Mahr v. G.d. Searle & Co.

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Rehearing denied June 27, 1979.

The defendant, G.D. Searle & Company (Searle), appeals from the entry of judgment in the Circuit Court of Cook County on a jury verdict for the plaintiff in the sum of $100,000. The plaintiff's amended complaint, filed on behalf of the husband and son of the deceased, alleged a cause of action for wrongful death and premised liability on Searle's manufacture and distribution of the oral contraceptive Enovid [1] without adequate warning of possible adverse effects. The deceased, Sandra Brewer, was alleged to have died as the result of an occlusion of the left internal carotid artery caused by the regular ingestion of Enovid. The record discloses the following facts as material to the issues raised by this appeal.

Sandra Brewer was born August 17, 1941. The evidence depositions of Sandra's mother and father indicate that the deceased enjoyed good health up to the time of the illness which resulted in her death. The father noted that Sandra had been using diet pills and that she had stopped taking them a substantial period of time prior to her death. These diet pills were shown to the attending physician at the Harris Hospital in Fort Worth, Texas, where Sandra was admitted following the manifestation of the illness which led to her death. Neither parent was aware of any history of ill health in Sandra's family. The family physician who treated Sandra from the time she was six years old until her marriage testified in his deposition that she was in good health during this period and that she had no history of convulsions.

Norman Elliot Brewer testified that his wife, Sandra, began taking Enovid for birth control purposes about one month following the birth of their son in 1963. The contraceptive was originally obtained on the prescription of Dr. Thomas Carroll Ford and later renewed on the prescription of Dr. Earl U. Sharf in May 1965. Brewer indicated that Sandra took the drug regularly until her final hospitalization in December 1966, at which time it was discontinued on order of the attending physician. In the early part of 1965 Sandra experienced and complained of blackouts or memory lapses, dizziness, headaches and tingling in the fingers. She consulted an osteopathic physician, Dr. George Luibel, who diagnosed an infection. In August 1965 the Brewers vacationed at Port Isabel, Texas, where Sandra experienced fainting and vomitting. These symptoms cleared up within a day and no treatment or medical advice was sought at that time.

In 1966 the Brewers visited the husband's parents in Breckenridge, Texas, for the Memorial Day holiday. Early in the morning on May 30, Sandra experienced, while sleeping, what the husband described as a seizure. Sandra was taken to the emergency room of Stevens Memorial Hospital in

Breckenridge and there attended by Dr. Edwin Goodall, who was substituting for Dr. Ford. Sandra was discharged the next day. The following day she was seen by Dr. William McKinney in Fort Worth, to whom she was referred by Dr. Goodall. Dr. McKinney administered an electroencephalogram (EEG) and prescribed an anticonvulsant drug for Sandra. After the 30 anticonvulsant pills were used, the prescription was not renewed. In October 1966 Sandra had a second seizure and was admitted to an osteopathic hospital in Fort Worth by Dr. Luibel. She was discharged three days later, at which time Dr. McKinney advised her by telephone to refill the anticonvulsant prescription. Brewer indicated that the diet pills his wife was using had been prescribed and supplied for her by Dr. O.W. Dana. Brewer noted that Sandra was about 5'1" tall and that she weighed 140 pounds.

In December 1966 Sandra sustained a third seizure while sitting on the edge of her bed. Dr. Luibel was consulted and Sandra's condition got worse. On December 30 she was admitted to Fort Worth's Harris Hospital with a paralysis of the right side of the body. The attending physician, Dr. George Prewitt, was given the remaining birth control pills and diet pills which Sandra had been taking. It was diagnosed that Sandra had suffered a cerebral vascular accident (stroke) resulting in the paralysis of the right side. For a while Sandra improved and was able to walk dragging the right leg. Between therapy sessions she was allowed to leave the hospital in the company of her husband. At this time Sandra was able to communicate only with the use of about three words. Sandra suffered a relapse in the latter part of January 1967, after which she became comatose and died on January 27.

It is not clear whether Dr. Luibel, Dr. Goodall or Dr. McKinney were aware that Sandra was using birth control pills. On cross-examination, however, Brewer did state that he never informed Dr. Luibel about his wife's use of Enovid.

Dr. Thomas Carroll Ford testified in his deposition that he was a physician in general practice in Breckenridge, Texas. He indicated that he cared for Sandra Brewer during and after her pregnancy in 1962-63. While she was pregnant Sandra's weight increased from 154 pounds to 190 1/2 pounds. Following the birth of Norman Brewer, in March 1963, Dr. Ford prescribed Enovid for Sandra; he wrote a prescription for a one-month supply of the pills and automatic renewal. Dr. Ford testified his patient was in good health and without signs of edema or circulatory problems; he indicated that her delivery had been normal. The doctor did not recall receiving so-called "Dear Doctor letters" from Searle during 1962-63; one of these letters related the fact that two California women had died while using Enovid. Ford stated that he was familiar with Searle's prescribing information concerning Enovid (package inserts), and that he had read the advertisements for the drug which indicated some women experienced weight gain, nausea and headaches with the use of Enovid. Dr. Ford also said that had he received any literature from Searle regarding Enovid he would have paid attention to it. Following Sandra's move from Breckenridge to Fort Worth in 1964, this doctor did not see her again as a patient.

The Enovid-E which Sandra was taking at the time of her admission to Harris Hospital in December

1966 was prescribed by Dr. Sharf, a Fort Worth specialist in internal medicine. However, Dr. Sharf could not locate his office records and did not recall prescribing the drug for Sandra; he did remember treating her for something very insignificant on one occasion.

In his deposition, Dr. Luibel testified he first treated Sandra in December 1965. She complained then of frequent and burning urination. There were no neurological complaints at that time. In October 1966 Dr. Luibel admitted Sandra to the Fort Worth Osteopathic Hospital for treatment of abdominal pains, cramping and a colon infection. She was discharged from the hospital three days later. On December 29, 1966, Dr. Luibel was called to see her at which time she was unable to speak. He gave her an injection of Compazine and suggested that she return to her anticonvulsant medication and discontinue her diet pills. The next day Sandra displayed positive hemi-paralysis of the right side, and Dr. Luibel referred her to Dr. George Prewitt.

Dr. Goodall, a Breckenridge physician in general practice, testified by deposition that he saw Sandra Brewer for the first time on May 30, 1966, in the emergency room of Stephens Memorial Hospital. From the description of the movements supplied by the husband to the emergency room nurse, Dr. Goodall diagnosed Sandra's condition as being a Jacksonian type seizure. She was admitted to the hospital for observation and discharged within a day.

The deposition of Dr. McKinney, a board-certified neurosurgeon in Forth Worth, indicates that he saw Sandra on referral from Dr. Goodall on June 1, 1966. He found no significant neurological symptoms and arranged for Sandra to have an EEG. The results of the EEG, as interpreted by Dr. Prewitt, revealed a mildly abnormal brain wave. No specific clinical correlation or diagnosis was assigned to Sandra's condition.

Dr. Prewitt, a neurologist on the staff at Forth Worth's Harris Hospital, assumed charge of Sandra's case upon her admission to the hospital in December 1966. He testified in his deposition he first saw the deceased in the hospital emergency room on December 30, at which time she was paralyzed on the right side of the body from a stroke. A spinal tap was performed which, along with other preliminary tests, disclosed no positive findings. An electrocardiogram (EKG), however, did indicate some findings which were not normal; these findings were never explained. A carotid arteriogram was performed, the results of which indicated a "beading appearance" in the left internal carotid artery. Dr. Prewitt tentatively diagnosed a spasm within the artery causing a blockage in the flow of blood to the left side of the brain. A second arteriogram was done and the results looked the same. Dr. Prewitt ruled out a spasm at that time and then believed that the blockage was due to a thrombosis (blood clot arising at the site of its formation). His review of the arteriograms disclosed an almost complete occlusion in the left internal carotid artery. This occlusion led to the patient's stroke and the resulting paralysis as well as the convulsions that had been experienced. Dr. Prewitt testified that he suspected that Enovid, the contraceptive pills Sandra had been taking, was responsible for the thrombosis. His other suspicion, fibromusculature hypoplasia, was definitively ruled out by the autopsy study.

