

# Unavoidably Unsafe Products

The Comment K Defense to Strict Liability for Pharmaceuticals, Medical Devices, and... What Else?

by William C. Hoffman\*

Insurers of liability risks will be interested to learn more about a recent trend in American law that permits a defense to strict liability for certain types of pharmaceuticals and medical products. It is of course well known that exports of products to the USA present a substantial product liability risk for manufacturers, exporters, distributors, and other sellers under the Restatement (Second) of Torts § 402A. In the case of prescription medical products, one may add the prescribing physician as a potential defendant, as well.

A recent trend in the court decisions of quite a number of American states indicates an increased willingness of the courts to rethink the strictness of product liability for certain types of products. These products, called "unavoidably unsafe" products, are held not to be subject to strict liability for design defect and failure to warn. The manufacturers of such products are therefore exempt from a major source of product liability claims. The reason for the exemption is that, though these products are dangerous, they are nonetheless of such benefit to society that strict liability is inappropriate. So far, the list of "unavoidably unsafe" products includes certain drugs and medical devices.

The list of "unavoidably unsafe" is growing, and it may be expected that it will continue to grow in the coming years. But how far will the list go? The following article explores this important trend by examining some of the cases in which the "unavoidably unsafe" product defense has been applied.

## 1. Introduction

Over the past decade, numerous American courts have adopted into law Comment K of § 402A of the Restatement (Second) of Torts. Comment K exempts manufacturers of "unavoidably unsafe products" from strict liability for defective design. Further, Comment K has been interpreted to preclude strict liability for failure to warn if the danger was not known or was not scientifically knowable at the time the product was distributed.

The main issue under Comment K to date has been: Which products qualify as "unavoidably unsafe"? On the whole, most of the products qualifying for the Comment K defense have been pharmaceuticals. However, a recent trend in the decisional law indicates that certain implanted medical devices also qualify.

\*) The author is international legal counsel for Cologne Reinsurance Company, Cologne, Germany. He received his Juris Doctor degree from the University of California in 1986, and is a member of the California State Bar.

Further, the impact of Comment K goes beyond medical products and has been felt in general product liability law, as the following discussion demonstrates.

## **2. Comment K to § 402A of the Restatement (2nd) of Torts**

The American Law Institute (ALI) researches and writes Restatements of many areas of the law, including but not limited to tort law, for the purpose of promoting law reform. The ALI is not a legislative body but a professional research institute; consequently, a Restatement of the law is not legislation and is not of itself binding on any court. However, the courts often consult an ALI Restatement for solutions to difficult legal problems. Thus, while an ALI Restatement has no legal force of itself, it may be said to become law to the extent that the courts or legislature of a particular state have adopted a solution proposed by the ALI.

Thus, the ALI and its Restatements often have a tremendous influence on the choice of a solution to important legal issues. Indeed, it would be difficult to exaggerate the influence of the ALI, for example, in the area of product liability. During the 1960s and 1970s, a great many of the American sister states adopted the strict product liability formulation that the ALI prepared and recommended in the form of § 402A of the Restatement (Second) of Torts of 1965 (hereinafter the "Restatement of Torts"). The widespread adoption of § 402A has, in turn, influenced the development of product liability legislation of other countries, including the European Community Directive of July 1985.

As is well known, § 402A of the Restatement of Torts imposes strict liability for products sold in a "defective condition unreasonably dangerous." Perhaps less well known is that the ALI also provided a number of "comments" intended to be used by the courts as

guidelines in interpreting § 402A. Comment K to § 402A provides:

*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 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.<sup>1</sup>

Comment K has been analyzed and criticized

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1) American Law Institute, Restatement (Second) of Torts § 402A, Comment K (1965).

