

THE IDC MONOGRAPH:

THE USE OF STANDARDS AND PREEMPTION IN THE DEFENSE OF PRODUCT DESIGN AND WARNING CASES:

MAKING YOUR GOVERNMENT WORK FOR YOU

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I. Introduction

Defense counsel and their clients often see statutes and industry standards as a problem in product liability matters because plaintiffs can use them to prove liability. There is little doubt that a failure to comply with a statute or industry standard can be very damning evidence in a product liability trial. Yet, compliance with these mandates can also be very helpful in defending our clients.

This Monograph will begin with a discussion of federal preemption, a doctrine which allows clients to use compliance with federal statutes and regulations to “end” lawsuits before they get started. The Monograph will then describe how statutes, regulations and industry standards can help defendants give juries a sense about why a product has been designed the way it was. In short, rather than being liabilities, statutes, regulations and standards can often be strong allies in the courtroom.

II. Federal Preemption

Industry standards, including those which are borne of state and federal regulations, are important evidentiary factors in almost every product liability case. The triers of fact may consider them in the context of determining whether or not a product was unreasonably dangerous, a manufacturer or supplier was negligent, or an implied warranty was breached. Despite compliance with both the letter and spirit of a standard, a jury may nonetheless find liability. That is not the case in instances where federal law has a preemptive effect.

Federal preemption arises under the supremacy clause of the United States Constitution:

This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every state shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

Constitution of the United States, Article VI, cl 2. Whether or not a federal act or regulation will preempt a state law cause of action has been the subject of significant debate and a number of parameters have emerged. The first parameter is the scope of federal law which can result in preemption. Under the cases, federal law encompasses the Constitution, federal statutes and regulations promulgated by federal agencies to implement those statutes, all of which have the power to preempt.¹ The second parameter is the scope of state law subject to preemption. State law which may be preempted includes state statutes, regulations

and common law tort actions. Even judicial involvement in facilitating a common law remedy is considered an exercise of state power subject to preemption.²

Preemption occurs when state law directly conflicts with federal law and federal law is deemed controlling.³ Battle lines usually form on the issue of whether a direct conflict exists, and begin with consideration of the nature of the state law, regulation or cause of action in the context of the type of preemption sought. Federal preemption can be express or implied, depending upon whether Congressional intent is explicitly stated in the language of the Act.⁴ Where there is no express language of preemption, the intention of Congress to that effect must be implied. Where the language is ambiguous, the “ultimate touchstone” is still congressional intent.⁵

Implied preemption exists in three instances. It is present where federal law so thoroughly occupies the field “as to make reasonable the inference that Congress left no room for the states to supplement it.”⁶ Preemption will also be implied where there is a direct conflict with federal law.⁷ In addition, preemption will be applied in areas where the federal interest is so dominant that the application of state law would be inimical to national interests.⁸

In some areas, states interests are favored over implied federal preemption. For example, “the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.”⁹ The arguments against preemption are also stronger where state interests in “matters of health and safety” exist.¹⁰ A state’s interest in “health and safety” carries over to certain tort law claims which involve the furtherance of those interests through the encouragement of an individual cause of action.¹¹ There is also a reluctance to find preemption where to do so would leave the injured party without a remedy.¹² Finally, the preemptive effect of federal *regulations* is less powerful than the preemption effect of federal *acts*.¹³

Implied preemption in product liability cases is most commonly found in the area of pharmaceuticals and medical devices. There, extensive regulation of manufacturing, labeling and marketing of those products by the Food and Drug Administration (FDA) pursuant to the Federal Food, Drug and Cosmetic Act (“FDC Act”) provide compelling arguments for preemption.¹⁴ An understanding of the pharmaceutical regulations of the FDC Act and the Medical Devices Amendments of 1976 (MDA)¹⁵ is critical to an appreciation of the various ways in which federal preemption has been addressed by federal and state courts.¹⁶

Under the FDC Act, FDA approval is required before a new drug can be marketed.¹⁷ Before FDA approval is possible, a pharmaceutical product must undergo rigorous documented scrutiny. The process is initiated by the filing of an investigational new drug application (IND) which contains comprehensive information regarding its purpose and chemical components, as well as preliminary *in vitro* and animal testing which suggests its safety and efficacy. If the FDA is satisfied with the IND, it then permits the applicant to conduct clinical testing to ascertain safety and efficacy for human use.

Clinical testing results regarding human response and adverse reactions go into the new drug application (NDA) which is then submitted for approval. The NDA also includes “specimens of the labeling proposed to be used for such drug.”¹⁸ Labeling requirements are found in 21 U.S.C. § 355(a), (b)(1)(F) and 21 C.F.R. § 201.50-201.57 (1994). When the drug is finally approved for marketing, the approval contains the labeling which was submitted with the NDA.¹⁹

Warnings which accompany the product cannot vary from the language which was specifically approved. The only exception to that prohibition is where subsequent evidence indicates that a new or stronger warning should be given.²⁰ However, even the stronger language is subject to FDA approval and may be used only while approval is pending.²¹ The “bottom line” is that no permanent changes to the label are possible without FDA approval.

Despite the intensive regulatory process which precedes the marketing of a new drug and prescribes the warnings which must accompany it, implied preemption has generally not precluded state common law tort and warranty claims for drug injuries.²² Indeed, both the state and federal courts of Illinois have refused to preempt drug injury cases based upon FDA regulation. *See, Martinkovic v. Wyeth Laboratories, Inc.*,²³ (“compliance [with FDA requirements] is but one factor for the jury to consider in deciding the reasonableness of the manufacturer’s conduct”) and *Mahr v. G.D. Searle & Co.*²⁴ (“compliance with FDA regulations . . . is only minimal and does nothing to abrogate or alter duties arising under the common law”) (citations omitted).²⁵ Only a few courts have been willing to preempt state tort claims in pharmaceutical cases based upon FDA regulation. Those authorities have limited application of the doctrine to failure to warn strict liability claims.²⁶

While there has been general reluctance to interpret FDA regulations as directly in conflict with state law, that reluctance does not exist in the area of medical devices. The MDA²⁷ provides as follows:

[N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement —

- (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
- (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.²⁸

This language has generally been considered to create an express preemption of state legislative or judicial requirements that are “different from, or in addition to” those mandated by federal law.²⁹ However, in *Weiland v. Telectronics Pacing Systems, Inc.*,³⁰ the Illinois Supreme Court expressed a different view which directly contradicted the Seventh Circuit holding in *Mitchell v. Collagen Corp.*³¹ The reasoning in each case was very different, a somewhat unexpected result given that both cases drew heavily upon the decision of the United States Supreme Court in *Medtronic, Inc. v. Lohr*.³²

While *Mitchell v. Collagen Corp.*³³ arose under Indiana law, the common law tort and warranty theories under consideration were parallel to those of Illinois.³⁴ The product in *Mitchell* was a collagen based substance, Zyderm, which was “used to fill in soft tissue under skin or scars when tissue has been lost due to injury, trauma, age, infection or other diseases.” The manufacturer contended that the FDA’s premarket approval of Zyderm by the FDA precluded a claim for damages under strict liability, negligence and breach of implied warranty claims.

