Legally Adequate Warning Labels: A Conundrum for Every Manufacturer

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A traditional axiom of products liability law is that a manufacturer or supplier of goods has a duty to warn of any danger from the intended or unintended but reasonably foreseeable use of its products. This duty extends to those using or purchasing the product, as well as to those who could reasonably be expected to be harmed by its use. While there are many ways in which to warn, warning labels attached to the product are a traditional method of fulfilling this duty. However, merely warning of the danger may not be enough. Even where a warning is provided, a manufacturer may still be liable if the warning is not deemed to be legally "adequate."

Under current products liability law, a determination of adequacy is a highly subjective and fact-intensive evaluation. As such, defining a step-by-step procedure for creating unassailably adequate warning labels is impossible. Nonetheless, an examination of current statutes and case law, voluntary consensus standards, and the new *Restatement (Third) of the Law of Torts: Products Liability* (hereinafter *Third Restatement*) does provide substantial insight into what information a court may consider when evaluating the adequacy of a warning.

This article will examine the law and standards and how they apply when a court is making a determination of legal sufficiency. With a clear understanding of this information, a manufacturer will be better able to develop warning labels that will satisfy the adequacy requirement.

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DUTY TO WARN

Generally, the manufacturer has a duty to warn where: (1) the product supplied is dangerous; (2) the danger is or should be known by the manufacturer; (3) the danger is present when the product is used in the usual and expected manner; and (4) the danger is not obvious or well known to the user. See *Billiar v. Minnesota Mining & Manufacturing Co.*, 623 F.2d 240, 243 (2d Cir. 1980).

Once a duty to warn arises, the manufacturer who has provided a warning may still be liable for harm if the warning provided is inadequate. That is, even if the manufacturer has provided a warning, a qualitative evaluation may result in a finding that the warning did not sufficiently warn of the product's potential dangers. "Providing an inadequate warning is no better than providing no warning at all." *American Law of Products Liability 3d*, §33:1.

The difficulty for manufacturers is, therefore, to prospectively determine what may be considered an "adequate" warning for each foreseeable risk. A lack of objective criteria makes this determination difficult. *Third Restatement* §2, comment i. The problem is compounded by the fact that adequacy determination is a factual issue most often left to the fact finder. The finder of fact often concludes that, if the plaintiff was injured, the warning must *per se* be inadequate. See Schwartz & Driver, "Warnings in The Workplace: The Need for a Synthesis of Law and Communication Theory," 52 U.Cin.L.Rev. 38, 54 (1983). These problems have made it difficult for even the most well intentioned manufacturers to ensure that they can successfully defend against a claim of inadequacy.

What, then, should a manufacturer do to ensure that its warning labels are legally adequate? To better answer that question, it is helpful to understand the social policy justification for imposing liability on manufacturers.

- **The Requirement of Adequacy**

The policy justification for the duty to warn is rooted in the notion that product manufacturers are best able to anticipate what dangers are inherent during the use of their products. The manufacturer then is in a better position to warn of these dangers. It would be fundamentally wrong to permit an exploitative manufacturer to profit from the sale of a product it knows or should know to be dangerous. By allocating the burden in this way, manufacturers are additionally provided an incentive to "achieve optimal levels of safety in designing and marketing products." *Third Restatement* §2, comment a. This is not to say that, as a society, we believe a manufacturer should be absolutely liable for its

products. Society does not benefit from "excessively safe" products that overly sacrifice utility any more than it benefits from unreasonably risky products. Rather, we are interested in encouraging the optimal balance of product safety and utility. Thus, the duty to warn enhances society's goal of risk reduction without eliminating the manufacturer's incentive to produce useful goods.

There are three types of warning defects: (1) failure to warn; (2) failure to provide an adequate warning; and (3) failure to adequately instruct. An inadequate warning differs from failure to warn in that adequacy addresses the qualitative characteristics of a warning while failure to warn addresses the quantitative aspects (*i.e.*, failure to warn asks: "is there a warning at all?" while adequacy asks "was the warning provided adequate?"). Adequacy of warnings may also be distinguished from adequacy of instructions. The fact that adequate instructions are provided that assist the operator in the correct operation of the product does not necessarily discharge the duty to provide an adequate warning. A warning may still be required to call attention to the dangers of using the product.

While not the exclusive method of providing a warning, labels are one of the most effective in communicating danger. This is especially true where the warning label is attached directly to the product. One reason for this increased effectiveness is that a warning label affixed directly to the product stays with the product even after transfer to subsequent users. This assures that the subsequent users are also warned. Additionally, warning labels attached to the product may improve effectiveness by warning non-users of the potential dangers. As discussed below, this is critical in some instances as a manufacturer may be liable for warning others in addition to the product user.

- **Who Must be Warned**

Generally, one who supplies a product directly or through a third party is subject to liability to those whom the manufacturer should expect to use the product or to be endangered by its probable use. *Restatement (Second) of Torts* §388. This may include not only the party to whom the product is given, but also friends or employees of the purchaser. While there is little doubt that a purchaser or known user should be warned, more difficult questions arise when a third party not in the chain of title alleges a warning defect.

