

Product Liability Act

Summary: The Model Product Liability Act (“Model PLA”) provides legislators with core product liability provisions reflecting the best practices of the states. Approximately twenty states have codified their product liability laws; several did so based on the original ALEC model Product Liability Act adopted in 1995 (“the 1995 Act”). The current Model PLA updates the 1995 Act to reflect three sets of developments: tort law theories advanced in legislatures and courts since 1995; product liability laws adopted in state legislatures since the 1995; and the adoption of the Restatement, Third of Torts: Products Liability in 1998. The goal of this updated Model PLA is to preserve the original intent of the 1995 Act, particularly where some courts have gone astray.

This Model PLA also assures that the ALEC’s model product liability act is internally consistent with the model acts ALEC has adopted since 1995. Specifically, ALEC has adopted separate model legislation to (1) address specific areas of product liability law, such as the effect of a product’s compliance with government regulations, a statute of repose, and the assumption of risk defense; (2) address reliability in expert testimony, which is applicable to any lawsuit but particularly important in product liability cases; and (3) address issues related to asbestos and silica litigation. When developing comprehensive product liability legislation, state legislators should consider incorporating these model acts, which are cross-referenced below.

{Title, enacting clause, etc.}

Section 1. {Title.}

This Act shall be known and may be cited as the Product Liability Act.

Section 2. {Definitions.}

The following shall have the meaning set forth below, unless the context clearly requires otherwise:

(A) “Claimant” means any person, including a class of persons, who brings a product liability action, and if such an action is brought through or on behalf of an estate, the term includes the claimant’s decedent, or if such an action is brought through or on behalf of a minor, the term includes the claimant’s parent or guardian.

(B) “Design” means the intended or known physical and material characteristics of a product and shall include any intended or known formulation or content of the product and the usual result of the intended manufacturing or other process used to produce the product.

(C) “Express warranty” means any material, positive statement, affirmation of fact, promise, or description relating to a product, including any sample or model of a product.

(D) “Harm” means:

- (1) damage to property other than the product itself;
- (2) personal physical injury, illness, or death;
- (3) mental anguish or emotional harm; or
- (4) any loss of consortium or services or other loss deriving from any type of harm described in Subsections (1), (2), or (3).

(E) “Manufacturer” means:

- (1) any person who is engaged in a business to design, produce, make, fabricate, construct, or remanufacture any product (or component part of a product); or
- (2) any product seller not described in Subsection (1) holding itself out as a manufacturer to the user of the product; except that any product seller who acts primarily as a wholesaler, distributor, or retailer of products may be a manufacturer with respect to a given product to the extent that such seller designs, produces, makes, fabricates, constructs, or remanufactures the product before its sale.

(F) “Material fact” means any specific characteristic or quality of the product, but does not include a general opinion about, or praise of, the product or its quality.

(G) “Person” means any individual, corporation, company, association, firm, partnership, society, joint stock company, or any other entity including any government entity or unincorporated association of persons.

(H) “Product” means any object, substance, mixture, or raw material in a gaseous, liquid, or solid state, possessing intrinsic value which is capable of delivery either as an assembled whole or as a component part and is produced for introduction to trade or commerce; but such term does not include human tissue, blood and blood products, or organs.

(I) “Product seller” means:

- (1) a manufacturer; or
- (2) a person who, in the course of business conducted for that purpose, sells, distributes, leases, installs, prepares, packages, labels, markets, repairs, maintains, or otherwise is involved in placing a product in the stream of commerce; but such term does not include:
 - (a) a seller of real property, unless that person is engaged in the sale of manufactured housing or in the mass production of dwellings;
 - (b) a provider of professional services in any case in which the sale or use of a product is incidental to the transaction and the essence of the transaction is the furnishing of judgment, skill, or services; or
 - (c) any person who:
 - (i) acts in only a financial capacity with respect to the sale of the product;
 - (ii) is not a manufacturer, wholesaler, distributor, or retailer; and
 - (iii) leases a product, without having a reasonable opportunity to inspect and discover defects in the product, under a lease arrangement in which the selection, possession, maintenance, and operation of the product are controlled by a person other than the lessor.

