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## Products Liability - Presumptions and Burden of Proof - A New Legal Theory, Obviating the Necessity to Identify the Manufacturer of an Injury-Causing Product, Is Adopted in a Products Liability Claim Against Manufacturers of DES

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## CASE COMMENTS

### PRODUCTS LIABILITY — PRESUMPTIONS AND BURDEN OF PROOF — A NEW LEGAL THEORY, OBTAINING THE NECESSITY TO IDENTIFY THE MANUFACTURER OF AN INJURY-CAUSING PRODUCT, IS ADOPTED IN A PRODUCTS LIABILITY CLAIM AGAINST MANUFACTURERS OF DES

The plaintiff<sup>1</sup> alleged that she had received personal injuries, in the nature of precancerous and cancerous tumors and lesions, from prenatal exposure to the drug diethylstilbesterol<sup>2</sup> (DES).<sup>3</sup> The drug was allegedly administered to plaintiff's mother as a miscarriage preventive.<sup>4</sup> Because of the time lapse between the intake of the DES and the manifestations of alleged injuries,<sup>5</sup> the plaintiff could not identify the manufacturer of the drug ingested by her mother.<sup>6</sup> The plaintiff, therefore, sought to hold a number of the major manufacturers<sup>7</sup> of the fungible drug<sup>8</sup> jointly liable for her

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1. The present case is a consolidation of two separate class action suits. *Sindell v. Abbott Laboratories*, 26 Cal. 3d 588, 597, 607 P.2d 924, 927, 163 Cal. Rptr. 132, 135, *cert. denied*, \_\_\_\_\_ U.S. \_\_\_\_\_, 101 S. Ct. 285 (1980). Each action was brought on behalf of an individual plaintiff and on behalf of other women similarly situated. "Plaintiff" in this discussion, as it did in the court's opinion, refers to plaintiff Judith Sindell and her claim. *Id.* at 593, 607 P.2d at 925, 163 Cal. Rptr. at 133.

2. Diethylstilbesterol (DES) is a synthetic female sex hormone which may be dispensed only when prescribed by a physician. *FACTS AND COMPARISONS* 96-98, 101(a) (E. Kastrup ed. 1980). For a collection of recent cases involving DES manufacturers, see *Annot.*, 2 A.L.R. 4th 1091 (1980).

3. 26 Cal. 3d at 595-96, 607 P.2d at 926, 163 Cal. Rptr. at 134. Plaintiff alleged that, as a result of the DES ingested by her mother, she developed a malignant bladder tumor which was removed by surgery. She further alleged that she suffers from adenosis, which must be constantly monitored by biopsy to insure early warning of further malignancy. *Id.*

4. *Id.* at 593, 607 P.2d at 925, 163 Cal. Rptr. at 133. DES was approved by the Food and Drug Administration in 1947 for preventing miscarriages and was used until 1971, when maternal administration was banned because of its dangers and ineffectiveness. See Herbst, Scully & Robboy, *Effects of Maternal DES Ingestion on the Female Genital Tracts*, *HOSPITAL PRACTICE*, Oct. 1975, at 51.

5. 26 Cal. 3d at 594, 607 P.2d at 925, 163 Cal. Rptr. at 133. The plaintiff alleged a minimum latent period of ten to twelve years. *Id.*

6. *Id.* at 601, 607 P.2d at 930, 163 Cal. Rptr. at 138. The court held that the impossibility of identification resulted primarily from the passage of time and the manner in which the plaintiff was allegedly injured. It was not the fault of the plaintiff, nor was it directly attributable to any negligent act of the defendants. *Id.* For a further discussion of this identification problem, see *infra* notes 24-30 and accompanying text.

7. 26 Cal. 3d at 596, 607 P.2d at 926, 163 Cal. Rptr. at 134. The appeal to the California Supreme Court involved five defendant manufacturers of DES. *Id.* The defendant manufacturers alleged that approximately two hundred drug companies made DES, any of which might have manufactured the injury-producing drug. *Id.* at 602, 607 P.2d at 931, 163 Cal. Rptr. at 139. The plaintiff alleged, however, that five or six of these companies produced ninety percent of the DES marketed. *Id.* at 612, 607 P.2d at 937, 163 Cal. Rptr. at 145.

8. *Id.* at 605, 607 P.2d at 933, 163 Cal. Rptr. at 141. The *Sindell* court noted that "[t]he formula

injuries.<sup>9</sup> The Supreme Court of California *held* that the plaintiff would have a cause of action against the DES manufacturers if she could establish that the named manufacturers together produced a substantial percentage of the DES marketed for the prevention of miscarriages,<sup>10</sup> and each manufacturer would be held liable for the portion of the judgment represented by its share of the market for the drug unless it demonstrated that it could not have made the product which caused plaintiff's injuries.<sup>11</sup> *Sindell v. Abbott Laboratories*, 26 Cal. 3d 588, 607 P.2d 924, 163 Cal. Rptr. 132, *cert. denied*, \_\_\_ U.S. \_\_\_, 101 S. Ct. 285 (1980).

DES, a female sex hormone,<sup>12</sup> was prescribed to millions of pregnant women from the 1940s through the 1960s as a miscarriage preventive.<sup>13</sup> In 1971, maternal administration of DES was banned by the Food and Drug Administration because of its questionable effectiveness and its propensity to cause gynecological anomalies in female offspring who were prenatally exposed to it.<sup>14</sup> DES daughters seeking to recover damages from pharmaceutical manufacturers for their injuries however,<sup>15</sup> faced a unique evidentiary burden in

for DES is a scientific constant. It is set forth in the *United States Pharmacopoeia*, and any manufacturer producing that drug must, with exceptions not relevant here, utilize the formula set forth in that compendium." *Id.* (citing 21 U.S.C.A. § 351(b)).