Many courts have, in accordance with section 388 of the Restatement, held that a manufacturer or distributor is required to warn only those that it could "reasonably foresee would be likely to use its product or who are likely to come into contact with the danger, if any, inherent in the use of its product." *Am.Law Prod.Liab.3d* §33:15. The warning given must be adequate to protect any and all foreseeable users from hidden dangers. While this duty may also extend to bystanders, warnings need not be given to the general public. See, *e.g.*, *Harrison v. McDonough Power Equipment, Inc.*, 381 F.Supp. 926, 929 (S.D.Fla. 1974) (the distributor of an inherently dangerous product must take reasonable precautions to avoid injuries to users and bystanders); *Eagle-Picher Industries, Inc. v. Balbos*, 84 Md.App.10, 578 A.2d 228, 251 (1990) ("[t]here is no longer any doubt that the negligence liability extends to any lawful use of the thing supplied, as well as to a mere bystander…").

There are also exceptions when certain intermediaries are involved. For example, where the user is not sufficiently sophisticated to evaluate the warning or when directly warning the user is not feasible, a warning may, in some circumstances, be given to an intermediary. This is a common occurrence with medical devices and pharmaceutical products. Under the "learned intermediary" doctrine, a drug manufacturer may typically rely on the doctor to provide the warnings to the patient. See *Ortho Pharmaceutical Corp. v. Chapman*, 388 N.E.2d 541, 548-49 (Ind.App. 1979). However, the drug manufacturer may not always discharge his duty by warning the intermediary. The sufficiency of a warning to third parties is evaluated using a reasonableness standard. See generally, *Second Restatement* §388, comment n.

A manufacturer may also be relieved of his duty to warn under the "sophisticated user" doctrine. As previously discussed, the duty to warn arises because it is assumed the manufacturer knows more about the product's dangers than the user. However, where the user is sophisticated (*i.e.*, the dangers of the product are known to the user), there is no duty to warn. See *White v. Amoco Oil Co.*, 835 F.2d 1113, 1118 (5th Cir. 1988). Similarly, "[t]he manufacturer… need not warn of dangers that users know or should know or of dangers that are or should be obvious to ordinary users." *Id.* at 1118. Finally, courts have generally found that a manufacturer is not liable for failure to warn of an "open and obvious" danger. "It is… well settled that a manufacturer is under no duty to warn a user of every danger which may exist during the use of the product, especially when such danger is open and obvious." *Gurley v. American Honda Motor Co.*, 505 So.2d 358, 361 (Ala. 1987).

Accordingly, the duty to warn extends to others besides the user/purchaser. Determining whether a warning will be considered adequate to all reasonably foreseeable parties is therefore a complex task. A manufacturer must be constantly aware of those affected by the use of its product and take reasonable steps to warn that audience. This burden can appear daunting, especially where a potential cause of action is brought under strict liability. However, modern courts have applied a more relaxed interpretation of strict liability to warning defect cases.

- **Strict Liability or Negligence**

As it pertains to warning defects, a claim under strict liability would presume a defendant has constructive knowledge of all product dangers, known and unknown, related to the use of its products, and must warn accordingly. Not only is holding a manufacturer to have knowledge not yet in existence unreasonable, enforcement of such a standard hinders innovation.

However, the modern view in warnings cases has been to hold defendants responsible for only that knowledge they had or should reasonably have had when they sold the product (ignoring for the moment any post-sale duty to warn). This effectively applies negligence principles to what is considered strict liability. Most courts have reasoned that under either strict liability or negligence, the standard applied is the same.

Consequently, the current trend is to analyze warning defects under a reasonableness standard regardless of whether the claim is brought in strict liability, negligence, or contract/warranty. Reasonableness does not mean that the warning has to be the best possible, but rather requires that it be one that a reasonably prudent manufacturer would provide under similar circumstances. *Gurley v. Honda*, *supra*, 505 So.2d at 361.

ELEMENTS OF AN ADEQUATE WARNING

What, then, constitutes an adequate warning? The *Third Restatement*, at §2(c), states that "[a] product… is 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."

While this reiterates the aspects of foreseeability and reasonableness already discussed, it does little to objectively define adequacy beyond these general concepts. Case law, however, does discuss the factual analysis required in making a determination of legal adequacy.

In *Bituminous Casualty Corp. v. Black & Decker Manufacturing Co.*, 518 S.W.2d 868 (Tex.App. 1974), the Texas Court of Civil Appeals summarized the state of the law. It said, at 872-73, that a warning is legally adequate if:

> (1) it is in a form that could reasonably be expected to catch the attention of a reasonably prudent person in the circumstances of the product's use;
> (2) the content is of such a nature as to be comprehensible to the average user; and
> (3) it conveys a fair indication of the nature and extent of the danger to the mind of a reasonably prudent person.