Section 3. {Effect on other laws.}

(A) Except as excluded under paragraph (B), a product liability action includes all actions brought for or on account of personal injury, death, or property damage caused by or resulting from the manufacture, construction, design, formula, preparation, assembly, testing, service, warning, instruction, marketing, packaging, or labeling of any product. This Act establishes the exclusive theories of liability for any civil action for harm caused by a product, irrespective of the substantive theory or theories underlying the claim, including any action which before the effective date of the Act would have been based on any of the following theories:

- (1) strict liability in tort;
- (2) negligence;
- (3) breach of express, implied, or statutorily established warranty;

- (4) failure to discharge a duty to warn or instruct;
- (5) misrepresentation, concealment, or nondisclosure; or
- (6) public nuisance; or
- (7) any other common law theory or theory established by statute that is the basis for an award of damages for harm caused by a product.

(B) A product liability action does not include any civil action against a manufacturer or seller for:

- (1) harm caused to a product itself;
- (2) damage to property under a breach of warranty theory if prohibited by the Uniform Commercial Code;
- (3) commercial loss, including incidental and consequential damages in commercial setting; or
- (4) commercial risks that are the subject of a contract between the manufacturer or a seller and a buyer. Suits described in Subsections (1), (2), (3), and (4) shall be governed by the Uniform Commercial Code.

(C) In any product liability action, no person is not liable to a claimant for mental anguish or emotional harm in the absence of proof of related and contemporaneous personal physical injury, illness, or death.

Section 4. {Product liability standards.}

(A) Bases of product liability. In any product liability action, a manufacturer shall be liable to a claimant if the claimant establishes all of the following by a preponderance of the evidence:

- (1) the product was unreasonably dangerous when the product left the control of the manufacturer because:
 - a. the product contains a manufacturing defect in that it deviated in a material way from the manufacturer's specifications or from the clear majority of otherwise identical units manufactured to the same design manufacturing specifications;
 - b. the product is defective in design;
 - c. the product failed to contain adequate instructions or warnings; or
 - d. the product did not conform to an express warranty with respect to the product made by the manufacturer or product seller;
- (2) the defendant was the manufacturer of the actual product that was the cause of harm for which the claimant seeks to recover compensatory damages; and
- (3) the unreasonably dangerous aspect of the product was the proximate cause of the harm complained of by the claimant.

(B) Design defects. In any action alleging that a product is unreasonably dangerous because of a defective design, the claimant shall prove by a preponderance of the evidence that, at the time the product left the manufacturer's control:

- (1) the manufacturer knew or, in light of then-existing scientific and technical knowledge, reasonably should have known of the danger that caused the claimant's harm; and
- (2) there existed a technologically feasible and practical alternative design that would have reduced or avoided a foreseeable risk of harm without significantly impairing the usefulness or desirability of the product to the group of persons who are the intended users of the product.

(C) Failure to warn. In any action alleging that a product is defective because it failed to contain adequate instructions or warnings:

- (1) An adequate warning or instruction is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and communicates sufficient information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to an ordinary consumer who purchases the product.
- (2) The claimant shall prove by a preponderance of the evidence that, at the time the product left the manufacturer's control, the manufacturer knew or, in light of then-existing scientific and technical knowledge, reasonably should have known of the danger that caused the claimant's harm.
- 3) A manufacturer shall not be liable for failure to instruct or warn about a danger that is known or open and obvious to the user or consumer of the product, or should have been known or open and obvious to the user or consumer of the product, taking into account the characteristics of, and the ordinary knowledge common to, the persons who ordinarily use or consume the product.

(D) Express warranty. A product may be unreasonably dangerous because it did not conform to an express warranty only if the claimant proves by a preponderance of the evidence that:

- (1) the claimant (or a person acting on the claimant's behalf) reasonably relied on an express warranty made by the manufacturer about a material fact concerning the safety of the product;
- (2) this express warranty proved to be untrue; and
- (3) had the representation been true, the claimant would not have been harmed. A manufacturer may be subject to liability under this section although it did not engage in negligent or fraudulent conduct in making the express warranty.

Section 5. {Misuse and modification.}

A product liability action may not be commenced or maintained against a product seller if, at the time the injury, death, or property damage occurred, the product was misused, altered, or modified in a manner that was not reasonably foreseeable, and such misuse, alteration, or modification of the product was a cause of the injury, death, or property damage.

