



1970

# Product Liability and the Pill

Joyce Barrett

Follow this and additional works at: <https://engagedscholarship.csuohio.edu/clevstrev>

 Part of the [Torts Commons](#)

**How does access to this work benefit you? Let us know!**

---

## Recommended Citation

Joyce Barrett, *Product Liability and the Pill*, 19 Clev. St. L. Rev. 468 (1970)  
available at <https://engagedscholarship.csuohio.edu/clevstrev/vol19/iss3/13>

This Article is brought to you for free and open access by the Law Journals at EngagedScholarship@CSU. It has been accepted for inclusion in Cleveland State Law Review by an authorized editor of EngagedScholarship@CSU. For more information, please contact [library.es@csuohio.edu](mailto:library.es@csuohio.edu).

## Product Liability and the Pill

Joyce Barrett\*

THE PILL IS BIG BUSINESS<sup>1</sup> to the eight United States manufacturers of oral contraceptives,<sup>2</sup> and serious business to the estimated 8.5 million American women who each day swallow the innocuous-looking little tablet. Grave doubts have been raised as to the safety of the Pill by physicians, psychologists, medical researchers,<sup>3</sup> and, finally, the Congress of the United States.<sup>4</sup> Some of these doubts are manifested in the lawsuits (over 300)<sup>5</sup> filed by Pill users (or their survivors) against Pill manufacturers.

### Searle—Where the Pill (and the Litigation)—Began

The lion's share of the oral contraceptive market belongs to G. D. Searle & Co.—“Where the Pill Began.”<sup>6</sup> The Pill did indeed begin at Searle, in May of 1960, when it received permission from the Food and Drug Administration to market *Enovid*.<sup>7</sup> Litigation stemming from alleged Pill-caused side effects began at Searle too. The first of such cases to come to trial was *Simonait v. Searle*,<sup>8</sup> which went to the jury on theories of negligence and breach of implied warranty. Plaintiff claimed that she had contracted thrombophlebitis (formation of blood clots within the veins) as a result of taking the defendant's oral contraceptive Enovid. She charged Searle with negligence in failing to warn of the possibility that Enovid might cause thrombotic disorders. Among the battery of doctors who testified for Searle were Victor A. Drill, who headed Searle's investigation of Enovid, and Celso-Ramon Garcia, who performed Searle's Puerto Rico field trials of Enovid. The doctors testi-

\* B.A., Cleveland State University; Third-Year student at Cleveland State University, Cleveland-Marshall College of Law.

<sup>1</sup> Williams, Harold (M.D., LL.B.), *Pregnancy or Dead? The Pill in New Perspective* (New Perspective Publications, 1969). At page 23, Dr. Williams estimates that the wholesale value of domestic sales of the Pill is presently \$100,000,000 per year, and export sales are equal to that or more.

<sup>2</sup> G. D. Searle & Co., Syntex Laboratories, Inc., Mead Johnson Co., Ortho Pharmaceutical Co., Parke, Davis & Co., Eli Lilly and Co., The Upjohn Co., and Wyeth Laboratories, Inc.

<sup>3</sup> Seaman, Barbara, *The Doctors' Case Against the Pill* (Peter H. Wyden, Inc., 1969).

<sup>4</sup> On January 13, 1970, Senator Gaylord Nelson's Small Business Monopoly Subcommittee began hearings on the safety of oral contraceptives.

<sup>5</sup> Letter to author dated January 16, 1970, from Attorney Paul D. Rheingold, Trustee of Birth Control Pill Group.

<sup>6</sup> G. D. Searle & Co. booklet, *Planning Your Family* (February 2, 1969), bears the following words on the back cover: “Searle—Where the Pill Began.”

<sup>7</sup> Federal Food, Drug, and Cosmetic Act § 505(b), 21 U.S.C.A. § 355(b).

<sup>8</sup> Circuit Court for County of Kent, Grand Rapids, Michigan, Civil Case No. 1916, tried May 18-26, 1965.

fied that they believed plaintiff's condition was caused by her varicose veins and not by her use of Enovid. The jury agreed, and after a short deliberation brought back a defendant's verdict.

