KeyCite Yellow Flag - Negative Treatment
Disagreed With by Brown v. Superior Court, Cal., March 31, 1988

97 N.J. 429
Supreme Court of New Jersey.

Carol Ann FELDMAN, Plaintiff-Appellant,
v.
LEDERLE LABORATORIES, a corporation, and American Cyanamid Company, a corporation, Defendants-Respondents.

Argued Jan. 10, 1984.
|
Decided July 30, 1984.

Synopsis

SYNOPSIS

Patient who suffered tooth discolorization as a result of taking a tetracycline drug brought action against manufacturer of the tetracycline drug which she believed she had taken. The Superior Court, Essex County, entered judgment on jury verdict in favor of manufacturer and patient appealed. The Superior Court, Appellate Division, affirmed. The Supreme Court, 450 A.2d 579, 91 N.J. 266,remanded. The Superior Court, Appellate Division, 460 A.2d 203, 189 N.J.Super. 424, again affirmed the judgment for the defendant. The Supreme Court, Schreiber, J., held that: (1) drug manufacturers are not immune from strict liability; (2) drug manufacturer can be held liable for failing to give adequate warnings of that which it knows or which it constructively knows; (3) drug manufacturer is held to the standard of an expert in the field; (4) reasonableness of manufacturer's conduct is a factor in determining liability; (5) manufacturer has a duty to warn of defects of which it becomes aware after distribution of the drug; and (6) state law cause of action based on strict liability principles is not preempted by federal regulation of the drug industry.

Reversed and remanded.

West Headnotes (23)

[1] Products Liability
Unavoidably unsafe products
Products Liability
Drugs in general

Comment k of § 402A the Restatement (Second) of Torts which suggests that strict liability should not apply to certain unavoidably unsafe products does not immunize all prescription drug manufacturers from strict liability; generally, principle of strict liability is applicable to manufacturers of prescription drugs.

27 Cases that cite this headnote

[2] Products Liability
Services as distinguished from products

When the essential nature of the transaction involves a service rather than a product, public policy may dictate that, in view of the status of the provider, the general welfare is served by inapplicability of the strict liability doctrine.

Cases that cite this headnote

[3] Products Liability
Persons Liable

When provider is a nonprofit institution which supplies a product and that product is vital to the public health, doctrine of strict liability may similarly be inapplicable.

Cases that cite this headnote

[4] Products Liability
Strict liability
Products Liability
Drugs in general

Regulation by the Food and Drug Administration of the drug industry does not justify immunization of drug manufacturers from all strict liability.

Cases that cite this headnote

[5] Products Liability
Unavoidably unsafe products
Products Liability

Drugs in general

Not all prescription drugs that are unsafe are unavoidably unsafe so as to render their manufacturers immune from strict liability; whether a drug is unavoidably unsafe should be decided on a case-by-case basis.

17 Cases that cite this headnote

[6] **Products Liability**
Warnings or Instructions

Products Liability
Drugs in general

Even if prescription drug were unavoidably unsafe, strict liability would not be eliminated for failure to provide a proper warning.

10 Cases that cite this headnote

[7] **Sales**
Particular Cases and Goods

Seller may be liable for an allergic response to a product when there is an implied warranty under the Uniform Commercial Code that the product is reasonably fit for the purpose for which it was acquired. N.J.S.A. 12A:2–315.

Cases that cite this headnote

[8] **Products Liability**
Presumptions and Burden of Proof

To establish strict liability, plaintiff must prove that the product was defective, that the defect existed when the product left the defendant's control, and that the defect caused injury to a reasonably foreseeable user.

19 Cases that cite this headnote

[9] **Products Liability**
Types of defects actionable

Defect in a product giving rise to strict liability may take the form of a manufacturing flaw, a design defect, or an inadequate warning.

15 Cases that cite this headnote

[10] **Products Liability**
Care required

Manufacturer of a product is under duty to produce and distribute a product that is reasonably fit, suitable, and safe; it has not met that obligation if it puts a defective article into the stream of commerce that causes injury or damage.

3 Cases that cite this headnote

[11] **Products Liability**
Nature of Product and Existence of Defect or Danger

Emphasis of the strict-liability doctrine is upon the safety of the product rather than the reasonableness of the manufacturer's conduct; it is a product-oriented approach to responsibility.

4 Cases that cite this headnote

[12] **Products Liability**
Design

Products Liability
Warnings or Instructions

When strict liability defect consists of an improper design or warning, reasonableness of the defendant's conduct is a factor in determining liability; question in strict-liability-design defect and warning cases is whether, assuming that the manufacturer knew of the defect in the product, it acted in a reasonably prudent manner in marketing the product or in providing the warnings given; once defendant's knowledge of the defect is imputed, strict liability analysis becomes almost identical to negligence analysis in its focus on the reasonableness of the defendant's conduct.

44 Cases that cite this headnote

[13] **Products Liability**
Warnings or Instructions

Conduct of manufacturer in giving warnings of possible defects should be measured at

the time the manufacturer distributed the product; question is whether the defendant knew, or should have known, of the danger in view of the scientific, technological, and other information available when the product was distributed; limiting *Beshada v. Johns-Manville Prods. Corp.*, 447 A.2d 539, 90 N.J. 191.

8 Cases that cite this headnote

[14] Products Liability
Knowledge of defect or danger

For purposes of determining manufacturer's knowledge of defect, manufacturer is held to the standard of an expert in the field.

4 Cases that cite this headnote

[15] Products Liability
Knowledge of defect or danger

Reasonably prudent manufacturer will be deemed to know of reliable information generally available or reasonably obtainable in the industry or in the particular field involved; such information need not be limited to that furnished by experts in the field but may also include material provided by others.

7 Cases that cite this headnote

[16] Products Liability
Design defect

In strict-liability-warning cases, unlike negligence cases, defendant should properly bear the burden of proving that the information was not reasonably available or obtainable and that it therefore lacked actual or constructive knowledge of the defect.

14 Cases that cite this headnote

[17] Products Liability
Learned intermediary

Products Liability
Drugs in general

Communication of a new warning concerning possible adverse effects of a drug should be given to prescribing physicians as soon as reasonably feasible; although manufacturer may not have actual and constructive knowledge of dangers so as to impose upon it a duty to warn, subsequently acquired knowledge, both actual and constructive, may also obligate the manufacturer to take reasonable steps to notify purchasers and consumers of the newly discovered danger.

25 Cases that cite this headnote

[18] Products Liability
Post-sale duties

Products Liability
Drugs in general

If physician already had drug on hand when manufacturer became aware of side effects, manufacturer would have an obligation to warn the physician promptly.

1 Cases that cite this headnote

[19] Products Liability
State of the art

Products Liability
Drugs in general

In products liability action against manufacturer of drug, it was error to refer the jury to the state of knowledge as evidenced by literature in the scientific community; reasonably prudent drug manufacturer should be deemed to know reasonably obtainable and available reliable information.

5 Cases that cite this headnote

[20] Products Liability
Warnings or Instructions

Products Liability
Drugs in general

Food and Drug Administration regulation providing that the holder of an effective new drug application should submit full details of any proposed change or changes to obtain

FDA opinion as to whether a supplemental application is required does not prevent drug manufacturer from adding additional warnings concerning its product as soon as it became aware of the necessity without obtaining FDA approval.

12 Cases that cite this headnote

[21] States
Product safety;food and drug laws

State law strict liability cause of action against manufacturer for failure to provide adequate warnings is not preempted by federal regulation of the drug industry.

10 Cases that cite this headnote

[22] Appeal and Error
Deference given to lower court in general

Appeal and Error
Review using standard applied below

Standard for appellate review of a trial court's decision on a motion for new trial is substantially the same as that controlling the trial court except that due deference should be made to the trial court's feel of the case, including credibility.

66 Cases that cite this headnote

[23] Products Liability
Drugs in general

Products Liability
Weight and Sufficiency of Evidence

Trial court erred in fixing date at which drug manufacturer's actual or constructive knowledge of defect was to be measured as 1960 where it was clear that patient received the drug, or a related drug, from approximately September of 1960 until the end of 1963.

Cases that cite this headnote

Attorneys and Law Firms

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Barry M. Epstein, Newark, submitted a separate brief on behalf of amicus curiae E.R. Squibb & Sons, Inc. (Sills, Beck, Cummis, Zuckerman, Radin & Tischman, Newark, attorneys; Marc S. Klein, Newark, on the brief).