Section 6. {Learned intermediary doctrine}

A prescription drug is not defective due to an inadequate warning or instruction if its manufacturer provides otherwise adequate warning or instruction to the physician or other legally authorized person who prescribes or dispenses that prescription drug for the claimant.

Section 7. {Warnings to third parties.}

In any product liability action based on the failure to provide adequate warnings or instructions, the manufacturer shall not be liable if:

- (A) The product was used in a workplace, and the manufacturer provided warnings or instructions to the employer of the claimant, because there was no practical and feasible means of transmitting them directly to the claimant;
- (B) The product was sold as a component or material to be incorporated into another product, and the manufacturer provided warnings or instructions to the manufacturer's immediate buyer, and the claimant was exposed to the component or material after it was incorporated or converted into another product; or

(C) The product was one that may legally be used or dispensed only by or under the supervision of a class of experts and the manufacturer employed means reasonably calculated to make warnings or instructions available to the using or supervising expert. As used in this subsection, "means reasonably calculated to make warnings or instructions available" does not require actual, personal notice to the expert where such personal notice would be impossible or impracticable.

Section 8. {Liability of product sellers.}

(A) No product liability action may be asserted against a product seller other than the manufacturer, unless:

- (1) the product seller exercised substantial control over the aspect of the design, testing, manufacture, packaging, or labeling of the product that caused the alleged harm for which recovery of damages is sought;
- (2) the product seller altered or modified the product, and the alteration or modification was a substantial factor in causing the harm for which recovery of damages is sought;
- (3) the product seller made an express warranty as to such product independent of any express warranty made by a manufacturer as to such product, such product failed to conform to the product seller's warranty, and the failure of such product to conform to the warranty caused the harm complained of by the claimant;
- (4) the claimant is unable, despite a good faith exercise of due diligence, to identify the manufacturer of the product;
- (5) the manufacturer is not subject to service of process under the laws of the state; or
- (6) the court determines that the claimant would be unable to enforce a judgment against the manufacturer;

(B) A product seller other than a manufacturer is liable to a claimant on the basis of negligence if the claimant establishes that:

- (1) the product seller sold the product involved in such action;
- (2) the product seller did not exercise reasonable care: (a) in assembling, inspecting, or maintaining such product; or (b) in passing on warnings or instructions from such product's manufacturer about the dangers and proper use of such product; and
- (3) such failure to exercise reasonable care was a proximate cause of the harm complained of by the claimant.

Section 9. {Alcohol and drug defense.}

In any product liability action a manufacturer shall not be liable if:

- (A) The claimant was under the influence of intoxicating alcohol or any non-over-the counter drug which has not been prescribed by a physician for use by the claimant; and
- (B) The claimant as a result of the influence of the alcohol or drug was more than 50 percent at fault for such claimant's harm.

Section 10. {Subsequent remedial measures.}

(A) In any product liability action, evidence of any measure taken by a manufacturer after the occurrence of a claimant's harm which, if taken previously, would have made the harm less likely to occur is not admissible to prove liability.

(B) Evidence described in Subsection (A) may be admitted only if necessary:

- (1) to prove ownership, control, or feasibility of precautionary measures, if these issues are controverted; or
- (2) for impeachment.

Section 11. {Concert of action.}

In any product liability action, a manufacturer or product seller shall not be liable to the claimant on any theory of express or implied agreement among sellers, parallel behavior, or independent adherence to industry-wide standards unless the claimant proves, by a preponderance of the evidence, that the seller engaged in concert of action. "Concert of action" means the conscious and deliberate agreement to, acknowledgment of, and collaborative participation in wrongful conduct by two or more persons who do not have the relationship of master and servant, principal and agent, parent and subsidiary, affiliates, or employer and employee.

Section 12. {Product Identification Requirement}

Proof that the product seller designed, formulated, produced, constructed, created, assembled, or rebuilt the type of product in question is not proof that the product seller formulated, produced, constructed, created, assembled, or rebuilt the actual defective product in the product liability action. A product seller may not be held liable in a product liability action based on market share, enterprise, or industry-wide liability.

Section 13. {Incorporation of Other ALEC Model Acts.}

(A) The REGULATORY COMPLIANCE CONGRUITY WITH LIABILITY ACT offers three options for addressing the impact of a product's compliance with government standards or agency approval of its design or warnings on liability.

