treated and healed. Until that time, he had never seen nor heard of her.

Today's case is on a par, and I for one decline to adopt the philosophy that there is any validity in calling the type of testimony here presented as being that *"substantial"* that it can prevail over all other expert professional testimony of witnesses who dealt with this claimant on a regular basis at the time she had the experiences which led to her inability to work.

The precedent being set is disastrous to the whole area of compensation to working men and women who are deserving of the sure and certain compensation promised them. Unless this Court retreats from the philosophy espoused today, the sureties of this state will have a field day until the day the legislature or the people intervene.

At the least, I sincerely hope that what I have written today sufficiently demonstrates that neither *Arnold* nor *Houser* can be said to justify the Court's judgment.

732 P.2d 297

David TONER, guardian ad litem for Kevin Toner, an infant child, and David Toner and Susan Toner, husband and wife, individually, Plaintiffs-Appellants,

v.

LEDERLE LABORATORIES, A DIVISION OF AMERICAN CYANAMID CO., Defendant-Respondent.

No. 16453.

Supreme Court of Idaho.

Feb. 4, 1987.

[redacted]

Kenneth L. Pedersen (argued) and Curtis Webb, Twin Falls, for plaintiffs-appellants.

Robert J. Koontz (argued), William J. Batt and Catherine A. King, Boise, for Lederle Laboratories.

Phillip M. Barber, Boise and Malcolm E. Wheeler (argued), Los Angeles, CA, for amicus curiae, Pharmaceutical Manufacturers Association.

BISTLINE, Justice.

In 1979, plaintiff child Kevin Toner, then three months old, received a vaccination of Tri-Immunol, a drug manufactured by defendant Lederle Laboratories and designed to immunize children against diphtheria, pertussis, and tetanus. Thereafter, Kevin suffered a rare condition of the spine known as transverse myelitis. The affliction permanently paralyzed Kevin from the waist down. Plaintiffs brought suit against Lederle in Idaho state court, but the suit was removed to federal district court on the basis of diversity jurisdiction. At trial, the jury found that Lederle's vaccine has caused Kevin's paralysis and found Lederle negligent, although it rejected plaintiffs' strict liability and breach of warranty claims. Lederle appealed the judgment to the United States Court of Appeals for the Ninth Circuit. Rather than render a decision, pursuant to I.A.R. 12.1 (Supp.1986) the Court of Appeals certified and this Court accepted two controlling questions of Idaho law. These questions center on the role in Idaho strict liability and negligence law of the so-called "unavoidably unsafe" product doctrine, as described in comment k of Restatement (Second) of Torts § 402A (1965) (quoted *infra*, p. 12).

I. BACKGROUND

[redacted] Toner found much with which to disagree in the Court of Appeals' summary of the facts. Two of the points of contention Toner raised we will set out in footnotes to our quotation of the Court of Appeals' opinion. As we do not have the trial record before us, we must use the Court of Appeals' summary as background to our decision. However, as we will explain below, the posture of the case, which includes a standing jury verdict that Lederle was negligent but that the vaccine was not in a "defective condition unreasonably dangerous to persons," requires certain factual presumptions regardless of the Court of Appeals' recitation.

The Court of Appeals states the facts as follows:

In 1979, Kevin Toner, then a three-month-old infant, was vaccinated with Tri-Immunol and suffered a rare condition of the spine known as transverse myelitis, the cause of which is unknown. As a result of the affliction, Kevin is permanently paralyzed from the waist down. His parents commenced litigation in Idaho state court, and appellant removed the case to federal court on the basis of diversity of citizenship. 28 U.S.C. § 1441 (1982). The suit was tried to the jury on theories of strict liability, negligence, breach of warranty of merchantability, and failure to warn. Appellees withdrew the failure to warn claim before the case was submitted to the jury. The jury found that the pertussis component of the vaccine had caused Kevin's paralysis; although in a special verdict the jury rejected the strict liability and breach of warranty claims, it found appellant negligent and assessed damages of $1,131,200.

In the early years of this century, pertussis was one of the leading causes of death in children. In recent years, however, the widespread availability of vaccines such as that marketed by defendant has virtually eradicated the disease. An instructive, brief description of common vaccines is found in an opinion by the Second Circuit, *Ezagui v. Dow Chemical Corp.*, 598 F.2d 727, 731 (2d Cir.1979), and we rely upon that description for the following background explanation.

By introducing an antigenic factor into the body, vaccines stimulate the production of antibodies that protect against disease. Some infectious organisms, such as those causing diphtheria and tetanus, excrete soluble toxins insoluble by medical research. The toxin is inactivated with formaldehyde and transformed into a toxoid. The toxoid is then used in a vaccine, as it can immunize against disease by stimulating the production of antibodies in the recipient, even though it has lost its own poisonous qualities.

This is not the case, however, with vaccines such as Tri-Immunol. Tri-Im-

munol is a so-called whole cell vaccine because it contains whole killed pertussis organisms. The whole organism is used because the pertussis organism contains fifteen or sixteen different antigens, and medical science has yet to isolate the one that stimulates protection against the disease. *See Tinnerholm v. Parke, Davis & Co.*, 411 F.2d 48, 50 (2d Cir. 1969). Courts that have addressed the issue of liability for adverse reactions to the DPT vaccine have commented that "the bacterial organism which causes pertussis is so complex as to make impossible the isolation and deactivation of the toxin or poison." *Ezagui*, 598 F.2d at 731; *accord Tinnerholm*, 411 F.2d at 50. Because of this difficulty, at the time of Kevin Toner's vaccination, the whole cell pertussis vaccine was the only pertussis vaccine licensed by the Food and Drug Administration (FDA) for use in the United States. It remains the only licensed vaccine today.

The whole cell pertussis vaccine is neurotoxic and can cause adverse reactions. These reactions are of two types: local and severe. Local reactions include swelling, fever, irritability, and crying spells. Severe reactions include encephalopathy, paralysis, and even death. The expected rate of severe reactions ranges between one in 100,000 and one in 310,000 doses. Prior to this incident, there had been only one case of transverse myelitis reported in connection with a DPT vaccine.

During the 1950's, the Eli Lilly Company developed a fractionated cell pertussis vaccine called Tri-Solgen that was prepared by treating whole killed pertussis cells with salt. Early studies indicated that this method of preparation resulted in a less toxic vaccine, and following its approval by the FDA in 1967, Tri-Solgen occupied a substantial share of the market. Lilly withdrew from the vaccine business in 1975 and stopped producing Tri-Solgen. Lilly sold the right to produce Tri-Solgen to Wyeth Laboratories; however, the FDA has refused to relicense the vaccine.[1]

Lederle was aware of the neurotoxicity of Tri-Immunol as early as the 1950's and since that time has received occasional reports of severe adverse reactions to the vaccine. Following FDA approval of Tri-Solgen, Lederle conducted an internal study comparing Tri-Immunol with Tri-Solgen in an effort to determine whether to develop its own fractionated cell product. The study found fewer local reactions associated with Tri-Solgen, but it noted no severe reactions in either cohort due to the restricted number of subjects studied. At trial, Dr. Frank Cano, the Manager of Biologics at Lederle, testified that the differences observed in the study lacked statistical significance. Lederle only experimented with the production of a fractionated cell product until 1975. Since then, Japan has developed a pertussis toxoid vaccine, and Lederle's research efforts to achieve that objective may reach fruition within the next few years.

The principal thrust of appellees' negligence argument at trial concerned Lederle's failure to develop a fractionated cell product. In support of this theory, appellees contend that Tri-Solgen was shown to be a safe yet equally efficacious pertussis vaccine. Appellees' experts testified that the whole cell vaccine was five times more reactive than the fractionated cell product, and that early studies indicated that Tri-Solgen caused fewer local reactions than the whole cell vaccine. The studies did not establish, however, that Tri-Solgen caused fewer severe reactions than the whole cell vaccine.[2] With regard to efficacy, appellees produced four studies that found that fractionated cell products produced

1. At oral argument, Toner disputed this assessment of the record, asserting that the Court of Appeals failed to account for the cross-examination of a certain key witness (whom Toner did not identify).

2. At oral argument, Toner claimed his experts testified that a fractionated cell vaccine would cause five times fewer catastrophic reactions.

an immune response to pertussis. However, in 1972, a review panel within the Bureau of Biologics of the FDA refused to certify Tri-Solgen as "safe and effective" although it did so certify the whole cell vaccines. Because the FDA has refused to relicense Tri-Solgen or any other fractionated cell product, the manufacture and sale of such a vaccine by Lederle, or any other pharmaceutical company, would constitute a criminal offense under the Food, Drug and Cosmetic Act. *See* 21 U.S.C. §§ 331(d), 333(a), 355(a) (1982). *Toner v. Lederle Laboratories,* 779 F.2d 1429, 1430–31 (9th Cir.1986) (footnotes added).

As noted, Toner vigorously disputes this characterization of the facts. Without the trial record (other than the proposed and given jury instructions) before us, we cannot make an independent assessment. However, until it is determined otherwise, we must presume that sufficient evidence supported the jury's verdict that Lederle was negligent. *See Glovatorium, v. N.C.R. Corp.,* 684 F.2d 658, 660 (9th Cir. 1982) ("This court will not disturb a jury verdict unless the evidence is such 'that no reasonable [person] would accept it as adequate to establish the existence of each fact essential to the liability.' *Kunz v. Utah Power & Light Co.,* 526 F.2d 500, 504 (9th Cir.1975)....").

By examining the allegations, the jury instructions, and the jury verdicts, we can further narrow that which we must presume. Lederle's standard of care relevant to the allegations of negligence was most specifically addressed in the following jury instruction, requested by Lederle and given by the trial court:

> INSTRUCTION NO. 27: A manufacturer of vaccines has the duty to exercise ordinary and reasonable care not to expose the potential consumer to an unreasonable risk of harm from the use of its products. The failure to meet this standard of due care in light of all the attendant circumstances will constitute negligence and subject the manufacturer to liability for the resulting consequences. The fact that the consumer's injuries were proximately caused by the manufacturer's product does not in and of itself constitute a sufficient basis upon which to predicate the manufacturer's liability. When the cause of action sounds in negligence, a manufacturer's duty to additionally test and investigate the propensities of its product is dependent upon the foreseeable risk of harm to potential users in light of then current scientific or medical knowledge and discoveries. R., Vol. II, p. 90, *quoted in Toner, supra,* 779 F.2d at 1431–32.

Toner specifically alleged "[t]hat Lederle was negligent in manufacturing and/or marketing the vaccine." R., Vol. 2, p. 85 (Jury Instruction No. 18). As we understand it, the thrust of Toner's case was not that the whole cell vaccine itself could have been more safely designed, but that Lederle knew of a safer alternative design—the fractionated cell vaccine—but failed to develop it and seek FDA certification of it. Toner alleged that Lederle could have marketed the safer alternative, but negligently failed to do so.

The jury returned the following verdict:

> QUESTION NO. 2: Was defendant Lederle Laboratories negligent in connection with the product Tri-Immunol which was the proximate cause of the plaintiff's injuries? Yes. *Toner, supra,* 779 F.2d at 1433.

Taking the jury instructions, the allegations, and the jury verdict together, we conclude the jury found that "in light of all the attendant circumstances," Lederle failed "to exercise ordinary and reasonable care not to expose the potential consumer to an unreasonable risk of harm from the use of its products," R., Vol. 2, p. 90 (Jury Instruction No. 27), that "the foreseeable risk of harm to potential users in light of then current scientific or medical knowledge and discoveries" was such that Lederle was negligent in failing to further "test and investigate the propensities of its product" relative to those of the allegedly safer product, *id.,* and that as a result Lederle was negligent for having "manu-

factur[ed] and/or market[ed] the [whole cell] vaccine" rather than the alternative. R., Vol. 2, p. 85 (Jury Instruction No. 18).

