

1996

## LDDL Contraceptive Manufacturer Has No Duty to Warn That Use of "The Pill" During Pregnancy May Cause Birth Defects

Lessie A. Gerhold-Lepp

Follow this and additional works at: <http://lawcommons.luc.edu/lclr>



Part of the [Consumer Protection Law Commons](#)

---

### Recommended Citation

Lessie A. Gerhold-Lepp *LDDL Contraceptive Manufacturer Has No Duty to Warn That Use of "The Pill" During Pregnancy May Cause Birth Defects*, 8 Loy. Consumer L. Rev. 283 (1996).

Available at: <http://lawcommons.luc.edu/lclr/vol8/iss4/7>

This Recent Case is brought to you for free and open access by LAW eCommons. It has been accepted for inclusion in Loyola Consumer Law Review by an authorized administrator of LAW eCommons. For more information, please contact [law-library@luc.edu](mailto:law-library@luc.edu).

where the duty of the party performing the service is defined by the contract between the [party] and [the] client.” *Kanter*, 648 N.E.2d at 1139. In this case, the court concluded that Deitelbaum’s duty to the plaintiffs to provide the requisite

competent service fell outside of the scope of duties imposed by the written contract and that this additional contractual professional duty is not subject to the economic loss doctrine. The court held that the plaintiffs could proceed with their

charges of negligence and were not barred from recovering damages for purely economic losses. The court reversed the lower court’s ruling and remanded the case for a ruling in concert with the appellate court opinion.

## ***LDDL contraceptive manufacturer has no duty to warn that use of “The Pill” during pregnancy may cause birth defects***

by *Lessie A. Gerhold-Lepp*

In *Martin by Martin v. Ortho Pharm. Corp.*, 661 N.E.2d 352 (Ill. 1996), the Illinois Supreme Court held that, under the learned intermediary doctrine, a pharmaceutical manufacturer who fails to directly warn a patient of the possible side effects of an oral contraceptive is not liable despite a federal regulation requiring such warnings. The court stated that a manufacturer’s duty ends when the manufacturer furnishes the necessary warnings to the prescribing physician.

Clyntie Martin (“Martin”) visited her physician, Dr. Sloniewicz (“Sloniewicz”), in April 1979, complaining of cramps and a missed menstrual period. During this appointment, Sloniewicz informed Martin she was not pregnant. At a subsequent appointment, Martin told Sloniewicz her concern about becoming pregnant, Sloniewicz reaffirmed that she was not pregnant. Sloniewicz prescribed Ortho-Novum 1/50, an oral contraceptive product of the Ortho Pharmaceutical Corporation (“Ortho”). Sloniewicz instructed Martin to begin use of the contraceptive at the end of her next menstrual cycle; however, Martin began use of the contraceptive seven days after her second visit to Sloniewicz. Martin discovered that she was pregnant after another missed menstrual period in July 1979. On December 8, 1979, Martin gave birth to Robert Lee Martin III (“Robert”). Robert was born with deformities to his arms, hands, and fingers.

In February 1981, Robert Lee Martin, Jr., and Clyntie

Martin (“the Martins”) filed suit against Ortho on behalf of their son. The Martins sought damages against Sloniewicz for malpractice and against Ortho, alleging that the contraceptive caused Robert’s deformities. Sloniewicz settled with the Martins in 1983. The Martins voluntarily dismissed their action against Ortho. However, the Martins refiled on January 7, 1991.

### **Courts apply learned intermediary doctrine to case**

The Martins alleged Ortho-Novum 1/50 was “unreasonably dangerous” because it carried no warning to consumers that it would cause birth defects if taken during pregnancy. Ortho argued the learned intermediary doctrine applied and the doctrine limited its duty to warn the physician who prescribed the drug. Ortho argued that its warnings to Sloniewicz were adequate as a matter of law. The circuit court granted summary judgment in Ortho’s favor.

