Rarely in law school are you directed to memorize information. This is the exception. You are required to memorize the ELEMENTS OF THE COMMON TORT CLAIMS.

The reason for inflicting this requirement on you is that a surprisingly large number of multi-state torts questions require, for a correct answer, only a confident grasp of the elements of the common tort claims. There is no Torts studying effort that will return a bigger payback for your time than mastering the elements of the common tort claims.

Twenty-five per cent (25%) of your Torts section exam will consist of short-answer questions testing your knowledge of the elements of the common tort claims. Also, Quiz #3 will test the same material.

Courts from state to state may differ as to their formulations of the elements of particular tort claims. For the purposes of the multi-state bar exam you should rely on the formulations set out in your instructor's chart, which are those found in the Second Restatement. The multi-state question writers believe that the Second Restatement is the tort law of the United States.
ELEMENTS OF THE COMMON TORT CLAIMS

Negligence:
1. Duty.
2. Breach.
3. Causation:
   a. cause in fact;
   b. "proximate" or "legal" cause.
4. Damages.

Trespass to land:
1. Intent.
2. Entry on real estate in possession of another.

Assault:
1. Intent.
2. Plaintiff’s apprehension
3. of an imminent harmful or offensive touching.

Battery:
1. Intent.
2. Harmful or offensive touching.

False imprisonment:
1. Intent.
2. Confinement of a person within a bounded area
3. by force or threat of force
   a. (can be by misuse of legal authority to confine);
4. Plaintiff is conscious of confinement, or else suffers actual harm.

Intentional infliction of emotional distress:
1. Intent.
2. Extreme and outrageous conduct.
3. Causation.
4. Plaintiff’s emotional distress is "severe."

Conversion:
1. Volitional and wrongful
2. exercise of dominion and control
3. over chattel property as to which plaintiff has the right of possession or ownership.
4. So substantial that defendant should be required to pay plaintiff the full value of the property.
Private nuisance:

1. Defendant maintains a condition or carries on an activity
2. that interferes with plaintiff’s use or enjoyment of real estate by non-trespassory means.
3. The harm suffered by plaintiff is substantial,
4. and unreasonable.

Public nuisance (private cause of action):

1. Defendant maintains or carries on a public nuisance.
2. Plaintiff’s injury is different in kind from, not just greater in degree than, the harm suffered by the public generally.

Defamation-- common law:

1. A statement capable of injuring reputation
2. of or concerning the plaintiff.
3. Publication to at least one other person.
4. Damages (presumed in libel and slander per se).

Defamation-- constitutional:

Where defendant is a media component entitled to protection under the First Amendment, plaintiff must prove the common-law elements plus

1. malice if the plaintiff is a public figure
   ("malice" in this context meaning publication while knowing the statement to be untrue, or with reckless disregard as to whether it is true or false), or
2. negligence if the plaintiff is a private figure.
3. Untruthfulness.
4. Actual, not presumed, damages.

Misrepresentation (simplified):

1. A statement by defendant misrepresenting a fact;
2. with knowledge of falsity, or reckless disregard as to whether it is true or false (this element is called "scienter"); and
3. with intent to induce the plaintiff’s reliance on the statement.
4. Plaintiff actually and justifiably relied on the statement.
5. Damages.
TORTS TOPICS COVERED ON THE MULTISTATE BAR EXAM
ACCORDING TO THE NATIONAL CONFERENCE OF BAR EXAMINERS

The outline printed below is an official release from the National Conference of Bar Examiners, stating the topics which are covered in torts questions on the multistate portion of the bar examination.

Note the initial paragraph, boxed for emphasis, stating "ground rules" for torts questions. Most likely you will encounter the same ground rules for torts questions when you take the bar. However, this is not certain. The ground rules have changed over time and may change again. Whatever this paragraph may say on your bar exam, pay attention to it!

The paragraph on ground rules won't help you if you don't understand it. Check out your own torts understanding by asking yourself if you know the meaning of "survival actions," "claims for wrongful death," "joint and several liability" and "pure comparative negligence."

Your instructor urges you to make this outline the basis for your own outline of torts for the bar.

NOTE: The Torts questions should be answered according to principles of general applicability. Examinees are to assume that there is no applicable statute unless otherwise specified; however, survival actions and claims for wrongful death should be assumed to be available where applicable. Examinees should assume that joint and several liability, with pure comparative negligence, is the relevant rule unless otherwise indicated.

I. Intentional torts
   A. Harms to the person: assault, battery, false imprisonment, infliction of emotional distress
   B. Harms to property interests; trespass to land and chattels, conversion
   C. Defenses to claims for physical harms
      1. Consent
      2. Privileges and immunities; protection of self and others; protection of property interests; parental discipline; protection of public interests; necessity; incomplete privilege
II. Negligence
   A. The duty question: including failure to act; unforeseeable plaintiffs; and obligations to control the conduct of third parties
   B. The standard of care
      1. The reasonably prudent person; including children, physically and mentally impaired individuals, professional people, and other special classes
      2. Rules of conduct derived from statutes and custom
   C. Problems relating to proof of fault, including res ipsa loquitur
   D. Problems relating to causation
      1. But for and substantial causes
      2. Harms traceable to substantial causes
      3. Questions of apportionment of responsibility among multiple tortfeasors, including joint and several liability
   E. Limitations on liability and special rules of liability
      1. Problems relating to "remote" or "unforeseeable" causes, "legal" or "proximate" cause, and "superseding" causes
      2. Claims against owners and occupiers of land
      3. Claims for mental distress not arising from physical harm; other intangible injuries
      4. Claims for pure economic loss
   F. Liability for acts of others
      1. Employees and other agents
      2. Independent contractors and nondelegable duties
   G. Defenses
      1. Contributory fault: including common law contributory negligence and last clear chance, and the various forms of comparative negligence
      2. Assumption of risk

III. Strict liability: claims arising from abnormally dangerous activities; the rule of Rylands v. Fletcher and other common law strict liability claims; defenses

IV. Products liability: claims against manufacturers and others based on defects in manufacture, design, and warning; defenses

V. Other torts
   A. Claims based on nuisance, and defenses
   B. Claims based on defamation and invasion of privacy; defenses and constitutional limitations
   C. Claims based on misrepresentations, and defenses
   D. Claims based on intentional interference with business relations, and defenses
HOW TO APPROACH A MULTISTATE TORTS QUESTION

Even when they know the law, more often than not bar candidates lack a systematic analytical approach to multistate questions. Instead they rely on memory, intuition, educated guesswork and uneducated guesswork. Here is a method of systematic analysis that will enable you to put your knowledge to best use when answering a multiple-choice Torts question.

1. SEE IF THE TORT CLAIM IS NAMED IN THE QUESTION. In approximately half of all multistate questions the tort claim is named in the text of the question (e.g. "trespass," "battery," "negligence"). If the tort claim is named in the question, put a circle around the name and skip to Step 4.

2. IF THE TORT CLAIM ISN’T NAMED IN THE QUESTION, RULE IN/OUT NEGLIGENCE. Fifty per cent of all torts questions on the multistate bar are about negligence. Therefore, if the tort claim isn’t named, there is a 50% likelihood that the question is about negligence. If you determine that the question is a negligence question, write "NEG" in the margin.

3. IF THE TORT CLAIM ISN’T NAMED IN THE QUESTION, AND ISN’T ABOUT NEGLIGENCE, FIGURE OUT WHICH TORT CLAIM IS PRESENTED BY THE FACTS. If the tort claim involved isn’t named in the question, and also isn’t negligence, then you have to figure out the claim from the facts that are presented. Most likely, this is the key issue on which the examiners are testing you. When you have figured out the tort claim that is involved, write it (or an abbreviation, e.g. "TPASS," "BAT") in the margin.

4. FIGURE OUT IF THE QUESTION IS ASKING YOU ABOUT THE CLAIM, ABOUT A DEFENSE TO THE CLAIM, OR ABOUT DAMAGES. A torts question just about has to be about the claim, or about a defense to the claim, or about damages. (Most torts questions are about the claim or about a defense to the claim. Relatively few questions are about damages). When you have figured out if the question relates to the claim, to a defense, or to damages, write in the margin "CL" for "claim," "DF" for "defense," or "DAM" for "damages."
5. IF THE QUESTION IS ABOUT THE CLAIM, IDENTIFY THE MISSING ELEMENT OR ELEMENTS. If the question is about the tort claim, it is likely to be a "missing element" question. In a "missing element" question, the fact pattern gives you all of the elements of the tort except one. From the four possible answers, you are required to select the answer that best supplies the missing element. In an alternative question format which is less frequently used by the bar examiners, the four answers will give you four possible combinations of elements. In only one answer are all of the elements of the tort included.

6. IF THE QUESTION IS ABOUT THE DEFENSE, REFER BACK TO STEPS 1 TO 3 WHERE YOU IDENTIFIED THE CLAIM. Ask yourself, what are the defenses to this claim? E.g. if the claim is "battery," the possible defenses are consent, self-defense, defense of others, protection of property interests, authority of law, parental discipline, public or private necessity. Then study the "call" of the question and choose the answer which best responds to the "call."

7. IF THE QUESTION IS ABOUT DAMAGES, ALSO REFER BACK TO STEPS 1 TO 3 WHERE YOU IDENTIFIED THE CLAIM. Damages questions are usually about special rules of damages applicable to particular tort claims (e.g. if the claim is trespass, no special damages are needed; if the claim is conversion, damages are the market value of the chattel at the time and place of the conversion). Less frequently, damages questions will involve distribution of damages via contribution or indemnity.

THIS ANALYTICAL APPROACH TO TORTS QUESTIONS IS NOT A SUBSTITUTE FOR KNOWING THE LAW. It is, instead, a systematic way of applying the knowledge that you have. If you lack knowledge of the law, no system will help you. You can’t analyze a tort claim according to its elements if you don’t know the elements. You can’t answer a question about tort defenses if you don’t know the defenses. You can’t answer a question about damages if you don’t know the rules about damages. So:

KNOW YOUR ELEMENTS!

KNOW YOUR DEFENSES!