by numerous commentators.<sup>2</sup> There is some disagreement as to its scope and meaning, but there is a general consensus that Comment K, while purporting to explain the strict liability doctrine, in fact states a principle based on negligence.<sup>3</sup> In short, Comment K appears to exempt the manufacturer of an "unavoidably unsafe product" from strict liability unless the manufacturer failed to warn the consumer of a danger of which the manufacturer either knew or should have known.<sup>4</sup> If this is accepted, then § 402A, pursuant to Comment K, would subject the manufacturer of an "unavoidably unsafe product" to strict liability neither for design defects nor for failure to warn. Recovery would be permitted for negligence in design or failure to warn, but strict liability — in the sense that the focus of the inquiry is the defectiveness of the product itself and not the reasonableness of the manufacturer's conduct — would be allowed only for a manufacturing defect. In adopting Comment K, a number of courts in recent years have taken precisely this position with respect to several types of "unavoidably unsafe" products.

### 3. Prescription Drugs as Unavoidably Unsafe Products

The text of Comment K does not expressly state that all prescription drugs are unavoidably unsafe. Comment K does, however, make express reference to the Pasteur rabies vaccine as a prime example of an unavoidably unsafe product.<sup>5</sup> It then goes on to state that "the same is true of many other drugs, vaccines,

2) See Schwartz, Unavoidably Unsafe Products: Clarifying the Meaning and Policy Behind Comment K, 42 Wash. & Lee L.Rev. 1139, 1141 (1985); McClellan, Drug Induced Injury, 25 Wayne L.Rev. 1, 2 (1978); Kidwell, The Duty to Warn: A Description of the Model of Decision, 53 Tex.L.Rev. 1375, 1377—78 (1975); Merrill, Compensation for Prescription Drug Injuries, 59 Va.L.Rev. 1, 50 (1973).

3) See, e.g., *Brown v. Superior Court*, 44 Cal.3d 1049, 1059 (1988).

4) *Ibid.*

and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician."<sup>6</sup> For this reason, manufacturers of prescription drugs have a very strong case for bringing their products within the scope of Comment K. In recent years manufacturers have successfully argued before numerous courts that Comment K precludes strict liability for such drugs.

#### 3.1 *Brown v. Superior Court*

In *Brown v. Superior Court*, the plaintiff sued manufacturers of diethylstilbestrol (DES), a drug that her mother had used while pregnant with the plaintiff.<sup>7</sup> The plaintiff alleged that she was injured *in utero* by the drug and sought to recover damages on claims based on, *inter alia*, strict liability for a design defect and for failure to warn. Prior to trial, the trial court dismissed these claims. The intermediate appellate court upheld that ruling,<sup>8</sup> and the plaintiff appealed to the California high court.

The California Supreme Court affirmed.<sup>9</sup> Adopting Comment K into California law, the court in *Brown* held that prescription drugs differ sufficiently from other consumer products so as to justify exempting the manufacturer from strict liability for design defects and failure to warn of a development risk. The court reasoned that strict liability should not be imposed on the sellers of such drugs because to do so would discourage the development, availability, and reasonable price of drugs. Strict liability for prescription drugs might be "against the public interest" because of "the very serious tendency to stifle medical research

5) See *supra* text accompanying note 1.

6) *Ibid.*

7) DES was manufactured in the USA between 1947 and 1971 by approximately 300 manufacturers, and was prescribed to pregnant women by their doctors for the purpose of preventing miscarriage.

8) 182 Cal.App.3d 1125 (1986).

9) 44 Cal.3d 1049 (1988).

and testing.”<sup>10</sup>

Accordingly, the court held that sellers of prescription drugs are subject to strict liability neither (1) for a design defect in the drug nor (2) for a failure to warn of effects of the drug that were not known or were not scientifically knowable at the time of distribution. As regards design defects, the court held neither the “consumer expectation” test nor the “risk/benefit” test applies to prescription drugs.<sup>11</sup> Further, as regards failure to warn, the court stated that the same policy reasons that underlie the Comment K defense to strict liability for design defects are equally compelling in the failure to warn area. Thus, the court held that liability for failure to warn may be imposed on a manufacturer of a prescription drug only for effects that were scientifically known or knowable at the time of distribution.<sup>12</sup> To impose liability for failure to warn of unknown or unknowable dangers “would make the manufacturer the virtual insurer of the product.”<sup>13</sup>