*Black v. Searle*<sup>9</sup> came to trial on May 12, 1969, and went to the jury on May 20 on counts of negligence, breach of implied warranty, and strict liability. This was an action brought by Raymond Black, as administrator of the estate of his deceased wife, Elizabeth, who had died on September 18, 1965, at the age of twenty-nine, from a pulmonary embolism allegedly caused by Enovid. Plaintiff charged that Searle had failed to adequately warn in its instruction booklets given to doctors, and, in turn, to patients, that the Pill could cause thromboembolic phenomena (clotting). The issue of warning went to the state of knowledge chargeable to Searle as of the date of Mrs. Black's death.<sup>10</sup> Plaintiff maintained that at that time there were approximately 600 reports of thromboembolic phenomena, including a number of deaths, among women using Enovid. The plaintiff had a difficult time, however, proving causation. There were several problems in that regard peculiar to this case, one being the fact that she had been in a minor automobile accident about two months prior to her death. Testifying on behalf of the defendant, Dr. Chris A. Pascuzzi, a pathologist at the South Bend Medical Foundation, stated that the fatal blood clot could have been caused by either inflammation from an upper respiratory infection or injury to a vein in the accident. Also testifying for Searle was Dr. Celso-Ramon Garcia, who stated that in his opinion there was no correlation between the use of the Pill and thromboembolic phenomena; that the Pill was safe; that he had no hesitancy about prescribing it for members of his family; that he had done so in the past and would continue to do so. Another pro-Pill doctor to testify for Searle was Robert Kistner, a gynecologist from Brookline, Massachusetts, and associated with Harvard's Medical School. Dr. Kistner testified that he had supervised the use of Enovid in five to six thousand women and had seen no evidence of thromboembolic disease. He further stated that he had operated on a number of these women and found nothing untoward in their pelvic organs, such as distended veins or evidence of clots. Still another Searle witness, Dr. Herbert S. Sise, a prolific writer on blood clots, testified that, in his opinion, there was no relationship between the use of the Pill and blood clots.

Plaintiff's experts included Dr. Herbert Ratner, Director of the Department of Public Health in Oak Park, Illinois, Dr. Paul E. Haley, a retired surgeon from South Bend, Indiana, and Dr. John F. Hillabrand, Director of Obstetrics and Gynecology at St. Vincent's Hospital in To-

---

<sup>9</sup> U. S. Dist. Ct. of Northern District of Indiana—South Bend Division, Civil Case No. 4082 (1969).

<sup>10</sup> Defendant's Tendered Instruction No. 10.

ledo, Ohio, and chairman of the National Commission of Human Reproduction and Rhythm. Dr. Hillabrand testified that, in his opinion, Enovid was directly connected with Mrs. Black's death. He said that the Pill slows down circulation of the blood and dilates the veins in the genital organs and chest so that the blood congeals. He further stated that the risks attendant with the use of the Pill for contraceptive purposes were not justified. Dr. Ratner agreed that fatal blood clots can be caused by the use of Enovid, but that the medical profession had not been given the objective story on this, so that they were not sure whether there was such a causal connection. Dr. Haley, who had performed over 400 autopsies, testified that he was medically certain that the Pill had a causal relation to Mrs. Black's death.

From this conflicting testimony emerged a "qualified" defendant's verdict. The jury found for the defendant on all three counts, but appended this recommendation to their verdict:

Further, it is the recommendation of this jury that, effective immediately, G. D. Searle & Company, in instruction literature both to doctors and patients, advise the dangers of the possibility of phlebitis, thrombotic, and embolic phenomena.<sup>11</sup>

Judge Robert Grant, however, advised the jury that their added directive would not be legally binding upon Searle.

