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UNITED STATES PRODUCT LIABILITY LAW

Recent Developments

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Table of Contents

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1. Strict Liability Update

As most of you probably know, most product liability claims in the U.S. are based on the doctrine of strict liability. This doctrine holds sellers of defective and unreasonably dangerous products responsible for injuries caused by those products, even without a showing of negligence. These products have included everything from food, furniture, and kitchen appliances to airplanes, building materials, and industrial machinery.

American plaintiffs' lawyers are continually trying to bring new products under the umbrella of strict liability, and there have been significant developments in this area of the law in recent years. For example, some American courts[1] over the past decade have permitted strict liability actions against:

· a condom manufacturer, for failure to prevent pregnancy;

· a truck manufacturer, for spinal injuries allegedly caused by the truck's rough ride;

· a restaurant, for a patron's severe adverse reaction after eating vegetable soup containing the food additive MSG;

· a gun manufacturer, for damage to the plaintiff's hearing caused by the gun's misfire, despite the manufacturer's instructions to wear hearing protection;

· McDonald's, for burns suffered by a customer who spilled scalding coffee on herself.

In each of these cases, courts held that juries should be permitted to hear evidence and decide if the product was "unreasonably dangerous" and whether the product caused the plaintiff's injuries, even without any showing of actual negligence – for example, in the condom case, the

[1] A caveat: American courts frequently do not rule uniformly. A court in New York, for example, may permit a claim that a court in Pennsylvania rejected. In my remarks today, I will try to give you information concerning majority outlooks and trends.

court held that pregnancy may constitute a "harm" and the jury could decide whether the allegedly defective condom was "unreasonably dangerous" and the proximate cause of the pregnancy.

On the other hand, many American courts have been skeptical of these sorts of extreme claims, and have refused to find sellers strictly liable for injuries caused by dozens of products, including beer and liquor (plaintiffs drank too much), firearms (plaintiffs were victims of gun violence), clothing (which caught fire), cigarette lighters (plaintiffs' children used them as toys), table saws (plaintiffs failed to use guard which would have prevented injuries), hot coffee and hot chocolate (in rulings subsequent to the McDonald's case), and fattening food (another McDonald's case). So, as you can see, the types of products that plaintiffs' lawyers complain about is limited only by their imagination.

2. Instruction and Warning Claims

Even if a product isn't defective, a claim can still be made that it lacked appropriate instructions and warnings. A product free from manufacturing and design defects may nevertheless give rise to a successful lawsuit if the consumer was not adequately informed of potential hazards arising from the product's reasonably foreseeable use. The scope of instruction and warning claims has been a complex and continually evolving area of product liability law over the past decade.

Unfortunately, the general trend among product sellers has been toward ever more burdensome warnings – to the extent that warning tags and stickers have become a frequent target of jokes among average Americans.

Although the foot stool card was a joke, some real warnings are almost as funny.

Perhaps in reaction to a situation which seems to be getting out of hand, American courts in recent years have established significant limits to product sellers' warning obligations. One court, for example, held that the manufacturer of a grandfather clock could not be held liable in negligence for injuries caused when a child tipped over the clock: there was no requirement for the maker of a simple product to design safety features to protect users (including children) from open and obvious dangers associated with the product, nor was there a duty to warn against such open and obvious dangers. Other courts have held that component part manufacturers – including auto manufacturers supplying parts for customized trucks and construction vehicles, and suppliers of raw materials for various medical implants, including breast implants – have no obligation to warn users of the ultimate product of risks associated with use of the component parts. That duty belongs to the manufacturer of the complete product. A California court held that an over-the-counter drug manufacturer had no obligation to warn in a language other than English, since

government regulations required warnings only in English. Several courts have limited the post-sale duty to warn (or recall) to those consumers who can be readily identified or traced.

Finally, the so-called "learned intermediary" defense, which first arose in prescription drug cases, has been expanded and refined to protect many manufacturers who sell their products to doctors or other intermediaries whose expertise places them in a better position to communicate warnings to the ultimate user. Thus, if a product is initially sold to a "learned intermediary" – such as an employer – who can reasonably be expected to warn users of reasonably foreseeable dangers, then a manufacturer's duty to warn the user may be eliminated.