Opinion

The opinion of the Court was delivered by

SCHREIBER, J.

In this case defendants and *amici* drug manufacturers argued that the doctrine of strict products liability should not apply to prescription drugs. We hold otherwise and conclude that drug manufacturers have a duty to warn of dangers of which they know or should have known on the basis of reasonably obtainable or available knowledge.

Plaintiff, Carol Ann Feldman, has gray teeth as a result of taking a tetracyline drug, Declomycin. Plaintiff's father, a pharmacist and a medical doctor, prescribed and administered the drug to her when she was an infant to control upper ***435** respiratory and other secondary types of infections. Since Dr. Feldman claimed that ****377** he had administered Declomycin, suit was instituted against defendant, Lederle Laboratories, [1] which manufactured and marketed Declomycin. [2] The action was presented to the jury on the theory that the defendant was strictly liable, not because the drug was ineffective as an antibiotic, but because defendant had failed to warn physicians of the drug's side effect, tooth discoloration.

Defendant contended that the plaintiff had not proven that the drug she received was Declomycin. Rather, according to the defendant, the plaintiff could have ingested one of several other tetracycline drugs, any of which could have caused the discoloration. Further, defendant argued that it had complied with the state of the art in its warning literature. It had not warned of possible tooth discoloration because, the defendant claimed, the possibility of that side effect was not known at the time its literature was disseminated.

The jury found for the defendant. The Appellate Division affirmed in an unreported opinion. Plaintiff petitioned for certification and we summarily remanded the cause to the Appellate Division to reconsider in light of *Beshada v. Johns-Manville Prods. Corp.,* 90 *N.J.* 191, 447 *A.*2d 539 (1982), which was decided after the Appellate Division decision. 91 *N.J.* 266, 450 *A.*2d 579 (1982). The Appellate Division reaffirmed the judgment for the defendant, holding that prescription drugs are a special category of products and that drug manufacturers would not be strictly liable for failing to warn of a side effect that was unknown when the drug was sold. 189 *N.J.Super.* 424, 460 *A.*2d 203 (1983). We granted plaintiff's petition for certification. 94 *N.J.* 594, 468 *A.*2d 230 (1983). We permitted ***436** the following *amici* to participate in the proceeding before us: ATLA–NJ, The New Jersey Affiliate of the Association of Trial Lawyers of America; the Pharmaceutical Manufacturers Association; and numerous drug manufacturers.

I

Most facts are undisputed, although there are some sharply disputed conclusions and opinions by the respective experts. Tetracyclines are a group of antibiotics that was first introduced in 1948. They were produced by different drug manufacturers that marketed the drugs under various trade names.

Defendant first marketed Declomycin in 1959. The *Physicians' Desk Reference (PDR),* a book used by doctors to determine effects of drugs, contains data furnished by drug manufacturers about drugs, their compositions, usages, and reactions. The 1959 *PDR* entry for Declomycin stated that it had a greater antibiotic potency that made it possible to achieve therapeutic activity with less weight of antibiotic; it had a reduced renal clearance rate that produced a prolongation of the antibacterial levels in the body; and it was therapeutically equally effective as other tetracyclines in infections caused by organisms sensitive to the tetracyclines. The *PDR* is produced annually. Until the 1965 or 1966 edition, the *PDR* did not mention that tooth discoloration was a possible side effect of Declomycin. Since 1965 or 1966 the *PDR* has stated that the drug, when administered to infants and children, could cause tooth discoloration that would be permanent if the drug were given during the developmental stage of the permanent teeth.

Plaintiff, Carol Ann Feldman, was born on February 8, 1960. Her father, Dr. Harold Feldman, asserted that he prescribed Declomycin for her approximately seven or more times from September or October, 1960, when she was eight or nine months old, until the end of 1963. She was given this drug to prevent secondary infections when she had different childhood diseases. ****378** In his words, "[i]t was a very effective drug for what ***437** I was using it for." He had been introduced to the drug by a medical representative employed by the defendant. The representative gave him a number of samples to be distributed to patients.

Plaintiff's baby teeth were discolored gray-brown. Her permanent teeth were more deeply discolored, being primarily gray. The parties agreed that this discoloration had resulted from use of a tetracycline, although they disputed whether Declomycin was the particular tetracycline involved. In this respect defendant relied in large part upon plaintiff's testimony that her parents had told her the discoloration had been caused by "tetracycline" and on testimony that plaintiff's mother

had stated to plaintiff's expert that her daughter had taken "tetracycline."

The respective experts, Dr. Bonda for the plaintiff and Dr. Guggenheimer for the defendant, agreed that scientific literature existed by 1960 that referred to tooth staining being caused by tetracycline. Dr. Bonda specifically mentioned a 1956 article by Dr. Andre reciting that tetracycline accumulated in mineralized portions of growing bones and teeth of mice; an article by Dr. Milch in the July, 1957 *Journal of the National Cancer Institute* reporting that laboratory animals had yellow fluorescents in bones, including teeth, following dosages of tetracycline; a second article by Dr. Milch in the July, 1958 issue of the *Journal of Bone and Joint Surgery* again describing fluorescents in the bones and incisor teeth of rodents that had been fed tetracycline; a 1959 article by Dr. Swackman noting that of 50 children with cystic fibrosis who had received massive doses of tetracycline, 40 had dark tooth staining; a 1960 letter from Dr. Sigrelli, a Columbia University professor, to the *Pediatric Journal* observing that patients with cystic fibrosis of the pancreas who had received tetracyclines as an antibiotic suffered severe discoloration of their teeth, possibly as a result of their tetracycline use; a May, 1961 article by Dr. Sigrelli in the *New Jersey/New York State Dental Journal* containing the same information; and an essay by Dr. Bevlander ***438** on "The Effect of the Administration of Tetracycline on the Development of Teeth" in the October, 1961 issue of the *Journal of Dental Research* reflecting the adverse effect of tetracycline on developing teeth in young laboratory animals. Dr. Bonda concluded the defendant should have begun to investigate the possible effects of all forms of tetracycline on teeth no later than 1956, when the Andre article appeared.

Defendant's expert, Dr. Guggenheimer, on the other hand, noted that before 1962 the literature on tooth discoloration concerned only patients with cystic fibrosis who had been receiving massive doses of tetracyclines. He pointed out that Dr. Milch's papers described only fluorescents, not tooth staining. He testified that Declomycin did not become available until 1959 and that it would take 2 ½ years for permanent teeth developing in 1959 to erupt. The completion of accurate controlled studies of multiple well-documented cases would have been the only way one could really know whether Declomycin caused tooth discoloration in permanent teeth. Dr. Guggenheimer's testimony is unclear as to whether a correlation between tetracycline and tooth discoloration had been established in 1962. One reading of his testimony indicates that such a correlation was not known to exist and that only by hindsight could that conclusion be drawn. It is also possible to interpret his opinion to be that such correlation had been established in 1962. In any event it is significant that Dr. Guggenheimer gave no opinion as to 1963.

On November 16, 1962, Dr. Swanzey, defendant's Director of Regulatory Agencies Relations, wrote to the Federal Food and Drug Administration (FDA) that the defendant proposed to add to the labels on all its tetracycline products the following warning: "During therapy tetracyclines may form a stable calcium complex in bone-forming tissue with no known harmful effects. Use of any tetracycline during teeth ****379** development in the neonatal period or early childhood may cause discoloration of the teeth." Dr. Swanzey explained that it was not necessary to obtain FDA approval before placing a warning on a label, but ***439** it was the practice to do so. On cross-examination, however, he indicated that although no FDA approval was needed to write letters to doctors informing them of this correlation, labeling the product without FDA approval could be considered a misbranding.

The FDA acknowledged receipt of Dr. Swanzey's letter on December 3, 1962, and advised him that the FDA "has been acutely interested by the increasing number of new and/or undesirable effects accompanying or following the use of these products," and would notify the defendant "as soon as any conclusion is reached." Dr. Swanzey telephoned Dr. Barzilai of the FDA, who advised against putting any statement in a circular proposed to be distributed by the defendant and that the FDA had the matter under study. On January 15, 1963, Dr. Swanzey sent to the FDA two articles on bone effects, including a copy of the Bevlander article. Dr. Swanzey also spoke with Dr. Sigrelli, who advised that staining would occur with some tetracyclines, but he had not observed that it occurred with Declomycin.