### 3.2 Other Courts

California in *Brown* joined a large group of other American states, including Alabama, Arkansas, Arizona, Idaho, Kansas, Maryland, New Jersey, Oklahoma, Washington and Wisconsin, that have adopted the defense to strict liability contained in Comment K.<sup>14</sup> Clearly, this list is growing as the courts and legislatures of more and more states are called upon to adopt Comment K. Most important, the California Supreme Court endorsed the view, now held by a number of these states, that Comment K is applicable to *all prescription drugs*.<sup>15</sup> If *Brown* gives momentum to this

trend and is followed by courts elsewhere, strict liability for prescription drugs would exist only for manufacturing defects. Design and warning claims would exist only for negligent design or negligent failure to warn.

However, a minority of the states that have adopted Comment K has rejected the position that Comment K provides a blanket defense for all prescription drugs.<sup>16</sup> These courts hold that, although Comment K is a defense for certain “unavoidably unsafe” products, Comment K should be applied only “when it is shown that the product is incapable of being made safe given the present state of human knowledge but possesses such high degree of social need that its use is warranted, provided warnings are adequate.”<sup>17</sup> While these courts concede that prescription drugs quite often are unavoidably unsafe, they hold that the issue of whether a product is “unavoidably unsafe” must be decided on a case-by-case basis. This approach is subject to the criticism, noted by one court of the majority camp, that it would involve the courts in too much guesswork and artificially-drawn fine

10) *Id.* at 1056.

11) *Id.* at 1060—65.

12) The court noted that, independently of Comment K, this rule was already the law of most American states. However, the court nonetheless justified its adoption of that rule by citing the policy reasons underlying Comment K. *Id.* at 1065—66.

13) *Id.* at 1066.

14) See *Stone v. Smith, Kline & French Lab.*; 447 So.2d 1301 (Ala. 1984); *Gaston v. Hunter*, 121 Ariz. 33 (1978); *Chambers v. G.D. Searle & Co.*, 441 F. Supp. 377 (D. Md. 1975); *Johnson v. American Cyanamid Co.* 239 Kan. 279 (1986); *Toner v. Lederle Labs.*, 112 Idaho 328 (1987); *Feldman v. Lederle Labs.*, 97 N.J. 429 (1984); *Collins v. Eli Lilly Co.*, 116 Wis.2d 166 (1984).

15) *McKee v. Moore*, 648 P.2d 21 (Okla. 1982); *Terhune v. A.H. Robins Co.*, 577 P.2d 975 (Wash. 1978). See also *Lindsay v. Ortho Pharmaceutical Corp.*, 637 F.2d 87 (2nd Cir. 1980).

16) These courts reject the reasoning adopted in *Brown* that to impose strict liability would negatively affect the development, availability, and reasonable pricing of drugs. See *Schanks v. Upjohn Co.*, CCH 13,229 (June 26, 1992) (Alaska); *Wheelahan v. G.D. Searle & Co.*, 814 F.2d 655 (4th Cir. 1987); *Coursen v. A.H. Robins Co.*, 764 F.2d 1329 (9th Cir. 1985); *Kociemba v. G.D. Searle & Co.*, 680 F. Supp. 1293 (D. Minn. 1988); *Patten v. Lederle Labs.*, 676 F. Supp. 233 (D. Utah 1987); *Hawkinson v. A.H. Robins Co.*, 595 F. Supp. 1290 (D. Colo. 1984).

17) *Hill v. Searle Labs.*, 884 F.2d 1064 (8th Cir. 1989) (applying Arkansas law).

distinctions and that the public policy basis of the Comment K defense is best implemented by a simple, bright-line test.

#### **4. Other Medical Products Potentially Qualifying as Unavoidably Unsafe**

More recently, manufacturers have had some successes in arguing that Comment K ought to apply to other types of products as well. So far, the arguments have been limited to non-prescription drugs and certain implanted medical devices.