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In *Shanks v. Upjohn Co.*, 835 P.2d 1189, 1200 (Alaska 1992), the court similarly found that, for a warning to be adequate, it should: "1) clearly indicate the scope of the risk or danger posed by the product; 2) reasonably communicate the extent or seriousness of harm that could result from the risk or danger; and 3) be conveyed in such a manner as to alert the reasonably prudent person."

Other cases have stressed: that the warning must inform the user of the product's potential risks, see *Hendrix v. Raybestos-Manhattan, Inc.*, 776 F.2d 1492, 1497 n.7 (11th Cir. 1985); that adequacy requires complete disclosure of the existence and extent of risk involved in the use of a product, see *Thornton v. E.I. DuPont de Nemours & Co.*, 22 F.3d 284, 289 (11th Cir. 1994); and that whether a warning is legally adequate depends on the language used and the impression that language is calculated to make upon the mind of the average product user, *id.* Courts also say that adequacy must be evaluated in conjunction with knowledge and expertise of those who may be reasonably expected to use or otherwise come in contact with the product. *Id.*

Many states have adopted legislation to address warning defects. For example, to determine whether a warning is adequate, Connecticut requires a trier of fact to consider: "(1) [t]he likelihood that the product would cause the harm suffered by claimant; (2) the ability of the product seller to anticipate at the time of manufacture that the expected product user would be aware of the product risk, and the nature of the potential harm; and (3) the technological feasibility and cost of warnings and instructions." Conn.Gen.Stat. §52-572q(b). New Jersey similarly defines an adequate warning as one that:

> a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to, the persons by whom the product is intended to be used.

N.J.S.A. 2A:58C-4. Mississippi has enacted a statute effectively identical to that of New Jersey. *See* Miss.Code §11-1-63(c)(ii).

The state of Washington has defined a product as not reasonably safe by virtue of inadequate warnings "if, at the time of manufacture the likelihood that the product would cause the claimant's harm or similar harms, and the seriousness of those harms, rendered the warnings or instructions of the manufacturer inadequate and the manufacturer could have provided the warnings or instructions which the claimant alleges would have been adequate." RCW 7.72.030(1)(b).

Finally, Louisiana's statute addresses the policy objective that a warning should provide a user sufficient information to decline purchasing the product if desired. "Adequate warning means a warning or instruction that would lead an ordinary reasonable user or handler of a product to contemplate the danger in using or handling the product and either to decline to use or handle the product or, if possible, to use or handle the product in such a manner as to avoid the damage for which the claim is made." La.Rev.Stat. §9:2800.53(9).

Thus, an analysis of the case law and existing state statutes suggests to the authors that a judicial determination of adequacy will depend on a factual evaluation of eight questions. These are discussed in detail below. Only by careful consideration of these questions can a manufacturer reasonably predict the result of subsequent litigation.

EVALUATING ADEQUACY

While the eight questions listed below begin to provide some insight into what constitutes an adequate warning, an analysis of recent court opinions clarifies just how these questions are answered. Adequacy is a factual issue and, as such, is typically a question for the trier of fact. Therefore, using the reasonableness standard and risk-utility balancing test, the fact finder need only conclude that, after balancing certain factors, the warning is reasonable (or unreasonable) under the circumstances. For an earlier analysis of this question under New York law, see Suhr, "Marketing Defects: What is a Legally Adequate Warning?," February 1991 *New York State Bar Journal* 40.

- **Was it likely that the product would cause the harm suffered?**

When evaluating the likelihood that the product would cause the harm alleged, there are several sub-issues to examine. First, it is necessary to examine whether the product itself was in a dangerous condition. See *Oman v. Johns-Manville Corp.*, 764 F.2d 224, 233 (4th Cir. 1985). This is highly dependent on the complexity of the product. Simple products may require only minimal warnings while complicated or extremely dangerous products typically require more detailed warnings.

Second, it is necessary to evaluate the purpose for which the product is used. If the product is or could reasonably be used in

a dangerous way, it may require more explicit warnings than it would otherwise.

Third, it is necessary to determine whether the product was being used in a reasonably foreseeable manner. For example, consider a power tool having a removable safety guard. Depending on the circumstances, it may be reasonable to assume that a consumer will operate the tool without the guard. If so, a warning about the dangers of operating the tool in such a manner would be appropriate. Unfortunately, deciding what constitutes a reasonably foreseeable use or misuse is a difficult determination. As a starting point, however, the prudent manufacturer is directed to *Third Restatement* §2, comment m. This section makes it clear that, at a minimum, "[the] manufacturer is charged with knowledge of what reasonable testing would reveal." That is, a manufacturer is deemed to know of any uses and misuses reasonably discoverable during product testing.

