PRODUCTS LIABILITY—STRICT LIABILITY IN TORT—STATE-OF-THE-ART DEFENSE INAPPLICABLE IN DESIGN DEFECT CASES—*Beshada v. Johns-Manville Products Corp.*, 90 N.J. 191, 447 A.2d 539 (1982).

Failure to warn of the dangerous propensities of a product sounds in both negligence and strict liability.[1] In a negligence action for failure to warn, defendants may assert a state-of-the-art defense,[2] which will exculpate a manufacturer or seller of an injury-causing product if the dangers were scientifically undiscoverable at the time the product was marketed.[3] Thus, when a claim of negligence is asserted, a defendant manufacturer has not breached his duty of reasonable care if the danger was undiscoverable.[4] In strict liability, however, knowledge is imputed to the manufacturer since the focus is on the safety of the product, not on the conduct of the manufacturer.[5] In *Beshada v. Johns-Manville Products Corp.*,[6] the Supreme Court of

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[1] *See* Jackson v. Coast Paint & Lacquer Co., 499 F.2d 809 (9th Cir. 1974); Phillips v. Kimwood Mach. Co., 269 Or. 485, 525 P.2d 1033 (1974); Berkebile v. Brantly Helicopter Corp., 462 Pa. 83, 337 A.2d 893 (1975). *But see* Sterling Drug, Inc. v. Yarrow, 408 F.2d 978 (8th Cir. 1969) (little, if any difference between strict liability and negligence theories in warning cases).

Negligence theories have been successfully applied in failure to warn cases when the manufacturer has provided no warning at all or when the warning given was inadequate. M. KRONISCH, *Theories of Liabilities*, TOXIC SUBSTANCES LITIGATION 9, 11 (S. Birnbaum & P. Rheingold eds. 1980). Under a theory of strict liability, however, a manufacturer and/or seller may be found liable for injuries caused by a defective product regardless of his exercise of reasonable care in the preparation of that product. *Id.* at 13-14. Many jurisdictions consider inadequate warnings or instructions sufficient to render the product defective, thus triggering the imposition of strict liability. *Id.* at 14.

[2] *See* Basko v. Sterling Drug, Inc., 416 F.2d 417 (2d Cir. 1969). One definition of the state-of-the-art is "the aggregate of product-related knowledge which may feasibly be incorporated into a product." Note, *Product Liability Reform Proposals: The State Of The Art Defense*, 43 ALB. L. REV. 941, 946 (1979). Evidence of the state-of-the-art may be introduced to prove that a defendant was not negligent or that its product was not defective. *Id.* at 945. Additionally, it has been found that subsequent technological improvements of a product are inadmissible to prove negligence. Stephan v. Marlin Firearms Co., 353 F.2d 819 (2d Cir.), *cert. denied*, 384 U.S. 959 (1965).

Generally, the concept of foreseeability performs a function similar to that of a knowledge-based defense. Foreseeability limits the scope of the manufacturer's duty to risks which could have been discovered by applying existing human knowledge. *See, e.g.*, Lartigue v. R.J. Reynolds Tobacco Co., 317 F.2d 19 (5th Cir. 1963).

[3] Beshada v. Johns-Manville Prods. Corp., 90 N.J. 191, 202, 447 A.2d 539, 545 (1982). The plaintiff must introduce evidence that this knowledge was available at the time the goods were manufactured. *Id.* at 203, 447 A.2d at 546.

[4] *See supra* note 2.

[5] Beshada v. Johns-Manville Prods. Corp., 90 N.J. 191, 204, 447 A.2d 539, 546 (1982) ("[I]n strict liability cases, culpability is irrelevant"); *see also* Freund v. Cellofilm Properties, Inc., 87 N.J. 229, 238, 432 A.2d 925, 929 (1981); Suter v. San Angelo Foundry & Mach. Co., 81 N.J. 150, 169, 406 A.2d 140, 149 (1979).

[6] 90 N.J. 191, 447 A.2d 539 (1982).

New Jersey determined the appropriateness of the state-of-the-art defense in the context of strict liability for failure to warn.[7]

Beshada involved six consolidated personal injury and wrongful death actions against manufacturers and distributors of asbestos.[8] The plaintiffs were employees or survivors of deceased employees who alleged injury from asbestos exposure.[9] Due to the long latency period preceding the manifestation of asbestos-related diseases[10] such as asbestosis[11] and mesothelioma,[12] causes of action have only recently arisen from exposure dating back to the 1930's.[13] Although the plaintiffs urged many legal theories in support of their claims for damages,[14] the appeal arose out of the strict liability claim for "failure to warn."[15] The plaintiffs claimed that at the time of their exposure, the

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[7] *Id.* at 204, 447 A.2d at 546.

[8] *Id.* at 197-98, 447 A.2d at 543. A total of 59 plaintiffs were involved in the consolidated suits. *Id.*

[9] *Id.*

[10] A latency period of approximately 20 years is associated with asbestosis, mesothelioma, and broncogenic carcinoma. *See* Insurance Co. of N. Am. v. Forty-Eight Insulations, Inc., 451 F. Supp. 1230 (E.D. Mich. 1978). "This latent period is explained by the fact that asbestos fibers, once inhaled, remain in place in the lung causing a tissue reaction that is slowly progressive and apparently irreversible." Borel v. Fibreboard Paper Prods. Corp., 493 F.2d 1076, 1083 (5th Cir. 1973); *see* Selikoff, Bader, Bader, Churg & Hammond, *Asbestosis and Neoplasia*, 42 AM. J. MED. 487 (1967); Selikoff, Churg & Hammond, *The Occurrence of Asbestosis Among Insulation Workers*, 132 ANN. N.Y. ACAD. SCI. 139 (1965). *See generally* R. GRAY, 4A ATTORNEYS' TEXTBOOK OF MEDICINE A 205c.72 (1981).

[11] Asbestosis is a nonmalignant scarring of the lungs. 90 N.J. at 196, 447 A.2d at 542. *See generally supra* note 10.

[12] Mesothelioma is a form of lung cancer caused by exposure to asbestos which affects the pleural and peritoneal cavities. 90 N.J. at 196, 447 A.2d at 542. *See generally supra* note 10.

[13] 90 N.J. at 196, 447 A.2d at 542.

[14] *See id.* at 196-97, 447 A.2d at 542.