Certain factual presumptions also flow from the instructions, allegations, and verdict on the strict liability claim. The jury was instructed as follows:

> INSTRUCTION NO. 21: A product is in a defective condition, unreasonably dangerous to persons if it is more dangerous than would be expected by an ordinary person who may reasonably be expected to use it. The law does not say what would be expected by an ordinary person or who may reasonably be expected to use the product. Both of these issues are for you to decide. R., Vol. 2, p. 87.

The jury received no instruction based on comment k of Restatement (Second) of Torts § 402A (1965).

Toner alleged "[t]hat at the time the vaccine was manufactured it was defective, in that it subjected the users to an unnecessary risk of serious harm or death." R., Vol. 2, p. 85 (Jury Instruction No. 18). However, the jury returned the following verdict:

> QUESTION NO. 3: Was the product Tri-Immunol manufactured by the defendant Lederle Laboratories in a defective condition unreasonably dangerous to persons which was the proximate cause of the plaintiff's injuries? No. *Toner, supra,* 779 F.2d at 1433.

Taking the instructions, arguments, and verdict together, we conclude that the jury found the vaccine not to be "in a defective condition unreasonably dangerous to persons...." *Id.* Nothing in the record before us indicates that either the jury or the trial court made any determination based on comment k.[3]

We undertook the above exercise in order to understand the jury's determinations in relation to the certified questions, and to put our answers to those questions in perspective.[4] As will become clear, the posture of this case dictates the extent of detail of our answers.

II. THE CERTIFIED QUESTIONS

The Court of Appeals posed the two questions which we accepted as follows:

> (1) Under Idaho law, do the principles set forth in *Restatement (Second) of Torts* § 402A comment k apply to strict liability and negligence claims, and in particular to the claims in this suit?
>
> ....
>
> (4) Were the jury instructions on the issue of negligence in full accordance with Idaho law, given the contentions of the parties in this case? *Toner, supra,* 779 F.2d at 1433.

However, the Court of Appeals invited us to "reformulate the relevant state law questions as [we] perceive[ ] them to be...." *Id.* Upon consideration, we find such reformulation necessary.

The first certified question in reality is two: do the principles of comment k apply to strict liability claims, and do they apply to negligence claims. We will address the first part of the first question separately.

3. However, the jury's apparent finding that there existed a safer alternative to the whole cell vaccine equates with a determination that the vaccine was not unavoidably unsafe, as will be explained *infra.*

4. More specifically, we were obliged to make these determinations by the certified questions. The Court of Appeals asked us to decide its questions on comment k in the context of the claims and contentions in this case. Thus, we found it necessary to determine whether comment k had been applied at the trial court level before determining whether it could be applied to this case. We also found it necessary to determine if any trial court findings bore on the application of comment k to the claims and contentions of this case. As explained *infra,* there is no occasion for us to decide whether comment k applies to the vaccine at issue, since (1) the jury's determination on negligence would appear to conflict with such a holding, *see* note 3, *supra,* (2) the trial court gave no instruction and made no determination as to the application of comment k, (3) Lederle prevailed against the strict liability claim, to which comment k provides a defense, and (4) the application of comment k is a question mixing law and fact which requires an evidentiary hearing.

The second question (numbered (4) above) appears to directly relate to the latter part of the first question, particularly in light of the Court of Appeals' following discussion:

> Appellant argues that the instruction [No. 27, quoted *supra*] is insufficient because it does not recognize that certain drugs have unavoidable risks but must, nevertheless, be used to protect the public health. To support its argument, appellant cites *Restatement (Second) of Torts* § 402A comment k (1965), which recognizes that the marketing of some drugs is fully justified to prevent disease despite risks inherent in their use. As appellant recognizes, the *Restatement* section and its comment pertain to strict liability; but, appellant argues, the controlling principles are also applicable to the question of liability for negligence.
>
> Though appellees contend that the issue in this case is not the applicability of comment k but, rather, the appellant's alleged negligence in failing to develop a fractionated cell vaccine, we see the questions as related. The concept of an unavoidably unsafe product seems necessarily to depend on whether research was properly pursued. If this is true, the trial court may have omitted a material element of negligence in failing to instruct the jury to decide whether Tri-Immunol was an unavoidably unsafe product. *Id.* at 1432.

The negligence instructions would seem to present no difficulties to the Court of Appeals, except in relation to Lederle's argument concerning comment k. The Court of Appeals apparently wishes this Court to determine both (1) whether the principles of comment k apply to negligence claims, (as stated in the latter part of the first question), and if they do apply, (2) whether the above quoted negligence instruction (or any other of the given negligence instructions) sufficiently incorporates those principles.

Accordingly, we reformulate the certified questions as follows:

(1) Under Idaho law, do the principles set forth in Restatement (Second) of Torts § 402A comment k (1965) apply to strict liability claims, and in particular to the claim in this suit?

(2)(a) Under Idaho law, do the principles set forth in Restatement (Second) of Torts § 402A comment k (1965) apply to negligence claims, and in particular to the claim in this suit? [5]

(b) If the above question no. (2)(a) is answered affirmatively, did the trial court's instructions on negligence sufficiently incorporate those principles?

III. QUESTION 1

We turn first to the question of whether the principles set forth in Restatement (Second) of Torts § 402A comment k apply to strict liability claims, and in particular to the claim in this suit. Our treatment of the question, however, will be general only. As best we can determine, the Court of Appeals poses the question for contextual purposes only. Nevertheless, we will examine comment k closely before venturing to adopt it or reject it.

5. Contrary to Toner's assertion, this question does not equate to "[w]hether the Toners had to prove that Tri-Immunol was unreasonably dangerous to prevail on their negligence claim." Appellants' Brief, p. 7. Unreasonable dangerousness, as used in this context, is an element of a strict liability cause of action, not of a negligence cause of action. There is no dispute that negligence and strict liability are separate, nonmutually exclusive theories of recovery, and that "[the] failure to prove one theory does not preclude proving another theory." *Chancler v. American Hardware Mutual Insurance Co.*, 109 Idaho 841, 846, 712 P.2d 542, 547 (1986). As the Washington Supreme Court stated: "Negligence and strict liability are not mutually exclusive because they differ in focus: negligence focuses upon the conduct of the manufacturer while strict liability focuses upon the product and the consumer's expectation." *David v. Globe Machine Manufacturing Co., Inc.*, 102 Wash.2d 68, 684 P.2d 692, 696 (1984), *cited in Chancler, supra*, 109 Idaho at 846, 712 P.2d at 547. The Court of Appeals' question concerns not the relationship between negligence and strict liability, but on the relationship between negligence and a *defense to* strict liability, *i.e.*, the "unavoidably unsafe" product doctrine.

Our belief that the Court of Appeals poses the question for contextual purposes only is based on our understanding that the issue the question involves is not before the court on appeal. Comment k provides an exception to strict liability for products deemed "unavoidably unsafe." Essentially, then, comment k is a defense to strict liability claims against products. In the instant case, the jury found the vaccine was not "in a defective condition unreasonably dangerous to persons which was the proximate cause of the plaintiff's injuries." *Toner, supra,* 779 F.2d at 1433 (quoting from the jury verdict). In other words, as the Court of Appeals noted, "the jury rejected the strict liability ... claim[ ].... *Id.* at 1430. The Toners do not appeal from that verdict. The viability of a defense to a claim, where the claim failed, and where the plaintiffs do not appeal, would not seem to be an issue on appeal.

The crux of Lederle's appeal involves whether the principles of comment k apply to a negligence claim—the claim upon which the jury found for the Toners. Comment k is a provision of Restatement (Second) of Torts § 402A (1965). Section 402A concerns claims based on the strict liability of sellers of products, and not claims based on negligence. The Court of Appeals may have thought it unlikely that this Court would apply the principles of comment k to a negligence claim without first determining that they apply to the strict liability claims for which the comment was designed. We will proceed with that understanding.

This Court adopted Restatement (Second) of Torts § 402A (1965) concerning the strict liability of sellers of products, of which comment k is a part, in *Shields v. Morton Chemical Co.,* 95 Idaho 674, 676–77, 518 P.2d 857, 859–60 (1974). Subsequently, this Court has consistently adhered to § 402A and often to its accompanying comments. *See, e.g., Rojas v. Lindsay Manufacturing Co.,* 108 Idaho 590, 592, 701 P.2d 210, 212 (1985) (applying comments i and l); *Fish Breeders of Idaho, Inc. v. Rangen, Inc.,* 108 Idaho 379, 391 n. 3, 700 P.2d 1, 13 n. 3 (1985) (applying comments g, h, and j); *Lasselle v. Special Products Co.,* 106 Idaho 170, 172, 677 P.2d 483, 485 (1984) (applying comment n); *Farmer v. International Harvester Co.,* 97 Idaho 742, 747, 749, 553 P.2d 1306, 1311, 1313 (1976) (applying comment i); *Mico Mobile Sales & Leasing, Inc. v. Skyline Corp.,* 97 Idaho 408, 414, 546 P.2d 54, 60 (1975) (applying comment h); *Rindlisbaker v. Wilson,* 95 Idaho 752, 759–60, 519 P.2d 421, 428–29 (1974) (applying comments h and n). To date, a case implicating comment k has not presented itself.

In its entirety, comment k reads:

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 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. (Emphasis original.)

Comment k establishes an exception to the test for strict product liability. That test as set out in § 402A imposes liability on "[o]ne who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his [or her] property ...," § 402A(1), whether or not "the seller has exercised all possible care in the preparation and sale of his product...." § 402A(2)(a). Comment g defines "defective condition" as "a condition not contemplated by the ultimate consumer which will be unreasonably dangerous to him [or her]." Comment k, however, defines a category of "unavoidably unsafe" products which, "when properly prepared, and accompanied by proper directions and warning, [are] not defective, nor ... *unreasonably* dangerous." (Emphasis original.) To leave no doubt, comment k restates the proposition: "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...." (Emphasis added.) Thus, if a product qualifies as "unavoidably unsafe," the seller is held not to the strict liability standard, but only to the standard of negligence.[6]

As precondition to its application, comment k requires that the product be "properly prepared, and accompanied by proper directions and warning...." Generally speaking, there are three varieties of product defects: manufacturing flaws, design defects, and inadequate warnings. *Feldman v. Lederle Laboratories,* 97 N.J. 429, 479 A.2d 374, 385 (1984). By its terms, comment k excepts unavoidably unsafe products from strict liability only where the plaintiff alleges a design defect, and not where the plaintiff alleges a manufacturing flaw or an inadequate warning.[7] Comment k intends to shield from strict liability products which cannot be designed more safely; however, if such products are mismanufactured or unaccompanied by adequate warnings, then the seller may be liable even if the plaintiff cannot establish the seller's negligence. Courts and commentators universally agree to this limitation on comment k's grant of immunity from strict liability. *See Brochu v. Ortho Pharmaceutical Corp.,* 642 F.2d 652, 657 (1st Cir. 1981); *Reyes v. Wyeth Laboratories,* 498 F.2d 1264, 1276 (5th Cir.), *cert. denied,* 419 U.S. 1096, 95 S.Ct. 1096, 42 L.Ed.2d 688 (1974); *Davis v. Wyeth Laboratories, Inc.,* 399 F.2d 121, 128–29 (9th Cir.1968); *Yarrow v. Sterling Drug, Inc.,* 263 F.Supp. 159, 163 (Dist.S.D.1967), *aff'd,* 408 F.2d 978 (8th Cir.1969); *Kearl v. Lederle Laboratories,* 172 Cal.App.3d 812, 218 Cal.Rptr. 453, 465 ([Div. 4] 1985); *Feldman, supra,* 479 A.2d at 384; V. Schwartz, *Unavoidably Unsafe Products: Clarifying the Meaning and Policy Behind Comment K,* 42 Wash. & Lee L.Rev. 1139, 1141 (1985); S. Willig, *The Comment k Character: A Conceptual Barrier to Strict Liability,* 29 Mercer L.Rev. 545, 546, 575 (1978).

