The State of the Art Defense in Strict Products Liability

James T. Murray Jr.
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I. INTRODUCTION

On first examination, the doctrine of strict products liability in tort as enunciated by section 402A of the Restatement (Second) of Torts appears to be a simple solution to the problems which an injured consumer had to surmount under negligence law in order to recover from the seller of a defective product for injuries caused by that defect. Ostensibly, since liability will attach even though the seller has exercised all reasonable care, negligence concepts such as foreseeability and reasonableness should have no application. As a matter of fact, however, such concepts do play a very important part in the application of this doctrine and, as will be seen, it is for that reason that state of the art evidence may play an important part in the defense of a strict products liability lawsuit.

II. THE STATE OF THE ART DEFENSE

A. In Negligence Cases

Before examining the meaning and utility of the state of the art defense in strict liability cases, it is helpful to consider its usage in negligence cases. Under negligence law, the state of the art defense is especially effective because it establishes a standard of care which the manufacturer is only required to meet, not exceed. A case which is often cited to demonstrate the importance of the state of the art defense in negligence cases is Day v. Barber-Colman Co. In that case the plaintiff was installing an overhead sliding door when the door fell down on top of him causing his injuries. The plaintiff sued the defendant manufacturer and alleged that it negligently failed to install a stopping device to prevent the door from closing during installation before the counterweights were attached. The court emphasized the defendant's state of the art evidence which indicated that the door was made according to a standardized design, in common use in the industry at the time, and stated:

1. Restatement (Second) of Torts § 402A (1965).
It is not of itself negligence to use a particular design or method in the manufacture or handling of a product . . . which is reasonably safe and in customary use in the industry, although other possible designs . . . might be conceived which would be safer . . . .

In view of such evidence, the court held:

The state of the art of the time and the prior history of the use of the product would not have indicated or required any material change in design or manufacture.

Similarly in *Schneider v. Chrysler Motor Corp.*, the court stated in response to the plaintiff's allegation of negligent product design:

A manufacturer is not an insurer and cannot be held to a standard of duty of guarding against all possible types of accidents and injuries. Standards of design and manufacturing skill must be consonant with the state of the art . . . .

Another more recent case involving the use of state of the art evidence in defense to a claim of negligent design is *Olson v. Arctic Enterprises, Inc.* The plaintiff in that case was injured when his foot became caught in the track of a snowmobile, manufactured by the defendant, on which the plaintiff was a passenger. Plaintiff alleged that the defendant was negligent in failing to install a passenger grip, failing to install adequate passenger footrests, and failing to adequately cover the track and sprocket mechanism. The defendant showed through the use of literature and specifications distributed by the manufacturers of competing snowmobiles, that no snowmobile sold at the time the injury-producing snowmobile was sold, incorporated any of the plaintiff's suggested modifications. The court held for the defendant on the negligent design claim and stated:

None of this "state of the art" testimony was rebutted by the plaintiff, nor did he carry his burden of bringing forth affirmative evidence of the defendant's failure to consider the safety aspect of design.

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4. *Id.* at 508, 135 N.E.2d at 238.
5. *Id.* at 507, 135 N.E.2d at 237.
6. 401 F.2d 549 (8th Cir. 1968).
7. *Id.* at 557.
9. *Id.* at 765.
Thus it appears that in a negligent design case, once the defendant comes forth with evidence showing his compliance with the state of the art, he has established a prima facie defense and the plaintiff then has the burden of proving either non-compliance in fact, or that the state of the art standard is a negligent one.\textsuperscript{10}

\textbf{B. In Strict Liability Cases}

1. Definition

While in negligence cases the state of the art defense refers primarily to the common or standard practices in the particular industry involved, the term seems to have a somewhat broader meaning in strict liability cases, encompassing two separate, albeit closely related, types of evidence.