9. 26 Cal. 3d at 598, 607 P.2d at 928, 163 Cal. Rptr. at 136. The plaintiff sought to hold the defendants liable for her injuries based upon three theories of joint liability: alternative liability, concert of action, and industry-wide liability. *Id.* For a discussion of these theories and their application to DES cases, see *infra* notes 32-55 and accompanying text.

10. 26 Cal. 3d at 611-12, 607 P.2d at 937, 163 Cal. Rptr. at 145. The court stated:

[W]e hold it to be reasonable in the present context to measure the likelihood that any of the defendants supplied the product which allegedly injured plaintiff 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 sold by all for that purpose.

*Id.*

11. *Id.* at 612, 607 P.2d at 937, 163 Cal. Rptr. at 145. The court created a new basis for joint liability to enable the plaintiff to more easily establish causation by a named defendant. See *infra* notes 58-62 and accompanying text.

The United States Supreme Court declined to review the *Sindell* decision. *E. R. Squib & Sons v. Sindell*, \_\_\_ U.S. \_\_\_, 101 S. Ct. 285 (1980). The drug manufacturers argued in their petitions for review before the Supreme Court that the California decision violated their right to due process, because the resultant shifting of the burden of proof created an "irrational and arbitrary" presumption of causation. [1980] 8 PROD. SAFETY & LIAB. REP. (BNA) 743. They also argued that the ruling represented a denial of equal protection and violated the supremacy clause of the Constitution by frustrating federal policies governing the development and marketing of prescription drugs. *Id.* at 608-09.

12. FACTS AND COMPARISONS, *supra* note 2, at 101(a).

13. 26 Cal. 3d at 597, 607 P.2d at 927, 163 Cal. Rptr. at 135 (citing Comment, *DES and a Proposed Theory of Enterprise Liability*, 46 FORDHAM L. REV. 963, 964-67 (1978)). The court noted that "estimates of the number of women who took the drug during pregnancy range from 1 1/2 million to 3 million. Hundreds, perhaps thousands, of the daughters of these women suffer from adenocarcinoma, and the incidence of vaginal adenosis among them is 30 to 90 percent." 26 Cal. 3d at 597, 607 P.2d at 927, 163 Cal. Rptr. at 135.

14. See Herbst, Scully & Robboy, *supra* note 4, at 51.

15. FACTS AND COMPARISONS, *supra* note 2, at 96. The use of female sex hormones during pregnancy may seriously damage the offspring:

It has been shown that females exposed *in utero* to diethylstilbesterol, a non-steroidal

attempting to establish causation under traditional tort standards.<sup>16</sup>

Causation is an essential element in any action in tort,<sup>17</sup> and the burden is on the plaintiff to establish it.<sup>18</sup> The plaintiff must first establish causation-in-fact,<sup>19</sup> requiring proof that the defendant's conduct was a "material element and substantial factor" in bringing about the plaintiff's injury.<sup>20</sup> The plaintiff must further establish proximate or legal causation,<sup>21</sup> requiring proof that the defendant had a legal duty to protect the plaintiff from the resulting injury.<sup>22</sup>

The unique evidentiary problem confronting DES plaintiffs is the difficulty they have in establishing one of the elements of causation-in-fact. To establish causation-in-fact in a products liability action, the plaintiff must show: (1) that the product involved was defective; (2) that the defect caused the injury complained of; and (3) that the defect can be traced to the defendant.<sup>23</sup> Many DES plaintiffs, however, cannot identify the manufacturer of the DES ingested by their mothers.<sup>24</sup> The sheer number of potential manufacturers makes identification difficult.<sup>25</sup> It has been estimated that as many as three hundred manufacturers were producing the drug from an identical formula during the 1940s, 1950s, and 1960s.<sup>26</sup> Additionally, the manner in which DES plaintiffs were allegedly injured inhibits identification.<sup>27</sup> There is a

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estrogen, have an increased risk of developing in later life a form of vaginal or cervical cancer that is ordinarily extremely rare. This risk has been estimated at no greater than 4 per 1000 exposures. Furthermore, a high percentage of such exposed women (from 30 to 90%) have been found to have vaginal adenosis, epithelial changes of the vagina and cervix. Although these changes are historically benign, it is not known whether they are precursors of malignancy.

*Id.*

16. See 26 Cal. 3d at 593, 607 P.2d at 925, 163 Cal. Rptr. at 133.

17. W. PROSSER, LAW OF TORTS § 41, at 236 (4th ed. 1971). "An essential element of the plaintiff's cause of action for negligence, or for that matter for any other tort, is that there be some reasonable connection between the act or omission of the defendant and the damage which the plaintiff has suffered." *Id.*

18. *Id.* at 241. The plaintiff, in general, has the burden of proof on all issues essential to his cause of action. *Id.*

19. *Id.* at 237.

20. *Id.* at 240.

21. *Id.* § 42, at 244. "Once it is established that the defendant's conduct has in fact been one of the causes of the plaintiff's injury, there remains the question whether the defendant should be legally responsible for what he has caused." *Id.* (footnote omitted).

22. *Id.*

23. 2 L. FRUMER & M. FRIEDMAN, PRODUCTS LIABILITY § 16A(4), at 3B-88 (1980).