Dr. Prewitt consulted with a hematologist, Dr. E. Richard Haulden; a program of Heparin therapy was ordered. Heparin is a drug which is used to reduce and dissolve clots. Sandra's condition improved for a while and she began to communicate through "yes" and "no" responses. On January 20, 1967, the patient suffered another convulsion and she relapsed into a state of deepening loss of consciousness. Sandra's brain began to swell and the dosage of Heparin was radically increased. On January 25 the Heparin was discontinued because the reduced clotting was affecting Sandra's ability to breathe — increased bleeding in her system had blocked her airways. On January 27 Sandra died from marked respiratory distress and extreme fever, both secondary to the thrombosis within the carotid artery. Dr. Prewitt testified that it was his opinion that Enovid causally contributed to Sandra's death. The fact that she had been taking the drug for several years did not rule out the contraceptive as the cause of the condition resulting in her death.

In his evidence deposition, Dr. Fred Aurin, a specialist in vascular surgery, testified that he was consulted by Dr. Prewitt for the purpose of evaluating Sandra's condition upon admission to Harris Hospital. His examination was conducted on January 5, 1967, at which time he also evaluated the arteriograms and concurred in Dr. Prewitt's interpretation. He noted an obstruction and occlusion of the internal carotid artery, two centimeters above the origin of the inner carotid artery on the left side. The occlusion displayed an unusual "beading appearance" and Dr. Aurin thought this to be rare in view of the patient's age and medical history. He suspected three reasons for the occlusion: congenital lesion, blood clot or malcoagulation of the blood flowing through the involved vessel. He testified that the internal carotid artery furnished blood to the left side of the brain and that surgery was ruled out in Sandra's case because of the location of the occlusion.

Dr. Aurin reviewed the autopsy findings and indicated that there had been a thorough and complete post-mortem examination of the arterial sections. However, he thought that in the autopsy report the description of the occluded area was ambiguous and for this reason a congenital lesion could not be positively ruled out. Nevertheless, it was Dr. Aurin's opinion that the unusual "beading appearance" also could lead one to the conclusion that the occlusion had formed as the result of Sandra's use of Enovid. Like Dr. Prewitt, he did not believe the length of the use of the contraceptive ruled out the possibility of its being causally related to the blockage of the artery.

Dr. Haulden, a hematologist and a specialist in internal medicine and clinical pathology, testified that he was consulted by Dr. Prewitt for the purpose of evaluating Sandra's condition and treatment. After seeing the patient at the Harris Hospital on January 8, 1967, Dr. Haulden suspected that the blockage was caused by cerebral embolism. Unlike a thrombosis, an embolism is a blood clot which forms in one part of the body, breaks free, and travels through the blood vessels until it lodges elsewhere. This suspicion, however, was later ruled out by the autopsy. Dr. Haulden prescribed Heparin to dissolve the blockage and noted that he expected Sandra's blood clotting time to be about 30 minutes with the administration of the drug — it was in fact, only 16 minutes. Indicating that this resistance to Heparin was unusual, this doctor testified it was his opinion that the short clotting time was in response to the occlusion itself and not indicative of abnormal clotting factors pre-existing in

the patient's system.

Dr. Haulden noted that medicine rarely supplies a definitive answer or diagnosis; nevertheless, he offered an opinion as to the cause of Sandra's condition and the resulting death. Based on experience in clinical practice, the age of the deceased, the presence of hypercoagulability, the disclosure by the autopsy of a normal arterial system and the absence of another satisfactory etiological explanation, Dr. Haulden stated that there was a causal connection between the deceased's use of Enovid and the occlusion of the carotid artery which produced death. He also believed that Sandra's length of use of the drug did not rule out the causal factor.

Dr. E. Ross Kyger, Jr., a board-certified specialist in internal medicine was also consulted in Sandra's case. He revealed in his deposition that he attended Sandra twice each day for three weeks following January 1, 1967. He testified that he was aware of the patient's history of Enovid use and that it was rare for a woman of 25 years to suffer a stroke as the result of a blood clot. Dr. Kyger reviewed the autopsy results and was of the opinion that no vascular disease had been found to account for the formation of the clot. [2] He believed the clot to be a thrombosis and not an embolism, and it was his opinion that the use of Enovid played a significant and important part in the production of the blood clot which led to Sandra's death. He stated that the length of use of the contraceptive could mitigate against its being a cause of the clot; nevertheless, the length of use would not rule out the causal connection entirely. He also noted that obesity is a factor which can trigger a clot, but only in the event there is pre-existing disease of the blood vessel walls, a disease Sandra did not have.

The autopsy performed on the body of Sandra Brewer was conducted by Dr. Donald M. Cohen, a board-certified pathologist. Dr. Cohen testified by deposition that the autopsy was done on the date of death, January 27, 1967. He indicated that he found no positive findings within the arterial system or venous system other than the occlusion of the left internal carotid artery and multiple thrombi in the medium sized arteries of the cerebral area. He found the cause of death to be the marked destruction of the brain as a result of the occlusion — a condition which produced pneumonia, the immediate cause of death. Dr. Cohen found no evidence of congenital defects or fibromuscular hypoplasia. The blood clot was found to be in the early stages of organization, no more than a few weeks old.

The plaintiff called Dr. Irwin Clinton Winter, Searle's vice-president for medical affairs, to testify as an adverse witness pursuant to section 60 of the Civil Practice Act (Ill. Rev. Stat. 1977, ch. 110, par. 60). He was also called as a witness for the defendant. Dr. Winter testified Enovid was first marketed and approved by the Federal Food and Drug Administration (FDA) for contraceptive purposes in 1960. For several years Searle had a monopoly on contraceptive pills in the United States. Dr. Winter noted that prior to 1960 it was known for at least 20 years that the synthetic hormones used in the manufacture of Enovid produced metabolic changes in humans. He noted that these hormones had been found to affect certain factors involved in the blood clotting process. Some researchers found factors promoting the process to increase, while others found factors inhibiting the process to

decrease.

Soon after 1960 Searle began to supply brochures to physicians and clinics for distribution to women for whom Enovid had been prescribed for birth control. [3] Dr. Winter testified that these brochures were not supplied directly to the women for whom Enovid had been prescribed and that the company never furnished any information about Enovid directly to the ultimate consumer until 1970, by which time the FDA had promulgated rules which required the uniform labeling of contraceptives and written warnings with every original and refill prescription. [4]

According to Dr. Winter several hundred articles concerning oral contraceptives have appeared in medical and scientific journals. Some of these articles were published prior to 1967 and suggested a connection between the use of oral contraceptives and the development or increased risk of thrombophlebitic disorders as manifested by findings indicating significant changes in blood clotting factors. (See, e.g., Margulis, Ambrus, Mink & Stryker, Progestational Agents and Blood Coagulation, 93 Am. J. Obst. & Gynec. 161 (1965); Thomson & Poller, Oral Contraceptive Hormones and Blood Coagulability, Brit. Med. J. 270 (July 31, 1965); Egeberg & Owren, Oral Contraception and Blood Coagulability, Brit. Med. J. 220 (Jan. 26, 1963).) Dr. Winter acknowledged that many of these articles had been received by the medical library at Searle and that he was familiar with the content and conclusions which had been published in them.

In 1962 Searle paid Dr. L.O. Pilgeram, a biochemist associated with the University of Minnesota, $3000 to conduct a study on the blood clotting effects of Enovid. Originally, Dr. Pilgeram had indicated that he believed the study would vindicate the drug; however, upon completion of the study he reported the research showed that Enovid produced significant changes in the blood clotting factors. He recommended the drug be withdrawn from the market until further studies could be made. He offered to conduct these studies if Searle would underwrite the costs. Upon receipt of Dr. Pilgeram's report Searle submitted it to several experts for their review and criticism. According to Dr. Winter, the comments obtained from these experts were for the most part negative — Pilgeram's methodology and conclusions were attacked. Searle never disclosed the Pilgeram report to the medical community; however, it was submitted to the FDA for filing with the new drug application regarding Envoid. Dr. Pilgeram later published his findings in the United Kingdom. His offer to conduct further studies for Searle was declined and the record indicates that these studies were never undertaken on behalf of Searle.

Dr. Winter testified Searle was aware that in 1961 two young women in Los Angeles died while using Enovid. Both of these women were the victims of pulmonary embolism and the subject of widespread new reports inculpating birth control pills. Responding to these deaths and reports of clotting problems and other deaths among women using oral contraceptives, Searle reported to physicians in the United States in a series of so-called "Dear Doctor" letters. The letters, dated August 7 and December 26, 1962, and August 7, 1963, indicated that no causal connection between oral contraceptives and thromboembolic disorders had been demonstrated. They also indicated there was

no available data to show a significant increase in the risk of death from blood clots among women using Enovid. Nevertheless, Searle requested physicians to report to the company all instances of thrombophlebitic disease developing in patients taking Enovid and assured the medical community that animal studies would be undertaken to gain further information. Results of these animal studies were never reported.