3. Advertising

Since at least the 1940s, American courts and commentators have debated the extent to which product advertisements – via television, radio, newspapers, and other media – should affect lawsuits concerning those products, but only in recent years have plaintiffs enjoyed some success in recovering on the basis of representations made in advertisements. The theory is that if the consumer suffers injury while using the product for the purpose for which it was advertised, then the seller has breached a warranty and should be held liable – although usually the customer must have read, heard, seen or known of the advertisement, and relied upon its promises or representations.

Two cases from the 1990s – one involving the Ford Bronco II, a popular sports utility vehicle (SUV), and the other involving Norplant, a federally approved contraceptive implanted under the skin – are important in this area. In the Ford Bronco case, the plaintiffs were injured in an accident when their vehicle rolled over, and the New York Court of Appeals held that although Ford was *not* liable under a design defect claim (because the vehicle's increased height and higher center of gravity, which made it more likely to roll over, also made it more appropriate for off-road travel), nevertheless it *could* be held liable on a breach of implied warranty claim, because Ford had advertised the Bronco II as appropriate for suburban driving and everyday road travel. Since routine highway and street driving was the ordinary purpose for which the Bronco II was advertised and sold, and since the evidence indicated that the vehicle was not safe for that purpose, the plaintiffs could prevail on their breach of warranty claim.

In the Norplant case, the plaintiffs were women who responded to a massive, nationwide advertising campaign on television and in stylish magazines such as *Glamour*, *Mademoiselle*, and *Cosmopolitan* by undergoing the surgical insertion of Norplant contraceptive capsules in their

arms. The implants allegedly caused many harmful side effects, and the women sued the manufacturer of Norplant, who responded with the learned intermediary defense: since the doctors not only prescribed Norplant, but also performed the surgical procedure, they were responsible for communicating information to the women concerning the potential hazards and side effects of using Norplant. The defendant won summary judgment on this basis at trial, and at the intermediate appellate level, but the Supreme Court of New Jersey held that the learned intermediary doctrine does *not* apply to the direct marketing of drugs to consumers. The court reasoned that in the new era of direct marketing of pharmaceutical products to consumers, an advertising campaign like Norplant's generates a corresponding duty requiring the manufacturer to warn consumers of defects in the product, rather than simply relying on the physician to talk with his patients about potential side effects.

By so holding, New Jersey became the only jurisdiction in the United States to recognize such an exception to the learned intermediary doctrine. Indeed, the vast majority of the thousands of Norplant cases brought in the federal courts were recently dismissed based on the learned intermediary doctrine. Only those governed by New Jersey law remain.

The consequences of these and similar decisions on American advertising have been significant. For example, one recent series of television advertisements for a prescription drug designed to treat depression and social anxiety disorder very effectively portrays the positive effects the drug may have – helping to eliminate constant depression, anxiety, and fear – but the ads conclude with a lengthy warning that the product "may not be for everyone" and that using it may cause nausea, loss of strength, sweating, decreased appetite, sleepiness, dizziness, insomnia, tremor, nervousness, and sexual side effects. This is the sort of warning that federal law has traditionally required manufacturers to give to "learned intermediaries," but not to the ultimate

consumer. Although it is too early to say if dramatic, long-term changes in American advertising practices will result from these sorts of legal liability issues, the short-term impact has been considerable.

4. Preemption

One of the most controversial and frequently litigated issues in American product liability law is the preemption defense. Preemption – or "federal preemption," as it is often called – is the defensive claim that a federal law or regulation under which product safety standards are established (for example, the National Traffic and Motor Vehicle Safety Act) supersedes any conflicting state law on the subject, including state common law tort principles. Therefore, manufacturers whose products comply with federal safety standards frequently argue that they cannot be held liable in product liability cases. Preemption defenses have arisen in variety of areas, including medical devices (governed by the federal Food, Drug and Cosmetic Act (FDCA)), tobacco, railroad crossing devices and automobiles. Unless preemption applies, compliance with governmental standards does not bar a common law products liability claim but is relevant evidence which a jury may consider when deciding liability. For example, an automobile crashworthiness case against Saab or Volvo could still proceed even though the car has successfully passed federally-mandated barrier testing.