(B) The TEN-YEAR STATUTE OF REPOSE ACT provides that an injury occurring ten years after a product is sold is presumed to not result from a defect in the product, with certain exceptions.

(C) The ASSUMPTION OF RISK ACT provides that a product seller (or other defendant) is not liable where the claimant knew of and appreciated the risk, and voluntarily encountered it.

(D) The RELIABILITY IN EXPERT TESTIMONY STANDARDS ACT adopts standards and procedures for admissibility of expert testimony that apply in federal courts and most state courts.

(E) The TRANSPARENCY IN LAWSUITS PROTECTION ACT provides that a court shall not create a new private right of action on the basis of a statute that provides regulatory requirements, such as product safety standards, unless the state legislature specifically provides a right to sue.

(F) The ASBESTOS AND SILICA CLAIMS PRIORITIES ACT ensures that those who are truly sick from exposure to asbestos or silica receive prompt, fair and efficient adjudication of their claims by requiring claimants to meet certain medical criteria for showing a physical impairment before proceeding with their claims.

(G) The ASBESTOS CLAIMS TRANSPARENCY ACT assures that courts and litigants have available to them information as to payments an asbestos claimant has or may receive from asbestos-related bankruptcy trusts.]

Section 14. {Severability clause.}

Section 15. {Repealer clause.}

Section 16. {Effective date.}



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(B) “Design” means the intended or known physical and material characteristics of a product and shall include any intended or known formulation or content of the product and the usual result of the intended manufacturing or other process used to produce the product.

(C) “Express warranty” means any material, positive statement, affirmation of fact, promise, or description relating to a product, including any sample or model of a product.

(D) “Harm” means:

- (1) damage to property other than the product itself;
- (2) personal physical injury, illness, or death;
- (3) mental anguish or emotional harm; or
- (4) any loss of consortium or services or other loss deriving from any type of harm described in Subsections (1), (2), or (3).

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- (1) any person who is engaged in a business to design, produce, make, fabricate, construct, or remanufacture any product (or component part of a product); or
- (2) any product seller not described in Subsection (1) holding itself out as a manufacturer to the user of the product; except that any product seller who acts primarily as a wholesaler, distributor, or retailer of products may be a manufacturer with respect to a given product to the extent that such seller designs, produces, makes, fabricates, constructs, or remanufactures the product before its sale.

~~(E)~~ "F" "Material fact" means any specific characteristic or quality of the product, but does not include a general opinion about, or praise of, the product or its quality.

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~~(F)~~ "Product" means any object, substance, mixture, or raw material in a gaseous, liquid, or solid state, possessing intrinsic value which is capable of delivery either as an assembled whole or as a component part and is produced for introduction to trade or commerce; but such term does not include human tissue, blood and blood products, or organs.

~~(G)~~ "Product seller" means:

- (1) a manufacturer; or
- (2) a person who, in the course of business conducted for that purpose, sells, distributes, leases, installs, prepares, packages, labels, markets, repairs, maintains, or otherwise is involved in placing a product in the stream of commerce; but such term does not include:
 - (a) a seller of real property, unless that person is engaged in the sale of manufactured housing or in the mass production of dwellings;
 - (b) a provider of professional services in any case in which the sale or use of a product is incidental to the transaction and the essence of the transaction is the furnishing of judgment, skill, or services; or
 - (c) any person who:
 - (i) acts in only a financial capacity with respect to the sale of the product;
 - (ii) is not a manufacturer, wholesaler, distributor, or retailer; and
 - (iii) leases a product, without having a reasonable opportunity to inspect and discover defects in the product, under a lease arrangement in which the selection, possession, maintenance, and operation of the product are controlled by a person other than the lessor.

Section 3. {Effect on other laws.}

(A) Except as excluded under ~~subsection paragraph~~ (B), ~~any civil a product liability action includes all actions brought against a manufacturer or product seller for harm caused by a product is a product liability action and is governed by the provisions of the Act for or on account of personal injury, death, or property damage caused by or resulting from the manufacture, construction, design, formula, preparation, assembly, testing, service, warning, instruction, marketing, packaging, or labeling of any product. This Act is intended to govern establishes the exclusive theories of liability for any civil action for harm caused by a product, irrespective of the substantive theory or theories underlying the claim, including any action which before the effective date of the Act would have been based on any of the following theories:~~

- (1) strict liability in tort;

- (2) negligence;
- (3) breach of express, implied, or statutorily established warranty;
- (4) failure to discharge a duty to warn or instruct;
- (5) misrepresentation, concealment, or nondisclosure; or
- (6) public nuisance; or
- (7) any other common law theory or theory established by statute that is the basis for an award of damages for harm caused by a product.