Meanwhile, several professional and governmental bodies, including the American Medical Association (AMA) and the FDA also began to look into the problem. Their reports revealed no significant statistical increase in blood clots or deaths among the population of women likely to be using Enovid. One of the reports submitted to the FDA by AMA through its Advisory Committee on Obstetrics and Gynecology in 1966 even suggested that oral contraceptives protect against clotting disorders. However, Searle and the FDA continued to recommend caution. Further research was conducted and the package inserts for Enovid were modified several times between 1962 and 1965.

Searle modified the package inserts by alerting physicians to thrombophlebitic problems in patients using Enovid as well as those who did not. In 1963 the company began to contraindicate Enovid for women with a prior history of thrombophlebitis or pulmonary embolism. The package insert for Enovid-E dated January 18, 1965, was the latest official prescribing information applicable to the contraceptive prescription Sandra Brewer was using just prior to her final hospitalization. Under the heading "Contraindications" the company listed:

"3. Previous Thrombophlebitis or Plumonary Embolism. Enovid-E is cffntraindicated in these patients unless the reason for its use in the judgment of the physician is overwhelming."

The "precautions" portion of the package insert presented a lengthy discussion of the blood clotting problem as an effect of oral contraceptive use. Under the subheading "Thrombophlebitis" Searle pointed out the ambiguity of knowledge linking Enovid to "hypercoagulability" and acknowledged the fact that the drug produces changes in clotting factors similar to those fouund during pregnancy. This section also noted the abundancy of published studies "to support the concept that the incidence of thrombotic episodes increases with age, parity, obesity [etc.]." This section of the package insert concluded with the statement:

"It seems a reasonable conclusion that these women [i.e., those with known predisposing factors linked to thrombosis] should be closely observed for the development of thromboembolic disease, whether or not they are receiving Enovid, particularly when they present signs and symptoms suggestive of acute pulmonary disease, even in the absence of clinical signs of peripheral thrombosis."

In all the information supplied to physicians prior to Sandra's death Searle continued to announce that no cause/effect relationship had been demonstrated between Enovid and an increased risk of blood clotting disorders. Likewise, the company never warned physicians to monitor patients using

Enovid in a manner different from the monitoring of those not using it, nor did it suggest Enovid be prescribed under circumstances which would insure a regular checkup for women using the drug. In January 1963 the FDA extended the recommended prescribing period for Enovid from two to four years. Thus, it became possible for a woman to secure a prescription for Enovid upon a single visit to a physician and then use it for years without further medical supervision.

Dr. Winter indicated that in addition to the "Dear Doctor" letters and the package inserts, Searle kept in contact with the medical community by way of its sales personnel (detailmen). Each physician in the United States was contacted an average of once every three months by a detailman. To assist them in their sales efforts Searle supplied various items for distribution as promotion pieces for Enovid. The detailmen were not trained to discuss the adverse effects of Enovid with the physicians on their sales routes; however, official prescribing information for Enovid was supplied to each physician whenever the detailmen made a call. The sales force also distributed information concerning Enovid to clinics, hospitals, nurses and pharmacists, and was encouraged to enlist the aid of everyone associated with the medical community for the purpose of promoting the demand for oral contraceptives and the sale of Enovid. The plaintiff introduced into evidence several documents which Searle addressed to its sales personnel in the campaign to promote the sale of Enovid. These documents present Enovid as a safe, unique, problem-solving pharmaceutical capable of producing substantial profits for Searle and its detailmen once exposed to the medical profession and the consuming public.

Throughout his testimony Dr. Winter maintained it has yet to be conclusively demonstrated that the use of oral contraceptives is causally related to the development of blood clots in humans. He criticized the studies which indicate a causal relation as being, for the most part, retrospective in design or affected by significant losses in follow-up studies. He noted the decision to market Enovid for birth control purposes was made by Searle and the FDA on the basis of information available at the time — information which, in his opinion, indicated that Enovid was a safe product when distributed to consumers only through the intervention of well-trained physicians. In his opinion the physicians who prescribe Enovid are knowledgeable in the processes of blood clotting, and the exercise of professional judgment in prescribing Enovid is made in light of this knowledge as well as the information supplied to them by Searle and that contained in the medical literature.

Dr. Fedor Bachmann was called as an expert witness for the plaintiff. As a specialist in hematology he directs the blood coagulation laboratory and thrombosis research unit located in the Rush-Presbyterian-St. Lukes Medical Center in Chicago. Dr. Bachmann testified that prior to 1965 research had established that the hormones used in the manufacture of oral contraceptives, including Enovid, elevated certain clotting factors in human blood. These elevations result in an increase in the metabolic processes which cause blood to clot. Following 1967 it was discovered that oral contraceptive hormones also decrease the level of antithrombin III, a blood factor which inhibits the clotting processes. By 1970 studies had determined not only significant changes in the clotting factors, but also the fact that oral contraceptives induce blood clots in the circulating blood system.

Dr. Bachmann stated, "It is my firm opinion that Enovid and other [birth control] pills to contribute to increased coagulation, that there is a positive relationship between clotting and the usage of the pill." With respect to the warnings expressed in the January 18, 1965, package insert and those in the unofficial prescribing literature listed in the 1965 edition of Physician's Desk Reference, Dr. Bachmann testified that they were inadequate in not specifically alerting physicians to specially monitor patients using Enovid for thrombosis, and in not directing the immediate withdrawal of the drug once thrombotic symptoms were manifest. It was his impression that the cautions provided by Searle were effectively "watered down."

For the defense, Searle called several expert witnesses in order to refute the plaintiff's evidence tending to establish that oral contraceptives cause thrombotic episodes, that Sandra Brewer suffered a thrombosis due to the use of Enovid, and that the warnings supplied by Searle to prescribing physicians were inadequate. Searle also introduced expert testimony to the effect that Sandra's death was the result of a diseased arterial system caused by her use of diet pills.

Dr. John Henry Isaacs, a board-certified specialist, clinical professor and past-chairman of the Department of Obstetrics and Gynecology at Loyola University of Chicago's Stritch School of Medicine, testified he had done some work for Searle regarding the effects of oral contraceptives. It was his opinion that the warnings in the 1965 package inserts regarding Enovid were adequate in light of the information known at that time. He also noted that the link between oral contraceptives and blood clotting disorders was a suspicion of "common knowledge" during Sandra Brewer's use of Enovid, and that a physician prescribing the drug at that time would take this suspicion into account.

Lawrence George Deysach, a mathematical biologist in Searle's employ, testified that he had worked with Dr. Fletcher, a hematologist associated with Barnes Hospital in St. Louis, Missouri. With Dr. Fletcher, Deysach developed a protocol for a clinical test of Ovulen-28, another oral contraceptive manufactured by Searle containing the same amount of estrogen as Enovid-E. Estrogen is the hormonal agent connected with clotting problems. Deysach indicated their double-blind prospective study on the effects of Ovulen-28 demonstrated no significant differences in clotting factors present in test women using the drug when compared with the test women using a placebo.

Dr. Jan E. Leestma, an assistant professor of pathology and neuropathology at Northwestern University and a board-certified pathologist, testified he could not say definitely that oral contraceptives do not produce clotting disorders. He noted that it has been established that the "pill" does alter some of the factors involved in the blood clotting processes. However, upon review of the autopsy findings and the tissue slides taken of the occluded artery removed from the body, Dr. Leestma was of the opinion that Enovid played no part in the death of Sandra Brewer.

Dr. Howard Lipton, a board-certified neurologist and a member of the faculty of Northwestern University Medical School, also reviewed the tissue slides made during the post-mortem examination of Sandra's body. He expressed his opinion that the occlusion of the left internal carotid artery was

the result of a disease process producing either a thrombosis or an embolus. He indicated this process had been going on within Sandra's system for at least six months as evidenced by the calcium deposits seen on the slides. In summary it was his opinion that the clot was produced by a diseased blood vessel, not by Enovid.