24. 26 Cal. 3d at 597, 607 P.2d at 927-28, 163 Cal. Rptr. at 135-36. The *Sindell* court, as did the trial court, accepted at face value plaintiff's assertion that she could not make identification. *Id.* at 600 n.12, 607 P.2d at 930 n.12, 163 Cal. Rptr. at 138 n.12.

25. *Id.* at 602-03, 607 P.2d at 931, 163 Cal. Rptr. at 139. The defendants in *Sindell* alleged that there were approximately two hundred drug companies which made DES, any of which might have manufactured the injury-causing drug. *Id.* However, many of these manufacturers may no longer be in business or they may not be subject to the jurisdiction of a particular court. *Id.* at 610, 607 P.2d at 936, 163 Cal. Rptr. at 144.

26. Comment, *DES and a Proposed Theory of Enterprise Liability*, 46 FORDHAM L. REV. 963, 964 n.3 (1978) [hereinafter cited as *Fordham Comment*].

27. 26 Cal. 3d at 600, 607 P.2d at 929, 163 Cal. Rptr. at 137.

minimum latent period of ten to fifteen years between *in utero* exposure and manifestation of the injury.<sup>28</sup> Because of this time lapse, many of the pharmaceutical and medical records have often been lost or destroyed.<sup>29</sup> Thus, no definite evidence is available to connect a particular manufacturer to the DES it produced.<sup>30</sup>

DES plaintiffs have sought to obviate the necessity to identify a precise manufacturer by advancing various theories of joint liability.<sup>31</sup> One theory which has been suggested is "concert of action,"<sup>32</sup> which provides that all actors who by express agreement or tacit understanding engage in tortious activity are jointly and severally liable for the injuries produced.<sup>33</sup> A typical application of concerted action to impose liability upon multiple defendants occurs when a bystander is hit by one of the participants in a drag race.<sup>34</sup> Although only one participant directly causes the bystander's injuries, liability is imposed upon all members of the

28. See Herbst, Scully & Robboy, *Problems in the Examination of the DES-Exposed Female*, 46 *OBSTETRICS & GYNECOLOGY* 353, 354 (1975).

29. 26 Cal. 3d at 600, 607 P.2d at 929, 163 Cal. Rptr. at 137.

30. See *Gray v. United States*, 445 F. Supp. 337, 338 (S.D. Tex. 1978) (DES plaintiff's claim dismissed because of her inability to provide any proof establishing the particular manufacturer of the injury-causing drug). The physician or pharmacist selects the manufacturer of a drug dispensed by prescription without consulting the patient. They in turn are in control of the only means available to identify the manufacturer: their records. If these records are destroyed, the patient generally will not be able to identify the product dispensed to them. *Id.*

31. Compare *Sindell v. Abbott Laboratories*, 26 Cal. 3d at 598, 607 P.2d at 928, 163 Cal. Rptr. at 136 (identifying precise manufacturer of drug which harmed plaintiff not required) with *McCreery v. Eli Lilly & Co.*, 87 Cal. App. 3d 77, 85, 150 Cal. Rptr. 730, 735 (1978) (plaintiff's claim failed because of inability to identify precise manufacturer; overruled by implication in *Sindell*). See also *Abel v. Eli Lilly & Co.*, 94 Mich. App. 59, \_\_\_\_\_, 289 N.W.2d 20, 24 (1979); *Lyons v. Premo Pharmaceutical Labs, Inc.*, 170 N.J. Super. 183, \_\_\_\_\_, 406 A.2d 185, 189-90, *cert. denied*, 82 N.J. 267, 412 A.2d 774 (1979).

Joint liability may arise in many instances in tort law. See generally *W. PROSSER, supra* note 17, § 52, at 314-17 (listing a number of the more common situations). DES plaintiffs have suggested three classifications of joint liability upon which multiple defendants could be held liable for their injuries: alternative liability, industry-wide liability, and concerted action. 26 Cal. 3d at 598, 607 P.2d at 928, 163 Cal. Rptr. at 136.

32. 26 Cal. 3d at 603, 607 P.2d at 931, 163 Cal. Rptr. at 139. The elements of the doctrine of concert of action are as follows:

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 or encouragement to the other so to conduct himself, or (c) gives substantial assistance to the other in accomplishing a tortious result and his own conduct, separately considered, constitutes a breach of duty to the third person.

RESTATEMENT (SECOND) OF TORTS § 876 (1979).

33. *W. PROSSER, supra* note 17, § 46, at 292. Although an express agreement is not necessary, something more than mere knowledge by each party of the other's conduct is needed to establish concert of action. Furthermore, it is essential that each defendant be proceeding tortiously, with intent to commit a tort or with negligence. *Id.*

34. *Agovino v. Kunzl*, 181 Cal. App. 2d 591, 5 Cal. Rptr. 534 (1960). The plaintiff sought to recover for injuries sustained in a collision between a vehicle in which he was riding and an automobile being driven by a third party. Plaintiff alleged that defendant was engaged in a drag race with the third party at the time the collision occurred. *Id.* at \_\_\_\_\_, 5 Cal. Rptr. at 535. The court held that defendant and the third party were jointly engaged in a series of acts which led directly to the collision, and they therefore were jointly and severally liable. *Id.* at \_\_\_\_\_, 5 Cal. Rptr. at 538.

joint enterprise.<sup>35</sup> The act of one is the act of all.<sup>36</sup> Each participant who willfully gave substantial assistance and encouragement to the cause-in-fact wrongdoer is jointly and severally liable for injuries produced.<sup>37</sup> DES plaintiffs have attempted to utilize this theory by alleging that their injuries were caused by the concerted tortious acts of various pharmaceutical manufacturers.<sup>38</sup>