The FDA, in a letter dated February 4, 1963, proposed that the defendant insert the following warning statement in "all" its tetracycline products:

> Tetracyclines may form a stable calcium complex in any bone forming tissue with no serious

> harmful effects reported thus far in humans. However, use of any tetracycline drug during tooth development (= last trimester of pregnancy, neonatal period and early childhood) may cause discoloration of the teeth (= yellow-grey-brownish). This effect occurs mostly during long-term use of the drug but it has also been observed in usual short treatment courses.

Dr. Swanzey responded that the suggested statement was satisfactory and would be incorporated in its literature. He added that he assumed that the directive was applicable to Declomycin as well as other tetracycline drugs. The FDA replied that "[t]here is practically no specific clinical evidence to substantiate such a labeling requirement" for Declomycin and the warning would have to appear only on labeling of other tetracycline drugs. On April 12, 1963, the FDA made it clear that the warning statement was to refer not to tetracyclines ***440** generally but only to the specific brand names of the implicated products.

In 1963, the defendant received complaints from eight doctors that Declomycin was causing tooth staining. In May, 1963 the defendant referred the FDA again to the side effect of Declomycin. Commencing in mid-December, 1963, after receipt of FDA approval, it included the same warning in the Declomycin literature as in other tetracyclines.

In 1975, Dr. Feldman questioned defendant's medical representative regarding dental discoloration related to the use of tetracycline. Lloyd Carr, defendant's Product Service Manager, wrote to Dr. Feldman in response to that inquiry:

> When the causal relationship between tooth staining and tetracycline became unquestionably demonstrated by our Company, we notified the Food and Drug Administration by letter of November 16, 1962 and requested of the Food and Drug Administration that appropriate warnings be included in the labeling of our tetracycline products.
>
> During April 1963, apparently after conducting their own investigation, the Food and Drug Administration concurred and at that time the Federal Agency directed all manufacturers of tetracycline to include appropriate warnings in their labeling.
>
> In April 1963 Lederle's labeling for ACHROMYCIN® tetracycline HCl was amended accordingly. DECLOMYCIN® demeclocycline HCl crystalline was specifically excluded as the Food and Drug Administration had no evidence that this ****380** analogue caused tooth staining. However, on or about May 1963 we informed the Food and Drug Administration that DECLOMYCIN was also implicated in reports of tooth staining and during December of 1963 this warning was approved for the DECLOMYCIN labeling.

The trial court's charge to the jury was directed to two substantive issues. One was whether Declomycin was ingested by the plaintiff. The second was whether the defendant knew or should have known of the need to place a warning on its literature accompanying the sale of Declomycin and in the literature distributed to the medical profession. The trial court also stated that if the defendant did not know of the danger of tooth discoloration, and if the application of reasonably developed human skill and foresight consistent with the state of the art and the knowledge of the scientific community existing during the periods in question would not have alerted defendant ***441** to the danger, then there would have to be a finding for the defendant. The trial court also charged that the defendant's reliance on the FDA would not serve to relieve defendant of its duty to insert a warning if it knew or should have known of the need for such a warning. No exceptions were taken to the charge.

II

Does Strict Liability Apply to Manufacturers of Prescription Drugs?

[1] The defendant never contended in its answer or at trial that the doctrine of strict liability should not apply to prescription drugs. It first raised this proposition after we had remanded the matter to the Appellate Division for reconsideration in light of *Beshada, supra,* 90 *N.J.* 191, 447 *A.*2d 539. The defendant and the drug manufacturing *amici curiae* urged that public policy as explicated in comment k to section 402A of the *Restatement (Second) of Torts* (1965) [3] [hereinafter cited as *Restatement*] should

immunize drug manufacturers from liability for side effects of prescription drugs. Comment k suggests that strict liability should not apply to certain unavoidably unsafe products. We do not agree that the protective shield of comment k immunizes all prescription drugs. Moreover, we are of the ***442** opinion that generally the principle of strict liability is applicable to manufacturers of prescription drugs.

There are some circumstances in which as a matter of public policy this Court has determined that strict liability should not be applied. Illustrative are *Magrine v. Krasnica,* 94 *N.J.Super* 228, 227 *A.*2d 539 (Cty.Ct.1967), aff'd, 100 *N.J.Super* 223, 241 *A.*2d 637 (App.Div.1968), aff'd on both opinions below, 53 *N.J.* 259, 250 *A.*2d 129 (1969); *Newmark v. Gimbel's Inc.,* 54 *N.J.* 585, 258 *A.*2d 697 (1969); *Baptista v. Saint Barnabas Medical Center,* 109 *N.J.Super.* 217, 262 *A.*2d 902 (App.Div.), aff'd o.b., 57 *N.J.* 167, 270 *A.*2d 409 (1970); and *Brody v. Overlook Hosp.,* 66 *N.J.* 448, 332 *A.*2d 596 (1975). Most recently we acknowledged that principle in *O'Brien v. Muskin Corp.,* 94 *N.J.* 169, 186, 463 *A.*2d 298 (1983).

[2] **[3]** Certain principles may be distilled from these cases. When the essential nature of the transaction involves a service rather than a product, public policy may dictate, in view of the status of the provider, that the general welfare is served better ****381** by inapplicability of the strict liability doctrine. Further, when the provider is a nonprofit institution that supplies a product and that product is vital to the public health, the doctrine may similarly be inapplicable. The common thread that runs through these cases is that in each of those situations there is a strong public policy rooted in the general welfare that justifies imposing responsibility only on the basis of a want of due care (negligence) rather than on the basis of a defective product (strict liability).

The first in this line of cases, *Magrine v. Krasnica, supra,* held that a dentist was not strictly liable when a hypodermic needle broke while in the patient's jaw. The trial court concluded that the strict liability principle was inapplicable because the dentist did not fit within the pattern of one putting goods in the stream of commerce. The dentist did not create the defect and was not in a position to control or discover a latent defect in the needle. 94 *N.J.Super.* at 234–35, 227 *A.*2d 539. According to the court, there was a basic difference between the commercial sale of a product, in which the essence of the transaction is the sale of an ***443** article, and the rendition of service by the dentist. The court reasoned that "[a] dentist or a physician offers, and is paid for, his professional services and skill. That is the *essence* of the relationship between him and his patient." *Id.* at 235, 227 *A.*2d 539 (emphasis in original). Moreover, the court concluded that imposing strict liability on the dentist would not promote the policy goals of placing the loss "on those best able to withstand it," because the dentist was unlike the manufacturer who made and placed the article in the stream of commerce. *Id.* at 239, 227 *A.*2d 539.

This reasoning was approved again in 1969 by this Court's decision in *Newmark v. Gimbel's Inc., supra,* 54 *N.J.* 585, 258 *A.*2d 697. There the plaintiff suffered a contact dermatitis as a result of a permanent wave administered in the defendant's beauty salon. We held that strict liability applied and took care to distinguish the services of hairdressers from those of dentists and doctors. We reasoned that doctors' and dentists' services

> bear such a necessary and intimate relationship to public health and welfare that their obligation ought to be grounded and expressed in a duty to exercise reasonable competence and care toward their patients. In our judgment, the nature of the services, the utility of and the need for them, involving as they do, the health and even survival of many people, are so important to the general welfare as to outweigh in the policy scale any need for the imposition on dentists and doctors of the rules of strict liability in tort. [54 *N.J.* at 597, 258 *A.*2d 697].

Thereafter this Court extended immunity to certain nonprofit health care entities that furnished products essential for the public health. *Baptista v. Saint Barnabas Medical Center, supra,* 109 *N.J.Super.* 217, 262 *A.*2d 902, decided in the following year, held that strict liability did not apply to a hospital that had furnished incompatible, but not defective, blood for a transfusion. The court found, for the same policy reasons expressed in *Newmark,* that there was "no justification" for extending the doctrine of strict liability to such cases. 109 *N.J.Super.* at 225, 262 *A.*2d 902.