Dr. Joseph W. Goldzieher, a specialist in clinical chemistry and director of clinical sciences and reproductive biology for the Southwest Foundation in San Antonio, Texas, had been involved in research on oral contraceptives since 1958. He criticized the studies indicating a cause/effect relationship between the "pill" and thromboembolic disease. Like Dr. Winter, Dr. Goldzieher viewed these studies skeptically because of their retrospective nature, the predisposition to thrombosis from other causes of many of the women studied, or the inability of the researchers to sample a broad enough population in those prospective studies which had been undertaken. From his own prospective double-blind study with women using oral contraceptives compared to women using placebos, Dr. Goldzieher concluded there is no causal connection between the use of the "pill" and thrombophlebitic or clotting problems. The fact that women taking Enovid have sustained strokes due to cerebral thrombosis was considered by him to be coincidental. Nevertheless, on cross-examination, Goldzieher agreed that oral contraceptives alter several of the factors which control the clotting mechanism of human blood.

A Boston physician and board-certified internist, Dr. Herbert Sise, testified he was president-elect of Boston City Hospital and an associate clinical professor of medicine at Tufts Medical School at the hospital. Since 1952 the doctor has specialized in the study and treatment of thrombosis and blood coagulation. He conducted a study on oral contraceptives and their effect on blood coagulation mechanism. It was his considered opinion that oral contraceptives do not cause increased blood clotting.

Dr. John Daniel Wilkes, a pathologist who had been studying blood coagulation and clotting disorders for six years, testified for Searle. After reviewing the autopsy slides, the doctor stated Sandra's death was caused by a recent clot in the left internal carotid artery and the artery had been diseased prior to the formation of the clot. From his observations of severe myocarditis, and abnormalities of the thyroid, spleen and liver, Dr. Wilkes concluded the clot was an embolus which had originated in the diseased heart. It was his opinion that the diseased condition of Sandra's heart was caused by her use of diet pills. Dr. Wilkes also indicated that in his opinion the use of Enovid did not contribute to the cause of Sandra's death.

As a rebuttal witness, the plaintiff presented Dr. Kyger whose testimony had been admitted by deposition in the case in chief. The doctor was asked to refresh his recollection of the case by reviewing the autopsy report; however, he testified from memory using only one of the tissue slides for reference. He indicated diet pills played no part in the cause of Sandra's death. Had the diet pills been involved the heart would have been affected in a particular manner. Contrary to Dr. Wilkes' impression, Dr. Kyger found only a slight sign of disease in the right side of the heart. He noted that

in order for the clot to be an embolus, the left side of the heart would have to be diseased, because a clot originating in the diseased area noted by Dr. Wilkes would travel to the lung, not the brain.

In prosecuting this appeal Searle presents seven major issues for review: (1) whether the trial court erred in failing to direct a verdict in whether the jury was erroneously instructed, (3) whether the plaintiff improperly cross-examined the defendant's witnesses, (4) whether one of the plaintiff's expert witnesses improperly expressed opinions on matters beyond his competency and which were based on hearsay and were irrelevant, (5) whether it was error not to strike certain portions of an evidence deposition, (6) whether it was proper to admit into evidence intracompany documents regarding Searle's promotion of Enovid and (7) whether the direct examination of the plaintiff's rebuttal witness was improper and the cross-examination of this witness unduly limited. Before we address these issues, however, we shall consider the nature of the plaintiff's cause of action and the burden of proof required to sustain a verdict for the plaintiff.

This is an action for strict liability in tort premised upon the manufacture and distribution of Enovid in such a manner as to make the drug unreasonably dangerous for use by women. The drug is claimed to be unreasonably dangerous by reason of Searle's inadequate warning of possible side effects. It is further claimed that as a proximate result of the manufacture and distribution of Enovid without adequate warning, Sandra Brewer sustained an occlusion of the left internal carotid artery through use of Enovid, and that this was the cause of her death.

• 1 As framed, the plaintiff's claims correspond to the theory of strict liability in tort as presented in section 402A of Restatement (Second) of Torts and explained by certain of the comments thereto. (Restatement (Second) of Torts § 402A, Comments h, i, j, k (1965).) Without doubt, section 402A, particularly comment k, discloses that a prescription drug may be deemed unreasonably dangerous if it is manufactured and distributed without adequate warnings of possible adverse reactions, and that the manufacturer may be held liable in tort for any injuries caused by the ingestion of the drug distributed without such warnings, even though the manufacturer has exercised all due care in the manufacturing process and the drug itself is free from impurities.

• 2 The record reveals that this matter concerns the death of a Texas resident as a result of transactions occurring solely within the State of Texas; consequently, the law of Texas governs the substantive issues involved. (Ingersoll v. Klein (1970), 46 Ill.2d 42, 262 N.E.2d 593; Jackson v. Miller-Davis Co. (1976), 44 Ill. App.3d 611, 358 N.E.2d 328.) Texas, like Illinois, has adopted section 402A as an accurate statement of common law in reference to strict liability in tort, and courts> in both states have applied the theory to cases concerning prescription drugs alleged to have been made unreasonably dangerous by inadequate warnings. (Lawson v. G.D. Searle & Co. (1976), 64 Ill.2d 543, 356 N.E.2d 776, rev'd (1975), 29 Ill. App.3d 670, 331 N.E.2d 75; Woodhill v. Parke Davis & Co. (1978), 58 Ill. App.3d 349, 374 N.E.2d 683; Crocker v. Winthrop Laboratories (Tex. 1974), 514 S.W.2d 429; Bristol-Myers Co. v. Gonzales (Tex. Civ. App. 1977), 548 S.W.2d 416, rev'd on other grounds (Tex. 1978), 561 S.W.2d 801; Ethicon, Inc. v. Parten (Tex. Civ. App. 1975), 520 S.W.2d 527.) However, neither

State has developed a body of decisional law sufficient to dispose of the issues presented by this appeal without further analysis; consequently, our opinion also refers to cases from other jurisdictions which we believe to be consistent with the law of Texas and not contrary to the public policy of Illinois.

• 3 Unlike an action premised on negligence, the standard by which the law measures the liability of a manufacturer sued for strict liability in tort does not relate to the reasonableness or due care of the conduct under scrutiny. Here the duty is stated in a more positive fashion and the breach is found in an undertaking which falls short of ordinary considerations of fault. (See, e.g., Phillips v. Kimwood Machine Co. (1974), 269 Ore. 485, 525 P.2d 1033.) Texas law is clear that the manufacturer of a prescription drug must adequately warn of potential adverse reactions of the drug and that liability arises from injuries sustained by reason of the failure to so warn. The duty to warn extends at least to all ill effects which the manufacturer knew or should have known of at the time of marketing. (Crocker v. Winthrop Laboratories; Bristol-Myers Co. v. Gonzales. See also Sterling Drug, Inc. v. Yarrow (8th Cir. 1969), 408 F.2d 978 (applying South Dakota law); Davis v. Wyeth Laboratories, Inc. (9th Cir. 1968), 399 F.2d 121 (applying Montana law); Stevens v. Parke, Davis & Co. (1973), 9 Cal.3d 51, 107 Cal.Rptr. 45, 507 P.2d 653; Hamilton v. Hardy (1976), 37 Colo. App. 375, 549 P.2d 1099.) The Supreme Court of Texas has indicated a willingness to go even further:

"The failure to warn of a danger cannot always be excused by the mere fact that the potentially endangered users are few in number. Furthermore, some products, though manufactured as designed and intended, are so dangerous in fact that the manufacturer should be liable for resulting harm though he did not and could not have known of the danger at the time of marketing." (Crocker v. Winthrop Laboratories; at 432.)

It suffices for this case, nevertheless, to treat the duty involved as one concerning adequate warnings of adverse effects of Enovid of which Searle knew or should have known during the time Sandra Brewer was taking the drug.

As to the claim concerning Searle's compliance with FDA regulations, we note simply that such compliance is only minimal and does nothing to abrogate or alter duties arising under common law. Bristol-Myers Co. v. Gonzales; Lawson v. G.D. Searle & Co.; Stevens v. Parke, Davis & Co.; McEwen v. Ortho Pharmaceutical Corp. (1974), 270 Ore. 375, 528 P.2d 522.

Having established the extent of Searle's duty to warn of potential adverse effects of Enovid, we now consider the means by which this duty is fulfilled. This consideration encompasses two factors: (1) the role of the physician as recipient of the warning, and (2) the form, content and intensity of the warning.