Still another case involving thromboembolism was *Carmichael v. Searle, et al.*<sup>12</sup> The plaintiff alleged that she had suffered thromboembolism while taking Enovid. She had, however, discontinued the use of this contraceptive and had recovered by the time of the trial. Searle used its perennial witnesses, among whom were Dr. Sise and Dr. Kistner, who gave their usual pro-Pill testimony. Among plaintiff's witnesses was a Dr. Samuels, a hematologist, who had done blood studies upon the plaintiff to show the change in her blood factors while on and off Enovid. The jury deliberated for a day and a half, but returned another defendant's verdict. An appeal has been taken from the decision in this case.

### The Manufacturer's Duty

As indicated by the foregoing, plaintiffs did not fare well in the early Pill litigation. To be sure, there were settlements,<sup>13</sup> but generally for very low amounts.<sup>14</sup> The three theories on which plaintiffs unsuccessfully sought recovery were negligence, breach of warranty, and strict liability.

<sup>11</sup> Surface, Bill, "Controversy Over the Pill," *Good Housekeeping* (Jan., 1970).

<sup>12</sup> Superior Court of California for the County of Los Angeles, No. SO C 10586 (1969).

<sup>13</sup> The Oct. 4, 1968 edition of *Medical World News* quotes Searle's president as saying: "If you can settle for \$500.00 instead of \$12,000 you do."

<sup>14</sup> *Supra* n. 5.

As regards negligence, when a drug manufacturer develops a new drug subsequently found to produce harmful side effects, he may be held liable for negligence where it is shown that he failed to exercise due care in the development of the drug,<sup>15</sup> failed to adequately test the drug,<sup>16</sup> or failed to warn of the subsequently-discovered dangerous side effects.<sup>17</sup> As an "ethical drug" (one that is available only by prescription), the Pill is supposed to be advertised and promoted only to physicians.<sup>18</sup> Therefore, the drug manufacturer owes a duty to the medical profession to warn it of dangers inherent in its drugs which, in the exercise of reasonable care, it knew or should have known, to exist.<sup>19</sup> Moreover, the drug manufacturer has a further duty to bring home to the prescribing physician warnings about the potential dangers involved in the use of the drug.<sup>20</sup> The medical profession has a right to rely on a drug company's representations concerning the safety of its products, so that the "watering down" of warnings by drug manufacturers concerning the safety of their products is tantamount to inadequate warning.<sup>21</sup> Therefore, a drug manufacturer which discovers harmful side effects produced by its product, yet fails to give adequate warnings to foreseeable users, is negligent.<sup>22</sup> Further duties imposed on the drug manufacturer include warning even a small idiosyncratic group of users of the potential dangerous propensities of its drugs,<sup>23</sup> keeping reasonably abreast of scientific knowledge and discoveries in the field,<sup>24</sup> and having knowledge of medical journals which warn of hazardous side effects.<sup>25</sup>

Turning now to warranty, recovery has been sought for breach of the implied warranties of merchantability<sup>26</sup> and fitness for purpose.<sup>27</sup> Plaintiffs have contended that a drug which is designed to prevent pregnancy, but also causes a side effect such as thrombophlebitis, is neither fit for a particular purpose nor merchantable. Liability for breach of these warranties is not based upon fault or failure of the manufacturer to exercise reasonable care. Merchantability is an implied-in-law representation that the thing sold is reasonably fit for the general purpose for

<sup>15</sup> *Toole v. Richardson-Merrell, Inc.*, 251 Cal. App. 2d 689, 60 Cal. Rptr. 398 (1967).

<sup>16</sup> *Roginsky v. Richardson-Merrell, Inc.*, 378 F. 2d 832 (2d Cir. 1967).

<sup>17</sup> *Tinnerholm v. Parke Davis & Co.*, 285 F. Supp. 432 (S.D.N.Y. 1968).

<sup>18</sup> *Williams, op. cit. supra* n. 1, at 80.

<sup>19</sup> *Tinnerholm v. Parke Davis & Co.*, *supra* n. 17.

<sup>20</sup> *Krug v. Sterling Drug, Inc., et al.*, 416 S.W. 2d 143 (Mo. Sup. Ct. 1967).

