PRODUCTS LIABILITY—POLIO VACCINE—DRUG MANUFACTURER STRICTLY LIABLE IN TORT UNDER RESTATEMENT 402a FOR FAILURE TO WARN PLAINTIFF CONSUMER OF RISK OF HARM ATTENDING IMMUNIZATION. *Davis v. Wyeth Laboratories, Inc.* (9th Cir. 1968).

In May 1962, Wyeth Laboratories was licensed[1] to market the Type III strain of Sabin oral vaccine as a prescription drug. The following September, a report issued by the Surgeon General of the United States revealed a causal relationship between the use of the vaccine and the incidence of polio in those inoculated. The statistical frequency of polio without immunization was .9 per million for those over 20 years of age and 7.6 per million for those under 20. The estimated occurrence of polio in those inoculated was less than one in a million, and most of these cases were adults.[2] Since the risk of contracting the dread disease from natural causes was substantially greater to children than to adults, and since the incidence of paralysis resulting from inoculation with Type III vaccine was lower in children than in the adult age group, the report recommended that use of the vaccine be limited to children. In the spring of 1963, the Idaho Falls Medical Society established clinics for the dispensing of this vaccine and, notwithstanding the Surgeon General's report, included adults within the program. Wyeth Laboratories through its agent, played an active role in setting up the program's advertising campaign which encouraged the community to participate. Although the package containing the vaccine included data as to the risk involved, the vaccine was administered with no warning to the participant of the hazard inherent in its use.

In March 1963, unaware of the danger involved, Mr. Glynn Richard Davis—a successful thirty-nine-year-old businessman enjoying good health—was inoculated at the West Yellowstone, Montana clinic. Within thirty days following immunization, he manifested symptoms of polio and suffered paralysis from the waist down. Plaintiff Davis and his wife brought an action against Wyeth Laboratories. Following the delivery of a verdict for the defendant, plaintiff appealed to the Ninth Circuit Court of Appeals, *held*, reversed and remanded: In light of the method of dispensing Type III vaccine at the medical clinic, and in view of the fact that the statistical prob-

[1] Wyeth was licensed by the Division of Biological Standards of the National Institute of Health.

[2] Davis v. Wyeth Laboratories, Inc., No. 20,995 (9th Cir. Jan. 22, 1968).

abilities of contracting polio either with or without the vaccine were approximately the same, the defendant was obligated to warn the plaintiff of the risks attending immunization in its advertising campaign, so that he could make an intelligent and voluntary choice. If inoculation caused plaintiff's injury, the defendant was liable, either on theories of warranty or strict liability in tort under the *Restatement. Davis v. Wyeth Laboratories, Inc.*, No. 20,995 (9th Cir. Jan. 22, 1968) *petition for rehearing pending.*

Section 402a[3] of the *Restatement* renders a seller of chattels strictly liable for damages caused by his product when it is "defective" and "unreasonably dangerous" without regard to the seller's lack of negligence or privity of contract between himself and the purchaser.[4]

In *Davis*, the defendant argued that the rule of strict liability did not apply because the product was not "defective." He contended that: (1) the danger arising from the use of Type III vaccine did not stem from any ascertainable defect or impurity in the product, and (2) the product was manufactured exactly in the manner intended. The term "defective" has perplexed legal writers in recent years,[5]

[3] Noting that the courts of the forum state, Montana, had disregarded the requirement of privity of contract in warranty actions involving food products, the *Davis* court extended this exception to include products intended for intimate bodily use such as drugs. Moreover, the court adjudged that a cause of action based on a theory of warranty without privity is synonymous with an action grounded on a theory of strict liability in tort and, therefore, applied section 402a of the *Restatement of Torts* to the fact situation of the instant case. Davis v. Wyeth Laboratories, Inc., No. 20,995.

[4] RESTATEMENT (SECOND) OF TORTS § 402a (1965).