If a particular product poses a risk that can be reasonably addressed with a redesign, a warning about that risk may be inadequate. See *Uloth v. City Tank Corp.*, 376 Mass. 874, 384 N.E.2d 1188 (1978). Some case law and the *Third Restatement* hold that the risk should be eliminated through redesign rather than reduced through warning on the theory that warnings are less effective. *Third Restatement* §2, comment l; *Uniroyal Goodrich Tire Co. v. Martinez*, 41 Tex.Sup.Ct.J. 1047, 1998 Westlaw 352929 (July 3, 1998). However, "when an alternative design to avoid risks cannot reasonably be implemented, adequate instructions and warnings will normally be sufficient to render the product reasonably safe." *Id.*

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- **How serious was the harm suffered?**

The probability and severity of the harm suffered weighs heavily in the evaluation of the adequacy of a warning. See *Oman v. Johns-Manville*, *supra*, 764 F.2d at 233. Generally speaking, the more serious the potential harm, the more descriptive the warning must be. Thus, a manufacturer must consider not only whether a warning is required but also whether the warning is sufficient to place the user on notice of the severity of the potential harm.

This is not to say that a manufacturer must warn of every conceivable danger. Rather, it must warn only of those dangers that are reasonably foreseeable. This concept deserves due consideration because it may be possible to overwarn a potential user. "Overwarning," or dilution as it is more often called, occurs when the manufacturer attempts either to warn about every conceivable danger or to warn in excessive detail. Overwarning will be discussed below.

Accordingly, where the magnitude of the danger is significant, a manufacturer should avoid all ambiguity in warning about that danger, both on the product warning label and in all other product information.

- **What was the technological feasibility and cost of providing a warning which the plaintiff now alleges would have been adequate?**

The answer to this question has varying impact depending on whether the allegedly defective product has not yet left the defendant's control or whether the defect is discovered after sale (in which case a post-sale duty to warn may exist). In either case, the burden imposed on the defendant manufacturer for disseminating the revised warning is weighed against the beneficial effect such a revised warning would provide to the user.

One factor used when evaluating feasibility and cost is the burden imposed on the manufacturer. See *Oman*, 764 F.2d at 233. Where the burden of providing improved or additional warnings is low, a court is more likely to perceive that the actual warning provided is inadequate. This is especially true where the plaintiff's proposed warning would have been adequate in preventing the harm.

Many courts determine that the burden of providing more sufficient warnings is very low for a manufacturer because the cost of revising or adding another warning is generally perceived to be minimal. This is particularly true during the marketing of the product (the post-sale burden is typically higher as the manufacturer has costs associated with finding and notifying affected users).

While the defendant cannot typically show that its burden would be substantial in providing a more in-depth warning, it may often claim that more detailed warnings lead to warning dilution. For example, in *Broussard v. Continental Oil Co.*, 433 So.2d 354 (La.App. 1983), the plaintiff was using a hand tool produced by the defendant. The tool had one warning label that instructed the user to read the operator's manual before use. The plaintiff failed to do so and was injured when the tool was used in an explosive environment (the manual included an adequate warning regarding operation in an explosive environment). The plaintiff argued that ten warnings should have been placed on the tool itself. The court rejected this view, noting that an otherwise adequate warning provided in the operator's manual was sufficient in this context. Placing too many warnings on the product, the court concluded, would "decrease the effectiveness of all of the warnings." *Broussard*, 433 So.2d at 358. See also, *Third Restatement* §2, comment i ("excessive detail may detract from the ability of typical users to focus on the important aspects of the warnings…").

Consequently, a manufacturer may have a valid reason for not providing more in-depth warning labels and similarly, for not attaching all warning labels directly to the product itself. Nonetheless, the diligent manufacturer should pursue every available means to ensure that warnings reach the intended audience. Providing warning labels directly on the product is a preferred method as they are then available to any user. If this is not possible, a warning to first review the operator's manual may be sufficient under a *Broussard* fact situation.

- **What knowledge could the defendant reasonably presume the user had of the potential risks?**

As discussed earlier, a manufacturer is not required to warn a user who is already aware of the product risks (*e.g.*, sophisticated user, user warned by a third party, informed intermediary). In these situations, the harm suffered is deemed not to have been caused by the defendant (*i.e.*, no causation). As such, courts have al-

lowed a defendant to escape liability for an otherwise defective warning when the defendant proves that the user was aware of or should have been aware of the risk that caused the harm.

There are several avenues by which a potential defendant may argue that it reasonably relied on the user having knowledge of product risks. First and most obvious, the manufacturer can directly warn the user (*e.g.*, verbal warning). Second, the defendant, in some circumstances, may argue that the status and general knowledge of the person using the product may be such that no warning is required. And finally, the manufacturer may, under certain circumstances, rely on an intermediary to convey adequate warnings concerning the use of its products where the manufacturer has provided adequate warning to the intermediary.

In the first instance, the manufacturer may rely on whatever information it has conveyed through its warnings. Adequacy is determined by the factors discussed herein. In the second instance, the manufacturer alleges reliance on the fact that some general knowledge of the particular user or group of users allows the manufacturer to reasonably assume that the user(s) had adequate knowledge of the dangers.

A manufacturer cannot downplay the danger of a product to increase its appeal to the purchasing audience. A fair indication of the actual harm must be conveyed.