<sup>21</sup> *Rheingold, Products Liability—The Ethical Drug Manufacturer's Liability*, 18 *Rutgers L. R.* 947 (1964).

<sup>22</sup> *Sterling Drug, Inc. v. Cornish*, 370 F. 2d 82 (8th Cir. 1966).

<sup>23</sup> *Love v. Wolf*, 249 Cal. App. 2d 822, 58 Cal. Rptr. 42 (1967).

<sup>24</sup> *Krug v. Sterling Drug, Inc., et al.*, *supra* n. 20.

<sup>25</sup> *Ibid.*

<sup>26</sup> *Unif. Coml. Code* § 2-314.

<sup>27</sup> *Id.* at § 2-315.

which it is used.<sup>28</sup> The fitness-for-particular-purpose warranty is basically the same, except that it requires reliance on a particular seller's skill and judgment. In the case of an ethical drug, the prescribing physician has been held to be his patient's agent for the special purpose of receiving statements from the manufacturer concerning the drug.<sup>29</sup>

Finally, plaintiffs have sought recovery under strict liability in tort. This theory has been characterized as a "hybrid, having its commencement in contract and its termination in tort,"<sup>30</sup> and is said to arise from the "mere presence of the product on the market."<sup>31</sup> To prevail under a strict liability theory, the plaintiff must establish the defendant's relationship to the product, its defective and unreasonably dangerous condition, and a proximate causal connection between the product's dangerous condition and the plaintiff's injuries.<sup>32</sup>

### The Anatomy of a Pill Case

Attorney Paul D. Rheingold<sup>33</sup> is trustee of a seventy-member Birth Control Pill Group comprised of attorneys with Pill cases who have banded together to render mutual assistance. Most of the group members have one or two cases; a few have a half dozen or more. Mr. Rheingold thinks that many more suits are imminent and will probably be joint malpractice-product liability actions.<sup>34</sup>

Such a suit is *Charles Gillette, Administrator of the Estate of Alinie Gillette vs. Samuel L. Friedman, M.D., and G. D. Searle and Company*.<sup>35</sup> Plaintiff's decedent was twenty-two years old, had two children, and a history of rheumatic heart disease, anemia, and pulmonary congestion. She had been using foam as a contraceptive when, in May of 1967, the defendant doctor started her on Searle's oral contraceptive Ovulen. During June and July Mrs. Gillette reported migraine headaches, menstrual frequency and irregularity, and small hair-like veins appearing on the lower extremities. She was hospitalized on August 27, 1967, and died two days later. The autopsy showed rheumatic heart disease, bilateral pulmonary congestion, edema, hemorrhage, and apparent obstruction of major bronchi.

The defendant doctor was charged with negligence in that he knew, or should have known, that oral contraceptives should not be prescribed

---

<sup>28</sup> 2 Frumer & Friedman, Products Liability § 16.01(1) (1967).

<sup>29</sup> Wechsler v. Hoffman-LaRoche, Inc., 198 Misc. 540, 99 N.Y.S. 2d 588 (1950).

<sup>30</sup> Santor v. A & M Karagheusian, Inc., 44 N.J. 52, 207 A. 2d 305 (1965).

<sup>31</sup> *Id.* at 311-12.

<sup>32</sup> 13 A.L.R. 3d 1066 (1967).

<sup>33</sup> Member of the New York City law firm of Speiser, Shumate, Geoghan, Krause & Rheingold.

<sup>34</sup> *Supra* n. 5.

<sup>35</sup> U. S. Dist. Ct. (N.D. Ohio), Case No. C 68-589.

for a patient with the medical history of plaintiff's decedent; that he assured her that Ovulen was safe; that thereafter he negligently examined, treated, and advised her and failed to observe and investigate the cause of certain warning symptoms and continued her on Ovulen until the date of the last treatment on August 5, 1967.