The appellate court, reversing the lower court, found that the learned intermediary doctrine contained an exception which applied to oral contraceptive manufacturers. The Supreme Court granted Ortho’s appeal and allowed amicus curiae briefs on behalf of both parties.

The Supreme Court of Illinois adopted the learned intermediary doctrine in *Kirk v. Michael Reese Hosp. & Med. Ctr.*, 513 N.E.2d 387 (Ill. 1987). The doctrine, an

exception to strict liability in tort, applies to manufacturers who fail to warn of a product's dangers. The doctrine requires drug manufacturers to warn only the prescribing physician of any dangers involved with a drug. The physician has the duty to warn the patient of any dangers associated with the drug.

### **Plaintiff argues exception to the doctrine created by federal regulation**

The Martins argued that a federal regulation provides an exception to the learned intermediary doctrine for oral contraceptives. The regulation, 21 C.F.R. § 310.501 (1978), in part, states:

[T]he safe and effective use of oral contraceptive[s] . . . requires that patients be fully informed of the benefits and risks involved . . . Information in lay language concerning effectiveness, contradiction, warnings, precautions, and adverse reactions shall be furnished to each patient . . . This information shall be given to the patient by the dispenser in the form of a brief summary of certain essential information included in each package dispensed . . . and in a longer detailed labeling piece in or accompanying each package dispensed to each patient. 21 C.F.R. § 310.501 (1978).

The Martins conceded that the warnings Ortho gave to Sloniewicz were adequate, under the learned intermediary doctrine. However, the Martins asserted that the regulation created an exception for instances in which the learned intermediary doctrine would not apply. The issue before the Court was whether the regulation creates a duty upon a pharmaceutical manufacturer to directly warn users.

### **Violation of statute doctrine not applicable to plaintiff**

The Supreme Court of Illinois held that the appellate court erred when it found that the Martins possessed a private right of action under the violation of statute doctrine, which views a violation of statute as prima facie evidence of negligence. The violation of statute doctrine requires that the plaintiff "fall within the class

intended to be protected; and . . . the injury suffered . . . [must be] a direct and proximate result of the violation." The supreme court stated the appellate court did not consider the legislative intent of Section 310.501 which was necessary because no specific statutory authority granted a cause of action. The supreme court further emphasized the importance of such considerations where the plaintiff pursues action under a federal regulation which conflicts with existing state law.

In order to recover, the Martins needed to show that Section 310.501 carries a private cause of action. The supreme court stated that Congress did not intend to create such a cause of action, especially those private actions under the Food, Drug, and Cosmetic Act ("FDCA").

### **Federal regulation does not create additional duty for defendant**

The Martins admitted that the FDCA created no private cause of action but argued that the regulation established a duty for Ortho, citing *Grove Fresh Distrib., Inc. v. Flavor Fresh Foods*, 720 F. Supp. 714 (N.D. Ill. 1989). In *Grove Fresh*, the court allowed the plaintiff to recover under the Lanham Act for the defendant's misrepresentation of its orange juice in violation of the FDA. In that case, the court emphasized that although there is not a recognized private cause of action under the FDCA, a plaintiff may rely on the FDA regulation to establish the standard duty a defendant must meet.

In *Grove Fresh*, the supreme court indicated that the FDA regulation was relevant to whether the Lanham Act had been violated. Distinguishing *Grove Fresh* from the present case, the court recognized that in *Grove Fresh* the Lanham Act afforded plaintiffs a private cause of action. However, in the present case, Martin was not provided a statutory right of action. The court concluded that *Grove Fresh* was not applicable to the present case. Notwithstanding its ruling, the court recognized that a minority of courts refuse to follow the learned intermediary doctrine.

Declining to recognize an exception for contraceptive manufacturers, the supreme court held that Ortho provided sufficient warnings to the prescribing physician and, therefore, fulfilled its duty. Thus, the Supreme Court of Illinois reversed the appellate court and affirmed the circuit court.