> (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
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> (a) the seller is engaged in the business of selling such a product, and
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> (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.
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> (2) The rule stated in Subsection (1) applies although
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> (a) the seller has exercised all possible care in the preparation and sale of his product, and
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> (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

The American Law Institute, discerning the recent trend of judicial opinion toward imposing strict liability on suppliers of chattels, either on a tort or warranty theory, and recognizing the public's reliance upon the manufacturers and sellers of consumer products, has promulgated the doctrine of strict enterprise liability for reasons of public policy: Those who are best able to absorb and spread the risk of accidental injury and damage to the consumer should bear the burden of liability. The advisors of the American Law Institute, intending to avoid the quagmire of rules that many courts have borrowed from commercial and contract law and traditionally applied to plaintiff's theory of breach of warranty, have based strict liability on a theory of tort, rather than warranty. RESTATEMENT (SECOND) OF TORTS § 402a, comments *c* and *m* (1965).

Hereinafter all *comment* references in the text, unless otherwise indicated, refer to RESTATEMENT (SECOND) OF TORTS § 402a.

[5] The *Restatement* defines a defective product as one which is "in a condition not contemplated by the ultimate consumer." RESTATEMENT (SECOND) OF TORTS § 402a,

with one noted jurist suggesting that the term defies any satisfactory definition that would encompass all hypothetical situations.[6] Avoiding this definitional problem, the *Davis* court accepted Professor John W. Wade's suggestion that the true test of strict liability under section 402a is whether the product is "unreasonably dangerous."[7]

In some circumstances, according to the *Restatement*, potentially harmful products are not "defective" nor "unreasonably dangerous." Comment *k*[8] of section 402a exempts from strict liability manufacturers and sellers of "unavoidably unsafe products" (*i.e.*, "incapable of being rendered safe for their intended and ordinary use") where

comment *g* (1965). This definition would encompass inherently dangerous products such as the Type III vaccine involved in the *Davis* case. *See* Comment, *The Manufacture, Testing and Distribution of Harmful New Drugs: The Applicability of Strict Liability*, 28 U. PITT. L. REV. 37, 44 n.36 (1966).

During the 1961 proceedings of the American Law Institute, section 402a was in its formative stages. At this time Professor Reed Dickerson suggested that the term "defective" was confusing and should be eliminated. He argued that the sole criteria for determining liability under the *Restatement* should be whether the product is classified as "unreasonably dangerous," for such a product would be defective per se. Professor William L. Prosser observed that a nondefective product such as tobacco or whiskey may nevertheless be "unreasonably dangerous" when excessively consumed. Dean Prosser argued that the adjective "defective" was included in section 402a in order to protect the manufacturer from strict liability for such products. The committee rejected Dickerson's proposal. 38 ALI PROCEEDINGS 87-89 (1961-1962). *See also* Wade, *Strict Tort Liability of Manufacturers*, 19 SW. L.J. 5, 14-15 (1965); Dickerson, *Products Liability: How Good Does a Product Have To Be?*, 42 IND. L.J. 301 (1967).

6 Traynor, *The Ways and Meanings of Defective Products and Strict Liability*, 32 TENN. L. REV. 363, 367 (1965). In Santor v. A & M Karagheusian, Inc., 44 N.J. 52, 67, 207 A.2d 305, 313 (1965), the court remarked that the judicial concept of a defective product "is a broad one. The range of its operation must be developed as the problems arise and by courts mindful that the public interest demands consumer protection."

7 Wade, *Strict Tort Liability of Manufacturers*, 19 SW. L.J. 5, 14-15 (1965).

8 RESTATEMENT (SECOND) OF TORTS § 402a, comment *k*:

> *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 warnings, 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 nothwithstanding 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.

(1) sufficient justification in terms of the public interest is shown in favor of their commercial distribution, (2) they are labelled with appropriate directions, and (3) "a proper warning is given, where the situation calls for it. . . ." The *Davis* court recognized that the Type III vaccine was properly classified as an "unavoidably unsafe product" and, thus, within the scope of comment *k*.