The Seventh Circuit agreed, and, in so doing, found that to the extent that common law liability is based on state law standards which vary from those of the FDA, the FDA standards control. The Seventh Circuit recognized that the premarket approval process of the FDA was “rigorous” and constituted “specific federal regulation of the product.” Thus, it concluded:

During the PMA process, the federal government, it can truly be said, has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers.³⁵

Having reached that determination, the court then focused upon whether or not a state court judgment in favor of the plaintiff “would impose on the manufacturer a burden incompatible with the requirements imposed by the FDA.” It concluded that liability on the part of the manufacturer presupposed a breach of duties which would directly conflict with the premarketing standards of the FDA. As such, the specter of liability would impede the implementation and enforcement of those specific federal requirements. *Mitchell* held that, to the extent the claims were based on requirements beyond the PMA, those claims were preempted.

The Illinois Supreme Court came to very different result in *Weiland v. Telectronics Pacing Systems*. Facing facts comparable to those in *Mitchell*, the court held that:

The premarket approval process allows the FDA to assure the minimal safety of medical devices which are marketed for human consumption; the premarket approval process simply does not address the appropriate standards of liability once the medical device enters the market . . .³⁶

The court described the FDA process as “general” and “non-specific” and said the PMA process “imposes no ascertainable substantive requirement on the manufacture or design of the device . . .” The court reasoned that the language of the United States Supreme Court in *Medtronic, Inc. v. Lohr*,³⁷ which required “a *specific* requirement which applies to a particular device and focuses on the safety and efficacy of that device,” did not apply to the FDA process. The court said that express preemption under *Medtronic* would exist only to the extent that the FDA had specifically approved a “particular design or manufacturing specifications.”

The analysis of preemption by the Seventh Circuit in *Mitchell* and the Illinois Supreme Court in *Weiland* are antipodal. For Illinois practitioners, the message of *Weiland* is “loud and clear:” Illinois courts will not preempt product claims unless the language of the federal Act imposes a specific requirement upon the manufacturer which is the basis for the state court claim. While express preemption remains an open issue in the federal courts, particularly where there is a conflict between state law liability elements and federal requirements for product approval, the United States Supreme Court has recently granted certiorari on the issue due to a conflict in the federal circuits.³⁸ A decision there which follows *Mitchell*³⁹ might overturn *Weiland*.⁴⁰

III. Use of Standards and Regulations as Evidence

The importance of proving compliance with either industry standards or government statutes or regulations when defending a products liability case cannot be overemphasized. Providing a context to help explain why the manufacturer made the product the way it did is extremely important, particularly where the defendant's conduct and its profit motive are juxtaposed against the plaintiff's injuries. Proving why a defendant and its employees made the choices they made in determining the design for a product, and explaining these choices by describing the months or years of work analyzing industry standards, gives a defendant a chance to win in the courtroom. The best way to see how statutes and standards can work in the courtroom is to examine the case law.

A. Preemption

Despite the limitations in Illinois law described above, the most effective use of federal statutes, regulations and standards is preemption. The most potent example of federal preemption is *Cipollone v. Liggett Group, Inc.*⁴¹ which involved warnings on packages of cigarettes. Once warnings were required, and the language and format determined, the court held that manufacturers could not be liable for failing to give other warnings. Many Illinois cases reach similar results.⁴²

Sometimes the language of a federal statute precludes preemption but supports a motion to bar certain evidence or limit the scope of the claim. One example of this is *Hilst v. General Motors*.⁴³ There, plaintiff was injured in a two-vehicle collision. The plaintiff sued General Motors alleging that his injuries were caused by the lack of an airbag, the failure of the seatbelt and an allegedly defective steering wheel. General Motors sought and received preemption summary judgment on the "no airbag" claim, as the federal regulation in place at the time of manufacture did not require air bags if the vehicle had automatic seatbelts.

The case then went to trial on the remaining claims. General Motors successfully moved, *in limine*, to preclude plaintiff from arguing that airbags were a feasible alternative design to the automatic seatbelts which were installed in the vehicle. GM won at trial and the trial court's *in limine* ruling was affirmed by the appellate court. Thus, aside from the claim preclusion effect of federal statutes, statutes can also effectively be used to preclude the introduction of evidence.

B. Evidentiary Requirements for Use of Statutes and Standards

Whether a given standard or government statute or regulation is admissible at trial is generally an evidence issue. In order to use standards at trial, whether government statutes or regulations, or voluntary standards promulgated by industry, the standard must be relevant.⁴⁴ *Murphy v. Messerschmidt*,⁴⁵ while not a products liability case, is illustrative of the applicable analysis.

In *Murphy*, plaintiff was injured in 1971 while walking down some stairs. She alleged that she slipped down the stairs because there were no handrails. The stairs were erected in 1952. The plaintiff sought to introduce portions of the 1963 BOCA Code which required handrails. At trial, the plaintiff's expert was allowed to quote from the 1963 edition of the BOCA Code as support for his opinion that the stairs did not comply with the Code and that the stairs were not properly maintained. The appellate court reversed a judgment for plaintiff, as the 1963 Code was not the standard applicable in 1952 when the stairs were erected. Nor was there a showing that the 1963 Code intended to address historical hazards.

In contrast, *Davis v. Marathon Oil Company*⁴⁶ involved a bulk oil dealer who sued an oil company after being injured in an explosion caused by overfilling. In *Davis*, the plaintiff filled service station gasoline storage tanks which overflowed and allowed the spilled gas to ignite. The plaintiff alleged that the oil company's service station gasoline storage tanks were not properly maintained because they could be overfilled. There was also evidence about a space heater in the station at the time of the explosion and that the gas station's door was closer to the gasoline fill pipes than allowed by a pertinent Illinois regulation.