Finally, a manufacturer, in certain circumstances, is permitted to rely on a third party to disseminate warnings to the ultimate user. While a manufacturer cannot completely delegate its duty to warn, the doctrine of superseding/intervening cause may allow a manufacturer to escape liability under some circumstances. See generally *Restatement (Second)* §388, comment n. For example, when the product is distributed for incorporation into another product over which the manufacturer has no control, it would be impossible to know and warn of all the possible dangers.

Alternatively, a manufacturer selling a product to a company does not know who will actually be using the product. For these reasons, a court, in making an adequacy determination, may examine the knowledge of the intermediary and the reasonableness of relying on that party to disseminate warnings.

While fulfilling the duty to warn by informing an intermediary can be of significant benefit to a manufacturer when defending an inadequacy allegation, it is important to note that this factor is subject to heightened judicial scrutiny. For example, in *Reed v. Pennwalt Corp.*, 22 Wash.App. 718, 591 P.2d 478 (1979), a caustic substance used during the course of employment injured an employee. While the defendant had provided warnings to the employer, the plaintiff alleged the defendant did not adequately warn the ultimate users about the dangers of the chemical. The court found that the plaintiff could not recover here, and specifically noted that: (1) the manufacturer had adequately warned the employer; (2) the product had been removed from its original container when it reached the end user; and (3) it was reasonable to expect that the plaintiff's employer had its own safety/training program. 591 P.2d at 481.

Reed and subsequent decisions indicate that courts are not willing to permit delegation entirely to a third party except in specific instances. Accordingly, such reliance on third parties is discouraged. When at all possible, directly warning the ultimate user is preferred. When not possible, a manufacturer should make every effort possible to ensure that it has adequately warned a reliable intermediary or pursued some other course that assures that the warnings will reach the ultimate users. To adequately protect itself, a manufacturer should ensure that the intermediary has procedures in place that will ensure the warnings are properly disseminated. Otherwise, reliance on the intermediary may be unreasonable.

- **Does the warning convey a fair indication of the nature and extent of the danger in the mind of a reasonably prudent person?**

This question is closely related to the extent of potential harm, as discussed above in the second question in this list. However, this fifth question is directed to the relationship of the potential harm to the content of the label instead of merely focusing on the extent of the injury. When answering this question, courts have typically examined such aspects as accuracy, content, and specificity of the warning label.

The specificity and content of the warning is critical to conveying the level of danger associated with the use of the product. For example, in *General Chemical Corp. v. De La Lastra*, 815 S.W.2d 750 (Tex.App. 1991), two shrimpers died from sulphur dioxide poisoning while processing shrimp with defendant's chemical. The defendant's warning noted that the product "[r]eacts with acids and water, releasing toxic sulfur dioxide gas." The court affirmed the lower court's verdict that this warning did not adequately emphasize that the product could potentially produce a deadly gas. Thus, where a product's use or reasonably foreseeable misuse can cause death, the magnitude of that harm should be conveyed.

The accuracy of the warning is equally as important. For example, a warning has been found inadequate where it gives some indication that the danger may be eliminated or controlled by the user when in fact it cannot. See *Thompson v. Tuggle*, 486 So.2d 144, 151 (La.App. 1986). Similarly, a label has been found inadequate where "it was unduly delayed, reluctant in tone or lacking in a sense of urgency." *MacDonald v. Ortho Pharmaceutical Corp.*, 394 Mass. 131, 475 N.E.2d 65, 71 (1985).

Some cases indicate that product information (*e.g.*, brochures, promotional activities) as a whole may be evaluated in determining whether a particular warning is inadequate. For example, in *Incollingo v. Ewing*, 444 Pa. 299, 282 A.2d 206, 221 (1971), the adequacy of a drug manufacturer's warning was tainted by the defendant's promotional efforts which minimized the dangers of the drug while emphasizing its effectiveness. The *Incollingo* court thus acknowledged that the adequacy of written warnings may be diluted by the manufacturer's contrary advertising practices.

Accordingly, a manufacturer cannot downplay the danger of a product to increase its appeal to the purchasing audience. A fair indication of the actual harm must be conveyed. If a manufacturer is generally in doubt about the specificity and content of a particu-

lar label, it should err on the side of caution and include a more specific warning. Several publications exist which may assist the user in formulating warnings. For example, ANSI Z535.4-1998, discussed below, provides a manufacturer with a standardized procedure for developing warning labels.

• **Was the warning comprehensible to the average user?**

With a few exceptions, if the reasonably anticipated users of the product cannot understand the warning, it is considered inadequate. *Am.Law Prod.Liab.3d* §33:10. It is therefore important to consider the intellectual and communication skills of the product's intended audience. These considerations are especially important when the product can reasonably be anticipated to be used by illiterate or non-English-reading users. Whether or not a product can reasonably be anticipated to be used by such groups depends on several factors including geographical marketing methods and the expected appeal of the product to specific consumer groups.