Comment *k* does not categorically state when a duty to warn is required. Therefore, the crucial and determinative issues in this case were (1) whether a duty to warn existed and (2) whether the defendant had breached this duty. In rendering its decision, the *Davis* court recognized that the substantive law of Montana which governed the case, had not settled the question of a pharmaceutical manufacturer's duty to warn the consumer of dangers inherent in its drug products.

The *Davis* court offered a standard which would determine whether a warning was appropriate:

> When in a particular case, the risk qualitatively (*e.g.* of death or major disability) as well as quantitatively, on balance with the end sought to be achieved, is such as to call for a true choice judgment, medical or personal, the warning must be given.[9]

The purpose of a warning, the court observed, is to apprise the consumer of the risk involved. The consumer then would determine if the benefit derived from the use of the product would justify assumption of the risk involved. While recognizing that human experimentation[10] with new drugs is essential for the progress and development of scientific and medical knowledge, the *Davis* court ruled that to deny the consumer the privilege of making a personal decision with full awareness of the danger would be unconscionable: the user would be reduced to the station of a "human guinea pig."[11]

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[9] Davis v. Wyeth Laboratories, Inc., No. 20,995.

[10] *Id.* The court's reference to human experimentation is difficult to reconcile in view of the evidence presented. There is no indication from the facts of the case that the defendant Wyeth Laboratories' sale of the Type III vaccine was linked to scientific experimentation. The Surgeon General's report revealing the risk of harm inherent in the product's use appeared several months before the clinics were organized. Furthermore, marketing of Type III was preceded by extensive testing. *Id.*

New drugs have been subdivided into two categories. Before the drug is approved by the Food and Drug Administration the new drug is denoted as "experimental." After receiving approval, it is termed an "established" drug. Comment *supra* note 5, at 42-43. Comment *k* recognizes this distinction; however, the determination of liability is the same in both cases.

[11] Davis v. Wyeth Laboratories, Inc., No. 20,995. The *Davis* court noted the recent trend of the allergy cases holding that a duty to warn may be necessary even when the

The defendant contended that the chances of an adult contracting polio were less than one in a million, and, thus there was no material advantage to be gained by a warning. Furthermore, defendant argued, no "true choice judgment" was present in the instant case. Since the probability of the plaintiff's contracting polio would have been substantially increased if immunization had been foregone, human experience would indicate that he would have assumed the risk if he had been informed of the hazard.[12]

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product causes an adverse reaction in a very small percentage of potential consumers. In Wright v. Carter Prods., Inc., 244 F.2d 53, 56-58 (2d Cir. 1957), the plaintiff suffered skin irritation from use of a deodorant manufactured by defendant. Only 373 complaints of similar injuries were known out of more than 82,000,000 jars of the product sold. In remanding the case, the United States Court of Appeals instructed the district court to determine whether (1) defendant, using reasonable care, could have foreseen injury to some of the consumers of the product and (2) a warning was necessary. The *Wright* court held that a duty to warn the consumer of latent dangers of which the manufacturer has knowledge may arise irrespective of the fact that the percentage of those susceptible to injury is minute. Furthermore, the gravity of the possible injury is a relevant factor in addition to the statistical incidence of harm. *Accord*, Sterling Drug, Inc. v. Cornish, 370 F.2d 82, 84-85 (8th Cir. 1967) (duty to warn physician of foreseeable danger of harm from use of a prescription drug may arise even though the evidence indicated plaintiff was hypersensitive).

Braun v. Roux Distrib. Co., 312 S.W.2d 758 (Mo. 1958), is the most extreme application of the foreseeability test in determining the necessity of a warning. Despite defendant's warning of certain possible allergic reactions, the plaintiff contracted a rare arterial disease following her use of defendant's hair dye product. Although there were no reported instances of any similar injury suffered by other users, the defendant was deemed negligent in failing to warn plaintiff of this danger. Constructive knowledge of the risk of contracting the rare disease was attributed to the defendant by presentation of evidence that scientific research had discovered a causal connection between the occurrence of disease and the consumption of an ingredient contained in defendant's product. One writer has criticized *Braun* for imposing strict liability on the manufacturer under the guise of a negligence-foreseeability standard for what was an unforeseeable result. Noel, *The Duty to Warn Allergic Users of Products*, 12 VAND. L. REV. 331, 333-34, 343, 367 (1959); Noel, *Recent Trends in Manufacturers' Negligence as to Design, Instructions or Warnings*, 19 Sw. L.J. 43, 55-56 (1965). The *Davis* court relied on *Braun*, as well as *Wright* and *Sterling* in formulating its standard for determining the applicability of a warning which does not rely solely on the statistical frequency of injury.