The defendant argued on appeal that this regulation, promulgated over ten years after the station itself was constructed, was not relevant. The Illinois Supreme Court, while reversing the trial court for other reasons, affirmed the use of a jury instruction indicating that a violation of a regulation was *prima facie* evidence of negligence. The Court found that the regulation at issue intended to eliminate all existing dangers, not just future dangers, and was relevant notwithstanding the fact it was issued more than ten years after the station was constructed.

In *Ruffiner v. Material Service Corp.*,⁴⁷ the Illinois Supreme Court again focused on the relevance of standards. There, plaintiff was injured when he fell off a ladder while working on a tugboat. The tugboat was built with a retractable pilot house to enable the boat to avoid river obstructions such as bridges. There were two ladders which were attached to the pilot house, such that when the pilot house was lowered, the ladders would rest side by side. When the pilot house was raised, a person using the ladders would need to step sideways to get from the top of the lower ladder to the bottom of the top ladder in order to get to the top of the pilot house. The plaintiff fell when attempting to reach the top of the pilot house.

At trial, the plaintiff asserted the applicability of an American National Standards Institute (ANSI) standard which prescribed certain guidelines and dimensions for fixed ladders. The plaintiff's expert opined that the pilot house ladders did not meet the ANSI standard in several respects and that the ladders were unsafe as a result. The standard was admitted into evidence, apparently because the trial court believed the ANSI standard applied.

The supreme court reversed the verdict for the plaintiff, finding that the defendant was prejudiced by the admission of the ANSI standard. Although the ladders were attached to the pilot house, the Court agreed with the defense that the way the ladders were integrated into the pilot house design made the standard inapplicable. The Court interpreted the standard to apply to ladders installed in land-based industrial facilities, although the standard itself was not limited in that way. The Court rejected the plaintiff's argument that because the ANSI standard was designed to promote safety, the standard should automatically apply.

Another instructive evidentiary decision is *Galindo v. Riddell, Inc.*⁴⁸ There, plaintiff was paralyzed after making a tackle in a high school football game. The plaintiff alleged that the football helmet he was wearing had a design defect which caused the rear of the helmet to fracture his neck. At trial, the plaintiff attempted to present evidence that the subject helmet failed an ANSI impact test standard. This standard set minimum requirements for protective headgear for vehicular uses. At trial, the defense objected to this evidence and the trial court refused to admit it.

Although the appellate court reversed a defense verdict, it affirmed the decision not to admit the evidence of lack of compliance with the ANSI headgear standard. The court found that plaintiff failed to demonstrate why a standard for vehicular headgear should apply to football helmets. Thus, the fact that a standard can be interpreted to apply to a product in a very general way may not support its admission into evidence.

Attempts to use standards applicable to a particular product do not necessarily apply to all uses of that product. In *Carrizales v. Rheem Manufacturing Co., Inc.*,⁴⁹ plaintiff was working on an automobile gasoline tank and ended up with gasoline on his skin and clothes. A gas water heater had been installed years earlier in the restroom of his place of employment. When he entered the restroom to clean up, the pilot light of the heater ignited the gasoline vapors from the plaintiff's clothing. The plaintiff alleged a design flaw relating to the lack of a stand which would raise the height of the heater such that the pilot would be above the floor where the heavier-than-air vapors congregated. The case resulted in a defense verdict.

At trial, the plaintiff tried to show that the defendant was aware of the risks associated with migrating gasoline vapors. The plaintiff offered an ANSI standard applicable to commercial water heater installers which required an 18-inch stand with the heaters. The trial court barred the use of the installation standard against the manufacturer, and the appellate court affirmed. While recognizing it could be possible for a standard relating to one industry or trade to apply to another, it found that the installers standard did not define the standard of care applicable to a manufacturer.

Relevance issues regarding competing industry standards can become fairly complicated. In *Anderson v. Hyster Company*,⁵⁰ plaintiff was injured when struck by a fork lift. The fork lift's transmission used floor pedals, but there was no neutral position and if the brake was not depressed, the fork lift would automatically move forward. Moreover, after the machine was shut off, it would begin to creep forward when restarted unless the brake was depressed. The plaintiff was hit by the fork lift when, after the fork lift was restarted, it lurched forward.

At trial, plaintiff's expert was allowed to testify that the fork lift's design was not consistent with standards promulgated by the Society of Automotive Engineers (SAE). The defendant argued that SAE standards did not apply to fork lifts, but standards by the American Standards Association did. The defendant offered a letter written by a member of the SAE committee which promulgated the SAE standard to a corporate officer of the defendant indicating the committee never intended the SAE standard to apply to fork lifts. The trial court barred the letter. The defendant then offered other ANSI standards, which, although not specific to the design of the fork lift at issue, did not prohibit the challenged fork lift design. The trial court also refused to admit these standards.

On appeal, the defense argued that the trial court erred by admitting the SAE standard and by not admitting the ANSI standard or the letter saying the SAE standard was inapplicable. The Illinois Supreme Court rejected these arguments and affirmed the verdict for plaintiff. The court found that it was a question of fact as to whether the SAE standard applied because there was evidence from plaintiff's expert that it was applicable. The court did not make clear why the ANSI standards were irrelevant, but voiced concern as to their length and the fact that the design at issue was not specifically addressed. Thus, where a standard is vague enough to encompass a product, and that standard does not specifically limit its application, there is some chance that the standard will be admitted.

Sometimes standards actually promulgated after the date of manufacture can still be used by the plaintiff to show design defects. In *Doyle v. White Metal Rolling and Stamping Corp.*,⁵¹ plaintiff alleged that a ladder collapsed as the result of a design

defect. At trial, plaintiff provided evidence that the ladder was manufactured in April 1982 and sold to plaintiff's employer in October 1982. It was uncontested that, at the time of manufacture, the ladder met the applicable 1972 Underwriters Laboratories (UL) and ANSI manufacturing standards. However, there was evidence that in 1980, both UL and ANSI began a process of amending their standards by requiring all ladders to pass a new more stringent test. In January 1981, the ladder manufacturer tendered ladders to UL for testing which failed the new test. Subsequently, a revised model was tendered and passed. The more stringent standards became effective June 1982 (UL) and October 1982 (ANSI).