The defendant Searle was charged with negligence in testing, manufacturing, labeling, marketing, and promoting Ovulen; in obtaining written permission from the government to market the drug; in failing to heed warnings which came to it from others about the dangerous properties of its product; and in failing to make adequate warnings about these properties to the medical profession and consumers of its products. Searle was also charged with breach of warranty in that at the time of the sale it knew or should have known that Ovulen was to be used for a particular purpose, and it was to be used for human consumption; that plaintiff's decedent relied on Searle's skill and judgment to select and furnish safe and suitable drugs; that Ovulen was neither safe nor suitable, and directly and proximately resulted in the death of Mrs. Gillette.

As "new drugs" under the provisions of the Federal Food, Drug, and Cosmetic Act, oral contraceptives must be proved both safe and effective before permission for commercial distribution is given by the Food and Drug Administration.<sup>36</sup> This entails the filing by the manufacturer of a new drug application, which is accompanied by full reports of tests made to show the safety of the drug, a full list of its components, a full statement of its composition, a full description of the methods, facilities, and controls used for its manufacture, processing, and packing, and specimens of proposed labeling.<sup>37</sup> Thus, to prove negligence on the part of the manufacturer in developing and testing the Pill, the plaintiff must have access to this data. Can the plaintiff obtain this information to aid him in proving his negligence claim?

The United States District Court for the Eastern District of New York answered this question affirmatively in *Meyer v. Searle*,<sup>38</sup> an action arising from plaintiff's sustaining of a coronary artery disease allegedly caused by Enovid. Plaintiff filed a motion for an order requiring defendant to produce and permit her to inspect and copy correspondence in defendant's files between it and the Food and Drug Administration concerning Enovid. The court granted plaintiff's motion, stating that since the defendant:

. . . controlled the information plaintiff needed, either directly to sustain her cause of action for negligence, breach of warranty, strict

---

<sup>36</sup> F.D.A. Fact Sheet on Oral Contraceptives (U.S. Dept. of Health, Educ. and Welfare CSS-D 5-7-69).

<sup>37</sup> *Supra* n. 7.

<sup>38</sup> 41 F.R.D. 290 (E.D.N.Y. 1966).

liability, and misrepresentation, or indirectly to lead her to useful and competent evidence, and in view of the nonavailability of the government's public record wherein a copy of the new drug application filed was to be found, good cause existed for discovery.<sup>39</sup>

As regards the failure-to-warn count, the plaintiff must establish the state of medical knowledge of oral contraceptives as of and prior to August 29, 1967, the date of his wife's death. In the year 1966, the Index Medicus,<sup>40</sup> for the first time under its general heading "Oral Contraceptives" listed a subheading called "Adverse Effects." Reports of vascular problems are prominent in this list.<sup>41</sup> Numerous other medical articles reporting adverse Pill effects had been published prior to August 29, 1967.<sup>42</sup> As early as 1964, the Physician's Desk Reference, the chief source of drug information that is available to physicians, reported "thromboembolic phenomena with some fatalities" among women on the Pill.<sup>43</sup>

Was Searle disseminating information about these side effects to prescribers and/or users of Ovulen? The package insert in the Ovulen-21 Compact<sup>44</sup> "warns" of the following "adverse effects":

1. Spotting or breakthrough bleeding.  
"Such irregular bleeding seldom occurs with Ovulen. . ."
2. Nausea.  
"A mild nausea may come and go for several days of the first cycle or two. The vast majority of women never experience this."
3. Feeling of fullness and weight gain.  
"A few women, once they no longer fear pregnancy, feel better and actually eat more, which, of course, will result in weight gain."

Searle's final "warning" is: "Unusual changes in your health should be reported to your physician—just as they should if you were not on Ovulen."

<sup>39</sup> *Ibid.*

<sup>40</sup> Cumulated Index Medicus, Contraceptives, Oral (D5) (1966).