[15] *Id.* Although the defendants claimed that they were unaware of the dangers of asbestosis, there is considerable dispute about the knowledge which the defendants had and when they acquired that knowledge. The *Beshada* court noted that in Hardy v. Johns-Manville Sales Corp., 509 F. Supp. 1352 (E.D. Tex. 1981), the trial judge concluded that "[k]nowledge of the danger can be attributed to the industry as early as the mid-1930's." 90 N.J. at 197, 447 A.2d at 542 (quoting *Hardy*, 509 F. Supp. at 1355). In 1924, an English researcher discovered asbestosis in a person who had worked 20 years in an asbestos textile mill. Borel v. Fibreboard Paper Prods. Corp., 493 F.2d 1076, 1083 n.4 (5th Cir. 1973) (citing Cooke, *Fibrosis of the Lungs Due to the Inhalation of Asbestos Dust*, 2 BRIT. MED. J. 147 (1924)). In the United States, the first official claim for compensation associated with asbestos was made in 1927. Lanza, *Asbestosis*, 106 J. AM. MED. A. 368 (1936). In addition, the asbestos industry, led by Johns-Manville, commissioned the Metropolitan Life Insurance Company in the early 1930's to investigate and determine the relationship between asbestos exposure and the high rate of pulmonary disease encountered among workers in the asbestos mines and factories. R. SWEENEY, *The Asbestos Time Bomb*, TOXIC SUBSTANCES LITIGATION 103, 104 (S. Birnbaum & P. Rheingold eds. 1980).

The defendants asserted in *Beshada* that it was not until the 1960's that the medical profession in the United States recognized that a potential health hazard arose from the use of insulation products containing asbestos. 90 N.J. at 197, 447 A.2d at 542. The court chose not to resolve the factual issues raised. *Id.*

defendants failed to provide warnings, handling instructions, or safety equipment.

The defendants raised a state-of-the-art defense,[16] asserting that at the time the asbestos was marketed no one knew that the product was dangerous.[17] Therefore, the only knowledge that could be imputed to them was the knowledge that existed at the time of manufacture,[18] thereby precluding any inference that they knew of the dangerous propensity of the product.[19] Since they could not have known that the product was dangerous, the defendants argued that it was unreasonable to impose a duty to warn of the unknowable,[20] and that their actions were reasonable in marketing the asbestos without a warning.[21] In response, the plaintiffs moved to strike the state-of-the-art defense[22] on the grounds that when claims are brought in strict liability, the plaintiff need not prove that the defendant knew that the product was dangerous, since this knowledge is imputed.[23] The key issue presented, therefore, was whether the presumed unawareness of the dangers of a product by the scientific and medical community is a defense in strict liability for failure to warn.[24]

The trial judge denied plaintiff's motion to strike the state-of-the-art defense,[25] concluding that the defendants' "knowledge" of the harmful propensities of their products was a rebuttable presumption which could be overcome by evidence that the danger was "unknowable" at the time of manufacture.[26] A motion for leave to appeal the trial court order was subsequently denied by the appellate division.[27] The Supreme Court of New Jersey granted the plaintiff's motion for direct certification to appeal the interlocutory order of the trial

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[16] 90 N.J. at 197, 447 A.2d at 542. The *Beshada* court described the state-of-the-art defense in a warning case as relieving distributors of liability for injuries caused by dangers undiscoverable at the time of manufacture. *Id.* at 202, 447 A.2d at 545.

[17] *Id.*

[18] *Id.* at 199, 447 A.2d at 543. The defendants argued that Freund v. Cellofilm Properties, Inc., 87 N.J. 229, 432 A.2d 955 (1981), imputed to defendants only the existing technological knowledge at the time of manufacture. 90 N.J. at 199, 447 A.2d at 543.

[19] 90 N.J. at 199, 447 A.2d at 543.

[20] *Id.* at 204, 447 A.2d at 546.

[21] *Id.*

[22] *Id.* at 197, 447 A.2d at 543.

[23] *Id.* at 198-99, 447 A.2d at 543. The plaintiffs argued that *Freund* disposed of the state-of-the-art issue since defendant's knowledge of the dangerous propensities of the product is imputed, thereby making it irrelevant whether such dangers were discoverable. *Id.*

[24] *Id.* at 197, 447 A.2d at 542.

[25] *Id.* at 199, 447 A.2d at 543.

[26] *Id.*

[27] *Id.*

court.[28] In a unanimous decision,[29] the court held that a state-of-the-art defense would not be allowed in strict liability for failure to warn,[30] and that the knowledge which existed at the time of trial rather than that which existed at the time of manufacture is imputed.[31]

While courts generally agree that a manufacturer has a duty to produce safe products and to warn of any known inherent dangers in the product,[32] there has been little conformity concerning what, if anything, should be the difference in the criteria for strict liability in the various types of design defect cases.[33] *Beshada* was rendered against the framework of design defect liability established by *Cepeda v. Cumberland Engineering Co.*,[34] *Suter v. San Angelo Foundry & Machine Co.*,[35] and *Freund v. Cellofilm Properties, Inc.*[36]

In *Cepeda*, the court distinguished design defects from manufacturing defects.[37] A design defect was defined as a condition "where the product is made as intended, but is asserted to be dangerous in some way,"[38] and a manufacturing defect as "a variance, latent or patent, from the manufacturer's intent."[39] The court noted that in manufacturing defect cases, *prima facie* liability for physical harm resulting

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[28] *Id.*

[29] *Id.* at 209, 447 A.2d at 549. *Beshada* was a unanimous 6-0 decision. Justices Pashman, Handler, Pollock, O'Hern, and Sullivan, and Judge Matthews joined in the opinion. Chief Justice Wilentz and Justices Clifford and Schreiber did not participate. *See id.*

[30] *Id.* at 196, 447 A.2d at 542.

[31] *Id.* at 203, 447 A.2d at 546.

[32] *See generally* W. PROSSER, THE LAW OF TORTS § 96 (1971). This duty is based on a responsibility to protect the ultimate consumer from defective goods. A defect may be any irregularity in the manufacture or design which renders the product unsafe or may be the failure to warn itself. *Id.* § 99, at 659-60; *see also* Keeton, *Product Liability And The Meaning Of Defect*, 5 ST. MARY'S L.J. 30 (1973); Wade, *On The Nature Of Strict Tort Liability For Products*, 44 MISS. L.J. 825, 841-43 (1973).

[33] *See supra* note 1.

[34] 76 N.J. 152, 386 A.2d 816 (1978).