The last occasion a comparable issue was raised in this Court was in *Brody v. Overlook Hosp., supra,* 66 *N.J.* 448, 332 *A.*2d 596, in 1975. There the blood used in a transfusion in a hospital was defective because it was infected with viral hepatitis. The presence of hepatitis was not discoverable by the county blood bank, a ***444** charitable nonprofit organization that supplied the blood, 121 *N.J.Super.* at 309, 296 *A.*2d 668, or by the hospital. 66 *N.J.* at 450, 332*A.*2d 596. We held again, for the policy reasons expressed in *Newmark,* that strict liability was not appropriate. The primary reason for our decision was the public policy advocating the inapplicability of the strict liability doctrine. *Id.* The Appellate Division in that case also relied upon comment ****382** k to section 402A of the *Restatement, supra,* and we agreed with that reliance. 66 *N.J.* at 451, 332 *A.*2d 596.

Drug manufacturers do not fall within the policy exceptions expressed in the foregoing cases. Drug manufacturers, unlike doctors and dentists, do not render to consumers professional services involving skills in judgment and diagnosis. They produce goods and place them into the stream of commerce. Although their products may be valuable to the public, the drug manufacturers are not nonprofit or charitable institutions. They are commercial profit-making enterprises upon which product responsibility properly rests.

In addition to the above described exemptions to the doctrine of strict liability, we referred in *O'Brien v. Muskin Corp., supra,* 94 *N.J.* 169, 463 *A.*2d 298, to the general category of situations in which one would reasonably conclude after a weighing of all pertinent factors, particularly those set forth in the risk-utility analysis, [4] that the strict liability principle should not be applied. ***445** *Id.* at 186, 463 *A.*2d 298. It may be that, after considering the risk-utility factors and other possible relevant considerations, a court could justifiably conclude, under some circumstances, that a manufacturer should not be strictly liable. Or, as this Court decided in *O'Brien,* the jury may be called upon to balance the risk-utility factors and decide whether the drug product should fall within the immunized category. *Id.*

The defendant has not presented any evidence to support the proposition that strict liability should not be applied to drug manufacturers that produce and distribute prescription drugs including Declomycin. Further, as observed previously, this proposition was not raised at trial. The record understandably has little, if any, evidence pertinent or material to that issue. For example, the record shows that before offering new drugs to the public, drug companies furnish certain material to scientists or doctors engaged in research. There is no evidence of the extent and nature of research that drug companies usually perform or that the defendant actually performed with respect to Declomycin. The evidence throws no light on whether all drugs should be treated alike, some being more vital to the public health and human survival than others. The evidence does not demonstrate why the drug-manufacturing industry should be placed in a different category from other manufacturers and suppliers of mass-produced products in which the enterprise bears the liability for a product that is not fit, suitable, or safe for its intended use. *Cf. Jackson v. Muhlenberg Hosp.,* 53 *N.J.* 138, 249 *A.*2d 65 (1969) (summary judgment dismissal of ***446** suit against hospital and blood bank by plaintiff, who contracted hepatitis allegedly due to blood transfusion, reversed because of inadequate record).

****383** **[4]** Nor are we satisfied on this record that regulation by the FDA of the drug industry justifies such a distinction. There has been no showing of the extent to which and how the FDA applies a risk-utility analysis in deciding whether a drug should be distributed or the effect of the FDA's determination on the drug manufacturer's options to distribute or not distribute the drug with or without warnings. Indeed, the FDA's determination, even if it consisted of a risk-utility analysis, would not supplant the risk-utility balancing required in the judicial process. The record is not sufficient to analyze fully the risks and benefits of prescription drugs and to conclude that drug manufacturers should be immune from strict liability for failure to produce drugs that are safe, suitable, and fit for their intended purposes. [5]

Defendant and drug manufacturing *amici* also contend that all prescription drugs are unavoidably unsafe and therefore that drug manufacturers of these products fall within the protective aegis of comment k of the *Restatement, supra.* Comment k reads as follows:

> *Unavoidably unsafe products.* 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. An outstanding example is the vaccine for

the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, *and accompanied by proper directions and warning,* is not defective, nor is it *unreasonably* [emphasis in original] dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to ***447** physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, *again with the qualification that they are properly prepared and marketed, and proper warning is given,* where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk. [Emphasis added.]

[5] Comment k immunizes from strict liability the manufacturers of some products, including certain drugs, that are unavoidably unsafe. However, we see no reason to hold as a matter of law and policy that all prescription drugs that are unsafe are unavoidably so. Drugs, like any other products, may contain defects that could have been avoided by better manufacturing or design. Whether a drug is unavoidably unsafe should be decided on a case-by-case basis; we perceive no justification for giving all prescription drug manufacturers a blanket immunity from strict liability manufacturing and design defect claims under comment k.

[6] **[7]** Moreover, even if a prescription drug were unavoidably unsafe, the comment k immunity would not eliminate strict liability for failure to provide a proper warning. As Justice Pollock stated in *O'Brien, supra,* "[w]ith those products, the determination of liability may be achieved ****384** more appropriately through an evaluation of the adequacy of the warnings." 94 *N.J.* at 183, 463 *A.*2d 298. Thus, a manufacturer who knows or should know of the danger or side effects of a product is not relieved of its duty to warn. Rather, as the comment expressly states, it is only the unavoidably unsafe product "*accompanied by proper * * * warning* " that is not defective. (Emphasis added.) *See Needham v. White Laboratories,* 639 *F.*2d 394, 402 (7th Cir.), *cert.* denied, 454 *U.S.* 927, 102 *S.Ct.* 427, 70 *L.Ed.*2d 237 (1981); *Singer v. Sterling Drug, Inc.,* 461 *F.*2d 288, 290 (7th Cir.), *cert.* denied, 409 *U.S.* 878, 93 *S.Ct.* 131, 34 *L.Ed.*2d 132 (1972). Contrary to *amici*'s claim, we find nothing in the proceedings ***448** of the American Law Institute that justifies a different conclusion. Irrespective of whether a court or a jury decides that the drug falls within the special category of comment k, that finding may not absolve the manufacturer of its failure to warn the physician or consumer of the condition within the manufacturer's actual or constructive knowledge affecting the safety, fitness, or suitability of the drug. *See* Wade, "On the Effect in Product Liability of Knowledge Unavailable Prior to Marketing," 58 *N.Y.U.L.Rev.* 734, 745 (1983) [hereinafter cited as Wade (1983)]. [6]

***449** In sum, we hold that none of the policy reasons for exempting certain products from strict liability is applicable to this case. Production and marketing of drugs do not fit within the public policy exemptions for doctors, dentists, and nonprofit or charitable health care institutions. There is insufficient evidence to find that Declomycin's utility so outweighs its risks that the manufacturer should be immune from strict liability under a risk-utility analysis. Finally, Declomycin would not be exempt from strict liability under comment k to the *Restatement, supra,* if the defendant failed to provide an adequate warning of the possible tooth-discoloration effect of administering the drugs to infants.

III

[8] **[9]** We commence our strict liability analysis with the now familiar refrain that to establish strict liability a plaintiff must prove that the product was defective, that the defect existed when the product left the ****385** defendant's control, and that the defect caused injury to a reasonably foreseeable user. *O'Brien, supra,* 94 *N.J.* at 179, 463 *A.*2d 298; *Michalko v. Cooke Color & Chem. Corp.,* 91 *N.J.* 386, 394, 451 *A.*2d 179 (1982). The defect may take one of three forms: a manufacturing flaw, a design defect,

or an inadequate warning. *O'Brien, supra,* 94 *N.J.* at 181, 463 *A.*2d 298.

This is a strict-liability-warning case. The product has been made as the manufacturer intended. The plaintiff does not contend that it contained a manufacturing defect. Declomycin's purpose was to act as did other tetracyclines—as an antibiotic. However, it had several advantages over other antimicrobial therapeutics. The plaintiff does not dispute this. Indeed, there is no evidence that plaintiff's usage of Declomycin was not adequate in this respect. Nor was there any proof that it was improperly designed. The crux of the plaintiff's ***450** complaint is that her doctor should have been warned of a possible side effect of the drug in infants, discoloration of teeth.

[10] The failure-to-warn strict liability classification is similar to the improper design category. *O'Brien, supra,* 94 *N.J.* at 181, 463 *A.*2d 298; *Freund v. Cellofilm Properties, Inc.,* 87 *N.J.* 229, 242, 432 *A.*2d 925 (1981). The manufacturer is under a duty to produce and distribute a product that is reasonably fit, suitable, and safe. It has not met that obligation if it puts a defective article into the stream of commerce that causes injury or damage. We acknowledged in *Suter v. San Angelo Foundry & Mach. Co.,* 81 *N.J.* 150, 176, 406 *A.*2d 140 (1979), that "a product may be unsafe because of inadequate instructions." Indeed, we held in *Freund, supra,* 87 *N.J.* at 236–41, 432 *A.*2d 925, that an inadequate warning could constitute a design defect.