After a verdict for plaintiff, the defendants appealed. Among the errors alleged was the introduction of post-manufacture industry standards. The defendants argued that the new standards were irrelevant because compliance was not mandated until after the ladder at issue was manufactured. The appellate court rejected these arguments, finding that the defendant had actual knowledge of the new standard and had been attempting to comply with it before the ladder at issue was manufactured. The Court also found that the standard was applicable because it was in place at the time the ladder was sold to the plaintiff's employer.

In *Smith v. Black & Decker (U.S.), Inc.*,⁵² the appellate court affirmed a defense verdict in a similar circumstance involving an intervening change in standards. In *Smith*, plaintiff's hand was amputated as a result of an accident involving a power saw. The plaintiff argued that the saw was unreasonably dangerous due to the lack of a guard over the lower right part of the saw blade. At the time the saw was manufactured in 1978, such blade guards were not required by Underwriters' Laboratories (UL) standards. There was testimony that, at the time of manufacture, the saw complied with existing UL standards. After the date of manufacture, UL changed the standard and a blade guard was required. In fact, when the standard changed, the defendant changed the saw design to add the guard. The defendant objected to evidence about the newer standard, and also objected to evidence of the design change as a subsequent remedial measure. The trial court barred this evidence.

On appeal, the appellate court affirmed the exclusion of this evidence, finding that the changed UL standard was irrelevant. While the defendant in *Smith* corresponded with UL about the new standard before its enactment, it did not do so before the date of manufacture. *Smith* did not cite *Doyle*, perhaps because the defendant in *Doyle* knew about the revised standards before the product was made.

C. Offensive Use of Statutes, Regulations and Standards.

The use of governmental or industry standards at trial can be very helpful where plaintiff claims a product defect exists but the product complies with a statute, regulation or standard. One of the early leading cases in this area is *Rucker v. Norfolk & Western Railway Co.*⁵³ In *Rucker*, plaintiff was injured when a liquid petroleum gas (LPG) tanker railroad car exploded after it was punctured by another railroad car in a rail yard. At trial, plaintiff argued that the LPG tanker car should have been equipped with a "headshield," a protective device which would protect a tanker car from damaging contact with other railcars and objects. At the time the tanker was manufactured, headshields were not required by federal regulations and the tanker car met then-existing regulatory standards.

At trial, the manufacturer of the exploding car was barred from admitting evidence that its tanker car complied with federal regulations. The defendant argued that this evidence proved the tanker was not unreasonably dangerous, but plaintiff argued that this evidence was irrelevant in a strict liability action. The plaintiff won at trial and the appellate court affirmed.

The Illinois Supreme Court reversed, indicating that the federal regulation was relevant to the product's condition, including whether it was defective or unreasonably dangerous. The court held that compliance with regulations is part of the "reasonableness" inquiry applicable in a strict liability action. However, the court rejected defense arguments that compliance, in and of itself, negated liability, as preemption was not an issue and the issue of whether a product is unreasonably dangerous is typically a fact issue for the jury. Thus, compliance was not conclusive evidence of lack of defect, but simply some evidence on the issue. This oft-cited aspect of *Rucker* has been the subject of much litigation.

In *Moehle v. Chrysler Motors Corporation*,⁵⁴ plaintiffs were injured when the rear seat of the vehicle in which they were riding became dislodged after an accident. The plaintiffs alleged severe abdominal injuries due to the way the seat belts contacted their bodies after the seat dislodged. The defendant introduced evidence of a federal motor vehicle standard concerning how the seat was to be anchored and that the defendant's anchoring system exceeded what was required. The defense won and plaintiffs appealed.

On appeal, plaintiffs argued that *Rucker*⁵⁵ was wrongly decided, and that introduction of federal standards unfairly highlighted the compliance evidence, and caused the jury to be misled by antiquated and inadequate standards. The Illinois Supreme Court affirmed the verdict and rejected plaintiffs' arguments. The Court indicated that plaintiffs could present

evidence of the perceived inadequacy of a given standard or otherwise argue its lack of importance, but these arguments did not make the standard inadmissible.

Moehle and *Rucker* demonstrate that evidence of conformity with a product-related statute, regulation or standard can be devastating to the plaintiff's defect claim. Moreover, evidence of regulatory compliance tends to show the defendant in a positive light, an important antidote in the face of a severely injured plaintiff.

Another example of the power of regulatory compliance is *Hubbard v. McDonough Power Equipment, Inc.*⁵⁶ There, plaintiff was injured after a riding lawnmower tipped over while he was mowing an inclined area. At trial, plaintiff argued that the lawnmower was defective because it tended to roll over on inclines and did not have a deadman's switch that would stop the cutting blade from moving when the operator was not seated. The plaintiff's hand was severed when the mower tipped and he reached up to keep it from falling on him. There was evidence that the time between the roll over and the injury was up to two seconds. At trial, plaintiff moved to bar the defendants from demonstrating compliance with certain industry standards, including a Consumer Products Safety Committee standard proposed after the date of manufacture but essentially identical to other pre-existing industry standards. The trial court granted the plaintiff's motions in limine and the plaintiff won at trial.

On appeal, the appellate court reversed, relying heavily on *Rucker*. The court noted that the lawnmower complied with ANSI standards which never required a deadman's switch until well after the mower was made. Further, the proposed Consumer Products Safety Committee standard which contained a provision for a deadman's switch only required the blades to stop within six seconds, by which time the plaintiff in *Hubbard* would already have been injured. The court also found that the trial court committed error by not allowing the defendant to prove that the lawnmower was tested by an independent testing body and passed those tests. While the plaintiff's trial strategy was clear-suggest a defect existed because the accident occurred, show how the injury could have been prevented (the use of a deadman's switch), and preclude the defense from proving compliance with industry standards - the appellate court ruled it unfair.

Standards regarding product use may also be admissible in product liability cases. An excellent example of this is *Turney v. Ford Motor Co.*,⁵⁷ where plaintiff was severely injured when a tractor he was riding tipped over. The tractor did not have any rollover protection, although years before the tractor was manufactured, agricultural safety committees recommended such protection. Eventually, an industry trade association adopted a standard requiring rollover protection, but Ford offered the protection only as an option, not standard equipment. Ford made this decision because some tractor jobs needed low clearances and tractors equipped with rollover protection would be too tall to be used safely in those applications.