• 4 The nature of prescription drugs and the ethics involved in the professional practice of medicine are such that it is a physician who decides what medications, if any, a patient is to take. Thus, while

the manufacturer's duty to warn is for the benefit of the ultimate consumer of its products, the physician, in the role of a learned intermediary, is the person to whom the warnings are to be communicated. (Crocker v. Winthrop Laboratories; Ethicon, Inc. v. Parten; Stevens v. Parke, Davis & Co.; Carmichael v. Reitz (1971), 17 Cal.App.3d 958, 95 Cal. Rptr. 381.) Contrary to Searle's position, however, the adequacy of the communication of the warning is not judged solely by reference to the information supplied by the manufacturer to the prescribing physicians. The Supreme Court of Oregon has described the responsibility of the manufacturer:

"[T]he ethical drug manufacturer's duty to warn has been discussed most often with reference to the prescribing physician, [but] the * * * reasoning applies with equal force to the treating physician. It is especially important that the treating doctor receive the manufacturer's warnings where it is impossible to predict in advance whether a particular patient is apt to suffer adverse effects from a drug, since the treating doctor may be more likely to observe the actual symptoms of the drug's untoward consequences. If the prescribing physician is entitled to make an informed choice in deciding whether the patient should begin taking a prescription drug, it follows that a treating physician should have the same information in making his decision as to whether the patient should stop taking that drug." (McEwen v. Ortho Pharmaceutical Corp., 270 Ore. 375, 387-88, 528 P.2d 522, 529. See also Vaughn v. G.D. Searle & Company (1975), 272 Ore. 367, 536 P.2d 1247.)

Therefore, we hold that Searle had the duty to adequately communicate the adverse effects of Enovid to all members of the medical profession who came into contact with Sandra Brewer in a decision-making capacity during the time she was using the drug.

• 5 Because the duty to warn is a duty to adequately warn, it is imperative that the communication of the warnings be given in a manner reasonably calculated to reach the medical profession. (See Sterling Drug, Inc. v. Yarrow.) In addressing this issue the Texas Court of Civil Appeals has concerned itself with a number of facets by which the adequacy of a required warning is defined:

"`* * * (1) [I]t must be in such form that it could reasonably be expected to catch the attention of the reasonably prudent man in the circumstances of its use [here, the members of the medical profession]; (2) the content of the warning must be of such a nature as to be comprehensible to the average [physician] and to convey a fair indication of the nature and extent of the danger to the mind of the reasonably prudent [physician]. . . . [T]he question of whether or not a given warning is legally sufficient depends upon the language used and the impression that such language is calculated to make upon the mind of the average user of the product.

Implicit in the duty to warn is the duty to warn with a degree of intensity that would cause a reasonable [physician] to exercise . . . the caution commensurate with the potential danger. . . . A clear cautionary statement setting forth the exact nature of the dangers involved would be necessary to fully protect the seller. . . .' (Emphasis supplied.)" (Bristol-Myers Co. v. Gonzales, at 423-24, quoting Muncy v. Magnolia Chemical Co. (Tex. Civ. App. 1968), 437 S.W.2d 15.)

The adequacy of Searle's warnings concerning Enovid is measured, therefore, not only by what is stated, but also by the manner in which it is stated. One finds from the facts of this case that a drug manufacturer has available to it a number of ways by which it communicates product information to the medical profession — package inserts, the PDR, "Dear Doctor" letters and detailmen. Ultimately, the sufficiency of form, content and intensity is not resolved by pointing to a single document, but remains a question to be resolved by the trier of fact in the light of all the information provided by the manufacturer and all that was reasonably possible to provide. See Lawson v. G.D. Searle & Co.; Stevens v. Parke, Davis & Co.; Carmichael v. Reitz.

• 6 In our discussion thus far it has been assumed that a warning was required. The nature of the action, however, makes no such assumption, for a prerequisite to the duty to warn is proof that the use of the involved drug subjects a user to a risk of injury. It was, therefore, the plaintiff's initial burden to prove that Enovid use involves the risk of thromboembolic disorders. Only if this risk were demonstrated was it proper to submit the adequacy of Searle's warnings to scrutiny, and subject the defendant to a finding of breach of duty to adequately warn.

• 7 Even if the duty to adequately warn was breached, liability does not attach simply by proof of use of Enovid and the disease and resulting death of Sandra Brewer. The plaintiff's burden also entails a showing that the use of Enovid resulted in, or contributed to cause, the arterial occlusion which led to the death. Furthermore, the plaintiff's burden required the demonstration that the deceased's initial and continued use of Enovid was a result of Searle's marketing of the drug in an unreasonably dangerous condition, e.g., without adequate warning of the risks involved.

In arguing that the motion for a directed verdict in its favor should have been granted, Searle appears to make the following points: (1) the warnings were not shown to be inadequate, (2) the proof was insufficient to show the arterial occlusion was caused by the use of Enovid, and (3) even if the warnings were inadequate and the occlusion was a result of Enovid use, there is no proof that the prescription and continued use of the drug was caused by a breach of duty to adequately warn Sandra's physicians. In responding to these points we need only consider whether there is evidence to support the court's denial of the motion and the subsequent submission of the case to the trier of fact.

The inadequacy of the warnings, as we have already indicated, is a question of fact within the prerogatives of the jury. Leaving aside the opinion of Dr. Bachmann that the warnings were inadequate, we are left with considerable evidence to indicate Searle should have warned of the danger of thromboembolic disease, and that it failed to so warn in an adequate manner. It must be remembered that while Searle vigorously contests any causal relationship between Enovid and clotting disorders, it continues to maintain it adequately warned against such disorders. Furthermore, the record is singularly void of any evidence which effectively rebuts the testimony indicating that the synthetic hormones used to manufacture Enovid have been found to alter blood factors involved in the clotting processes, and that these findings were available to Searle prior to the

manifestations of Sandra's fatal illness.

• 8 If we focus merely upon Searle's involvement with and reaction to the studies conducted by Dr. Pilgeram, one can reasonably conclude that Searle was itself suspicious of the causal link it has so painstakingly attempted to deny. Indeed, the evidence is clear that such suspicions existed as early as the reports concerning the deaths of the Los Angeles women, and continued to the time of the trial. More so than anyone else, Searle's knowledge of its products' effects must be measured by standards applied to an expert in the field; if it did not know what it should have known, it failed in its duty as an expert. (See Lawson v. G.D. Searle & Co.; McEwen v. Ortho Pharmaceutical Corp.) Nor is it fulfilling the duties of an expert to wait for what it considers to be sufficient proof of a cause-effect relationship before supplying the medical profession with an appropriate alert to the possibility of a risk involved in the use of one of its products. Hamilton v. Hardy.

• 9 The warnings concerning Enovid, available to the medical profession during Sandra's use of the drug, never really admitted the risks of blood clotting disorders in persons using the product. While certain cautions were directed in regard to women predisposed to such risks, and physicians were advised not to prescribe Enovid for patients with a prior history of thrombophlebitis or pulmonary embolism, no warning was given for healthy women without such predisposition or prior history. Moreover, Searle's discussion of any connection between Enovid use and clotting disorders always concluded with assurances that no scientific demonstration of such a connection had been made. While the defendant may have disagreed with the scientific findings suggesting the connection, it had not itself concluded research conclusively demonstrating its statements that Enovid was not known to produce clotting disorders. A jury was entitled to conclude that Enovid does produce such disorders and that "the cumulative effect of [Searle's warnings] was a definite assurance that no risk of thrombotic disorders was connected to the use of [Enovid], contrary to the defendant's actual [or constructive] knowledge." McEwen v. Ortho Pharmaceutical Corp. (1974), 270 Ore. 375, 528 P.2d 522, 535.

• 10 The evidence also would support submitting to the jury the question of inadequacy of the warnings by reason of their form. It is unrebutted that whatever warnings were given were written and that the 1965 PDR information concerning Enovid was in part disclaimed by Searle since it was not the official prescribing literature at that time. Thus, the relevant communications are the package inserts available prior to Sandra's fatal illness and the "Dear Doctor" letters of 1962-63. It is also unrebutted that Searle's sales personnel were not trained as a medium for orally conveying information about the adverse effects of Enovid. Given the evidence that detailmen called upon practicing physicians an average of four times per year, it is reasonable to conclude, from the circumstances of this case, that the practice of promotion of the drug through personal contact by the sales force permitted an effective form of communicating the risks involved in the use of Enovid. The failure of Searle to make use of this form indicates that it also failed to make reasonable efforts to effectively warn the medical community about the dangers of Enovid. (Sterling Drug, Inc. v. Yarrow.) This is especially the case when the evidence indicates Dr. Ford's inability to recall receipt

of the 1962-63 series of "Dear Doctor" letters, his acknowledgement that he would have paid attention to Searle's literature about Enovid had it been received, and corroborating evidence that practicing physicians are bombarded with mail and promotion pieces relating to all kinds of prescription medicines. See Stevens v. Parke, Davis & Co.