Another proposed basis for liability is the concept of "industry-wide liability" suggested in *Hall v. E.I. DuPont de Nemours*.<sup>39</sup> The plaintiff in *Hall* sought to hold six blasting cap manufacturers jointly liable because he could not identify the supplier of the cap which exploded and injured him.<sup>40</sup> The court found a valid claim in the plaintiff's allegation that there was industry-wide cooperation in the manufacture and design of blasting caps which resulted in inadequate industry-wide safety standards.<sup>41</sup> Furthermore, upon establishment of joint control of risk, the court held that the burden of proving who actually caused the injury would shift to the joined defendants if the plaintiff could establish by a preponderance of the evidence that the injury-producing cap was manufactured by any one of the defendants.<sup>42</sup> DES plaintiffs have unsuccessfully attempted to use the *Hall* rationale by alleging that the pharmaceutical manufacturers adhered to an industry-wide safety standard and collaborated in the marketing of DES.<sup>43</sup>

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35. *Id.* at \_\_\_\_\_, 5 Cal. Rptr. at 538.

36. W. PROSSER, *supra* note 17, § 46, at 292.

37. *Id.*

38. 26 Cal. 3d at 604-05, 607 P.2d at 932, 163 Cal. Rptr. at 140. The plaintiff in *Sindell* alleged a tacit understanding among defendants to commit a tortious act. She alleged express and implied agreements, collaboration in, reliance upon, acquiescence in, ratification, exploitation, and adoption of each other's testing, marketing methods, and lack of warnings. *Id.*

39. 345 F. Supp. 353 (E.D.N.Y. 1972).

40. *Hall v. E.I. DuPont de Nemours*, 345 F. Supp. 353, 358 (E.D.N.Y. 1972). The plaintiffs were seeking to recover for injuries to children caused by the explosion of dynamite blasting caps. *Id.* The evidence of the individual manufacturer's identity was destroyed by the explosions. *Id.* at 378.

41. *Id.* at 372-78. The court noted that "joint control of risk can exist among actors who are not bound in a profit-sharing joint venture." *Id.* at 373. The court further held that, "[t]o establish that the explosives industry should be held jointly liable on enterprise liability grounds, plaintiffs, pursuant to their pleading, will have to demonstrate defendants' joint awareness of the risks at issue in this case and their joint capacity to reduce or affect those risks." *Id.* at 378.

42. *Id.* at 380. The court stated:

If plaintiffs can establish by a preponderance of the evidence that the injury-causing caps were the product of some unknown one of the named defendants, that each named defendant breached a duty of care owed to plaintiffs and that these breaches were substantially concurrent in time and of similar nature, they will be entitled to a shift of the burden of proof on the issue of causation.

*Id.*

43. 26 Cal. 3d at 608, 607 P.2d at 934, 163 Cal. Rptr. at 142. The court noted that plaintiff alleged 'joint enterprise and collaboration among defendants in the production, marketing, promotion, and testing of DES, and 'concerted promulgation and adherence to industry-wide testing, safety, warning and efficiency standards' for the drug." *Id.*

The third theory which has been proposed to alleviate the DES plaintiff's identification problem is alternative liability.<sup>44</sup> Under this principle, the plaintiff's burden of proving causation is relaxed.<sup>45</sup> Alternative liability was first adopted in *Summers v. Tice*,<sup>46</sup> in which the plaintiff was injured when two companion hunters simultaneously and negligently shot in his direction.<sup>47</sup> Only one shot struck the plaintiff, but it was impossible to determine which of the two hunters had fired the injury-causing shot.<sup>48</sup> The court held that it would be unfair to allow independently acting wrongdoers to escape liability when they had created a situation in which an innocent plaintiff could not identify the cause of his injury.<sup>49</sup> Therefore, the burden of proof was shifted to the defendants, each to absolve himself if he could;<sup>50</sup> if not, each would be jointly and severally liable, whether they were acting in concert or independently.<sup>51</sup> Because alternative liability shifts the burden of proving causation to a named defendant, DES plaintiffs have attempted to use the theory by alleging that all DES manufacturers behaved tortiously, making it impossible to determine which manufacturer's product caused their injuries.<sup>52</sup>

Attempts by DES plaintiffs to solve their problem of proving

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*Hall* has been described as a variation of concerted action — joint liability. *Fordham Comment*, *supra* note 26, at 981. A more accurate description, however, which might explain its limitations, would be joint and several liability resulting not from a common design, but from the independent tortious actions of two or more defendants which concur in producing a single indivisible result. The *Hall* court expressly limited its theory of joint liability to industries composed of a small number of units: "What would be fair and feasible with regard to an industry of five or ten producers might be manifestly unreasonable if applied to a decentralized industry composed of thousands of small producers." 345 F. Supp. at 378. The court further required that the plaintiffs establish "that each named defendant breached a duty of care owed to plaintiffs and that these breaches were substantially concurrent in time and of similar nature" in order to be entitled to a shift of the burden of proof. *Id.* at 380.

For a discussion of industry-wide liability and its applicability to actions alleging injuries from DES, see *Fordham Comment*, *supra* note 26, at 995-1007. *But see* Note, *Industry-wide Liability*, 13 SUFFOLK U.L. REV. 980, 997-1022 (1979) (discussing industry-wide liability as an unnecessary expansion of products liability law). The *Sindell* court expressly rejected the industry-wide theory of liability proposed in the *Fordham Comment*. 26 Cal. 3d at 609, 607 P.2d at 935, 163 Cal. Rptr. at 143.

