When Warnings Alone Won't Do: A Reply to Professor Phillips

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WHEN WARNINGS ALONE WON’T DO:
A REPLY TO PROFESSOR PHILLIPS

by Richard C. Ausness

INTRODUCTION

In his paper, Professor Phillips contends that questions about the adequacy of a product’s design should be resolved by the use of a risk-utility test and that the existence of an adequate warning should merely be one factor for the jury to take into account. This is essentially the position espoused by the Restatement (Third) of Torts: Products Liability (hereinafter Third Restatement), section 2, comment l. On the other hand, Professor Phillips is very critical of subsections 6(c) and 6(d). These provisions establish liability for the sellers of prescription drugs and medical devices. Section 6(c), which is concerned with design defect claims, protects manufacturers and other sellers from liability as long as a reasonable health-care provider would prescribe their product to some class of patients. Section 6(d), which deals with the duty to warn, permits manufacturers of prescription drugs and medical devices to satisfy their duty to warn, at least in most instances, by communicating the warning to the prescribing physician rather than the patient. In other words, section 6(d) retains the traditional “learned intermediary” rule.

Although I agree with Professor Phillips that a manufacturer should not always avoid liability for defective design by proving that it provided an adequate warning, I have serious doubts about the wisdom of adopting a sweeping rule such as the one set forth in comment l. In my opinion,

1. Ashland Oil Professor of Law, University of Kentucky.
4. See id. §§ 6(c)-(d); See also Phillips, supra note 2, at 9-16 (noting the provisions lack any precedent in case law, are filled with ambiguities, and will probably prove unworkable).
5. See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(c).
6. See id. § 6(d).
7. Id. § 2 cmt. l.
comment I's approach is economically inefficient and undercuts the moral values of individual autonomy and personal responsibility. There is simply no social or economic benefit to be gained by giving large damage awards to product users who fail to follow simple instructions or heed clear warnings.

I also disagree with Professor Phillips' view of section 6 of the Third Restatement. I believe that the Third Restatement's approach in section 6(c), which gives broad protection to manufacturers of prescription drugs and medical devices, is the correct one even though it leaves injured consumers with less protection than they might otherwise have. I also believe that section 6(d)'s retention of the learned intermediary rule is sensible and I find the Reporters' policy justifications for retaining the rule to be persuasive.

THE RELATION BETWEEN DESIGN DEFECT AND FAILURE-TO-WARN CLAIMS

Section 2 of the Third Restatement identifies three categories of product defect: manufacturing defects, design defects and defects arising from inadequate instructions or warnings. According to the Third Restatement, a manufacturing defect occurs when a product fails to conform to its intended design. In contrast, a product is defectively designed when product-related risks could be reduced or avoided by the use of a reasonable alternative design and when the failure to incorporate such a design causes the product to be "not reasonably safe." Finally, a product may be defective when product-related risks could be lowered or prevented by

8. See Phillips, supra note 2, at 10 (concluding that the provisions lack any precedent in case law, are filled with ambiguities, and will probably prove unworkable).
9. See id. § 2.
11. Id. § 2(a) (stating that a product "contains a manufacturing defect when the product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product").
12. Id. § 2(b) (declaring a product is defective in design "when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the alternative design renders the product not reasonably safe").
reasonable instructions or warnings and when the failure to provide such instructions or warnings results in a product that is not reasonably safe. This classification scheme is widely accepted by courts and legal commentators.

According to Professor Phillips, design defect claims and failure-to-warn claims should be regarded as separate and independent and not mutually exclusive. He bases this conclusion, at least in part, on the text of the Third Restatement. As mentioned earlier, the Third Restatement

13. Id. § 2(c) (providing that a product may be defective because of inadequate instructions or warnings when "the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the instructions or warnings renders the product not reasonably safe").

14. See, e.g., Lantis v. Astec Indus., Inc., 648 F.2d 1118, 1120 (7th Cir. 1981) (declaring that "a product may be found defective within the meaning of Section 402(A) because of either a manufacturing flaw, a defective design or a failure to warn of dangers in the use of the product"); Gianitis v. American Brands, Inc., 685 F. Supp. 853, 856 (D.N.H. 1988) (observing that plaintiff may bring a claim "for injuries arising out of the defective design of the product, defect in the manufacture of a product, or a defect in the failure to provide adequate warnings in conjunction with the use of the product"); Piper v. Bear Medical Systems, 883 P.2d 407, 410-11 (Ariz. Ct. App. 1993) (stating that "three types of defects can result in an unreasonably dangerous product: manufacturing defects, design defects, and informational defects encompassing instructions and warnings").

15. See, e.g., David G. Owen, The Graying of Products Liability Law: Paths Taken and Untaken in the New Restatement, 61 TENN. L. REV. 1241, 1243 (1994) (declaring that "[t]oday, most courts and commentators accept as axiomatic the fundamental distinctions between three very different forms of product defect: (1) manufacturing flaws, (2) design inadequacies, and (3) insufficient warnings of danger and instructions on safe use"); Jerry J. Phillips, A Synopsis of the Developing Law of Products Liability, 28 DRAKE L. REV. 317, 342 (1978) (stating that "[p]roduct defects are now typically divided into three categories: manufacturing or production defects; design defects; and defects attributable to the absence or insufficiency of warnings or instructions for use of the product"); William C. Powers, Jr., The Persistence of Fault in Products Liability, 61 TEX. L. REV. 777, 782 (1984) (observing that "[d]efects generally are classified in three categories: flaws or manufacturing defects, design defects, and warning or informational defects"); but see Frank J. Vandall, The Restatement (Third) of Torts, Products Liability, Section 2(b): Design Defect, 68 TEMPLE L. REV. 167, 176-79 (1995) (pointing out that courts do not always clearly distinguish between manufacturing or design defects).


17. Id. at 4 (quoting comment I to section 2 stating that "[w]arnings are not ... a substitute for the provision of a reasonably safe design").
recognizes the aforementioned three types of product defect and establishes separate criteria for each category. It would seem to follow, therefore, that if one product can be defective because it has a bad design as defined by section 2(b), while another product can be defective because it has a bad warning as defined by section 2(c), it is possible that a third product may suffer from both a defective design and an inadequate warning. In such a case, there is nothing in the Third Restatement that would require the plaintiff to elect between the design defect claim and the inadequate warning claim. On the contrary, in such a case, the plaintiff could presumably proceed under either or both theories.