(B) A product liability action does not include any civil action against a manufacturer or seller for:

- (1) harm caused to a product itself;
- (2) damage to property under a breach of warranty theory if prohibited by the Uniform Commercial Code;
- (3) commercial loss, including incidental and consequential damages in commercial setting; or
- (4) commercial risks that are the subject of a contract between the manufacturer or a seller and a buyer. Suits described in Subsections (1), (2), (3), and (4) shall be governed by the Uniform Commercial Code.

(C) In any product liability action, ~~the product seller~~ no person is not liable to a claimant for mental anguish or emotional harm in the absence of proof of related and contemporaneous personal physical injury, illness, or death.

Section 4. ~~{Standards}~~Product liability standards.

(A) Bases of product liability. In any product liability action, a manufacturer shall be liable to a claimant ~~if and only if~~ if the claimant establishes all of the following by a preponderance of the evidence that:

- (A1) the product was unreasonably dangerous:
- ~~(1) in construction;~~ (2) when the product left the control of the manufacturer because:
 - a. the product contains a manufacturing defect in that it deviated in a material way from the manufacturer's specifications or from the clear majority of otherwise identical units manufactured to the same design manufacturing specifications;
 - b. the product is defective in design;
 - c. the product failed to contain adequate instructions or warnings; or
 - d. the product did not conform to an express warranty with respect to the product made by the manufacturer or product seller;
- ~~(3) in design; or~~
- ~~(4) because the manufacturer failed to provide adequate warnings or instructions;~~ (B2) the defendant was the manufacturer of the particular actual product unit that caused was the cause of harm for which the claimant's harm seeks to recover compensatory damages; and
- ~~(C3) the unreasonably dangerous aspect of the product was the proximate cause of the harm complained of by the claimant.~~

Section 5. ~~{Government standards.}~~

~~In any product liability action, a manufacturer shall not be liable to a claimant if the aspect of the product alleged to have caused the claimant's harm complied in material respects, at the time of manufacture, with standards, conditions, or specifications established, adopted, or approved~~

by a federal or state statute or by an agency of the federal or state government responsible for the design, formulation, labeling, packaging, performance, or approval of the product, unless the claimant proves by clear and convincing evidence that the defendant intentionally and fraudulently withheld from or misrepresented to the agency information known to be material and relevant to the harm in question.

Section 6. {Defectless products.}

In any product liability action, a manufacturer shall not be liable for harm caused by an inherent characteristic of the product that would be recognized by the ordinary person who uses or consumes the product with the ordinary knowledge common to the community.

(B) Design defects. In any action alleging that a product is unreasonably dangerous because of a defective design, the claimant shall prove by a preponderance of the evidence that, at the time the product left the manufacturer's control:

- (1) the manufacturer knew or, in light of then-existing scientific and technical knowledge, reasonably should have known of the danger that caused the claimant's harm; and
- (2) there existed a technologically feasible and practical alternative design that would have reduced or avoided a foreseeable risk of harm without significantly impairing the usefulness or desirability of the product to the group of persons who are the intended users of the product.

Section 7. {Misuse and modification.}

In any product liability action, a manufacturer shall not be liable for harm caused by product misuse, alteration, or modification. Misuse, alteration, or modification shall include but is not limited to:

- (1) any use, alteration, or modification contrary to or inconsistent with a manufacturer's warnings or instruction; or
- (2) any use, alteration, or modification involving a risk of harm which was known or

(C) Failure to warn. In any action alleging that a product is defective because it failed to contain adequate instructions or warnings:

- (1) An adequate warning or instruction is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and communicates sufficient information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to an ordinary consumer who purchases the product.
- (2) The claimant shall prove by a preponderance of the evidence that, at the time the product left the manufacturer's control, the manufacturer knew or, in light of then-existing scientific and technical knowledge, reasonably should have known of the danger that caused the claimant's harm.

should have been known by the ordinary person who uses or consumes
(3) A manufacturer shall not be liable for failure to instruct or warn about a danger that is known or open and obvious to the user or consumer of the product, or should have been known or open and obvious to the user or consumer of the product, taking into account the characteristics of, and the ordinary knowledge common to, the persons who ordinarily use or consume the product.