##### **4.1 Non-Prescription drugs**

In *Rodriguez v. Glenbrook Laboratories*, a minor child sued for injuries he suffered due to his use of a baby aspirin product made by the defendant manufacturer. The trial court, applying the ruling in *Brown*, dismissed the claims for strict liability for failure to warn. In holding for the drug manufacturer, the trial court stated:

While it is self-evident that the rationale of *Brown* cannot be applied willy-nilly to all over-the-counter medications and nostrums, it is logical to apply it to aspirin, given its status as a beneficial drug whose efficiency is still being investigated in certain applications, and which carries with it certain well-known and unavoidable risks.<sup>18</sup>

The intermediate appellate court held that the complaint sufficiently alleged a failure to warn claim based on known dangers, so that *Brown* did not preclude a strict liability claim.<sup>19</sup> Thus, the appellate court did not reach the issue of whether baby aspirin, a non-prescription drug, falls within the scope of Comment K under the decision in *Brown*. Conceivably, however, numerous non-prescription drugs (including baby aspirin) might be described, in the words of the *Rodriguez* court, as being "beneficial" and "whose efficiency is still being investigated in certain

applications" and which carry "certain well-known and unavoidable risks." The court's broad language and its expansive reading of *Brown* will no doubt be used in future cases to support the argument that non-prescription drugs qualify as unavoidably unsafe.

##### **4.2 Implanted Medical Devices**

Comment K also has application outside the pharmaceuticals area. Arguably, many types of implanted medical products, such as heart valves, pacemakers, catheters, dental products, etc., might qualify as "unavoidably unsafe." In at least three recent cases, the courts have addressed the applicability of the Comment K defense in cases involving implanted medical devices. In two of the three, the courts held that Comment K applied.

###### *4.2.1 Inflatable Penile Prosthesis*

In *Hufft v. Horowitz*, the plaintiff underwent surgical implantation of an inflatable penile prosthesis to correct an erectile dysfunction.<sup>20</sup> The device caused him to experience an almost constant erection, persistent pain, and emotional distress. He sued his doctors and the manufacturer of the device, basing his claims on strict liability for design defect and failure to warn.

The trial court granted the manufacturer's motion for judgment, and the plaintiff appealed.

The appellate court affirmed in part.<sup>21</sup> In a very expansive reading of *Brown*, the court held that Comment K's exception to strict liability for design defects applied to manufacturers of implanted medical devices. In so ruling, the court distinguished between some important medical products that are quite similar

18) *Rodriguez v. Superior Court*, 221 Cal. App.3d 1371, CCH 12,581 (1990) (quoting from the trial court's order).

19) *Ibid.*

20) An inflatable penile prosthesis is a device that facilitates sexual intercourse for the impotent male.

21) *Hufft v. Horowitz*, 4 Cal.App.4th 8 (1992).

to prescription drugs and therefore deserve the protection of Comment K, and other such products that are less similar to prescription drugs and therefore do not deserve the protection of Comment K:

*Brown* distinguishes prescription drugs from "other important medical products (wheelchairs, for example)," on the basis that "harm to some users from prescription drugs is unavoidable." We perceive the risks attendant to implanted medical devices are akin to those of prescription drugs. Just as drugs and vaccines are injected or ingested into the body, implant devices must be "plugged in" to the individual, to work their effect upon or respond to complex systems imperfectly understood by medical science. Just as with drugs and vaccines, the result may be dependent upon the peculiar physical characteristics of the individual ... Thus, when distinctions are made among medical products, implanted medical devices must be placed in a category with prescription drugs, not wheelchairs or other important items that are of comfort or assistance to patients, but do not become an integrated part of the person.<sup>22</sup>

The court in *Hufft* emphasized that Comment K's defense to strict liability applied to medical devices for the same reasons as those given in *Brown*. The court thus stated that

the public's interest in development, availability and affordability of medical devices demands rejection of strict liability and adoption of the Comment K standard. As with prescription drugs, the harsher rule of strict liability may discourage manufacturers from researching and marketing new medical devices due to realistic fear of substantial adverse judgments, the high cost of strict liability insurance and the uncertainty that such insurance will even be available.<sup>23</sup>