[11] The emphasis of the strict liability doctrine is upon the safety of the product, rather than the reasonableness of the manufacturer's conduct. It is a product-oriented approach to responsibility. *O'Brien, supra,* 94 *N.J.* at 180, 463 *A.*2d 298; *Freund, supra,* 87 *N.J.* at 238, 432 *A.*2d 925. Generally speaking, the doctrine of strict liability assumes that enterprises should be responsible for damages to consumers resulting from defective products regardless of fault. The doctrine differs from a negligence theory, which centers on the defendant's conduct and seeks to determine whether the defendant acted as a reasonably prudent person. This difference between strict liability and negligence is commonly expressed by stating that in a strict liability analysis, the defendant is assumed to know of the dangerous propensity of the product, whereas in a negligence case, the plaintiff must prove that the defendant knew or should have known of the danger. *Freund, supra,* 87 *N.J.* at 238–39, 432 *A.*2d 925; *Suter, supra,* 81 *N.J.* at 171, 406 *A.*2d 140; *Cepeda v. Cumberland Eng'g Co.,* 76 *N.J.* 152, 172, 386 *A.*2d 816 (1978); Wade (1983), *supra,* at 762–64. This distinction is particularly pertinent in a manufacturing defect context.

***451** **[12]** When the strict liability defect consists of an improper design or warning, reasonableness of the defendant's conduct is a factor in determining liability. *See Suter, supra,* 81 *N.J.* at 171, 406 *A.*2d 140; *Cepeda, supra,* 76 *N.J.* at 171–72, 386 *A.*2d 816; *Torsiello v. Whitehall Laboratories,* 165 *N.J.Super.* 311, 320 n. 2, 398 *A.*2d 132 (App.Div.), certif. denied, 81 *N.J.* 50, 404 *A.*2d 1150 (1979). The question in strict liability design defect and warning cases is whether, assuming that the manufacturer knew of the defect in the product, he acted in a reasonably prudent manner in marketing the product or in providing the warnings given. Thus, once the defendant's knowledge of the defect is imputed, strict liability analysis becomes almost identical to negligence analysis in its focus on the reasonableness of the defendant's conduct. In *Cepeda, supra,* 76 *N.J.* at 172, 386 *A.*2d 816, and *Suter, supra,* 81 *N.J.* at 171, 406 *A.*2d 140, we quoted approvingly Prosser's treatise on torts: "Since proper design is a ****386** matter of reasonable fitness, the strict liability adds little or nothing to negligence on the part of the manufacturer * * *." *W. Prosser, Law of Torts* 659 n. 72 (4th ed. 1971).

Generally, the state of the art in design defect cases and available knowledge in defect warning situations are relevant factors in measuring reasonableness of conduct. Thus in *Suter, supra,* we explained that other than assuming that the manufacturer knew of the harmful propensity of the product, the jury could consider "the technological feasibility of manufacturing a product whose design would have prevented or avoided the accident, given the known state of the art." *Id.* at 172, 406 *A.*2d 140. We observed that "the state of the art refers not only to the common practice and standards in the industry but also to the other design alternatives within practical and technological limits at the time of distribution." *Id.* Moreover, in *O'Brien, supra,* we again referred to the state of the art as an appropriate factor to be considered by the jury to determine whether feasible alternatives existed when the product was marketed. 94 *N.J.* at 183–84, 463 *A.*2d 298.

***452** **[13]** Similarly, as to warnings, generally conduct should be measured by knowledge at the time the

manufacturer distributed the product. Did the defendant know, or should he have known, of the danger, given the scientific, technological, and other information available when the product was distributed; or, in other words, did he have actual or constructive knowledge of the danger? The *Restatement, supra,* has adopted this test in comment j to section 402A, which reads in pertinent part as follows:

> *Directions or warning.* In order to prevent the product from being unreasonably dangerous, the seller may be required to give directions or warning, on the container, as to its use. * * * Where the product contains an ingredient * * * whose danger is not generally known, or if known is one which the consumer would reasonably not expect to find in the product, the seller is required to give warning against it, *if he has knowledge, or by the application of reasonable, developed human skill and foresight should have knowledge,* of the presence of the ingredient and the danger. [Emphasis added.]

Under this standard negligence and strict liability in warning cases may be deemed to be functional equivalents. *See Sterling Drug, Inc. v. Yarrow,* 408 *F.*2d 978, 992 (8th Cir.1969); *Chambers v. G.D. Searle & Co.,* 441 *F.Supp.* 377, 380 (D.Md.1975), aff'd *per curiam,* 567 *F.*2d 269 (4th Cir.1977); *Incollingo v. Ewing,* 444 *Pa.* 263, 285 n. 8, 282 *A.*2d 206, 220 n. 8 (1971); 2 *Interagency Task Force on Product Liability, U.S. Dep't of Commerce, Product Liability: Legal Study* 67–68 (1977). Constructive knowledge embraces knowledge that should have been known based on information that was reasonably available or obtainable and should have alerted a reasonably prudent person to act. Put another way, would a person of reasonable intelligence or of the superior expertise of the defendant charged with such knowledge conclude that defendant should have alerted the consuming public? *See Restatement, supra,* § 12(2).

[14] Further, a manufacturer is held to the standard of an expert in the field. *Karjala v. Johns-Manville Prods. Corp.,* 523 *F.*2d 155, 159 (8th Cir.1975); *see Garst v. General Motors Corp.,* 207 *Kan.* 2, 20, 484 *P.*2d 47, 61 (1971); *Micallef v.* ***453** *Miehle Co.,* 39 *N.Y.*2d 376, 386, 348 *N.E.*2d 571, 578, 384 *N.Y.S.*2d 115, 121 (1976). A manufacturer should keep abreast of scientific advances. Harper and James, in their treatise on torts, explained that a manufacturer is

> held to the skill of an expert in that particular business and to an expert's knowledge of the arts, materials and processes. Thus he must keep reasonably abreast of scientific knowledge and discoveries touching his product and of techniques and devices used by practical ****387** men in his field. He may also be required to make tests to determine the propensities and dangers of his product. [2 *F. Harper & F. James, The Law of Torts* § 28.4 (1956) (footnotes omitted).]

See 2 *R. Hursch & H. Bailey, American Law of Products Liability* 153–54 (2d ed. 1974). Were the available scientific data or other pertinent information such as to "give rise to a reasonable inference that the danger is likely to exist"? Wade (1983), *supra,* at 749. Implicit in the requirement that such a manufacturer is held to the standard applicable to experts in the field is the notion that at least in some fields, such as those impacting on public health, a manufacturer may be expected to be informed and affirmatively to seek out information concerning the public's use of its own product.

[15] Furthermore, a reasonably prudent manufacturer will be deemed to know of reliable information generally available or reasonably obtainable in the industry or in the particular field involved. Such information need not be limited to that furnished by experts in the field, but may also include material provided by others. Thus, for example, if a substantial number of doctors or consumers had complained to a drug manufacturer of an untoward effect of a drug, that would have constituted sufficient information requiring an appropriate warning. *See Hoffman v. Sterling Drug, Inc.,* 485 *F.*2d 132, 146 (3d Cir.1973) (in judgment for plaintiff alleging negligence and strict products liability in failure-to-warn case against prescription drug manufacturer of Aralen, court found jury question whether defendants used foresight appropriate to their enterprise in view of the number of letters from physicians reporting visual injury in patients using Aralen and subsequent medical literature); ***454** *Skill v. Martinez,* 91 *F.R.D.* 498, 514 (D.N.J.1981), aff'd on other grounds, 677 *F.*2d 368 (3d Cir.1982) (jury finding in products liability action for plaintiff upheld because "sufficient knowledge" existed, in the form of articles of preliminary findings by two leading researchers in the field, of danger inherent in taking birth-control pill while smoking to warrant drug manufacturer's

giving proper warning); *Hamilton v. Hardy,* 37 *Colo.App.* 375, 385, 549 *P.*2d 1099, 1108 (1976) (under strict liability theory, manufacturer of prescription drugs must warn of dangers and risks, whether or not a causal relationship between use of product and various attendant injuries has been definitively established at the time of the warning); *McKee v. Moore,* 648 *P.*2d 21, 24 (Okla.1982) (duty to warn requires prescription drug manufacturer to maintain current information "gleaned from research, adverse reaction reports, scientific literature and other available methods") (footnote omitted); 39 Fed.Reg. 33,230–31 (1974) (FDA requires warnings on drug labels "when there is significant medical evidence of a possible health hazard, without waiting for a causal relationship to be established by definitive studies which, in some instances, may not be feasible or would take many years").