[35] 81 N.J. 150, 406 A.2d 140 (1979).

[36] 87 N.J. 229, 432 A.2d 925 (1981).

[37] 76 N.J. at 169, 386 A.2d at 824. The plaintiff in *Cepeda* lost four fingers while operating a pelletizing machine with a bolt-on-finger guard removed, and sued the manufacturer for negligence and breach of warranty. *Id.* at 160, 386 A.2d at 820.

[38] *Id.* at 169, 386 A.2d at 824; *see also* Bexiga v. Havir Mfg. Corp., 60 N.J. 402, 290 A.2d 281 (1972) (failure to provide safety device on punch press rendered machine defective and unreasonably dangerous). As a standard for design defects, the court adopted the "defective condition unreasonably dangerous" language of § 402A of the RESTATEMENT (SECOND) OF TORTS (1965). 76 N.J. at 171-72, 386 A.2d at 825. This language was rejected by the *Suter* court the following year. *See infra* note 48 and accompanying text.

[39] 76 N.J. at 169, 386 A.2d at 824; *see also* Moraca v. Ford Motor Co., 66 N.J. 454, 332 A.2d 599 (1975) (defectively manufactured steering wheel); Scanlon v. General Motors Corp., 65 N.J. 582, 326 A.2d 673 (1974) (defectively manufactured automobile accelerator).

from the defect arises, since the product is unreasonably dangerous[40] as a matter of law.[41] The *Cepeda* court explained, however, that in a design defect case the standards for determining liability in negligence and strict liability are identical except that in strict liability, the foreseeability of the dangerous propensity of the product is imputed to the manufacturer.[42] Since the manufacturer is charged with this knowledge, the inquiry becomes whether the defendant was reasonable in marketing the product.[43] In answer to this inquiry, the court in *Cepeda* adopted a risk-utility analysis[44] in which the benefits of the product's design and marketing are balanced against the product's danger existing at the time of trial.[45]

The following year the court in *Suter* stated that a manufacturer will be liable for injuries[46] caused by a product if at the time of distribution the product is not "reasonably fit, suitable and safe" for its intended purpose.[47] By adopting this standard, the court rejected

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[40] 76 N.J. at 170, 386 A.2d at 824. The *Cepeda* court stated that the manufacturer would be liable " 'if the product left their hands in a defective condition proximately causing the mishap.' " *Id.* at 171, 386 A.2d at 825 (quoting Scanlon v. General Motors Corp., 65 N.J. 582, 590, 326 A.2d 673, 680 (1974)).

[41] 76 N.J. at 170, 386 A.2d at 824 (citing Keeton, *supra* note 32, at 39).

[42] *Id.* at 172, 386 A.2d at 825. The court adopted the explication of strict liability offered by Dean Wade in which the scienter is supplied as a matter of law and need not be proven by plaintiff as a matter of fact. *Id.* at 172, 386 A.2d 825 (citing Wade, *supra* note 32, at 834-35).

[43] *Id.* at 172-75, 386 A.2d at 825-26. The *Cepeda* court referred to the seven factors proposed by Dean Wade for evaluating the seller's reasonableness in marketing the product.

> "(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.
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> (3) The availability of a substitute product which would meet the same need and not be as unsafe.
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> (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.
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> (5) The user's ability to avoid danger by the exercise of care in the use of the product.
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> (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.
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> (7) The feasibility, on the part of the manufacturer, of spreading the loss by setting the price of the product or carrying liability insurance."

Id. at 174, 386 A.2d at 826-27 (quoting Wade, *supra* note 32, at 837-38).

[44] *Id.* at 172-75, 386 A.2d at 825-27.

[45] *Id.* at 173, 386 A.2d at 825.

[46] In this design defect action, the plaintiff's hand was injured when it was caught in the cylinders of an industrial sheet metal rolling machine which was not equipped with a kill switch to prevent false starts. The trial court charged the jury on the theory of strict liability. *Suter*, 81 N.J. at 154, 406 A.2d at 141-42.

[47] *Id.* at 169, 406 A.2d at 149. This definition was approved by the *Beshada* court. *See Beshada*, 90 N.J. at 201, 447 A.2d at 544.

the "defective condition unreasonably dangerous" language of section 402A of the *Restatement (Second) of Torts*, which they had relied upon in *Cepeda*.[48] Applying the risk-utility analysis developed in *Cepeda*, the court in *Suter* stated that the reasonableness of the manufacturer's actions should be examined in light of the "technological feasibility of manufacturing a product whose design would have prevented or avoided the accident, given the known state of the art."[49]

The court in *Freund* applied the principles of strict liability enunciated in *Cepeda* and *Suter* to a factual setting involving an inadequate warning.[50] Writing for the court, Justice Handler noted that "where the design defect consists of an inadequate warning" as to safe use, the utility of the product, as counterbalanced against the risks of its use, is rarely at issue[51] because a warning can make a product safer at virtually no added cost and without limiting the product's utility.[52] The court stressed that a warning should "be sufficient to protect adequately any and all foreseeable users from hidden dangers presented by the product."[53] Furthermore, the court noted that the duty to warn attaches "without regard to prevailing industry standards" and that a strict liability charge should not be riddled with references to negligence, knowledge, and reasonable care on the part of the manufacturer.[54] As a result, the *Freund* court held that a strict liability charge must focus on safety and affirmed the *Cepeda* and

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[48] 81 N.J. at 173-75, 406 A.2d at 151-53. This modification removed from the plaintiff the burden of proving there was a "defective condition unreasonably dangerous." The product must be safe to use in reasonably foreseeable environments. A product which does not meet this standard is defective as a matter of law. *Id.* at 169, 406 A.2d at 149.

[49] *Id.* at 171-72, 406 A.2d at 150. According to Keeton, when applying the risk-utility test "[u]nder the heading of benefits one would include anything that gives utility of some kind to the product; one would also include the infeasibility and additional cost of making a safer product." Keeton, *supra* note 32, at 37-38.

[50] The plaintiff in *Freund* suffered serious injuries when utilizing a product known as nitrocellulose. Plaintiff sought recovery in negligence, strict liability, and breach of warranty contending that the defendant marketed a dangerous product without providing a proper warning. 87 N.J. at 233-34, 432 A.2d at 927.

[51] *Id.* at 242, 432 A.2d at 929.