KNOW THE RULES ABOUT DAMAGES!
Customer, aged twenty, went into Store at approximately 6:54 p.m. to look at some suits that were on sale. The clerks were busy, and one of them told him that he should wait on himself. Customer selected three suits from a rack and went into the dressing room to try them on. Signs posted on the walls of Store state that closing time is 9:00 p.m.; however, because of a special awards banquet for employees, Store was closed at 7:00 p.m. on this day. The employees, in a hurry to get to the banquet, did not check the dressing rooms or turn off the lights before leaving. When Customer emerged from the dressing room a few minutes after 7:00 p.m., he was alone and locked in. Customer tried the front door, but it was secured on the outside by a bar and padlock, so he went to the rear door. Customer grabbed the door knob and vigorously shook the door. It did not open, but the activity set off a mechanism that had been installed because of several recent thefts committed by persons who had hidden in the store until after closing time. The mechanism sprayed a chemical mist in Customer's face, causing him to be temporarily blind. The mechanism also activated an alarm carried by Store's employee, Watchman, who was just coming to work. Watchman unlocked the front door, ran into the store, and grabbed Customer. Customer, who was still unable to see, struck out at this person and hit a metal rack, injuring his hand. Watchman then identified himself, and Customer did the same. After assuring himself that Customer was telling the truth, Watchman allowed him to leave.

If Customer is to prevail on a claim against Store based on battery from the use of chemical spray, Customer must establish that

(A) he suffered severe bodily harm
(B) the spray mist was an offensive or harmful contact
(C) he suffered severe emotional distress
(D) his conduct was not a factual cause of the chemical's spraying him

1. STEP ONE. IS THE TORT CLAIM NAMED IN THE QUESTION? Yes, it is. Put a circle around the word "battery." Skip to Step Four.

4. STEP FOUR: IS THE QUESTION ASKING YOU ABOUT THE CLAIM, ABOUT A DEFENSE TO THE CLAIM, OR ABOUT DAMAGES? It's asking you about the plaintiff's, Customer's, claim. Write "CL" in the margin.

5. STEP FIVE: WHAT IS THE MISSING ELEMENT OR ELEMENTS? The elements of the tort claim called battery are two and two only: (1) intent, and (2) harmful or offensive touching. The missing element is "harmful or offensive touching." Therefore answer "B" is the correct choice.
ASSIGNMENT

For Monday, August 23, 2010, please review the first ten questions in the Torts section of your book.

Attached to this page is an outline of the topics that we will be covering in the (unfortunately short) Torts section of the Comparison course. Try to plan your studying so as to cover all of them.

The first class on August 23rd will concentrate on the following:

- Res ipsa loquitur
- Private nuisance
- Invasion of privacy
- Strict product liability: introduction
- Trespass to land
- Proximate cause: introduction
- Violation of statute as affecting liability for negligence.

Also attached to this memo are pages from the new Restatement 3d, Torts: Product Liability, that cover topics of the most general interest in the field of products liability. Please read these pages in preparation for the class on Monday, August 23rd. The quiz on Wednesday, August 25th will test your ability to distinguish products liability concepts from negligence liability concepts.
COMPARISON - TORTS
Mr. Martin
Fall, 2010

SYLLABUS, READING ASSIGNMENT, AND NOTES

Monday, August 23: Questions 1-10.

Res ipsa loquitur
Private nuisance
Invasion of privacy
Strict product liability: introduction
Trespass to land
Proximate cause: introduction
Violation of statute as affecting liability for negligence


Strict product liability distinguished from negligence
Owners and occupiers of premises
Causation in fact
Rescue and other proximate cause paradigms
Multiple causation
Intentional infliction of emotional distress

Saturday, August 28 (first half): Questions 21-30.

Defenses to intentional torts
Emotion distress as a component of negligence damages
Contributory and comparative negligence
Respondeat superior
Product liability: design defect, reasonable alternative design

Questions 31-36 will not be covered in class.

Saturday, August 28 (second half): Questions 37-48.
Duty to act
Thin skull rule and more paradigms of proximate cause
Conversion
Misrepresentation

Monday, August 30: Questions 49-59.

Unauthorized use of name or image for commercial purposes
Defamation ☐ common law
Contribution and indemnity
Joint tortfeasors, concurrent tortfeasers
Divisible and indivisible harm

Questions 61-70 will not be covered in class.

Wednesday, September 1: Handout on subjects otherwise omitted.

Torts of children; child trespassers
Independent contractors and non-delegable duties
Defamation ☐ constitutional
Professional liability
Transferred intent
Strict liability: wild animals
Strict liability: abnormally dangerous activities

Saturday, September 4: Final Exam in Torts, 9:45 a.m. to Noon

FIRST THREE QUIZZES

The first quiz (on Monday, August 23) will be on negligence.

The second quiz (on Wednesday, August 25) will test your ability to distinguish negligence concepts from strict product liability concepts.

The third quiz (on Saturday, August 28) will test your memorization of the elements of the common tort claims.
READING ASSIGNMENT

You should be aware that a third Restatement of Torts is in process of adoption and publication by the American Law Institute. The first component of the third Restatement to be adopted and published was its section on product liability.

Attached to this memo are pages from the Restatement 3d, Torts: Product Liability that cover topics of the most general interest in this field. Please read these pages in preparation for the classes on Monday and Wednesday, August 23rd and August 25th.

A NOTE ON MISSED QUIZZES

I return graded quizzes to students at the beginning of the next class. At this point the correct answers to the quiz questions are known and further use of the quiz has been compromised. Therefore I do not allow students to make up missed quizzes.

As an alternative, I offer a make-up quiz (Quiz No. 6) which may be taken by any student in place of any quiz that has been missed. Quiz No. 6 will be administered after the class on Wednesday, September 1st.
RESTATEMENT OF THE LAW THIRD
TORTS

PRODUCTS LIABILITY

[Editorial Note: Restatement Third, Torts: Products Liability, promulgated in 1997, superseded the Institute's previous formulation of products-liability law, found primarily in the influential § 402A of Restatement Second, Torts, supra].

Chapter 1

LIABILITY OF COMMERCIAL PRODUCT SELLERS BASED ON PRODUCT DEFECTS AT TIME OF SALE

TOPIC 1. LIABILITY RULES APPLICABLE TO PRODUCTS GENERALLY

Section
1. Liability of Commercial Seller or Distributor for Harm Caused by Defective Products
2. Categories of Product Defect
3. Circumstantial Evidence Supporting Inference of Product Defect
4. Noncompliance and Compliance with Product Safety Statutes or Regulations

TOPIC 2. LIABILITY RULES APPLICABLE TO SPECIAL PRODUCTS OR PRODUCT MARKETS

6. Liability of Commercial Seller or Distributor for Harm Caused by Defective Prescription Drugs and Medical Devices
7. Liability of Commercial Seller or Distributor for Harm Caused by Defective Food Products
TOPIC 1. LIABILITY RULES APPLICABLE TO PRODUCTS GENERALLY

§ 1. Liability of Commercial Seller or Distributor for Harm Caused by Defective Products

One engaged in the business of selling or otherwise distributing products who sells or distributes a defective product is subject to liability for harm to persons or property caused by the defect.

Comment:

a. History. This Section states a general rule of tort liability applicable to commercial sellers and other distributors of products generally. Rules of liability applicable to special products such as prescription drugs and used products are set forth in separate Sections in Topic 2 of this Chapter.

The liability established in this Section draws on both warranty law and tort law. Historically, the focus of products liability law was on manufacturing defects. A manufacturing defect is a physical departure from a product's intended design. See § 2(a). Typically, manufacturing defects occur in only a small percentage of units in a product line. Courts early began imposing liability without fault on product sellers for harm caused by such defects, holding a seller liable for harm caused by manufacturing defects even though all possible care had been exercised by the seller in the preparation and distribution of the product. In doing so, courts relied on the concept of warranty, in connection with which fault has never been a prerequisite to liability.

The imposition of liability for manufacturing defects has a long history in the common law. As early as 1266, criminal statutes imposed liability upon victualers, vintners, brewers, butchers, cooks, and other persons who supplied contaminated food and drink. In the late 1800s, courts in many states began imposing negligence and strict warranty liability on commercial sellers of defective goods. In the early 1960s, American courts began to recognize that a commercial seller of any product having a manufacturing defect should be liable in tort for harm caused by the defect regardless of the plaintiff's ability to maintain a traditional negligence or warranty action. Liability attached even if the manufacturer's quality control in producing the defective product was reasonable. A plaintiff was not required to be in direct privity with the defendant seller to bring an action. Strict liability in tort for defectively manufactured products merges the concept of implied warranty, in which negligence is not required, with the tort concept of negligence, in which contractual privity is not required. See § 2(a).
Questions of design defects and defects based on inadequate instructions or warnings arise when the specific product unit conforms to the intended design but the intended design itself, or its sale without adequate instructions or warnings, renders the product not reasonably safe. If these forms of defect are found to exist, then every unit in the same product line is potentially defective. See § 2, Comments d, f, and i. Imposition of liability for design defects and for defects based on inadequate instructions or warnings was relatively infrequent until the late 1960s and early 1970s. A number of restrictive rules made recovery for such defects, especially design defects, difficult to obtain. As these rules eroded, courts sought to impose liability without fault for design defects and defects due to inadequate instructions or warnings under the general principles of § 402A of the Restatement, Second, of Torts. However, it soon became evident that § 402A, created to deal with liability for manufacturing defects, could not appropriately be applied to cases of design defects or defects based on inadequate instructions or warnings. A product unit that fails to meet the manufacturer's design specifications thereby fails to perform its intended function and is, almost by definition, defective. However, when the product unit meets the manufacturer's own design specifications, it is necessary to go outside those specifications to determine whether the product is defective.

Sections 2(b) and 2(c) recognize that the rule developed for manufacturing defects is inappropriate for the resolution of claims of defective design and defects based on inadequate instructions or warnings. These latter categories of cases require determinations that the product could have reasonably been made safer by a better design or instruction or warning. Sections 2(b) and 2(c) rely on a reasonableness test traditionally used in determining whether an actor has been negligent. See Restatement, Second, Torts §§ 291-293. Nevertheless, many courts insist on speaking of liability based on the standards described in §§ 2(b) and 2(c) as being “strict.”