Interestingly, the court in *Hufft* refused to distinguish among various types of implanted prescription medical devices. Emphasizing the

bright-line nature of the *Brown* court's application of the Comment K defense for all prescription drugs, the court in *Hufft* held that Comment K therefore applied to all prescription devices. In the implanted medical devices area, this meant that it was improper to distinguish among various devices, such as for example heart valves, intrauterine devices, or inflatable penile prostheses. The court held:

*Brown* teaches that we should eschew engaging in a case-by-case risk/benefit analysis to ascertain whether Comment K should or should not apply because to do so would diminish the benefit of Comment K's negligence standard. Therefore, we do not compare the (inflatable penile prosthesis) to a heart valve ... *Brown* tells us that in a world of trade-offs, society is well served by restricting available avenues of monetary recovery in exchange for increasing availability of life-saving, suffering-alleviating products. That policy applies to medical devices and prescription drugs alike. Following *Brown's* lead, we draw a bright line within which the Comment K test is applied to all implanted medical devices. We hold that a manufacturer is not strictly liable for injuries caused by an implanted prescription medical product which has been (1) properly made and (2) distributed with information regarding risks and dangers of which the manufacturer knew or should have known at the time.<sup>24</sup>

However, while the court in *Hufft* recognized that Comment K precluded suit on the theory of design defect, it went on to reverse the judgment as to the claims for manufacturing defect and failure to warn. Thus, the plaintiff would be permitted to pursue his strict liability claims for failure to warn and manufacturing defect.

#### 4.2.2 Intrauterine Device

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22) Id. at 18—19.

23) Id. at 19.

24) Id. at 19—20.

In *Hill v. Searle Laboratories*, the defendant's product was a contraceptive intrauterine device (IUD) known as the CU-1, which was designed and implanted for the purpose of preventing pregnancy. After the plaintiff had had CU-7 implantation surgery, she became pregnant. It was discovered after the birth that surgery was required to remove the CU-1 which, over the course of time, had perforated her uterus and was partially embedded in her small bowel. A federal trial court in Arkansas dismissed the plaintiff's claims and granted the manufacturer summary judgment on the basis that the IUD was a prescription drug product within the meaning of Comment K.<sup>25</sup>

The United States Court of Appeals for the Eighth Circuit, applying the law of Arkansas, reversed.<sup>26</sup> The federal appellate court agreed with the trial court that the Supreme Court of Arkansas would join the majority of courts in adopting the Comment K defense to strict liability into the state law of products liability. However, the Eighth Circuit held that Comment K ought not to apply to all prescription drugs, thus endorsing the minority view that the product must be "incapable of being made safe." The court stated:

The drafters of Comment K did not intend to grant all manufacturers of prescription drugs a blanket exception to strict liability. . . . The language of Comment K suggests that only exceptional products, albeit such exceptional products are more likely to be found in the field of prescription drug products, should be excluded from the strict liability provisions. But more importantly, the example given — the vaccine for the Pasteur treatment of rabies — suggests that only special products, those with exceptional social need, fall within the gamut of Comment K. . . . The better reasoned opinions support the view that the unavoidably unsafe exception

should only apply upon a showing of exceptional social need.<sup>27</sup>

Besides this "exceptional social need" requirement, the Eighth Circuit also rejected the public policy basis of the decision in *Brown*. The court stated that this argument, i.e., "that the public interest in the development of prescription drug products requires the user to bear all the costs of injury unless the drug product was negligently manufactured or designed or unaccompanied by proper warnings — is unconvincing."<sup>28</sup> Thus, the court in *Hill* ruled that the application of Comment K to a particular product presents an issue that must be determined on a case-by-case basis. In the case before it, the Eighth Circuit held that, since the CU-1 was "certainly not the *sine qua non* for birth control, as is the Pasteur vaccine for the treatment of rabies,"<sup>29</sup> the judgment for the manufacturer in the court below was reversed and the case was remanded to the trial court for further proceedings.