[52] *Id.* The *Beshada* court analogized warnings and automobiles unequipped with seatbelts:

> Because of the great utility of cars, few would dispute that even without seatbelts, a car's utility to society outweighs its risks. Thus, cars would be considered safe under the first aspect of the test. However, since seatbelts make cars safer without hindering utility, cars without seatbelts are deemed unsafe by virtue of the second part of the *Freund* test. Warnings are like seatbelts: regardless of the utility and risk of a product without warnings, a warning can generally be added without diminishing utility.

90 N.J. at 201 n.5, 447 A.2d at 545 n.5.

[53] 87 N.J. at 241-43, 432 A.2d at 929-31.

[54] *Id.*

Suter proposition that knowledge of the dangerousness of the product is imputed to the manufacturer.[55]

Justice Pashman, writing for the *Beshada* court, adopted the *Suter* definition of strict liability, stating that the *Cepeda* risk-utility equation must be applied when determining whether a product is "reasonably fit, suitable and safe."[56] The *Beshada* court approved the distinction between negligence and strict liability set forth in *Freund*, wherein the court noted that "negligence is conduct-oriented, asking whether defendant's actions were reasonable; strict liability is product-oriented, asking whether the product was reasonably safe for its foreseeable purposes."[57] Following the *Cepeda* rationale, the *Beshada* court further held that in strict liability actions alleging design defects, the foreseeability of the dangerous propensity of the product, as manifested at the time of trial, is imputed to the manufacturer.[58]

The *Beshada* court recognized that warning cases constitute one category of strict liability cases[59] and identified *Freund* as the leading case in this area.[60] The court applied the two-prong test enunciated in *Freund* to determine whether a product is safe: "1) does its utility outweigh its risks? and 2) if so, has that risk been reduced to the greatest extent possible? . . ."[61] Under the first part of the test, if the risk outweighs the utility of the product, strict liability can be imposed without determining whether the product could have been made safer.[62] If a product passes the first part of the test, however, it will not be deemed reasonably safe if it could have been manufactured more safely.[63] The *Beshada* court noted that the second part of the test is of particular importance in warning cases, as a warning can make a product safer without hindering utility or adding cost.[64]

Imputed knowledge distinguishes strict liability from negligence.[65] In *Beshada*, the disputed issue was not whether knowledge is

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[55] *Id.*; *accord* Shatz v. TEC Technical Adhesives, 174 N.J. Super. 135, 148-149, 415 A.2d 1188, 1195 (App. Div. 1980).

[56] 90 N.J. at 199, 447 A.2d at 544.

[57] *Id.* at 200, 447 A.2d at 544 (adopting *Freund*, 87 N.J. at 238, 432 A.2d at 929-30).

[58] *Id.*

[59] *Id.* at 201, 447 A.2d at 544-45.

[60] *Id.* at 202, 447 A.2d at 545.

[61] *Id.* at 201, 447 A.2d at 545 (adopting *Freund*, 87 N.J. at 238 n.1, 432 A.2d at 930 n.1).

[62] *Id.*

[63] *Id.* The *Beshada* court stated that "[i]n actuality, the only test for product safety is whether the benefit outweighs the risk." *Id.* at 201 n.4, 447 A.2d at 545 n.4.

[64] *Id.* at 202, 447 A.2d at 545.

[65] *Cepeda*, 76 N.J. at 172, 386 A.2d at 825. In strict liability it is no longer necessary to prove that the seller had or should have had any personal knowledge of the hazards known to the

imputed, but rather, whether knowledge at the time of manufacture or at the time of trial is imputed.[66] The defendants contended that the technology available at the time of distribution should act as a limitation on the determination of whether a product could have been made safer.[67] Absent this limitation, argued the defendants, liability would be absolute since a product would be judged according to a constantly-improving standard of technology.[68]

The defendants in *Beshada* contended that a warning was not feasible within the meaning of the *Freund* standard that risk be reduced "to the greatest extent possible" because of the scientific unknowability of the dangers of asbestos at the time of distribution.[69] The defendants agreed that knowledge is imputed in strict liability, but they construed *Freund* as imputing only known dangers existing at the time of manufacture or sale.[70] The court agreed that *Freund* had not directly addressed this question, but stressed that a state-of-the-art defense is a negligence defense,[71] and its application in failure to warn cases would contravene the principles annunciated in *Freund*.[72] To preclude any allusion to the conduct of the manufacturer, the court stated that since "culpability is irrelevant" in strict liability, the focus is on the product, not on the conduct of the manufacturer.[73]

According to the *Beshada* court, the primary purpose of strict liability "is to compensate victims of defective products."[74] In light of this purpose, the defendant's argument that the duty to warn should be limited to knowable dangers was found unpersuasive by the

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scientific community. *Id.* The plaintiff need only show that the defect existed and that " 'the risk created by the dangerous condition of the product was outweighed by the social utility attained by putting it out in this fashion.' " *Id.* at 172, 386 A.2d at 826 (quoting Wade, *supra* note 32, at 834-35); *see also supra* note 5 and accompanying text. *See generally* Wade, *Strict Tort Liability of Manufacturers*, 19 Sw. L.J. 5 (1965).

[66] 90 N.J. at 202-03, 447 A.2d at 545-46.

[67] *Id.* at 202, 447 A.2d at 545.

[68] *Id.*

[69] *Id.* at 203, 447 A.2d at 546.

[70] *Id.*

[71] *Id.* at 204, 447 A.2d at 546.

[72] *Id.* Justice Pashman rejected the defendants' interpretation of *Freund* as creating an illogical dichotomy in warning cases. *Id.* at 205, 447 A.2d at 547. The court deemed untenable the defendants' position that if the danger were discoverable they would be liable for failure to warn even if they were not negligent in failing to discover it, whereas if the danger were undiscoverable, they would suffer no liability. *Id.; see* Keeton, *Products Liability—Inadequacy Of Information*, 48 TEX. L. REV. 398, 408 (1970); *see also supra* notes 20 & 21 and accompanying text.

[73] 90 N.J. at 204, 447 A.2d at 546; *accord* Keeton, *supra* note 72, at 408.