Several factors help to explain this rhetorical preference. First, in many design defect cases, if the product causes injury while being put to a reasonably foreseeable use, the seller is held to have known of the risks that foreseeably attend such use. See § 2, Comment m. Second, some courts have sought to limit the defense of comparative fault in certain products liability contexts. In furtherance of this objective, they have avoided characterizing the liability test as based in negligence, thereby limiting the effect of comparative or contributory fault. See § 17, Comment d. Third, some courts are concerned that a negligence standard might be too forgiving of a small manufacturer who might be excused for its ignorance of risk or for failing to take adequate precautions to avoid risk. Negligence, which focuses on the
conduct of the defendant-manufacturer, might allow a finding that a
defendant with meager resources was not negligent because it was too
burdensome for such a defendant to discover risks or to design or
warn against them. The concept of strict liability, which focuses on the
product rather than the conduct of the manufacturer, may help make
the point that a defendant is held to the expert standard of knowledge
available to the relevant manufacturing community at the time the
product was manufactured. Finally, the liability of nonmanufacturing
sellers in the distributive chain is strict. It is no defense that they
acted reasonably and did not discover a defect in the product, be it
from manufacturing, design, or failure to warn. See Comment e.

Thus, "strict products liability" is a term of art that reflects the
judgment that products liability is a discrete area of tort law which
borrows from both negligence and warranty. It is not fully congruent
with classical tort or contract law. Rather than perpetuating confusion
spawned by existing doctrinal categories, §§ 1 and 2 define the
liability for each form of defect in terms directly addressing the
various kinds of defects. As long as these functional criteria are met,
courts may utilize the terminology of negligence, strict liability, or the
implied warranty of merchantability, or simply define liability in the
terms set forth in the black letter. See § 2, Comment n.

b. Sale or other distribution. The rule stated in this Section
applies not only to sales transactions but also to other forms of
commercial product distribution that are the functional equivalent of
product sales. See § 20.

c. One engaged in the business of selling or otherwise distribut-
ing. The rule stated in this Section applies only to manufacturers and
other commercial sellers and distributors who are engaged in the
business of selling or otherwise distributing the type of product that
harmed the plaintiff. The rule does not apply to a noncommercial seller
or distributor of such products. Thus, it does not apply to one who
sells foodstuffs to a neighbor, nor does it apply to the private owner of
an automobile who sells it to another.

It is not necessary that a commercial seller or distributor be
engaged exclusively or even primarily in selling or otherwise distribut-
ing the type of product that injured the plaintiff, so long as the sale of
the product is other than occasional or casual. Thus, the rule applies to
a motion-picture theater's routine sales of popcorn or ice cream, either
for consumption on the premises or in packages to be taken home.
Similarly, a service station that does mechanical repair work on cars
may also sell tires and automobile equipment as part of its regular
business. Such sales are subject to the rule in this Section. However,
the rule does not cover occasional sales (frequently referred to as
§ 1 RESTATEMENT OF TORTS 3D

"casual sales") outside the regular course of the seller's business. Thus, an occasional sale of surplus equipment by a business does not fall within the ambit of this rule. Whether a defendant is a commercial seller or distributor within the meaning of this Section is usually a question of law to be determined by the court.

d. Harm to persons or property. The rule stated in this Section applies only to harm to persons or property, commonly referred to as personal injury and property damage. For rules governing economic loss, see § 21.

e. Nonmanufacturing sellers or other distributors of products. The rule stated in this Section provides that all commercial sellers and distributors of products, including nonmanufacturing sellers and distributors such as wholesalers and retailers, are subject to liability for selling products that are defective. Liability attaches even when such nonmanufacturing sellers or distributors do not themselves render the products defective and regardless of whether they are in a position to prevent defects from occurring. See § 2, Comment a. Legislation has been enacted in many jurisdictions that, to some extent, immunizes nonmanufacturing sellers or distributors from strict liability. The legislation is premised on the belief that bringing nonmanufacturing sellers or distributors into products liability litigation generates wasteful legal costs. Although liability in most cases is ultimately passed on to the manufacturer who is responsible for creating the product defect, nonmanufacturing sellers or distributors must devote resources to protect their interests. In most situations, therefore, immunizing nonmanufacturers from strict liability saves those resources without jeopardizing the plaintiff's interests. To assure plaintiffs access to a responsible and solvent product seller or distributor, the statutes generally provide that the nonmanufacturing seller or distributor is immunized from strict liability only if: (1) the manufacturer is subject to the jurisdiction of the court of plaintiff's domicile; and (2) the manufacturer is not, nor is likely to become, insolvent.

In connection with these statutes, two problems may need to be resolved to assure fairness to plaintiffs. First, as currently structured, the statutes typically impose upon the plaintiff the risk of insolvency of the manufacturer between the time an action is brought and the time a judgment can be enforced. If a nonmanufacturing seller or distributor is dismissed from an action at the outset when it appears that the manufacturer will be able to pay a judgment, and the manufacturer subsequently becomes insolvent and is unable to pay the judgment, the plaintiff may be left to suffer the loss uncompensated. One possible solution could be to toll the statute of limitations against nonmanufacturers so that they may be brought in if necessary. Second, a nonmanufacturing seller or distributor occasionally will be responsible for the
introduction of a defect in a product even though it exercised reasonable care in handling or supervising the product in its control. In such instances, liability for a § 2(a) defect should be imposed on the nonmanufacturing seller or distributor. See § 2, Illustration 2.

§ 2. Categories of Product Defect

A product is defective when, at the time of sale or distribution, it contains a manufacturing defect, is defective in design, or is defective because of inadequate instructions or warnings. A product:

(a) contains a manufacturing defect when the product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product;

(b) is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the alternative design renders the product not reasonably safe;

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

Comment:

a. Rationale. The rules set forth in this Section establish separate standards of liability for manufacturing defects, design defects, and defects based on inadequate instructions or warnings. They are generally applicable to most products. Standards of liability applicable to special product categories such as prescription drugs and used products are set forth in separate sections in Topic 2 of this Chapter.

The rule for manufacturing defects stated in Subsection (a) imposes liability whether or not the manufacturer's quality control efforts satisfy standards of reasonableness. Strict liability without fault in this context is generally believed to foster several objectives. On the premise that tort law serves the instrumental function of creating safety incentives, imposing strict liability on manufacturers for harm caused by manufacturing defects encourages greater investment in
product safety than does a regime of fault-based liability under which, as a practical matter, sellers may escape their appropriate share of responsibility. Some courts and commentators also have said that strict liability discourages the consumption of defective products by causing the purchase price of products to reflect, more than would a rule of negligence, the costs of defects. And by eliminating the issue of manufacturer fault from plaintiff's case, strict liability reduces the transaction costs involved in litigating that issue.

Several important fairness concerns are also believed to support manufacturers' liability for manufacturing defects even if the plaintiff is unable to show that the manufacturer's quality control fails to meet risk-utility norms. In many cases manufacturing defects are in fact caused by manufacturer negligence but plaintiffs have difficulty proving it. Strict liability therefore performs a function similar to the concept of res ipsa loquitur, allowing deserving plaintiffs to succeed notwithstanding what would otherwise be difficult or insuperable problems of proof. Products that malfunction due to manufacturing defects disappoint reasonable expectations of product performance. Because manufacturers invest in quality control at consciously chosen levels, their knowledge that a predictable number of flawed products will enter the marketplace entails an element of deliberation about the amount of injury that will result from their activity. Finally, many believe that consumers who benefit from products without suffering harm should share, through increases in the prices charged for those products, the burden of unavoidable injury costs that result from manufacturing defects.

An often-cited rationale for holding wholesalers and retailers strictly liable for harm caused by manufacturing defects is that, as between them and innocent victims who suffer harm because of defective products, the product sellers as business entities are in a better position than are individual users and consumers to insure against such losses. In most instances, wholesalers and retailers will be able to pass liability costs up the chain of product distribution to the manufacturer. When joining the manufacturer in the tort action presents the plaintiff with procedural difficulties, local retailers can pay damages to the victims and then seek indemnity from manufacturers. Finally, holding retailers and wholesalers strictly liable creates incentives for them to deal only with reputable, financially responsible manufacturers and distributors, thereby helping to protect the interests of users and consumers. For considerations relevant to reducing nonmanufacturers' liability, see § 1, Comment e.

In contrast to manufacturing defects, design defects and defects based on inadequate instructions or warnings are predicated on a different concept of responsibility. In the first place, such defects
cannot be determined by reference to the manufacturer’s own design or marketing standards because those standards are the very ones that plaintiffs attack as unreasonable. Some sort of independent assessment of advantages and disadvantages, to which some attach the label “risk-utility balancing,” is necessary. Products are not generically defective merely because they are dangerous. Many product-related accident costs can be eliminated only by excessively sacrificing product features that make products useful and desirable. Thus, the various trade-offs need to be considered in determining whether accident costs are more fairly and efficiently borne by accident victims, on the one hand, or, on the other hand, by consumers generally through the mechanism of higher product prices attributable to liability costs imposed by courts on product sellers.

Subsections (b) and (c), which impose liability for products that are defectively designed or sold without adequate warnings or instructions and are thus not reasonably safe, achieve the same general objectives as does liability predicated on negligence. The emphasis is on creating incentives for manufacturers to achieve optimal levels of safety in designing and marketing products. Society does not benefit from products that are excessively safe—for example, automobiles designed with maximum speeds of 20 miles per hour—any more than it benefits from products that are too risky. Society benefits most when the right, or optimal, amount of product safety is achieved. From a fairness perspective, requiring individual users and consumers to bear appropriate responsibility for proper product use prevents careless users and consumers from being subsidized by more careful users and consumers, when the former are paid damages out of funds to which the latter are forced to contribute through higher product prices.