Lawsuits based on both defective design and failure-to-warn theories have been brought without challenge for many years. Indeed, Gosewisch v. American Honda Company was the only appellate case I could find where a defendant even raised the issue. The plaintiff in Gosewisch was severely injured while riding a three-wheel All Terrain Cycle (ATC) manufactured by the defendant, Honda Motor Company. He alleged that the vehicle had a number of design flaws which caused it to flip forward unexpectedly. The plaintiff also claimed that Honda was grossly negligent because it failed to warn customers about the unstable characteristics of its ATCs. The trial court refused to allow the plaintiff’s failure-to-warn claim to go before the jury because the plaintiff had already alleged that the product was defectively designed. The jury subsequently found in favor of the defendant on the design defect claim and the plaintiff

20. Id. at 378.
21. Id. These design flaws included (1) low tire pressure; (2) failure to install a mechanical suspension system; (3) a high center of gravity; (4) weak front forks; and (5) badly designed front wheel brakes. Id.
22. Id.
23. Id.
The intermediate appellate court affirmed the lower court’s decision, but was itself reversed by the Arizona Supreme Court. That court acknowledged that the defective design claim and the failure-to-warn claim were independent of each other and, therefore, could be separately considered by the jury. According to the Gosewisch court, “[a] plaintiff is not required to make an election between pursuing a case on a strict products liability theory of either design defect or failure to warn.”

ADEQUATE WARNINGS AS A SUBSTITUTE FOR SAFER PRODUCT DESIGN

Professor Phillips concludes that because design defects and inadequate warning defects are distinct categories, a manufacturer should not be able to cut off liability for defective design simply by providing an effective warning about design-related (as opposed to inherent) risks. I must concede that the Third Restatement, as well as many appellate court decisions, agree with Professor Phillips.

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24. Id.
25. See Gosewisch v. American Honda Company, 737 P.2d 365, 368 (Ariz. Ct. App. 1985) (declaring that “[b]ecause plaintiffs here did not contend at trial that the ATC was faultlessly manufactured and designed—their sole contention being that the vehicle had design defects—there was no error in failing to give the instruction”). The intermediate appellate court relied on Embry v. General Motors Corp., 565 P.2d 1294 (Ariz. Ct. App. 1977), a case which involved allegedly defective motor mounts. The court in Embry also affirmed a lower court’s refusal to give a failure-to-warn instruction, finding that it was redundant because the only danger involved was that created by the defective design. Id. at 1297.
26. Id. at 383.
27. Id. at 379.
28. Id.
29. Professor Phillips has maintained this view for years. See Jerry Phillips, The Standard for Determining Defectiveness in Products Liability, 46 U. Cin. L. Rev. 101, 106 (1977) (“There may be instances where the product is so dangerous that the courts will find the seller’s obligation cannot be fulfilled merely by warning.”). See also Phillips, supra note 2, at 4-8 (citing Rogers v. Ingersoll-Rand Co., 114 F.3d 841, 843 (D.C. Cir. 1998)).
A. The Issue from a Doctrinal Perspective

As Professor Phillips points out, there is considerable doctrinal support for the proposition that adequate warnings will not necessarily insulate a manufacturer from liability when it is possible to reduce or avoid the harm by redesigning the product. A few courts, however, have taken the opposite view.

1. The Third Restatement and Comment 1

Although section 2 of the Third Restatement identifies three distinct types of product defects and implies that litigants are not required to elect among them when they bring suit against manufacturers, it does not tell us whether a manufacturer may respond to a product-related risk by providing an adequate warning as an alternative to eliminating the risk by an improved design. Comment 1 to section 2, however, does expressly address this issue. This provision states that "[i]n general, when a safer design can reasonably be implemented and risks can reasonably be designed out of a product, adoption of the safer design is required over a warning that leaves a

30. Phillips, supra note 2, at 4-8 (citing Uloth v. City Tank Corp. 384 N.E.2d 1188, 1193 (1978) (holding that a product may be defectively designed even if there are warnings to be found adequate, or if the dangers are obvious); Rogers v. Ingersoll-Rand Co., 144 F.3d 841, 843 (D.C. Cir. 1998) (holding that an adequate warning will not automatically discharge the defendant manufacturer's duty to design a safer product)).

31. See Sturm, Ruger & Co., Inc. v. Day, 594 P.2d 38, 44 (Alaska 1979) (declaring that where the most stringent warning will not protect the public, gun manufacturer must eliminate the defect itself); Eads v. R.D. Werner Co., 847 P.2d 1370, 1372 (Nev. 1993) (holding that an adequate warning will not shield a ladder manufacturer from liability if the defect involved could have been corrected through the use of a commercially feasible alternative design); Robinson v. G.G.C., Inc., 808 P.2d 522, 524-25 (Nev. 1993) (concluding that an adequate warning will not prevent the manufacturer of a box-crushing machine from being held liable for defective design if it fails to provide a safety device that is commercially feasible and will not affect product efficiency).

significant residuum of such risks." This, of course, is fully consistent with Professor Phillips' position.

The Reporters of the *Third Restatement* offer the following rationale to support their position in comment I: An obvious risk puts the user or consumer on notice that the product is dangerous in some respect. However, the obviousness of the risk does not ordinarily relieve the manufacturer of its duty to provide a safer design because consumers who are unable to avoid obvious risks will suffer avoidable injuries unless manufacturers are encouraged to develop safer designs for their products. Warnings are similar to obvious risks in the sense that they also provide notice to consumers. Since consumers often ignore warnings, just as they ignore obvious risks, the same accident-cost-avoidance considerations that require manufacturers to eliminate obvious risks through better design also justify requiring manufacturers to eliminate latent risks through better design as opposed to merely warning about them.

In the Reporters' Note to section 2, the drafters tacitly acknowledge that the new comment I is inconsistent with comment j to the superseded section 402A of the *Restatement (Second) of Torts* (hereinafter the *Second Restatement*). Comment j declared that "[w]here a warning is given, the seller may reasonably assume that it will be read and heeded; and a product

34. See Phillips, *supra* note 2, at 8 (indicating that "it seems more responsible to put the loss on the generally better accident avoider, the manufacturer . . .").
35. Id.
36. See Camacho v. Honda Motor Ltd., 741 P.2d 1240, 1246 (Colo. 1987) (declaring that "[u]ncritical rejection of design defect claims in all cases wherein the danger may be open and obvious thus contravenes sound public policy by encouraging design strategies which perpetuate the manufacture of dangerous products").
37. See *Restatement (Third) Of Torts: Products Liability* § 2 cmt. I (1998). Moreover, some courts have concluded that there may be duty to warn even when the risk is an obvious one. See Banks v. Iron Hustler Corp., 475 A.2d 1243, 1252 (Md. Ct. Spec. App. 1984) (holding that there is no valid reason for automatic preclusion of liability based solely upon obviousness of danger in an action based on failure to warn); Campos v. Firestone Tire & Rubber Co., 485 A.2d 305, 309-10 (N.J. 1984) (stating that "in our state the obviousness of a danger, as distinguished from a plaintiff's subjective knowledge of the danger, is merely one element to be factored into the analysis to determine whether a duty to warn exists").
bearing such a warning, which is safe for use if it is followed, is not in
defective condition, nor is it unreasonably dangerous.\textsuperscript{39} The drafters of
comment\textsuperscript{1} have rejected the approach of the old comment\textsuperscript{j} for two reasons:
first, it is inconsistent with the judicial abandonment of the patent danger
rule;\textsuperscript{40} and, second, a growing body of social science research suggests that
warnings are not always very efficient accident-cost-avoidance
mechanisms.\textsuperscript{41}

