

1991

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Recommended Citation

Gregory R. Bockin *New Jersey Supreme Court Finds Tooth Discoloration Strict Liability Claim Not Preempted by FDA Regulation*, 4 Loy. Consumer L. Rev. 33 (1991).

Available at: <http://lawcommons.luc.edu/lclr/vol4/iss1/10>

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to the appropriate remedy and associated costs, the record was sufficient to justify the trial court's judgment on the issue of damages. Thus, the Wyoming Supreme Court affirmed the damage awards.

The Dissenting Opinion

The dissent argued that the majority held the Builder liable even in the absence of negligence. This strict liability theory, based on the Wyoming Uniform Commercial Code, was incorrect because the code does not apply to real property. The dissent also argued that under the strict liability theory, all builders would be forced to insure the construction of the houses they built. Such a standard would require builders to attend to and repair even the slightest defects and would result in increased costs to consumers. Finally, the dissent argued, the majority's approach was unnecessary because the remedies developed in the Wyoming Supreme Court's prior cases were sufficient to protect homeowners.

Richard B. Vaughn

New Jersey Supreme Court Finds Tooth Discoloration Strict Liability Claim Not Preempted By FDA Regulation

In *Feldman v. Lederle Laboratories*, 592 A. 2d 1176 (N.J. 1990), the Supreme Court of New Jersey held that federal law did not require prior approval from the Food and Drug Administration ("FDA") before a drug manufacturer could warn of a known or knowable danger in its products. Consequently, the court found that federal law did not preempt a strict liability claim brought under New Jersey state tort law against a drug manufacturer for failure to warn that one of its products could cause tooth discoloration.

Background

This case involved tetracyclines, a group of antibiotics first produced in 1948, which are primarily

used to treat bacterial infections. In 1959, Lederle Laboratories ("Lederle") introduced a new form of tetracycline, demethylchlortetracycline, marketed under the trade name Declomycin.

Dr. Harold Feldman had treated his daughter, Carol Ann Feldman ("Feldman"), with Declomycin two or three times a year between 1960 and 1963. Feldman's baby teeth were discolored gray-brown. When her permanent teeth emerged in 1965, they too were discolored. Prior to 1963, Declomycin contained no warning of tooth discoloration as a potential side effect.

Lederle had a long history of correspondence with the FDA regarding the potential side effects of various tetracyclines. In November, 1962, Dr. Swanzey, an employee of Lederle, wrote a letter to the FDA notifying the administration of the possible correlation between tooth discoloration and tetracycline use. In this letter, Dr. Swanzey proposed adding a warning of the potential side effects to the labels of all Lederle tetracycline products.

The FDA responded that it had not yet reached any conclusions, but would contact Dr. Swanzey once it made a final determination. In January, 1963, Dr. Swanzey wrote the FDA with additional information regarding the side effects of tetracycline use, one of which was tooth discoloration. In February, 1963, the FDA informed Lederle of its conclusion that tetracycline use had an effect on the bones and teeth. Furthermore, the FDA proposed that a warning be placed on Tetracycline, Chlortetracycline, and Oxytetracycline. At this time, the FDA had no specific clinical evidence that Declomycin caused tooth discoloration, but confirmed that it would remain alert for the possibility of such correlation.

Through Dr. Swanzey, Lederle continued to correspond with the FDA regarding the possibility that Declomycin caused tooth staining. In July, 1963, the FDA stated that it required factual evidence of adverse reactions to substantiate any official regulatory change in warnings. Because Lederle could only

speculate as to the connection between Declomycin and tooth discoloration, the FDA had chosen not to change its official stance regarding the warning.

Finally, on November 11, 1963, after negotiations with the FDA, a Lederle official wrote the Administration that the company would include a warning statement on its Declomycin label. The FDA accepted the proposed warning, which was incorporated into the packaging of Declomycin in December, 1963.

Subsequently, in 1978, Feldman, through her father as guardian ad litem, sued Lederle in New Jersey state court to recover damages for her tooth discoloration under theories of negligence, gross negligence, breach of express and implied warranties, and strict products liability.

Lower Court Proceedings

The trial court entered judgment on a jury verdict in favor of Lederle, and Feldman appealed. The Superior Court, Appellate Division, affirmed. The New Jersey Supreme Court granted Feldman's petition for certification and remanded the case back to the appellate division for reconsideration. The appellate division affirmed its original position. This time the supreme court reversed and remanded for a new trial. At the second trial, the jury returned a verdict for Feldman on the sole count of strict liability for failure to warn under state tort law. The appellate division reversed and remanded for entry of judgment in favor of Lederle. From this ruling, the New Jersey Supreme Court again granted Feldman's certification petition.

