Loyola Consumer Law Review

Volume 2 | Issue 2 Article 5

1990

Eighth Circuit Holds That Neither the Comment K Strict Liability Defense Nor the Individualized Medical Judgment Rule Relieved an IUD Manufacturer's Duty to Warn Consumers Directly

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Recent Cases

Eighth Circuit Holds that Neither the Comment K Strict Liability Defense Nor the Individualized Medical Judgment Rule Relieved an IUD Manufacturer's Duty to Warn Consumers Directly

In *Hill v. Searle Laboratories,* 884 F.2d 1064 (8th Cir. 1989), the United States Court of Appeals for the Eighth Circuit found that Arkansas would adopt comment k of section 402A of the Restatement (Second) of Torts as a qualified affirmative defense to strict liability for "unavoidably unsafe products." However, the court held that the comment k defense was not applicable to Searle's CU-7 IUD contraceptive because that device was not an "unavoidably unsafe" product serving an exceptional social need. Furthermore, the court held that Searle was not relieved of its duty to warn consumers concerning the dangers and side effects of using the CU-7 because a woman's decision to use an IUD did not involve an individualized medical judgement.

Background

The Copper 7 ("CU-7") contraceptive is an intrauterine device ("IUD") composed substantially of copper. Because copper is a potentially reactive chemical, the Food and Drug Administration ("FDA") has classified the CU-7 as a prescription drug. Thus, the CU-7 is unavailable without a physician's order and must be inserted by a physician.

Searle Laboratories ("Searle") began marketing the CU-7 during the early 1970s, when IUDs became accepted as a safe alternative to oral contraceptives. The FDA tested and approved the CU-7 as a safe and effective medical device. The FDA also approved the labeling and patient brochure that accompanied the CU-7.

In July 1981, Dr. Dennis Davidson ("Davidson") surgically implanted a CU-7 intrauterine device in Mrs. Connie Hill ("Hill"). Approximately three years later, Hill gave birth to a child. Shortly thereafter, she underwent tubal ligation surgery. During the course of the surgery, Hill's treating physician, Dr. Roland Reynolds, discovered that the CU-7 had perforated Hill's uterus and become partially embedded in her small bowel.

Hill sued Searle in the United States District Court for the Eastern District of Arkansas. The suit alleged that Searle was liable for Hill's injuries under the theories of negligence, strict liability, and breach of warranty. Hill claimed that Searle had failed to provide her with proper warning as to the possible side effects of the CU-7 and denied that she had ever received the CU-7's patient brochure.

The District Court's Decision

Under Arkansas law, a manufacturer may be strictly liable if its product is in a defective condition which renders the product unreasonably unsafe. A product is considered defective if the manufacturer did not adequately warn consumers about the product's dangers.

Comment k of section 402A of the Restatement (Second) of Torts provides a qualified defense to strict liability. Restatement (Second) of Torts § 402 comment k (1965). Numerous states have incorporated comment k into their product liability laws. Comment k applies to "unavoidably unsafe" products which are considered extraordinarily beneficial or critically necessary to the public. Because consumers need such products despite the risks, the comment k defense shifts the duty of care from the manufacturer to the consumer. A manufacturer may thereby escape liability for any injuries the product causes unless the manufacturer negligently manufactured the product or failed to warn consumers of the product's possible side effects.

Although Arkansas courts had not yet expressly adopted the comment k defense, the district court determined that Arkansas courts probably would do so. In addition, the court held that the comment k defense applied to all prescription drugs, including IUDs.

The district court also held that Arkansas courts would adopt the "learned intermediary" rule. Under this rule, a manufacturer fulfills its duty to warn consumers if it provides proper warnings to prescribing physicians, rather than directly to the consumers. The court determined that the package inserts accompanying the CU-7 were sufficient to fully apprise Hill's treating physician of the risks associated with the device. Therefore, Searle had sufficiently warned Hill regarding the CU-7's possible side effects. The court also noted that Hill had signed a form stating that she understood the risks of the operation before the CU-7 was inserted. Accordingly, the court granted Searle's motion for summary judgment. Hill appealed the ruling to the United States Court of Appeals for the Eighth Circuit.

The Eighth Circuit's Opinion

The Comment K Defense to Strict Liability. Hill argued that the Arkansas courts would not adopt comment k. Hill noted that although the Arkansas legislature had adopted section 402A of the Restatement (Second) of Torts, it had not explicitly adopted comment k. Searle, on the other hand, identified numerous Arkansas Supreme Court decisions referring to the comments of section 402A and argued that the court implicitly adopted all of the section 402A comments. Searle also noted that comment k had been adopted overwhelmingly by other jurisdictions. The court of appeals agreed that

Arkansas probably would adopt comment k as a qualified defense to strict liability.