There are two types of preemption: express and implied. Express preemption exists where a federal statute explicitly bars the States from regulating in that area. For example, the FDCA provides that "[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." By contrast, implied preemption exists where the federal government either extensively regulates an area, thereby manifesting an intent to preclude state regulation, or where state regulation directly conflicts with federal requirements.

Until two or three years ago, it appeared that there was a gradual trend toward narrowing and chipping away at the implied preemption defense, and although there has been no sweeping reversal of direction, recent U.S. Supreme Court decisions have reinvigorated the preemption doctrine. Two decisions are of particular importance. The first is *Geier v. American Honda Motor Co.* (2000), in which the Supreme Court held that a claim against Honda relating to a vehicle not equipped with air bags was implicitly preempted by a Federal Motor Vehicle Safety Standard dealing with passenger restraint devices. *Geier* is a confusing decision, however, and in its wake the lower courts struggled to understand how broadly the implied preemption defense should be applied.

The second decision may help eliminate this confusion. Two months ago, in *Sprietsma v. Mercury Marine* (2002), the Supreme Court held that the Federal Boat Safety Act and its attendant regulatory scheme did not implicitly preempt a state common law tort action arising out of an incident involving a boat propeller. In so holding, the Court noted the enforcing agency's position that such actions were not preempted and concluded that allowing them would further the Act's primary objective of promoting boating safety. Thus, in *Sprietsma*, the Supreme Court established a limit on the application of the implied preemption defense and provided further guidance as to when the defense is available.

In summary, preemption is one of the most significant and hotly debated topics in product liability law. The Supreme Court has been unusually active in this area, most of its decisions have involved 5-4 or 6-3 votes,[2] and most of its decisions (notably *Geier*) seem to have generated more confusion than clarity. The plaintiffs' bar is furious over what it regards as yet another roadblock devised by courts and defense counsel to prevent recovery in legitimate product liability cases,

[2] Note that *Sprietsma* was a unanimous decision.

while preemption advocates worry that the doctrine as currently formulated does not sufficiently protect manufacturers who have fully complied with federal regulations pertaining to their products. We can therefore expect continuing developments and changes in this area of the law in coming years.

5. Evidentiary Issues: *Daubert/Kumho Tire*

One of the most frequently criticized aspects of the American civil litigation system is the role of expert testimony: in nearly every big lawsuit, the plaintiff and defendant each produce a small army of well-paid experts whose respective testimony leads inescapably to the conclusion that *their* party ought to prevail. This "battle of the experts" often reduces the jury verdict to little more than an evaluation of the testimony of competing experts – a situation crying out for at least some judicial oversight and evaluation of expert testimony.

The Supreme Court took a first significant step in this direction in *Daubert v. Merrell Dow Pharmaceuticals, Inc.* (1993), a case involving disputed expert testimony regarding birth defects allegedly caused by mothers' ingestion of an anti-nausea drug, and recently broadened and clarified the *Daubert* decision in *Kumho Tire Co. v. Carmichael* (1999), a case involving the reliability of an engineering expert's testimony regarding allegedly defective automobile tires. The standard established under *Daubert/Kumho Tire*, and subsequently enshrined in the Federal Rules of Evidence, is that all expert testimony – whether relating to scientific, technical, or other specialized knowledge – must (1) be based upon sufficient facts and data; (2) be a product of reliable principles and methods; and (3) reliably apply these principles and methods to the facts of the case. These factors must be evaluated by the trial judge – acting as a so-called "gatekeeper" – to determine whether a challenged "expert" will be permitted to testify. The result has been to raise a protective barrier against at least some of the "junk science" generated by unscrupulous experts-for-hire, but also – according to the plaintiffs' bar – to increase costs substantially, and thereby eliminate many valid claims that are no longer cost-effective, to the benefit of manufacturers of dangerous products.