In general, the rationale for imposing strict liability on manufacturers for harm caused by manufacturing defects does not apply in the context of imposing liability for defective design and defects based on inadequate instruction or warning. Consumer expectations as to proper product design or warning are typically more difficult to discern than in the case of a manufacturing defect. Moreover, the element of deliberation in setting appropriate levels of design safety is not directly analogous to the setting of levels of quality control by the manufacturer. When a manufacturer sets its quality control at a certain level, it is aware that a given number of products may leave the assembly line in a defective condition and cause injury to innocent victims who can generally do nothing to avoid injury. The implications of deliberately drawing lines with respect to product design safety are different. A reasonably designed product still carries with it elements
of risk that must be protected against by the user or consumer since some risks cannot be designed out of the product at reasonable cost.

Most courts agree that, for the liability system to be fair and efficient, the balancing of risks and benefits in judging product design and marketing must be done in light of the knowledge of risks and risk-avoidance techniques reasonably attainable at the time of distribution. To hold a manufacturer liable for a risk that was not foreseeable when the product was marketed might foster increased manufacturer investment in safety. But such investment by definition would be a matter of guesswork. Furthermore, manufacturers may persuasively ask to be judged by a normative behavior standard to which it is reasonably possible for manufacturers to conform. For these reasons, Subsections (b) and (c) speak of products being defective only when risks are reasonably foreseeable.

b. The nonexclusiveness of the definitions of defect in this Section. When a plaintiff seeks recovery under the general rule of liability in § 1, in most instances the plaintiff must establish a prima facie case of product defect by satisfying the requirements of § 2. Section 2 is not, however, the exclusive means by which the plaintiff may establish liability in a products case based on the general rule in § 1. Some courts, for example, while recognizing that in most cases involving defective design the plaintiff must prove the availability of a reasonable alternative design, also observe that such proof is not necessary in every case involving design defects. Sections 3 and 4 and Comment e to § 2 provide approaches to the establishment of defective design other than that provided in § 2(b).

c. Manufacturing defects. As stated in Subsection (a), a manufacturing defect is a departure from a product unit's design specifications. More distinctly than any other type of defect, manufacturing defects disappoint consumer expectations. Common examples of manufacturing defects are products that are physically flawed, damaged, or incorrectly assembled. In actions against the manufacturer, under prevailing rules concerning allocation of burdens of proof the plaintiff ordinarily bears the burden of establishing that such a defect existed in the product when it left the hands of the manufacturer.

d. Design defects: general considerations. Whereas a manufacturing defect consists of a product unit's failure to meet the manufacturer's design specifications, a product asserted to have a defective design meets the manufacturer's design specifications but raises the question whether the specifications themselves create unreasonable risks. Answering that question requires reference to a standard outside the specifications. Subsection (b) adopts a reasonableness ("risk-utility balancing") test as the standard for judging the defectiveness of
product designs. More specifically, the test is whether a reasonable alternative design would, at reasonable cost, have reduced the foreseeable risks of harm posed by the product and, if so, whether the omission of the alternative design by the seller or a predecessor in the distributive chain rendered the product not reasonably safe. (This is the primary, but not the exclusive, test for defective design. See Comment b.) Under prevailing rules concerning allocation of burden of proof, the plaintiff must prove that such a reasonable alternative was, or reasonably could have been, available at time of sale or distribution. See Comment f.

Assessment of a product design in most instances requires a comparison between an alternative design and the product design that caused the injury, undertaken from the viewpoint of a reasonable person. That approach is also used in administering the traditional reasonableness standard in negligence. See Restatement, Second, Torts §283, Comment c. The policy reasons that support use of a reasonable-person perspective in connection with the general negligence standard also support its use in the products liability context.

How the defendant's design compares with other, competing designs in actual use is relevant to the issue of whether the defendant's design is defective. Defendants often seek to defend their product designs on the ground that the designs conform to the "state of the art." The term "state of the art" has been variously defined to mean that the product design conforms to industry custom, that it reflects the safest and most advanced technology developed and in commercial use, or that it reflects technology at the cutting edge of scientific knowledge. The confusion brought about by these various definitions is unfortunate. This Section states that a design is defective if the product could have been made safer by the adoption of a reasonable alternative design. If such a design could have been practically adopted at time of sale and if the omission of such a design rendered the product not reasonably safe, the plaintiff establishes defect under Subsection (b). When a defendant demonstrates that its product design was the safest in use at the time of sale, it may be difficult for the plaintiff to prove that an alternative design could have been practically adopted. The defendant is thus allowed to introduce evidence with regard to industry practice that bears on whether an alternative design was practicable. Industry practice may also be relevant to whether the omission of an alternative design rendered the product not reasonably safe. While such evidence is admissible, it is not necessarily dispositive. If the plaintiff introduces expert testimony to establish that a reasonable alternative design could practically have been adopted, a trier of fact may conclude that the product was defective notwithstanding that such a design was not adopted by any
manufacturer, or even considered for commercial use, at the time of sale.

Early in the development of products liability law, courts held that a claim based on design defect could not be sustained if the dangers presented by the product were open and obvious. Subsection (b) does not recognize the obviousness of a design-related risk as precluding a finding of defectiveness. The fact that a danger is open and obvious is relevant to the issue of defectiveness, but does not necessarily preclude a plaintiff from establishing that a reasonable alternative design should have been adopted that would have reduced or prevented injury to the plaintiff.

The requirement in Subsection (b) that the plaintiff show a reasonable alternative design applies in most instances even though the plaintiff alleges that the category of product sold by the defendant is so dangerous that it should not have been marketed at all. See Comment e. Common and widely distributed products such as alcoholic beverages, firearms, and above-ground swimming pools may be found to be defective only upon proof of the requisite conditions in Subsection (a), (b), or (c). If such products are defectively manufactured or sold without reasonable warnings as to their danger when such warnings are appropriate, or if reasonable alternative designs could have been adopted, then liability under §§ 1 and 2 may attach. Absent proof of defect under those Sections, however, courts have not imposed liability for categories of products that are generally available and widely used and consumed, even if they pose substantial risks of harm. Instead, courts generally have concluded that legislatures and administrative agencies can, more appropriately than courts, consider the desirability of commercial distribution of some categories of widely used and consumed, but nevertheless dangerous, products.

Illustrations:

3. ABC Co. manufactured and sold a high-speed printing press to XYZ Printers, by whom Robert is employed. The press includes a circular plate cylinder that spins at a very high speed. On occasion, a foreign object, known in the trade as a “hickie,” finds its way onto the plate of the unit, causing a blemish or imperfection on the printed page. To remove a hickie, it is customary practice for an employee to apply a piece of plastic to the printing plate while it is spinning. Robert performed this practice, known as “chasing the hickie,” and while doing so suffered serious injuries to his hand. All employees, including Robert, knew that chasing the hickie was a dangerous procedure. Plaintiff’s expert testifies that a safety-guard at the point of operation, which could have prevented Robert’s injury, was both
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technologically and economically feasible and is utilized in similar machinery without causing difficulty. The fact that the danger is open and obvious does not bar the design claim against ABC.

4. XYZ Co. manufactures above-ground swimming pools that are four feet deep. Warnings are embossed on the outside of the pools in large letters stating "DANGER—DO NOT DIVE—SHALLOW WATER." In disregard of the warnings, Mary, age 21, dove head first into an XYZ pool and suffered serious injury. Expert testimony establishes that when Mary's outstretched hands hit the pool's slippery vinyl bottom her hands slid apart, causing her to strike her head against the bottom of the pool. For the purposes of this illustration it is assumed that the warnings were adequate and that the only issue is whether the above-ground pool was defectively designed because the bottom was too slippery. All the expert witnesses agree that the vinyl pool liner that XYZ utilized was the best and safest liner available and that no alternative, less slippery liner was feasible. Mary has failed to establish defective design under Subsection (b).

e. Design defects: possibility of manifestly unreasonable design.

Several courts have suggested that the designs of some products are so manifestly unreasonable, in that they have low social utility and high degree of danger, that liability should attach even absent proof of a reasonable alternative design. In large part the problem is one of how the range of relevant alternative designs is described. For example, a toy gun that shoots hard rubber pellets with sufficient velocity to cause injury to children could be found to be defectively designed within the rule of Subsection (b). Toy guns unlikely to cause injury would constitute reasonable alternatives to the dangerous toy. Thus, toy guns that project ping-pong balls, soft gelatin pellets, or water might be found to be reasonable alternative designs to a toy gun that shoots hard pellets. However, if the realism of the hard-pellet gun, and thus its capacity to cause injury, is sufficiently important to those who purchase and use such products to justify the court's limiting consideration to toy guns that achieve realism by shooting hard pellets, then no reasonable alternative will, by hypothesis, be available. In that instance, the design feature that defines which alternatives are relevant—the realism of the hard-pellet gun and thus its capacity to injure—is precisely the feature on which the user places value and of which the plaintiff complains. If a court were to adopt this characterization of the product, and deem the capacity to cause injury an egregiously unacceptable quality in a toy for use by children, it could conclude that liability should attach without proof of a reasonable alternative design. The court would declare the product design to be defective and not reasonably safe because the extremely high degree
of danger posed by its use or consumption so substantially outweighs its negligible social utility that no rational, reasonable person, fully aware of the relevant facts, would choose to use, or to allow children to use, the product.

Illustration:

5. ABC Co. manufactures novelty items. One item, an exploding cigar, is made to explode with a loud bang and the emission of smoke. Robert purchased the exploding cigar and presented it to his boss, Jack, at a birthday party arranged for him at the office. Jack lit the cigar. When it exploded, the heat from the explosion lit Jack's beard on fire causing serious burns to his face. If a court were to recognize the rule identified in this Comment, the finder of fact might find ABC liable for the defective design of the exploding cigar even if no reasonable alternative design was available that would provide similar prank characteristics. The utility of the exploding cigar is so low and the risk of injury is so high as to warrant a conclusion that the cigar is defective and should not have been marketed at all.

f. Design defects: factors relevant in determining whether the omission of a reasonable alternative design renders a product not reasonably safe. Subsection (b) states that a product is defective in design if the omission of a reasonable alternative design renders the product not reasonably safe. A broad range of factors may be considered in determining whether an alternative design is reasonable and whether its omission renders a product not reasonably safe. The factors include, among others, the magnitude and probability of the foreseeable risks of harm, the instructions and warnings accompanying the product, and the nature and strength of consumer expectations regarding the product, including expectations arising from product portrayal and marketing. See Comment g. The relative advantages and disadvantages of the product as designed and as it alternatively could have been designed may also be considered. Thus, the likely effects of the alternative design on production costs; the effects of the alternative design on product longevity, maintenance, repair, and esthetics; and the range of consumer choice among products are factors that may be taken into account. A plaintiff is not necessarily required to introduce proof on all of these factors; their relevance, and the relevance of other factors, will vary from case to case. Moreover, the factors interact with one another. For example, evidence of the magnitude and probability of foreseeable harm may be offset by evidence that the proposed alternative design would reduce the efficiency and the utility of the product. On the other hand, evidence that a proposed alternative design would increase production costs may be
offset by evidence that product portrayal and marketing created substantial expectations of performance or safety, thus increasing the probability of foreseeable harm. Depending on the mix of these factors, a number of variations in the design of a given product may meet the test in Subsection (b). On the other hand, it is not a factor under Subsection (b) that the imposition of liability would have a negative effect on corporate earnings or would reduce employment in a given industry.