Having met these preconditions, a seller next must establish that the product's risk is in fact "unavoidable." Comment k states: "There are some products which, in

6. In the next section, we will discuss further our conclusion that comment k immunity extends in a literal sense only to strict liability claims, and not to negligence claims. Our observation is no semantic distraction or confusion, as Justice Bakes states, but rather is based on the express language of comment k and on unanimous authority.

7. However, as we recently stated: "[T]here generally is little difference in the requirements and analysis of the duty to warn under either a negligence or strict liability theory.... *See Feldman v. Lederle Laboratories,* 97 N.J. 429, 479 A.2d 374, 386 (1984) and cases cited therein; *see generally* J. Wade, *On the Nature of Strict Tort Liability for Products,* 44 Miss.L.J. 825, 842 (1973)." *Sliman v. Aluminum Company of America,* 112 Idaho 277, 280, 731 P.2d 1267, 1270 (1986) (footnote omitted).

the present state of human knowledge, are *quite incapable* of being made safe for their intended and ordinary use." (Emphasis added.); *see also, e.g., Belle Bonfils Memorial Blood Bank v. Hansen,* 665 P.2d 118, 122 (Colo.1983) ("[T]he risk must be unavoidable under the present state of knowledge."). Obviously, for this to be true, the design must be as safe as the best available testing and research permits. Schwartz, *supra,* 42 Wash. & Lee L.Rev. at 1141.

As an additional element of an "unavoidable risk," there must be, at the time of the subject product's distribution, no feasible alternative design which on balance accomplishes the subject product's purpose with a lesser risk. *See Kearl, supra,* 218 Cal. Rptr. at 464; *Belle Bonfils, supra,* 665 P.2d at 123; Prosser and Keeton, *The Law of Torts* § 99, p. 700 (5th ed. 1984). If there were, then the risk would not be "unavoidable" or "apparently reasonable." Nor would the "marketing and use of the [product] be fully justified" if there were such an alternative design. Consequently, comment k by definition would not apply. The evaluation of a purported alternative design and the subject product's design should consider the magnitude of the subject product's risk that the alternative avoids, the financial costs of the compared designs, the benefits of the compared designs, and the relative safety of the compared designs, including any new risk that the alternative would pose. *See Kearl, supra,* 218 Cal.Rptr. at 464, *Belle Bonfils, supra,* 665 P.2d at 123; Prosser and Keeton, *supra,* § 99, p. 700.

Where their risks are unavoidable, comment k shields from strict liability those sellers who "supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk." As examples of such products the comment cites (1) the Pasteur treatment of rabies, which averts "a dreadful death" while "not uncommonly lead[ing] to very serious and damaging consequences when it is injected," and (2) "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." Clearly, the comment contemplates a weighing of the benefit of the product against its risk. Obviously, for comment k to apply, the benefit must outweigh the risk. This weighing process should consider the value of the benefit, the seriousness of the risk, and the likelihood of both. *Belle Bonfils, supra,* 665 P.2d at 122; *Kearle, supra,* 718 Cal.Rptr. at 464. We agree with Professor Sidney Willig that "[i]t does not serve society that an unavoidably unsafe product, which has occasional or fractious benefit, should enjoy insulation from strict liability in tort when the product's predominant effects are detrimental to individual and public safety." Willig, *supra,* 29 Mercer L.Rev. at 545. Consequently, the scales must clearly tip in favor of the benefits for comment k to apply. *Cf. Brochu, supra,* 642 F.2d at 657 ("If, as Comment k explains, the danger is unavoidable and the utility is great, liability may be avoided with proper warning." (Footnote omitted.)); *Belle Bonfils, supra,* 665 P.2d at 122 ("The product's utility must greatly outweigh the risk created by its use...."); *Kearl, supra,* 218 Cal.Rptr. at 464 ("If the court concludes after taking such evidence that (1) the product was intended to provide an exceptionally important benefit that made its availability highly desirable, (2) the risk posed by the product was substantial and unavoidable when distributed, and (3) the interest in availability, measured as of the time of distribution, outweighs the interest in promoting enhanced accountability, the product will be deemed unavoidably dangerous and exempted from strict products liability design defect analysis.")

The weighing must be done as of the time the product is distributed to the plaintiff. *Belle Bonfils, supra,* 665 P.2d at 122–23; *Kearl, supra,* 218 Cal.Rptr. at 464; *Cochran v. Brooke,* 243 Or. 89, 409 P.2d 904, 906 (1966). Comment k does not re-

quire sellers to be clairvoyant. When, a product is "*apparently* useful and desirable," (emphasis added), considering its benefits and risks, then it ought to be immune from strict liability. Such products can include new or experimental drugs for which "there can be no assurance of safety." Comment k only requires that the balance "*apparently*" tip toward the benefit of a product at the time of distribution. *Accord,* Schwartz, *supra,* 42 Wash. & Lee L.Rev. at 1144. No strict liability attaches if, contrary to the best available information, the risk later proves greater. In this manner, comment k removes a disincentive to "the development of *new* drugs that have the potential for conquering disease." *Id.* (emphasis original).

It follows that when the balance appears at the time of distribution to tip toward the benefit of a product, strict liability will not attach when an unexpected and unknown risk injures a user. *Id.* (see cases cited therein); *see also 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); 3 L. Frumer and M. Friedman, *Products Liability* § 33.02[4] (1983). Taken out of context, comment k's reference to a "known but apparently reasonable risk" can be read to extend its coverage to only known risks. *See Belle Bonfils, supra,* 665 P.2d at 123. However, by specifically including new and experimental drugs for which "there can be no assurance of safety," and other products whose benefits appear to outweigh their risks at the time of distribution, comment k clearly intends to guard against strict liability resulting from unknown risks as well as known risks. When comment k then refers to "a known but apparently reasonable risk," it refers not to specific side-effects or other hazards known at the time of distribution, but rather to what is known to be the over-all risk of the product, perhaps including the possibility of unknown side-effects or other hazards in addition to those already known. *Accord,* Schwartz, *supra,* 42 Wash. & Lee L.Rev. at 1144–45 (see cases cited therein); 3 Frumer and Friedman, *supra,* § 33.02[4]. Commentator Schwartz aptly observed:

> [A]s a practical matter, there is little difference in the terms of actual harm between a risk that was "apparently reasonable" and turned out not to be (for example, risk of slight impairment of vision was known but *blindness* resulted) and a totally unknowable risk. To differentiate between the known risk that turns out to be more serious and a totally new risk, which may indeed be a minor risk, does not square with the policy underlying comment k or for that matter with common sense. The only reasonable conclusion is that comment k includes products which contain risks that were not knowable at the time of manufacture. Schwartz, *supra,* 42 Wash. & Lee L.Rev. at 1145 (emphasis original).

While sellers need not be clairvoyant, they are held to the knowledge and experience of experts in their fields. *Feldman, supra,* 479 A.2d at 386–87; *Belle Bonfils, supra,* 665 P.2d at 126. Knowledge of the product's risks based on reliable and obtainable information is imputed to the seller. *Id.* Thus, the balancing between benefits and risks is based on the best available information at the time of distribution, not merely the information known to the seller.

Where the balancing results in the application of comment k's immunity from strict liability, the immunity is not perpetual. If new information later tips the balance toward the risk of a product, or if new developments make possible a safer design, at that point further distributions of the product are not protected by comment k. Says Schwartz: "The public policy of encouraging the production of new and hopefully efficacious drugs is not compromised by imposing a reasonable standard on manufacturers to be responsible for new developments and risks in drugs they have marketed." Schwartz, *supra,* 42 Wash. & Lee L.Rev. at 1147.

Finally, the seller has the burden to establish the application of comment k. *Belle Bonfils, supra,* 665 P.2d at 122–23.

Thus, comment k is an affirmative defense to a claim based on strict liability.

To summarize, comment k immunizes certain products from strict liability claims based on an alleged defective design, though not from strict liability claims based on alleged defective manufacture or inadequate warning. The products comment k shields cannot be designed to be more safe at the time of distribution, but bestow benefits which clearly appear at the time of distribution to outweigh their concomitant risks. This seems to us to be a sensible system. It also serves important policy considerations, particularly in the area of ethical drug manufacture. Commentator Schwartz puts it simply: "Society wishes to encourage the manufacture of ethical drugs, and the research and development of new drugs. The imposition of strict liability would stifle these goals." Schwartz, *supra,* 42 Wash. & Lee L.Rev. at 1141. As the citations within our discussion above evince, comment k has been widely adopted. *See also* Restatement (Second) of Torts § 402A comment k Appendices; *but see Collins v. Eli Lilly Co.,* 116 Wis.2d 166, 342 N.W.2d 37, 52 (1984) (Rejects comment k as "too restrictive and, therefore, not commensurate with strict products liability law in Wisconsin."). We hold that comment k applies to strict liability claims based on an alleged defective design of a product, where that product qualifies under the comment k test as set out above.

[redacted] We do not believe comment k was intended to provide nor should it provide all ethical drugs with blanket immunity from strict liability design defect claims. The comment refers to *"some"* products which are unavoidably unsafe; the comment states such products are "especially *common* in the field of drugs;" the comment cites certain examples from that field deserving of its protection and notes that "[t]he same is true of *many* other drugs, vaccines, and the like ... [and] of *many* new or experimental drugs...." (Emphasis added.) Obviously, the comment does not apply to *all* drugs. Rather, the comment applies "when the situation calls for it," which is when the product is unavoidably unsafe, but is "an apparently useful and desirable product, attended with a known but apparently reasonable risk," or with an unknown risk which was not yet reasonably discoverable at the time of marketing. It is equally obvious that not all drugs are so perfectly designed that they cannot be made more pure or more safe, or that there are not safer, suitable alternatives; nor do the benefits of all drugs necessarily outweigh their risks. *Brochu, supra,* 642 F.2d at 655; *Singer, supra,* 461 F.2d at 290–91; *Flood v. Wyeth Laboratories, Inc.,* 183 Cal.App.3d 1272, 228 Cal. Rptr. 700, 702–03 ([Div. 5] 1986); *Kearl, supra,* 218 Cal.Rptr. 463–64; *Feldman, supra,* 479 A.2d at 380, 383; Schwartz, *supra,* Wash. & Lee L.Rev. at 1141.

[redacted] In this case, as previously explained, we need not determine whether or not the vaccine at issue qualifies for comment k protection. In any event, it is not for a court sitting on appeal to make such a determination.[8] The determination would require a full evidentiary hearing such as only a trial court can provide. *Flood, supra,* 228 Cal.Rptr. at 703 (involved DPT vaccine); *Kearle, supra,* 218 Cal.Rptr. at 463; *Feldman, supra,* 479 A.2d at 383–84.[9] Like the *Kearl* court,

8. The issue of whether the application of comment k is a question of pure law upon which a court on appeal may pass, or of mixed law and fact requiring a full evidentiary hearing, clearly is substantive in nature.

9. The instant case does not present this issue of whether the judge or the jury ought to determine the application of comment k to a particular product. Some courts and commentators, emphasizing the factual determinations necessary, leave it to the jury. *Ortho Pharmaceutical Corp. v. Heath,* 722 P.2d 410, 416 (Colo.1986); Willig, *supra,* 29 Mercer L.Rev. at 579; W. Prosser, *The Law of Torts* § 99, p. 662 (4th ed. 1971) ("When any evidence can be produced that [the risk] might have been avoided, [strict liability] becomes a question for the jury, and may lead to liability." (Footnote omitted.)) Others, concerned with the policy implications of the decision, would have the court decide comment k's application as a matter of law. *Johnson v. American Cyanamid Co.,* 239 Kan. 279, 718 P.2d

> we are uncomfortable with the rather routine and mechanical fashion by which many appellate courts have concluded that certain products, particularly drugs, are entitled to such special treatment. Indeed, "[t]he statement that drugs are unavoidably [dangerous], and therefore within the protection of Comment k, has become almost tautological." (Comment, *supra,* 31 DePaul L.Rev. at 254.) 218 Cal.Rptr. at 463.