The upshot of these (and other) recent Supreme Court decisions is as follows:

· First, expert testimony will be allowed only if it is based on a methodology shown to be both reliable and relevant;

· Second, the trial court gets broad leeway in selecting the criteria it will use to analyze the experts' methodologies;

· Third, *ipse dixit* – Latin, roughly, for "because I'm an expert, and I say so" – no longer suffices as a basis for expert opinion, no matter how qualified the expert. The basis for the expert's conclusions – whether founded in scientific experimentation, application of physical principles, or experience and observation – must be explained and supported;

· Fourth, the reliability and relevance of expert testimony depends on whether an expert – basing testimony on either professional studies or personal experience – uses the same level of analysis as other experts in the relevant field.

6. Punitive Damages

No aspect of the American legal system looks stranger and more potentially frightening to non-American lawyers (and sometimes to American lawyers) than punitive damages awards. The most notorious case in recent years was the $2.7 million in punitive damages awarded (but reduced by the trial court to $480,000 – three times compensatory damages) to a woman who spilled a cup of hot McDonald's coffee in her lap. The largest award? A $145 billion verdict returned by a Florida jury in 2000 in that state's class action litigation against the tobacco industry.[3] The largest award to an individual was a $28 billion verdict returned by a California jury in 2002 against Philip Morris in favor of a cancer stricken former smoker (later reduced to $28 million and currently being appealed). Other notable punitive damages awards in product liability cases include $4.8 billion against General Motors (reduced by the trial court to $1.1 billion), $3 billion against Philip Morris, $480 million against Cessna Aircraft, $250 million against Chrysler, and – in the case that got the ball rolling on enormous punitives – $125 million against Ford Motor Company for its easily ignited Pinto automobile in the *Grimshaw* case of 1978 (reduced by the trial court to $3.5 million).

Before attempting to understand why punitive damages of this magnitude are awarded in the American system, we should pause to put some of these astronomical figures in perspective. In the first place, punitive damages are awarded relatively infrequently: according to one recent estimate, they have been awarded in only about 2% of product liability cases over the past twenty-five years, although the trend has been sharply upward (both in frequency and amount of awards) over that period. Furthermore, as noted above, many large awards are remitted by the trial court

[3] In 1997 and 1998, the tobacco industry settled most of the cases brought against it by all 50 states to recover for their health care costs for $246 billion. However, several states opted out of the settlement and have pursued their own litigation, and lawsuits by individuals continue to generate multi-million dollar punitive damages awards.

or reduced on appeal. Nevertheless, many of these are still enormous awards, especially in a legal system that permits plaintiffs' attorneys to collect their fees on a contingency basis – usually amounting to at least one-third of the award.

What sorts of manufacturer misconduct are responsible for most punitive damages awards? Some are fairly easy to predict: fraud, or knowingly violating safety standards, or failing to conduct adequate tests to uncover dangerous defects. Others are a bit trickier. Failure to "design out" a known danger, especially if fixing the problem would have been inexpensive relative to the degree of possible harm, may result in punitives (for example, the $250 million verdict against Chrysler resulted from a young boy's death in a case involving a flimsy door latch, which Chrysler engineers had repeatedly warned about and proposed fixing at a cost of 25-50 cents per latch). Another possible reason for assessing punitive damages is failure to warn of known dangers: thus the McDonald's hot coffee case, which involved evidence that McDonald's served its coffee 20-40 degrees hotter than most of its competitors and had received over 700 complaints of burns, but decided not to warn customers about the possibility of severe burns. Finally, a punitive damages award may result from the manufacturer's post-sale failure to warn or recall, but only in exceptional circumstances in which the manufacturer's failure to take remedial action was consciously and flagrantly indifferent to public safety.

The amount of a punitive damages award is based upon consideration of three factors: the seriousness of the wrong, the seriousness of the plaintiff's injury, and the extent of the defendant's wealth. Courts in recent years have especially emphasized the third element – an award should be large enough to have a noticeable impact on the defendant (but not to bankrupt it). This standard for determining punitive damages has been criticized for its vagueness and risk of over-

punishment (especially in mass tort cases), but is so well established that it is likely to remain in place for the foreseeable future.