At trial, Ford elicited from plaintiff's expert that the Occupational Safety and Health Administration (OSHA) has issued regulations requiring employers to provide tractors with rollover protection, but that those regulations exempted the type of multi-use tractor included here. The plaintiff objected to this evidence, arguing that this regulation improperly diverted attention from Ford's duty to make a safe product to the intended use of the tractor by the plaintiff's employer. The plaintiff also objected to Ford's use of OSHA regulations regarding *employers*.

The appellate court rejected these arguments and affirmed the defense verdict. The court noted that Ford never denied the existence of its duty to provide a safe product, and that the OSHA regulations enabled the jury to determine whether the failure of Ford to install rollover protection as original equipment rendered the tractor unreasonably dangerous. Thus, the court permitted the jury to see why Ford did what it did (or in this case what it did not do), despite the fact that the regulation did not apply directly to Ford.

Compliance with voluntary industry standards can also be admitted to show lack of defect, especially if those standards were formulated by industry groups of which the defendant manufacturer was a member. In *Dugan v. Sears, Roebuck and Co.*,⁵⁸ a minor was blinded when a piece of debris was thrown by a lawnmower into his eye. At trial, plaintiff argued that alternative designs would have prevented the accident. The defendant argued that the relevant ANSI standard did not require the design alternatives proposed by plaintiff and that the lawnmower was not unreasonably dangerous. The defense won and plaintiff appealed.

In the appellate court, plaintiff attempted to distinguish *Rucker*⁵⁹ by suggesting that a difference existed between government regulations and voluntary industry standards. Further, plaintiff argued that the ANSI standard used by the defendant failed to require testing for the type of debris-throwing that caused the injury. The appellate court, however, found no reason to distinguish between governmental and industry standards, finding both relevant to assess product defect. The strengths and weaknesses of the voluntary standard were all subjects for cross-examination and argument by counsel. The defense verdict was affirmed.

Even subsequent regulations which approve a purported design flaw can still be admissible as part of the defense of a product. In *Jones v. Black & Decker Manufacturing Co.*,⁶⁰ a miner was electrocuted while using a drill which was not double

insulated, but instead was equipped with a three-prong grounding plug. The employer removed the plug, eliminating the grounding protection. The plaintiff argued that double insulation would have prevented the accident.

The defendant asserted a U.S. Bureau of Mines regulation applicable at the time of the accident requiring the grounding of drills used in mines. This regulation applied to mining operations, not to equipment manufacturers. The defendant successfully argued that in order to sell drills for use in mines, it had to provide grounding protection, but not double insulation. Despite the fact that the Bureau of Mines regulation was not in effect at the time of manufacture, the appellate court affirmed a verdict for the defendant, finding the regulation relevant because it was in effect at the time of the accident.

Compliance with a regulation or standard is not the only way to use them to defend a product. A product may be defended by proving that it has been approved for use by a governmental agency. In *Hatfield v. Sandoz-Wander, Inc.*,⁶¹ a failure to warn case involving a prescription drug, a plaintiff went blind after taking a prescription drug in amounts beyond what was prescribed by her physician. Blindness was a known complication from overuse of the medication, and this complication was disclosed in the package insert which accompanied the medication. At trial, plaintiff argued that the seriousness and likelihood of blindness was not adequately addressed in the warnings. The plaintiff also moved *in limine* to bar the defendant from mentioning that the medication was approved by the U.S. Food and Drug Administration (FDA). The trial court denied this motion, but did bar the defendant from discussing the FDA approval process. In closing arguments, the defense attorney argued the FDA approval of the product and the warning. The defense won and plaintiff appealed.

On appeal, plaintiff attempted to distinguish *Rucker*⁶² and *Moehle*⁶³ by arguing that evidence of FDA approval should be barred because approval is based on information submitted by the defendant and was not the result of independent judgment exercised by the governmental agency. Affirming the defense verdict, the court rejected these arguments for the reasons stated in *Moehle*: that plaintiff was entitled to argue that FDA approval was of little value and was based on test results submitted by the defendant. The court held these arguments went to the weight of the evidence and did not justify excluding the evidence of FDA approval.

Evidence of a defendant's general intention to comply with relevant standards is not admissible in a strict liability action, as such evidence relate to defendant's conduct and not the product. In *Kwon v. M.T.D. Products, Inc.*,⁶⁴ a minor was injured when he attempted to jump onto the rear of a riding lawnmower which happened to change direction and move in reverse. At trial, defendant's employee testified that it was the defendant's policy to comply with all applicable safety standards and that it would not introduce any consumer products which were outside compliance. However, there was no evidence that the mower in question complied with any specific industry standard, and, after a verdict for the defendant, the plaintiff appealed. Although the appellate court affirmed, it did hold it was error to admit this general statement regarding compliance, albeit harmless error.

Jury instructions have also been the focus of litigation regarding the evidentiary implications of compliance with statutes, regulations and industry standards. While plaintiffs have requested limiting instructions as to the effect of such compliance, the admission of a standard does not necessitate a jury instruction that compliance is not a defense to a product liability suit. In *Malek v. Lederle Laboratories*,⁶⁵ a minor plaintiff was injured as the result of a vaccination. The plaintiff argued that the written materials which accompanied the vaccine were inadequate. The defense evidence consisted largely of information regarding compliance with governmental regulations and licensing requirements, including the need to obtain approval from the Bureau of Biologics, a branch of the Food and Drug Administration (FDA). The defendant also provided evidence of FDA regulations and Bureau approval concerning package inserts and other written materials supplied with the vaccine.

The plaintiff sought to have the jury instructed with a non-Illinois Pattern Jury Instruction which read as follows:

If you decide that the plaintiff has proved all of the propositions of either count, then it is not a defense that the defendant complied with the Food and Drug Administration regulations.

The defendant agreed not to make such an argument and the court refused this instruction. The defense won and plaintiff appealed. In affirming the result, the appellate court ruled that while compliance itself is not a defense, and is only one factor the fact finder may consider in determining whether a product is unreasonably dangerous, giving an instruction might confuse the jury by suggesting that evidence of compliance was somehow different from all other evidence. Such an instruction could result in the jury ignoring evidence of compliance.