When evaluating the reasonableness of a design alternative, the overall safety of the product must be considered. It is not sufficient that the alternative design would have reduced or prevented the harm suffered by the plaintiff if it would also have introduced into the product other dangers of equal or greater magnitude.

While a plaintiff must prove that a reasonable alternative design would have reduced the foreseeable risks of harm, Subsection (b) does not require the plaintiff to produce expert testimony in every case. Cases arise in which the feasibility of a reasonable alternative design is obvious and understandable to laypersons and therefore expert testimony is unnecessary to support a finding that the product should have been designed differently and more safely. For example, when a manufacturer sells a soft stuffed toy with hard plastic buttons that are easily removable and likely to choke and suffocate a small child who foreseeably attempts to swallow them, the plaintiff should be able to reach the trier of fact with a claim that buttons on such a toy should be an integral part of the toy’s fabric itself (or otherwise be unremovable by an infant) without hiring an expert to demonstrate the feasibility of an alternative safer design. Furthermore, other products already available on the market may serve the same or very similar function at lower risk and at comparable cost. Such products may serve as reasonable alternatives to the product in question.

In many cases, the plaintiff must rely on expert testimony. Subsection (b) does not, however, require the plaintiff to produce a prototype in order to make out a prima facie case. Thus, qualified expert testimony on the issue suffices, even though the expert has produced no prototype, if it reasonably supports the conclusion that a reasonable alternative design could have been practically adopted at the time of sale.

The requirements in Subsection (b) relate to what the plaintiff must prove in order to prevail at trial. This Restatement takes no position regarding the requirements of local law concerning the adequacy of pleadings or pretrial demonstrations of genuine issues of fact. It does, however, assume that the plaintiff will have the opportunity to
g. Consumer expectations: general considerations. Under Subsection (b), consumer expectations do not constitute an independent standard for judging the defectiveness of product designs. Courts frequently rely, in part, on consumer expectations when discussing liability based on other theories of liability. Some courts, for example, use the term "reasonable consumer expectations" as an equivalent of "proof of a reasonable, safer design alternative," since reasonable consumers have a right to expect product designs that conform to the reasonableness standard in Subsection (b). Other courts, allowing an inference of defect to be drawn when the incident is of a kind that ordinarily would occur as a result of product defect, observe that products that fail when put to their manifestly intended use disappoint reasonable consumer expectations. See § 3. However, consumer expectations do not play a determinative role in determining defectiveness.
See Comment a. Consumer expectations, standing alone, do not take into account whether the proposed alternative design could be implemented at reasonable cost, or whether an alternative design would provide greater overall safety. Nevertheless, consumer expectations about product performance and the dangers attendant to product use affect how risks are perceived and relate to foreseeability and frequency of the risks of harm, both of which are relevant under Subsection (b). See Comment f. Such expectations are often influenced by how products are portrayed and marketed and can have a significant impact on consumer behavior. Thus, although consumer expectations do not constitute an independent standard for judging the defectiveness of product designs, they may substantially influence or even be ultimately determinative on risk-utility balancing in judging whether the omission of a proposed alternative design renders the product not reasonably safe.

Subsection (b) likewise rejects conformance to consumer expectations as a defense. The mere fact that a risk presented by a product design is open and obvious, or generally known, and that the product thus satisfies expectations, does not prevent a finding that the design is defective. But the fact that a product design meets consumer expectations may substantially influence or even be ultimately determinative on risk-utility balancing in judging whether the omission of a proposed alternative design renders the product not reasonably safe. It follows that, while disappointment of consumer expectations may not serve as an independent basis for allowing recovery under Subsection (b), neither may conformance with consumer expectations serve as an independent basis for denying recovery. Such expectations may be relevant in both contexts, but in neither are they controlling.

i. Inadequate instructions or warnings. Commercial product sellers must provide reasonable instructions and warnings about risks of injury posed by products. Instructions inform persons how to use and consume products safely. Warnings alert users and consumers to the existence and nature of product risks so that they can prevent harm either by appropriate conduct during use or consumption or by choosing not to use or consume. In most instances the instructions and warnings will originate with the manufacturer, but sellers down the chain of distribution must warn when doing so is feasible and reasonably necessary. In any event, sellers down the chain are liable if the instructions and warnings provided by predecessors in the chain are inadequate. See Comment o. Under prevailing rules concerning allocation of burdens of proof, plaintiff must prove that adequate instructions or warnings were not provided. Subsection (c) adopts a reasonableness test for judging the adequacy of product instructions and warnings. It thus parallels Subsection (b), which adopts a similar
standard for judging the safety of product designs. Although the liability standard is formulated in essentially identical terms in Subsections (b) and (c), the defectiveness concept is more difficult to apply in the warnings context. In evaluating the adequacy of product warnings and instructions, courts must be sensitive to many factors. It is impossible to identify anything approaching a perfect level of detail that should be communicated in product disclosures. For example, educated or experienced product users and consumers may benefit from inclusion of more information about the full spectrum of product risks, whereas less-educated or unskilled users may benefit from more concise warnings and instructions stressing only the most crucial risks and safe-handling practices. In some contexts, products intended for special categories of users, such as children, may require more vivid and unambiguous warnings. In some cases, excessive detail may detract from the ability of typical users and consumers to focus on the important aspects of the warnings, whereas in others reasonably full disclosure will be necessary to enable informed, efficient choices by product users. Product warnings and instructions can rarely communicate all potentially relevant information, and the ability of a plaintiff to imagine a hypothetical better warning in the aftermath of an accident does not establish that the warning actually accompanying the product was inadequate. No easy guideline exists for courts to adopt in assessing the adequacy of product warnings and instructions. In making their assessments, courts must focus on various factors, such as content and comprehensibility, intensity of expression, and the characteristics of expected user groups.

Depending on the circumstances, Subsection (c) may require that instructions and warnings be given not only to purchasers, users, and consumers, but also to others who a reasonable seller should know will be in a position to reduce or avoid the risk of harm. There is no general rule as to whether one supplying a product for the use of others through an intermediary has a duty to warn the ultimate product user directly or may rely on the intermediary to relay warnings. The standard is one of reasonableness in the circumstances. Among the factors to be considered are the gravity of the risks posed by the product, the likelihood that the intermediary will convey the information to the ultimate user, and the feasibility and effectiveness of giving a warning directly to the user. Thus, when the purchaser of machinery is the owner of a workplace who provides the machinery to employees for their use, and there is reason to doubt that the employer will pass warnings on to employees, the seller is required to reach the employees directly with necessary instructions and warnings if doing so is reasonably feasible.
In addition to alerting users and consumers to the existence and nature of product risks so that they can, by appropriate conduct during use or consumption, reduce the risk of harm, warnings also may be needed to inform users and consumers of nonobvious and not generally known risks that unavoidably inhere in using or consuming the product. Such warnings allow the user or consumer to avoid the risk warned against by making an informed decision not to purchase or use the product at all and hence not to encounter the risk. In this context, warnings must be provided for inherent risks that reasonably foreseeable product users and consumers would reasonably deem material or significant in deciding whether to use or consume the product. Whether or not many persons would, when warned, nonetheless decide to use or consume the product, warnings are required to protect the interests of those reasonably foreseeable users or consumers who would, based on their own reasonable assessments of the risks and benefits, decline product use or consumption. When such warnings are necessary, their omission renders the product not reasonably safe at time of sale. Notwithstanding the defective condition of the product in the absence of adequate warnings, if a particular user or consumer would have decided to use or consume even if warned, the lack of warnings is not a legal cause of that plaintiff's harm. Judicial decisions supporting the duty to provide warnings for informed decisionmaking have arisen almost exclusively with regard to those toxic agents and pharmaceutical products with respect to which courts have recognized a distinctive need to provide risk information so that recipients of the information can decide whether they wish to purchase or utilize the product. See § 6, Comment d.

j. Warnings: obvious and generally known risks. In general, a product seller is not subject to liability for failing to warn or instruct regarding risks and risk-avoidance measures that should be obvious to, or generally known by, foreseeable product users. When a risk is obvious or generally known, the prospective addressee of a warning will or should already know of its existence. Warning of an obvious or generally known risk in most instances will not provide an effective additional measure of safety. Furthermore, warnings that deal with obvious or generally known risks may be ignored by users and consumers and may diminish the significance of warnings about nonobvious, not-generally-known risks. Thus, requiring warnings of obvious or generally known risks could reduce the efficacy of warnings generally. When reasonable minds may differ as to whether the risk was obvious or generally known, the issue is to be decided by the trier of fact. The obviousness of risk may bear on the issue of design defect rather than failure to warn. See Comments d and g.
k. **Warnings: adverse allergic or idiosyncratic reactions.** Cases of adverse allergic or idiosyncratic reactions involve a special subset of products that may be defective because of inadequate warnings. Many of these cases involve nonprescription drugs and cosmetics. However, virtually any tangible product can contain an ingredient to which some persons may be allergic. Thus, food, nonprescription drugs, toiletries, paint, solvents, building materials, clothing, and furniture have all been involved in litigation to which this Comment is relevant. Prescription drugs and medical devices are also capable of causing allergic reactions, but they are governed by § 6.