This test does not conflict with the assumption made in strict liability design defect and warning cases that the defendant knew of the dangerous propensity of the product, if the knowledge that is assumed is reasonably knowable in the sense of actual or constructive knowledge. A warning that a product may have an unknowable danger warns one of nothing. Neither *Cepeda* nor *Suter* stated that the manufacturer would be deemed to know of the dangerous propensity of the chattel when the danger was unknowable. *See Ferrigno v. Eli Lilly and Co.,* 175 *N.J.Super.* 551, 576, 420 *A.*2d 1305 (Law Div.1980). In our opinion *Beshada, supra,* would not demand a contrary conclusion in the typical design defect or warning case. If *Beshada* were deemed to hold generally or in all cases, particularly with respect to a situation like the present one involving drugs vital ***455** to health, that in a warning context knowledge of the unknowable is irrelevant in determining the applicability of strict liability, we would not agree. Many commentators have criticized this aspect of the ****388** *Beshada* reasoning and the public policies on which it is based. *See, e.g.,* Page, "Generic Product Risks: The Case Against Comment K and for Strict Tort Liability," 58 *N.Y.U.L.Rev.* 853, 877–82 (1983); Schwartz, "The Post-Sale Duty to Warn: Two Unfortunate Forks in the Road to a Reasonable Doctrine," 58 *N.Y.U.L.Rev.* 892, 901–05 (1983); Wade (1983), *supra,* at 754–56; Comment, "Requiring Omniscience: The Duty to Warn of Scientifically Undiscoverable Product Defects," 71 *Geo.L.J.* 1635 (1983); Comment, "*Beshada v. Johns Manville Products Corp.:* Adding Uncertainty to Injury," 35 *Rutgers L.Rev.* 982, 1008–15 (1983); Note, "Products Liability—Strict—Liability in Tort—State-of-the-Art Defense Inapplicable in Design Defect Cases," 13 *Seton Hall L.Rev.* 625 (1983). *But see Hayes v. Ariens Co.,* 391 *Mass.* 407, 413, 462 *N.E.*2d 273, 277–78 (1984) (citing *Beshada* with approval for the proposition that in strict liability the seller "is presumed to have been informed at the time of sale of all risks whether or not he actually knew or reasonably should have known of them"). The rationale of *Beshada* is not applicable to this case. We do not overrule *Beshada,* but restrict *Beshada* to the circumstances giving rise to its holding. *See, e.g., Friedman v. Podell,* 21 *N.J.* 100, 105, 121 *A.*2d 17 (1956); *Konrad v. Anheuser-Busch, Inc.,* 48 *N.J.Super.* 386, 388, 137 *A.*2d 633 (Law Div.1958) ("Cases state principles but decide facts, and it is only the decision on the facts that is binding precedent."). We note, in passing, that, although not argued and determined in *Beshada,* there were or may have been data and other information generally available, aside from scientific knowledge, that arguably could have alerted the manufacturer at an early stage in the distribution of its product to the dangers associated with its use.

[16] In strict liability warning cases, unlike negligence cases, however, the defendant should properly bear the burden of proving that the information was not reasonably available or ***456** obtainable and that it therefore lacked actual or constructive knowledge of the defect. Wade (1983), *supra,* at 760–61; *see* Pollock, "Liability of a Blood Bank or Hospital for a Hepatitis Associated Blood Transfusion in New Jersey," 2 *Seton Hall L.Rev.* 47, 60 (1970) ("burden of proof that hepatitis is not detectable and unremovable should rest on the defendant" blood bank or hospital). The defendant is in a superior position to know the technological material or data in the particular field or specialty. The defendant is the expert, often performing self-testing. It is the defendant that injected the product in the stream of commerce for its economic gain. As a matter of policy the burden of proving the status of knowledge in the field at the time of distribution is properly placed on the defendant. *See State v. Toscano,* 74 *N.J.* 421, 443, 378 *A.*2d 755 (1977) (shifting burden to criminal defendant of proving duress); *Anderson v. Somberg,* 67 *N.J.* 291, 300–02, 338 *A.*2d 1 (*per* Pashman, J., with two Justices concurring, and one Justice concurring in the result) (placing burden of persuasion on multiple defendants in malpractice action where plaintiff was not in a position to identify the responsible party), *cert.* denied, 423 *U.S.* 929, 96 *S.Ct.* 279, 46 *L.Ed.*2d 258 (1975); *cf. Griggs v.*

Bertram, 88 *N.J.* 347, 365–68, 443 *A.*2d 163 (1982) (in insurance case, shifting to settler insured burden of going forward, but not of persuasion, on question of whether a settlement was made in good faith); *NOPCO Chem. Div. v. Blau-Knox Co.,* 59 *N.J.* 274, 284–85, 281 *A.*2d 793 (1971) (shifting burden of production to defendants where machine damaged in transit but buyer did not know which carrier or bailee had damaged it).

[17] One other aspect with respect to warnings based on subsequently obtained knowledge should be considered. Communication of the new warning should unquestionably be given to prescribing physicians as soon as reasonably feasible. Although a manufacturer may not have actual or constructive knowledge of a danger so as to impose upon it a duty to warn, subsequently ****389** acquired knowledge, both actual and constructive, also may obligate the manufacturer to take reasonable steps to ***457** notify purchasers and consumers of the newly-discovered danger. *Compare Bacardi v. Holzman,* 182 *N.J.Super.* 422, 425, 442 *A.*2d 617 (App.Div.1981) (holding that "[t]he manufacturer has no duty to prepare a warning for the consumer when, under all circumstances, the product only comes into the consumer's hands after it is prescribed by the physician"), *with Lukaszewicz v. Ortho Pharmaceutical Corp.,* 510 *F.Supp.* 961 (E.D.Wis.1981) (manufacturer of oral contraceptive had duty under strict liability to warn patients directly of possible side effects where FDA regulation mandated such warning and Wisconsin law made a violation of such a regulation negligence *per se*) *and Pharmaceutical Mfrs. Ass'n v. Food and Drug Administration,* 484 *F.Supp.* 1179, 1182 (D.Del.), aff'd *per curiam,* 634 *F.*2d 106 (3d Cir.1980) (upholding FDA regulation requiring direct warning to consumers of prescription drugs containing estrogens because Congress, in enacting the Food, Drug, and Cosmetic Act, "intended patients using prescription drugs, as well as those using over-the-counter drugs, to receive" material facts directly).

[18] The timeliness of the warning issue is obliquely present in this case. It is possible that Dr. Feldman already had Declomycin on hand when defendant became aware of Declomycin's side effect. If that state of affairs existed, defendant would have had an obligation to warn doctors and others promptly. This most assuredly would include those to whom defendant had already furnished the product. *See Schenebeck v. Sterling Drug, Inc.,* 423 *F.*2d 919, 922 (8th Cir.1970); *Basko, supra,* 416 *F.*2d at 426. *See generally* Note, "The Manufacturer's Duty to Notify of Subsequent Safety Improvements," 33 *Stan.L.Rev.* 1087 (1981). The extent and nature of post-distribution warnings may vary depending on the circumstances, but in the context of this case, the defendant at a minimum would have had a duty of advising physicians, including plaintiff's father, whom it had directly solicited to use Declomycin.

***458** **[19]** The trial court charged the jury that the manufacturer of a drug has the obligation to warn if he knew or should have known of the need to issue such a warning. In determining whether defendant should have known of the danger, it referred the jury to the circumstances, relating particularly to the state of knowledge, as evidenced by the literature, in the scientific community. However, upon the retrial the charge should also include the principle expressed herein that a reasonably prudent drug manufacturer should be deemed to know of reasonably obtainable and available reliable information.[7] In addition, we now place the burden of proving the lack of knowledge on the defendant.