44. RESTATEMENT (SECOND) OF TORTS § 433 B(3) (1965). This section provides:

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

*Id.*

45. *Id.*

46. 33 Cal. 2d 80, 199 P.2d 1 (1948).

47. *Summers v. Tice*, 33 Cal. 2d 80, 84, 199 P.2d 1, 2 (1948).

48. *Id.*

49. *Id.* at 86, 199 P.2d at 4.

50. *Id.*

51. *Id.* at 87, 199 P.2d at 5. The doctrines of alternative liability and *res ipsa loquiter* have also been used together to impose joint and several liability when the evidence does not establish that all defendants behaved tortiously. See *Ybarra v. Spangard*, 25 Cal. 2d 486, 490-91, 154 P.2d 687, 689 (1944).

52. 26 Cal. 3d at 598, 607 P.2d at 928, 163 Cal. Rptr. at 136.

causation have been largely unsuccessful,<sup>53</sup> due to the complexity of the pharmaceutical industry. The doctrines of concerted action, industry-wide liability, and alternative liability have usually been applied only in simple tort situations in which there is a reasonable connection between the defendants' acts or omissions<sup>54</sup> and the plaintiff's injury.<sup>55</sup> The complex factual circumstances of the DES cases, however, make proof of this causal link, under traditional tort principles,<sup>56</sup> difficult if not impossible.<sup>57</sup>

In *Sindell v. Abbott Laboratories*, the court created a new theory of joint liability to enable DES plaintiffs to more easily establish causation by a named defendant.<sup>58</sup> Its holding was based upon an extension of the alternative liability doctrine of *Summers v. Tice*.<sup>59</sup>

53. *Id.* at 597, 607 P.2d at 927-28, 163 Cal. Rptr. at 135-36.

54. Causation requires that there be "some reasonable connection between the act or omission of the defendant and the damage which the plaintiff has suffered." W. PROSSER, *supra* note 17, § 41, at 236.

55. Under the doctrine of concerted action there must be either an express agreement or tacit understanding to willfully engage in a common design. 26 Cal. 3d at 604, 607 P.2d at 932, 163 Cal. Rptr. at 140. However, common industrial marketing procedures do not necessarily constitute concerted tortious activity. DES plaintiffs have therefore generally failed in their attempts to establish joint liability under the doctrine of concerted action, because their complaints allege no more than parallel or imitative conduct, which does not constitute concerted tortious action. *Id.* at 605, 607 P.2d at 933, 163 Cal. Rptr. at 141; *accord*, Lyons v. Premo Pharmaceutical Labs, Inc., 170 N.J. Super. 183, \_\_\_\_\_, 406 A.2d 185, 190-91, *cert. denied*, 82 N.J. 267, 412 A.2d 774 (1979). *But cf.* Abel v. Eli Lilly & Co., 94 Mich. App. 59, \_\_\_\_\_, 289 N.W.2d 20, 25 (1979) (summary judgment improper, plaintiff's mere allegations of concerted action were sufficient to state a cause of action); Bichler v. Eli Lilly & Co., \_\_\_\_\_ A.D.2d \_\_\_\_\_, \_\_\_\_\_ N.Y.S.2d \_\_\_\_\_ (1981) (court upheld jury verdict for plaintiff, finding there was ample evidence from which a jury could determine that the defendant-manufacturer was engaged in concerted action).

The doctrine of industry-wide liability formulated by the *Hall* court was expressly limited to industries involving a small number of manufacturers. 345 F. Supp. at 378. In *Sindell*, over two hundred manufacturers were involved, and many of the safety regulations in the drug industry are promulgated by the Food and Drug Administration. 26 Cal. 3d at 609, 607 P.2d at 935, 163 Cal. Rptr. at 143. Consequently, attempts by DES plaintiffs to use the doctrine of industry-wide liability have also failed. *Id.* at 609-10, 607 P.2d at 935, 163 Cal. Rptr. at 143; *accord*, Abel v. Eli Lilly & Co., 94 Mich. App. at \_\_\_\_\_, 289 N.W.2d at 27.

In *Summers*, both defendants had been negligent toward the plaintiff, and all parties who were or could have been responsible for the harm to the plaintiff were joined in the action. 33 Cal. 2d at 86, 199 P.2d at 4. In the DES cases, however, it generally cannot be shown that the allegedly tortious activity of each manufacturer was directed at the plaintiff and that all potentially responsible parties are joined. 26 Cal. 3d at 602, 607 P.2d at 931, 163 Cal. Rptr. at 139. Therefore, alternative liability claims by DES plaintiffs have generally been rejected. *Id.* In *Abel v. Eli Lilly & Co.*, the court upheld the DES plaintiff's alternative liability claim. 94 Mich. App. at \_\_\_\_\_, 289 N.W.2d at 26. The plaintiff had alleged in her complaint that the named defendants constituted all the known manufacturers of DES whose products were distributed in Michigan during the relevant period of time. *Id.* at \_\_\_\_\_, 289 N.W.2d at 22.

56. See *Wetzel v. Eaton Corp.*, 62 F.R.D. 22, 29-30 (D. Minn. 1973) (court notes that it is essential in a products liability action against the alleged manufacturer or seller that plaintiff identify the defendant as either the manufacturer or seller of the product). See also Annot., 51 A.L.R.3d 1344, 1351 (1973) (general rule that defendant must be identified as manufacturer or seller).

57. See *supra* notes 24-30 and accompanying text.

58. 26 Cal. 3d at 598, 607 P.2d at 928, 163 Cal. Rptr. at 136.