<sup>41</sup> Thrombosis of the hepatic veins. "The Budd-Chiara syndrome"—a possible link between oral contraceptives and thrombosis formation, Ecker, J.A. et al. *Amer. J. Gastrent* 45:429-43, June '66; Oral Contraceptives and cerebral arterial occlusion, Illis, L., et al., *Brit. Med. J.* 5471:1164-6, 13 Nov. 65; Oral contraceptives, thrombosis, and cyclical factors affecting veins, Payne, R.T., *Brit. Med. J.* 5490:802, 26 Mar. 66; Vascular headaches and oral contraceptives, Trimble, G. X., *Canad. Med. Assn., J.* 94:1241, 4 June 66; Recurring pulmonary embolisms with secondary thrombosis of the pulmonary arteries due to taking an oral contraceptive, *Schweiz Med. Wschr.* 95:1367-72, 9 Oct. 65, etc.

<sup>42</sup> A case of multiple arterial thromboses after oral contraceptives and ergotamine, Brohult, J., et al., *Acta Med. Scand.* 181:453-6, April, 1967; Liver damage from oral contraceptives, Stoll, B.A., et al., *Brit. Med. J.* 5493:960, 16 Apr. 66; Breast problems and oral contraceptives: a clinical note, Morin, J.E., et al., *Conn. Med.* 30:569-70, Aug. 66; Oral contraceptives and thromboembolic episodes, Cahal, D.A., *Lancet* 2:1013, 13 Nov. 65, etc.

<sup>43</sup> Williams, *op. cit. supra* n. 1, at 123.

<sup>44</sup> Copyright 1966, "Directions for Use."



Were Searle's detail men "bringing the warning home" to physicians about the Pill's harmful side effects? Searle's suggested presentation of Ovulen by detail men to doctors went like this:

Dr. -----:

Searle is happy to present a chemically new, clinically unique oral contraceptive—OVULEN—offering at the lowest dosage, positive prevention of pregnancy, with the lowest incidence of side effects—at the lowest price. The safety of Ovulen has been well established by world-wide experience including 4 million women's cycles. Ovulen has no additional contraindications or precautions to those that apply to all oral contraceptives.<sup>45</sup>

As a result of the British studies indicating a seven-to-tenfold increase in fatal and disabling blood clotting diseases among Pill users as opposed to non-Pill users,<sup>46</sup> the Food and Drug Administration directed that new label warnings for oral contraceptives reflecting these British findings be required to accompany all packages of oral contraceptives coming off the production line after June 30, 1968; and that advertisements are to reflect these labeling revisions beginning September 1, 1968.<sup>47</sup> The uniform labeling must contain the following table on thromboembolic disease:

	Death Rates		Hospitalization Rates
	Age 20-34	Age 35-44	Age 20-44
Pill Users	1.5/100,000	3.9/100,000	47/100,000
Nonusers	0.2/100,000	0.5/100,000	5/100,000

Four other contraindications were also required to be listed: thrombophlebitis, or history of thrombophlebitis or pulmonary embolism; liver dysfunction; carcinoma of the breast or genital organs; undiagnosed vaginal bleeding. Three warnings were required to be given as to when to discontinue medication. Mentioned are loss of vision or migraine, the missing of two consecutive periods, and any manifestation or thrombotic disorders.<sup>48</sup>

These guidelines are a far cry from the "warnings" being given by Searle at the time of Mrs. Gillette's death.

Turning back to the theory of strict liability, the chief roadblock to the argument for strict liability to the drug manufacturer is found in Comment k to § 402A of the Second Restatement of Torts, which provides:

<sup>45</sup> G. D. Searle & Co. Code 963, June 20, 1966.

<sup>46</sup> Inman & Vessey, Investigation of Deaths from Pulmonary, Coronary, and Cerebral Thromboembolism and Embolism in Women of Child-bearing Age, *L. Brit. Med. J.* 193 (4-27-68); Vessey & Doll, Investigation of Relationship Between Use of Oral Contraceptives and Thromboembolism Disease, *id.* at 199.

<sup>47</sup> Williams, *op. cit. supra* n. 1, at 34.