However, a number of cases deny plaintiff recovery on a theory of the manufacturer's failure to fulfill its duty to warn when the plaintiff is shown to have a peculiar idiosyncratic allergy; in these cases no warning is required. In Briggs v. National Indus., Inc., 92 Cal. App. 2d 542, 207 P.2d 110 (1949), the plaintiff, after contracting dermatitis following use of defendant's hair preparation, sued on the theory that defendant failed to apprise plaintiff of the risk involved in the product's use. In affirming a judgment for defendant, the California District Court of Appeal stated that the defendant was under no obligation to warn since plaintiff did not prove that a substantial number of persons were similarly susceptible. The rationale for denying recovery was enunciated in Merril v. Beaute Vues Corp., 235 F.2d 893, 897 (10th Cir. 1956), where the court said that the hypersensitive plaintiff is not reasonably foreseeable and that his hypersensitivity is deemed to be the cause of the injury. *Accord*, Cudmore v. Richardson-Merrell Inc., 398 S.W.2d 640, 643-47 (Tex. Civ. App. 1965). Under this traditional view it is not always clear how many other persons must have been shown to have suffered similar reactions.

[12] Davis v. Wyeth Laboratories, Inc., No. 20,995.

Rejecting the factual basis of defendant's argument, the *Davis* court noted that the geographical location in which plaintiff resided was not an area threatened by an epidemic and that the paralytic rate was extremely low; therefore, it concluded that the statistical probabilities of the plaintiff's contracting polio from Type III vaccine or from natural causes were approximately the same.[13] Furthermore, the court observed that the disagreement between the Surgeon General and the Idaho Falls Medical Society, as to whether use of the vaccine was justified in view of the attending risk, indicated the presence of a "true choice judgment."[14] Moreover, the court declared that the vaccine was designed to prevent the occurrence of polio, not to relieve or to cure those already afflicted. In the latter instance, risks would be more readily countenanced.[15] Reviewing the evidence of the case, the *Davis* court held that a duty to warn was a necessary adjunct to the commercial marketing of the Type III vaccine.[16]

Proceeding to the question of whether the defendant breached its duty to warn, the court acknowledged that when the Type III vaccine was first marketed, the defendant was not obligated to warn of the danger inherent in its product, since the risk of harm was unknown.[17] While declining to specify the precise date when defendant was charged with a duty to warn, the court held that by March 1963—when the plaintiff was immunized—medical science had confirmed the existence of a danger, thereby dictating a warning.[18]

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13 *Id.*

14 *Id.*

15 *Id.* The *Davis* court did not offer any reasons to support its conclusions that inherent risks of harm are more acceptable when a drug product is designed to cure or relieve the diseased victims. While each case must be adjudicated on the merits of its particular factual situation, it seems that prevention of disease carries as great a social value as cure or alleviation.

16 *Id.*

17 *Id.*

18 *Id.* It is well settled that the manufacturer can be held to a duty to warn only when he is deemed to have knowledge of the specific danger. However, actual knowledge of the risk of harm is not required; constructive knowledge can be attributed to the manufacturer. Stromsodt v. Parke-Davis & Co., 257 F. Supp. 991, 996-97 (D.N.D. 1966); Yarrow v. Sterling Drug, Inc., 263 F. Supp. 159, 162 (D.S.D. 1967). The rationale of imputing constructive knowledge to the manufacturer is that "a person who undertakes such manufacturing will be held to the skill of an expert in that 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." 2 F. HARPER & F. JAMES, THE LAW OF TORTS § 28.4 (1956). *See* Wright v. Carter Prods., 244 F.2d at 59.