A leading decision in this area is *Ramirez v. Plough, Inc.*, 6 Cal.4th 539, 25 Cal.Rptr.2d 97 (1993). A caretaker who could not understand or read English gave the defendant's drug product to the four-month-old plaintiff. The package insert warned that use of the drug could cause Reye's Syndrome in young children. However, the caretaker could not read the directions and made no effort to have them translated. The child then suffered damage as a result of the drug. The child's guardian sued, alleging that the defendant's warnings were inadequate because they were not in Spanish.

The California Supreme Court concluded that, although it may be reasonable to anticipate a non-English-reading person would use the product, legislative and regulatory standards in the area of drug warnings were substantial and required only English language warnings. The court acknowledged that both state and federal agencies were aware of possible dangers to those unable to read English warning labels and had still mandated English-only labels. The court was compelled to defer to the expertise of these governmental bodies. *Ramirez*, 25 Cal.Rptr.2d at 107.

In another recent decision, on an appeal from the federal district court in Puerto Rico, the First Circuit held that warnings on industrial cleaners need not be in Spanish because the labeling regulation, at 29 C.F.R. §1910.1200(f)(1), does not explicitly contain a language requirement. *Torres-Rios v. LPS Laboratories, Inc.*, CCH Products Liability Reports p.15,303, 1998 Westlaw 429337. This regulation makes it clear that it is the employer's responsibility to add other languages if appropriate. The court cited the *Ramirez* decision's deference to legislative and administrative bodies to decide when other languages might be required.

It must be emphasized that the *Ramirez* and *Torres-Rios* decisions concerned warning labels on regulated products. Attempts to apply their holdings to non-regulated products should be undertaken with great care. Generally speaking, the regulatory intervention in drug and industrial cleaner warnings to which the *Ramirez* and *Torres-Rios* courts gave great deference does not exist for most products. In the context of non-English language warnings, a court may evaluate other products under the more common reasonableness standard. Therefore, if a manufacturer may reasonably anticipate that its products will be used by non-English-reading users, it should make an effort to warn in an alternative way.

If a manufacturer may reasonably anticipate that its products will be used by illiterate or non-English-reading users, it should make an effort to warn in an alternative way, through the use of symbols or pictorial warnings.

One generally acceptable method of communicating a warning to illiterate or non-English-reading users is through the use of symbols or pictorial warnings. For example, a skull and crossbones is commonly associated with poison. The American National Standards Institute (ANSI) has promulgated a national standard for the design and use of product safety labels. This standard, referred to as ANSI Z535.4, provides for the use of symbols within warning labels and states that "[s]ymbols and pictorials may be used to clarify, supplement or *substitute* for a portion of the word message found [on the label]. Only symbols validated for recognition should be used" [emphasis added]. ANSI Z535.4, §11.2. A symbol/pictorial may be validated for recognition if it is: included in a U.S. or international standard; achieved through training; or "meet[s] the comprehensive test criteria outlined in ANSI Z535.3-1998, Annex B." *Id.*

The court in *Torres-Rios* also commented on the flammability pictorial contained on the cleaner's label. One problem with the use of pictorials is that it is usually impossible to fully communicate the entire safety message. The hope, therefore, is that the non-English reader will have the English translated. The court confirmed the validity of this approach by stating that although this pictorial did not fully explain the danger, it provided a clear enough warning to the user to either read the safety instructions or to find someone to translate them.

Another possible method of warning non-English-reading users is to warn in their native language. This assures that the user has received the same or similar warnings as the English reading users. However, multi-lingual warnings present several problems. First, linguistic idiosyncracies may make a literal translation difficult. Since these foreign language labels are evaluated identically to their English language counterparts, they may well be found inadequate when analyzed separately. Additionally, a manufacturer who chooses to include one foreign language on its product labels may be liable for not including other languages. See Ross, "The Duty To Warn Illiterate and Non-English-Reading Product Users," *BNA Product Safety and Liability Reporter* 1097, 1100 (October 13, 1995). There is also no guarantee that the users for which the foreign language label is directed are even literate. *Id.* at 1101. In addition, inclusion of a foreign language can diminish the conspicuity of the English text which, by all measures, is the most important part of the label. *Id*. Therefore, multi-lingual warnings may not be the most effective method of warning non-English-reading users.

While it is not clear exactly what is required of a manufacturer regarding warnings to non-English-reading users, a manufacturer

should attempt to ensure that its warnings are understandable to reasonably anticipated users. While English language warnings may be sufficient, multi-lingual or pictorial representations of the warning may better satisfy the ultimate goal of providing a safer product. Multi-lingual warnings, however, may raise more troubling issues for the concerned manufacturer than simply using pictorial representations (see discussion above). Although such comprehensive labels may still be found inadequate, they are at least evidence of the manufacturer's reasonable care in attempting to improve the understandability of its warnings and the safety of the product.