The first type of state of the art evidence is that of the industry-wide standards to which the defendant has conformed. This is similar to the state of the art evidence employed in negligence cases and is intended to demonstrate that the defendant's product conforms with the products of other manufacturers. A recent example of an unsuccessful attempt by a defendant to utilize this type of the state of the art evidence is \textit{Gelsumino v. E. W. Bliss Co.},\textsuperscript{11} a case in which the plaintiff, a punch press operator, was injured when his foot slipped onto a floor pedal control which activated the punch while his hand was under it. The defendant attempted to introduce evidence of the fact that the design of the foot pedal was similar to that used by other manufacturers, but the court held that such evidence was irrelevant and stated:

\textit{[D]efendants in the instant case (cannot) avoid the issue of strict liability by attempting to show merely that they had done what the rest of their industry had done to make their products safe.}\textsuperscript{12}

\textsuperscript{10} \textit{See: March Wood Products Co. v. Babcock & Wilcox Co.,} 207 Wis. 209, 219, 240 N.W. 392, 396 (1932), where the Wisconsin Supreme Court held:

\textit{The fact that the custom of manufacturers generally was followed is evidence of due care, but it does not establish its exercise as a matter of law. Obviously, a manufacturer cannot, by concurring in a careless or dangerous method of manufacture, establish their own standard of care.}

Similarly in \textit{The T.J. Hooper}, 60 F.2d 737, 740 (2d Cir. 1932), Judge Learned Hand stated:

\textit{Indeed in most cases reasonable prudence is common prudence; but strictly it is never its measure; a whole calling may have unduly lagged in the adoption of new and available devices. It may never set its own tests, however persuasive its usages. Courts must in the end say what is required; there are precautions so imperative that even their universal disregard will not excuse their omission.}

\textsuperscript{11} 10 Ill. App. 3d 604, 295 N.E.2d 110 (1973).

\textsuperscript{12} \textit{Id.} at 609, 295 N.E.2d at 113.
The second type of state of the art evidence is that which is offered to show that the product cannot, within the current limits of scientific knowledge, be made more safe. An illustrative case is *E.R. Squibb & Sons, Inc. v. Stickney*,¹³ where the plaintiff, who had undergone surgery involving the unsuccessful implantation of a bone transplant product manufactured by the defendant, contended that the product was unreasonably dangerous in that it involved a fifteen percent failure rate. The court held for the defendant however, emphasizing defendant's evidence that "Squibb had developed its process to the highest degree attainable by it at the time. . . ."¹⁴ In using this type of state of the art evidence, the emphasis is not on what other manufacturers are doing, but rather on the fact that everything that is technically possible is being done to make the product safe.

It is important to note that a manufacturer can never plead that his product fell short of the state of the art, in either sense of the term, because he was unaware of the standards adhered to by his competitors in the industry or because he was ignorant of the technical advances in the field. This is so because:

[A] manufacturer is held to the knowledge and skill of experts . . . . This standard imposes the duty to keep abreast and informed of the developments in his field, including safety devices and equipment used in his industry with the type of products he manufactures.¹⁵

2. Uses of the State of the Art Defense in Strict Liability Cases

The term "state of the art defense" is actually somewhat of a misnomer in strict products liability cases because, unlike in negligence cases, the mere fact that the defendant establishes that he has conformed with the state of the art does not constitute a prima facie defense to strict liability. This is because under section 402A, the manufacturer or seller can be liable even though he "has exer-

¹³. 274 So. 2d 898 (Fla. 1973). Although this case dealt with breach of implied warranty of merchantability rather than strict liability, there is a considerable amount of overlap between the two theories, making them:


¹⁴. 274 So. 2d at 901.

cised all possible care in the preparation and sale of his product."\textsuperscript{16} Therefore, as a technical defense, state of the art evidence used to establish a standard of care is irrelevant. This was demonstrated in \textit{Gelsumino v. E.W. Bliss Co.},\textsuperscript{17} an Illinois decision, where the defendant attempted to introduce evidence of his compliance with industry-wide standard designs as a defense to the plaintiff's claim of defective design in strict liability. The court stated:

Plaintiff questions whether defendants actually showed conformity to the state of the art, but we do not resolve that issue since we find that the "state of the art" defense is irrelevant with respect to the two strict liability counts . . . .

. . . Conformity to the state of the art is not a defense to a claim involving an unreasonably dangerous product.\textsuperscript{18}

This result seems inescapable in light of section 402A's mandate, but the fact that compliance with the state of the art is not a defense in itself should not wholly diminish the utility of state of the art evidence in other aspects of the defendant's case. Such evidence has been used, with varying degrees of success, for two principal purposes: (1) to show that a product is not defective, and (2) to show that a product is unavoidably unsafe and within the exception to strict liability delineated by comment k to section 402A.\textsuperscript{19}