Comment *j* is consistent with this view and requires either actual or constructive knowledge of the risk involved in the consumption of the product before a duty to warn will obtain. The *Davis* court did not have the issue of constructive knowledge before it because in March 1963, the defendant was aware of the hazard accompanying the use of the Type III vaccine.

The defendant argued that its disclosure of the danger to the medical society by its agent satisfied its obligation to warn. The court conceded that ordinarily a prescription drug manufacturer's warning to a physician of the risk of harm is sufficient,[19] but found that the instant factual situation was readily distinguishable. While Type III vaccine was nominally denoted as a prescription drug, the manner in which it was dispensed was more akin to that of a drug sold over-the-counter. In the impersonal, assembly line atmosphere of the clinic, the individual medical attention that is characteristic of the doctor-patient relationship was lacking.[20] Thus, only a warning directed to the consumer of the vaccine would fulfill Wyeth Laboratories' duty to warn.[21] However, Wyeth had not fulfilled this legal duty since: (1) the defendant's only warning was a written insert enclosed in the vaccine containers, (2) the defendant was aware that its notices were not being transmitted to those inoculated, and (3) the defendant actively participated in the advertising campaign that promoted the clinic's program.[22]

While the *Davis* court professed acceptance of the doctrine of strict liability as provided by section 402a, it did not specifically apply the criteria mentioned in comment *j*[23]—the only explanatory comment in section 402a offering a standard to determine when a warning is needed. While there are some similarities between the comment *j*

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19 Davis v. Wyeth Laboratories, Inc., No. 20,995. *See* Magee v. Wyeth Laboratories, Inc., 214 Cal. App. 2d 340, 350-53, 29 Cal. Rptr. 322, 327-28 (1963); Krug v. Sterling Drug, Inc., 416 S.W.2d 143, 151-52 (Mo. 1967); Stottlemire v. Cawood, 213 F. Supp. 897, 899 (D.D.C. 1963). While a manufacturer generally is charged with the legal obligation to warn the foreseeable user of the dangerous propensities of its product, an exception is made where an intervenient agent administers or prescribes it on an individual basis. Prescription drugs fall within this exception. Rheingold, *Products Liability—The Ethical Drug Manufacturer's Liability*, 18 RUTGERS L. REV. 937, 985-87 (1964); *see also* Freedman, *Prescription or Ethical Drugs: Fallacies as to Warranties, Failure to Warn and Strict Liability in Tort*, 21 FOOD DRUG COSM. L.J. 599 (1966).

20 Davis v. Wyeth Laboratories, Inc., No. 20,995.

21 *Id.* The court observed that the defendant could have reasonably been expected to use one of several means at his disposal to insure that notice of the inherent risk involved in immunization with Type III vaccine reached the plaintiff. Posters situated in the clinic, advertisements, releases of liability to be signed by those inoculated, or oral communication from the personnel of the clinic to the plaintiff would have been effective methods by which defendant Wyeth could have discharged its duty to warn.

22 *Id.* It is not clear from the *Davis* opinion whether defendant's participation—through its agent—in organizing the clinics and encouraging the public to undergo immunization through an advertising campaign was a crucial factor in the court's determination that defendant had breached its duty to warn as a matter of law. The *Davis* court seems to emphasize the importance of defendant's role in the program as evidence that it was aware that its warning to the clinic was not being relayed to those persons who were inoculated.

23 RESTATEMENT (SECOND) OF TORTS § 402a, comment *j* (1965).

approach and the *Davis* test,[24] they seem to differ as to the purpose of a warning. Comment *j* concludes:

> Where warning is given, seller may reasonably assume that it will be read and heeded; and a product bearing such a warning, which is safe for use if it is followed, is not in defective condition, nor is it unreasonably dangerous.[25]

This excerpt indicates that the purpose of a warning is to render the product safe for consumption: If the warning is observed, and if those endangered would refrain from using the product, the product is not "unreasonably dangerous."