- **Was the warning in such a form that it could reasonably be expected to catch the attention of a reasonably prudent person?**

The adequacy determination depends heavily on the presentation of the warning label itself. A manufacturer who has supplied an otherwise adequate warning label cannot then attach the label in an inconspicuous place or make it difficult to read and still expect that he has complied with the law. On the other hand, a manufacturer cannot plaster his product with every conceivable warning as this may dilute the effect of all the warnings. Therefore, the "form" of the warning label is an important aspect of adequacy determination.

Factors that a court looks to when evaluating form include the manner in which the warning is stated and the conspicuity of the warning. Conspicuity refers to the aspects of the label that make it conspicuous. For example, the location, position, color, size of label and size of print, and shape of the label are all evaluated in making an adequacy determination.

Location is important in two contexts. First, the location of the label should be such that it is reasonably expected to catch the attention of the user—meaning it is located near the hazard. In this context, a court will evaluate whether the label is located in a conspicuous location (*e.g.*, not underneath a cover or mounted to a part commonly removed from the product).

Second, the location of the warning is closely related to the dilution problem discussed earlier in the context of *Broussard v. Continental Oil Co.* Specifically, a manufacturer who attempts to locate too many labels in one area runs the risk of dilution. While there are no cases known to the authors where a defendant has been at fault merely for providing too many labels, dilution remains a constant concern for manufacturers. In theory, it sets an unclear upper limit which, if exceeded, may nullify otherwise adequate warnings.

While attempting to draw the line between effective warning and dilution is not realistic, the manufacturer is reminded that its efforts are measured against the standard of reasonableness. At one extreme, a product should minimally include a warning directing the user to read the operator's manual prior to use. In such a case, the warnings in the manual should be clearly distinguished from the operating instructions. Additionally, the warning placed on the product itself should convey the extent of the potential danger inherent in not abiding by this direction. At the other end of the spectrum, the operator, where feasible, may be required to place all warning labels on the product itself. Most cases will fall somewhere in between these two extremes.

The color, organization, and shape of the label are other important factors to consider in making an adequacy determination. Once again, hard and fast rules do not exist. However, guidelines are available. For example, ANSI Z535.4-1998 provides detailed information concerning size, color, and content of the label. Label colors, the size of label, and the size of print are also important factors to consider. Suggested parameters are outlined in ANSI Z535.4, §§8-9. Thus, conspicuity is a significant aspect of warning label adequacy.

A prudent manufacturer can significantly improve its chances of rebutting an inadequacy charge by demonstrating that a reasonable, detailed procedure was followed when developing the allegedly defective warning label.

- **What procedures did the defendant utilize in designing the warning provided?**

As indicated throughout this article, the defendant's actions are measured against the standard of reasonableness. While this is a subjective standard, a prudent manufacturer can significantly improve its chances of rebutting an inadequacy charge by demonstrating that a reasonable, detailed procedure was followed when developing the allegedly defective warning label. The importance of such a procedure becomes apparent when one considers that no warning label is 100% effective. As such, any information a manufacturer can provide that shows it made a diligent attempt to maximize the effectiveness of an allegedly defective warning label is beneficial.

There are several sources to assist the manufacturer in developing legally adequate warning labels. While adherence to these standards will not typically result in *per se* adequacy, it is at least evidence of due care. Courts may also look to industry standards as an indicator that a warning is adequate. Some plaintiffs' attorneys have publicly stated that compliance with a recognized standard such as ANSI Z535 will encourage them not to allege failure to warn unless the content of the text was inadequate.

One method for evaluating adequacy that is currently receiving increased attention is the testing of warning labels. Proponents of this practice believe that the duty to warn should be measured not by the factors discussed above, but rather by a testing procedure used to develop the warning. William H. Hardie discusses this idea at length in his article "Liability Based on Testing Product Warning Labels," October 1997 *For The Defense* 27. While Mr. Hardie acknowledges the appeal to manufacturers of having some assurance of label adequacy, he ultimately believes the approach is flawed. He bases his conclusion on several factors.

First, he believes that measuring the duty to warn based on testing will result in an adequacy determination based on scientific interpretation of behavior theory rather than on law. That is, the standard of reasonableness will be replaced by generalized studies of human behavior and questionable conclusions drawn therefrom. Second, Mr. Hardie believes that a duty to test will unnecessarily

burden the court with new issues concerning validity of test methods and scientific techniques. Third, Mr. Hardie asserts that, as with the law, there is no agreement in the behavioral sciences as to what constitutes an "adequate" warning. Finally, Mr. Hardie concludes that no reliable empirical data exists that shows test results are an accurate reflection of real world responses. *Id*. at 30.

William Hardie concludes that testing alone is not a suitable indicator of adequacy. In reality, he continues, determining adequacy based on testing will actually increase the court's burden by raising questions about the test methods themselves. Whether or not Mr. Hardie's conclusions are correct, it is presently unclear how courts will ultimately interpret an alleged "duty to test" warning labels.