Hill next argued that even if Arkansas would adopt comment k, comment k is an affirmative defense and Searle failed to prove that the CU-7 is within the scope of that defense. Searle responded that three factors supported the district court's finding that CU-7 is an unavoidably unsafe product: 1) the CU-7 received FDA approval; 2) the CU-7 was a prescription drug; and 3) uncontradicted expert testimony indicated that the CU-7 contained the same risks as any IUD.

The court rejected each of Searle's arguments. First, the court found that FDA approval was not an automatic shield to liability. Rather, FDA standards set a minimum safety requirement. The court further reasoned that FDA approval militated against finding that the CU-7 was unavoidably unsafe: the CU-7 could not be "generally safe" according to the FDA and "unavoidably unsafe" according to the comment k definition. In addition, Searle offered no evidence that the product was unavoidably unsafe.

Second, the court rejected Searle's argument that the comment k defense should apply to all prescription drugs to encourage development of new drugs. The object of strict liability, the court noted, was to require the manufacturer of a defective product to bear the cost of injury. The comment k exception to strict liability only applies where an extraordinary social need for the product justifies shifting the cost of injury to the consumers. The example given in comment k of an extraordinarily necessary product is Pasteur's rabies vaccine. A product's prescription status does not indicate an extraordinary need for the product. Rather, courts must determine on a case-by-case basis whether the need for a product justifies granting it the comment k protection. The court held that Searle failed to prove such an extraordinary need for the CU-7 to justify allowing a comment k defense. In addition, unlike Pasteur's vaccine, the CU-7 was not the only product that could accomplish its designed objective.

The court cited other factors in rejecting the comment k defense. IUD manufacturers created a sense of product quality through advertising which made it difficult for consumers to appreciate the risks of using an IUD. Also, IUD manufacturers were in a better position to identify product risks and spread the costs of injury to all consumers. Accordingly, the manufacturer is better suited to absorb the loss in these cases. Thus, the court concluded that Searle must bear the cost of injury from the CU-7 if the device is found to be defective and unreasonably dangerous.

The Independent Medical Judgment Rule. Generally, under the theories of strict liability, breach of warranty, and the comment k defense, a manufacturer has a duty to warn consumers directly of a product's risks. The learned intermediary rule is an exception to this duty. Under the learned intermediary rule, a manufacturer may rely on doctors to warn their patients where the product's risks are too technical for patients to understand and the manufacturer cannot directly warn each patient. Searle argued that Arkansas courts would apply the learned intermediary rule in this type of case. Searle further argued that under the learned intermediary rule it adequately warned Hill's physician of possible uterine perforation.

The court declined to apply the learned intermediary rule. Rather, it held that the Arkansas courts would adopt the test established in *Reyes v. Wyeth Laboratories,* 498 F.2d 1264 (5th Cir. 1974), to determine whether adequate warning was given. Under the *Reyes* test, consumers receive adequate warnings if (1) the manufacturer provides a meaningful, complete warning which patients can understand; or (2) physicians routinely make an intervening individualized medical judgment that this particular drug or treatment is necessary and desirable for a patient.

The court held that Searle failed to satisfy either requirement of the *Reyes* test. The court noted that IUDs and other forms of birth control differ from most prescription drugs. Normally, a physician will make an individualized independent determination that a prescription drug is warranted. However, a physician usually does not make an individualized medical judgment in a woman's birth control decision. While the physician may recommend a certain method of birth control, the patient usually decides, based upon personal factors often undisclosed to the physician, whether or not to use birth control and which method to use. Thus, the court held that Dr. Davidson was not an intervening party between Hill and Searle. In addition, the court found that it was feasible for Searle to warn Hill directly of the risks. Furthermore, the FDA required such warnings.

Accordingly, the court remanded the case to the district court to determine whether Hill received adequate warning about the risks and hazards associated with using the CU-7.

Dissenting Opinion

In a dissenting opinion, Judge Magill argued that the CU-7 was not defective in its design or manufacture, and that Searle had not failed to give adequate warnings. Hill's own expert witness testified that the CU-7 was not defectively manufactured. In addition, Hill's expert witness testified that the labeling and physician warnings were adequate to inform Hill's doctor about the risk of uterine perforation. Judge Magill noted that a pharmaceutical company generally has a duty to warn only the physician. He saw no reason why this rule should not apply to all prescription pharmaceutical products, including IUDs. Judge Magill also disagreed with the majority on whether Arkansas would adopt the *Reyes* test in place of the learned intermediary rule. Thus, Judge Magill would have affirmed the district court's ruling.

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