<sup>48</sup> *Ibid.*

There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are *especially common in the field of drugs*. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. *Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified*, notwithstanding the unavoidable degree of risk which they involve. Such a product, properly prepared and *accompanied by proper directions and warning*, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also 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 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 situation calls 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, attended with a known but apparently reasonable risk. (Emphasis added)

The question then to be considered is what constitutes a "defective condition"? Comment g to § 402A defines it as a "condition not contemplated by the ultimate consumer, which will be unreasonably dangerous to him," and Comment h goes a step further by suggesting that where a defendant has reason to anticipate a possible danger from a particular use, and it fails to give adequate warning thereof, a product sold without such warning is in a defective condition.

The thrust of Comment k seems to be directed at products for which there is a dire need and no safe alternative available. Do these criteria apply to the Pill? Can pregnancy be categorized as a "disease which invariably leads to a dreadful death?" Furthermore, while they may not be as effective or convenient as the Pill, there is an abundance of other contraceptive methods available.<sup>49</sup>

There is precedent for imposing strict liability on the drug manufacturer. In *Toole v. Richardson-Merrell, Inc.*,<sup>50</sup> the court said that strict liability could be imposed on a drug manufacturer for eye injuries incurred by plaintiff as a result of the use of defendant's MER/29, where there was evidence that the manufacturer had been informed of the

---

<sup>49</sup> Planned Parenthood Federation of America, Inc.'s pamphlet "Modern Methods of Birth Control" (No. 401 — 11-68) recommends seven other effective means of contraception.

<sup>50</sup> *Op. cit. supra* n. 15.

dangerous propensities of the drug and yet failed to label the product with any warnings to that effect.

The reason for joining as a defendant the prescribing physician in a Pill case is that it is he to whom the duty to warn of the potential adverse effects of the Pill runs. He is then supposed to inform the patient of these hazards, so that the decision of the patient to still take the Pill is an "informed consent." With the sword of legal responsibility for Pill harm hanging over the prescribing physician's head as well as the manufacturer's, one insurance company, providing malpractice coverage for some 18,000 physicians, sent out on May 14, 1969, the following "Dear Doctor" letter:

Dear Doctor:

Contraceptive Pills

Because of the increasing awareness of potential complications from contraceptive pills, and because we are already handling lawsuits dealing with some of these complications, we are advising physicians to obtain signed statements from their patients which acknowledge requests for these pills despite awareness of the serious risks involved.

We offer the enclosed form which can be used in most instances.

Sincerely,

The suggested form:

CONTRACEPTIVE DRUGS

Read Carefully Before Signing!

The prescription for contraceptive drugs on this date and for every refill hereafter is at my request. In making this request, I am aware that such drugs can cause serious reactions and complications, both known and presently unknown.

Date: \_\_\_\_\_ Signature of patient \_\_\_\_\_<sup>51</sup>

**The Pill's Halo Tarnishes**

The great social value of the Pill in this era of the population explosion has been stressed. As the simplest and most effective form of contraception available, the Pill has enjoyed a "diplomatic immunity"<sup>52</sup> from criticism. However, in light of the Senate hearings into the Pill and other reports of its adverse effects,<sup>53</sup> the Pill's halo is rapidly tar-

<sup>51</sup> Williams, *op. cit. supra* n. 1, at 95.

<sup>52</sup> Seaman, *op. cit. supra* n. 3, at 239.

<sup>53</sup> FDA requires manufacturers of oral contraceptives to revise labeling in light of British studies linking pills with blood clotting problems, source: New York Times, May 1, 1968; Health Bulletin, Nov. 9, 1968, Pill-cancer link not ruled out; Committee on Safety of Drugs in Great Britain says pills with more than 75 micrograms of estrogen likely to cause blood clotting, source: New York Times, December 14, 1969, etc.

nishing. Also ending is the immunity from liability enjoyed by Pill manufacturers for the past five years.