IV

At the second proceeding before the Appellate Division, the defendant raised for the first time the claim that it could not lawfully have modified the warnings without FDA approval, an approval that was not obtained until the end of 1963. It raised this defense even though its witness, Dr. Swanzey, testified there was "no prohibition" against inserting the additional warning without FDA approval. Indeed, defendant did not object to the trial court's charge that the FDA's actions "would not serve to relieve the defendant of any obligation to place a warning if in fact during the critical periods involved in this case it knew or should have known of the need for such a warning." Under these circumstances we would ordinarily defer discussion of the issue. However, since the trial court may be faced with the problem on the retrial, see Point V herein, some comments are in order.

****390** **[20]** Defendant bases its contention on an FDA regulation, 21 *C.F.R.* § 130.9 (1964). That regulation provided that "[t]he ***459** holder of an effective new-drug application should submit * * * full details of any proposed change or changes, and he will be notified in writing whether, in the Food and Drug Administration's

opinion, the submission of a supplemental application is *required* for such change or changes." 25 Fed.Reg. 12,595 (1960) (emphasis added). We note that the regulation did not prevent a drug manufacturer from adding an additional warning as soon as it was aware of its necessity. Nor has counsel submitted to us any FDA administrative decision to the contrary effect. It would seem anomalous for the FDA to have prevented a drug manufacturer from advising the public immediately of a newly discovered danger while waiting for FDA approval. *But see Roginsky v. Richardson-Merrell, Inc.,* 378 *F.*2d 832, 835, 848 (2d Cir.1967) (in dictum citing 21 *C.F.R.* § 130.9 for the proposition that FDA regulations required approval before modification). Such a stand would have undercut the primary purpose of protecting the public under the Food, Drug, and Cosmetic Act, 21 *U.S.C.* §§ 301–92 (1972) (the Act). *See 62 Cases of Jam v. United States,* 340 *U.S.* 593, 596, 71 *S.Ct.* 515, 518, 95 *L.Ed.* 566, 570(1951). Furthermore, in 1965 the regulation was amended, 30 Fed.Reg. 993–94 (1965), to require that drug manufacturers inform the public immediately of newly discovered dangers before waiting for the FDA to act. *See McEwen, v. Ortho Pharmaceutical Corp., 270* Or. *375, 398, 528* P.2d *522, 534-535 (1974), (construing the 1965 amendment to give drug manufacturers, and not the FDA, responsibility for the adequacy and timeliness of warnings);* see also *44 Fed.Reg. 37, 447 (1979) (FDA discussing the 1965 amendment and citing*McEwen%i).

Defendant also argues that the plaintiff's cause of action for personal injury due to mislabeling is barred because Congress has preempted the field by enacting the Act pursuant to its power under the commerce clause. *United States v. Walsh,* 331 *U.S.* 432, 434, 67 *S.Ct.* 1283, 1284, 91 *L.Ed.* 1585, 1587 (1947). The preemption question thus centers on whether Congress intended to eliminate a plaintiff's common law action for negligence ***460** or for production and distribution of a defective drug product.

The cause of action under state law involves the injury suffered by a particular plaintiff and focuses for preemption purposes on whether the federal statute, expressly or impliedly, indicates exclusivity; whether the federal scheme is so pervasive that it precludes such litigation; and whether such causes of action are "an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz,* 312 *U.S.* 52, 67–68, 61 *S.Ct.* 399, 404–405, 85 *L.Ed.* 581, 581 (1941) (footnote omitted). *See generally U.S.A. Chamber of Commerce v. State,* 89 *N.J.* 131, 141–43, 445 *A.*2d 353 (1982) (discussing preemption).

Justice Brennan reminds us that "[t]he principle to be derived from our decisions is that federal regulation of a field of commerce should not be deemed preemptive of state regulatory power in the absence of persuasive reasons—either that the nature of the regulated subject matter permits no other conclusion, or that the Congress has unmistakably so ordained." *Florida Lime & Avocado Growers v. Paul,* 373 *U.S.* 132, 142, 83 *S.Ct.* 1210, 1217, 10 *L.Ed.*2d 248, 257, reh'g denied, 374 *U.S.* 858, 83 *S.Ct.* 1861, 10 *L.Ed.*2d 1082 (1963).

Defendant has not directed our attention to anything in the Act or in the legislative history suggesting that Congress intended that an individual's cause of action for personal injuries due to a failure to warn was to be eliminated. Defendant's reliance on *Cosmetic, Toiletry & Fragrance Ass'n v. Minnesota,* 440 *F.Supp.* 1216 (D.Minn.1977), aff'd *per curiam,* 575 *F.*2d 1256 (8th Cir.1978), is misplaced. *Cosmetic, Toiletry* involved an FDA regulation and a Minnesota statute, both of which required identical warnings on certain aerosol containers but ****391** differed most significantly on where the warnings should be placed. 440 *F.Supp.* at 1219. The state argued that manufacturers could meet both requirements. The district court rejected this argument and held that "the nature of consumer product ***461** labeling requires exclusive federal regulation in order to achieve uniformity vital to national interests." *Id.* at 1223. This case stands only for the proposition that in limited areas, *viz,* location of a label on the container and not the content of the label, state action had been preempted by specific federal regulations. *See Pharmaceutical Soc'y of New York v. Lefkowitz,* 586 *F.*2d 953, 958 (2d Cir.1978) (the Act preempts neither all state regulation of drugs nor all state regulation of drug labeling). On the other hand, it has been stated that the FDA's "regulations and requirements" are "minimal" standards and that "[t]he Defendant still owes a duty to warn of dangers of which it knew or should have known in the exercise of reasonable care." *Stromsodt v. Parke-Davis & Co.,* 257 *F.Supp.* 991, 997 (D.N.D.1966), aff'd, 411 *F.*2d 1390 (8th Cir.1969); *accord Brochu v. Ortho Pharmaceutical Corp.,* 642 *F.*2d 652, 658–59 (1st Cir.1981) (when by 1970 oral contraceptive manufacturer had information not available in 1968, it could be expected to do more than satisfy 1968 FDA uniform labeling requirements); *Bristol-Myers Co. v. Gonzales,* 548 *S.W.*2d

416, 423 (Tex.Civ.App.1976), aff'd, 561 *S.W.*2d 801, 804 (Tex.1978) (instructions that did not recommend the proper frequency of drug use are not adequate as a matter of common law, even when they have been approved by the FDA).

[21] The underlying conduct that is the essence of the private cause of action is not exclusively regulated under the Act. Hence the state cause of action does not constitute regulation of conduct that Congress intended to protect. Further, there is a strong state interest in compensating those who are injured by a manufacturer's defective products. There is little risk that this cause of action would interfere with the effective administration of the Act, an important factor in preemption analysis. *See Farmer v. United Bhd. of Carpenters and Joiners,* 430 *U.S.* 290, 302, 97 *S.Ct.* 1056, 1064, 51 *L.Ed.*2d 338, 351 (1977). In our opinion, the record does not justify defendant's preemption claim.

***462** V

The jury was given two basic issues: (1) did plaintiff take Declomycin, and (2) did defendant know (actually or constructively) of its side effect. The jury returned a general verdict for the defendant and we do not know the basis of its decision. *See Ettin v. Ava Truck Leasing, Inc.,* 53 *N.J.* 463, 480, 251 *A.*2d 278 (1969). We must assume, therefore, that the jury's determination hinged on the absence of proof of knowledge. *Cf. Neumann v. Wildermann,* 35 *N.J.Super.* 562, 566, 114 *A.*2d 560 (App.Div.1955) (when there are two theories of liability, jury should be instructed to return separate verdicts on each theory unless it should find for defendant on all grounds, in which case a general verdict would be acceptable).

Plaintiff moved for a new trial on the ground that the verdict was against the weight of the evidence. The trial court denied the motion, resting its decision on what defendant's knowledge of the graying side effect was or should have been in 1960. Upon her first appeal, plaintiff raised the weight-of-the-evidence argument again and the Appellate Division affirmed, relying on the trial court's opinion. We do not agree because, during at least some of the period when the defendant was marketing Declomycin and the drug was being administered to plaintiff, defendant, fully aware of the discoloring side effect, continued distributing it without warning.