The Reporters cite \textit{Uloth v. City Tank Corp.}\textsuperscript{42} to support their
conclusion that an adequate warning cannot redeem a defective design.\textsuperscript{43}
The plaintiff in \textit{Uloth}, a sanitation worker, was injured when a garbage truck
packer blade severed his foot.\textsuperscript{44} The plaintiff brought suit against the
manufacturer of the truck, claiming that the truck’s compactor mechanism
had been defectively designed.\textsuperscript{45} The plaintiff also showed that several
safety devices were available that would have prevented the accident
without affecting the efficiency of the product.\textsuperscript{46} In response, the defendant
argued that the court should disallow the plaintiff’s design defect claim if an
adequate warning had been given.\textsuperscript{47} The trial court rejected this argument
and the jury eventually found in favor of the plaintiff.\textsuperscript{48}

The lower court’s judgment for the plaintiff was affirmed on

\textsuperscript{39} See \textit{RESTATEMENT (SECOND) OF TORTS} § 402A cmr. j (1965).
\textsuperscript{40} See \textit{Camacho v. Honda Motor Ltd.}, 741 P.2d 1240, 1246-47 (Colo. 1987)
(rejecting the patent danger rule in a design defect case involving failure to provide crash bars on
motorcycle); \textit{Koske v. Townsend Engineering Co.}, 551 N.E.2d 437, 442 (Ind. 1990)
(rejecting the patent danger rule in a products liability case where the manufacturer of a
meat-slicing machine failed to provide shielding); \textit{Owens v. Allis-Chalmers Corp.}, 326
N.W.2d 372, 377 (Mich. 1982) (rejecting the patent danger rule in a design defect case
involving failure to provide driver restraint devices on forklift).
\textsuperscript{41} See \textit{RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY} § (1998)
(Reporters’ Note 101) (citing Howard Latin, "Good" Warnings, Bad Products, and Cognitive Limitations,
41 \textit{UCLA L. REV.} 1193 (1994)).
\textsuperscript{42} 384 N.E.2d 1188 (Mass. 1978).
\textsuperscript{43} See \textit{RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY} § 2 (1998)
(Reporters’ Note 101).
\textsuperscript{44} \textit{Uloth}, 384 N.E.2d at 1190-91.
\textsuperscript{45} \textit{Id.} at 1191.
\textsuperscript{46} \textit{Id.}
\textsuperscript{47} \textit{Id.} at 1191-92.
\textsuperscript{48} \textit{Id.} at 1190.
appeal. The appellate court refused to adopt a rule which permitted a manufacturer to discharge its duty to consumers by simply issuing a warning about product-related dangers. Instead, the court declared that the adequacy of any warning given (or the obviousness of the danger if a warning was not given) was a factor that could be considered in determining whether the product was defectively designed.

The Uloth court based its decision on the assumption that manufacturers had more control over product-related risks than consumers. For example, the court observed that workers often had no choice but to work with dangerous products and almost no ability to reduce these product-related risks. In addition, warnings did little to eliminate accidents that were caused by inadvertence, instinctual reactions or forgetfulness. Manufacturers, on the other hand, could anticipate these accident scenarios and often had the ability, through design changes, to reduce or eliminate product-related risks at relatively small cost. For this reason, in the court’s view, it made sense to place the burden of reducing product-related risks on manufacturers instead of allowing this burden to be shifted to users and consumers.

2. Recent Decisions Adopting the Third Restatement’s Position

Recently, a number of courts have expressly relied on comment to conclude that adequate warnings are no substitute for safer designs. Two of these cases, discussed by Professor Phillips, are Rogers v. Ingersoll-Rand Co. and Uniroyal Goodrich Tire Co. v. Martinez.

In Rogers, the plaintiff, a member of a road construction crew, was seriously injured when a large machine backed into her while she was directing traffic at a busy work site. The machine in question, known as

49. Id. at 1195.
50. Id. at 1192.
51. Id.
52. Id.
53. Id.
54. Id.
55. Id.
56. 144 F.3d 841 (D.C. Cir. 1998).
57. 977 S.W.2d 328 (Tex. 1998).
58. Rogers, 144 F.3d at 842.
a MT-6520 milling machine, was being used to strip away layers of asphalt from a road.59 The driver of the MT-6520 did not see the plaintiff because she was standing in a blind spot, and the plaintiff did not hear the machine approaching because its alarm system did not function properly.60 The plaintiff sued the manufacturer of the MT-6520, alleging that the machine was defectively designed because it did not have rear-view mirrors, kill switches or a reliable alarm system.61 At the end of the trial, the defendant proposed a jury instruction that would have effectively precluded liability as long as the manufacturer provided an adequate warning.62 The trial court, however, refused to give the requested instruction and the jury returned a $16.7 million verdict for the plaintiff.63

On appeal, the District of Columbia Court of Appeals affirmed the lower court's ruling.64 It concluded that courts in the District of Columbia had adopted a risk-utility test for use in design defect cases.65 Under this approach, the Rogers court declared, a defendant could show that a warning reduced a product's dangers (and, therefore, reduced the risk side of the risk-utility equation), but that a warning would not necessarily be determinative on the issue of defectiveness when an alternative safer design was available.66 In the court's words, "[i]t is thus not correct that a manufacturer may, under the law of the District of Columbia, merely slap a warning onto its dangerous product, and absolve itself of any obligation to do more."67

Indeed, as the court observed, a warning would have done very little to reduce the danger that the MT-6520 would accidently back into an

59. Id.
60. Id.
61. Id. at 843.
62. Id. The MT-6520's maintenance manual stated that other workers should stay at least ten feet away from the machine while it was operating. It also admonished the operator to verify that the alarm worked and to check for people in the area. Finally, a sign on the machine itself warned people to stay ten feet away. Id.
63. Id. at 842-43. Ten million and two-hundred thousand dollars were awarded for compensatory damages along with another $6.5 million in punitive damages. Id. at 842. The district court opinion is reported at 971 F. Supp. 4 (D.D.C. 1997).
64. See Rogers, 144 F.3d at 842.
65. Id. at 843 (citing Warner Fruehauf Trailer Co., Inc. v. Boston, 654 A.2d 1272, 1276 (D.C. 1995)).
66. Id. at 844-45.
67. Id. at 844.
unsuspecting worker. In such a case, therefore, the manufacturer was legally obligated to incorporate additional safety features, where feasible, to guard against foreseeable harm. The Rogers court bolstered its decision by citing comment I of the Third Restatement, implicitly adopting the reasoning of that comment and the Uloth case.

The Third Restatement's approach was also endorsed by the Texas Supreme Court in Uniroyal Goodrich Tire Co. v. Martinez. In that case, an automobile mechanic was injured when a 16-inch tire exploded as he was attempting to mount it on a 16.5-inch rim. The plaintiff contended that the tire was defectively designed because it used a 0.037-inch multi-strand weftless bead on the tire instead of safer 0.050-inch single strand programmed bead. The jury found in the plaintiff's favor and awarded him $5.5 million in compensatory damages and $11.5 million in punitive damages. This judgment was affirmed by an intermediate appellate court, and ultimately by the Texas Supreme Court.