While there is evidence to the contrary, there is, in our opinion, substantial expert testimony from which a reasonable jury could find that the occlusion of Sandra Brewer's left internal carotid artery was a result of her ingestion of the defendant's product. Again we shall not at this point refer to those portions of the plaintiff's evidence to which Searle raises specific objections, i.e., the deposition of Dr. Haulden and the rebuttal testimony of Dr. Kyger.

• 11 It was the opinion of Dr. Prewitt, Sandra's chief treating physician, that Enovid causally contributed to produce a thrombosis which occluded the involved artery. Dr. Aurin, the consulting vascular surgeon, was unable to rule out congenital disease as the cause of the occlusion; nevertheless, he was also unwilling to say that Enovid was not the cause. In the deposition presented in the case in chief, Dr. Kyger, also one of the treating physicians, concluded that Enovid played a significant and important part in the production of the blood clot which led to Sandra's death. However controversial these opinions might have been, the record adequately demonstrates that they are supported by an impressive body of professional and scientific knowledge concerning the role of oral contraceptive hormones in the production of blood clots, particularly the rather unusal type of cerebral occlusion these physicians found to exist in the case of their patient. [5] This testimony was not so speculative as to require disbelief, in spite of other expert testimony introduced by the defendant which, if believed, adequately rebuts it. Consequently, it was not error for the trial court to submit this element of the case for resolution by the jury.

Searle's final point in contending error in the denial of a directed verdict is that there was no evidence to prove a breach of duty to warn was responsible for the prescription and continued use of Enovid. Specifically, the defendant claims that without testimony from the prescribing physicians indicating their knowledge or lack of knowledge about the effects of Enovid, or some evidence showing the drug would not have been prescribed had an adequate warning been given, it cannot be said the failure to warn was involved in the decision to put Sandra on the "pill." As we have already noted, the plaintiff's burden of proof required a connection between the failure to warn and the prescription or continued use of Enovid; nevertheless, we do not agree the plaintiff failed to meet this burden.

• 12 Searle's argument claims that the plaintiff's evidence failed to eliminate the physicians' negligence or malpractice as being responsible for the prescription of its product. The claim, of course, extends further to apply also to the failure of the treating physicians to inquire about oral contraceptives and withdraw the drug once premonitory signs of Sandra's condition became manifest. Several comments in response to this reasoning are appropriate. First, the defendant's duty to warn was non-delegable. In other words, the failure of the prescribing and treating physicians to

learn of the risks of Enovid from sources other than Searle does not relieve the manufacturer of liability for harm resulting from its own failure to adequately warn. (Sterling Drug, Inc. v. Yarrow; Sterling Drug, Inc. v. Cornish (8th Cir. 1966), 370 F.2d 82.) Secondly, even if the evidence would support a finding of negligent failure to learn on the part of the physicians, Searle would not be relieved of liability because such negligence would have been a foreseeable consequence of its own breach of duty to warn. Bristol-Myers Co. v. Gonzales.

• 13 Searle's point, however, also entails the failure of the plaintiff to eliminate a positive form of negligence on the part of Sandra Brewer's physicians, i.e., they knew of the risks involved in the use of Enovid, but prescribed or failed to discontinue it anyway. Again, there is no evidence that such was the case and we believe that if such evidence was available it should have been presented by way of an affirmative defense. That is to say, there is a presumption the physicians did not act negligently, and the burden of showing they took it upon themselves to assume the responsibility for a known risk belonged to Searle. See Carmichael v. Reitz; Williams v. Brown Manufacturing Co. (1970), 45 Ill.2d 418.

Moreover, even positive malpractice by the physicians would not necessarily relieve Searle of liability vis a vis the plaintiff. In the case of Stevens v. Parke, Davis & Co., for example, the California Supreme Court was faced with substantial evidence indicating the physician had prescribed an antibiotic drug, Chloromycetin, while aware of the risk of aplastic anemia. Indeed, the physician admitted to such an awareness. Nevertheless, the court held such conduct was not, as a matter of law, a sufficient intervening cause, and it did not insulate the manufacturer from liability for failure to adequately warn of the risk:

"[I]f it was reasonably foreseeable that physicians, despite awareness of the dangers * * *, would be consciously or subconsciously induced to prescribe the drug when it was not warranted, Parke, Davis cannot be relieved of liability because of the intervening act of [the physician] in prescribing the drug while cognizant of its dangers. If there is room for reasonable men to differ as to whether the intervening act was reasonably foreseeable, then the question is properly left to the jury. "(9 Cal.3d 51, 69, 507 P.2d 653, 664, 107 Cal.Rptr. 45, 56.)

See also Bristol-Myers Co. v. Gonzales; Hamilton v. Hardy.

• 14 The defendant also claims to be entitled to a directed verdict because there is no evidence Enovid would not have been prescribed, or, by extension, would have been appropriately supervised and withdrawn in time, in the event adequate warnings had been supplied by Searle. This claim is also without merit. The law presumes that warnings, if given, will be heeded and followed and that medical practitioners will act competently.

"[T]he prescribing doctor's conduct may not insulate the manufacturer from liability where the inadequacy of the warning may have contributed to the plaintiff's injury. What the doctor might or

might not have done had he been adequately warned is not an element plaintiff must prove as a part of her case." Hamilton v. Hardy (1976), 37 Colo. App. 375, 549 P.2d 1099, 1109.

• 15 In summary, therefore, we believe the evidence of this case is sufficient to have put to the jury the questions of whether the use of Enovid subjected a user to injury, whether Searle breached a duty to warn, whether Sandra Brewer's use of Enovid caused her death and whether a failure to communicate properly the risks involved in the use of Enovid was a factor resulting in the deceased's use of the drug. The reasonable juror could infer that had an adequate warning been provided the drug would never have been prescribed, the use of the drug would have been more closely supervised, and the use of the drug might have been terminated in time to save Sandra Brewer's life.

The second major contention of error concerns the instructions given to the jury. Specifically, Searle complains that the court erred in giving the burden of proof instruction and an instruction defining the word "condition":

"The plaintiff has the burden of proving each of the following propositions:

First, that the defendant failed to adequately and accurately warn doctors prior to May 11, 1965, that abnormal blood clotting and arterial occlusions were a possible side effect of the drug Enovid; Second, that at the time Enovid was used by Sandra Brewer it contained one or more of the conditions claimed by the plaintiff as stated to you in these instructions and that in such condition the drug was not reasonably safe for her;

Third, that Sandra Brewer died;

Fourth, that one or more of the claimed conditions was a proximate cause of her death;

Fifth, that her widower and son have sustained pecuniary loss by reason of her death.

If you find from your consideration of all the evidence that each of these propositions has been proved then your verdict should be for the plaintiff. If, on the other hand, you find from your consideration of all the evidence, that any of these propositions has not been proved, then your verdict should be for the defendant." (Plaintiff's instruction No. 13-a.)

"When I use the word `condition' I mean any state of being or any factor of the product's existence that pertains to the product. The condition complained of may refer to its chemical composition, or it may refer to the failure to give adequate and accurate warning or instruction regarding the product." (Plaintiff's instruction No. 11-a.)

The word "condition" as used in the burden of proof instruction, however, relates to "conditions claimed by the plaintiff as stated to you in these instructions." Thus, the issues instruction is also

relevant to a proper understanding of this case as it was submitted to the jury:

"The plaintiff claims that Sandra Brewer took Enovid which was manufactured and sold by the defendant and that she died.

The plaintiff further claims that one or more of the following conditions rendered the product not reasonably safe:

1. Defendant used a formula for Enovid that was likely to result in causing, aggravating or activating arterial occlusions in some women taking the drug.

2. Defendant failed to warn adequately that a side effect of the use of Enovid might be arterial occlusions so severe that death could result.

3. Defendant failed to subject Enovid to adequate tests and clinical trials.

The plaintiff further claims that one or more of the foregoing conditions was a proximate cause of the death of Sandra Brewer." Plaintiff's instruction No. 18-C.