A trial court shall grant a motion for a new trial "if, having given due regard to the opportunity of the jury to pass upon the credibility of the witnesses, it clearly and convincingly appears that there was a miscarriage of justice under the law." *R.* 4:49–1(a). This Court has construed a verdict that is "a miscarriage of justice" as ****392** one that "shock[s] the conscience of the court and convince[s] it that to sustain the verdict would be manifestly unjust." *Carrino v. Novotny,* 78 *N.J.* 355, 366, 396 *A.*2d 561 (1979). The trial court does not sit as a thirteenth juror but canvasses the record "to correct clear error or mistake by the jury." *Dolson v. Anastasia,* 55 *N.J.* 2, 6, 258 *A.*2d 706 (1969). On a motion ***463** for a new trial, a trial court takes into account not only the tangible evidence presented but also the "intangible 'feel of the case' " and "matters of credibility," *i.e.,* demeanor evidence. *Id.*

[22] A trial court's determination is "not reversed [by an appellate court] unless it clearly appears that there was a miscarriage of justice under the law." *R.* 2:10–1. The standard for appellate review of a trial court's decision on a motion for a new trial is substantially the same as that controlling the trial court except that due deference should be made to its "feel of the case," including credibility. When criteria that are not transmitted by the written record, such as witness demeanor, are determinative,

> the appellate court must give deference to the views of the trial judge thereon. His decision, however, is not entitled to any special deference where it rests upon a determination as to worth, plausibility, consistency or other tangible considerations apparent from the face of the record with respect to which he is no more peculiarly situated to decide than the appellate court. [*Dolson v. Anastasia, supra,* 55 *N.J.* at 7, 258 *A.*2d 706.]

[23] The trial court erred in fixing the date at which defendant's actual or constructive knowledge was to be measured. It was undisputed that plaintiff had received

Declomycin or another tetracycline from approximately September, 1960 until the end of 1963. When the trial court considered the motion, it referred to the conflict in the evidence on whether defendant knew or should have known of the correlation between an infant's ingestion of Declomycin and tooth discoloration in *1960,* when the plaintiff first began receiving the drug.

However, the evidence is overwhelming that at least by mid-November, 1962, defendant had sufficient information to warrant that it warn doctors of the possible tooth discoloration effects of Declomycin when administered to infants. According to Dr. Swanzey, then defendant's Director of Regulatory Agency Relations, defendant had "strong suspicions" of the connection between tetracyclines and the discoloration of the teeth by the end of 1962. However, the defendant's actions indicate that ***464** its awareness at that time went beyond the stage of suspicion. There was no equivocation in its letter to the FDA on November 16, 1962. The letter proposed that defendant add to the labels on all its tetracycline products, including Declomycin, the following warning: "Use of *any* tetracycline during teeth development in the neonatal period or early childhood may cause discoloration of the teeth." (Emphasis added.) Lloyd Carr, defendant's Product Service Manager, explained in a letter to Dr. Feldman that "[w]hen the causal relationship between tooth staining and tetracycline became *unquestionably* demonstrated by our Company, we notified the Food and Drug Administration by letter of November 16, 1962." (Emphasis added.) Mr. Carr testified that he was referring in his letter to all of defendant's tetracycline drugs, including Declomycin. Viewing the testimony of Dr. Guggenheimer, defendant's expert witness, from the viewpoint most favorable to defendant, he testified that a manufacturer could not have been expected to draw a correlation between tooth discoloration and Declomycin in 1962, although, at the time of trial, in hindsight, it was clear that the correlation in fact existed in 1962.

Apart from plaintiff's evidence to the effect that defendant should have known of the side effect as early as 1960, the record overwhelmingly demonstrates that defendant actually knew of the danger by the end of 1962. Defendant nonetheless continued to market the drug in 1963 and plaintiff ****393** continued to ingest the drug that year. Insofar as that period of time is concerned, a jury determination based on defendant's lack of knowledge would be "a miscarriage of justice under the law." *See R.* 2:10–1. In that event defendant would be responsible at least for the enhancement of the condition.

We reverse and remand for a new trial.

For reversal and remandment —Chief Justice WILENTZ and Justices CLIFFORD, SCHREIBER, HANDLER, POLLOCK, O'HERN and GARIBALDI—7.

For affirmance —None.

All Citations

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Footnotes

1 Lederle Laboratories is a division of the defendant, American Cyanamid Company. All references in this opinion to "defendant" are to Lederle Laboratories.

2 Declomycin is defendant's trade-mark name for demethylchlortetracycline, an antibiotic that falls within the tetracycline category.

3 § 402A. Special Liability of Seller of Product for Physical Harm to User or Consumer

(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if

(a) the seller is engaged in the business of selling such a product, and

(b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

(2) The rule stated in Subsection (1) applies although

(a) the seller has exercised all possible care in the preparation and sale of his product, and

(b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

4 We have on other occasions referred to seven factors borrowed from Wade, "On the Nature of Strict Tort Liability for Products," 44 *Miss.L.J.* 825, 837–38 (1973), to be considered in this context. *See Cepeda v. Cumberland Eng'g Co.,*

76 *N.J.* 152, 174, 386 *A.*2d 816 (1978), and *O'Brien v. Muskin Corp.,* 94 *N.J.* 169, 182, 463 *A.*2d 298 (1983), quoting the following from Dean Wade:

(1) The usefulness and desirability of the product—its utility to the user and to the public as a whole.

(2) The safety aspects of the product—the likelihood that it will cause injury, and the probable seriousness of the injury.

(3) The availability of a substitute product which would meet the same need and not be as unsafe.

(4) The manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility.

(5) The user's ability to avoid danger by the exercise of care in the use of the product.

(6) The user's anticipated awareness of the dangers inherent in the product and their avoidability, because of general public knowledge of the obvious condition of the product, or of the existence of suitable warnings or instructions.

(7) The feasibility, on the part of the manufacturer, of spreading the loss by setting the price of the product or carrying liability insurance.

5 No claim is made that "the standard to measure [Declomycin] reflects a policy judgment that [it is] so dangerous that [it] create[s] a risk of harm outweighing [its] usefulness." *O'Brien, supra,* 94 *N.J.* at 181, 463 *A.*2d 298.

6 A seller may be liable for an allergic response to a product when there is an implied warranty under the Uniform Commercial Code that the product is reasonably fit for the purpose for which it was acquired. *See N.J.S.A.* 12A:2–315. In *Zirpola v. Adam Hat Stores, Inc.,* 122 *N.J.L.* 21, 4 *A.*2d 73 (E. & A.1939), the Court held that under the Uniform Sale of Goods Law, *R.S.* 46:30–21(1), which provided for an implied warranty of fitness for the purpose for which a product was acquired, the defendant, the maker and seller to the plaintiff of a hat, was responsible in damages for plaintiff's allergic reaction to the hat band. In *Reynolds v. Sun Ray Drug Co.,* 135 *N.J.L.* 475, 52 *A.*2d 666 (E. & A.1947), the plaintiff successfully relied on the same implied warranty concerning a lipstick sold to her by the defendant. The Court rejected defendant's attempt to distinguish *Zirpola* on the ground that the defendant was the manufacturer and therefore knew or should have known of the poisonous ingredients in the hat band.

In *Newmark v. Gimbel's, Inc.,* 54 *N.J.* 585, 599 n. 5, 258 *A.*2d 697 (1969), this Court refused to overrule *Zirpola* and *Reynolds,* stating that "[t]hese cases hold that an implied warranty of fitness of an article for the purpose for which it is sold binds the seller even though only a small proportion of those who use such an article are injuriously affected thereby." No reference was made to comment j to section 402A of the *Restatement (Second) of Torts* (1965) indicating that a seller need give a warning only where the product contains an ingredient to which a substantial number of the population are allergic and the ingredient is one whose danger is not generally known, or if known, one that the consumer would reasonably not expect to find in the product. Comment j implies that there may not be liability if the allergic reaction occurred or would occur in an insubstantial number of users.

The implied warranty of fitness for a particular purpose has been retained in the Uniform Commercial Code in language substantially similar to the Uniform Sale of Goods Law. *Compare N.J.S.A.* 12A:2–315 *with R.S.* 46:30–21(1) (the most notable difference being elimination under the Code of a sale of an article under its patent or trade name). Such an implied warranty "extends to any natural person who is in the family or household of [the] buyer or who is a guest in his home if it is reasonable to expect that such person may use, consume or be affected by the goods and who is injured in person by breach of the warranty." *N.J.S.A.* 12A:2–318.

7 The plaintiff did not object to the charge and did not raise this issue on her initial appeal. Since the cause must be retried, see Point V herein, and the issue was raised and argued before us, we have decided the question.