Courts must decide the applicability of comment k case-by-case, and only after taking evidence related to the various factors discussed above. *Id.* at 463–64; *Feldman, supra,* 479 A.2d at 383.[10] Courts on appeal may review the finding below; "it is not [their] proper role, however, to assume or take judicial notice of facts sufficient to support such a finding." *Kearl, supra,* 218 Cal.Rptr. at 464.

IV. QUESTION NO. 2(a)

Question 2(a) asks: Under Idaho law, do the principles set forth in Restatement (Second) of Torts § 402A comment k (1965) apply to negligence claims, and in particular to the claim in this suit?

In a literal sense, comment k, when applicable, quite clearly does not act as a bar to negligence claims. By its own terms, the comment only bars claims that the product's design was "defective" and "*unreasonably* dangerous" (emphasis original)—in other words, strict liability claims. The comment expressly states that the seller of "unavoidably unsafe" products "is not to be held to strict liability for unfortunate consequences attending their use...." The authorities universally agree that where a product is deemed unavoidably unsafe, the plaintiff is deprived of the ad-

1318, 1323–24 (1986); Schwartz, *supra,* 42 Wash. & Lee L.Rev. at 1147–48; Wade, *supra,* 44 Miss.L.J. at 838, 844.

Either way, the decision of the applicability of comment k pertains only to claims based on defective design, and not to those based on defective manufacture or inadequate warning. The latter two raise questions of fact to be decided by the jury. *Sliman, supra,* 112 Idaho at 281, 731 P.2d at 1271 (on adequacy of warning); *Farmer v. International Harvester Co.,* 97 Idaho 742, 748–49, 553 P.2d 1306, 1312–13 (1976) (on defective manufacture).

10. The criticisms of this aspect of *Kearl* to be found in *Brown v. Superior Court,* 182 Cal. App.3d 1125, 227 Cal.Rptr. 768 (1st Dist. [Div. 3] 1986), *review pending,* are singularly unpersuasive. The *Brown* court's own approach is unclear, but it appears to advocate blanket immunity from strict liability for all prescription drugs rather than require any showing that comment k applies. *Id.* at 772, 774. As we explained above, such a rule runs counter both to the express language of comment k and to common sense. *Brown* provides no explanation for granting such immunity to all drugs.

The *Brown* court faults *Kearl* for leaving the questions related to comment k's applicability to the judge when "a trier of fact could determine the existence of risks and benefits." *Id.* at 774. This is an argument for the jury to make the determination, not for a court on appeal to arbitrarily declare all prescription drugs "unavoidably unsafe" as defined in comment k.

The *Brown* court asserts that "[t]he *Kearl* court failed to articulate standards for how these interests [which *Kearl* found relevant to whether comment k ought to apply] would be balanced by the trial court." *Id.* To the contrary, *Kearl* carefully defines the elements of its three-part test, particularly the requirements that a risk be "substantial" and "unavoidable" in order to guide the trial court's assessment of whether "the interest in availability ... outweighs the interest in promoting enhanced accountability through strict liability." *Kearl, supra,* 218 Cal.Rptr. at 464. It is at least inadvisable if not impossible to provide some exact standard for comparing risks and benefits; nevertheless, it is far better to pose the correct questions raised by comment k itself, as does *Kearl,* than to merely attach indiscriminant and *carte blanche* immunity to all drugs as *Brown* seems to do.

Brown decries the possibility of trial courts inconsistently applying comment k to the same drug. In the process, *Brown* ignores its own observation that "at the review stage the appellate courts would harmonize the cases and establish legal guidelines satisfying the *Kearl* objective." 227 Cal.Rptr. at 775.

Finally, in contradiction to its earlier intimations that all prescription drugs ought to be immune from strict liability claims based on defective design, the *Brown* court appears to advocate "appellate courts [rather than trial courts] ruling as a matter of law that particular drugs are immune...." *Id.* at 775. *Brown* fails to explain, nor can we imagine, just how an appellate court would make such a determination without hearing evidence and without a record developed below. *Kearl* correctly notes, "it is not our proper role ... to assume or take judicial notice of facts sufficient to support such a finding." *Kearl, supra,* 218 Cal.Rptr. at 464.

vantage of a strict liability cause of action, but may proceed under a negligence cause of action. *E.g., Johnson v. American Cyanamid Co.*, 239 Kan. 279, 718 P.2d 1318, 1319 (1986); *Kearl, supra*, 218 Cal. Rptr. at 465; *Feldman, supra*, 479 A.2d at 381; *Stone v. Smith, Kline & French Laboratories*, 447 So.2d 1301, 1303 (Ala.1984); Schwartz, *supra*, 42 Wash. & Lee L.Rev. at 1139–41; 3 Frumer and Friedman, *supra*, § 33.02[4], p. 328; Prosser, *supra*, § 99, p. 661.

By denying plaintiffs recovery based on the dangerousness of the product and requiring plaintiffs to prove negligent conduct on the part of the defendants, comment k furthers the policy of encouraging the production and marketing of useful products. Schwartz, *supra*, 42 Wash. & Lee L.Rev. at 1144. However, to immunize sellers of products deemed unavoidably unsafe pursuant to comment k from negligence claims would remove needed incentive for safe design. *Id.* at 1141; 3 Frumer and Friedman, *supra*, § 33.02[4], p. 328.2. In the process of arguing that comment k covers unknown as well as known risks, Schwartz illustrates the balance comment k achieves between encouraging development and promoting safety—a balance which would topple were there no action in negligence:

> Applying comment k to drugs that contain risks that were unknown at the time of manufacture simply keeps these drugs within the ambit of negligence law. Under negligence law, the pharmaceutical company is held to the very *highest* of standards. The pharmaceutical company must act as a reasonable person would have acted in the same or similar circumstances. The circumstances in which pharmaceutical manufacturers must deal directly involve severe risks to human life. Thus, their standard of care is not the "reasonableness" of a person who repairs a television set or drives a car—it is the most serious and intense obligation that one can find in the entire body of negligence law. To go beyond this, and require manufacturers to be responsible for the unknown (that is, to impose absolute or strict liability), flies in the face of the overall policy underlying the section. Schwartz, *supra*, 42 Wash. & Lee L.Rev. at 1144–45 (emphasis original) (footnotes omitted).

Professor Willig aptly concludes:

> If plaintiff cannot adduce evidence to prove that the product was defective, improperly prepared or unaccompanied by proper direction and warning, § 402A should not be available; but unlikely as it might sound, plaintiff should not be precluded in essaying a cause of action in negligence. *Willig, supra*, 29 Mercer L.Rev. at 546 (footnote omitted).

Thus, when comment k applies, the plaintiff still may allege negligence. Further, even if the application of comment k is a question for the judge (*see supra*, n. 7), the determination of negligence remains for the jury.[11]

In a general sense, however, the comment k concerns and its required balancing between risks and benefits are similar to those involved in a negligence claim. As the Restatement notes, for an act to be unreasonable and thus a breach of duty under negligence analysis, the risk must be "of such magnitude as to outweigh what the law regards as the utility of the act or of the particular manner in which it is done." Restatement (Second) of Torts § 291 (1965); *see also Brizendine v. Nampa-Meridian Irrigation Dist.*, 97 Idaho 580, 586, 548 P.2d 80, 86 (1976) (" '[I]n negligence cases, the duty is always the same, to conform to the legal standard of reasonable conduct in the light of the apparent risk.' " *Quoting* Prosser, *supra*, § 53, p. 324); *United States v. Carroll Towing Co.*, 159 F.2d 169, 173 (2d Cir. 1947). Comment k requires a similar weighing. Under negligence analysis, the utility of the act depends upon the value of

11. By this, we mean the determination of whether there has been a breach of duty. As shown, *infra*, balancing risk against utility tests whether the conduct was unreasonable and thus a breach of duty. *See* W. Prosser, *The Law of Torts* §§ 31 and 37, pp. 148–49 (4th ed. 1971).

the interest advanced, the extent to which it is advanced, and the opportunity for a less dangerous course of conduct, Restatement (Second) of Torts § 292 (1965), just as comment k's application depends on the value of the product's benefit, the extent to which the benefit accrues, and the availability of a feasible alternative design. The risks too are similarly considered by comment k and negligence law. *See* Restatement (Second) of Torts § 293 (1965). Such a weighing is implicit in the duty to use due care to avoid injuries while rendering services. *Stephens v. Stearns*, 106 Idaho 249, 257, 678 P.2d 41, 49 (1984). In sum, the determination under comment k that the design of a product is unavoidably unsafe and yet affords benefits outweighing its risks varies little from the determination under negligence law that the designing and marketing of the product was reasonably done. *Cf. Feldman, supra*, 479 A.2d at 385–86 (" 'Since proper design is a 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)."); Willig, *supra*, 29 Mercer L.Rev. at 545 ("In terms of negligence liability, an unavoidably unsafe product with high benefit potential certainly may overcome an argument that its sponsor is derelict in duty, provided that its design or formulation, its instructions as to use, and its warnings as to dangers are reflective of the present state of human skill, knowledge and maker expertise."); Wade, *supra*, 44 Miss.L.J. at 841 ("There is little difference here [in cases of improper design] between the negligence action and the action for strict liability." (Footnote omitted.)).

[redacted] We conclude that the principles of comment k do not literally apply to negligence claims. More specifically, comment k does not shield sellers of products from negligence claims. On the other hand, in a general sense, the principles of comment k relate to the negligence concepts as expressed in Restatement §§ 291–93. However, the question of negligence remains for the jury to decide.[12]

V. QUESTION 2(b)

[redacted] In answer to question 2(b), we hold that the jury instructions on negligence, particularly Jury Instruction No. 27, quoted *supra*, p. 6, adequately incorporated many though not all the principles common to comment k and negligence law as discussed above.[13] Like comment k, In-

12. Lederle and *amicus* argue that FDA certification ought to constitute non-negligence *per se*, even though to our knowledge Lederle did not request an instruction to that effect. The weight of authority and reason dictate otherwise. FDA certification represents only the FDA's opinion, albeit an informed one, of the safety and efficacy of the drug. Regrettably, drugs occasionally prove not so safe as the FDA first believed. *See, e.g., Singer, supra*, 461 F.2d at 290–91 (Certified drug Aralen proves to cause blindness.); *Feldman, supra*, 479 A.2d at 378–79, 392 (Studies showed tetracycline stained teeth well in advance of FDA action to require warnings.); *Cudmore v. Richardson-Merrell, Inc.*, 398 S.W.2d 640 (Tex.1965), *cert. denied*, 385 U.S. 1003, 87 S.Ct. 705, 17 L.Ed.2d 542 (1967) (Certified drug MER–29 proves to cause cataracts.). Despite the FDA's best efforts, negligently designed drugs may and apparently do sometimes reach the market. Nothing in federal statutory or regulatory law indicates that FDA certification intends to preclude allegations of negligence in these cases. *See MacDonald v. Ortho Pharmaceutical Corp.*, 394 Mass. 131, 475 N.E.2d 65, 70–71 (1985); *Michael v. Warner/Chilcott*, 91 N.M. 651, 579 P.2d 183, 186 (App.1978). We hold that FDA certification of a drug is evidence but not conclusive evidence of the drug manufacturer's reasonableness; the trier of fact may assign FDA approval the weight it deserves. *Accord, e.g., id.; Brochu, supra*, 642 F.2d at 658 (*see also* cases cited therein); *Feldman, supra*, 479 A.2d at 383; *Barson v. E.R. Squibb & Sons, Inc.*, 682 P.2d 832, 836 (Utah 1984); *Ferrigno v. Eli Lilly & Co.*, 175 N.J.Super. 551, 420 A.2d 1305, 1320 (1980); *McEwen v. Ortho Pharmaceutical Corp.*, 270 Or. 375, 528 P.2d 522, 534–35 (1974); *Stevens v. Parke Davis & Co.*, 9 Cal.3d 51, 107 Cal.Rptr. 45, 507 P.2d 653, 661 (1973); Willig, *supra*, 29 Mercer L.Rev. at 558, 563; Restatement (Second) of Torts § 288C (1965).