Section 8. {Construction defects.}

~~In any product liability action, a product may be unreasonably dangerous because it is defective in manufacture or construction only if the claimant proves by a preponderance of the evidence that, when the product left the control of the manufacturer, it deviated in a material way from the established design specifications, formula, or performance standards of the manufacturer, or from the clear majority of otherwise identical units manufactured to the same design specifications, formula, or performance standards.~~

Section 9. ~~{(D) Express warranty.}~~(A) ~~In any product liability action, a~~ A product may be unreasonably dangerous because it did not conform to an express warranty only if the claimant proves by a preponderance of the evidence that:

- (1) the claimant (or a person acting on the claimant's behalf) reasonably relied on an express warranty made by the manufacturer about a material fact concerning the safety of the product;
- (2) this express warranty proved to be untrue; and
- (3) had the representation been true, the claimant would not have been harmed.

~~(B) "Express warranty" means any material, positive statement, affirmation of fact, promise, or description relating to a product, including any sample or model of a product.~~

~~(C) "Material fact" means any specific characteristic or quality of the product, but does not include a general opinion about, or praise of, the product or its quality.~~

~~(D)~~ A manufacturer may be subject to liability under this section although it did not engage in negligent or fraudulent conduct in making the express warranty.

Section 10. ~~{Knowledge of danger.}~~5. ~~{Misuse and modification.}~~

~~In any~~

~~A~~ product liability action based upon defective design, a manufacturer shall not be liable unless the claimant proves by a preponderance of the evidence that, at the time the product left the manufacturer's control, the manufacturer knew or, in light of then existing scientific and technical knowledge, reasonably should have known of the danger that caused the claimant's harm.

Section 11. ~~{Feasible alternative design.}~~

~~In any product liability action based upon defective design, a manufacturer shall not be liable unless the claimant proves by a preponderance of the evidence that, at the time the product left the manufacturer's control, there existed a practical and technically feasible alternative design or formulation that would have prevented the harm without significantly impairing the usefulness or desirability of the product to the group of persons who are the intended users of the product.~~

Section 12. ~~{Unavoidably unsafe products.}~~

~~On any product liability action, a manufacturer is not liable to the claimant for harm caused by an unavoidably unsafe aspect of a drug, biological, or medical device unless the claimant proves by a preponderance of the evidence that:~~

~~(A) At the time the product left the manufacturer's control, the manufacturer knew or, in light of then existing and reasonably available scientific and technical knowledge, reasonably should have known of the danger that caused the claimant's harm; and~~

~~(B) The manufacturer failed to provide adequate warnings or instructions. An aspect of a product shall be considered unavoidably unsafe unless the danger could have been eliminated by~~

use of an existing, practical, and technically feasible alternative design or formulation that would have prevented the harm without significantly impairing the usefulness or desirability of the product to the group of persons who are the intended users of the product. An adequate warning is either:

- (1) one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger; or
- (2) one that conforms to the requirements of a federal or state statute or agency regulation or the conditions of the approval of a product by a federal or state agency that prescribes the form or language of the warning or instruction.

Section 13. {Assumption of the risk.}

(A) In any tort action, a defendant shall not be liable if the injured person assumed the risk of injury or harm to property. Assumption of the risk shall mean that the injured person:

- (1) knew of and appreciated the risk; and
- (2) voluntarily exposed himself or herself to the danger that proximately caused the injury or damage.

(B) The elements of assumption of the risk may be inferred, as a matter of either fact or law, from circumstantial evidence that the injured person must have known and appreciated the risk and voluntarily encountered it. may not be commenced or maintained against a product seller if, at the time the injury, death, or property damage occurred, the product was misused, altered, or modified in a manner that was not reasonably foreseeable, and such misuse, alteration, or modification of the product was a cause of the injury, death, or property damage.