[74] 90 N.J. at 204, 447 A.2d at 546.

court.[75] The court noted that "[t]he most important inquiry . . . is whether imposition of liability for failure to warn of dangers which were undiscoverable at the time of manufacture will advance the goals and policies sought to be achieved by our strict liability rules."[76] The court discussed three policy considerations which are relevant to this inquiry: simplification of the fact-finding process, risk spreading, and accident avoidance.[77]

In discussing simplification of the fact-finding process, the court indicated that proof of scientific knowability in a trial setting would be too complex, costly, confusing, and time consuming.[78] In addition, because the state-of-the-art is affected by the amount of industry investment in safety research,[79] further determination would be required as to whether the defendants' conduct had contributed to making the dangers unknowable.[80] The resolution of this issue would result in a battle of experts,[81] increased legal costs, and consequently "great difficulties . . . in a courtroom."[82] The court further expressed the concern that a jury might interpret the concept of state-of-the-art as a question of fault for not knowing of the danger of the product.[83] The court observed that this would constitute negligence, which was discredited as a liability theory in design defect cases.[84] Accordingly, the court concluded that tort trials would be simplified by denying the defendants' state-of-the-art defense.[85]

On the concept of risk spreading, Justice Pashman stated that manufacturers can effectively allocate the cost of injuries caused by defective products by incorporating the cost of insuring against liability into the cost of the product.[86] The defendants argued that since unknowable risks are by definition unpredictable, there is no effective method of adjusting the price of products to reflect this potential

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[75] *Id.*

[76] *Id.* at 205, 447 A.2d at 547.

[77] *See id.* at 205-08, 447 A.2d at 547-48.

[78] *Id.* at 207, 447 A.2d at 548.

[79] *Id.* at 208, 447 A.2d at 548. Manufacturers which do not invest in product safety research create an artificially low level of state-of-the-art knowledge. *Id.*

[80] *See id.* at 207-08, 447 A.2d at 548.

[81] *Id.* at 207, 447 A.2d at 548. Experts in the history of science and technology would be required to speculate as to what knowledge was feasible at a given time in the past. *Id.*

[82] *Id.* at 208, 447 A.2d at 548.

[83] *Id.*

[84] *See id.* at 208, 447 A.2d at 548-49; *see Freund*, 87 N.J. at 243, 447 A.2d at 932; *see also* Keeton, *supra* note 72, at 409.

[85] 90 N.J. at 207-09, 447 A.2d at 548-49.

[86] *Id.* at 205, 447 A.2d at 547. The court maintained that liability from unreasonable risks should be a cost of doing business. *Id.; see* W. PROSSER, *supra* note 32, § 75, at 495; Keeton, *supra* note 72, at 408.

liability.[87] Instead, the defendants asserted that these costs would be shifted to the consumer since manufacturers would be faced with "across the board" increases in their insurance premiums.[88] The *Beshada* court recognized that the defendants' predictions were possible, but indicated that "it is not a bad result."[89] First, the court stated that there was no rational basis for distinguishing between unknown and unknowable risks since knowledge is imputed in both instances.[90] Second, the court asserted that the costs of injuries from a defective product should be placed on those responsible for introducing the product into the stream of commerce, rather than on the innocent victim.[91] Finally, the court dismissed the defendants' contention that risk spreading would increase production costs and consumer prices beyond the level of economic efficiency.[92]

In considering the concept of accident avoidance, the *Beshada* court noted that responsibility for "accident costs and accident avoidance costs" is best placed on the manufacturer.[93] By imposing strict liability for failing to discover dangerous propensities of a product, and therefore for failing to warn, the court indicated that it was attempting to create an incentive for more active safety research.[94] The court reasoned that this goal would be advanced by imposing liability for failure to warn even though the dangers were undiscoverable at the time of manufacture.[95]

The law of strict liability in design defect cases evolved from manufacturing defect cases in which liability is imposed, regardless of the exercise of due care.[96] Inadequate safety devices,[97] inadequate

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[87] 90 N.J. at 207, 447 A.2d at 548.

[88] *Id.*

[89] *Id.*

[90] *Id.*

[91] *Id.*

[92] *Id.*

[93] *Id.* at 206-07, 447 A.2d at 547-48 (citing Calabresi & Hirschoff, *Toward a Test for Strict Liability in Torts*, 81 YALE L.J. 1055, 1060 (1972), *quoted in Suter*, 81 N.J. at 173-74, 406 A.2d at 151-52).

[94] *Id.* at 207, 447 A.2d at 548.

[95] *Id.*

[96] *See* Putnam v. Erie City Mfg. Co., 338 F.2d 911 (5th Cir. 1964) (defective wheelchair); Moraca v. Ford Motor Co., 66 N.J. 454, 332 A.2d 599 (1975) (defective steering wheel); Scanlon v. General Motors Corp., 65 N.J. 582, 326 A.2d 673 (1974) (defective automobile accelerator); Henningsen v. Bloomfield Motors Inc., 32 N.J. 358, 161 A.2d 69 (1960) (defective steering wheel); Goldberg v. Kollsman Instrument Corp., 12 N.Y.2d 432, 191 N.E.2d 81, 240 N.Y.S.2d 592 (1963) (defective airplane altimeter). *See generally* W. PROSSER, *supra* note 32, § 99, at 661.

[97] Cepeda v. Cumberland Eng'g Co., 76 N.J. 152, 386 A.2d 816 (1978).

warnings,[98] and failure to warn of known dangers[99] are examples of design defects. Since the dangerous propensity of the product is recognized in these cases, it is proper to apply the product-oriented standard associated with manufacturing defect cases. In *Freund*, the manufacturers were aware of the product's risk and were capable of making the product safer; therefore, the court correctly borrowed the product-oriented standard applied in manufacturing defect cases.

The court in *Freund* relied upon *Phillips v. Kimwood Machine Co.*[100] in determining that strict liability is product-oriented, rather than conduct-oriented.[101] The *Phillips* court, however, imputed the dangerousness of the product but noted that "[t]he question of whether the design is unreasonably dangerous [(i.e., defective)] can be determined only by taking into consideration the surrounding circumstances and knowledge at the time the article was sold."[102] In extending the product-oriented standard to claims predicated on failure to warn of unknown dangers,[103] the *Beshada* court relied heavily on *Freund*.[104] *Freund*, however, was an inadequate warning case wherein the defendant admitted knowledge of the hazard and placed a warning on the product.[105] While it is reasonable, therefore, to impose strict liability for failing to update a warning to include dangers discovered prior to the occurrence of an injury, the *Beshada* court's application of strict liability for failing to warn of dangers which were unknowable at the time of manufacture and injury is logically unsound.

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[98] Freund v. Cellofilm Properties, Inc., 87 N.J. 229, 432 A.2d 925 (1981).

