup>129</sup>

Although most courts have rejected the concert of action theory in DES cases,<sup>130</sup> the theory has, nevertheless, found some support. The lower court in *Sindell* applied this theory as well as alternative liability.<sup>131</sup> In *Bichler v. Eli Lilly & Co.*,<sup>132</sup> a case involving a DES action against only that named manufac-

<sup>122</sup>*Id.* at 378.

<sup>123</sup>*Id.* at 359.

<sup>124</sup>*Id.* at 380.

<sup>125</sup>FORDHAM Comment, *supra* note 26, at 981-83.

<sup>126</sup>The manufacturers were (and are) required to use the same formula set forth in the *United States Pharmacopoeia*. See *Sindell*, 26 Cal. 3d at 605, 607 P.2d at 933, 163 Cal. Rptr. at 140-41; 21 U.S.C. § 351(b) (1976).

<sup>127</sup>*Sindell*, 26 Cal. 3d at 605, 607 P.2d at 933, 163 Cal. Rptr.

<sup>128</sup>See 21 U.S.C. § 355(a) (premarketing testing); 21 U.S.C. § 351(b) (1976) (misbranding); Comment, *supra* note 47, at 794-95.

<sup>129</sup>See Note, *supra* note 2, at 1008-09. In *Hall*, the manufacturers had agreed not to place warnings on the blasting caps.

<sup>130</sup>See generally *Ryan v. Eli Lilly & Co.*, 514 F. Supp. 1004 (D.S.C. 1981); *Payton v. Abbott Laboratories*, 512 F. Supp. 1031 (D. Mass. 1981); *Sindell*, 26 Cal. 3d at 588, 607 P.2d at 924, 163 Cal. Rptr. at 132.

<sup>131</sup>148 Cal. Rptr. at 145.

<sup>132</sup>79 A.D.2d 317, 436 N.Y.S.2d 625 (1981).

turer, the New York appellate court ruled there was sufficient evidence to support the jury's finding of concerted action.<sup>133</sup> The reasoning of this case has been criticized, in particular because of the reliance placed by the court upon parallel activity by the drug companies prior to their efforts to seek approval of DES as a miscarriage preventative.<sup>134</sup> Another DES case, *Abel v. Eli Lilly & Co.*,<sup>135</sup> approved the concert of action theory as having stated a cause of action which should go to the jury.

#### D. Enterprise Liability

Enterprise liability is the term used for the theory developed by the author of the "DES Comment." According to the author, it is available whenever the plaintiff cannot identify the cause-in-fact of the injury. The elements of enterprise liability as stated are:

- 1) Plaintiff is not at fault for his inability to identify the causative agent and such liability [sic] is due to the nature of the defendant's conduct.
- 2) A generically defective product was manufactured by all the defendants.
- 3) Plaintiff's injury was caused by this product defect.

<sup>133</sup>The court stated:

In the instant case, there was ample evidence from which a jury could determine Lilly was engaged in concerted action. The original cooperation by the 12 manufacturers and pooling of information, the agreement on the same basic chemical formula, and the adoption of Lilly's literature as a model for package inserts for joint submission to the FDA in 1941, can rationally be construed as an express agreement for purposes of finding concerted action, even if such cooperation was first invited by the FDA. . . . There was evidence in abundance of conscious parallel activity thereafter by the drug companies which later sought FDA approval of DES for use in treating risks of pregnancy, evidence from which may be inferred a tacit understanding.

*Id.* at 330, 426 N.Y.S.2d at 633.

<sup>134</sup>A New Jersey case held the pre-1947 activities to be irrelevant. The court in *Lyons v. Premo Pharmaceutical Labs, Inc.* stated:

The 1940 applications do not support the "drag race" analogy because there was nothing anti-social about placing DES on the market for its pre-1947 purposes. Plaintiffs apparently overlook the fact that products containing DES are still in use today with full approval of the FDA and the Surgeon General. It can hardly be said, therefore that the drug companies' conduct in seeking approval for the drug in 1940 should be classified as tortious.