59. *Id.* at 611, 607 P.2d at 936, 163 Cal. Rptr. at 144. The *Sindell* court found that a modification of the rule in *Summers* was warranted in this instance. *Id.*

A New Jersey trial court also recently held that the alternative liability theory was appropriate for DES cases. *Ferrigno v. Eli Lilly & Co.*, [1980] 8 PROD. SAFETY & LIAB. REP. (BNA) 795 (N.J. Super. Ct. 1980). The court did not follow the *Sindell* decision, but applied the precedent established in *Anderson v. Somberg*, 67 N.J. 291, 338 A.2d 1 (1975). In *Anderson*, an action was brought against a surgeon, a hospital, a manufacturer of a surgical instrument, and the supplier of the instrument for injuries sustained during the course of a surgical operation when the tip of a forceps broke off and lodged in the patient's spinal canal. *Id.* at \_\_\_\_\_, 338 A.2d at 3. The Supreme Court of New Jersey

The court recognized that the drug was produced by all manufacturers from an identical formula, and that the plaintiff, through no fault of her own, could not identify which manufacturer had caused her injuries.<sup>60</sup> The court therefore held that proof of causation would be satisfied by joinder of those defendants who had together manufactured a substantial percentage of the DES which plaintiff's mother might have taken.<sup>61</sup> The burden of proof would then shift to each manufacturer to demonstrate that it could not have made the particular drug which allegedly injured the plaintiff.<sup>62</sup>

The majority in *Sindell* also adopted a unique basis for apportionment of damages.<sup>63</sup> The court held that damages were to be apportioned among the manufacturers based upon each defendant's probability of causation.<sup>64</sup> The likelihood that a manufacturer might have been the actual cause-in-fact of the plaintiff's alleged injuries was measured by the manufacturer's percentage share of the relevant drug market.<sup>65</sup> Each defendant-manufacturer, therefore, became liable for the judgment in proportion to its market share.<sup>66</sup> The court reasoned that, "[u]nder this approach, each manufacturer's liability would approximate its responsibility for the injuries caused by its own products."<sup>67</sup>

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held that, because it was apparent that at least one of the defendants was liable for the plaintiff's injury, and because the defendants had engaged in conduct which placed legal obligations to the plaintiff upon each of them, the burden of proof shifted to the defendants to prove their non-liability. *Id.* at \_\_\_\_\_, 338 A.2d at 5.

60. 26 Cal. 3d at 611, 607 P.2d at 936, 163 Cal. Rptr. at 144. Each manufacturer's product was made from the same formula and plaintiff's inability to identify the manufacturer who had produced the injury-causing drug resulted primarily from the passage of time. *Id.*

61. *Id.* at 611-12, 607 P.2d at 936-37, 163 Cal. Rptr. at 144-45. Under the *Summers* doctrine, the probability that any one tortfeasor was the cause-in-fact of defendant's injury is measured by the number of possible tortfeasors. *Id.* at 611, 607 P.2d at 936, 163 Cal. Rptr. at 144. The *Sindell* court held, however, that in the "present context" the probability of causation was better measured by the market share of each defendant. *Id.* at 612, 607 P.2d at 937, 163 Cal. Rptr. at 145. The court did not define what would constitute a "substantial share" of the relevant market. It implied, however, that this figure is something less than seventy-five percent. *Id.*

62. *Id.* at 612, 607 P.2d at 937, 163 Cal. Rptr. at 145.

63. Generally, damages are to be "apportioned among two or more causes when (a) there are separate harms, or (b) there is a reasonable basis for determining the contribution of each cause to a single harm." RESTATEMENT (SECOND) OF TORTS § 433A (1965).

64. 26 Cal. 3d at 612, 607 P.2d at 937, 163 Cal. Rptr. at 145. Because the court had established fictional causation based upon the aggregate market shares of the joined defendants, *see supra* note 61, the court apportioned damages among them based upon each manufacturer's contribution to the fictional causation. 26 Cal. 3d at 612, 607 P.2d at 937, 163 Cal. Rptr. at 145.

65. 26 Cal. 3d at 611-12, 607 P.2d at 937, 163 Cal. Rptr. at 145. The relevant market was the entire industry's production of DES for the purpose of preventing miscarriage. *Id.*

66. *Id.* at 612, 607 P.2d at 937, 163 Cal. Rptr. at 145.

67. *Id.* The court explained the connection between percentage of market share and liability in this way:

If X manufacturer sold one-fifth of all the DES prescribed for pregnancy and identification could be made in all cases, X would be the sole defendant in approximately one-fifth of all cases and liable for all the damages in those cases. Under alternative liability, X would be joined in all cases in which identification could not be

The court justified its extension of the *Summers* doctrine on policy grounds.<sup>68</sup> One reason cited was that, as between an innocent plaintiff and tortiously acting defendants, the latter should bear the cost of injury.<sup>69</sup> The defendants had allegedly manufactured a defective product, the effects of which were delayed for several years, thereby creating the circumstances which prevented the plaintiff from identifying the precise product which injured her.<sup>70</sup>

The *Sindell* court also recognized that traditional tort standards are not always appropriate in the era of mass production and complex marketing procedures.<sup>71</sup> Advancements in science and technology create fungible goods which may harm consumers, and which cannot be traced to any specific manufacturer.<sup>72</sup> In light of this changing relationship between consumer plaintiffs and manufacturer defendants, the court elected to create a new theory of causation and liability which would more equitably govern the obligations of manufacturers to consumers.<sup>73</sup>

The court also noted the broad policy of allocating the risk of harm to those who are in the best position to control the risks<sup>74</sup> and to absorb the costs of injury when harm actually occurs.<sup>75</sup> The court acknowledged the unfairness which might result if the actual manufacturer is not among the joined defendants, but reasoned that under the rule it had adopted each manufacturer's liability would be approximately equivalent to the damages caused by the

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made, but liable for only one-fifth of the total damages in these cases. X would pay the same amount either way.