[99] *See supra* note 32.

[100] 269 Or. 485, 525 P.2d 1033 (1974).

[101] *See Freund*, 87 N.J. at 238, 432 A.2d at 929; *accord* Jackson v. Coast Paint & Lacquer Co., 499 F.2d 809, 812 (9th Cir. 1974). *But cf. Phillips*, 269 Or. at 498, 525 P.2d at 1039 (in determining the dangerousness of product, "assume the seller knew of the product's propensity to injure . . . and then . . . ask whether, with such knowledge, he would have been negligent in selling it without a warning").

[102] 269 Or. at 498, 525 P.2d at 1037.

[103] 90 N.J. at 204-09, 447 A.2d at 546-49; *accord* Michalko v. Cooke Color & Chem. Corp., 91 N.J. 386, 451 A.2d 179 (1982). In *Michalko*, the Supreme Court of New Jersey reaffirmed that claims brought in strict liability for design defects include failure to warn of known or unknown dangers and inadequate warnings and are thus analyzed according to the product-oriented standard. *Id.* at 394, 451 A.2d at 182-83. The court held that "an independent contractor who undertakes to rebuild part of a machine in accordance with the specifications of the machine's owner can be held strictly liable for breach of its legal duty to the machine's foreseeable users to make the machine safe or to warn of the dangers inherent in its use." *Id.* at 403, 451 A.2d at 187-88.

[104] *See supra* notes 60-64 and accompanying text.

[105] *Freund*, 87 N.J. at 243, 432 A.2d at 932.

Historically, courts have struggled to place limitations on the imposition of strict liability. One limitation is the risk-utility analysis which exculpates a defendant manufacturer if the utility of the product outweighs its inherent risks. Another limitation on the imposition of strict liability on sellers is the requirement that the danger be reasonably foreseeable or scientifically discoverable.[106] By imputing knowledge of the dangerous propensities of a product existing at the time of trial, the *Beshada* court has adopted a hindsight standard for imposing liability on manufacturers.[107] Although Dean Keeton was cited in *Beshada* as favoring the imputation of knowledge manifested at the time of trial,[108] Keeton has expressed his opposition to the application of a hindsight standard in cases involving post-distribution increases in knowledge of risk-reducing measures.[109] Obligating manufacturers to warn of the unknown and the unknowable transforms the manufacturer into an insurer against all injuries, even though the danger could not have been discovered by human skill and foresight.[110] This approach, in effect, imposes absolute liability on manufacturers for design defects.[111] The *Beshada* court cited Dean Wade in support of its decision,[112] however, as Wade explains, the purpose of "[s]trict liability for products is clearly not that of an insurer. If it were, a plaintiff would need only to prove that the product was a

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[106] Borel v. Fibreboard Paper Prods. Corp., 493 F.2d 1076, 1088 (5th Cir. 1973); *see* Karjala v. Johns-Manville Prods. Corp., 523 F.2d 155, 159 (8th Cir. 1975) ("[o]f course, a manufacturer is only required to warn of foreseeable dangers").

[107] In Jackson v. New Jersey Mfg. Ins. Co., 166 N.J. Super. 448, 400 A.2d 81 (App. Div.), *certif. denied*, 81 N.J. 330, 407 A.2d 1204 (1979), the appellate division refused to hold a successor manufacturer strictly liable for failing to incorporate design features which were not within the state-of-the-art at the time of sale but were developed 40 years after the machine had been sold. *Id.* at 463-64, 400 A.2d at 88-89. The court concluded that the defect would have to be determined as of the date of sale and that the subsequently developed state-of-the-art could not establish a *prima facie* case under strict liability. *Id.; accord Cepeda*, 76 N.J. at 193, 386 A.2d at 836; *see* Lynch v. Galler Seven-Up Pre-Mix Corp., 74 N.J. 146, 152, 376 A.2d 1211, 1214 (1977) (per curiam); Herbstman v. Eastman Kodak Co., 68 N.J. 1, 7-8, 342 A.2d 181, 184 (1975). *See generally* Annot., 54 A.L.R. 3d 1079 (1974).

[108] *See Beshada*, 90 N.J. at 200, 447 A.2d at 544.

[109] *See* Keeton, *The Meaning of Defect In Product Liability Law—A Review Of Basic Principles*, 45 Mo. L. REV. 579, 595 (1980).

[110] Wade, *supra* note 32, at 828. *See generally* W. PROSSER, *supra* note 32, § 99; Freedman, *"Defect in the Products: The Necessary Basis For Products Liability In Tort And In Warranty*, 33 TENN. L. REV. 323 (1966); Keeton, *supra* note 32; Rheingold, *Proof Of Defect In Products Liability Cases*, 38 TENN. L. REV. 325 (1970); Wade, *Strict Tort Liability Of Manufacturers*, 32 ALA. LAW. 455 (1971).

[111] *See* Heritage v. Pioneer Brokerage & Sales, Inc., 604 P.2d 1059, 1063-64 (Alaska Sup. Ct. 1979) (criticizing approach which holds manufacturer liable for unknowable defects since "no indication of danger exists and no techniques for obtaining such information are available, [thus] a manufacturer has no basis for concluding that the product should not be marketed").

[112] *See* 90 N.J. at 200, 447 A.2d at 544.

factual cause in producing his injury."[113] It appears, therefore, that the *Beshada* court has gone beyond the scope of strict liability as delineated by the scholarly authority upon which it relied.

It is also questionable whether this hindsight standard adopted in *Beshada* promotes the public policy objectives underlying strict liability in design defect cases.[114] One reason enunciated for imposing strict liability was that those engaged in manufacturing can best spread the risk by accepting these losses as a cost of doing business.[115] When there is an extended period of time between manufacture and injury, as in latent design defect cases, many companies go out of business, thereby inequitably spreading the risk and loss among those companies remaining. The *Beshada* court also suggested that the cost of potential liability can be absorbed by insuring against this risk and by incorporating the cost of insurance into the price of the product.[116] This assumption is unwarranted in latent design defect cases in which the injury-causing products were sold many years ago. The prices of products manufactured decades ago did not reflect the cost of potential injuries, and insurance premiums at the time did not reflect unknowable risks. Furthermore, product liability insurance is becoming scarce, and rising premiums for unanticipated risks have virtually rendered it unattainable.[117] The result will be across-the-board increases in the costs of new products as manufacturers bear the costs prospectively. There is a point, however, beyond which a marketplace will not tolerate additional price increases to "pay the premiums" as manufacturers are forced to assume an insurer's liability. The resulting decrease in business carries a concomitant threat of stagnation in research and development and, consequentially, an arrest in technological improvement.