The general rule in cases involving allergic reactions is that a warning is required when the harm-causing ingredient is one to which a substantial number of persons are allergic. The degree of substantiality is not precisely quantifiable. Clearly the plaintiff in most cases must show that the allergic predisposition is not unique to the plaintiff. In determining whether the plaintiff has carried the burden in this regard, however, the court may properly consider the severity of the plaintiff's harm. The more severe the harm, the more justified is a conclusion that the number of persons at risk need not be large to be considered "substantial" so as to require a warning. Essentially, this reflects the same risk-utility balancing undertaken in warnings cases generally. But courts explicitly impose the requirement of substantiality in cases involving adverse allergic reactions.

The ingredient that causes the allergic reaction must be one whose danger or whose presence in the product is not generally known to consumers. When both the presence of an allergenic ingredient in the product and the risks presented by such ingredient are widely known, instructions and warnings about that danger are unnecessary. When the presence of the allergenic ingredient would not be anticipated by a reasonable user or consumer, warnings concerning its presence are required. Similarly, when the presence of the ingredient is generally known to consumers, but its dangers are not, a warning of the dangers must be given.

Finally, as required in Subsection (c), warnings concerning risks of allergic reactions that are not reasonably foreseeable at the time of sale need not be provided. See Comment m.

1. **Relationship between design and instruction or warning.** Reasonable designs and instructions or warnings both play important roles in the production and distribution of reasonably safe products. In general, when a safer design can reasonably be implemented and risks can reasonably be designed out of a product, adoption of the safer design is required over a warning that leaves a significant residuum of such risks. For example, instructions and warnings may be ineffective
because users of the product may not be adequately reached, may be likely to be inattentive, or may be insufficiently motivated to follow the instructions or heed the warnings. However, when an alternative design to avoid risks cannot reasonably be implemented, adequate instructions and warnings will normally be sufficient to render the product reasonably safe. Compare Comment e. Warnings are not, however, a substitute for the provision of a reasonably safe design.

The fact that a risk is obvious or generally known often serves the same function as a warning. See Comment j. However, obviousness of risk does not necessarily obviate a duty to provide a safer design. Just as warnings may be ignored, so may obvious or generally known risks be ignored, leaving a residuum of risk great enough to require adopting a safer design. See Comment d.

m. Reasonably foreseeable uses and risks in design and warning claims. Subsections (b) and (c) impose liability only when the product is put to uses that it is reasonable to expect a seller or distributor to foresee. Product sellers and distributors are not required to foresee and take precautions against every conceivable mode of use and abuse to which their products might be put. Increasing the costs of designing and marketing products in order to avoid the consequences of unreasonable modes of use is not required.

In cases involving a claim of design defect in a mechanical product, foreseeability of risk is rarely an issue as a practical matter. Once the plaintiff establishes that the product was put to a reasonably foreseeable use, physical risks of injury are generally known or reasonably knowable by experts in the field. It is not unfair to charge a manufacturer with knowledge of such generally known or knowable risks.

The issue of foreseeability of risk of harm is more complex in the case of products such as prescription drugs, medical devices, and toxic chemicals. Risks attendant to use and consumption of these products may, indeed, be unforeseeable at the time of sale. Unforeseeable risks arising from foreseeable product use or consumption by definition cannot specifically be warned against. Thus, in connection with a claim of inadequate design, instruction, or warning, plaintiff should bear the burden of establishing that the risk in question was known or should have been known to the relevant manufacturing community. The harms that result from unforeseeable risks—for example, in the human body's reaction to a new drug, medical device, or chemical—are not a basis of liability. Of course, a seller bears responsibility to perform reasonable testing prior to marketing a product and to discover risks and risk-avoidance measures that such testing would reveal. A seller is charged with knowledge of what reasonable testing
would reveal. If testing is not undertaken, or is performed in an inadequate manner, and this failure results in a defect that causes harm, the seller is subject to liability for harm caused by such defect.

Illustration:

15. ABC Adhesives Inc. manufactures a chemical adhesive for use in laying ceramic tile. Recently it has become known that prolonged use of its ceramic adhesive over many years by diabetics can cause severe aggravation of the diabetic condition. Diabetics who have been using the ABC adhesive and have suffered serious aggravation of their condition bring an action against ABC for failing to warn about the risks of prolonged product use. However, it cannot be established that, at the time ABC's product was distributed, special risks to diabetics were reasonably foreseeable or that reasonable testing of the product would have led to the discovery of the risks. ABC is not liable since the risks attendant to such product use were not reasonably foreseeable.

o. Liability of nonmanufacturing sellers for defective design and defects due to inadequate instructions or warnings. Nonmanufacturing sellers such as wholesalers and retailers often are not in a good position feasibly to adopt safer product designs or better instructions or warnings. Nevertheless, once it is determined that a reasonable alternative design or reasonable instructions or warnings could have been provided at or before the time of sale by a predecessor in the chain of distribution and would have reduced plaintiff's harm, it is no defense that a nonmanufacturing seller of such a product exercised due care. Thus, strict liability is imposed on a wholesale or retail seller who neither knew nor should have known of the relevant risks, nor was in a position to have taken action to avoid them, so long as a predecessor in the chain of distribution could have acted reasonably to avoid the risks. See Comment a. For exceptions to the general rule regarding the liability of a nonmanufacturer seller, see § 1, Comment e.

p. Misuse, modification, and alteration. Product misuse, modification, and alteration are forms of post-sale conduct by product users or others that can be relevant to the determination of the issues of defect, causation, or comparative responsibility. Whether such conduct affects one or more of the issues depends on the nature of the conduct and whether the manufacturer should have adopted a reasonable alternative design or provided a reasonable warning to protect against such conduct.

Under the rule in Subsection (b), liability for defective design attaches only if the risks of harm related to foreseeable product use could have been reduced by the adoption of a reasonable alternative
design. Similarly, under the rule in Subsection (c), liability for failure to instruct or warn attaches only if the risks presented by the product could have been reduced by the adoption of reasonable instructions or warnings. Foreseeable product misuse, alteration, and modification must also be considered in deciding whether an alternative design should have been adopted. The post-sale conduct of the user may be so unreasonable, unusual, and costly to avoid that a seller has no duty to design or warn against them. When a court so concludes, the product is not defective within the meaning of Subsection (b) or (c).

A product may, however, be defective as defined in Subsection (b) or (c) due to the omission of a reasonable alternative design or the omission of an adequate warning, yet the risk that eventuates due to misuse, modification, or alteration raises questions whether the extent or scope of liability under the prevailing rules governing legal causation allow for the imposition of liability. See § 15.

Moreover, a product may be found to be defective and causally responsible for plaintiff's harm but the plaintiff may have misused, altered, or modified the product in a manner that calls for the reduction of plaintiff's recovery under the rules of comparative responsibility. Thus, an automobile may be defectively designed so as to provide inadequate protection against harm in the event of a collision, and the plaintiff's negligent modification of the automobile may have caused the collision eventuating in plaintiff's harm. See § 17.

It follows that misuse, modification, and alteration are not discrete legal issues. Rather, when relevant, they are aspects of the concepts of defect, causation, and plaintiff's fault. Jurisdictions differ on the question of who bears the burden of raising and introducing proof regarding conduct that constitutes misuse, modification, and alteration. The allocation of burdens in this regard is not addressed in this Restatement and is left to local law.

Illustration:

20. The ABC Chair Co. manufactures and sells oak chairs. The backs of the chairs have five horizontal wooden bars shaped to the contour of the human back. John, a college student, climbed up to the top bar of an ABC chair to reach the top shelf of a bookcase. The chair tipped and John fell, suffering serious harm. John brings an action against ABC, alleging that the chair should either have had the stability to support him when standing on the top bar or have had a differently designed back so that he could not use the bars for that purpose. The ABC chair is not defectively designed. John's misuse of the product is so unreasonable that the risks it entails need not be designed against.

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q. *Causation.* Under § 1, the product defect must have caused harm to the plaintiff. See §§ 17 and 18.

r. *Warranty.* Liability for harm caused by product defects imposed by the rules stated in this Chapter is tort liability, not liability for breach of warranty under the Uniform Commercial Code (U.C.C.). Courts may characterize claims under this Chapter as claims for breaches of the implied warranty of merchantability. But in cases involving defect-caused harm to persons or property, a well-coordinated body of law dealing with liability for such harm arising out of the sale of defective products would adopt the tort definition of product defect. See Comment n.

§ 3. *Circumstantial Evidence Supporting Inference of Product Defect*

It may be inferred that the harm sustained by the plaintiff was caused by a product defect existing at the time of sale or distribution, without proof of a specific defect, when the incident that harmed the plaintiff:

(a) was of a kind that ordinarily occurs as a result of product defect; and

(b) was not, in the particular case, solely the result of causes other than product defect existing at the time of sale or distribution.

§ 4. *Noncompliance and Compliance with Product Safety Statutes or Regulations*

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

(a) a product's noncompliance with an applicable product 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.
§ 6. Liability of Commercial Seller or Distributor for Harm Caused by Defective Prescription Drugs and Medical Devices

(a) A manufacturer of a prescription drug or medical device who sells or otherwise distributes a defective drug or medical device is subject to liability for harm to persons caused by the defect. A prescription drug or medical device is one that may be legally sold or otherwise distributed only pursuant to a health-care provider’s prescription.

(b) For purposes of liability under Subsection (a), a prescription drug or medical device is defective if at the time of sale or other distribution the drug or medical device:

(1) contains a manufacturing defect as defined in § 2(a); or

(2) is not reasonably safe due to defective design as defined in Subsection (c); or

(3) is not reasonably safe due to inadequate instructions or warnings as defined in Subsection (d).

(c) A prescription drug or medical device is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients.

(d) A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to:

(1) prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings; or

(2) the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.
(e) A retail seller or other distributor of a prescription drug or medical device is subject to liability for harm caused by the drug or device if:

(1) at the time of sale or other distribution the drug or medical device contains a manufacturing defect as defined in § 2(a); or

(2) at or before the time of sale or other distribution of the drug or medical device the retail seller or other distributor fails to exercise reasonable care and such failure causes harm to persons.

