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Case Commentary

The DES product liability story in America: The third generation litigation

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In the medical-injury field, issues of ethics and principles of law often overlap. In my own career spanning some 40 years, I have practiced and taught in each field and have contributed to American textbooks that have examined developments in each field. [1,2].

In my judgement, the tragedy and drama of DES (diethylstilbestrol) played out over these same decades could be analyzed as a single-textbook, case study of medical ethics and law in action. The broad history of DES has been reviewed in this *Journal* before [3,4].

The drug was marketed from the late 1940s by over 300 manufacturers in the U.S.A. and prescribed for millions of women during pregnancy as a miscarriage prevention. (The serious dangers of any form of drug-intervention during pregnancy had not yet sobered the enthusiasm of most practicing physicians in this expansive era before thalidomide shattered all illusions.)

Early on, the complexities of the DES story began to sift out. It was soon evident that damage could and did often occur in the developing female fetus exposed to the drug in utero. Studies linked the drug to vaginal and cervical cancers and to serious malformations of the uterus, cervical and Fallopian tube deformities, and other abnormal cell and tissue problems. There was a marked increase in infertility, miscarriage and ectopic pregnancies. It was not until 1971, however, that diethylstilbestrol was removed from the American market.

In litigation, the first ethical/legal controversy revolved around the manufacturer's obligations to the DES daughters. Why, asked opponents of recovery, should product liability (either for negligence or sales warranty) be extended to include persons not born at the time of the wrongdoing or exposure? In ethics, this is the subject matter of *deontology*, the study of moral duties. Most ethicists had little trouble supporting a duty by manufacturers (and attending physicians or obstetricians) to the daughters since the pregnancy was known at the time of exposure. Legal analysis was more complex, but the same conclusion was reached. In hotly contested judicial inquiries and scholarly reviews, it was determined that product liability should be imposed because the drug was being used for a pregnancy-related treatment objective and the developing fetus was within "the

zone of danger" of the ingested agent. The jurisprudential position accepted the concept of a prenatal and previable right of the daughter to recover damages in a civil lawsuit.

In this early litigation period, these philosophical points were quickly overshadowed. Other serious problems of a practical nature were much more urgent. The plaintiffs were required to prove a scientific causal relationship between their particular deformity and the mother's ingestion of the drug. There were many scientific difficulties in individual cases, particularly when the mother had not herself suffered ill effects and may not have adequate records herself or through her physician.

The most serious impasse loomed when hundreds of plaintiffs were not able to provide reliable indication of what particular manufacturer had supplied the product to this patient. How could it be fair to allow lawsuits for huge monetary awards against companies that could be completely innocent of injuring this particular mother and daughter? Could the plaintiffs merely be allowed to choose whomever they could reach with legal jurisdictional service? This would be justice by whim or lottery.

A response to this problem came largely due to the massive volume of the lawsuits themselves. The litigated cases tended to pool into the hands of a small, select number of expert attorneys who could argue distributive justice, social policy, and macroeconomics to the sophisticated judges assigned to preside over these extremely important and complex trials.

What solution prevailed? It was more macroeconomics than deontology. The courts in America came up with an ingenious distributive justice theory based upon corporate market share of the entire volume of sales at the time of the mother's ingestion of DES. The companies joined in the lawsuits were required to pay a share of the total damages depending on their percentage of the total market at the time [5–7].

But, as the title of this commentary indicates, the voluminous literature of the DES story was not yet exhausted. Before the litigation over claims of the daughters had run its course, speculation had begun over potential for later-generational claims. How could any line be drawn for individual or wholesale denial of claims if the scientific evidence was adequately convincing [8,9]?

The first case to be decided by a state highest court has now quite recently been reported [10]. There are other claims before the American courts [11]. This key first-impression decision was produced in the New York Court of Appeals, undoubtedly one of the most prestigious and influential state tribunals in the country.

In a detailed and soberly written opinion, the New York Court adopted a general rule against all recoveries by these later generations in DES litigation. The court held that no other result could be tolerated. To rule otherwise would create product liability of "staggering implications". There would be no way to confine recoveries except by "artificial and arbitrary boundaries". A clearly manageable limit could be set at those women who ingested the drug and those exposed to it in utero.

The New York Court was helped by the fact that recoveries for later-conceived persons had been denied in a well known 1981 decision in New York involving medical malpractice [12]. That earlier situation had involved a later-conceived and born male child to the same woman who was injured in the alleged obstetrical malpractice. It was therefore not a third-generational claim. Some other American courts have disagreed with New York State and imposed liability for some "preconception torts" [13,14].

In the third-generation DES case, the New York Court specifically reexamined the earlier precedent noted above. The plaintiff's attorney argued that the *Albala* case should not be followed because DES was a favored area of recovery in so many American courts. This turned out to be very bad strategy for the plaintiff. Chief Judge Wachtler, in his opinion for the Court, specifically rejected this idea and reaffirmed the earlier *Albala* ruling. He denied any judicial uniqueness or favored position for DES litigation. In fact, he stressed that the "public policy" of the United States favors the availability of prescription drugs even though most carry some risks. He also cautioned against extending liability beyond manageable and predictable limits because of what he called:

"...the dangers of overdeterrence – the possibility that research will be discouraged or beneficial drugs withheld from the market".

He concluded in a most forceful manner with this statement:

"These dangers are magnified in this context, where we are asked to recognize a legal duty to generations not yet conceived."

Chief Judge Wachtler cited one more public policy reason in support of the court's determination to limit the scope of pharmaceutical product liability. He noted that the civil courts and financial awards to plaintiffs were not the only available public means "of encouraging prescription drug safety; the Federal Food and Drug Administration has *primary responsibility* for that task". (Emphasis supplied.)

It remains to be seen whether other American high courts and other national tribunals will agree with the *Enright* case in its reasoning, its philosophy, and its public policy.

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