Accident avoidance is another rationale articulated for the imposition of strict liability in design defect cases.[118] Since the state-of-the-

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[113] Wade, *supra* note 32, at 828.

[114] *See generally supra* notes 77-95 and accompanying text.

[115] 90 N.J. at 205, 447 A.2d at 546; *see* Wade, *supra* note 32, at 826; *see also* Greenman v. Yuba Power Prods., Inc., 59 Cal. 2d 57, 377 P.2d 897, 27 Cal. Rptr. 697 (1962); Henningsen v. Bloomfield Motors, Inc., 32 N.J. 358, 161 A.2d 69 (1960).

[116] 90 N.J. at 205, 447 A.2d at 547.

[117] BUREAU OF DOMESTIC COMMERCE, PRODUCT LIABILITY INSURANCE: ASSESSMENT OF RELATED PROBLEMS AND ISSUES PAPER No. PB-252, 204 (1976); *see also* Escola v. Coca Cola Bottling Co., 24 Cal. 2d 453, 150 P.2d 436 (1944); Decker & Sons, Inc. v. Capps, 139 Tex. 609, 164 S.W.2d 828 (1942); Keeton, *Products Liability—Some Observation About Allocation Of Risk*, 64 MICH. L. REV. 1329, 1333 (1966); Keeton, *supra* note 32, at 34; Prosser, *The Assault Upon The Citadel (Strict Liability To The Consumer)*, 69 YALE L.J. 1099, 1119 (1960).

[118] 90 N.J. at 206-07, 447 A.2d at 547-48.

art is determined to a great extent by industry investment in safety research, the *Beshada* court indicated that strict liability would create an incentive for manufacturers to increase product safety.[119]

The hindsight standard of *Beshada* does not encourage a manufacturer to test a product after distribution because a subsequent discovery of danger would constitute *prima facie* evidence that the product was defective when it was sold. A manufacturer will not feel compelled to invest additional capital in research if it will be held strictly liable for unknowable dangers discovered decades later, regardless of the standard of care exercised. Instead, the fear of discovering a harmful characteristic in a product will encourage a "wait-and-see" attitude marked by increased product costs to cover premiums. The possibility of total economic annihilation by a single group of claims is awesome.[120] This threat encourages technological stagnation since new safety discoveries carry the threat of future liability. Accordingly, "the desire to reduce accidents justifies shifting losses to a maker only if he could have eliminated a danger that ought not to have existed."[121]

The *Beshada* court justified striking the state-of-the-art defense to simplify the plaintiff's proofs and to avoid jury confusion, thereby advancing simplification of the fact-finding process.[122] Although striking the state-of-the-art defense may advance this policy justification of strict liability,[123] it adversely affects fundamental fairness during litigation. In effect, the decision precludes a manufacturer from conducting a meaningful defense during trial, thus converting manufacturers into absolute insurers of their products.

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[119] *Id.* at 207, 447 A.2d at 548.

[120] On August 26, 1982, facing 16,500 lawsuits filed by disabled workers who had been exposed to asbestos and with new lawsuits being filed at the rate of 500 per month, Manville Corporation filed for reorganization under chapter 11 of the Bankruptcy Code. Manville is not the first asbestos company to file for bankruptcy. UNR Industries of Chicago filed in July, 1982 under the burden of 17,000 asbestos damage claims. *See* Wall St. J., Aug. 30, 1982, at 12, col. 1; N.Y. Times, Aug. 27, 1982, at D4, col. 1.

[121] Keeton, *supra* note 32, at 34; *see id.* at 30-34.

[122] 90 N.J. at 207-08, 447 A.2d at 548.

[123] The *Beshada* court additionally noted that simplifying the plaintiff's proofs furthers the ultimate goal of compensating injured consumers. *Id.* at 209, 447 A.2d at 549. The court stated: "We impose strict liability because it is unfair for the distributors of a defective product not to compensate its victims." *Id.; accord* Greenman v. Yuba Power Prods., Inc., 59 Cal. 2d 57, 63, 377 P.2d 897, 901, 27 Cal. Rptr. 697, 701 (1962) ("The purpose of [strict] liability is to insure that the costs of injuries resulting from defective products are borne by the manufacturers that put such products on the market rather than by the injured persons who are powerless to protect themselves"); *see* Birnbaum, *Unmarking The Test For Design Defect: From Negligence To Warranty To Strict Liability To Negligence*, 33 VAND. L. REV. 593, 596 (1980).

The underlying rationale of *Beshada*—1. defendant is a better risk spreader; 2. defendant is responsible for product safety research; and 3. the fact-finding process of tort trials should be simplified—is equally applicable in cases involving drug manufacturers.[124] *Beshada*, therefore, raises questions concerning the continued vitality of the New Jersey appellate court's adoption of the Restatement (Second) of Torts § 402A comment k.[125]

Comment k recognizes that prescription drugs are "unavoidably unsafe products" and immunizes drug manufacturers from liability if their products are properly prepared, marketed, and accompanied by adequate warnings and directions.[126] The concepts of fault and foreseeability are key elements in determining liability under the negligence standard of comment k.[127] The state-of-the-art defense, there-

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[124] Subsequent to *Beshada*, the New Jersey Supreme Court remanded Feldman v. Lederle Laboratories, No. A-4428-79-T1 (N.J. App. Div.), to the appellate division for that court to reconsider its summary affirmance of the trial court's dismissal in light of *Beshada*. The parties were directed to address, *inter alia*, whether the state-of-the-art defense remained available in pharmaceutical products liability actions.

[125] The Supreme Court of New Jersey has never explicitly adopted comment k although the court affirmed the appellate court's application of this provision in Brody v. Overlook Hospital, 127 N.J. Super. 331, 317 A.2d 390 (App. Div. 1974), *aff'd*, 66 N.J. 448, 332 A.2d 596 (1975), and subsequently in Calabrese v. Trenton State College, 162 N.J. Super. 145, 392 A.2d 600 (App. Div. 1979), *aff'd*, 82 N.J. 321, 413 A.2d 315 (1980).

[126] The applicable standard of liability in cases involving prescription medicines is set forth in RESTATEMENT (SECOND) OF TORTS § 402A comment k (1965).

> 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* 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 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.