Courts generally cite two purposes of punitive damages: to *punish* the defendant for outrageous misconduct, and to *deter* the defendant and others from similar misbehavior in the future. Punitive damages may also serve an informal "law enforcement" function: they encourage people who have been injured by allegedly defective products to bring lawsuits, thereby increasing enforcement of product liability law and encouraging manufacturers to comply with their legal obligations. Further, some commentators believe that punitive damages serve an educational function, informing the parties and the general public of their legal rights and responsibilities in the product liability context, and publicly condemning flagrant invasions of consumers' rights. Lastly, punitive damages are sometimes used as a means of socially-conscious wealth distribution. The quintessential example is a recent Ohio Supreme Court decision in which the court, without statutory authority, ordered a plaintiff who prevailed against an insurance company on claims arising out of his wife's prolonged battle with cancer to pay $20 million of his $30 million punitive damages award to a cancer research fund. Along similar lines, eight states have statutes requiring the plaintiff to pay between one half and three quarters of any punitive damages award to the government.

Whether or not, on balance, punitive damages create any societal benefit is a subject of heated debate in the United States, as we shall see in a few minutes when we discuss tort reform proposals. The Supreme Court recently held in *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.* (2001), a trademark infringement case involving a $4.5 million punitive damages award, that the U.S. Constitution forbids "grossly excessive" punitive damages, and that appellate review of punitive damages awards must be "de novo" – i.e., rather than simply reviewing the trial

court's award under an abuse of discretion standard, the appellate court must make *its own determination* of whether or not a punitive damages award is "grossly excessive" and therefore unconstitutional. This term, in *State Farm Mutual Automobile Insurance Co. v. Campbell*, (a case arising out of an automobile insurer's bad faith refusal to settle and suspect business practices) the Court will revisit the question of when punitive damages become "grossly excessive" in a case where the jury awarded $145 million in punitive damages to a plaintiff who suffered $2.6 million in compensatory damages (an almost 56:1 ratio) as a result of his insurer's bad faith actions. (The award was subsequently reduced to $1 million in compensatory damages and $25 million in punitive damages, a ratio of 25:1).

Although appellate courts have been increasingly willing to strike down multi-million and -billion dollar awards, for the foreseeable future it appears that very large (but not "grossly excessive") punitive damages awards will remain an integral part of American product liability law.

7. Class Actions/Mass Torts

Most high-profile product liability cases in American courts are brought as class actions, from tobacco and asbestos to pacemakers and diet drugs – firearms and lead paint seem to be in fashion at the moment, although without any great success so far. As with punitive damages, the class action has no real European equivalent, but has become an increasingly prominent feature of the American legal system in recent years. And, as might be expected, the entire topic is highly controversial. What began as a procedure for aggregating multiple claims in complex civil litigation has evolved into an immensely complicated and unwieldy form of litigation, in which an attorney actively offers representation to a class of consumers who have allegedly been harmed by a product, files a lawsuit on behalf of the class, and if the suit is successful, the individual class members receive a very small share of a huge damages award, while the attorney takes one-third.

It is difficult to predict the future of class action litigation. The Supreme Court has issued a series of decisions explaining how a class of plaintiffs should be defined and how its interests must be litigated (and/or settled), and tort reformers have placed class actions at the top of their list for complete overhaul. Like punitive damages, the class action lawsuit is a feature of the American legal system that is likely to remain in place for a long time to come.

8. Tort Reform/Politics

Tort reform has been a live issue in American politics since at least the late 1970s, and momentum toward reform has increased over the past decade, especially due to the growing size of punitive damages awards and the increasing number of class action lawsuits.

The election of a Republican president in 2000, who has publicly said that "junk lawsuits" hurt the economy and has expressed disdain for plaintiffs' attorneys, again ignited hopes that tort reform might be just around the corner, and the success of the Republican party in the 2002 mid-term elections has created the most favorable climate for tort reform in recent memory.

If federal tort reform is enacted during the Bush administration, I expect it to include at least some of the following features, which have been included in prior reform proposals:

· Punitive Damages: tort reformers have consistently advocated a national standard for punitive damages awards, usually something along the lines of "clear and convincing evidence that the harm suffered by the claimant was the result of conduct manifesting...conscious, flagrant indifference to the safety of those persons who might be harmed by the product;" they have proposed eliminating punitive damages entirely for products such as prescription drugs, medical devices, aircraft, and aircraft components which meet federal safety standards; and they have proposed absolute caps on punitive damages awards, for example $250,000 or twice the amount of compensatory damages, whichever is greater.