*Lyons v. Premo Pharmaceutical Labs, Inc.*, 170 N.J. Super. 183, 194, 406 A.2d 185, 190-91.

*Bichler*, moreover, has been severely criticized. One observer commented:

Not only does this instruction represent a broad departure from traditional tort notions of concert of action and even from antitrust application of the theory of conscious parallelism, but the very evidence cited by the *Bichler* opinion to support the jury's finding that Lilly participated in concerted conduct with other drug manufacturers is inconsistent with established principles of products liability law. . . . Thus, although the conduct of the original 12 drug manufacturers may indeed be defined as a joint undertaking, it cannot be deemed tortious and therefore it necessarily falls well outside the doctrine of concerted action.

Birnbaum, *DES Concert-of-Action Theory: New Cases Bring Confusion*, NAT'L L.J., May 5, 1981, at 32. *Bichler*, in effect, imposed absolute liability, although Lilly was allowed to bring in other manufacturers. See *Bichler*, 79 A.D.2d at 331, 436 N.Y.S.2d at 634.

<sup>135</sup>94 Mich.App. 59, 389 N.W.2d 20 (1979). *Abel* also ruled the alternative liability theory was sufficient to take the case to the jury. See *supra* note 133 and accompanying text.

- 4) The defendants owed a duty to the class of which plaintiff was a member.
- 5) There is a clear and convincing evidence that plaintiff's injury was caused by the product of some one of the defendants. For example, the joined defendants accounted for a high percentage of such defective products on the market at the time of plaintiff's injury.
- 6) There existed an insufficient, industry-wide standard of safety as to the manufacture of this product.
- 7) All defendants were tortfeasors satisfying the requirements of whatever cause of action is proposed: negligence, warranty, or strict liability.<sup>136</sup>

Enterprise liability was developed specifically for the identification problem of the DES cases. After proving these elements the burden of proof or causation is shifted to the defendants. Any defendant can then absolve himself by showing that his product could not have caused the injury.<sup>137</sup> In order to meet the clear and convincing evidence standard of element number five, a plaintiff must join manufacturers of "a high percentage of the defective products on the market, approximately 75% to 80%."<sup>138</sup>

This theory was designed to correct some of the logical inconsistencies found when trying to fit DES cases into concert-of-action or alternative liability theories.<sup>139</sup> The author justifies the theory upon a basic policy argument that the United States drug industry, as a whole, caused this problem and that it, therefore, should be liable. Further, the author stated that by the use of self-insurance and captive insurers, the drug industry can better afford to pay the cost. Other policy arguments include: that enterprise liability would provide incentives for the drug companies to improve their testing and adverse reaction reporting systems; that the drug industry is financially sound and can easily afford these losses; that drug companies presently do not spend sufficient amount of funds on research and development; and that any losses could be easily passed along to the consumer through higher prices.<sup>140</sup>

The *Sindell* court rejected enterprise liability by first distinguishing *Hall*, upon which the theory relies.<sup>141</sup> Justice Mosk felt that the differences between a six-member blasting cap industry and the DES industry of over 200 firms were simply too great.<sup>142</sup> Most importantly, however, the *Sindell* majority felt

<sup>136</sup>FORDHAM Comment, *supra* note 26, at 995.

<sup>137</sup>*Id.* at 995. For example, a drug company could show that they never made (or note at that time) a pill in that size, shape, color, or strength. Note that DES made for use as a miscarriage preventative was usually of a dosage of 25 mg., while DES made for other uses was usually 5 mg. See SWEIG, *supra* note 1, at 2.

<sup>138</sup>FORDHAM Comment, *supra* note 26, at 996.

<sup>139</sup>*Id.* at 998-1000.

<sup>140</sup>*Id.* at 1003-06.