*Id.* at 612 n.28, 607 P.2d at 937 n.28, 163 Cal. Rptr. at 145 n.28 (citing *Fordham Comment*, *supra* note 26, at 994).

68. 26 Cal. 3d at 610-11, 607 P.2d at 936, 163 Cal. Rptr. at 144. Requiring plaintiff to identify the manufacturer which supplied the DES used by her mother or to join all DES manufacturers would effectively preclude her recovery. *Id.*

69. *Id.* (citing *Summers v. Tice*, 33 Cal. 2d 80, 199 P.2d 1 (1948)).

70. 26 Cal. 3d at 611, 607 P.2d at 936, 163 Cal. Rptr. at 144.

71. *Id.* at 610, 607 P.2d at 936, 163 Cal. Rptr. at 144 (citing *Escola v. Coca Cola Bottling Co.*, 24 Cal. 2d 453, 467, 150 P.2d 436, 440-41 (1940) (Traynor, J., concurring) (the contemporary complex industrialized society may necessitate adaptation of traditional tort principles)).

72. 26 Cal. 3d at 610, 607 P.2d at 936, 163 Cal. Rptr. at 144 (citing RESTATEMENT (SECOND) OF TORTS § 433B, comment h (1965) (modification of the *Summers* rule may be necessary if one of the actors is not or cannot be joined, or because of the effects of lapse of time or other circumstances)).

73. 26 Cal. 3d at 611, 607 P.2d at 936, 163 Cal. Rptr. at 144 ("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.").

74. *Id.* (citing *Cronin v. J.B.E. Olson Corp.*, 8 Cal. 3d 121, 129, 501 P.2d 1153, 1159, 104 Cal. Rptr. 433, 439 (1972) (public policy requires that responsibility be fixed where it will most effectively reduce "hazards to life and health")).

75. 26 Cal. 3d at 611, 607 P.2d at 936, 163 Cal. Rptr. at 144 (citing *Escola v. Coca Cola Bottling Co.*, 24 Cal. 2d at 462, 150 P.2d at 441 (Traynor, J., concurring) ("the cost of an injury and the loss of time or health may be an overwhelming misfortune to the person injured, and a needless one, for the risk of injury can be insured by the manufacturer and distributed among the public as a cost of doing business")).

DES it had in fact manufactured.<sup>76</sup> The joined defendants could also file cross-complaints against DES manufacturers not joined in the action and allege that they might have supplied the injury-causing product.<sup>77</sup>

Although the *Sindell* decision can be described as a deliberate policy decision seeking to compensate the plaintiff,<sup>78</sup> it did not impose liability on the manufacturers. The case was on appeal from judgments granting the defendants' demurrers.<sup>79</sup> The plaintiff will still have to prove at trial that the DES was the cause-in-fact of her injuries<sup>80</sup> and that the allegedly tortious manufacturing and marketing of DES was the legal cause of her injuries.<sup>81</sup> Furthermore, any individual defendant will not be liable if it can prove that its product could not have caused the plaintiff's injury.<sup>82</sup>

76. 26 Cal. 3d at 613, 607 P.2d at 938, 163 Cal. Rptr. at 146; *see supra* note 67. The court acknowledged that a minor discrepancy in the correlation between market share and liability is inevitable, but indicated that when a correct division of liability cannot be made "the trier of fact may make it the best it can." 26 Cal. 3d at 613, 607 P.2d at 937, 163 Cal. Rptr. at 145. The discrepancy would develop when the joined defendants produced only a portion of the relevant market, but would still be held liable for all of the plaintiff's damages. *See id.* at 617, 607 P.2d at 940, 163 Cal. Rptr. at 148 (Richardson, J., dissenting).

77. 26 Cal. 3d at 613, 607 P.2d at 937, 163 Cal. Rptr. at 145. Allowing cross-complaints against DES manufacturers not joined in the action would help correct the possible discrepancy in the correlation between market share and liability. *See supra* note 76.

78. 26 Cal. 3d at 610, 607 P.2d at 936, 163 Cal. Rptr. at 144. After recognizing arguments against allowing the plaintiff's claim, the *Sindell* court stated: "There are, however, forceful arguments in favor of holding that plaintiff has a cause of action." *Id.*

79. *Id.* at 596, 607 P.2d at 926, 163 Cal. Rptr. at 134.

80. The general rule is that in order for the plaintiff to recover in a products liability action he must show that the product is defective, that the defect caused his injury, and that the defective product is attributable to the party held responsible. 2 L. FRUMER & M. FRIEDMAN, PRODUCTS LIABILITY § 16A(4), at 3B-88 (1980). The *Sindell* court, however, held only that plaintiff need not establish the precise manufacturer of the injury-causing product. 26 Cal. 3d at 611-12, 607 P.2d at 937, 163 Cal. Rptr. at 145.

81. W. PROSSER, *supra* note 17, § 42, at 244. The issue of proximate or legal causation may limit liability even when the fact of causation is clearly established. *Id.* For a discussion of the various causation issues involved in *Sindell*, *see supra* notes 17-22 and accompanying text.