Attached to the tire in question was a prominent label which warned against mounting the tire on a 16.5-inch rim, failing to use a tire mounting machine, inflating the tire without using an extension hose, or reaching over the tire during inflation. The plaintiff, who had inflated more than a thousand tires during his career, ignored all of these warnings. The tire manufacturer urged the court to adopt the rule enunciated in comment j to section 402A of the Second Restatement, which provided that an adequate warning would prevent design defect liability. The court, however, rejected comment j in favor of the position set forth in comment I of the

68. Id. at 845.
69. Id.
70. Id.
71. 977 S.W.2d 328 (Tex. 1998).
72. Id. at 331-32.
73. Id. at 333-34.
74. Id. at 334. The compensatory award was later reduced to $4.1 million and the punitive award was reduced to $4.1 million as well, resulting in a final award of $10.3 million, including interest. Id.
75. 928 S.W.2d 64 (Tex. Ct. App. 1995).
76. Martinez, 977 S.W.2d at 331.
77. Id. at 332.
78. Id. at 343 (Hecht, J., dissenting).
79. Martinez, 977 S.W.2d at 335-36.
Third Restatement\textsuperscript{80} and held that "warnings and safer alternative designs are factors, among others, for the jury to consider in determining whether the product as designed is reasonably safe."\textsuperscript{81} Applying the Third Restatement's approach, the court in \textit{Martinez} concluded that the jury could have reasonably found that the tire was defectively designed.\textsuperscript{82}

3. \textit{The Minority View}

Although the rule set forth in the \textit{Third Restatement} no doubt represents the prevailing view, there is some case law to the contrary. \textit{Simpson v. Standard Container Co.}\textsuperscript{83} and \textit{Taylor v. Yale & Towne Manufacturing Co.}\textsuperscript{84} are illustrative. The \textit{Simpson} case involved a four-year-old child who was injured by burning gasoline.\textsuperscript{85} The plaintiff and a companion took the cap off a gasoline container and spilled it on the floor\textsuperscript{86}. The fumes from the spilled gasoline somehow ignited, injuring the plaintiff.\textsuperscript{87} The plaintiff sued the manufacturer of the gasoline container, arguing that the container should have been equipped with a child-proof cap.\textsuperscript{88} The trial court dismissed the case and the plaintiff appealed.\textsuperscript{89} The Maryland Court of Special Appeals upheld the lower court's ruling.\textsuperscript{90}

The appellate court based its conclusion in part on the fact that the product was not being used for its intended purpose.\textsuperscript{91} In the court's view, the storing of the gasoline container where unsupervised four-year-old children could play with it was unforeseeable misuse.\textsuperscript{92} In addition, the court relied on section 402A, comment\textit{j} to conclude that the container was not unreasonably dangerous since clear warnings were affixed to it which

\begin{footnotesize}
\begin{enumerate}
\item[80.] \textit{Id.} at 336.
\item[81.] \textit{Id.}
\item[82.] \textit{Id.}
\item[84.] 520 N.E.2d 1375 (Ohio Ct. App. 1987).
\item[85.] \textit{Simpson}, 527 A.2d at 1339.
\item[86.] \textit{Id.}
\item[87.] \textit{Id.} at 1339
\item[88.] \textit{Id.}
\item[89.] \textit{Id.} at 1338.
\item[90.] \textit{Id.} at 1341.
\item[91.] \textit{Id.} at 1340-41.
\item[92.] \textit{Id.} at 1341.
\end{enumerate}
\end{footnotesize}
directed consumers to “Keep Out of Reach of Children” and “Do Not Store in Vehicle or Living Space.”93 Apparently, the Simpson court felt that it was appropriate to put the burden on the parents to keep the gasoline container away from small children.

An Ohio intermediate appellate court reached a similar result in Taylor v. Yale & Towne Manufacturing Co.94 In that case, a worker was injured by an explosion at a cement plant.95 The explosion occurred when sparks from a truck manufactured by the defendant ignited fumes that were emanating from the “mix center” at the plant.96 The injured worker brought suit against the truck manufacturer, alleging failure to warn and defective design; however, the trial court granted a motion for directed verdict in favor of the defendant.97 This decision was affirmed by the Ohio Court of Appeals.98

According to the Taylor court, the only evidence the plaintiff presented in support of his design defect claim was that the defendant failed to warn about the Yale truck’s tendency to spark.99 The court, however, observed that the plaintiff and other workers at the plant were well aware of this characteristic100 and, consequently, rejected the plaintiff’s design defect claim.101 Relying on section 402A, comment j, the Taylor court also disallowed the plaintiff’s failure-to-warn claim, declaring that the manufacturer had no duty to warn about an obvious hazard.102

B. The Issue from a Policy Perspective

Various policies can be invoked to support the approach taken by comment l. For example, the comment l approach appears to promote economic efficiency by imposing liability on the cheapest cost avoider.103
In addition, one can argue that the rule set forth in comment 1 is consistent with tort law's distributive goals because it shifts accident costs to the best loss-spreader. In my view, however, the efficiency and loss-spreading effects of comment 1's approach are overrated. Furthermore, the comment 1 approach arguably produces outcomes that are inconsistent with moral values.

1. **Accident Costs**

It is generally assumed that accident costs will be optimized if product sellers are held liable for product-related injuries. Producers, because of their control over the design and production processes, are deemed to be in a better position than consumers to discover and correct dangerous characteristics in their products. Subjecting producers to liability provides an incentive for them to improve the safety of their products when it is cost-effective to do so. However, producers are not always the cheapest cost avoiders. Sometimes, consumers are able to bear some product-related risks more cheaply than producers, and in such cases, it may be better to shift these risks to them. Thus, it makes sense to require manufacturers to make design improvements when the risk involved is inherent and unavoidable or when consumers cannot reasonably be expected initial bearer of accident costs would (in the absence of transaction and information costs) find it most worthwhile to 'bribe' in order to obtain that modification of behavior which would lessen accident costs most." See Guido Calabresi, The Costs Of Accidents 135 (1970).

104. See George L. Priest, The Invention of Enterprise Liability: A Critical History of the Intellectual Foundations of Modern Tort Law, 14 J. LEGAL STUD. 461, 520 (1985) (declaring that "[s]ociety will benefit from internalizing the costs of operation to product manufacturers, including losses resulting from product-related injuries").

105. See David G. Owen, Rethinking the Policies of Strict Products Liability, 33 VAND. L. REV. 681, 711 (1980) (observing that manufacturers "often are in a far better position than consumers to discover, evaluate, and act upon, dangers that inhere in the products that they make and sell").