Id.

[127] *See* Chambers v. G.D. Searle & Co., 441 F. Supp. 337 (D. Md. 1975), *aff'd*, 567 F.2d 269 (4th Cir. 1977) (defendant manufacturer held not liable for inadequate warning of potential side effects of oral contraceptives since company had warned against all adverse side effects which

fore, is vital to the presentation of a meaningful defense by pharmaceutical manufacturers.

Public policy considerations mandate that the negligence standard embodied in comment k continue to govern drug liability cases. The policy behind comment k is the desire to encourage the development and marketing of medicines, even when there is a medically recognizable risk due to "lack of time and opportunity for sufficient medical experience" to insure safety or purity.[128] While no medicine is free from adverse toxic effects on certain users,[129] the same drugs often save countless lives. By making manufacturers liable for even unforeseeable effects which may arise after the use of a drug, the development of new drugs becomes financially risky. Without the state-of-the-art defense, insurers will exclude coverage of many new and existing drugs in policies or drastically increase premiums to cover unanticipated liability.[130] Faced with potentially crippling liability, it is foreseeable that manufacturers would reduce research and development, thereby decreasing pharmacological advances and the availability of new drugs to the public.[131] Additionally, drugs which a manufacturer decided to market would require even more arduous testing than is presently required.[132] Thus, costs would escalate and

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were scientifically knowable at time of ingestion); Gaston v. Hunter, 121 Ariz. 33, 588 P.2d 326 (1981) (under comment k there can be no strict liability when charge of inadequate warning is based on subsequent technological advancements); Ortho Pharmaceutical v. Chapman, 388 N.E.2d 541 (Ind. Ct. App. 1981) (court rejected imputing the knowledge of the dangerous hazards of birth control pill to manufacturer and held that comment k requires proof that manufacturers had knowledge of danger).

[128] *See supra* note 126. Since some adverse effects of a drug do not appear until years after ingestion, evaluation of a medicine must continue into the period of clinical use. *See* L. GOODMAN & A. GILMAN, THE PHARMACOLOGICAL BASIS OF THERAPEUTICS 30 (4th ed. 1970).

[129] *See* L. GOODMAN & A. GILMAN, *supra* note 128, at 25.

[130] Joint Brief of *Amici Curiae* on behalf of Eli Lilly & Co., Pfizer, Inc., Warner-Lambert Co., Abbot Laboratories, E.R. Squibb & Sons, Inc., The Upjohn Co., Schering Corp., Emons Indus., Burroughs Wellcome Co. at 42, Feldman v. Lederle Laboratories, No. A-4428-79-T1 (N.J. App. Div.).

[131] *See id.* at 34-36.

[132] Presently there are eight stages of testing involved in the process of obtaining Food and Drug Administration approval for a new medicine.

> 1. Discovery. This stage involves basic research syntheses of new medicines and studies of chemical properties to identify new medicines for further study.
>
> 2. Preclinical Animal Testing. After the discovery of a new medicine, short-term animal toxicity studies are performed in order to determine safety for human testing.
>
> 3. Investigational New Drug (IND) Filing. If preclinical studies are favorable, a request is made to the FDA for authorization to begin human testing. If the FDA feels further testing is warranted, an investigational exemption—an IND—is granted.

scientific response to new diseases would be delayed. The increased costs resulting from increased testing and unforeseeable liability will undoubtedly be passed on to the consumer. Given today's economic realities, price increases in pharmaceutical products may render medical treatment unaffordable for many.

The scientific and pharmacological advances in the past several decades have helped improve the quality of life by eliminating disease and by easing pain and suffering.[133] These advances give hope for many others afflicted with uncommon diseases for which there is no present cure. Although there have been drugs whose benefits have been outweighed by their detrimental effects, for each failure, there have been numerous successes. The hands of science should not be tied to the loadstone of strict liability.

The standard of comment k encourages innovation and research while requiring that manufacturers properly produce and market their products with adequate warnings as to their deleterious effects. Only when these standards are shown to have been breached should liability be imposed. Since drug manufacturers are held to a standard of reasonable care, it is apparent that the full range of negligence defenses, including the state-of-the-art defense, should continue to be available in pharmaceutical product liability cases. Any application of *Beshada* to drug cases would extend the holding beyond its limits and would be inconsistent with the special rules developed to govern drugs.

As the law in New Jersey now stands, the same standard of strict liability is applied whether a product is improperly designed or manu-

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4. Phase I Clinical Testing. This is the first of three sequential tests of a proposed new medicine in humans, all of which are monitored by the FDA. A medicine is given to healthy volunteers in order to discover any evidence of its toxicity in humans.

5. Phase II Clinical Testing. These tests are designed to evaluate the therapeutic values of a new medicine. It is estimated that only half of the initial clinical testings produce results which warrant advancing to this stage.

6. Phase III Clinical Testing. In this phase, large scale human tests are conducted to uncover as yet unanticipated side effects of the proposed new medicine. Only some 19 percent of new chemical entities proceed to this phase of testing.

7. Long-Term Animal Studies. These studies are designed to determine the effects of prolonged exposure to the new chemical entity and its effects on subsequent generations.

8. New Drug Application (NDA) Approval.

Hansen, *The Pharmaceutical Development Process: Estimates of Development Costs and the Effects of Proposed Regulatory Changes*, ISSUES IN PHARMACEUTICAL ECON. 425 (1975).

[133] *See* V. FUCHS, WHO SHALL LIVE? (1974). The death rate from pneumonia, tuberculosis, and influenza declined after the introduction and wide use of penicillin, sulfonomide, and streptomycin. *Id.* New drugs have also been effective in combating polio, measles, and typhoid, thus decreasing the death rate from these diseases. *Id.*

factured or whether inadequate instruction or warnings are provided to ensure safe usage. In attempting to develop a theory of strict liability free from references to negligence, the court has moved toward absolute liability veiled in the policy rationale of strict liability. Courts and consumers have let it be known that the manufacturing community must pay close attention to the safety of manufactured products. Greater efforts to openly warn of limitations and dangers are now being demanded, and failure to meet this duty will be met by the imposition of liability to compensate those injured. While a miscarriage of the manufacturing process may be a proper risk to allocate to the maker, it is not equally clear that a scientifically unknowable risk should be imputed. This standard holds a manufacturer to a burden of clairvoyance and is tantamount to the imposition of insurer's liability—a standard beyond the purview of strict liability.

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