(a) To Show that the Product is not Defective

One of the basic elements which every plaintiff must establish in order to make out a prima facie case of strict products liability (or any kind of products liability) is the existence of a defect in the product which was, if not the sole cause, at least a contributing cause of his injury.\textsuperscript{20} A product is defective if it is unsafe for normal handling and consumption, in light of the directions and warnings accompanying the product.\textsuperscript{21} Whether a product is defective is usually analyzed in terms of the reasonable expectations of the consumer or user.\textsuperscript{22} Since many products, such as knives or matches, may be incapable of being made perfectly safe, this re-

\textsuperscript{16} Restatement (Second) of Torts § 402A (1965).
\textsuperscript{17} 10 Ill. App. 3d 604, 295 N.E.2d 110 (1956).
\textsuperscript{18} Id. at 609, 295 N.E.2d at 113.
\textsuperscript{19} Restatement (Second) of Torts § 402A, comment k at 353-54 (1965).
\textsuperscript{21} Restatement (Second) of Torts § 402A, comment h at 351-52 (1965).
requirement serves to prevent the imposition of liability in cases where a user is injured even though the product was performing as expected by both the manufacturer and the user. According to the Restatement, in order to impose strict liability:

The article sold must be dangerous to an extent 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.23

Since whether or not a product is defective depends upon whether or not the danger involved in its use would be apparent to a reasonable consumer, state of the art evidence can be useful in establishing that the product involved is similar to all other products of that type and that therefore "an ordinary consumer . . . with the ordinary knowledge common to the community as to its characteristics"24 would have realized the potential danger.

An example is the case of Jackson v. Biloxi,25 where the five year old plaintiff kicked over a kerosene warning lamp manufactured by the defendant, and was burned when some of the kerosene splashed on his leg. In rejecting plaintiff's claim of strict liability based on improper product design, the court placed great emphasis on the evidence that the design was "an old and apparently accepted means of handling a warning situation,"26 and stated, "defective condition means that the article has something wrong with it, that it did not function as expected."27

Similarly in Olson v. Arctic Enterprises, Inc.,28 the plaintiff claimed that his injury resulted from a design defect in a snowmobile manufactured by the defendant. The court examined the state of the art evidence produced by the defendant in the form of specifications and promotional information of other manufacturers' snowmobiles and held:

Although the definitions of the term "defect" in the context of products liability law use varying language, all of them rest upon the common premise that those products are defective which are dangerous because they fail to perform in the manner reasonably to be expected in light of their nature and intended function.
25. 272 So. 2d 654 (Miss. 1973).
26. Id. at 656.
27. Id.
To refuse to consider the "state of the art" as it relates to the operational aspects of a snowmobile would be to hold the manufacturer liable for merely marketing a functionable product—in effect placing absolute liability upon such manufacturer. 29

Unquestionably the product was capable of causing harm, but that fact alone did not render it defective. Since the machine represented the highest degree of safety attainable at the time, as evidenced by other manufacturers' products, while still being functional, it was not defective because it didn't present a danger which would not be anticipated by a reasonable consumer.

_E.R. Squibb & Sons, Inc. v. Stickney_ 30 is yet another example. Although the defendant's bone transplant product had experienced a fifteen percent failure rate in the past, it was not defective because the failure rate of other similar products was at least equally high.

(b) To Show that the Product was "Unavoidably Unsafe" within the Meaning of section 402A, comment k.

According to section 402A, comment k: 31

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... Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous... 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 recognized risk. The seller of such products... is not to be held to strict liability for unfortunate consequences... merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk. 32

Putting aside the question of proper warning for the moment, it seems that whether or not a product will fall within this section

29. _Id._ at 764-65.
30. 274 So. 2d 898 (Fla. 1973).
31. _Restatement (Second) of Torts_ § 402A, comment k at 353-54 (1965).
32. _Id._
is dependent on two factors: (1) whether or not the risk is unavoida-
ble under the "present state of human knowledge," and (2) whether
the utility of the product justifies its exception from strict liability.

With respect to the first factor, it should be remembered that
the manufacturer is held to the knowledge of an expert and
therefore is required to be aware of the state of the art. Such
evidence in this context is absolutely essential and will generally be
of the type intended to demonstrate that the product cannot be
made more safe in light of current scientific knowledge (although
evidence of what other manufacturers are doing might well be
relevant to that determination).