• 16 It is Searle's position that these instructions were erroneous for two reasons: (1) they ignore the knowledge of Sandra's physicians regarding the adverse effects of Enovid, and (2) they permitted the jury to hold Searle liable upon a finding that Enovid's chemical composition resulted in Sandra's death without any consideration of the failure to adequately warn as being causally related to her use of the drug. For the reasons already stated in our discussion of the directed verdict issue, we find no merit in Searle's contention that the plaintiff had the burden of establishing the knowledge of the physicians regarding the effects of Enovid. The second objection advanced against the instructions, however, requires further analysis.

As already indicated, the liability of Searle depends upon a finding that Enovid was manufactured and distributed in an unreasonably dangerous condition which resulted in the death of Sandra Brewer. Specifically stated, the jury should have been instructed that if the death was caused by the marketing of Enovid in an unreasonably dangerous condition, Searle is liable. However, the instructions indicate that the plaintiff had the burden of proving that one or more of the claimed conditions was a proximate cause of Sandra's death, and the claimed conditions refer to the absence of required warnings, the chemical composition of Enovid and the failure of Searle to subject the drug to adequate testing. Were it not for the giving of defendant's instruction No. 20(a) and defendant's instruction No. 7A, we would agree with Searle that the jury was misled in believing that liability could be based solely upon a causal connection between the "pill" and Sandra's death.

Defendant's instruction No. 20(a) indicated:

"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. * * * Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it not reasonably safe [i.e., nor is it unreasonably dangerous]. * * * [This applies to] drugs, vaccines and the like, many of which for this reason cannot legally be sold except to physicians, or under the prescription of a physician."

Relating this instruction to the facts of this case, it is clear that the jury was informed that Enovid could not be considered unreasonably dangerous in the event it was marketed under conditions which adequately warned of adverse effects. Conversely, the jury was informed that Enovid, in spite of dangerous propensities in its chemical composition, could not be considered unreasonably dangerous unless it was marketed without adequate warnings. Through defendant's instruction No. 7A the jury was informed of the elements necessary to establish strict liability in tort under the theory of section 402A of the Restatement (Second) of Torts. This instruction, therefore, directed the jury to those conditions of Enovid which made it unreasonably dangerous.

• 17 We believe that the jury found Searle liable because it marketed Enovid in an unreasonably dangerous condition, and because Enovid was so marketed Sandra Brewer died. Consequently, even though the jury was directed to other conditions of the drug in the burden of proof instruction, the verdict necessarily encompassed the finding that one of the conditions proximately causing the death was a condition of the product which made it unreasonably dangerous. Under the facts of this case such a condition could only refer to the manufacturer's failure to adequately warn.

• 18, 19 Searle also maintains that the burden of proof instruction was erroneous because it implied the defendant had a duty to warn of all possible side effects. It is our opinion that any error in this regard was cured by the giving of defendant's instruction No. 18(a), which stated the duty to warn as follows:

"A manufacturer of a prescription drug is bound to exercise ordinary care in marketing, testing and warning of probable adverse reactions. The drug manufacturer's duty to warn of potential dangers in the use of the drug is commensurate with its actual knowledge of the risk involved to those users, or the knowledge constructively imparted to it by competent scientific or other medical information available at the time of the warning."

Furthermore, it is our view that because this instruction was given, the court's decision to give only the first sentence of defendant's instruction No. 19 was also correct. As tendered, No. 19 read:

"Defendant's duties on the issue of warning is to be considered as of May of 1965. If, at the time the decedent was prescribed Enovid, the state of medical knowledge was not such that defendant could reasonably have discovered whether or not Enovid might cause clotting then your decision should be for the defendant as to this issue."

The second sentence merely restates in an unduly emphasized manner one of the ways in which the duty, already adequately stated in No. 18(a), might have been found to be fulfilled.

Other problems Searle raises regarding the instruction concern the court's failure to give defendant's instructions Nos. 25 and 20C. In addition to restating the dimensions of the duty to warn and elements of strict liability already well covered in defendant's instruction 20(a), these instructions sought to have Searle judged in relation to what "an ordinary, reasonable, prudent drug manufacturer would have done * * *." Also, the tendered instructions sought to have the dangerousness of Enovid measured by weighing the benefits of the drug against its risks. It would have been error to have given these instructions, for the standards they put forth are appropriate to negligence, and have no role in deciding whether or not Searle failed in fulfilling its duty to warn of the dangers of its product.

We feel that the jury was correctly instructed. Instructions are to be considered as a whole and a deficiency in one instruction may be cured by another. Wood v. Mobil Chemical Co. (1977), 50 Ill. App.3d 465, 365 N.E.2d 1087.

In the third major contention of error Searle objects to the manner in which the plaintiff was allowed to cross-examine the defendant's expert witnesses. Basically this argument centers on the use of articles published in professional medical journals for impeachment purposes, and a general inquiry into whether the defendant's witnesses agreed with the conclusions of published articles linking oral contraceptives to blood clotting disorders. The defendant also has objected to alleged impeachment without proper foundation and the propounding of hypothetical questions based on facts not in evidence.

• 20 Upon review of the record we conclude that the plaintiff's use of the medical articles for impeachment purposes did not always conform to the technicalities of the learned treatise rule enunciated in Darling v. Charleston Community Memorial Hospital (1965), 33 Ill.2d 326, 211 N.E.2d 253. However, no harm has resulted from their use. At the time the articles and their conclusions were referred to by the plaintiff's attorney, it had already been understood by both parties that medical and scientific studies published prior to Sandra Brewer's death would be admissible as evidence relevent to the issue of Searle's notice of the clotting problem. The court was careful to instruct the jury regarding this limited purpose on numerous occasions. Later in the course of the trial, however, it was decided that the cutoff date for the notice issue would be May 1965. Under the original understanding, all but one of the five publications specifically objected to on appeal were published prior to the death and thus admissible as substantive evidence relevant to the notice issue. The remaining article, Irey, Manion & Taylor, Vascular Lesions in Women Taking Oral Contraceptives, 89 Arch. Pathology 1 (1970), was recognized by Dr. Winter as the work of competent authorities, and, therefore, in our opinion, was properly utilized for impeachment purposes under the Darling rule.

• 21 During the cross-examination of Drs. Goldzieher and Sise, general questions were asked about

studies indicating a causal relationship between the "pill" and blood clotting disorders. Both of these witnesses acknowledged the existence of and their familiarity with such studies, and both of them disagreed with the conclusions. Dr. Sise volunteered his opinion disagreeing with a study by Dr. Von Kaula and later indicated other researchers had agreed with Dr. Von Kaula's conclusions. By the time these witnesses were cross-examined the jury already had heard evidence that studies showing a causal connection between oral contraceptives and blood clotting disorders had been published; under these circumstances we see no prejudice resulting from the evidence elicited from Drs. Goldzieher and Sise.

• 22, 23 The issue concerning alleged impeachment without proper foundation relates, in part, to the plaintiff's inquiries about published articles adverse to Searle's position. In this regard we find that the defendant's objections to paraphrasing the content and conclusions of such articles are without merit. On the whole these objections were cured during the trial by a verbatim reading of the articles involved. The other facets of this issue, concerning impeachment of Dr. Isaacs and Sise with sworn testimony given in prior lawsuits, are also without merit. The defendant objected to the questioning of Dr. Isaacs about his prior testimony, and this line of questioning was discontinued when the witness indicated no recollection of what he had said in the other case. Dr. Sise indicated confusion about the plaintiff's attorney's reference to his prior testimony about being "self-trained" in hematology. When the prior testimony was read the doctor indicated that he indeed "had no specific training in hematology because I'm not a hematologist." While the effect was not impeaching in a strict sense, we believe that the plaintiff was entitled to have the jury made aware of the doctor's training and credentials in relation to the area of medicine concerning diseases and disorders of the blood.

• 24 Likewise, there is no foundation to the defendant's contention that the plaintiff asked hypothetical questions based on facts not in evidence. The complained-of questions involved the pathological findings in relation to Sandra Brewer's illness and referred to the existence of a thrombus or blood clot in the artery of the deceased. When the questions were asked, the jury had already heard the testimony of Sandra's treating physicians and the examining pathologist, which clearly established a factual basis for assuming the deceased died of a blood clot in the left internal carotid artery and that the clot was the result of thrombosis.