Another way to maximize the effect of compliance is through jury instructions which focus the jury's attention on the standards in a neutral way. Unfortunately, there is no Illinois Pattern Instruction which deals directly with compliance with statutes, regulations and standards. Only lack of compliance is specifically addressed in the I.P.I. (Civil) 3d,⁶⁶ and that

instruction indicates that a violation of state law, municipal ordinance or administrative rule or order is something the jury can consider in determining whether a party is negligent:

There was in force in the [State of Illinois] [City of *e.g.*, *Peoria*] at the time of the occurrence in question a certain [statute] [ordinance] [administrative (regulation) (rule) (order)] which provided that:

[*Quote or paraphrase applicable part of statute, ordinance or regulation as construed by the courts.*]

If you decide that [a party] [the parties] [*description of non-party*] violated the [statute] [ordinance] [regulation] [rule] [order] on the occasion in question, then you may consider that fact together with all the other facts and circumstances in evidence in determining whether and to what extent, if any, [a party] [the parties] [*description of non-party*] [was] [were] negligent before and at the time of the occurrence.⁶⁷

Nevertheless, there is Illinois case law which has essentially approved instructions that compliance, while not an absolute defense, is evidence that relates to a product defect. *Galowich v. Beech Aircraft Corp.*⁶⁸ involved a fatality arising out of a private airplane crash allegedly caused by a faulty propeller. The defendant offered evidence of various types of Federal Aviation Administration (FAA) approval, including design approval before manufacture, and airworthiness after manufacture. In *Galowich*, the FAA actually approved the design for the propeller system which allegedly failed. At trial, the following instruction was given over plaintiff's objection:

There was in force in the United States at the time of the occurrence in question, and at the time of the type certification of the propeller reversing system on the King Air Aircraft, certain statutes with respect to airworthiness which provided as follows:

* * *

An applicant is entitled to a type certificate for an aircraft * * *, if —

- (b) The applicant submits to the type design, test reports, and computations necessary to show that the product to be certificated meets the applicable airworthiness . . . requirements of the Federal Aviation Regulations and any special conditions prescribed by the Administrator, and the Administrator finds —
 - (1) Upon examination of the type design, and after completing all tests and inspections, that the type design . . . meet[s] the applicable airworthiness requirements of the Federal Aviation Regulations or that any airworthiness provisions not complied with are compensated for by factors that provide an equivalent level of safety; and
 - (2) For an aircraft, that no feature or characteristic makes it unsafe for the category in which certification is requested.

The FAA's special finding of compliance with the special conditions issued by the Administrator relative to the reversing propeller system on the King Air may be considered by you, together with all the other facts and circumstances in evidence in determining whether or not the aircraft was in an unreasonably dangerous condition, bearing in mind that you may conclude that the aircraft was in an unreasonably dangerous condition notwithstanding its conformance to the Federal Standards.⁶⁹

The aircraft manufacturer won and plaintiff appealed, in part based on the above instruction. The appellate court affirmed the admission of evidence regarding the certification process and found that the instruction clearly stated that compliance was not conclusive and was to be considered with all other evidence. This holding was thus perfectly consistent with *Rucker*.⁷⁰

Finally, compliance with industry standards can help win summary judgment, even in a failure to warn case. In *Ford ex rel. Ford v. Naim*,⁷¹ a minor plaintiff was injured while she and another child were jumping on a trampoline. The plaintiff alleged that the warnings which accompanied the trampoline were inadequate even though the warnings were sewn onto the mat and the

manual and placard specifically warned against more than one person jumping at a time. The trial court granted summary judgment based on the open and obvious rule, but also found the warning to be adequate. On appeal, the appellate court affirmed and approved the trial court reliance on an ANSI standard to assess whether the warning was adequate as a matter of law.

As the above cases demonstrate, evidence of either compliance or noncompliance with governmental regulations or industry standards can be compelling evidence at trial. Defense counsel should look for opportunities to demonstrate compliance and offer such statutes, regulations and standards into evidence. Doing so will focus the jury on independent grounds to exonerate the allegedly defective product.

D. Illinois Tort Reform

The fate of the Civil Justice Reform Amendments of 1995, commonly known as the Tort Reform Act, is well-known to Illinois defense lawyers.⁷² Although the Act was found to be unconstitutional, the product liability provisions were not struck down. As these unreviewed sections would be a logical starting point for any renewed tort reform effort, it seems useful to discuss the section relating to the evidentiary effect of compliance with governmental regulation. Section 2-2103 of the Illinois Code of Civil Procedures stated:

Section 2-2103. Federal and State Standards; presumption. In a products liability action, a product or product component shall be presumed to be reasonably safe if the aspect of the product or product component that allegedly caused the harm was specified or required, or if the aspect is specifically exempted for particular applications or users, by a federal or State statute or regulation promulgated by an agency of the federal or State government responsible for safety or use of the product before the product was distributed into the stream of commerce.⁷³

The language of this provision shows that it is different from current Illinois law, at least as to governmental regulations. The Tort Reform Act created a presumption against an “unreasonably dangerous” finding where the product or specific component in issue was either specified or required by federal or state law or regulation, or if that product or component was “specifically exempted for particular applications or users” by federal or state law or regulation. Thus, under the Tort Reform Act, governmental standards triggered a statutory presumption but industry standards did not. Despite this limitation, the presumption created by the Tort Reform Act would have helped create uniformity and predictability for product defendants.

E. The Restatement Approach

Current Illinois law relating to the use of governmental statutes and regulations and industry standards is very much in line with Section 288 C of the Restatement 2d Torts. This section, which applies directly to negligence actions, provides as follows:

Compliance with a legislative enactment or an administrative regulation does not prevent a finding of negligence where a reasonable man would take additional precautions.⁷⁴

As the comment to this section points out,⁷⁵ this provision suggests that governmental compliance is the minimum expected of a defendant (or product), and that a stricter standard may apply if circumstances warrant. This is very much in line with the cases discussed above which indicate that compliance is evidence of lack of defect, but not dispositive as a matter of law. This restatement provision is also consistent with I.P.I. (Civil) 3d, § 60.01 (1995) described above.