Comment:

a. History. Subsections (b)(1) and (d)(1) state the traditional rules that drug and medical-device manufacturers are liable only when their products contain manufacturing defects or are sold without adequate instructions and warnings to prescribing and other health-care providers. Until recently, courts refused to impose liability based on defective designs of drugs and medical devices sold only by prescription. However, consistent with recent trends in the case law, two limited exceptions from these traditional rules are generally recognized. Subsection (d)(2) sets forth situations when a prescription-drug or medical-device manufacturer is required to warn the patient directly of risks associated with consumption or use of its product. And Subsection (c) imposes liability for a drug or medical device whose risks of harm so far outweigh its therapeutic benefits that reasonable, properly informed health-care providers would not prescribe it.

b. Rationale. The obligation of a manufacturer to warn about risks attendant to the use of drugs and medical devices that may be sold only pursuant to a health-care provider’s prescription traditionally has required warnings directed to health-care providers and not to patients. The rationale supporting this “learned intermediary” rule is that only health-care professionals are in a position to understand the significance of the risks involved and to assess the relative advantages and disadvantages of a given form of prescription-based therapy. The duty then devolves on the health-care provider to supply to the patient such information as is deemed appropriate under the circumstances so that the patient can make an informed choice as to therapy. Subsection (d)(1) retains the “learned intermediary” rule. However, in certain limited therapeutic relationships the physician or other health-care provider has a much-diminished role as an evaluator or decisionmaker. In these instances it may be appropriate to impose on the manufacturer the duty to warn the patient directly. See Subsection (d)(2).
The traditional refusal by courts to impose tort liability for defective designs of prescription drugs and medical devices is based on the fact that a prescription drug or medical device entails a unique set of risks and benefits. What may be harmful to one patient may be beneficial to another. Under Subsection (c) a drug is defectively designed only when it provides no net benefit to any class of patients. Courts have concluded that as long as a drug or medical device provides net benefits to some persons under some circumstances, the drug or device manufacturer should be required to instruct and warn health-care providers of the foreseeable risks and benefits. Courts have also recognized that the regulatory system governing prescription drugs is a legitimate mechanism for setting the standards for drug design. In part, this deference reflects concerns over the possible negative effects of judicially imposed liability on the cost and availability of valuable medical technology. This deference also rests on two further assumptions: first, that prescribing health-care providers, when adequately informed by drug manufacturers, are able to assure that the right drugs and medical devices reach the right patients; and second, that governmental regulatory agencies adequately review new prescription drugs and devices, keeping unreasonably dangerous designs off the market.

Nevertheless, unqualified deference to these regulatory mechanisms is considered by a growing number of courts to be unjustified. An approved prescription drug or medical device can present significant risks without corresponding advantages. At the same time, manufacturers must have ample discretion to develop useful drugs and devices without subjecting their design decisions to the ordinary test applicable to products generally under § 2(b). Accordingly, Subsection (c) imposes a more rigorous test for defect than does § 2(b), which does not apply to prescription drugs and medical devices. The requirement for establishing defective design of a prescription drug or medical device under Subsection (c) is that the drug or device have so little merit compared with its risks that reasonable health-care providers, possessing knowledge of risks that were known or reasonably should have been known, would not have prescribed the drug or device for any class of patients. Thus, a prescription drug or medical device that has usefulness to any class of patients is not defective in design even if it is harmful to other patients. Because of the special nature of prescription drugs and medical devices, the determination of whether such products are not reasonably safe is to be made under Subsections (c) and (d) rather than under §§ 2(b) and 2(c).

The rules imposing liability on a manufacturer for inadequate warning or defective design of prescription drugs and medical devices assume that the federal regulatory standard has not preempted the
imposition of tort liability under state law. When such preemption is found, liability cannot attach if the manufacturer has complied with the applicable federal standard. See § 4, Comment e.

The doctrine of preemption based on supremacy of federal law should be distinguished from the proposition that compliance with statutory and regulatory standards satisfies the state’s requirement for product safety. Subsections (c) and (d) recognize common-law causes of action for defective drug design and for failure to provide reasonable instructions or warnings, even though the manufacturer complied with governmental standards. For the rules governing compliance with governmental standards generally, see § 4(b).

c. Manufacturers’ liability for manufacturing defects. Limitations on the liability for prescription drug and medical-device designs do not support treating drug and medical-device manufacturers differently from commercial sellers of other products with respect to manufacturing defects. Courts have traditionally subjected manufacturers of prescription products to liability for harm caused by manufacturing defects.

d. Manufacturers’ liability for failure adequately to instruct or warn prescribing and other health-care providers. Failure to instruct or warn is the major basis of liability for manufacturers of prescription drugs and medical devices. When prescribing health-care providers are adequately informed of the relevant benefits and risks associated with various prescription drugs and medical devices, they can reach appropriate decisions regarding which drug or device is best for specific patients. Sometimes a warning serves to inform health-care providers of unavoidable risks that inhere in the drug or medical device. By definition, such a warning would not aid the health-care provider in reducing the risk of injury to the patient by taking precautions in how the drug is administered or the medical device is used. However, warnings of unavoidable risks allow the health-care provider, and thereby the patient, to make an informed choice whether to utilize the drug or medical device. Beyond informing prescribing health-care providers, a drug or device manufacturer may have a duty under the law of negligence to use reasonable measures to supply instructions or warnings to nonprescribing health-care providers who are in positions to act on such information so as to reduce or prevent injury to patients.

e. Direct warnings to patients. Warnings and instructions with regard to drugs or medical devices that can be sold legally only pursuant to a prescription are, under the “learned intermediary” rule, directed to health-care providers. Subsection (d)(2) recognizes that direct warnings and instructions to patients are warranted for drugs
that are dispensed or administered to patients without the personal intervention or evaluation of a health-care provider. An example is the administration of a vaccine in clinics where mass inoculations are performed. In many such programs, health-care providers are not in a position to evaluate the risks attendant upon use of the drug or device or to relate them to patients. When a manufacturer supplies prescription drugs for distribution to patients in this type of unsupervised environment, if a direct warning to patients is feasible and can be effective, the law requires measures to that effect.

Although the learned intermediary rule is generally accepted and a drug manufacturer fulfills its legal obligation to warn by providing adequate warnings to the health-care provider, arguments have been advanced that in two other areas courts should consider imposing tort liability on drug manufacturers that fail to provide direct warnings to consumers. In the first, governmental regulatory agencies have mandated that patients be informed of risks attendant to the use of a drug. A noted example is the FDA requirement that birth control pills be sold to patients accompanied by a patient package insert. In the second, manufacturers have advertised a prescription drug and its indicated use in the mass media. Governmental regulations require that, when drugs are so advertised, they must be accompanied by appropriate information concerning risk so as to provide balanced advertising. The question in both instances is whether adequate warnings to the appropriate health-care provider should insulate the manufacturer from tort liability.

Those who assert the need for adequate warnings directly to consumers contend that manufacturers that communicate directly with consumers should not escape liability simply because the decision to prescribe the drug was made by the health-care provider. Proponents of the learned intermediary rule argue that, notwithstanding direct communications to the consumer, drugs cannot be dispensed unless a health-care provider makes an individualized decision that a drug is appropriate for a particular patient, and that it is for the health-care provider to decide which risks are relevant to the particular patient. The Institute leaves to developing case law whether exceptions to the learned intermediary rule in these or other situations should be recognized.

When the content of the warnings is mandated or approved by a governmental agency regulation and a court finds that compliance with such regulation federally preempts tort liability, then no liability under this Section can attach. For the rules governing compliance with governmental standards generally, see § 4(b).
§ 6  RESTATEMENT OF TORTS 3D

f. Manufacturers' liability for defectively designed prescription drugs and medical devices. Subsection (c) reflects the judgment that, as long as a given drug or device provides net benefits for a class of patients, it should be available to them, accompanied by appropriate warnings and instructions. Learned intermediaries must generally be relied upon to see that the right drugs and devices reach the right patients. However, when a drug or device provides net benefits to no class of patients—when reasonable, informed health-care providers would not prescribe it to any class of patients—then the design of the product is defective and the manufacturer should be subject to liability for the harm caused.

A prescription drug or device manufacturer defeats a plaintiff's design claim by establishing one or more contexts in which its product would be prescribed by reasonable, informed health-care providers. That some individual providers do, in fact, prescribe defendant's product does not in itself suffice to defeat the plaintiff's claim. Evidence regarding the actual conduct of health-care providers, while relevant and admissible, is not necessarily controlling. The issue is whether, objectively viewed, reasonable providers, knowing of the foreseeable risks and benefits of the drug or medical device, would prescribe it for any class of patients. Given this very demanding objective standard, liability is likely to be imposed only under unusual circumstances. The court has the responsibility to determine when the plaintiff has introduced sufficient evidence so that reasonable persons could conclude that plaintiff has met this demanding standard.

Illustration:

1. ABC Pharmaceuticals manufactures and distributes D, a prescription drug intended to prolong pregnancy and thus to reduce the risks associated with premature birth. Patricia, six months pregnant with a history of irregular heart beats, was given D during a hospital stay in connection with her pregnancy. As a result, she suffered heart failure and required open-heart surgery. In Patricia's action against ABC, her expert testifies that, notwithstanding FDA approval of D five years prior to Patricia's taking the drug, credible studies published two years prior to Patricia's taking the drug concluded that D does not prolong pregnancy for any class of patients. Notwithstanding a finding by the trier of fact that ABC gave adequate warnings to the prescribing physician regarding the serious risks of heart failure in patients with a history of irregular heart beats, the trier of fact can find that reasonably informed health-care providers would not prescribe D for any class of patients, thus rendering ABC subject to liability.
g. Foreseeability of risks of harm in prescription drug and medical device cases. Duties concerning the design and marketing of prescription drugs and medical devices arise only with respect to risks of harm that are reasonably foreseeable at the time of sale. Imposing liability for unforeseeable risks can create inappropriate disincentives for the development of new drugs and therapeutic devices. Moreover, because actuaries cannot accurately assess unknown and unknowable risks, insuring against losses due to unknowable risks would be problematic. Drug and medical device manufacturers have the responsibility to perform reasonable testing prior to marketing a product and to discover risks and risk-avoidance measures that such testing would reveal. See § 2, Comments a and m.