The "unavoidably unsafe" exception has found its greatest ap-
plication in the drug field. In Basko v. Sterling Drug, Inc., for
example, the plaintiff had undergone extended treatment with the
drugs Aralen and Triquin for a skin disease. Both were manufac-
tured by the defendant and both contained chloroquine. Plaintiff
eventually went blind, and expert testimony at trial identified the
condition as chloroquine retinopathy, a reaction to the chloroquine
in the drugs. The court held that comment k was clearly applicable
and stated that the exception covered products, especially drugs,
because:

[C]onsumers for a long time have lived with and accepted the
risks inherent in their use . . .

The reason for relaxing strict liability . . . is because "(s)suffi-
cient user experience is indispensable to research, and making the
supplier a guarantor of safety without such research may be
regarded as too burdensome".

Another case, not involving drugs, which demonstrates the
importance of the two factors mentioned above with respect to
comment k is Borel v. Fibreboard Paper Products Corp. The
plaintiff in that case, an industrial insulation worker, had been
exposed to asbestos dust for 36 years. He developed asbestosis, had
a lung removed, and eventually died as a result of such exposure.
In the case against the asbestos manufacture, the court took note
of the fact that the asbestos dust could not be avoided in the
manufacture of asbestos insulation and then stated:

34. 416 F.2d 417 (2d Cir. 1969). See also Incollingo v. Ewing, 444 Pa. 263, 292 A.2d
206 (1971).
"[U]navoidably unsafe products" are those which, in the present state of human knowledge, are incapable of being made safe for their ordinary and intended use. Strict liability may not always be appropriate in such cases because of the important benefits derived from the use of the product. This is especially so with respect to new drugs that are essential in treating disease but involve a high degree of risk. It may be so with respect to other commercial products possessing both unparalleled utility and unquestioned danger. As a practical matter, the decision to market such a product requires a balancing of the product's utility against its known or foreseeable danger.37

If a manufacturer intends to rely on the "unavoidably unsafe" exception carved out by comment k, he will have no choice but to implement evidence demonstrating that the state of the art has not progressed to the point where the risk is no longer unavoidable. Likewise, since it must also be shown that the utility of the product justifies its exception from strict liability, the manufacturer may also wish to demonstrate that the state of the art is not such that the need for the product is obviated, i.e. that the product's benefits cannot be achieved in some other manner.

3. Warning
(a) In General

According to section 402A comment j, the seller or manufacturer may be required to give a warning as to the risks involved in the use of the product, to prevent it from being unreasonably dangerous. As stated in comment h, such duty exists when the manu-

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37. Id. at 12,214. A case which seems to fly in the face of the two-pronged test for the application of comment k (unavoidably unsafe and unquestioned utility) is Cunningham v. MacNeal Memorial Hospital, 47 Ill. 2d 443, 266 N.E.2d 897 (1970), where the plaintiff contracted serum hepatitis due to a transfusion of blood from defendant hospital. The defendant argued that since there was no possible method of detecting impure blood, and since the need for the blood was unquestionable, comment k's exception should apply. The court stated however:

We believe it clear that the exception set forth in the quoted Comment [(k)] relates only to products which are not impure and which, even if properly prepared, inherently involve substantial risk of injury to the user. Such exception cannot avail where, as here, the product is alleged to be impure. Id. at 456, 266 N.E.2d at 904. Although this inherently dangerous-impure distinction has been employed in other cases, such as Community Blood Bank v. Russell, 196 So. 2d 115 (Fla. 1967) and Cochran v. Brooke, 243 Ore. 89, 409 P.2d 904 (1966), it is certainly an insignificant distinction. If the product is needed and the user is made aware of the risks involved, then technical niceties as to the exact nature of the risk involved should not be determinative of whether the seller will be held liable. The policy is the same in both cases. See Note, Strict Liability for Diseases Contracted from Blood Transfusions, 66 Nw. U.L. Rev. 80 (1971).
manufacturer or seller "has reason to anticipate that danger may result from particular use."

As stated by the court in *Oakes v. Geigy Agricultural Chemicals*:

A manufacturer or supplier of a product must give warning of any dangerous propensity of an article produced or sold by him in the product or in its use of which he knows or should know, and which the user of the product would not ordinarily discover.

It appears therefore, that the duty to warn depends upon the foreseeability of the use to which the product is put.