Section 4 of the Restatement 3d of Torts: Products Liability, takes a somewhat different approach in that compliance and noncompliance are considered together. This section provides as follows:

In connection with liability for defective design or inadequate instructions or warnings:

- (a) A product's noncompliance with an applicable safety statute or administrative regulation renders the product defective with respect to the risks sought to be reduced by the statute or regulation; and
- (b) A product's compliance with an applicable product safety statute or administrative regulation is properly considered in determining whether the product is defective with respect to the risks sought to be reduced by the statute or regulation, but such compliance does not preclude as a matter of law a finding of product defect.⁷⁶

While section 4(b) is essentially consistent with current Illinois law, section 4(a) is very different because it appears to render noncompliance negligence *per se*. This is arguably more harsh than current Illinois law where noncompliance would simply be one piece of evidence regarding product defect.⁷⁷

F. Approaches Used by Other States.

States take various approaches regarding a presumption for regulatory or industry standard compliance. Some states, including Kansas and Colorado, create presumptions much like the former section 2-2103 of the Illinois Code of Civil Procedures.⁷⁸ Others have stronger statutes, such as Washington, where compliance with a government specification provides an absolute defense.⁷⁹ In Maryland, compliance with a governmental standard is one piece of evidence to be considered in determining whether a product is defective, but compliance without evidence that something more was required can support a defense finding as a matter of law.⁸⁰

A presumption for regulatory compliance makes tremendous sense and would promote compliance, as to do so would lessen the likelihood of being sued. Although case law in Illinois does not go that far, the evidentiary rulings regarding standards can still be very helpful to defendants. Even without preemption, evidence of compliance helps the jury understand why decisions were made and provides some perspective and balance at trial.

IV. Conclusion

We have a highly regulated society and the use of regulations in the prosecution or defense of litigated matters is inescapable. Nowhere is the sword and shield duality more evident than in the assertion of statutes, regulations and standards in product liability cases.

Federal preemption is a sword of inestimable value which can win cases outright for product defendants, although the Illinois Supreme Court has essentially limited the doctrine to express preemption specifically aimed at the alleged defect.⁸¹ However, the more expansive approach of the Seventh Circuit in *Mitchell v. Collagen Corp.*⁸² may emerge as the preferred approach during the next term of the United States Supreme Court.⁸³

Beyond preemption, compliance with federal acts and regulations, including pre-market approval, can be valuable evidence in product liability litigation. Specifically, compliance is a powerful tool to rebut arguments that a product is defective and unreasonably dangerous. It is essential for all defense lawyers to understand those regulations and standards which apply to a product and, to the extent possible, assert them in the defense of an action involving that product.

Endnotes

¹ *Hillsborough County v. Automated Medical Laboratories*, 471 U.S. 707, 713, 105 S. Ct. 2371, 2379 (1985), *United States v. Shimer*, 367 U.S. 374, 381, 81 S. Ct. 1854 (1961) and *Fidelity Federal Savings & Loan Association v. De La Cuesta*, 458 U.S. 141, 153, 102 S. Ct. 3014, 3022 (1982).

² *Sperry v. Florida*, 373 U.S. 379, 403, 83 S. Ct. 1322 (1963).

³ *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 120 L.Ed.2d 407, 422, 112 S. Ct. 2608, 2617 (1992).

⁴ *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 120 L.Ed.2d 407, 422, 112 S. Ct. 2608, 2617 (1992).

⁵ *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516, 120 L.Ed.2d 407, 422, 112 S. Ct. 2608, 2617 (1992) and *Busch v. Graphic Color Corp.*, 169 Ill. 2d. 325, 334, 662 N.E.2d 397 (1996).

⁶ *Pacific Gas & Electric Co. v. Energy Resources Conservation & Development Commission*, 461 U.S. 190, 204, 103 S. Ct. 1713, 1722 (1983).

⁷ *Nash v. Florida Industrial Commission*, 389 U.S. 235, 239, 88 S. Ct. 362 (1967).

⁸ *Hines v. Davidowitz*, 312 U.S. 52, 62, 61 S. Ct. 399 (1941) and *Crosby v. National Foreign Trade Council*, 530 U.S. ___, 2000 W.L. 775550 (U.S.) (2000).

⁹ *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485, 135 L.Ed.2d 700, 715, 116 S. Ct. 2240, 2250 (1996).

¹⁰ *Hillsborough County v. Automated Medical Laboratories*, 471 U.S. 707, 715, 105 S. Ct. 2371, 2379 (1985).

¹¹ *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251, 104 S. Ct. 615 (1984).

¹² *Abbott v. American Cyanamid Co.*, 844 F.2d 1108, 1112 (4th Cir., 1988).

¹³ *Hillsborough County v. Automated Medical Laboratories*, 471 U.S. 707, 717, 105 S. Ct. 2371, 2379 (1985).

¹⁴ 21 U.S.C. § 301, *et seq.*

¹⁵ 21 U.S.C. § 360(k) (1994).

¹⁶ *Mitchell v. Collagen Corp.*, 126 F.3d 902, 911 (7th Cir. 1997) and *Weiland v. Telectronics Pacing Systems, Inc.*, 188 Ill. 2d 415, 721 N.E.2d 1149 (1999).

¹⁷ 21 U.S.C. § 355(a) (1994).

¹⁸ 21 U.S.C. § 355(b)(1) and 21 C.F.R. § 314.50 (1995).

¹⁹ 21 C.F.R. § 601.12 (1995).

²⁰ 21 C.F.R. § 314.70(c) (1995).