<sup>141</sup>See *supra* note 120 and accompanying text.

that it was unfair to condemn the industry for standards which were so highly compelled by the federal government. Justice Mosk stated:

But since the government plays such a pervasive role in formulating the criteria for the testing and marketing of drugs, it would be unfair to impose upon a manufacturer liability for injuries resulting from the use of a drug which it did not supply simply because it followed the standards of the industry.<sup>143</sup>

There are also several policy considerations which argue against the theory of enterprise liability. It remains questionable whether a drug manufacturer should be held liable for a product which only "could" have caused the injury. As already noted, plaintiffs who cannot identify the manufacturer will be favored over those who can by having a larger pool of defendants. Further, expansion of manufacturers' liability will further increase the cost of products liability insurance, if it is indeed available at all. It is highly questionable whether liability here will serve any deterrence function since the injuries were arguably not foreseeable to begin with.<sup>144</sup> Apparently, no court has adopted the enterprise liability theory as proposed in the "DES Comment."<sup>145</sup>

### E. Market Share Liability

As previously discussed, *Sindell* created the theory of market share liability.<sup>146</sup> Justice Richardson, in dissent, aptly recognized that although the majority rejected enterprise or industry-wide liability, the difference between it and the majority's market share liability was a difference of form rather than substance.<sup>147</sup>

The theories are not, however, identical. As already noted, enterprise liability requires a 75-80% joinder while *Sindell* requires only a "substantial share."<sup>148</sup> The theoretical differences of each theory have been observed by many commentators.<sup>149</sup> One writer observed that allocatoin under enterprise liability is based on a national market, the *Sindell* approach is presumably based on the California market.<sup>150</sup> Similarly, each defendant under enterprise liability

<sup>143</sup>*Id.*, at 610, 607 P.2d at 935, 163 Cal. Rptr. at 143. See generally 21 C.F.R. §§ 436.100-.542 (1982) (testing); 21 C.F.R. § 429.10 (1982) (packing); 21 C.F.R. § 369.20 (1982) (warnings); 21 C.F.R. §§ 211.22-.208 (1982) (manufacturing standards).

<sup>144</sup>See Note, *supra* note 2, at 1009-15.

<sup>145</sup>The author of this article could find no cases which specifically adopted it, although it must be recognized that the *Sindell* approach is substantially the same.

<sup>146</sup>See *supra* notes 75 and 76 and accompanying text.

<sup>147</sup>*Sindell*, 26 Cal. 3d at 616, 607 P.2d at 940, 163 Cal. Rptr. at 148. See Comment, *supra* note 47, at 799.

<sup>148</sup>See *supra* notes 88 and 138.

<sup>149</sup>See generally, *supra* note 47; Note, *Industry-Wide Liability and Market Share Allocation of Damages*, 15 GA. L. REV. 423 (1981); Note, *supra* note 3.

<sup>150</sup>Comment, *supra* note 47, at 811-12. Obviously, the determination of the relevant market will be difficult. An argument in favor of a national market was presented by Justice Richardson:

[I]t is readily apparent that 'market share' liability will fall unevenly and disproportionately upon those manufacturers who are amenable to suit in California. On the assumption that no other state

faces joint and several liability, while under *Sindell* he arguably only faces liability for his proportional share of the market. This can lead to profound differences to defendants and to plaintiffs.<sup>151</sup>

will adopt so radical a departure from traditional tort principles, it may be concluded that under the majority's reasoning those defendants who are brought to trial in this state will bear effective joint responsibility for 100 percent of plaintiffs' injuries despite the fact that their 'substantial' aggregate market share may be considerably less.

*Sindell*, 26 Cal. 3d at 617, 607 P.2d at 940, 163 Cal. Rptr. at 148 (Richardson, J., dissenting).