13. We fail to see grounds for Lederle to appeal from these instructions, since Lederle itself requested Jury Instruction No. 27, and did not request an instruction directly applying comment k to Toner's negligence claim. Nevertheless, we will assume the Court of Appeals had reason to pose the question concerning negli-

struction No. 27 imposed on Lederle not the requirement of clairvoyance, but only the duty to act reasonably given "the foreseeable risk of harm to potential users in light of then current scientific or medical knowledge and discoveries." While the instruction did not explicitly establish a balancing between utility and risk, as we noted earlier, such a balancing is implicit in the instruction's requirement that the manufacturer "exercise ordinary and reasonable care not to expose the potential consumer to an unreasonable risk of harm from the use of its products." *See Stephens, supra,* 106 Idaho at 257, 678 P.2d at 49. Certainly the following admonition invited the jury to consider the benefits of the vaccine as well as its risks: "The failure to meet this standard of due care [not to expose the potential consumer to an unreasonable risk of harm] *in the light of all the attendant circumstances* will constitute negligence...." R., Vol. II, p. 90 (Jury Instruction No. 27) (emphasis added). Further, the instruction clearly indicated that the fact the vaccine caused Kevin's injury by itself did not justify a finding of negligence: "The fact that the consumer's injuries were proximately caused by the manufacturer's product does not in and of itself constitute a sufficient basis upon which to predicate the manufacturer's liability." *Id.* Thus instructed, the jury undoubtedly considered the state of scientific knowledge and the utility of the vaccine before assigning negligence. Apparently, the jury was convinced that Lederle was negligent for having manufactured and marketed the whole cell vaccine instead of a safer alternative. However, the negligence principles common to comment k and Restatement (Second) of Torts §§ 291–93 (1965) could have been stated more explicitly. Had Lederle requested an instruction based on Restatement (Second) of Torts §§ 291–93, such an instruction would have accurately reflected Idaho law.

gence instructions. Of course, it is for the Court of Appeals to decide whether Lederle had grounds to appeal from the instructions.

VI. CONCLUSION

We have answered the certified questions in accordance with Idaho law and with well established precepts of strict liability and negligence law. Our answers in part may disappoint Lederle and *amicus* Pharmaceutical Manufacturers Association. Both sought total immunity from both strict liability and negligence claims for sellers of drugs so long as those drugs satisfied the requirements of the FDA and comment k. Their arguments were based less on legal authority than on policy considerations. Even without the record before us, we are aware of society's critical need for the DPT vaccine. No doubt liability flowing from the occasional injuries inflicted by the vaccine acts as a disincentive to its manufacture. However, this Court is not equipped to decide as a matter of public health policy that the relative efficacy and safety of the whole cell vaccine is so well established and the plight of Lederle so dire that injured persons such as Kevin Toner should be denied any recourse. Faced with similar supplications, the California Court of Appeals, Second District, Division 5, observed:

> Wyeth is not alone in predicting that a DPT vaccine shortage will be caused by the suits brought against the manufacturers, because production will become unprofitable. (See Horn, *Vaccine Crisis Spurs Bills in Congress* (Summer 1985) 10 Litigation News 5.) If this should occur, we would expect the Legislature to intervene to prevent the resulting health crisis. This is a legislative function. *Flood, supra,* 228 Cal.Rptr. at 703.

The *Flood* court's expectation was not unrealistic. At the time of this writing, the United States Congress has passed and the President has signed a bill "that would establish a federal 'no fault' compensation program for children injured as a result of routine, required vaccinations...." *The Idaho Statesman,* October 15, 1986. This approach radically revises tort law in order

to simultaneously protect the interests of society, the drug industry, and innocent victims of the rare but catastrophic severe reactions. It is an approach quite within the capacity of the legislative branch of government, but quite beyond the capacity of the judicial branch.

Remanded to the Court of Appeals.

DONALDSON and HUNTLEY, JJ., concur.

HUNTLEY, Justice, concurring specially.

I concur in the majority opinion and write further to address two points.

POINT I: All who read this opinion and that of the 9th Circuit at 779 F.2d 1429, should be aware that Lederle and the Amicus Curiae Pharmaceutical Manufacturers Association, in seeking to engraft comment k into negligence law, are proposing something far more revolutionary in its effect than most would realize.

They seek by the device of engrafting comment k into negligence law to actually abolish negligence causes of action in this field and substitute the Food and Drug Administration for the jury.

The parties and Amicus were all in agreement in their presentations to this Court that not one state as yet has ruled that comment k applies to negligence causes of action.

Perhaps the reason that no state has done so is that no state supreme court has yet become convinced that the FDA has either adequate staffing, expertise, or data base to warrant its being substituted for the judicial system.

The full implications of the Pharmaceutical Manufacturers proposal can be more fully realized upon consideration of the partial transcript of the oral argument before this Court of attorney Robert Koontz, arguing for Lederle, attached hereto as Appendix A and the entire transcript of attorney Malcolm Wheeler, arguing for the Pharmaceutical Manufacturers Association, attached hereto as Appendix B.

I fear the day when any supreme court can be convinced that an agency such as the FDA, no matter how well-intentioned, can supplant the American judicial system.

POINT II: There are two statements in the 9th Circuit opinion which trouble me as running counter to FDA procedures as I understand them:

> Lilly sold the right to produce Tri-Solgen to Wyeth Laboratories; however, the FDA has refused to relicense the vaccine.
>
> ....
>
> However, in 1972, a review panel within the Bureau of Biologics of the FDA refused to certify Tri-Solgen as "safe and effective" although it did so certify the whole cell vaccines. Because the FDA has refused to relicense Tri-Solgen or any other fractionated cell product, the manufacture and sale of such a vaccine by Lederle, or any other pharmaceutical company, would constitute a criminal offense under the Food, Drug and Cosmetic Act. *See* 21 U.S.C. §§ 331(d), 333(a), 355(a) (1982).

The foregoing statements seem to suggest that the fractionated vaccine Tri-Solgen is *disapproved* by the FDA.

It is my understanding that the FDA does not license a medication in a "vacuum." That is, a medication is licensed only to a specific manufacturer presenting a specific product which has undergone specific testing, with adequate data having been presented to the FDA. The FDA does not, for example, issue generalized approval for anyone who wishes to manufacture a specific medication.

Thus, the fact that a fractionated cell vaccine is not now licensed does not mean it is disapproved—it merely means either that no manufacturer has sought and obtained approval or that, in the instance of the 1972 refusal by a review panel of the Bureau of Biologics, the application therein failed to make an adequate showing of safety or efficacy, which is not to say that another manufacturer could not have made a successful application.

BAKES, Justice, specially concurring in part:

I concur in the result reached by the majority opinion and but for the somewhat equivocal means by which the majority reaches its result I would have fully concurred in its opinion. I write only to clarify the analysis of the issues, as I view them, raised by the questions presented by the Ninth Circuit's certificate to this Court.

I.

Questions Not Presented

First, given some of the language in the majority opinion, it is necessary to identify those issues which are not before this Court for its determination. I refer primarily to those issues concerning federal procedural law. It is at once clear that the Ninth Circuit desires only advice regarding matters of Idaho substantive law. Issues concerning procedure within the federal court system are necessarily for that court to determine. *Erie R.R. v. Tompkins,* 304 U.S. 64, 58 S.Ct. 817, 82 L.Ed. 1188 (1938). Thus, we are not required, nor would it be proper for us, to determine whether Lederle has waived its right to challenge Jury Instruction No. 27. Therefore, I do not join in that portion of the majority opinion which intimates an opinion on that issue; specifically, I do not join in the language found in footnote 13, *ante* at 342–343, 732 P.2d at 311–312. I likewise view the issue of whether the determination of the applicability of comment k to a given product is one of law or fact, and thus for the court or the jury to decide, is an issue for the federal court to decide. Certainly, the federal court has not requested us to give an opinion on that issue. Thus, it is not appropriate for this Court to say that "it is not for a court sitting on appeal to make such a determination." *Ante* at 339, 732 P.2d at 308. Consequently, I decline to join in language to the contrary found in the majority opinion. That language is pure *dicta* and in no way binding on the federal court.

Finally, no question is presented by the Ninth Circuit certificate which requires us to second-guess the jury's verdicts in this case. There is no need to engage in any presumptions as to the evidence adduced at trial or as to the findings of the jury. Therefore, I do not join in any of the majority's attempts at such presumptions.[1] The Ninth Circuit expressly stated that any questions regarding evidence adduced at trial or regarding the sufficiency of such evidence to support the jury verdicts are matters for its resolution. *Toner v. Lederle Laboratories,* 779 F.2d 1429, 1431 (9th Cir.1986). Rightly so; they are, again, matters of federal procedural law and not of substantive state law. If the Ninth Circuit has inaccurately characterized the facts in its opinion to us, as the majority attributes to counsel for Toner, *ante* at 332, 732 P.2d at 301, then the Ninth Circuit is the proper forum to determine such matters. Again, any presumptions made by the majority regarding what Toner proved and what the jury found are entirely unwarranted. They are not required in order to adequately address the questions presented.

II.

Questions Presented

The Ninth Circuit certified the following four questions to this Court pursuant to I.A.R. 12.1(a).

(1) Under Idaho law, do the principles set forth in *Restatement (Second) of Torts*

1. Specifically, I do not join in the majority's presumption that "the jury found that 'in light of all the attendant circumstances,' Lederle failed 'to exercise ordinary and reasonable care not to expose the potential consumer to an unreasonable risk of harm from the use of its products,' ... that 'the foreseeable risk of harm to potential users in light of then current scientific or medical knowledge and discoveries' was such that Lederle was negligent in failing to further test and investigate the propensities of its product' *relative to those of the allegedly safer product, ... and that as a result Lederle was negligent for having 'manufactured and/or marketed the whole cell vaccine' rather than the alternative." Ante* at 332, 732 P.2d at 301 (emphasis added). I specifically disagree with the majority's presumption regarding the underscored material in the above quote.

§ 402A comment k apply to strict liability and negligence claims, and in particular to the claims in this suit?

(2) If yes, is there evidence from which a jury could find Tri-Immunol unavoidably unsafe?

(3) Under Idaho law, could the jury, on this record, find the defendant negligent for failure to develop a fractionated cell vaccine, or for any other reason?

(4) Were the jury instructions on the issue of negligence in full accordance with Idaho law, given the contentions of the parties in this case?

As the majority opinion correctly states, we accepted certification of only two of the four questions, numbers (1) and (4).

Though phrased in terms regarding the applicability of comment k, it is clear that the Ninth Circuit desires to know the elements which must be established to state a cause of action in a products liability case under state substantive law. "[W]e must look to the substantive law of the State of Idaho to determine the elements of plaintiffs' cause of action." *Toner v. Lederle Laboratories,* 779 F.2d 1429, 1431 (9th Cir. 1986). Faced with a claim of inconsistent jury verdicts [2] which, as stated by the Ninth Circuit is a matter for their resolution, the Court of Appeals essentially desires that we (1) set forth the distinction between the elements of a products liability action based on strict liability and one based on negligence; (2) determine the applicability of the "unavoidably unsafe" doctrine of comment k of the Restatement (Second) of Torts, § 402A, to both strict liability and negligence actions; and then (3) indicate whether the jury instructions given in this case adequately set forth those elements. As stated by the Ninth Circuit, "The question whether the trial court instructed the jury in accordance with Idaho law necessarily precedes resolution of the inconsistency claim." *Id.* at 1434.

A.