106. See Craig Brown, Deterrence and Accident Compensation Schemes, 17 W. ONT. L. REV. 111, 128 (1977-78) (stating that strict liability "provides an incentive for those engaged in a particular activity to make it safer, for by doing so, their costs will be lower"); Richard J. Pierce, Jr., Encouraging Safety: The Limits of Tort Law and Government Regulation, 33 VAND. L. REV. 1281, 1289 (1980) (declaring that "forcing individuals and firms with a measure of control over accident costs to absorb those costs provides an incentive to reduce the accident rate, the consequences of accidents, or both").
to exercise sufficient vigilance to avoid injury. At the same time, it seems appropriate to allow warnings to suffice in cases where consumers can easily avoid injury by heeding warnings or following directions. To require manufacturers to redesign their products in such cases will cause resources to be wasted on over-designed products.

But if this is the case, then neither the old comment $j$ approach nor the new comment $l$ approach will necessarily optimize accident costs. Comment $j$ assumes that consumers will always be the cheapest accident cost avoiders, while comment $l$ stands for the proposition that producers are inherently better at preventing accidents than consumers. Since neither of these assumptions is universally correct, I believe that it is better to allow manufacturers to provide warnings, even when it was possible to eliminate the risk by redesigning the product, when the additional cost of the alternative design is greater than the increased accident costs that occur when only a warning is provided. To illustrate this point, assume that a warning would be essentially costless and would reduce existing accident costs by $200, while a safer alternative design would cost the manufacturer an additional $500, but would reduce accident costs by $600. The original design plus warning option would result in a net reduction in social costs of $200. A safer alternative design would also result in a net reduction of social costs, but only of $100 ($600-$500) even though it would produce fewer accident costs. In this case, therefore, the first alternative would be more cost efficient than the second alternative, although both alternatives would be more efficient than doing nothing at all. Consequently, the most efficient liability rule is one which would encourage the first alternative rather than the second.

Of course, one could argue that the comment $l$ approach does not always require the manufacturer to redesign a dangerous product. In the

example discussed above, a manufacturer would theoretically escape liability if it could show that a warning was more cost-effective than a safer alternative design. Unfortunately, few juries really understand, or sympathize with, the notion that a manufacturer could deliberately choose to subject consumers to a known risk when this risk could be eliminated by an alternative safer design. What is needed, therefore, if economic efficiency is an important goal, is a rule that effectively protects producers from jury scrutiny when they make product safety decisions based on an objective assessment of costs and benefits.

2. Distributive Effects

Commentators often argue that the secondary costs of accidents can be reduced if losses are spread among a large group of people instead of being allowed to fall entirely on a small group of individuals. Since product sellers are thought to be better loss-spreaders than individual consumers, it advances the goal of loss-spreading if accident costs are shifted from consumers to producers. Since the approach embodied in comment 1 is more expansive, than the approach embodied in the old comment j, one can argue perhaps that comment 1’s approach is superior because it results in more liability, and hence more loss spreading, than the

\[108. \text{See Guido Calabresi, Some Thoughts on Risk Distribution and the Law of Torts, 70 YALE L.J. 499, 517 (1961) (maintaining that “taking a large sum of money from one person is more likely to result in economic dislocation . . . than taking a series of small sums from many people . . . ”). Secondary accident cost avoidance, therefore, is concerned with reducing the adverse economic effects that result when people suffer serious personal injuries. See Stanley Ingber, Rethinking Intangible Injuries: A Focus on Remedy, 73 CAL. L. REV. 772, 794 (1985) (declaring that “secondary cost avoidance involves allocating injury costs so as to decrease the economic dislocation caused by injuries”).}

\[109. \text{See James A. Henderson, Jr., Coping with the Time Dimension in Products Liability, 69 CAL. L. REV. 919, 934 (1981) (stating that “manufacturers are believed to be better able to obtain insurance than are consumers, and are assumed to be able to pass on most, if not all, of the insurance costs by raising the prices of products”).}

\[110. \text{See Escola v. Coca Cola Bottling Co., 150 P.2d 436, 441 (Cal. 1944) (Traynor, J., concurring) (declaring that “the cost of an injury and the loss of time or health may be an overwhelming misfortune to the person injured, and a needless one, for the risk of injury can be insured by the manufacturer and distributed among the public as a cost of doing business”).} \]
I am skeptical of this argument, not because it is illogical, but because I have doubts about the use of loss spreading as a rationale for the existing tort liability regime.

First, as mentioned above, the conventional case for loss spreading assumes that product sellers can spread losses more cheaply and effectively than consumers. However, this assumption has not been proven and it is quite possible that individual consumers can insure against loss more cheaply than producers. Second, the vast majority of consumers already have health, life, disability insurance or workers compensation protection and, therefore, any additional loss-spreading by means of tort liability is redundant. Finally, the high cost of litigation makes a tort system much more expensive to operate than private first-party insurance schemes.

111. I am not suggesting that Professor Phillips would make such an argument.
112. See Sheila L. Birnbaum, Unmasking the Test for Design Defect: From Negligence [to Warranty] to Strict Liability to Negligence, 33 Vand. L. Rev. 593, 596 (1980) (contending that “[t]he manufacturer can spread the risk through insurance and price adjustments, whereas the injured individual might suffer a crushing financial blow underwriting the loss himself”).
113. See James E. Brittain, Product Honesty Is the Best Policy: A Comparison of Doctors’ and Manufacturers’ Duty to Disclose Drug Risks and the Importance of Consumer Expectations in Determining Product Defect, 79 Nw. U. L. Rev. 342, 410 (1984) (declaring that “[t]he blithe assumption underlying loss-spreading arguments that manufacturers are in a better position than consumers to both bear and spread losses has never been empirically verified”).
114. See Stephen D. Sugarman, Doing Away With Tort Law, 73 Cal. L. Rev. 558, 647-48 (1985) (pointing out that approximately 85% of the American population is protected against accidents, either through private insurance or through government health care and welfare programs).
115. See Stephen D. Sugarman, Serious Tort Law Reform, 24 San Diego L. Rev. 795, 798 (1987) (observing that “[o]nce tort law finally does deliver money to victims, a considerable sum goes to duplicate compensation that they otherwise have or will receive from other sources, such as health insurance, sick leave, Social Security, and the like”).
116. Private insurance systems spend about 15 percent of their premium income on administrative expenses. See Robert E. Litan, The Liability Explosion and American Trade Performance: Myths and Realities, in Tort Law and the Public Interest 127, at 135 (Peter H. Schuck ed., 1991) (stating that transaction costs “consume 30 percent of the costs of the workers’ compensation system, 15 percent of health insurance, and just 1 percent of the social security system”). In contrast, the tort system’s overhead rate is closer to 50 percent. See Robert L. Rabin, Some Reflections on the Process of Tort Reform, 25 San Diego L. Rev. 13, 35 (1988) (“Reduced to a single figure, injury victims were receiving slightly less than half of every dollar expended by the system on accident claims”).
3. **Moral Issues**