The DES plaintiff faces a number of problems in establishing legal causation. First, the plaintiff may not be able to utilize strict liability to hold the manufacturers liable. An exception to the application of strict liability to drugs exists in cases in which the drugs are unavoidably unsafe, are properly prepared and marketed, and are accompanied by proper warnings. RESTATEMENT (SECOND) OF TORTS § 402A, comment k (1965). The duty to issue proper warnings is apparently conditioned upon a seller's actual or constructive knowledge of the danger. *Id.* at comment j; *accord*, *Needham v. White Laboratories, Inc.*, 639 F.2d 394, 400 (7th Cir. 1981) (manufacturer of synthetic estrogen is subject to strict liability on the basis of failure to warn of a known or foreseeable danger); *Christofferson v. Kaiser Foundation Hosps.*, 15 Cal. App. 3d 67, \_\_\_, 92 Cal. Rptr. 825, 826 (1971) (scienter required before pharmaceutical manufacturer is under a duty to warn). *But see Crocker v. Winthrop Laboratories*, 514 S.W.2d 429, 432 (Tex. 1974) (Suit for wrongful death resulting from addiction to a drug; court held that some drugs are so dangerous that the manufacturer should be liable for harm caused by them even though the manufacturer did not know of the dangers involved when the drug was marketed). *See also Fordham Comment, supra* note 26, at 971 n.25 (DES manufacturers may have been on notice of some of the carcinogenic properties of the drug in early 1950s). Another obstacle which must be overcome in establishing legal causation is whether the DES plaintiff's injuries were reasonably foreseeable when her mother ingested the drug. Pharmaceutical manufacturers may not have been under a duty to test for second generation injuries in 1947 when DES was originally marketed. *Id.*

82. 26 Cal. 3d at 612, 607 P.2d at 937, 163 Cal. Rptr. at 145. Although the manufacturers do not have knowledge superior to that of the plaintiff regarding causation, "they may in some instances be able to prove they did not manufacture the injury-causing substance." *Id.* at 601-02, 607 P.2d at 930, 163 Cal. Rptr. at 138.

Thus, the *Sindell* court merely adopted a method of establishing causation-in-fact not possible under traditional tort doctrines, leaving to the defendants the task of resolving the question of responsibility among themselves.<sup>83</sup>

The significance of the *Sindell* decision lies in the court's willingness to adopt a new basis for recovery in products liability actions.<sup>84</sup> The Supreme Court of California has been a strong force in the development of products liability law, and the decision may signal a movement toward judicially created no-fault compensation in products liability actions involving fungible products.<sup>85</sup> Three points within the court's opinion indicate this possibility. First, the court recognized that the pharmaceutical industry should bear the loss, rather than the unfortunate consumer who fortuitously incurred the injury.<sup>86</sup> The court recognized that traditional causation and liability rules are not always appropriate in this era of mass production and complex marketing procedures.<sup>87</sup> Therefore, a new theory was adopted, allowing a plaintiff to fictionally establish causation-in-fact by a named defendant. Second, the burden placed upon the plaintiff to establish fictional causation was minimal. The court required only that the plaintiff join those manufacturers which together made up a "substantial percentage" of the relevant enterprise.<sup>88</sup> Finally, the manner in which damages were apportioned indicates the court's willingness to adopt no-fault liability. Each defendant was proportionately liable for the judgment based upon its status in the relevant enterprise, and not upon its personal fault for the plaintiff's injury.<sup>89</sup> The *Sindell* decision thus may be viewed not only as an adaptation of the rules of causation and liability to our complex industrialized society, but may also be characterized as a purely deliberate policy decision, necessary because of an apparent breach

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83. *Id.* at 610, 607 P.2d at 936, 163 Cal. Rptr. at 144.

84. *Id.* at 598, 607 P.2d at 928, 163 Cal. Rptr. at 136.

85. "No-fault" is used here in the context of creating liability without establishment of traditional causation-in-fact by a named defendant manufacturer. The plaintiff must still establish causation by a particular defective fungible product and that each joined manufacturer has in fact marketed that product. *See supra* notes 79-82 and accompanying text.

86. 26 Cal. 3d at 610-11, 607 P.2d at 936, 163 Cal. Rptr. at 144. The court also noted that manufacturers "are better able to bear the cost of injury resulting from the manufacture of a defective product." *Id.*

87. *Id.*

88. *Id.* at 612, 607 P.2d at 937, 163 Cal. Rptr. at 145. The court stated that the defendants must represent a "substantial market share," but did not indicate what would be considered "substantial." It implied, however, that it was something less than seventy-five percent. *Id.* The court also did not define "market share." The majority described the practical problems involved in defining the market and determining market share as "matters of proof." *Id.* at 613, 607 P.2d at 937-38, 163 Cal. Rptr. at 145-46.

89. *Id.* at 612, 607 P.2d at 937, 163 Cal. Rptr. at 145. The court correlated causation and liability to each manufacturer's share of the relevant market. *Id.* For a discussion of the court's unique basis for apportioning damages, see *supra* notes 63-67 and accompanying text.

of a special responsibility undertaken by pharmaceutical manufacturers in supplying medication to pregnant women.<sup>90</sup>

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90. See W. PROSSER, *supra* note 17, § 39, at 223. Many products liability attorneys apparently believe that the *Sindell* holding is applicable to products other than DES. The potential list of cases could include litigation involving "chemical substances, agricultural products, and consumer items — any case where there is a defective design that is followed by many companies in making an identical product." Wall St. J., Dec. 30, 1980, at 1, col. 6.