Products Liability Based On Strict Liability in Tort

As noted by the majority opinion, this Court in *Shields v. Morton Chemical Co.,* 95 Idaho 674, 518 P.2d 857 (1974), "accepted the doctrine of strict liability in tort in products liability actions." *Id.* at 676, 518 P.2d at 859. The rule of strict liability we adopted was that set forth in the Restatement (Second) of Torts § 402A (1965). Under that rule a cause of action exists against a seller of a product if a plaintiff establishes that he suffered injury resulting from his proper use of the product which, though properly used, was "in a defective condition" such as rendered it "unreasonably dangerous" to the user or consumer.

The difficulty in applying the rule of strict liability set forth in § 402A usually surfaces in regard to the meaning to be given the phrase "in a defective condition unreasonably dangerous to the user or consumer." As the majority opinion notes, comment g to § 402A defines "defective condition" as "a condition not contemplated by the ultimate consumer, which will be unreasonably dangerous to him." Comment i defines "unreasonably dangerous" as a danger "beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics." In *Rojas v. Lindsay Mfg. Co.,* 108 Idaho 590, 701 P.2d 210 (1985), we approved the following definition of the phrase: "A product is in a defective condition unreasonably dangerous ... if it is more dangerous than would be expected by an ordinary person who may reasonably be

2. Lederle contends that the jury's answers to the following two questions on the special verdict form are inconsistent.

"*QUESTION NO. 2:* Was defendant Lederle Laboratories negligent in connection with the product Tri-Immunol which was the proximate cause of the plaintiff's injuries? Yes.

"*QUESTION NO. 3:* Was the product Tri-Immunol manufactured by the defendant Lederle Laboratories in a defective condition unreasonably dangerous to persons which was the proximate cause of the plaintiff's injuries? No." *Toner v. Lederle Laboratories, supra,* 779 F.2d at 1433.

expected to use it. * * * *i.e.*, for whose use it must be safely designed." *Id.* at 591, 592, 701 P.2d at 211.

The definition of "in a defective condition unreasonably dangerous to the user or consumer" also takes on somewhat different meanings depending on the context of the products liability cause of action, *i.e.*, whether the cause of action is premised on an alleged defect in the product's design, or in the product's manufacture (the design was not followed in the production phase), or in the product's warning concerning its known dangers. *See* W. Keeton, *Prosser and Keeton on The Law of Torts* § 99 (5th ed. 1984) (hereinafter *Prosser*). We need not fully discuss these different bases for strict liability and their concomitant definitions of "defective condition" since only the first is presented by this case. The heart of Toners' products liability claim is that a safer, more feasible alternative existed to Tri-Immunol. This claim relates solely to design defect.[3] As explained by the majority, comment k only applies, if at all, to design defect cases. *Ante* at 335, 732 P.2d at 304.

In a design defect products liability case, the effect of comment k is to modify the definition of when a product is "in a defective condition unreasonably dangerous" by stating that "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 * * *. Such a product, properly prepared, and accompanied by proper instructions and warning, *is not defective, nor is it unreasonably dangerous.*" Restatement § 402A (comment k). Thus, under comment k, if a product is "unavoidably unsafe," it is neither "defective" nor "unreasonably dangerous." Contrary to the majority opinion, comment k does not "immunize certain products from strict liability claims," *ante* at 339, 732 P.2d at 308, but merely defines which products are defective and unreasonably dangerous, and which are not. Thus, comment k clearly requires a utility-risk analysis, as the majority opinion concedes. The majority opinion acknowledges that comment k applies to actions for product liability based on strict liability in tort, although incorrectly describing the effect of comment k as resulting in an "immunity," rather than merely acknowledging that unavoidably unsafe products are neither defective nor unreasonably dangerous.

B.

Products Liability Based on Negligence

While this Court has addressed strict products liability several times, as noted by the Ninth Circuit, we have never been presented with a case requiring a determination of "the duty, or standard of care, applicable to the manufacturer of drugs that are unsafe in some respects but that are necessary for the control of disease." *Toner v. Lederle Laboratories, supra,* 779 F.2d at 1432. Thus, we have never addressed the question of whether a product which is socially desirable or necessary, even though "unavoidably unsafe," may expose the manufacturer of that product to a products liability action whether on the theory of strict liability or negligence. On such a negligence claim, or upon any negligence claim for that matter, we have indicated that there are certain basic "concepts fundamental to any negligence action: duty, breach, proximate cause and damages," *Blake v. Cruz,* 108 Idaho 253, 257, 698 P.2d 315, 319 (1985). Or, as more accurately stated by Chief Justice Donaldson in *Alegria v. Payonk,* 101 Idaho 617, 619 P.2d 135 (1980), cited by the Ninth Circuit Court of Appeals:

> "The elements of common law negligence have been summarized as (1) a duty, *recognized by law,* requiring a defendant to conform to a certain standard of conduct; (2) a breach of that duty; (3) a causal connection between the defendant's conduct and the resulting injuries;

3. As noted in the Ninth Circuit's opinion, Toners abandoned their allegations of defective warnings prior to submitting the case to the jury. *Toner v. Lederle Laboratories, supra,* 779 F.2d at 1430.

and (4) actual loss or damage." *Alegria v. Payonk,* 101 Idaho 617, 619, 619 P.2d 135, 137 (1980) (emphasis added).

The majority opinion fails to adequately analyze the present case under these "concepts fundamental to any negligence action." Instead the majority simply states "the determination of negligence remains for the jury." That statement is inadequate and to the extent it is inadequate, it is also misleading and incorrect.

The statement is correct only insofar as it applies to questions of fact. This Court has consistently held that if there is sufficient evidentiary support, all fact questions as to negligence are for the jury or trier of fact to decide. *O'Connor v. Meyer,* 66 Idaho 15, 154 P.2d 174 (1944). Questions of fact are usually raised in regard to elements (2), (3) and (4) above.[4] However, as both the quote and the holding in *Alegria* indicate, the question of "duty" is not for the jury, rather it is a question of law for the court to decide. Essentially, the question of the existence of a duty involves a legal determination that some relationship exists between the defendant and the plaintiff which gives rise to an obligation of conduct toward a particular person in the first instance. "[D]uty is a question of whether the defendant is under any obligation for the benefit of the particular plaintiff." *Prosser* at § 53. "[W]hether the interest of the plaintiff which has suffered invasion was entitled to legal protection at the hands of the defendant ... is entirely a question of law to be determined by reference to the body of statutes, rules, principles and precedents which make up the law; and it must be determined only by the court." *Id.* at § 37. The court is required to determine if, under the facts of a given case a duty is owed by defendant to plaintiff *and,* also, to determine the scope or extent of that duty.

"The existence of 'duty' is a question of law. (Citations omitted) 'Legal duties are not discoverable facts of nature, but merely conclusory expressions that, in cases of a particular type, liability should be imposed for damage.' *Tarasoff v. Regents of University of California,* [17 Cal.3d 425, 131 Cal.Rptr. 14, 551 P.2d 334 (Cal.1976).]" *Thompson v. County of Alameda,* 27 Cal.3d 741, 167 Cal.Rptr. 70, 614 P.2d 728, 732 (1980).

Furthermore, a determination of the existence of a duty in a particular case involves consideration of several factors, including:

" 'the foreseeability of harm to the plaintiff, the degree of certainity that the plaintiff suffered injury, the closeness of the connection between the defendant's conduct and the injury suffered, the moral blame attached to the defendant's conduct, the policy of preventing future harm, the extent of the burden to the defendant and the consequences to the community of imposing a duty to exercise care with resulting liability for breach, and the availability, cost, and prevalence of insurance for the risk involved.' " *Thompson v. County of Alameda,* 27 Cal.3d 741, 167 Cal.Rptr. 70, 614 P.2d 728, 732–33 (1980) *quoting Rowland v. Christian,* 69 Cal.2d 108, 70 Cal.Rptr. 97, 443 P.2d 561, 564 (1968).

The analysis is the same in a products liability case. The question of duty involves a consideration or balancing of all of the above factors. "It is no part of the province of a jury to decide whether the manufacturer of goods is under any obligation for the safety of the ultimate consumer." *Prosser* at § 37.

As indicated in the majority opinion this balancing of risk versus utility in a negligence case is the same as that required in a strict liability case where comment k is deemed applicable. There is little difference between a products liability action in negligence and one in strict liability relating to the definition of the unsafe character of the product which allegedly causes the

4. To the extent the majority opinion uses the term "negligence" to mean conduct contrary to that required by the duty owed by defendant to plaintiff, the term "negligent" essentially refers to element (2), *i.e.,* breach of duty. In such a context the assertion in the majority opinion that the determination of negligence is for the jury is correct since whether a defendant has breached his duty of care is a question of fact, not of law.

injury. In negligence law, and as the jury was instructed in Instruction 27 in this case, the product must not "expose the potential consumer to an unreasonable risk of harm." In strict liability, the product must not be in a "condition unreasonably dangerous to the user." The determination in negligence law of whether the product presents an "unreasonable risk of harm" to the consumer is really no different from the determination in strict liability law that a product is "unreasonably dangerous" to the consumer. The majority opinion acknowledges this, stating that there is, in reality, "little difference here [in cases of improper design] between the negligence action and the action based on strict liability." [5] *Ante* at 342, 732 P.2d at 311, *citing* W. Prosser, Law of Torts, 659, n. 72 (4th ed. 1971), *and quoting* Wade, On the Nature of Strict Tort Liability for Products, 44 Miss.L.J. 825, 841 (1973).

Since there is little or no difference between the negligence test of "unreasonable risk of harm" and the strict liability test of "unreasonably dangerous to the consumer," Comment k and its rationale applies to both products liability actions based on strict liability and those based on negligence. By definition, a product which is "unavoidably unsafe" is neither "unreasonably dangerous to the consumer" (the strict liability standard) nor does it create an "unreasonable risk of harm" to the consumer (the negligence standard).

Nevertheless, the majority states, *ante* at 342, 732 P.2d at 311. "We conclude that the principles of comment k do not literally apply to negligence claims. More specifically, comment k does not shield sellers of products from negligence claims." That statement exposes a misconception prevalent throughout the majority opinion that comment k "immunizes certain products from strict liability claims ...," *ante* at 339, 732 P.2d at 308, and that "if a product qualifies as 'unavoidably unsafe,' [under comment k] the seller is held not to the strict liability standard but only to the standard of negligence." *Ante* at 336, 732 P.2d at 305. Comment k is not an "immunity" or a "shield." Comment k merely limits the definition of defective products under Section 402A, excluding "unavoidably unsafe products" as being "not defective, nor ... unreasonably dangerous." Therefore, the semantical distractions of "immunity" and "shields" employed in the majority opinion tend to confuse rather than enlighten its products liability analysis. Those terms distract the reader's attention from the fact that whether a particular products liability claim is phrased in terms of negligence or strict liability, there must either be a product which exposes the potential consumer to an "unreasonable risk of harm" (Negligence Instruction 27), or a product which is "unreasonably dangerous" Restatement (Second) § 402A. There is "little difference." between those two standards, as the majority opinion acknowledges. *Ante* at 342, 732 P.2d at 311.

C.

The Jury Instructions

Having hopefully helped explain the Court's decision regarding the elements of a cause of action for products liability based on strict liability and negligence, and the distinction between the two causes of action, the third question presented by the Ninth Circuit was whether the jury instructions given in this case adequately state the law in Idaho regarding a products liability action based on negligence. The majority's treatment of this issue is inadequate due in large part to its concern that Lederle should not be permitted to raise the issue. However, as noted earlier, any question regarding Lederle's ability to challenge the jury instructions is purely a question of federal law and not for this Court to decide. The question before this Court is not whether the *proposed* jury instructions ad-

5. This conclusion reached by the majority opinion in Part IV negates the seemingly contrary assertion contained in footnote 6, *ante* at 336, 732 P.2d at 305. That footnote states, "In the next section, we will discuss further our conclusion that comment k immunity extends ... only to strict liability claims, and not to negligence claims."

equately express Idaho law, but whether the instructions actually given by the trial court do.