Some legal commentators stress that product sellers have a strong moral responsibility to protect consumers against harm from defective products.117 They are right, of course, but I would suggest that consumers and other parties have moral responsibilities as well. For example, I believe as a matter of personal autonomy, that one should be allowed to consume products, such as whiskey, butter or tobacco, that are inherently dangerous or unhealthy;118 but at the same time, an individual who engages in such risky behavior can not expect product sellers to compensate them when they are injured while engaging in risky behavior. Unfortunately, many consumers seem to feel that they are entitled to compensation regardless of how much they may have contributed to their own injury.119

As a matter of personal autonomy and responsibility, when consumers have the ability to prevent injury by heeding warnings or following simple directions but deliberately fail to do so, I do not believe that they should recover from product manufacturers for their own carelessness.120 The unfairness of this practice is exacerbated by the large damage awards that these people often receive. For example, in *Martinez*, the plaintiff, an individual who ignored clear warnings and refused to use safety equipment obtained a judgment of more than $10 million.121 Even if the plaintiff actually received only $6 million after paying attorneys' fees

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118. See Robin L. West, *Taking Preferences Seriously*, 64 TUL. L. REV. 659, 673 (1990) ("He chooses what he prefers, he prefers what he wants, he wants what he desires, and he desires what is in his interest. Therefore, his interest is best promoted by leaving him with whatever his choices have yielded.").
119. See Robert M. Ackerman, *Tort Law and Communitarianism: Where Rights Meet Responsibilities*, 30 WAKE FOREST L. REV. 649, 674 (1995) (observing that "[t]here is no shortage of people who could have protected themselves through simple, inexpensive measures but preferred to expose themselves to injury and then sue others who arguably might have protected them through more complex, expensive measures").
120. I would not characterize inadvertent or reflexive actions as either deliberate or careless.
121. See Uniroyal Goodrich Tire Co. v. Martinez, 977 S.W.2d 328 (Tex. 1998).
WHEN WARNINGS ALONE WON'T DO

and litigation expenses, this would have produced a comfortable income of at least $300,000 a year without having to dip into his multi-million dollar nest egg. Overcompensation on that scale is bad enough under any circumstances, but it is particularly outrageous when the recipient is largely responsible for his injuries. Of course, it is not the manufacturer who ultimately pays when it is forced to design "foolproof" products; rather, this financial burden falls primarily upon responsible consumers who are required to pay for safety features they neither want nor need.

Of course, as Professor Phillips points out, courts can instruct juries to apply comparative fault principles and reduce damage awards when injured consumers are careless or negligent. Thus, at least in theory, comparative fault forces careless victims to bear some of the losses they inflict on themselves. That is the way comparative fault is supposed to work; in reality, comparative fault works somewhat differently. Although I have no empirical evidence to support my conclusions, I strongly suspect that when juries are sympathetic to the plaintiff, they either refuse to apply comparative fault principles at all or they increase the size of their award (after all no one can objectively measure pain and suffering) prior to applying the comparative fault formula, thereby ending up with the verdict they would have reached anyway.

Another problem with the approach taken by comment 1 is that it allows third parties to escape responsibility for their wrongdoing. Parents, fellow employees and employers are some of the worst offenders. In Simpson v. Standard Container, for example, primary responsibility for the child's injury ought to have been placed on the parents who ignored explicit warnings and allowed two small children to play with a container filled with gasoline. Arguably, this act of stupidity pales in comparison with the failure of the manufacturer to equip the container with a child-proof cap. Likewise, in Rogers v. Ingersoll Rand Co., the employee who

122. See Phillips, supra note 2, at 7-8 (citing Uniroyal Goodrich Tire Co. v. Martinez, 928 S.W.2d 64, 68 (Tex. Ct. App. 1995).

123. For example, the jury in Uniroyal Goodrich Tire Co. v. Martinez refused to attribute any responsibility to the victim even though he failed to determine the correct size of the tire and declined to use a tire-changing machine. 977 S.W.2d at 340. The jury's decision was upheld by two appellate courts. Id.


125. See also Larue v. National Union Electric Corp., 571 F.2d 51 (1st Cir. 1978) (parents
backed up a heavy machine in an area crowded with people without bothering to see if anyone was in the path of the vehicle was the one who was primarily responsible for the plaintiff's injuries, not the machine's manufacturer.\textsuperscript{127} Of course, the guilty employee paid nothing, while the product manufacturer was stuck with a $17 million dollar judgment.\textsuperscript{128} In the \textit{Martinez} case, while the victim contributed to the accident by ignoring the tire manufacturer's warnings, his employer also was at fault for failing to provide an operable tire-changing machine, an action that would have prevented the accident as effectively as anything the tire manufacturer could have done.\textsuperscript{129}

In sum, the liability rule reflected in comment 1 unfairly shifts the entire accident-cost-avoidance burden to product sellers while exonerating more culpable parties, such as victims, parents, employers and fellow workers. Such results are morally suspect to say the least.

C. \textit{An Alternative Approach}

Professor Phillips rightly criticizes the approach reflected in comment 1 because it allows a manufacturer to satisfy its duty to the consumer by providing a warning even in cases where the warning will not be effective. On the other hand, the approach adopted by comment 1 does not place sufficient responsibility on consumers; even they can and should take the initiative to look out for their own safety. This suggests that a new approach might be superior to either of these alternatives.

Unfortunately, it is difficult to develop an approach that will avoid

\textsuperscript{126} 144 F.3d 841 (D.C. Cir. 1998).
\textsuperscript{128} See Rogers, 144 F.3d 841.
the Scylla and Charybdis of comments \( j \) and \( l \). One possibility would be to return to the approach taken by comment \( j \), that a safer design is not required when a warning will do,\(^{130}\) but articulate this as a strong presumption rather than as a categorical rule. A presumptive approach, such as this, would provide a safe harbor for producers, but still allow a court to impose liability in particularly egregious cases. Courts could also give more weight to compliance with statutory or administrative safety standards.\(^{131}\) Thus, manufacturers who complied with statutory design standards could argue that their products were presumptively reasonably safe, thereby reducing the opportunity for juries to second guess their design decisions.\(^{132}\)

**DEFECTIVE WARNINGS, DEFECTIVE DESIGNS, AND PRESCRIPTION DRUGS**

Section 6(c) of the *Third Restatement* sets forth the requirements victims must meet in order to recover against sellers of prescription drugs or medical devices under a design defect claim, while section 6(d) establishes the criteria for failure-to-warn claims.\(^{133}\) Professor Phillips believes that these provisions do not provide enough protection for consumers.\(^{134}\) On the other hand, I would conclude that the FDA’s strict licensing process and the availability of trained personnel to serve as learned intermediaries provide adequate protection for consumers. Consequently, I would conclude that tort law should not play a significant role in the

132. See Richard C. Ausness, *The Case for a “Strong” Regulatory Compliance Defense*, 55 Md. L. Rev. 1210, 1253-57 (1996) (proposing that sellers whose warnings and designs comply with applicable government product safety standards be protected against liability unless plaintiffs can establish by clear and convincing evidence that the applicable safety standards are grossly inadequate).
133. See *Restatement (Third) of Torts: Products Liability* §§ 6(c)-(d)(1998).
production and marketing of prescription drugs or medical devices.