· Expedited Judgments and Alternative Dispute Resolution: reform initiatives have included detailed frameworks for early resolution of product liability controversies, encouraging the parties to settle before trial, including the use of mediation, arbitration, or other ADR procedures; many of these proposals have been aimed particularly at class action litigation.

· Liability of Non-Manufacturing Sellers: tort reformers have suggested that non-manufacturing sellers such as retailers, distributors, and wholesalers should be subject to a limited range of liability claims – based on negligence and express warranty – rather than the full range of tort recovery theories, including strict liability and implied warranty.

· Statutes of Limitation and Repose: reform initiatives have included proposals establishing a two-year statute of limitations from the time the plaintiff discovered the harm, and also a statute of repose, eliminating all claims more than a certain number of years after sale of the product, no matter when the injury occurred. (Suggestions have ranged from 10 to 25 years, with 18 as the most popular figure.)

One of the strongest arguments advanced by tort reformers is the need for standards that will apply across the 50 states. Right now, product liability law is grounded primarily in the common law, which differs from state to state. Some states have already enacted tort reform measures: some have placed caps on punitive damages (usually around $250,000), and others require a substantial portion of any punitive damages award to be paid to the state rather than going to the plaintiff. Without uniformity, it is impossible for manufacturers to engage in certain kinds of economic forecasting: they cannot predict how extensive their legal liabilities for any given product may be, because there is no nationwide standard for litigating disputes and awarding damages. One of the great attractions of federal tort reform, therefore, especially for foreign manufacturers, is that it would introduce an element of predictability and reliability into the system.

Federal tort reform legislation has been introduced in Congress almost every year since 1979, but no comprehensive measure has ever been adopted into law. The most nearly successful effort came in 1996, when Congress passed the "Common Sense Product Liability Reform Act,"

which was vetoed by then-President Clinton. More recently, tort reformers in Congress have adjusted their tactics and introduced piecemeal legislation aimed at specific industries, especially health care. The most recent example is HR 321, introduced January 8, 2003, which features a proposed punitive damages cap of $250,000 or twice the amount of compensatory damages, whichever is greater, in all health care litigation. This bill is currently before two House committees, where it awaits consideration. It, and bills like it that will almost certainly be introduced in the 108th Congress, will provide the ultimate test of whether the climate surrounding tort reform in the United States has truly changed. If so, the legal landscape may be fundamentally altered. If not, those bills may be consigned to the dust bin along with all the other federal tort reform proposals of recent years.

United States Product Liability Law

Recent Developments

By Jeremy G. Zimmermann

Wiggin & Dana LLP

Strict Liability Claims

YES:

- Condom → Pregnancy
- Truck → Back Injury
- Restaurant → Allergic Reaction
- Firearm → Hearing Damage
- McDonald's Coffee → Burns

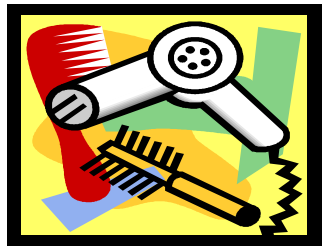
Strict Liability Claims

NO:

- Beer/Liquor → Drunken Mishaps
- Firearms → Gun Violence
- Clothing → Fire Injuries
- Cigarette Lighters → Children Injured
- Table Saws → Hand Injuries
- Hot Coffee/Chocolate → Burns
- Fattening Foods → Obesity

WARNING!

"Do not use hairdryer while sleeping"



"Do not put any person in this washer"

"Do not clean pets with vacuum"

WARNING!

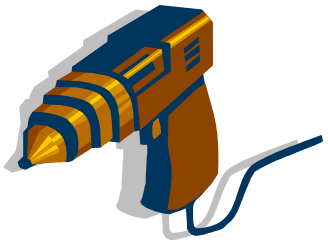
"Blanket not to be used as protection from a tornado"

"Wearing of this garment does not enable you to fly"

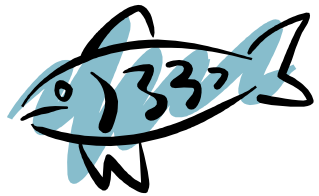
WARNING!