The majority opinion correctly holds, though in a very equivocal manner, that the instructions given are *not* adequate statements of Idaho law on negligence given the facts as related by the Court of Appeals and the contentions of the parties in the present case. The instructions are entirely devoid of any reference to comment k's "unavoidably unsafe" standard or the requirement that the jury engage in a comment k risk *versus* utility balancing test. The majority asserts that the instructions implicitly required the jury to engage in such a balancing test. *Ante* at 342, 732 P.2d at 311. However, the majority opinion earlier concludes just the opposite, *ante* at 333, 732 P.2d at 302, when it states that, *"Nothing in the record before us indicates that either the jury or trial court made any determination based on comment k."* Given that statement, I fail to see on what basis the majority opinion then asserts that "a balancing between utility and risk ... is implicit in [Jury Instruction No. 27]." *Ante* at 343, 732 P.2d at 312. Furthermore, the majority's assertion that "the jury undoubtedly considered the state of scientific knowledge and the utility of the vaccine before assigning negligence," *ante* at 343, 732 P.2d at 312, is mere speculation at best.

Even assuming, *arguendo*, that the comment k test was implicit in the jury instructions and that the jury did in fact consider the utility of the vaccine and the state of scientific knowledge before assigning negligence, it is entirely inconsistent for the majority to then conclude, based on the jury's verdicts, "that Lederle was negligent for having manufactured and marketed the whole cell vaccine instead of a safer alternative." *Ante* at 343, 732 P.2d at 312. Such a conclusion is directly contrary to the jury's verdict that Tri-Immunol was not "in a defective condition unreasonably dangerous" to the consumer. In short, if the majority's assertion that neither the parties nor the trial court addressed comment k is true, then it is clear beyond cavil that the jury instructions did not adequately state the law of Idaho regarding negligence in a products liability case.

Conclusion

In conclusion, while the answers set out in the majority opinion to the two certified questions are less than clear, I believe the Court's opinion can ultimately be distilled down to the following responses.

As to question one, whether or not comment k applies to both strict liability and negligence claims in products liability actions, the answer is yes. The predicate for a products liability claim, whether based on negligence or strict liability, is a product which is "unreasonably dangerous," or which creates an "unreasonable risk of harm." Since there is little or no difference between those two standards, an "unavoidably unsafe" product whose utility outweighs the risk created by its use is by definition not "unreasonably dangerous" nor does it create an "unreasonable risk of harm."

As to the second question certified and accepted by this Court, *i.e.*, whether the jury instructions on the issue of negligence were in full accordance with Idaho law given the contention of the parties in this case, the Court's answer is an apparent no. The court's instructions did not instruct the jury regarding comment k's "unavoidably unsafe" standard and the risk *versus* utility balancing test contained therein.

What effect the answers to the certified questions have on the disposition of this case is a matter entirely for the federal courts to determine.

SHEPARD, C.J., concurs.

SHEPARD, Chief Justice, specially concurring in part:

I view the holding of the majority to be that comment k applies to negligence claims as well as claims based in strict liability. I draw that conclusion from the language of the majority:

> [W]e conclude that the principles of comment k do not literally apply to negligence claims. More specifically, comment k does not shield sellers of products from negligence claims. On the other hand, in a general sense, the *principles of comment k relate to the negligence concepts* as expressed in Restatement §§ 291–93. (emphasis added)

As to the remainder of the opinion, I concur in the special concurrence of BAKES, J.

APPENDIX A

Partial Oral Argument of Mr. Koontz for Lederle Laboratories

JUSTICE HUNTLEY: Now, Mr. Koontz, for the reasons you and Justice Bakes have just discussed, I have to admit that as I read through the briefs my first inclination was that perhaps it would be desirable to engraft comment k on the negligence law, because we do need these ethical drugs. But when I try to take it a step further and see what we're doing if we do it, and neither of you have gotten to it in the briefing, what is—what are you ultimately doing? Are you asking for us now—if we buy your program here, will we now in the future instruct the jury that a manufacturer may manufacture an unavoidably unsafe drug in a negligent and careless manner?

MR. KOONTZ: No.

JUSTICE HUNTLEY: What are—what do we have when we put comment k together with negligence? What will we tell the jury?

MR. KOONTZ: Well let—let me tell you, because, obviously, Justice Huntley I've —you know, thought about that long and hard. And you'll hear from the Pharmaceutical Manufacturers Association. And we—we talked about this in the 9th circuit. As a matter of fact the judge who had that case asked me almost that very—very same question. And I think with comment k this Court has the opportunity to engraft on comment k a rather limited exception. And that limited exception is this; that if medical science has only one product, i.e. the DPT vaccine, which is this case, there's no other licensed drug on the market. That given that set of circumstances, the Court as a matter of law must defer to the FDA, they must defer to the National Institute of Health, they must defer to the CDC and they must defer to the Bureau of Biologics in terms of study committees which are the people who make the policy for the United States.

JUSTICE HUNTLEY: Okay now. Okay, go ahead.

MR. KOONTZ: Let me just—I've only got ...

JUSTICE HUNTLEY: Go ahead, finish. I've got to follow up ...

MR. KOONTZ: ... I'm saying that there is—that you can engraft on comment k a rather limited exception with the one vaccine. Now I'm excluding from that (inaudible) out the Johnson case, because Johnson there are two (inaudible). And I'm saying here in this case with the DPT vaccine, if you want to do that. I prefer the pharmaceutical manufacturers position that if you—if you find a social mandate to give a drug that—and I'm not talking about cosmetic drugs or anything like that. I'm talking about cancer drugs, DPT vaccine, Reubella, those kinds of things. That if the FDA approves those drugs you should limit it to warning and you should limit it to efficacy of manufacture, that it was made appropriately.

JUSTICE HUNTLEY: Okay now. You've focused me very well, and that's why—and getting me right to the problem I'm having. You framed that that the narrow rule would be that if there is only one product then we defer to the F—we tell the jury we defer to the FDA.

MR. KOONTZ: I'm simply saying, Justice Huntley, if you want to do that.

JUSTICE HUNTLEY: Okay. Okay now, I'm going to take ...

MR. KOONTZ: If you want to really narrow the issue you can do it—you can do it that way.

JUSTICE HUNTLEY: I want to take you just one—one step at a time. Now, let's try that one. Now if we adopted that rule, you then would not foreclose a plaintiff from bringing a case saying there is a way to make another product and you're negligent in not doing it.

MR. KOONTZ: The answer to that is, Justice Huntley, that you give me the proposition in a products liability case and I'll find you an expert to testify to that fact. They're all trial lawyers and you'd—that's a fact of life in our business. I'll give you somebody who will say, you could have made a better product. Now I think comment k is saying, no, you can't—you can't do that because where does it put the manufacturer? Because I'll tell you the next case. The next case is when you let a jury in Idaho reallocate American Cyanamid resources in R & D. They're big in the chemotherapy area. They're big in the (inaudible) cancer research area. Is our next case a cancer victim who says, well you developed a cure in—in, you know, in 1989, but you should have done it in '86 because ...

JUSTICE HUNTLEY: Okay.

MR. KOONTZ: ... you didn't allocate your resources right.

JUSTICE HUNTLEY: The short answer then is—is you're saying then that the rule of law would go one step further and it would say that there is no way to—in the circumstance we just described, that a party can bring an action on the basis of negligence in that a different or better product could have been made.

MR. KOONTZ: That's right.

JUSTICE HUNTLEY: So you would foreclose that type of action.

MR. KOONTZ: That's what comment k says.

JUSTICE HUNTLEY: Okay.

MR. KOONTZ: And that's what Dean Prosser discusses in great detail when that—and you have to understand that comment k is a national public health policy.

JUSTICE HUNTLEY: I understand that ...

MR. KOONTZ: We're not talking about negligence or some—you know, a bunch of lawyers sitting around a table talking about strict liability and negligence. We're talking about a national public health policy.

JUSTICE HUNTLEY: Okay. I understand. I'm trying to have a conversation with you here so I can understand this. Now aren't we, if we applied comment k to this case and gave it the answer and the gloss that you've just discussed with me, don't we run into a little bit of a problem that, by definition the jury in having found for the plaintiff on negligence in this case has to have found that there was a better way to build this mouse trap?

MR. KOONTZ: Well, I've got a couple of responses to that. First of all, this case was—I'm not sure of the year. Maybe Ken can—Ken can correct me. The vaccine was given in 1979, and we all live in a real world. It's 1986 and we don't see Tri-solgen on the market today, and we don't see it in any country in the world. And what I'm saying is, Justice Huntley, that you cannot—and it's what the Johnson court said in determining that case on the Sabin vaccine....

JUSTICE HUNTLEY: Well then you're saying the jury was wrong in what it found.

MR. KOONTZ: Well, it isn't that the jury's wrong.

JUSTICE HUNTLEY: Well, they're either right or wrong.

MR. KOONTZ: I'm not arguing that—you know, that the jury is wrong, because—you know, I've tried lawsuits all my life, and you never say—you know, quote "juries are wrong." What I'm saying is, you don't submit that action to them. You can't have juries deciding what the—what the United States Public Health Service should do. I mean, you get into this interesting anomaly and I'd like you to consider it. If the 9th circuit—if—if you rule against us and say comment k doesn't apply, the instruc-

tions were okay, the verdict ought to stand as it is, where does that leave American Cyanamid? Where does it leave people who make vaccines, not just Cyanamid? What are we saying, in the 9th circuit we can't sell it, but we can sell it in the 10th circuit? You know, I think sometime you have to say that the feds have to control this type of vaccine, that you have to have professionals back there that say, we deem it—and you're talking about the American Pediatrics Society, the American Medical Association, the NRH, the CDC, everybody says, give this vaccine. What are we suppose to say now? You can't give it in Idaho?

JUSTICE HUNTLEY: Well, Mr. Koontz, you are in effect, I think on the bottom line here, virtually asking us to take this out of the jury system and defer to the FDA. Now ...

MR. KOONTZ: No. No, I'm not asking ...

JUSTICE HUNTLEY: You're not ...

MR. KOONTZ: No, and I think—and that's why I asked you to defer to the ... PMA amicus brief, to say—this is how—this is the history of comment k that started, you know, way back when. They're not talking necessarily about FDA approval. What they're saying is, if medical science can't develop anything any better, we're not going to let a lay jury sit here with some expert who comes from Kuna, Idaho, saying, Hey I can build a better mouse trap and they should have built it. That's what we're saying. It's a warning issue, and it's an improper manufacture issue.

JUSTICE HUNTLEY: Well, I'm genuinely trying to have this discussion with you to get the concepts clear in my mind as to what you're proposing and what the consequence of it is. I have to say that it seems to me where you've taken us is to the point of saying that in the case where there is at a present moment in history only one product on the market and it's unavoidably unsafe, we cannot have a jury question and should not submit to the jury the question of whether it was negligent to have produced that drug even if a plaintiff can establish that there was a way to manufacture a better and safer drug.

MR. KOONTZ: I think that's—that's accurate given the limitations of comment k, that it was manufactured in accordance with FDA, NIH, CDC or whatever standard you want to talk about. But it was not a defectively manufactured product in the sense that it wasn't what it was suppose to be when it was manufactured, and that there was proper warning given. Because every case, and this is interesting, every case. Mr. Pederson criticizes me because all I cited was warning cases. I look at his brief, all he cites are warning cases, because from Davis on, that's all you're talking about, are warning cases. You know, were the warnings proper to the learned intermediary. He's got to ultimately make the decision. Because I think you have to think, Justice Huntley, not in a sense just of this vaccine, but think about the new drugs that are coming out for—you know, for heart patients, the artificial heart. Are we now going to have a year from now somebody saying Debachy didn't do it right....