This area of the law is still developing and its future is uncertain. While testing of warning labels may be particularly beneficial under some circumstances, the high cost associated with testing may lead a fact finder to conclude that, under a risk-utility balancing test, it is not economically feasible. However, the defendant should keep in mind that the ultimate goal is to protect the user. Where testing is the only way to ensure adequacy (*e.g.*, where a product is so unique that industry customs or standards do not yet exist), testing may be a reasonable requirement. Under most circumstances though, adequacy of warning labels may be determined by consideration of the other factors described herein.

The manufacturer should ask the eight above-mentioned questions and answer them with reference to the relevant factors. While there is no guarantee, adhering to such a procedure should significantly improve the chances of prevailing in subsequent litigation.

ADEQUACY DECIDED AS A MATTER OF LAW

While adequacy of warning is typically a question for the trier of fact, it is occasionally decided as a matter of law. One area where adequacy is often summarily determined is where a specific federal statute defines the extent of a warning that must be provided. Where federal law is involved, the federal statute may preempt both state statutes and state common law actions.

For example, in *Moe v. MTD Products, Inc.*, 73 F.3d 179 (8th Cir. 1995), the plaintiff alleged the defendant had failed to adequately warn users of the possible failure of the control cable for the blade brake/clutch on a lawn mower. In this instance, the cable had frayed and the blade failed to stop as it was supposed to. The defendant argued that its label satisfied the regulations promulgated by the Consumer Product Safety Commission (CPSC) in its "Safety Standard for Walk-Behind Power Lawn Mowers." 16 C.F.R., Part 1205. The enabling act of the CPSC states, at 15 U.S.C. §2075(a), that:

> Whenever a consumer product safety standard under this chapter is in effect and applies to a risk of injury associated with a consumer product, no State or political subdivision of a State shall have any authority either to establish or to continue in effect any provision of a safety standard or regulation which prescribes any requirements as to the… labeling of such product which are designed to deal with the same risk of injury associated with such consumer product, unless such requirements are identical to the requirements of the Federal standard.

The *Moe* court then concluded, as a matter of law, that adherence to the CPSC standard was all that the defendant was required to prove. While other courts have found adherence to other federal statutes to also demonstrate sufficient proof of adequacy (see, *e.g., Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992) (federal labeling requirements for cigarettes preempt state law) and 27 U.S.C. §216 (federal labeling requirements for alcoholic beverages preempt state law)), it is generally understood that these findings of preemption are the exception to the rule.

Meeting statutory minimums does not necessarily assure a subsequent finding of adequacy, although it is evidence of due care. Failure to meet statutory minimums, on the other hand, permits a court to find a warning inadequate *per se*. Thus, regulations for warning labels should be viewed as a minimum which the manufacturer must either comply or exceed.

Other cases have found adequacy as a matter of law where the warning clearly met the requirements discussed herein. For example, in *Ruggles v. R.D. Werner Co.,* 203 App.Div.2d 913, 611 N.Y.S.2d 84 (1994), the plaintiff was injured when he fell from a damaged ladder. The warning label on the ladder instructed the user to inspect the ladder before use and to "never climb a damaged ladder." The court concluded the warning was adequate as a matter of law. In *Phan v. Presrite Corp.*, 100 Ohio App.3d 195, 653 N.E.2d 708 (1994), the plaintiff alleged that the warning regarding a foot switch for a power tool was inadequate. The experts agreed that, had the label instructions been followed, the accident would not have occurred. The court concluded that this necessitated a finding that the warning was adequate as a matter of law.

Note too that adequacy determined as a matter of law can just as easily work against a manufacturer. In *Delery v. Prudential Insurance Co. of America*, 643 So.2d 807 (La.App. 1994), the defendant placed an otherwise adequate warning label on the bottom side of a chair, reasoning that placement elsewhere would result in removal of the label. The plaintiff was then injured by the chair. While the trial court found the plaintiff partially liable, the appeal court reversed, concluding that the location of the warning label alone mandated a finding that it was inadequate.

While these cases show that, in some circumstances, a court will determine adequacy as a matter of law, it is evident that they do so only where the factors discussed above so clearly weigh in one direction or the other that a reasonable jury could not conclude otherwise. As such, a manufacturer is encouraged to direct its attention to the eight questions discussed above. By properly addressing these issues, a potential defendant is in a much better position to argue that its warnings are adequate as a matter of law or at least reasonable in light of the facts.

CONCLUSION

It is critical that a manufacturer develop adequate warning labels to protect itself from product liability claims. Warning defect claims are often added as a matter of course to products liability complaints. With more manufacturers aware of the warning issue and thus providing more warnings, modern warning defect claims often allege inadequacy instead of failure to warn.

Unfortunately, adequacy of warnings is often overlooked during warning label design. Then, the unfortunate manufacturer is left fighting to prove retrospectively that it took all reasonable steps to ensure the allegedly defective label was adequate. It is often too late at this point. By instituting a procedure that analyzes the questions and factors listed herein, a manufacturer stands a substantially greater chance of prevailing during a subsequent determination of adequacy. ■