<sup>151</sup>Note, *Industry-Wide Liability and Market Share Allocation of Damages*, 15 GA. L. REV. 423, 438-46 (1981). The writer presented these tables to illustrate the differences:

Table 2  
Market Share Allocation of Damages — Industry-Wide Liability

Defendant	Market Share	Market Share %/ Total % of Market Represented by Joined Defendants X Total Damages	Amount of Damage for Which Defendant is Responsible	% of Total Amount of Damage for Which Defendant is Responsible
A	30%	$\frac{30}{75} \times \$1,000,000$	\$ 400,000.00	40.0%
B	19%	$\frac{19}{75} \times 1,000,000$	253,333.33	25.3%
C	8%	$\frac{8}{75} \times 1,000,000$	106,666.67	10.7%
D	13%	$\frac{13}{75} \times 1,000,000$	173,333.33	17.3%
E	5%	$\frac{5}{75} \times 1,000,000$	66,666.67	6.7%
	<u>75%</u>		<u>\$1,000,000.00</u>	<u>100.0%</u>

*Id.* at 439.

Table 3  
Market Share Allocation of Damages — *Sindell* Market Share Approach

Defendant	Market Share	Market Share X Total Damages	Amount of Damages for Which Defendant Is Responsible
A	30%	30% X \$1,000,000	\$300,000
B	19%	19% X 1,000,000	190,000
D	8%	8% X 1,000,000	80,000
D	13%	13% X 1,000,000	130,000
E	5%	5% X 1,000,000	50,000
	<u>75%</u>		<u>\$750,000</u>

## V. CONCLUSIONS AND RECOMMENDATIONS

The extensive efforts made by courts and commentators to expand traditional products liability and tort doctrines to solve the identification problem faced by DES plaintiffs are understandable. As one writer observed, "*Sindell* is a classic example of the admonition that hard cases make bad law. While pursuing a noble motive — the compensation of innocent victims of adverse drug reactions — the *Sindell* court gravely overstepped the boundaries of judicial lawmaking."<sup>152</sup> The same, of course, can be said for the enterprise liability theory and the alternative liability and concert of action theories which are logically inapplicable anyway.

The most basic reason to resist these theories is the tremendous break they make from prior law. The causation issue is such a fundamental requirement of products liability law that it should not be eliminated.<sup>153</sup> As Dean Prosser noted: "[the plaintiff] must introduce evidence which affords a reasonable basis for the conclusion that it is more likely than not that the conduct of the defendant was a substantial factor in bringing about the result. A mere possibility of such causation is not enough . . ."<sup>154</sup> These theories similarly have extended potential liability so far that "a particular defendant may be held proportionately liable even though mathematically it is much more likely than not that it played no role whatever in causing plaintiffs' injuries."<sup>155</sup>

Extension of liability here would severely strain the drug companies' ability to obtain adequate insurance coverage. Products liability insurance rates for United States drug companies already reflect the tremendous liability exposures.<sup>156</sup> In fact, many United States drug companies have already been forced to self-insure because insurance companies are unwilling to underwrite these risks.<sup>157</sup> The risks are large enough that at least one company is now viewed as a poor investment risk.<sup>158</sup>

Despite protestations to the contrary, United States drug manufacturers do put forth great amounts of effort and resources into research and development.<sup>159</sup> Public policy obviously favors the development of new drugs,

<sup>152</sup>See Comment, *supra* note 47, at 811-12.

<sup>153</sup>As it would be by shifting the burden to the defendants, who are in no better position than are the plaintiffs to make identification.

<sup>154</sup>W. PROSSER, *supra* note 17, § 41, at 241.

<sup>155</sup>*Sindell*, 26 Cal. 3d at 616, 607 P.2d at 939, 163 Cal. Rptr. at 147 (Richardson, J., dissenting).

<sup>156</sup>Payne, *Products Liability — An Underwriter's View*, PRODUCT LIABILITY AND INSURANCE (1977) (published seminar, Lloyd's of London Press) at 8.

<sup>157</sup>U.S. DEPT. OF COMMERCE, INTERAGENCY TASK FORCE ON PRODUCT LIABILITY FINAL REPORT OF THE INSURANCE STUDY (Jan., 1977) at 3-34 (printed by Nat'l Technical Informational Services).

