

1989

## Florida Supreme Court Upholds Adequacy of Product Warnings Regarding Accutane

Elizabeth A. Mitchell

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

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

---

### Recommended Citation

Elizabeth A. Mitchell *Florida Supreme Court Upholds Adequacy of Product Warnings Regarding Accutane*, 1 Loy. Consumer L. Rev. 105 (1989).

Available at: <http://lawcommons.luc.edu/lclr/vol1/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).

## FLORIDA SUPREME COURT UPHOLDS ADEQUACY OF PRODUCT WARNINGS REGARDING ACCUTANE

In *Felix v. Hoffmann-LaRoche, Inc.*, 540 So. 2d 102 (Fla. 1989), the Supreme Court of Florida held that while the adequacy of a product warning provided by a manufacturer is usually a question of fact for the jury, adequacy may become a question of law where the warning is accurate, clear and unambiguous. The court held that the warnings accompanying Accutane which were addressed to physicians rather than patients were adequate and were not the proximate cause of the wrongful death of a patient's child.

### Background

Accutane is a drug usually prescribed for severe and disfiguring cases of acne.<sup>1</sup> It was approved for sale in this country by the United States Food and Drug Administration ("the FDA") in 1982. At that time, Hoffmann-LaRoche, Inc., ("Hoffmann-LaRoche") began manufacturing and selling Accutane in the United States. Late in 1982, Yolanda Felix went to a physician, Dr. Greenwald, for treatment of a persistent and prolonged cystic acne condition of her face and shoulders. Greenwald prescribed Accutane, then considered a "miracle drug" for acne treatment. Felix was pregnant at the time she received the prescription. Greenwald claimed that he warned Felix against the use of Accutane during pregnancy, but Felix denied receiving any such warning. Greenwald admittedly knew of the product's teratogenicity,<sup>2</sup> because he independently had researched the side effects of the drug and had attended seminars regarding Accutane's dangers. Greenwald was also aware of the warnings accompanying the drug. These warnings recommended that the drug not be used during pregnancy.

Felix subsequently gave birth to a child with severe birth defects. She attributed the birth defects and premature death of her child to her ingestion of Accutane during pregnancy. Consequently, she filed a lawsuit against Hoffmann-LaRoche for the wrongful death of her child. She alleged that the failure of Hoffmann-LaRoche to furnish adequate warnings about the dangerous effects of consuming Accutane during pregnancy had caused the death of her child.

The trial court rejected Felix's contention and entered summary judgment in favor of Hoffmann-LaRoche. The appellate court affirmed the lower court's judgment for two reasons. First, the appellate court reasoned that Hoffmann-LaRoche's warnings were adequate as a matter of law and second, even if the warnings were inadequate, they were not the proximate cause of the child's birth defects and death because Greenwald knew of the teratogenicity of the product.

### Supreme Court: Adequacy of Warnings May Be a Question of Law

On appeal to the supreme court of Florida, Felix argued that the adequacy of a drug warning is always a question of fact for the jury and can never be decided as a matter of law. Felix relied upon several Florida cases to support her argument. In response, Hoffmann-LaRoche contended that making the adequacy of a drug warning *solely* a question of fact for the jury would hamper product development and marketing. The supreme court rejected Felix's argument, thus deviating from the precedent set by lower courts. The court stated that questions relating to the adequacy of product warnings will be questions of law when the warnings are accurate and clear.

The supreme court noted that because physicians were to serve as " 'learned intermediaries]' between the manufacturer and the consumer," 540 So. 2d at 104, Hoffmann-LaRoche properly directed the warnings about Accutane's dangers to physicians and not to consumers. Hoffmann-LaRoche thus had no duty to warn consumers directly of the product's dangers. According to the court, the language used in the warnings, though technical, was undoubtedly familiar to those in the medical profession and clearly defined the risks of Accutane.

The warnings reported that no reliable studies had been conducted on pregnant women ingesting Accutane but that studies conducted on rats and rabbits revealed that animals exposed to the drug suffered teratogenic side effects. Based on these observations in animals, the warnings cautioned that pregnant women should not receive Accutane. The warnings also recommended that women of childbearing years use an effective form of contraception while undergoing Accutane therapy.