JUSTICE HUNTLEY: Well, there—there's a problem that we've all had experience with. The testing on these new drugs is usually done by the proponents who wish to market them or their independent labs. And we know of case after case in history where the data they have submitted to the FDA was incorrect.

MR. KOONTZ: Oh, Judge—I mean, Justice Huntley, that's a separate exception in comment k, the fraud exception. I mean, if American Cyanamid produces a drug—if the DPT vaccine, if they had erroneous information, the FDA, I don't have any problem in saying that's a jury issue, back there. If they submitted erroneous information, the FDA stick 'em. I don't have any problem with that at all. I mean, those are questions where there was fraud involved, and I'm sure if fraud is not too strong a term, but I'll ... accept what you said.

JUSTICE HUNTLEY: I didn't say fraud. I said inadequate testing ...

MR. KOONTZ: Well you and I are talking about the same thing. You're talking about hoodwinking the government in terms of what happens with a drug that you want to license. Now, that's not the DPT vaccine, its' been licensed since 1944 or 45. Nobody has ever suggested, and it as not—Mr. Patterson will agree, in this case, nobody's ever suggested in this case that American (inaudible) would ever produce any evidence to the FDA or the NIH or the CDC, or anybody else, but Bureau of Biologics that was inaccurate information. And I would agree with you that inaccurate information which you're getting into some of the—the recent cases of (inaudible) basically fraud with the government where the drug company lied to them. And I don't have any problem with—that's an exception to 402(a)(k) which is in there. It says we—we accept the fraud rule. That's—that has no part of this case, and I don't want you to get confused on that—that area.

APPENDIX B

Oral Argument of Malcolm E. Wheeler for Pharmaceutical Manufacturers Association

MR. WHEELER: May it please the Court. Your Honors, I'm here on behalf of the Pharmaceutical Manufacturers Association and as such I don't propose to get into the specific facts of this case and I think it probably will even help the Court's analysis, and certainly my own, if we don't get into a discussion or any bickering between me and the plaintiff's counsel over whether we are, in fact, trying to engraft comment k onto negligence. Because what I view as being the question that's before this Court today is, in fact, much more easily framed than to talk about comment k. It's a policy question. And the question is, does this Court, as the highest court in the state of Idaho, and the court that is ultimately responsible for articulating the common law of this jurisdiction, want to articulate a common law that allows a plaintiff to sue a pharmaceutical manufacturer when that plaintiff has, (1) voluntarily chosen to use a particular vaccine or a drug, as the case may be, having been fully warned of what the possible risks, what the possible consequences and side effects of that drug might be ...

JUSTICE SHEPARD: Warned by who?

MR. WHEELER: ... or in this case a vaccine. A learned intermediary, namely a doctor. And that's a persevering point, Your Honor. And, (3) where the plaintiff does not contend in any way, shape or form that the warnings were inadequate, that the product was improperly manufactured, that it failed to do what it was held out to do, or that it did something ... (END OF TAPE) ... common law policy to allow a plaintiff to sue on the ground that this manufacturer, having developed a drug or a vaccine in this case, that prevents illness and disease and suffering. Having done that, now it thereby incurs an obligation to do more research and develop an alternative arguably safer or more efficacious product. That is really the issue. And I want to go directly, if I may, to Justice Huntley's question, because I will take that one head on. And Your Honor, the answer is, I think that what this Court ought to do, as a matter of common law policy, is to rule that a plaintiff ought not to be allowed, in fact, to bring an action in negligence or in strict liability in which the contention is that a product, a pharmaceutical product that is a prescription medicine that has in fact been certified or licensed by the FDA, cannot bring an action that says that manufacturer has an obligation to make a different product. The plaintiff can bring the following actions—can bring an action in which the plaintiff argues that the product was improperly made. That is to say, it was impure, there was something about the process by which it was made so that the person in fact incur an illness, a disease, or some harm that wasn't anticipated. That's a legitimate claim. Number two, a plaintiff ought to be able to sue on the ground that the manufacturer did not

sufficiently test so as to be able to discover what side effects this drug might have. Number three, the plaintiff ought to be able to sue on the ground that the manufacturer had knowledge. They should have generated warnings of a different type than the warnings that were given. And finally, the plaintiff ought to be able to sue on the following ground, and I'm quoting directly from McDaniel v. McNeil Laboratories, which is a case cited by both sides. On page 828 of the McDaniel case, the Nebraska Supreme Court said, "The FDA's determination is persuasive and controlling in the absence of evidence that the determination was based upon inaccurate, incomplete, misleading or fraudulent information. And that goes directly to the question that you asked, Justice Huntley, which is, "If the information is incomplete because the manufacturer did inadequate testing, or its incomplete because the manufacturer withheld it, whether intentionally, or negligently or recklessly," a suit would be proper. But what we cannot have, what makes no sense, as a matter of public policy, is to have a rule of law that says that someone who does a good deed, a manufacturer who develops a lifesaving, or illness preventing, or a disease preventing product, that by having done that and having put that product on the market and made it available to the public to prevent disease or cure illness, thereby incurs an obligation to use its earnings to generate a better product. That kind of a rule just doesn't make any sense and you can see what the ramifications of a rule like that have to be. What the ramifications have to be are (1) you will get some manufacturers—or forget manufacturers, you will get some scientists, some independent researchers, who having developed a new product will say to themselves, do I dare put this product on the market today? Do I dare apply for a license from the FDA? Because, even if it get the FDA license, some plaintiff can come down and say, "Well wait a minute. You should not have put that product out so fast, even though everybody agrees that its social utility outweighs its risks, because if you just waited a little longer and spent a little more money, you might have developed even a better product." So you'll have people who are going to refrain from putting a product on the market at a time when it could help people; (2) And this is not a threat, and it's not blackmail as plaintiff's counsel would have it. If you look at the examples that we've cited in our brief of the DPT vaccine history, of the polio vaccine history, of the measles and mumps vaccine history, you will see that it is empirically the case that when this kind of liability follows that what the manufacturers are forced to do—they have no choice, is withdraw from the market. Now that's not blackmail, that's empirical fact. So, what I ask the Court to do is to focus both in the conceptual underpinnings of what the plaintiff's claim is an on the empirical evidence. And what I would like to do now is to go through and explain, not so much in terms of comment k, or why comment k should apply to negligence claims. I'd like to just go through and explain what the policy reasons are that, in fact, make the pharmaceutical industry, that is, prescription drugs as opposed to patent-type drugs. What makes them unique? Why do we need to treat them differently than we treat automobiles and why do we need to treat them differently than we treat drill presses and punch presses? Let me begin again by reference to Justice Huntley's question. "Is the result of this that manufacturers are going to be able to market negligently made products?" The answer to that is clearly, no. What it is is its a rule that says who should determine whether the manufacturer engaged in negligent conduct? Should that determination of negligence vel non be made by jury after jury, after jury, some in Idaho, some in Washington, some in California, some in Missouri, or, should it be made by the expert agency, in this case the FDA, that has the massive scientific knowledge and the expertise to be able to make that reasonable determination. Let me—let me in fact be very specific with an example. Someone mentioned the Pinto. The Pinto, of course, received a lot of adverse notoriety. But what very few people realize is that after the very famous Pinto

case, which was the Grimshaw case, that Indiana criminal case occurred and the jury found for not guilty on the charge. Seven months later, Ford Motor Company tried another Pinto case in San Antonio, Texas, and the jury found there was no defect and no negligence. Now, was Ford negligent? Was the Pinto defective? You have a San Antonio jury that says no. You have a California jury that says yes. You have an Indiana jury that says no criminal liability. Well, I don't know what the answer is on the Pinto, but what I do know is that the answer with respect to a pharmaceutical prescription drug is one that has to be determined once and for all. You can't have a situation where you put out a life-saving, illness preventing, disease curing product and then subject the manufacturer of that product, when the agency has said that the—that the benefits outweigh the risks, you can't subject that manufacturer over and over and over again to potential liability.

JUSTICE HUNTLEY: Counsel, I'm sure you're aware of the limitations of staff and the funding that the FDA has, like almost any other agency has. This suggestion that we should defer, take it away from the jury—well, for example to be—to give a gross example, thalidomide was approved by the same agent—the FDA-type agencies of both Germany and England. Isn't it a pretty astonishing thing you're asking us to take all this away from the jury system?

MR. WHEELER: I don't think—I think it's unusual, Your Honor. I don't think its astonishing. It's—there's no question. No one's going to stand up. I think even the FDA itself, and try to represent to this Court or any other forum that they're perfect, and that they're not going to make mistakes. thalidomide it's my recollection and also in the MER cases was that there was in fact the finding that information was withheld, that the information was incomplete. And I don't mean fraudulently, I mean either negligently or—or in some form. That would answer those questions. But I'm prepared to go beyond that, Your Honor. There are going to be cases, over the years, I don't know how many it will be. Maybe it will be one, maybe it will be five, some percentage of the time the FDA will make mistakes. But the fact is that juries make mistakes. Again, which jury was right in the Pinto case? Was the San Antonio jury right? Was the California jury right? Was Ford negligent or was it not? We don't really know. There's no—that's a—an imponderable, unanswerable question because you have two findings and you simply can't say what the answer is. It's going to be the case that some people within the FDA as to a particular application will say, we shouldn't approve that. And other people within the FDA undoubtedly, on some cases, are going to say, yes we should approve that. And there will be a difference of opinion. But at least in those instances the people making the judgment will have the benefit of years of experience and of all the data that they're able to compel the manufacturers to produce. The jury doesn't have that. As the Court knows, in a typical negligence trial there are all the artificial constraints of hearsay, the limitations on who can testify and what they can say, and you get a very, very different kind of analysis. But the bottom line question that the FDA people are asking is the same bottom-line question, which is, does the benefit of this product outweigh the risk of this product? But they're in a much better position to make that determination. Let me make—let me give you a couple of other examples of why. In the typical negligence case, automobile, punch press, drill press, ladder, anything of that nature, what the jury is asked to do is to go through the typical Judge Learned Hand formula from U.S. v. Carroll Towing Co. where they simply asked the question in gross, what are the risks of this product? What are the benefits of this product compared to some alternative design, and does the marginal risk outweigh the marginal utility. That's—it's in gross. It's a fairly easy question, although its in abstract terms, for a jury to answer. That's not the way it's done in the drug area. Why is that? Because in the

drug area, the question is going to be, you have some benefits accruing to group A. In the case of a vaccine, all of the people who are prevented from catching this disease, 50,000, 40,000 whatever the number might be, they get the benefit of having had Tri-immunol on the market. Some smaller number of people are going to suffer and suffer terribly as a result. Juries are going to have to ask the question, group A v. group B. Efficacy with respect to group A v. harm in group B. That's a very difficult question. It's essentially a moral question. It's a legislative question. It's the kind of a question that juries ought not to be asked to answer. They're ill-equipped to do it, and it's really an unfair question for juries. But it is a fair question for the legislatures and regulatory bodies that are created by legislatures to be required to answer. I see I'm out of time. I have many other points, but I thank you for your attention.

732 P.2d 326

TREASURE VALLEY BANK, a state chartered banking institution, Plaintiff-Appellant,

v.

KILLEN & PITTENGER, P.A.; William M. Killen and Kathy Killen, husband and wife; and Gregory C. Pittenger and Linda Pittenger, husband and wife, Defendants-Respondents.

No. 16186.

Supreme Court of Idaho.

Feb. 5, 1987.

Rolf M. Kehne, Boise, for plaintiff-appellant.

W. Scott Wigle of Quane, Smith, Howard & Hull, Boise, for defendants-respondents.

BAKES, Justice.

The appellant, Treasure Valley Bank (TVB), brought a legal malpractice action against the law firm of Killen & Pittenger, P.A. (Killen), alleging negligent representation in a bankruptcy proceeding. Killen moved for summary judgment alleging that the appropriate statute of limitations set forth in I.C. § 5–219(4) [1] had run. The

1. "5–219. Actions against officers, for penalties, on bonds, and for professional malprac-