<sup>158</sup>See SWEIG, *supra* note 1, at 2, this firm was Eli Lilly. It does not appear to have affected Lilly's stock price significantly. See Eli Lilly & Co., *Trendline's Current Market Perspective*, 140 (Jan. 1982); Eli Lilly & Co., *Moody's Handbook of Common Stocks* (Summer 1981).

<sup>159</sup>See Comment, *supra* note 47, at 810 (estimating the average cost of a significant new drug to be \$24 million).

but as each new product faces huge and seemingly unlimited liability, the incentive to continue research is reduced.<sup>160</sup> One writer analyzed the harm done society as strict liability is imposed:

There are two risks involved in the development of new drugs: (1) the risk that unforeseen, perhaps catastrophic, injuries will result because a new drug is used in man too soon; and (2) the risk that needless human suffering and death will occur because a beneficial drug is withheld from mankind too long. Absolute liability for the adverse effects of new drugs would enlarge the latter risk to unacceptable proportions, while giving a remedy to those injured by the former risk.<sup>161</sup>

Thus, society as a whole is better off by not further expanding our products liability laws in this setting.

Further doctrinal expansion will serve only a compensation function and not a deterrence function. If we are to hold drug companies liable for latent defects in their products, then we should at least leave the causation burden with the plaintiff.<sup>162</sup> In this way the defendant who caused the harm would be the one deterred.

As already noted, defense costs in DES cases are high, and the actual amount received by plaintiffs low.<sup>163</sup> This points up the tremendous costs of using the legal system to solve this problem. The DES cases are very complicated, legally and medically. The costs mount up with each new case, a new jury, a new judge, and often new attorneys must be taught the unique facts of a DES case.

The market share and enterprise liability theories were developed for the DES cases, but their impact could extend much further. It was observed that “*Sindell* is potentially applicable in any case where identification of the manufacturer is impossible or where a generically similar defective product is produced by multiple manufacturers.”<sup>164</sup> An especially likely area of exportation would be the over 6,000 already pending cases involving asbestos.<sup>165</sup>

<sup>160</sup>See Note, *supra* note 2, at 1004.

<sup>161</sup>Note, *The Liability of Pharmaceutical Manufacturers for Unforeseen Adverse Drug Reactions*, 48 *FORDHAM L. REV.* 735, 756 (1980) (quoting *Gaston v. Hunter*, 121 *Ariz.* 33, 48-49, 588 P.2d 326, 341-42 (Ct. App. 1978)).

<sup>162</sup>See Note, *supra* note 2, at 1013-14.

<sup>163</sup>See *supra* notes 69 and 70 and accompanying text. Similarly, manufacturers with small market shares will nevertheless likely be brought into many suits after *Sindell* and will, as a result, face high litigation expenses. Lnad & Mahlman, *The New California 'Market Share' Theory in Drug Liability Cases*, 36 *FOOD DRUG COSM. L.J.* 39, 44 (1981).

<sup>164</sup>Comment, *Sindell v. Abbott Laboratories — A High Water Mark in Tort Law*, 1981 *UTAH L. REV.* 655, 671.

<sup>165</sup>Podgers, *DES Ruling Shakes Products Liability Field*, 66 *A.B.A.J.* 827 (1980). See *Hardy v. Johns-Manville Sales Corp.*, 509 F. Supp. 1353 (E.D. Tex. 1981); *Insurance Co. of North America v. Forty-Eight Insulations, Inc.*, 633 F.2d 1212 (6th Cir. 1980).  
<https://ideaexchange.uakron.edu/akronlawreview/vol16/iss3/>

## VI. TOWARD A PRINCIPLED APPROACH

## A. FDA Regulation

While it cannot compensate the victims, the FDA should be allowed to continue to regulate the drug industry. The suggestions to let products liability actions take the place of federal regulation seem ludicrous in the DES context.<sup>166</sup>