The fourth principle contention involves the testimony of Dr. Bachmann. Searle contends that this witness was permitted to express opinions on matters beyond his competency and which were based on hearsay, were irrelevant and inadmissible. We disagree.

• 25 As already indicated, Dr. Bachmann was a licensed physician specializing in hematology and involved in research on blood coagulation and thrombosis. His opinion that oral contraceptives contribute to increased coagulation and that there is a positive relationship between blood clotting disorders and the "pill" was admittedly not based upon his own scientific experimentation. Rather, the opinion was premised upon his knowledge and understanding of a body of existing medical

research and reported information discovered by others. Such a premise, however, does not make the opinion either incompetent or inadmissible as hearsay. As noted in the Darling case, an expert's opinion is legitimately formed even though not the product of personal scientific or clinical observations, for one becomes an expert, not usually through knowledge acquired on a firsthand empirical basis, but by training, study and synthesis of a body of knowledge generally originating in the work of others. See Lawson v. G.D. Searle & Co.

• 26 Dr. Bachmann's other opinion, that the warnings available regarding Enovid in 1965 were inadequate, was also legitimately presented to the jury. We find no support in the law for Searle's suggestion that such an opinion could only be given by one whose practice of medicine involves the prescription of oral contraceptives. Indeed, we have stated that the duty to warn extends beyond this limited number of practitioners to include all members of the medical profession likely to come in contact with one using the drug. As a hematologist, Dr. Bachmann certainly would be a member of the profession required to be warned, for his specialty involves the treatment of those with reactions and complications which are the very subject of the required warning. Consequently, we believe Dr. Bachmann was qualified to express his understanding of the Enovid warnings and to relate that understanding to adverse effects of the drug known or suspected in 1965. That this would result in an opinion that the 1965 literature was inadequate was well within the expertise of a physician to whom the warnings were to mean something. See Bristol-Myers Co. v. Gonzales (Tex. Civ. App. 1977), 548 S.W.2d 416, 431.

• 27 Nor do we feel that Dr. Bachmann's alleged "speculation" concerning the knowledge the average medical practitioner has regarding blood coagulation problems or the attention the average physician pays to package inserts regarding prescription drugs, merits reversal. Our review of the record establishes that Dr. Bachmann was associated in a medical practice which was intimately involved in the teaching of medicine, and in this capacity he had accumulated a basis for appraising the knowledge of his less-specialized colleagues concerning blood clotting. Furthermore, we believe that the doctor's comments were primarily directed to his own experience with respect to receipt and utilization of the package inserts. • 28 In the fifth major issue for review Searle claims that the trial court erred in not striking those portions of Dr. Haulden's evidence deposition wherein the opinion was expressed as to the cause of Sandra Brewer's illness and death. The defendant argues that Dr. Haulden's inability to definitively diagnose the deceased's condition legally disqualified him from stating an opinion as to the "pill's" causal involvement with the condition. We cannot agree with such a narrow limitation of opinion testimony, for an expert need not base an opinion upon absolute scientific certainty, but only upon a reasonable degree of certainty. The record amply supports the view that the doctor possessed the requisite degree of certainty, and that he based his opinion upon a synthesis of observed clinical facts and available scientific knowledge, not speculation. Therefore, we sustain the decision of the trial court to admit the doctor's opinion into evidence and to leave to the jury the weight and significance to be attached to it.

The sixth major contention relates to alleged erroneous admission into evidence of the plaintiff's

exhibits Nos. 49-61. These exhibits were various letters, directives and memoranda addressed by Searle to its detailmen during the period 1962 through September 1965. Each of the exhibits concerns the marketing of Enovid, and Searle contends that their contents were neither relevant nor material to the issues raised at trial and that they were highly prejudicial. The plaintiff maintains the exhibits were properly admitted as evidence of Searle's "overpromotion" of Enovid, and, therefore, relevant to the issue of adequate warning. Stevens v. Parke, Davis Co.

• 29 We have already indicated the relevance of Searle's sales techniques and the conduct of its sales personnel regarding the question of adequate communication of warnings concerning the adverse effects of its product. Having established this link of relevance, the informaon which Searle supplied to the detailmen becomes a relevant consideration as well. The questioned exhibits indicate an aggressive promotional compaign aimed at increased exposure and prescription of Enovid for birth control purposes. The exhibits placed into the hands and minds of the sales force suggestions for marketing the drug only in a most positive light and without much attention to the possible side effects. Given the motives for profit, both for Searle and its commissioned sales representatives, it cannot be said that the information contained in the exhibits did not, to a degree, affect the marketing of Enovid in such manner as to play down or ignore those warnings of dangers available only in writing. That such a manner of marketing was intended and encouraged by Searle is manifested by the exhibits, and it is our opinion that the jury was entitled to consider them in arriving at a decision as to the adequacy of the warnings.

In the seventh and final principle contention Searle has objected to the manner in which the plaintiff was allowed to examine Dr. Kyger as a rebuttal witness and to the restrictions the court placed on Searle when cross-examining the doctor. Dr. Kyger, whose testimony had been presented in the plaintiff's case in chief by way of deposition, was called as a rebuttal witness in order to refute the defendant's attempts to show that Sandra died as a result of the ingestion of diet pills and not because of Enovid use.

• 30 When Searle attempted to impeach the witness regarding his knowledge of the reasons for FDA withdrawal of the diet pills from the market, the plaintiff's objection was sustained. Searle claims it should have been allowed to show that the reasons for this FDA action were not restricted to misuse of the pills as Dr. Kyger is said to have asserted in his testimony. The testimony, however, did not assign misuse as a basis for FDA action; rather, the doctor gave no reason at all for the action and had merely stated that "whatever action the FDA took, they [i.e., the diet pills] were definitely misused."

• 31, 32 The defendant's objection to Dr. Kyger's examination as a rebuttal witness involves two points: the correction of Kyger's evidence deposition and the use of the autopsy report to refresh the witness' recollection. Kyger's deposition indicated that the autopsy proved Sandra Brewer "had a blood vessel disease." In his rebuttal testimony the witness corrected this to indicate that he had actually stated she had no blood vessel disease. Since the deposition itself elsewhere confirms the

meaning given by the correction, we find no error in permitting it. Nor do we find a reason for reversal in the use of the autopsy report for purposes of recollection. The report was tendered to the witness in order to give him the opportunity to refresh his memory of the findings; however, when the defendant objected, the doctor testified from memory and consulted only one of the tissue slides to which no objection was raised.

Accordingly, for the reasons stated, the judgment of the Circuit Court of Cook County confirming the jury's verdict in favor of the plaintiff and against the defendant is affirmed.

Affirmed.

SIMON, P.J., and JIGANTI, J., concur.

1. Two forms of the drug are involved in this case: Enovid 5 mg. tablets (norethynodrel (5.0 mg.) + mestranol (0.075 mg.)), prescribed for Sandra Brewer by Dr. Ford, March 7, 1963; Enovid-E tablets (norethynodrel (2.5 mg.) + mestranol (0.1 mg.)), obtained on prescription of Dr. Sharf, March 11, 1965. The mestranol (synthetic hormonal agent) content of Enovid-E is greater than that of the 5 mg. Enovid tablet.

2. The original deposition notes at one point a finding of a blood vessel disease; this was later corrected to indicate no such disease when Dr. Kyger testified in person as a rebuttal witness.

3. Plaintiff's Exhibit No. 5 is a copy of a booklet entitled "Planning Your Family" copyrighted by Searle in 1964. Mr. Brewer identified the exhibit as having been found among the deceased's possessions following her death. The booklet indicates that "morning sickness," breast enlargement, weight gain or loss, relief from premenstrual tension, regulation of the menstrual cycle, and happier marital relationships are among the "other pill effects." Purporting to explain Enovid-E to the patient-consumer, the booklet contains no warning or reference to abnormal clotting problems as an effect of the drug's use.

4. Since 1970 the warning required by the FDA to be given in writing to the consumer states, in part: "The oral contraceptives are powerful and effective drugs which can cause side effects in some users and should not be used at all by some women. The most serious known side effect is abnormal blood clotting which can be fatal."

5. The cerebral occlusion found in Sandra's left internal carotid artery resembled lesions found in 20 cases reported in an article published in 1970. See Irey, Manion & Taylor, Vascular Lesions in Women Taking Oral Contraceptives, 89 Arch. Pathology 1 (1970).