(continued on page 106)

## ACCUTANE WARNINGS (from page 105)

At the time Felix ingested Accutane, these warnings were accurate. Documented cases of Accutane-related teratogenicity in human fetuses and offspring appeared only *after* Felix had ingested Accutane. The language used in the warnings thus contained no misrepresentations that would mislead a physician prescribing the drug. For these reasons, the Supreme Court held the warnings were comprehensive, clear, and accurate. Thus, the court affirmed the judgment of the appellate court.

### Warnings Not Proximate Cause of Infant's Death

The supreme court similarly adopted the reasoning of the appellate court that, although Greenwald's alleged failure to share his knowledge of the dangers of Accutane with Felix might be important in a claim against the doctor himself, such was irrelevant in a liability action against the manufacturer Hoffmann-LaRoche. Both courts observed that the manufacturer could not be held liable for a doctor's failure to impart knowledge to a patient.

The supreme court concluded that the death of Felix's child could not be attributed to an inadequacy in the warnings because the warnings were adequate at the time Greenwald prescribed the drug to Felix. Moreover, Hoffmann-LaRoche had only the duty to warn the prescribing physician of the drug's dangers unless the FDA stipulated otherwise. Because Hoffmann-LaRoche had fulfilled its duty, it could not be held liable.

**Elizabeth A. Mitchell**

1. Accutane, derived from Vitamin A, falls within a class of drugs known as retinoids. Since 1954, retinoids have been known to cause birth defects in children whose mothers ingested them in large doses during pregnancy. Patients taking Accutane suffer side effects which include loss of vision, severe depression, gastrointestinal and cardiac problems, and central nervous system disorders. See Nygaard, *Accutane: Is the Drug a Prescription for Birth Defects?*, 24 TRIAL 81 (1988).
2. Teratogenicity is defined as the ability to create a deformed, abnormal being. Accutane's teratogenicity was first noted by Dr. Wener Bollag of Hoffmann-LaRoche's parent company. Bollag compared Accutane's effects to those of thalidomide, the highly-publicized tranquilizer that was withdrawn from the market in the 1960s because it caused severe limb deformities in the children of mothers who had used the drug. *Id.*

---

## IOWA SUPREME COURT HOLDS INSURANCE COVERAGE IS UNAVAILABLE IF UNIDENTIFIED HIT AND RUN DRIVER DOES NOT PHYSICALLY CONTACT VICTIM

In *Moritz v. Farm Bureau Mut. Ins. Co.*, 434 N.W.2d 624 (Iowa 1989), the Iowa Supreme Court ruled that the "uninsured motorist" clause of an automobile insurance policy does not apply when there is no physical contact between the insured car and a vehicle which is claimed to have caused the accident. Reasoning that insurance companies must be protected from fraudulent claims, the court held that the companies need not provide coverage when there is no physical contact between the insured car and the unidentified vehicle. In addition, the court held that the doctrine of reasonable expectations, which requires that insurance policies be construed as the insured layperson would construe them, was properly considered and re-

jected by the lower court. Finally, the court rejected the plaintiff's claims that Iowa's uninsured motorist statute, Iowa Code Ann. 516A.1-516A.4 (West 1988) ("the Act"), violates the equal protection clauses of the Iowa and the United States Constitutions.

### Background

In September, 1986, Michaela Moritz (Moritz) was a passenger in a car that was forced off the road by an unidentified driver of another vehicle. The car ran into a tree and Moritz was injured. Moritz brought suit against the Farm Bureau Mutual Insurance Company ("Mutual Insurance"), the insurer of the car in which she was riding, to recover for her injuries under the policy's "uninsured motorist" clause. Two counts of her complaint alleged that Mutual Insurance was liable for Moritz' injuries caused by the unidentified driver of the other vehicle. In its motion for summary judgment, Mutual Insurance maintained that collisions caused by unidentified motorists were covered only when there was physical contact between the un-