In contrast, the *Davis* court held that when the product is "unavoidably unsafe," the purpose of notice is to inform the consumer of the hazards in the product's use and thus afford him the opportunity to make an intelligent and voluntary choice whether to assume the attendant risk.

Although comment *j* refers to all products,[26] while the *Davis* test applies only to "unavoidably unsafe products," these differing legal standards may sometimes have the same effect when the product is known to imperil an ascertainable group of persons. Under the comment *j* approach a warning is appropriate since it will ipso facto render the product safe for use. If the risk of injury balanced with the value to society were to present a "true choice judgment," *Davis* would also require a warning.

When, as in *Davis*, the "unavoidably unsafe product" presents a foreseeable danger to physiologically unidentifiable consumers, the application of these two standards yields contrary conclusions. In this factual situation it would be nearly impossible to deter those potential consumers who would be injured by use of the product. Since admonition of the danger would not make use of the product safe, no warning would be required by comment *j*. However, where the factual pattern presents a "true choice judgment," *Davis* would require a warning in order to apprise the consumer of the risk involved.

Comment *k* does not offer a definitive standard for determining the necessity of a warning. It requires a warning only "where the

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[24] Comment *j* requires a warning where: (1) the seller has actual or constructive knowledge of the danger involved, (2) the danger is not known to the public, or if known, is not expected by potential consumers to be present in the seller's product, and (3) a substantial number of persons may be expected to suffer an adverse reaction or where the product is "unduly dangerous."

The *Davis* court's emphasis on the qualitative and quantitative risks seems to parallel the criteria of comment *j*.

[25] RESTATEMENT (SECOND) OF TORTS § 402a, comment *j* (1965).

[26] *Id.*

situation calls for it." Thus, it is arguable that the authors of the *Restatement* intended that the appropriateness of notice under comment *k* should be interpreted in light of comment *j*; explanatory comments to a particular *Restatement* section should be construed *in pari materia*. If this construction were accepted, it would foreclose use of a warning whenever an "unavoidably unsafe product" was found to be inherently dangerous to consumers whose physiological susceptibility was not detectable.[27] This would contradict the holding in *Davis*.

The hypothetical illustration found in comment *k* describes the Pasteur rabies vaccine. Since consumers vulnerable to an adverse reaction are unascertainable, the rabies vaccine is analogous to the Type III vaccine in *Davis*. The *Restatement* declares that this product is not "unreasonably dangerous" when it is marketed with a warning of the risks attending its use.[28] Thus, it may be hypothesized that comment *k* does not impliedly refer to the provisions of comment *j*; rather it reflects a tacit acceptance of the concept that a warning accompanying a product denoted as "unavoidably unsafe" is intended to inform the consumer of the inescapable hazard.

The significance of *Davis* lies in its formulation of a test for judging the necessity of a warning and its declaration of the public policy argument underlying the seller's duty to warn. In view of the remarkable progress of recent scientific research accompanying the modern phenomenon of mass immunization clinics, it is likely that *Davis v. Wyeth* will presage the appearance of similar factual patterns. Whether a warning to the ultimate consumer is necessary will devolve upon a balancing of potentially contrary public policy considerations: (1) the individual's right to be informed, and (2) the achievement of a public health objective which might be frustrated if a warning were to deter potential consumers. The initial decision to warn is determined by the drug manufacturer when the product is marketed and this responsibility places it in a difficult position. As a member of the private economy, accustomed to thinking primarily in terms of sales in a competitive marketplace, the pharmaceutical firm is required to answer what is essentially a public policy question.

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[27] *See* Note, *Products Liability and Section 402a of the Restatement of Torts*, 55 GEO. L.J. 286, 313 n.153 (1966), where it is suggested that a warning may only be required by comment *k* where it would render the "unavoidably unsafe product" safe for use.

[28] RESTATEMENT (SECOND) OF TORTS § 402a, comment *k* (1965).