Were DES introduced today for the use of preventing miscarriages it would surely not be approved by the FDA. While the benefit of hindsight is difficult to ignore, the FDA's testing procedures have been vastly improved since the 1940's.<sup>167</sup> The tests done in the 1940's did not generally include possible effects on a fetus, although today the FDA would certainly require such studies, especially for a drug meant to be given to pregnant women.<sup>168</sup> DES would not be approved today for use as a miscarriage preventative for the additional reason that the drug has been proven not effective for that use. Since the Kefauver-Harris Amendments of 1962, drugs must be safe and effective to receive FDA approval.<sup>169</sup>

## B. Legislative Solutions

Many observers have suggested a no-fault insurance system for product injuries. Even the "DES Comment" recommended this, but recognized it was within the province of the legislature.<sup>170</sup>

Most of these proposals would apply to all industries. One especially notable proposal appears in a 1979 law review comment.<sup>171</sup> The author proposes a "latent technological injury compensation" system where an injured party could go to an administrative body for relief if his injury was not discoverable within a certain specified period after initial purchase. After this "statute of limitations" ran, the plaintiff would lose his tort or products liability actions. The plaintiff would be compensated by the administrative body upon: showing that she was injured; tracing her injury to a type of product; and showing her injury was not discoverable during the statutory period. Compensation would be for bodily injuries including medical expenses and lost earnings but not for pain and suffering. This system would be funded by a uniform tax on all manufacturers.<sup>172</sup>

<sup>166</sup>See *supra* note 4 and accompanying text.

<sup>167</sup>See 21 U.S.C. § 355 (1976). In general the drug company must produce animal toxicity studies along with a protocol of proposed clinical investigations upon submission of a Notice of Claimed Investigational Exemption for a New Drug (IND). See 21 C.F.R. § 314.1(d) (1978). The drug is then put through a three phase clinical investigation. See Note, *supra* note 161, at 754.

<sup>168</sup>*Bichler*, 79 A.D.2d at 323, 436 N.Y.S.2d at 629. Some testimony indicated that early rat and mice studies had discovered some effects on the fetus.

<sup>169</sup>See *supra* note 13 and accompanying text.

<sup>170</sup>FORDHAM Comment, *supra* note 26, at 1007. See Note, *Industry-Wide Liability and Market Share Allocation of Damages*, 15 GA. L. REV. 423, 450 (1981).

<sup>171</sup>Note, *supra* note 2, at 980.

<sup>172</sup>*Id.* at 1019-22. The tax would be uniform because the product defect is unknowable at time of manufacture and therefore the predictions of drug product types would be unreliable.



While this system has much to commend it, the authors would prefer a system limited to the DES situation. Other industries and products, such as asbestos, could be added later as the legislature saw fit. Such a system would be similar to the one suggested by Justice Richardson in *Sindell*.<sup>173</sup> It is believed, however, that a national system would be preferable to a state-by-state approach.

This proposed national system should be funded by a tax upon the manufacturers who produced DES for use as a miscarriage preventative. The tax should be equitably imposed upon them, most probably based upon total national market share. While it is true, that this will involve some of the same difficulties presented by the *Sindell* approach, figures for such a national market are already available.<sup>174</sup> As with the "latent technological injury compensation system" discussed earlier, recovery should be limited to medical expenses and lost earnings and it would, of course, displace other remedies. Hopefully, the cooperation of the drug companies could be obtained since they have much to gain by the system, most importantly avoiding needless defense costs and possible awards for pain and suffering.

In conclusion, *Sindell* and the enterprise liability proposal were indeed noble efforts to compensate the innocent victims of DES exposure. It is hard to imagine plaintiffs more innocent than those who were exposed to the drug before their birth. The judicial theories, however, wreak too much havoc upon our legal doctrines. The solution must be of legislative origin, not judicial. The DES identification problem must be answered finally by a policy decision. The difficulties and adverse effects of a judicial solution make the legislative one preferable.

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<sup>173</sup>See *supra* note 98 and accompanying text.

<sup>174</sup>See *supra* note 93.