"Eating rocks may lead to broken teeth" *on a novelty rock garden*

"This product not intended for use as a dental drill" *on an electric rotary tool*



"The contents of this bottle should not be fed to fish" *on a bottle of dog shampoo*



Instruction and Warning Claims

- No duty to warn against obvious dangers
- Components: no warning duties
- English language warnings only
- Post-sale warnings: easily identified users
- “Learned Intermediary” defense

Advertising

- Theory: Breach of Implied Warranty
- Ford Bronco II
- Norplant Contraceptive Capsules

Preemption

- Federal Safety Standards vs. State Tort Claims
- *Geier vs. American Honda Motor Co.* (2000)
- *Sprietsma vs. Mercury Marine* (2002)
- Medical Devices and Pesticides
- Food, Drug and Cosmetic Act
- Tobacco
- Railroad Crossing Devices
- Automobiles

Express Preemption:
The Federal Food, Drug and Cosmetic Act

"No 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."

Evidentiary Issues:
Daubert/Kumho Tire

- "Battle of the Experts"
- *Daubert* (1993) and *Kumho Tire* (1999)
    1. Sufficient Facts and Data
    2. Reliable Principles and Methods
    3. Reliably Applied to Facts of Case
    4. Judge as "Gatekeeper"

PUNITIVE DAMAGES

$2,700,000

Reduced to $480,000

PUNITIVE DAMAGES

Tobacco Companies

$145,000,000,000

PUNITIVE DAMAGES

- Philip Morris: $28 Billion → $28 Million
- General Motors: $4.8 Billion → $1.1 Billion
- Philip Morris: $3 Billion
- Cessna Aircraft: $480 Million
- Chrysler: $250 Million
- Ford: $125 M → $3.5 M (*Grimshaw*, 1978)

PUNITIVE DAMAGES

CAUSES:

- Fraud
- Knowing violation of safety standards
- Failure to conduct adequate tests
- Failure to “design out” known danger
- Failure to warn of known danger
- Post-sale failure to warn or recall

PUNITIVE DAMAGES

AMOUNT:

- Seriousness of the Wrong
- Seriousness of Plaintiff's Injury
- Extent of Defendant's Wealth

PUNITIVE DAMAGES

PURPOSES:

- PUNISH outrageous misconduct
- DETER future misbehavior
- ENFORCE manufacturer compliance
- EDUCATE parties and general public
- U.S. Supreme Court 2001 *Leatherman* decision: appellate courts must determine if punitive damages are “grossly excessive” and therefore unconstitutional

Class Actions/Mass Torts

- Tobacco
- Asbestos
- Pacemakers
- Diet Drugs
- Firearms
- Lead Paint

Tort Reform/Politics

- Punitive Damages
  - National standard: “conscious, flagrant indifference”
  - Exemption for products meeting federal safety standards
  - Cap: $250,000 or twice the compensatory damages
- Expedited Judgments and ADR
- Liability of Non-Manufacturing Sellers
- Statutes of Limitation and Repose
- Need for National Uniformity
- 2003 Medical Malpractice Legislation:
  in House committees


MAY ALL OF YOUR GIFTS BE AS SAFE AS A THREE-LEGGED STOOL!
"WARNING: DO NOT USE THIS PRODUCT AS A STEP STOOL TO REACH SHARP OBJECTS ON A HIGH SHELF. DO NOT SET ON FIRE AND LEAVE ON CARPET. DO NOT GRIND INTO SAWDUST AND INGEST. DO NOT MELT WITH ACID AND INHALE FUMES. DO NOT STRIKE REPEATEDLY AGAINST YOUR HEAD. DO NOT DROP FROM BRIDGE ONTO PASSING MOTORISTS.
INJURIES RESULTING FROM IMPROPER USE OF THIS PRODUCT WILL NOT BE THE RESPONSIBILITY OF THE MANUFACTURER."
3 LEGGED FOOT STOOL
3 LEGGED FOOT STOOL
PIRARO
9-4