²¹ *Id.*

- ²² *Tobin v. Astra Pharmaceutical Products, Inc.*, 993 F.2d 528 (6th Cir. 1993), *Graham v. Wyeth Laboratories*, 906 F.2d 1399 (10th Cir. 1990), *Abbott v. American Cyanamid*, 844 F.2d 1108 (4th Cir. 1988), *Osburn v. Anchor Laboratories, Inc.*, 825 F.2d 908, 912 (5th Cir. 1987).
- ²³ 669 F.Supp. 212, 217 (N.D. Ill. 1987).
- ²⁴ 72 Ill. App. 3d 540, 561, 390 N.E.2d 1214 (1st Dist. 1979).
- ²⁵ While the *Mahr* court was interpreting Texas law, there is no reason to believe that a different approach would follow in construing the law of Illinois.
- ²⁶ *Hurley v. Lederle Laboratories*, 863 F.2d 1173, 1179 (5th Cir. 1988) and *Perez v. Wyeth Laboratories, Inc.*, 734 A.2d 1254, 1259 (N.J. 1999).
- ²⁷ 21 U.S.C. § 360(k).
- ²⁸ 21 U.S.C. § 360k(a) (1994).
- ²⁹ Geiger and Rosen, RATIONALIZING PRODUCT LIABILITY FOR PRESCRIPTION DRUGS: IMPLIED PREEMPTION, FEDERAL COMMON LAW, AND OTHER PATHS TO UNIFORM PHARMACEUTICAL SAFETY STANDARDS, 45 DePaul L.Rev. 395, Winter 1966.
- ³⁰ 188 Ill. 2d 415; 721 N.E.2d 1149 (1999).
- ³¹ 126 F.3d 902, 911 (7th Cir. 1997).
- ³² 518 U.S. 470, 135 L.Ed.2d 700, 715, 116 S. Ct. 2240 (1996).
- ³³ *Supra*.
- ³⁴ *Id.*, at 423.
- ³⁵ *Id.*, at 911.
- ³⁶ *Id.*, at 422.
- ³⁷ 518 U.S. 470, 485, 135 L.Ed.2d 700, 715, 116 S. Ct. 2240, 2250 (1996).
- ³⁸ *In re Orthopedic Bone Screw Liability Litigation*, 159 F.2d 817 (3rd Cir. 1998), *Buckman Co. v. Plaintiff's Legal Committee*, 98-1768 (cert. granted June 9, 2000).
- ³⁹ 126 F.2d 902 (7th Cir. 1997).
- ⁴⁰ 188 Ill. 2d 415, 423 (1999).
- ⁴¹ *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 112 S. Ct. 2608, 120 L.Ed.2d 407 (1992).
- ⁴² *Busch v. Color Graphic Corp.*, 169 Ill. 2d 325, 662 N.E.2d 397 (1996) (existence of federally mandated design and content criteria precluded claims that paint stripper warning was inadequate); *Verb v. Motorola, Inc.*, 284 Ill. App. 3d 460, 672 N.E.2d 1287 (1st Dist. 1996) (statute gave the Food and Drug Administration (FDA) exclusive control over health and safety issues surrounding cellular telephone use).
- ⁴³ 305 Ill. App. 3d 792, 713 N.E.2d 792 (3rd Dist. 1999). Note that in *Geier v. American Honda Motor Company, Inc.*, Slip Op No. 98-1811 (May 22, 2000) the U.S. Supreme Court held that no airbag claims were preempted by Federal Motor Vehicle Standards then in effect.
- ⁴⁴ *Rucker v. Norfolk & Western Railway*, 77 Ill. 2d 434, 396 N.E.2d 534 (1979).
- ⁴⁵ 68 Ill. 2d 79, 368 N.E.2d 1299 (1977).
- ⁴⁶ 64 Ill. 2d 380, 356 N.E.2d 93 (1976).
- ⁴⁷ 116 Ill. 2d 53, 506 N.E.2d 581 (1987).
- ⁴⁸ 107 Ill. App. 3d 139, 437 N.E.2d 376 (3rd Dist. 1982).
- ⁴⁹ 226 Ill. App. 3d 20, 589 N.E.2d 569 (1st Dist. 1991).
- ⁵⁰ 74 Ill. 2d 364, 385 N.E.2d 690 (1979).
- ⁵¹ 249 Ill. App. 3d 370, 618 N.E.2d 909 (1st Dist. 1993).
- ⁵² 272 Ill. App. 3d 451, 650 N.E.2d 1108 (3rd Dist. 1995).
- ⁵³ 77 Ill. 2d 434, 396 N.E.2d 534 (1979).
- ⁵⁴ 93 Ill. 2d 299, 443 N.E.2d 575 (1982).
- ⁵⁵ *Supra*.
- ⁵⁶ 83 Ill. App. 3d 272, 404 N.E.2d 311 (5th Dist. 1980).
- ⁵⁷ 94 Ill. App. 3d 678, 418 N.E.2d 1079 (1st Dist. 1981).
- ⁵⁸ 113 Ill. App. 3d 740, 447 N.E.2d 1055 (1st Dist. 1983).
- ⁵⁹ *Supra*.
- ⁶⁰ 202 Ill. App. 3d 401, 559 N.E.2d 1004 (1st Dist. 1990).
- ⁶¹ 124 Ill. App. 3d 780, 464 N.E.2d 1105 (1st Dist. 1984).
- ⁶² *Supra*.
- ⁶³ *Supra*.
- ⁶⁴ 285 Ill. App. 3d 192, 673 N.E.2d 408 (1st Dist. 1996).
- ⁶⁵ 125 Ill. App. 3d 870, 466 N.E.2d 1038 (1st Dist. 1984).
- ⁶⁶ See I.P.I. (Civil) 3d, § 60.01 (1995).
- ⁶⁷ I.P.I. (Civil) 3d, § 60.01 (1995).
- ⁶⁸ 209 Ill. App. 3d 128, 568 N.E.2d 46 (1st Dist. 1991).
- ⁶⁹ 568 N.E.2d, at 50.
- ⁷⁰ *Supra*.
- ⁷¹ 307 Ill. App. 3d 296, 717 N.E.2d 525 (4th Dist. 1999).
- ⁷² Public Act 89-7, § 15, effective March 9, 1995. This Act was found unconstitutional by the Illinois Supreme Court in *Best v. Taylor Machine Works*, 179 Ill. 2d 367, 689 N.E.2d 1057 (1997).
- ⁷³ 735 ILCS 5/2103 (1995).
- ⁷⁴ Restatement of Torts (2nd), § 288 C (1965).
- ⁷⁵ See Comment a to § 288 C of Restatement (2nd) Torts (1965).
- ⁷⁶ Restatement 3d Torts: Products Liability, § 4.

⁷⁷ See, *Doyle v. White Metal Rolling & Stamping Corp.*, 249 Ill. App. 3d 370, 618 N.E.2d 909 (1st Dist. 1993); *King v. American Food Equipment Co.*, 160 Ill. App. 3d 898, 513 N.E.2d 958 (1st Dist 1987).

⁷⁸ See, *Miller*, supra; K.S.A. 60-3304(a); *States v. R.D. Werner Co., Inc.*, 799 P.2d 427 (Colo. Ct. App. 1990).

⁷⁹ *Foster v. Fibreboard Corp.*, 55 Wash.App. 545, 779 P.2d 272 (1989).

⁸⁰ *Beatty v. Trailmaster Products, Inc.*, 330 Md. 726, 625 A.2d 1005 (1993).

⁸¹ *Weiland v. Telectronics Pacing Systems, Inc.*, 188 Ill. 2d 415, 721 N.E.2d 1149 (1999).

⁸² *Mitchell v. Collagen Corp.*, 126 F.3d 902, 911 (7th Cir. 1997).

⁸³ *In re Orthopedic Bone Screw Liability Litigation*, 159 F.2d 817 (3rd Cir. 1998), *Buckman Co. v. Plaintiff's Legal Committee*, 98-1768 (cert. Granted June 9, 2000).