Most recently, in *Plenger v. Alza Corp.*,<sup>30</sup> the court held that under California law an intrauterine device did indeed fall within the ban of Comment K. In *Plenger*, the plaintiffs were the family of a woman who had died from an infection allegedly caused by an IUD manufactured by the defendant. The IUD product in question had contained a warning to the physician of the danger of infection but not of death by infection. In their suit for failure to warn of the risk of death, plaintiffs argued that under *Brown* Comment K should apply only to prescription drugs and not to prescription medical devices.

The California Court of Appeal rejected this argument, holding that the *Brown* and *Hufft* cases, *supra*, supported a finding that the IUD

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25) 686 F.Supp.720 (E.D. Ark.1988).

26) 884 F.2d 1064, CCH12,250 (8th Cir.1989).

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27) CCH 12,250 at 35,967.

28) *Ibid*.

29) *Ibid*.

30) No. E009093, 92 Daily Journal D.A.R. 15999 (Cal. App., Nov. 30, 1992)

as a prescription medical device was within the scope of Comment K. In so doing, the court cited the same public policy considerations that had moved the courts in *Brown* and *Huff* to apply the Comment K exemption to prescription drugs and inflatable penile prostheses. As in those prior cases, the court noted that non-prescription medical devices, e.g., wheelchairs, which are not "plugged in" to the patient, would not qualify for the exemption. Thus, the California court's ruling in *Plenger* stands in direct contrast to the federal court's application of Arkansas law in *Hill*.

### 5. Conclusion

Pursuant to Comment K of the Restatement of Torts § 402A, manufacturers of "unavoidably unsafe products" today may in many states of the USA enjoy the benefit a complete defense to strict liability for design defects. In recent years, numerous courts have adopted the Comment K defense, although the courts do not all agree as to the reasoning and policies that underlie Comment K. Reasoning that to impose strict liability for prescription drugs would create a disincentive for research and development of highly useful drugs, some courts today hold that Comment K applies to all prescription drugs. Other courts hold that a blanket defense is not available and the Comment K defense depends upon the nature of the particular product.

Further, in its influential decision in *Brown*, the California Supreme Court held that the same logic, reasoning, and policies that underlie the Comment K defense to strict liability for defectively designed prescription drugs also precludes liability for failure to warn of dangers that are not known, i.e., development risks. Today and in a majority of US jurisdictions, the plaintiff, in order to prevail on a failure to warn claim, must establish that the danger was known or was scientifically knowable. As reported in

PHI 3/92, the decision in *Anderson v. Owens-Corning* made this aspect of the *Brown* decision applicable to all products under California law.<sup>31</sup> Thus, Comment K's impact has not been limited to "unavoidably unsafe" products per se.

However, it remains to be seen just which specific types of products are exempt from strict liability under Comment K for design defects or, under the parallel reasoning of *Brown*, for failure to warn, remains to be seen. Baby aspirin, inflatable penile prostheses, and intrauterine devices are just a few of the many possible candidates, but as the cases involving those products illustrate non-pharmaceutical products have not enjoyed uniform acceptance by the courts as being unavoidable unsafe. As more and more state supreme courts take a position on Comment K, this lack of uniformity in the law may recede. But until the application of Comment K becomes more uniform, it will be difficult to predict, for purposes of distributing a product, whether or not the manufacturer's strict liability risk is reduced under Comment K. Nevertheless, the logic and reasoning of the courts applying Comment K may also prove compelling for a variety of highly useful products that, because of their nature, are also unavoidably dangerous.

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31) 53 Cal.3d 987 (1991). See Glaser and DeBusschere, *Anderson v. Owens-Corning Fibreglas Corp.*: Neueste Rechtsprechung in Kalifornien zum Thema Warnpflicht und Entwicklungsrisiko, PHI 3/92 (May 1992).