(b) In Regard to Unavoidably Unsafe Products

Comment k provides an exception from strict liability for unavoidably unsafe products only if they are accompanied by a proper warning. As noted above, the duty to warn depends on what is foreseeable—clearly a negligence concept. As stated by the court in *Basko*, "Comment k simply adopts the ordinary negligence concept of duty to warn." By the very nature of the products likely to fall within the "unavoidably unsafe" exception however, the duty to warn becomes especially important. Because the product is dangerous and because of the often unknown propensities involved, the manufacturer not only has a duty to warn in the first instance, when the product is sold, but he also has a continuing duty to warn of newly discovered dangers involved in the product's use.

Also, because of the technical nature of some of the products involved, such as prescription drugs, the warning will often be directed to a third person, such as a doctor or pharmacist.

The warning must be such as to impress upon the user the actual magnitude of the risk involved, and once again, the manufacturer must not engage in practices designed to nullify its effect. An example here is *Stevens v. Parke, Davis & Co.*, where defendant drug manufacturer's labels contained adequate warnings as to possible dangerous effects of prolonged use, but the court held that liability could nonetheless be imposed because the vigorous promotion of the drug by defendant's detailmen was such as to erode the warning by encouraging prescribing doctors to ignore it.
In summary, the question of when a warning must be given and whether one given is adequate involves a balancing test. As the court stated in *Davis v. Wyeth Laboratories, Inc.*, after rejecting a purely statistical approach to the problem (i.e., judging the need for a warning by the size of the population likely to be adversely affected):

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

III. Conclusion

There appear to be three primary reasons for imposing strict tort liability on a manufacturer or seller of products. First, it is said that the consumer is entitled to rely on the product being what it purports to be, and not a dangerous instrumentality. Second, the imposition of such liability will serve as a deterrent against the sale of other defective products and as an inducement to improve the safety of the product. Third, imposing such loss on the manufacturer allows him to pass it on to his other customers and thus, the loss is effectively distributed throughout society.

With regard to the product whose risks cannot be eliminated and which is accompanied by a proper warning, only the third of these reasons has any validity. If the consumer is warned of the dangers involved in the use of the product, then he cannot reasonably expect the product not to involve a risk. If a product cannot possibly be made more safe, then any attempt at deterrence or inducement is misdirected. Therefore the question becomes whether a product is of enough value to society so that when a manufacturer sells it with a proper warning, he should not be held liable. However, since under the distribution of loss theory the manufacturer will have to pass the cost of such liability on to his customers, who will pass it on to the consumers, the real question becomes how much society is willing to pay for the product. As

45. 399 F.2d 121 (9th Cir. 1968).
46. *Id.* at 129-30. *Accord* Borel v. Fibreboard Paper Products Corp., CCH Prod. Liability R. ¶ 7017 (5th Cir. Sept. 10, 1973), where the court held:
   
   [A] duty to warn attaches whenever a reasonable man would want to be informed of the risk in order to decide whether to expose himself to it.
the cost of a product rises, a consumer must decide if he really needs the product. If he doesn't, sales will decline and the manufacturer might be forced to stop producing the product. If the product is essential, then the consumer will pay irrespective of costs.

On first glance, this "natural selection" approach might seem to be an appropriate means of ridding the market of unsafe products. If the consumer will bear the cost of liability for the unsafe product, then the product should remain available. The problem, however, is that the type of product which is likely to fall under the title of "unavoidably unsafe" is not a product which is used by a large percentage of the population. Drugs and other medical and pharmaceutical products may be used by a relatively small segment of the consuming public and therefore when the cost of liability is passed on, it will be especially hard to bear. Yet if the product is really necessary, as many drugs are, the individual may have no choice but to pay. Thus the exception to strict liability provided in comment k is well justified. State of the art evidence is indispensable in bringing this important exception into play because without it, the product cannot be shown to be "unavoidably unsafe."

JAMES T. MURRAY, JR.

STRICT LIABILITY AND THE SCIENTIFICALLY UNKNOWABLE RISK

I. INTRODUCTION

This comment deals with the question of whether or not a manufacturer should be excused from liability in a "strict liability" case because the injury resulted from a danger that was a scientifically unknowable risk prior to the injury. Basically, this question is concerned with defining the outer limits of the concept of "defective" products and, thereby, the scope of the strict liability theory in products liability cases. The black letter rule of section 402A of the Restatement (Second) of Torts imposes liability on sellers or manufacturers if their product is in a "defective condition un-

50. Restatement (Second) of Torts § 402A, comment k at 353-54 (1965).

1. 2 L. FRUMER AND M. FRIEDMAN, PRODUCTS LIABILITY § 16A(4)(3), p. 3-332.