Illustrations:

2. DEF Pharmaceuticals, Inc., manufactures and distributes prescription drugs. Seven years ago DEF, after years of research and testing, received permission from the FDA to market X, a drug prescribed for the treatment of low-grade infections. Three years later, Jim, age 12, began taking X on his physician’s prescription for a recurring respiratory-tract infection. Jim took X for approximately one year. Two years after Jim had stopped taking X, medical research discovered that X causes loss of vision in adolescents. Prior to this discovery DEF had not warned of this risk. Jim has begun to manifest symptoms of the sort caused by the drug. No evidence suggests that DEF’s testing of X was substandard, or that any reasonable drug company should have discovered the side effects sooner than they were discovered. In a failure-to-warn action by Jim against DEF, the court should direct a verdict in favor of the defendant.

3. The same facts as Illustration 2, except that two years before Jim began taking X, medical researchers published a credible study in a leading medical journal concerning the possibility that a drug with toxicological effects very similar to X adversely affects vision in adolescents. After publication of the study suggesting a possible link between X and loss of vision in adolescents, DEF did not conduct further research or provide warnings to physicians of the risk of X causing loss of vision. Jim’s expert witness testifies that a reasonable manufacturer would have tested further and that such testing would have revealed that X causes vision loss in time to have warned Jim’s physician. In Jim’s failure-to-warn action against DEF, the trial court should submit the issue of DEF’s failure to warn to the trier of fact on appropriate instructions.
§ 6

h. Liability of retail seller of prescription drugs and medical devices for defective designs and defects due to inadequate instructions or warnings. The rule governing most products imposes liability on wholesalers and retailers for selling a defectively designed product, or one without adequate instructions or warnings, even though they have exercised reasonable care in marketing the product. See § 1, Comment e, and § 2, Comment o. Courts have refused to apply this general rule to nonmanufacturing retail sellers of prescription drugs and medical devices and, instead, have adopted the rule stated in Subsection (e). That rule subjects retailers to liability only if the product contains a manufacturing defect or if the retailer fails to exercise reasonable care in connection with distribution of the drug or medical device. In so limiting the liability of intermediary parties, courts have held that they should be permitted to rely on the special expertise of manufacturers, prescribing and treating health-care providers, and governmental regulatory agencies. They have also emphasized the needs of medical patients to have ready access to prescription drugs at reasonable prices.

Illustration:

4. ABC Pharmaceuticals manufactures and distributes a prescription drug to reduce blood pressure. ABC supplies pharmacies with pamphlets explaining the risks and warning patients against drinking alcohol while taking the drug. ABC asks the pharmacies to give the pamphlets to patients when dispensing the drug. The P Pharmacy received the pamphlets but negligently failed to give them to patients. P is subject to liability to those patients suffering injury for whom the pamphlets would have been effective in avoiding risks of usage.

§ 7. Liability of Commercial Seller or Distributor for Harm Caused by Defective Food Products

One engaged in the business of selling or otherwise distributing food products who sells or distributes a food product that is defective under § 2, § 3, or § 4 is subject to liability for harm to persons or property caused by the defect. Under § 2(a), a harm-causing ingredient of the food product constitutes a defect if a reasonable consumer would not expect the food product to contain that ingredient.

Comment:

a. General applicability of §§ 2, 3, and 4 to food products. Except for the special problems identified in Comment b, liability for
harm caused by defects in commercially distributed food products are determined under the same rules generally applicable to non-food products. A food product may contain a manufacturing defect under § 2(a), as when a can of peas contains a pebble; may be defectively designed under § 2(b), as when the recipe for potato chips contains a dangerous chemical preservative; or may be sold without adequate warnings under § 2(c), as when the seller fails to inform consumers that the dye applied to the skins of oranges contains a well-known allergen. Section 3 may allow a plaintiff to reach the trier of fact when, unable to identify the specific defect, the plaintiff becomes violently ill immediately after consuming the defendant's food product and other causes are sufficiently eliminated. And § 4 may apply when a commercially distributed food product fails to conform to applicable safety statutes or administrative regulations.

b. The special problem under § 2(a). When a plaintiff suffers harm due to the presence in food of foreign matter clearly not intended by the product seller, such as a pebble in a can of peas or the pre-sale spoilage of a jar of mayonnaise, the claim is readily treated under § 2(a), which deals with harm caused by manufacturing defects. Food product cases, however, sometimes present unique difficulties when it is unclear whether the ingredient that caused the plaintiff's harm is an unanticipated adulteration or is an inherent aspect of the product. For example, is a one-inch chicken bone in a chicken enchilada, or a fish bone in fish chowder, a manufacturing defect or, instead, an inherent aspect of the product? The analytical problem stems from the circumstance that food products in many instances do not have specific product designs that may be used as a basis for determining whether the offending product ingredient constitutes a departure from design, and is thus a manufacturing defect. Food recipes vary over time, within the same restaurant or other commercial food-preparation facility, from facility to facility, and from locale to locale.

Faced with this indeterminacy, some courts have attempted to rely on a distinction between "foreign" and "natural" characteristics of food products to determine liability. Under that distinction, liability attaches only if the alleged adulteration is foreign rather than natural to the product. Most courts have found this approach inadequate, however. Although a one-inch chicken bone may in some sense be "natural" to a chicken enchilada, depending on the context in which consumption takes place, the bone may still be unexpected by the reasonable consumer, who will not be able to avoid injury, thus rendering the product not reasonably safe. The majority view is that, in this circumstance of uncertainty, the issue of whether a food product containing a dangerous but arguably natural component is defective under § 2(a) is to be determined by reference to reasonable
consumer expectations within the relevant context of consumption. A consumer expectations test in this context relies upon culturally defined, widely shared standards that food products ought to meet. Although consumer expectations are not adequate to supply a standard for defect in other contexts, assessments of what consumers have a right to expect in various commercial food preparations are sufficiently well-formed that judges and triers of fact can sensibly resolve whether liability should be imposed using this standard.

Chapter 4

PROVISIONS OF GENERAL APPLICABILITY

TOPIC 2. AFFIRMATIVE DEFENSES

17. Apportionment of Responsibility Between or Among Plaintiff, Sellers and Distributors of Defective Products, and Others

(a) A plaintiff's recovery of damages for harm caused by a product defect may be reduced if the conduct of the plaintiff combines with the product defect to cause the harm and the plaintiff's conduct fails to conform to generally applicable rules establishing appropriate standards of care.

(b) The manner and extent of the reduction under Subsection (a) and the apportionment of plaintiff's recovery among multiple defendants are governed by generally applicable rules apportioning responsibility.

Comment:

a. History. The rule stated in this Section recognizes that the fault of the plaintiff is relevant in assessing liability for product-caused harm. Section 402A of the Restatement, Second, of Torts, recognizing strict liability for harm caused by defective products, was adopted in 1964 when the overwhelming majority rule treated contributory negligence as a total bar to recovery. Understandably, the Institute was reluctant to bar a plaintiff's products liability claim in tort based on conduct that was not egregious. Thus, § 402A, Comment n, altered the
general tort defenses by narrowing the applicability of contributory negligence and emphasizing assumption of risk as the primary defense. Since then, comparative fault has swept the country. Only a tiny minority of states retain contributory fault as a total bar.

A strong majority of jurisdictions apply the comparative responsibility doctrine to products liability actions. Courts today do not limit the relevance of plaintiff’s fault as did the Restatement, Second, of Torts to conduct characterized as voluntary assumption of the risk. See Comment d.

Certain forms of consumer behavior—product misuse and product alteration or modification—have been the subject of much confusion and misunderstanding. Early decisions treated product misuse, alteration, and modification, whether by the plaintiff or a third party, as a total bar to recovery against a product seller. Today misuse, alteration, and modification relate to one of three issues in a products liability action. In some cases, misuse, alteration, and modification are important in determining whether the product is defective. In others, they are relevant to the issue of legal cause. Finally, when the plaintiff misuses, alters, or modifies the product, such conduct may constitute contributory fault and reduce the plaintiff’s recovery under the rules of comparative responsibility. See Comment c.

§ 18. Disclaimers, Limitations, Waivers, and Other Contractual Exculpations as Defenses to Products Liability Claims for Harm to Persons

Disclaimers and limitations of remedies by product sellers or other distributors, waivers by product purchasers, and other similar contractual exculpations, oral or written, do not bar or reduce otherwise valid products liability claims against sellers or other distributors of new products for harm to persons.

Comment:

a. Effects of contract defenses on products liability tort claims for harm to persons. A commercial seller or other distributor of a new product is not permitted to avoid liability for harm to persons through limiting terms in a contract governing the sale of a product. It is presumed that the ordinary product user or consumer lacks sufficient information and bargaining power to execute a fair contractual limitation of rights to recover. For a limited exception to this general rule, see Comment d. The rule in this Section applies only to “sellers or other distributors of new products.” For rules governing commercial sellers of used products, including whether they may rely on disclaim-
ers, waivers, and other contractual defenses, see § 8. Nothing in this Section is intended to constrain parties within the commercial chain of distribution from contracting inter se for indemnity agreements or save-harmless clauses.

d. Waiver of rights in contractual settings in which product purchasers possess both adequate knowledge and sufficient economic power. The rule in this Section applies to cases in which commercial product sellers attempt unfairly to disclaim or otherwise limit their liability to the majority of users and consumers who are presumed to lack information and bargaining power adequate to protect their interests. This Section does not address whether consumers, especially when represented by informed and economically powerful consumer groups or intermediaries, with full information and sufficient bargaining power, may contract with product sellers to accept curtailment of liability in exchange for concomitant benefits, or whether such consumers might be allowed to agree to substitute alternative dispute resolution mechanisms in place of traditional adjudication. When such contracts are accompanied by alternative nontort remedies that serve as an adequate quid pro quo for reducing or eliminating rights to recover in tort, arguments may support giving effect to such agreements. Such contractual arrangements raise policy questions different from those raised by this Section and require careful consideration by the courts.