Sindell v. Abbott Laboratories (1980) [1]

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Sindell v. Abbott Laboratories was a 1980 California case that established the doctrine of market share liability for personal injury cases. For such liability, when a drug causes personal injury and the manufacturer of the drug cannot be identified, each producer is responsible for paying the settlement in proportion to the percentage of the market they supplied. Judith Sindell and Maureen Rogers brought the case against the producers of diethylstilbestrol (DES), which their mothers had taken during pregnancy [4] to prevent miscarriage [5] and other complications. Sindell and Rogers alleged that their mothers' ingestions of DES during pregnancy [4] later caused Sindell and Rogers to develop cancers at the onset of puberty, but they could not identify the specific manufacturer of the drug. The market share liability ruling in *Sindell* allowed millions of DES-affected individuals to seek restitution for reproductive cancers caused by prenatal exposure to DES.

In 1938, Edward Charles Dodds [6] and his colleagues synthesized diethylstilbestrol (DES), a synthetic compound that mimics estrogen [7], at the University of Oxford [8] in Oxford, England. DES was similar to naturally occurring estrogens, cheap to manufacture, and remained potent and effective after administration. Because Dodds synthesized DES at a publically funded university in England, the drug could not be patented, so many drug companies produced DES as a generic drug.

Doctors prescribed DES to treat different gynecological problems, including menopausal and postmenopausal issues. In 1949 researchers Olive Watkins Smith and George Van Siclen Smith at Harvard University in Cambridge, Massachusetts, found that a variety of pregnancy [4] complications, like premature birth and fetal death in the womb [9], correlated to a decrease in the amount of estrogen [7] in pregnant women's urine. They hypothesized that administering DES during pregnancy [4] would simulate estrogen [7] production and prevent those complications. US doctors began to prescribe DES in the mid-twentieth century to prevent miscarriages, particularly in women with a history of miscarriages.

In 1953, William Dieckmann at the University of Chicago [10] in Chicago, Illinois, and other colleagues established that if women used DES during pregnancy [4], they did not prevent complications. In the late 1960s, Arthur L. Herbst at the Massachusetts General Hospital in Boston, Massachusetts, observed vaginal cancers (adenocarcinoma) in five teenagers. The unlikelihood of that cancer occurring in so many young women led Herbst and others to suggest a causal connection between pregnant women who ingested DES, and later reproductive cancer in their exposed children during early adulthood. Those effects included enlargement of the glands in the breast (adenosis), and glandular cancer in the vagina [11] and bladder.

In November of 1971, the US Food and Drug Administration [12], headquartered in Maryland, banned the use of DES during pregnancy [4]. Doctors later identified DES as an endocrine disruptor, as something that impacts the endocrine system as it distributes and concentrates hormones [13] throughout the body. When human embryos or fetuses were exposed to DES *in utero*, the drug impacted the mechanism for regulating sex hormones [13], and upon reaching puberty, women prenatally exposed began to develop cancer.

Between 1938 and 1971, an estimated four million women in the United States took DES while pregnant, resulting in millions of affected children and spawning many lawsuits. One was a personal injury case brought by Sindell in the late 1970s against eleven DES drug manufacturers, including Abbott Laboratories, in the Los Angeles County Superior Court in California. Sindell alleged that her mother's ingestion of DES caused her malignant bladder cancer, and vaginal, cervical, and breast tumors. Her lawsuit charged DES manufacturers as liable for the negligent marketing and sale of an unsafe drug. Rogers brought a similar suit against DES manufacturers in Ventura County Superior Court in California. In her lawsuit, Rogers claimed that her mother's ingestion of DES and her subsequent prenatal exposure later caused Rogers's vaginal and cervical cancers.

Sindell and Rogers filed toxic tort cases, in which they claimed that prenatal contact with DES caused them personal injury. As a toxic tort case, Sindell and Rogers were responsible for proving their injuries and that DES had caused their injuries. Sindell and Rogers were both affected by specific kinds of cancer, shown in multiple studies to correlate with DES consumption and abnormal development. However, neither Sindell nor Rogers could specify the drug company that had produced the DES ingested by their mothers. Trial courts at the county level dismissed Sindell's and Rogers's cases due to their inability to identify a single manufacturer as liable.

Sindell and Rogers independently appealed their cases to the California Courts of Appeal, which also dismissed them in 1978. Sindell and Rogers again independently appealed their cases to the Supreme Court of California in San Francisco. In 1980, the court accepted the two cases and merged them into the single case *Sindell v. Abbott Laboratories*, due to the similarity between the two cases and the damages each woman sought. Jason G. Brent, Laurence M. Marks, and Jay H. Sorensen represented Sindell and Rogers. A twelve-person legal team represented the drug manufacturers. Eleven *amicus curiae* briefs were submitted on behalf of Sindell and Rogers.

The California Supreme Court heard testimony and in a four to three decision reversed the lower trial courts' decisions to dismiss Sindell and Rogers's cases. Justice Stanley Mosk wrote the majority opinion, joined by Chief Justice Rose Elizabeth Bird, Justice Frank C. Newman, and Justice White. The justices addressed Sindell's petition, as Rogers' petition differed slightly in that it attempted to identify Eli Lilly and Company as the specific company that had manufactured her mother's DES. The majority opinion contained four parts, three parts about the different legal precedents comprising Sindell's case, and one part elucidating the court's decisions.