Supreme Court Opinion

The New Jersey Supreme Court first addressed Lederle's argument that Feldman's cause of action based on state law failure to warn was preempted because of an actual conflict with federal laws and regulations. The court made clear that Lederle first had to overcome a presumption against preemption, since state power is not to be superseded by federal acts unless it

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is the clear purpose of Congress.

Lederle argued that the FDA regulations in effect before the 1965 amendments did not permit the company to add warning labels regarding tooth staining without FDA approval. Lederle did not obtain the approval until 1963. Lederle also claimed that warning without approval would have violated federal regulation 21 C.F.R. 146.4, which prohibits the relabeling of drugs without FDA permission. Thus, Lederle asserted that it would have violated federal regulations by complying with the New Jersey law requiring a warning to be communicated as soon as reasonably feasible once a company gained actual or constructive knowledge of a danger.

Feldman argued that Lederle knew or, through the exercise of reasonable diligence, should have known of the potentially serious and permanent side effects of Declomycin at the time she ingested the drug. Feldman also asserted that, in light of this knowledge, Lederle failed to warn antibiotic consumers of these dangers in a timely and reasonable fashion and thereby violated state tort law.

The supreme court found no direct conflict between federal and state law. The court expressed concern that, since nothing in the federal regulations explicitly preempted claims brought under state law, a finding of preemption would leave Feldman without a remedy. Thus, the court asserted that using the FDA regulation governing label changes as Lederle proposed infringed on the state's powers to protect and promote the safety of its citizens.

The New Jersey Supreme Court then considered whether the FDA regulations actually precluded Lederle from warning of Declomycin's dangerous side effects. Lederle argued that by warning without permission, it would have been subject to either punishment for misbranding or removal of its product from the market. The court disagreed, stating that the FDA had determined that warning of dangerous side effects at the

earliest possible time was consistent with its goal of protecting public health. The court offered some alternatives Lederle could have considered, including not distributing the drug, trying harder to get approval, or waiting until more tests were done to ascertain if the drug caused tooth discoloration.

Finally, Lederle contended that if the case were retried, Feldman would not prevail. It relied on the newly created New Jersey Products Liability Statute, N.J.S.A. 2A:58C-4, which states that where a warning or instruction has been approved by the FDA, there is a rebuttable presumption that the label is adequate. However, the court disagreed, asserting that label adequacy standards were different in the 1960s and that a strong likelihood of rebutting the presumption existed in this case.

Dissenting Opinion

Dissenting Judge Garibaldi criticized the majority's narrow view of the FDA's role in society. The FDA's mission is to make a risk-utility analysis of drugs in order to determine if the benefit to society outweighs the potential dangers. The Judge asserted that the FDA has a greater accumulation of information and expertise on drugs than any other source, including Lederle. Thus, the majority opinion upset this risk-balancing analysis by imposing the court's judgment in hindsight upon drug manufacturers.

Judge Garibaldi recognized that promoting uniformity is another goal of the FDA. Thus, the majority's contention that pre-1965, drug manufacturers could change a product warning without FDA approval was erroneous. Otherwise, with each manufacturer changing labels upon its own prerogative, labels would become useless and unbelievable.

Gregory R. Bockin

Underinsured Motorists Provisions Do Not Cover Accident Victims Whose Household Membership Is Not Readily Apparent

In *Vaiarella v. Hanover Insurance Company*, 567 N.E.2d 916 (Mass. 1991), the Supreme Judicial Court of Massachusetts held that a mother involved in an automobile accident was not entitled to a settlement under the underinsured motorist provision of her son's automobile insurance policy because she was not a member of his household at the time of the accident.

Background

Salvatore and Italia Vaiarella ("Mr. and Mrs. Vaiarella", respectively) lived in both East Boston and Winthrop, Massachusetts between 1941 and 1984. Their son Joseph ("Son") lived in Brockton, Massachusetts, and their daughter in East Boston. In August, 1984, the Vaiarellas had their mail transferred to their daughter's address but began living with their Son, bringing with them some personal items and furniture. Thereafter, the Son began remodeling his garage into living quarters for his parents.

In November, 1984, the Vaiarellas moved to Winter Haven, Florida. They planned to live there from January to May each year and to live in Brockton, Massachusetts with their Son from May to December. Upon moving to Florida, the Vaiarellas bought a mobile home. This purchase required Mr. Vaiarella to have a Florida driver's license and a Florida registration for the car he had bought in Brockton.

During the 1984 Christmas holidays, the Vaiarellas visited their Son and returned to Florida immediately thereafter. At that time, their living quarters in their Son's garage had not yet been finished. On May 3, 1985, after their winter stay in Florida, the Vaiarellas started out for Brockton by car. En route, the two were in a car accident that killed Mr. Vaiarella and injured Mrs. Vaiarella.