A. Requirements for Design Defect and Failure-to-Warn Claims

Section 6(c) declares that a prescription drug or medical device will be regarded as defectively designed if the foreseeable risks posed by the product "[a]re sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients." As Professor Phillips observes, this provision effectively limits the design defect liability of drug manufacturers to situations where the product has virtually no therapeutic value. If this minimal threshold requirement is met, injured parties can recover only if the manufacturer fails to warn their prescribing physicians about foreseeable risks of harm.

According to Professor Phillips, the drafters of this provision mistakenly assume that if a manufacturer is forced to redesign a drug which is useful for one class of patients in order to make it safer for another class of users, the redesigned drug will then be less useful to the original class of users. In his view, it makes sense to encourage the manufacturer to redesign a dangerous drug because the redesigned drug might be safer for the second class of users without necessarily losing its utility for the first class of users. In the alternative, the manufacturer might develop separate designs for each class of user and thereby minimize the harmful effects of the first design.

Section 6(d) states that the supplier of a prescription drug or medical device will be subject to liability if reasonable instructions or warnings are not provided to prescribing physicians or other health care providers. This provision also declares that drug manufacturers may be held liable for failure to warn patients (as opposed to the prescribing physicians and health care providers) when they know that these learned

135. See RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY § 6(c)(1998).
136. See Phillips, supra note 2, at 13.
137. Id. at 11-13.
138. Id.
139. See RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY § 6(c)(1998).
intermediaries will be unable to reduce product-related risks by following instructions or warnings.\textsuperscript{140} Professor Phillips questions the merits of this provision on two grounds: first, the Reporters are wrong to assume that learned intermediaries will always act reasonably;\textsuperscript{141} second, the direct marketing of prescription drugs by pharmaceutical companies undermines the learned intermediary doctrine’s rationale.\textsuperscript{142}

\textbf{B. The Issue from a Doctrinal Perspective}

Section 6(c) departs from section 402A, comment k’s “unavoidably unsafe” analysis. Comment k provided that when products were incapable of being made safe for their intended use, but were sufficiently beneficial, their continued production and use was fully justified, notwithstanding the high degree of risk associated with their use, and they would be classified as “unavoidably unsafe.”\textsuperscript{143} Sellers of such unavoidably unsafe products would not be subject to strict liability in tort as long as the products were properly prepared and marketed, and as long as a proper warning was given.\textsuperscript{144} Although comment k was not expressly limited to any particular kind of product, courts traditionally applied it only to pharmaceutical products.\textsuperscript{145}

Although section 6(c) does not use the term “unavoidably unsafe” like its predecessor, section 402A, comment k, its treatment of prescription drugs and medical devices is similar to section 402A’s basic approach. For example, section 6(c) appears to cover the same sorts of pharmaceuticals as its predecessor, namely chemical drugs, biologics such as antibiotics, blood and vaccines, as well as medical devices. Furthermore, like comment k, section 6(c) requires drug manufacturers to warn about inherent product-related risks if they wish to avoid tort liability. However, section 6(c)’s

\textsuperscript{140} \textit{Id.}
\textsuperscript{141} See Phillips, \textit{supra} note 2, at 13-16.
\textsuperscript{142} \textit{Id.}
\textsuperscript{143} \textit{See Restatement (Second) Of Torts § 402A cmt. k (1965).}
\textsuperscript{144} \textit{Id.}
\textsuperscript{145} See Richard C. Ausness, \textit{Unavoidably Unsafe Products and Strict Products Liability: What Liability Rule Should be Applied to the Sellers of Pharmaceutical Products?}, 78 KY. L.J. 705, 713-15 (1989-90) (observing that almost all comment k cases have involved pharmaceuticals, but discussing a few that have involved other products).
formula for determining the product’s social utility is somewhat different than comment k’s. In theory, under comment k, courts engaged in a perfunctory form of risk-utility analysis in order to determine whether a product’s therapeutic benefits outweighed its inherent risks. In contrast, section 6(c) uses the prescribing practices of “reasonable health care providers” as a proxy for determining a prescription drug’s therapeutic utility. The assumption seems to be that courts should not independently evaluate the risks and benefits of prescription drugs, but should instead defer to the judgment of health care professionals. This is reminiscent of the deference shown to the medical profession in malpractice cases by courts which employ the “accepted practice” rule.

Section 6(d) declares that pharmaceutical manufacturers can satisfy their duty to warn in most instances by communicating their warnings to “prescribing and other health care professionals” and do not have to directly warn the ultimate users or consumers of their products. This approach follows the traditional “learned intermediary” rule, which provides that the manufacturer of a prescription drug has no duty to inform a patient about drug-related risks as long as it provides an adequate warning to the patient’s prescribing physician. The rule also applies to medical devices.

146. Id. at 716.
148. See Joseph H. King, Jr., In Search of a Standard of Care for the Medical Profession: the “Accepted Practice” Formula, 28 VAND. L. REV. 1213, 1234-36 (1975) (discussing the accepted practice rule).
149. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(d) (1998).
150. See Thomas v. Hoffman-LaRoche, Inc., 949 F.2d 806, 811 (5th Cir.), cert. denied, 504 U.S. 956 (1992) (failure to communicate directly with patient does not make a product defective as long as manufacturer provides an adequate warning to learned intermediary); Anderson v. McNeilab, Inc., 831 F.2d 92, 93 (5th Cir. 1987) (seller of prescription drug satisfies its duty to warn by informing prescribing physician about product’s inherent dangers); Tracy v. Merrell Dow Pharmaceuticals, Inc., 569 N.E.2d 875, 878 (Ohio 1991) (manufacturer discharges its duty to warn by adequately communicating with prescribing physician). See also Richard C. Ausness, Learned Intermediaries and Sophisticated Users: Encouraging the Use of Intermediaries to Transmit Product Safety Information, 46 SYRACUSE L. REV. 1185, 1195-200 (1996) (discussing the learned intermediary rule).
Warnings can be communicated to physicians by means of package inserts, advertisements in medical journals or the Physician’s Desk Reference, letters to physicians or by office visits from company representatives (formerly known as “detail men”).

The learned intermediary rule assumes that the prescribing physician will act as an intermediary between the manufacturer and the patient. Consequently, once the manufacturer warns the physician, the burden shifts to the physician to pass this information on to his or her patients. Although the learned intermediary doctrine has been criticized by some commentators, it continues to be recognized in almost all jurisdictions. Thus, the Third Restatement’s retention of the learned intermediary rule is entirely consistent with the prevailing case law.

C. The Issue from a Policy Perspective

In my opinion, section 6’s treatment of prescription drugs and medical devices appears to optimize accident costs and it also establishes a liability regime which permits manufacturers to market essential products at reasonable cost to consumers.