As legal decisions are decided based on the precedents set in previous cases, Sindell and Rogers's case relied on three precedents. They relied on alternative liability, concert of action, and enterprise liability. The court addressed those precedents in the first three parts of the majority opinion.

First, the court addressed Sindell and Rogers's claim that alternative liability, a precedent set in *Summers v. Tice* (1947), applied to their case. *Summers v. Tice* was a California Supreme Court case in which three men had gone quail hunting, and Summers was shot twice by the other men. Summers sued both of them for personal injury, but he could not identify from which gun the shots originated. The California Supreme Court decided that both men who shot at Summers were liable, and the burden of proof shifted to the shooters to prove their innocence. That doctrine became called alternative liability, when multiple parties are liable for a single injury and the burden of proof is too high to assure a favorable outcome for the injured party, the burden of proof shifts to the wrongdoer to exonerate him or herself.

However, the 1980 California Supreme Court found that the precedent of alterative liability did not apply in the *Sindell* case because Sindell sued only eleven manufacturers, but greater than two hundred companies had produced and marketed DES. As Sindell could not ascertain which manufacturers produced the drug her mother had consumed, the companies being sued might not have caused Sindell's injuries. The court decided that it was unfair to burden each of the eleven companies with proving their innocence, when all of them could be innocent.

The second part of the majority opinion addressed Sindell's claim that the precedent of concert of action applied. Concert of action refers to the legal theory that when a party is injured by a group activity, the injured party can sue all participants of the group as equally liable for the injury if there is evidence that they were working toward a common goal. Though only one party may have caused the injury, all other parties are responsible if it can be shown that the group acted in concert.

The California Supreme Court held that the precedent of concert of action did not apply to *Sindell*. Though the industry as a whole had acted similarly, many of those actions arose from US Food and Drug Administration (FDA) regulations. Thus, the manufacturers were not responsible for the consequences of the actions taken pursuant to FDA regulation [14]. Furthermore, Sindell and Rogers didn't show that any of the manufacturer had knowledge of other manufacturers causing injury.

The third precedent invoked by Sindell and addressed in the majority ruling was enterprise liability, established in a federal district court case, *Hall v. E.I. du Pont de Nemours & Co.* (1972). In *Hall*, exploding blasting caps had injured thirteen children in different accidents. Those injured had brought the case against six blasting cap manufacturers and their trade association. Because all six manufacturers and the trade association had followed the same safety procedures and cooperated to design and manufacturer almost identical products, the *Hall* decision held that all were liable for the injuries. If any injured party demonstrated that the blasting cap that injured them was produced by any of the six manufacturers, the burden of proof shifted to the manufacturer to prove they did not produce the blasting cap. The *Hall* decision established the doctrine of enterprise liability, in which individual entities are responsible for a single injury if they are part of a joint enterprise.

Again, the California Supreme Court found that the precedent invoked was not applicable to *Sindell*, because the manufacturers of DES were too numerous. *Hall* applied only to cases in which relatively few holders comprised the industry. In the case of DES, two hundred entities comprised the industry, and the eleven sued by Sindell were too few to represent the industry.

The final section of the majority opinion contained the court's decision with regards to *Sindell*. Justice Mosk, who wrote the the majority opinion, stated that the extant precedents required the California Supreme Court to uphold the lower courts' decisions to dismiss the case. However, Mosk noted that Sindell and others affected by DES had cause to sue and receive compensation, and the court did not want to dismiss the case without awarding such compensation. The majority opinion held each DES manufacturer responsible for the percentage of Sindell's damages equivalent to their market share of DES at the time the pregnant mother ingested the drug. However, an individual manufacturer could prove their product was not responsible for injury and not pay damages, based on the market share liability doctrine.

Justice Frank K. Richardson wrote a dissenting opinion, joined by Justices William P. Clark and Wiley M. Manuel. The dissenting opinion stated that market share liability allowed for injured parties, who were not present at the time of injury, to sue many years after the initial injury. Furthermore, market share liability assured compensation from drug companies that may not have been responsible for those injuries. Richardson argued that the majority opinion spread liability too far and overturned causation as the traditional requirements to establish liability. Injured parties no longer had to establish that a specific product from a specific manufacturer caused a specific injury. If a manufacturer made up a substantial market share, it was liable for damages caused by any manufacturer in the market.

Further, Richardson questioned how the court established market share, as the injuries occurred many years ago and market share changes rapidly, preventing the courts from accurately determining the market share at the time of injury. Some legal

scholars echoed Richardson's worries about defining market share and calculating damages. Some suggested that *Sindell* could encourage more safety testing of drugs prior to their release on the market.

The US Supreme Court, in Washington, D.C., declined to accept the case on further appeals, so the *Sindell* decision set a precedent. The decision established a precedent that individuals affected by prenatal exposure to medicines could bring suits against pharmaceutical companies decades after the time of injury. The *Sindell* decision had implications not only for the first and second generation of offspring affected by DES, but also for those affected by other endocrine disruptors that act prenatally.

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Subject

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