On April 15, 1970, after a five-week trial, a Brooklyn, New York jury returned a \$250,000.00 plaintiff's verdict in *Meinert v. Searle*.<sup>54</sup> Mrs. Meinert developed a mesenteric thrombosis in 1962 after taking Enovid for eight months, necessitating an operation to remove portions of her intestines. Plaintiff proceeded on the bases of express warranty, implied warranty, strict liability, and common-law negligence; the latter theory being subdivided into failure to properly test before marketing and failure to warn of dangers known or which should have been known. The court rejected the express warranty theory, but submitted the other three to the jury, along with interrogatories asking the jury to specify on which theory it made its findings. The jury brought back a verdict for the plaintiff on all of the three submitted counts.

Lightning struck again on April 24, 1970, when a Federal District Court jury in Detroit brought back a plaintiff's verdict in *Tobin v. Searle*.<sup>55</sup> Mrs. Tobin was awarded \$225,000.00 (her husband received \$50,000.00 for the loss of her consortium) for clotting in the deep veins of her right leg following the use of Enovid. Plaintiff was hospitalized eight times from 1963 through 1965, and underwent surgery twice—once to sever a nerve in an attempt to end severe pain in her groin and right leg, and a second time to replace her destroyed long thigh bone with artificial tissue. Bolstering plaintiff's case was testimony from plaintiff's own prescribing physician that he had relied on data sent to him by Searle, which was incomplete, and some 350 case reports of other clotting incidents obtained from Searle by discovery.

### The Future of Pill Litigation

Attorney Paul D. Rheingold believes that there is cause for general optimism in future Pill cases, but that much depends upon the date of the use, the notice, the warning, the prescribing physician's role, and the skill of the individual counsel.<sup>56</sup> Mr. Rheingold also feels that Searle gave neither the Meinert nor the Tobin case an all-out defense, in view of the abundance of proof now available about the Pill's harmful effects and the growing number of witnesses who are willing to testify.

Moreover, plaintiffs' attorneys have received judicial sanction for the sharing of their pre-trial discoveries. In *Williams v. Johnson & Johnson*,<sup>57</sup> the defendant sought a protective order prohibiting plaintiff from divulging any material obtained from the defendant to any other person. Judge Tyler denied the motion, explicitly passing upon the objection

<sup>54</sup> Supreme Court, Kings County, N. Y. Case No. 2549-65 (1970).

<sup>55</sup> U. S. Dist. Ct., Det., Mich., Case No. 25669 (1970).

<sup>56</sup> Twelfth Report to the Birth Control Pill Group (May 7, 1970).

<sup>57</sup> U. S. Dist. Ct. (S.D.N.Y.), 66 Civ. 3650 (1970).

made by defendant that a group of lawyers was sharing documents among themselves. He stated:

Without more, the charging of fees between attorneys collaborating in similar cases and the collaboration itself both seem reasonable on their face. There is simply no evidence here that plaintiffs' attorneys are stirring up litigation. This court will not issue a protective order when it appears that there is nothing from which to legitimately protect the movants.

### Conciusion

The Pill has been on the market now for ten years and has been in wide use for five. Only within the last year, however, have widespread reports of the adverse effects associated with the Pill been publicized. The Pill has now been associated with maladies that run the gamut from thrombotic disorders, strokes, cancer, and jaundice on the one hand, to weight gain, irritability, nausea and depression on the other.<sup>58</sup> But, these problems may be only the exposed part of the iceberg, and proof positive of what lies beneath may not be established for another ten years.

If the Pill was born from an urgent public policy consideration to not propagate ourselves off the face of the earth, should not liability for harm done by it also be grounded on the same consideration? It must be remembered that the Pill is not a drug which must be taken to control the ravages of some serious disease. It does not directly alleviate human suffering, but is taken by normal, healthy women. While the Pill manufacturers may be aiding society by providing a convenient and effective method of checking the overpopulation problem, they are also handsomely profiting from Pill sales. Thus, the burden of compensating those injured by oral contraceptives should properly fall on the manufacturers and be treated as a cost of production. This, in turn, should prompt the manufacturers to initiate more ambitious testing and research programs which may ultimately result in the development of a convenient, effective, and safe Pill.

---

<sup>58</sup> Seaman, *op. cit. supra* n. 3.