Issues, 32 GA. L. REV. 141, 156 (1997) (declaring that some courts have extended the learned intermediary doctrine to implantable medical devices).
154. See Brooks v. Medtronic, Inc., 750 F.2d 1227, 1232 (4th Cir. 1984) (declaring that once the manufacturer warns the physician, “the choice of treatment and the duty to disclose properly fall on the doctor”).
155. See, e.g., Margaret Gilhooley, Learned Intermediaries, Prescription Drugs and Patient Information, 30 ST. LOUIS U. PUB. L. REV. 633, 657-58 (1986) (contending that “[t]he change in the informed consent doctrine makes appropriate a corresponding change in the role that the physician should perform as ‘learned intermediary’ ”); Susan A. Casey, Comment, Laying an Old Doctrine to Rest: Challenging the Wisdom of the Learned Intermediary Doctrine, 19 WM. MITCHELL L. REV. 931, 958 (1993) (arguing that “the learned intermediary doctrine is based on medical paternalism that is inconsistent with the concept of informed consent”).
156. See Barbara P. Flannagan, Comment, Products Liability: The Continued Viability of the Learned Intermediary Rule as It Applies to Product Warnings for Prescription Drugs, 20 U. RICH. L. REV. 405, 411 (1986) (acknowledging that the learned intermediary doctrine is universally recognized in the United States).
I. Accident Costs

Arguably, section 6(c) optimizes accident costs by ensuring that the benefits of a prescription drug will outweigh its benefits. However, instead of allowing juries to evaluate a drug's risks and benefits in the context of litigation, which is the way section 2 deals with design defect claims, section 6(c) employs surrogates to perform this function. The first of these surrogates is the FDA, which engages in a sophisticated risk-benefit analysis as part of its drug-licensing process. The Reporters expressly rely on the FDA to act as a regulatory watchdog and keep unreasonably dangerous drugs off the market. The medical profession also acts as a surrogate. Section 6 immunizes only drugs which have been recognized as effective and beneficial by prescribing physicians. Thus, physicians as a group determine the drug's overall utility by deciding whether to prescribe it or not.

Section 6(d) also promotes economic efficiency by allowing physicians to make individualized determinations of costs and benefits for each of their patients. While manufacturers could warn patients directly by means of package inserts, it would be difficult to communicate such complex and technical information in a way that would be comprehensible to ordinary consumers. In contrast, physicians are ideal sources of information for consumers. Not only can prescribing physicians understand technical data, but they can translate this information into language that lay persons can understand. In addition, physicians can screen information provided by the manufacturer so that patients receive only such information

158. See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 (1998) (Reporters' Note 146) (stating that "government regulatory agencies adequately review new prescription drugs and devices, keeping unreasonably dangerous products off the market").
159. See Lars Noah, Advertising Prescription Drugs to Consumers: Assessing the Regulatory and Liability Issues, 32 GA. L. REV. 141, 159 (1997) (pointing out that "because of the complexity of risk information about prescription drugs, comprehension problems would complicate any effort by manufacturers to translate physician labeling for lay patients").
as is directly relevant to their medical condition.\textsuperscript{160} Thus, by utilizing physicians to communicate information about product-related risks to their patients, the learned intermediary rule takes advantage of the existing physician-patient relationship and thus ensures that such information will be communicated to the ultimate recipient cheaply and effectively.\textsuperscript{161}

2. Distributive Effects

The liability rules adopted by section 6 of the \textit{Third Restatement} are less favorable to injured consumers than the approaches suggested by Professor Phillips. In effect, individual product users will be prevented from shifting product-related losses to drug manufacturers and, instead, will have to bear these losses themselves. At first blush, this result seems contrary to the loss-spreading goals of products liability. However, some countervailing arguments can be made in response to this claim. First, most of those who suffer drug-related injuries will have health insurance (since by hypothesis they are receiving medical treatment) and may also have disability or life insurance. Consequently, a large proportion of their out-of-pocket expenses will be spread by means of first-party insurance. In such cases, the primary loss that would be left unspread would be pain and suffering, a type of loss that most victims are less concerned with recouping, at least as compared with pecuniary losses.\textsuperscript{162} Second, and more

\textsuperscript{160} See Brooks v. Medtronic, Inc., 750 F.2d 1227, 1232 (4th Cir. 1984).
\textsuperscript{161} See Richard C. Ausness, \textit{Learned Intermediaries and Sophisticated Users: Encouraging the Use of Intermediaries to Transmit Product Safety Information}, \textit{46 Syracuse L. Rev.} 1185, 1229 (1996) (arguing that physicians can transmit information to patients more effectively than drug manufacturers).
\textsuperscript{162} See Jeffrey O'Connell, \textit{A Proposal to Abolish Defendant's Payment for Pain and Suffering in Return for Payment of Claimants' Attorneys' Fees}, 1981 \textit{U. Ill. L. Rev.} 333, 364 (declaring that "[e]ven among the seriously injured, payment for pain and suffering, while more important than to the general public, was still ranked much less important than protection against the claims of others and payment for medical expenses, property damage, and wage loss"). This conclusion is reinforced by data that suggests that most people would be unwilling to purchase private insurance to compensate them for nonpecuniary injuries. See Patricia M. Danzon, \textit{Tort Reform and the Role of Government in Private Insurance Markets}, \textit{13 J. Legal Stud.} 517, 520 (1984); Alan Schwartz, \textit{Proposals for Products Liability Reform: A Theoretical Synthesis}, \textit{97 Yale L.J.} 353, 362-67 (1988) (describing the insurance theory of compensation); Ellen S. Pryor, \textit{The Tort Law Debate, Efficiency, and the Kingdom of the Ill: A Critique of the Insurance Theory of Compensation}, \textit{79 Va. L. Rev.}
importantly, prescription drugs are vital necessities for many people. At the same time, the drug industry has historically been prone to over deterrence. Thus, in many instances, drug producers have taken apparently useful products off the market, or raised drug prices dramatically, in response to concerns about tort liability. Arguably, the Third Restatement's approach, though ungenerous to injured consumers, is necessary to protect a greater public interest.

CONCLUSION

Sections 2 and 6 of the Third Restatement deal with a number of difficult and interesting matters. Although Professor Phillips and I do not see eye to eye on very much, we agree on this much: The Third Restatement is not consistent in its treatment of the duty-to-warn/duty-to-design issue. Under Section 2 a warning will not do when the product seller can eliminate or reduce the danger by redesigning the product; however, under section 6, a manufacturer need only warn about a product-related risk and is under no duty to redesign the product in order to make it safer. The Reporters justify this apparent discrepancy on the basis that different liability rules are needed for prescription drugs. Professor Phillips and I would prefer to see the same set of liability rules applied to all products. We differ, however, over what the appropriate liability rule should be. In general, Professor Phillips would prefer that producers be required to take active steps to make their products more safe; on the other hand, I would prefer to shift more responsibility for product safety to users and consumers and, thus, would give more protection to producers as long as they provide adequate warnings and instructions.


164. See Phillips, supra note 2, at 26-31.

165. Id. at 32-33.