Section 14. {Warnings.}

(A) In any product liability action, a manufacturer shall not be liable for harm caused by a failure to warn if the product contains an adequate warning or instruction. An adequate warning is either:

- (1) one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger; or
- (2) one that conforms to the requirements of a federal or state statute or agency regulation or the conditions of the approval of a product by a federal or state agency that prescribes the form or language of the warning or instruction.

(B) In any product liability action based on the failure to provide adequate warnings or instructions, the manufacturer shall not be liable for failure to warn or instruct about:

- (1) a danger that is an open and obvious risk or that is a matter of common knowledge;
- (2) a product misuse, alteration or modification, which means:
 - (a) any use, alteration or modification contrary to or inconsistent with a manufacturer's warnings or instruction; or
 - (b) any use, alteration, or modification involving any risk of harm which was known or should have been known by the ordinary person who uses or consumes the product.

6. {Learned intermediary doctrine}
A prescription drug is not defective due to an inadequate warning or instruction if its manufacturer provides otherwise adequate warning or instruction to the physician or other legally authorized person who prescribes or dispenses that prescription drug for the claimant.

Section 15.7. {Warnings to third parties.}

In any product liability action based on the failure to provide adequate warnings or instructions, the manufacturer shall not be liable if:

(A) The product was used in a workplace, and the manufacturer provided warnings or instructions to the employer of the claimant, because there was no practical and feasible means of transmitting them directly to the claimant;

(B) The product was sold as a component or material to be incorporated into another product, and the manufacturer provided warnings or instructions to the manufacturer's immediate buyer, and the claimant was exposed to the component or material after it was incorporated or converted into another product; or

(C) The product was one that may legally be used or dispensed only by or under the supervision of a class of experts and the manufacturer employed means reasonably calculated to make warnings or instructions available to the using or supervising expert. As used in this subsection, "means reasonably calculated to make warnings or instructions available" does not require actual, personal notice to the expert where such personal notice would be impossible or impracticable.

Section 16.8. {Liability of product sellers.}

~~(A) A product seller shall be liable for harm to the claimant caused by a product as if the No product liability action may be asserted against a product seller were other than the manufacturer of the product if, unless:~~

~~(1) the manufacturer is not subject to service of process under the laws of the state; or~~

~~(2) the court determines that the claimant would be unable to enforce a judgment against the manufacturer.~~

~~(B) A product seller other than a manufacturer is liable to a claimant for the failure of the product involved in such action to conform to a warranty made with respect to such product if the claimant establishes by a preponderance of the evidence that:~~

~~(1) the product seller sold such product exercised substantial control over the aspect of the design, testing, manufacture, packaging, or labeling of the product that caused the alleged harm for which recovery of damages is sought;~~

~~(2) the product seller altered or modified the product, and the alteration or modification was a substantial factor in causing the harm for which recovery of damages is sought;~~

~~(3) the product seller made an express warranty as to such product independent of any express warranty made by a manufacturer as to such product; and (4) the failure of such product to conform to the product seller's warranty, and (5) the failure of such product to conform to such the warranty caused the harm complained of by the claimant;~~

~~(6) the claimant is unable, despite a good faith exercise of due diligence, to identify the manufacturer of the product;~~

~~(7) the manufacturer is not subject to service of process under the laws of the state; or~~

~~(8) the court determines that the claimant would be unable to enforce a judgment against the manufacturer;~~

~~(B) A product seller other than a manufacturer is liable to a claimant on the basis of negligence if the claimant establishes by a preponderance of the evidence that:~~

~~(1) the product seller sold the product involved in such action;~~

- (2) the product seller did not exercise reasonable care: (a) in assembling, inspecting, or maintaining such product; or (b) in passing on warnings or instructions from such product's manufacturer about the dangers and proper use of such product; and
- (3) such failure to exercise reasonable care was a proximate cause of the harm complained of by the claimant.

Section 17.2. {Alcohol and drug defense.}

In any product liability action a manufacturer shall not be liable if:

- (A) The claimant was under the influence of intoxicating alcohol or any non-over-the counter drug which has not been prescribed by a physician for use by the claimant; and
- (B) The claimant as a result of the influence of the alcohol or drug was more than 50 percent at fault for such claimant's harm.

Section 18.10. {Subsequent remedial measures.}

(A) In any product liability action, evidence of any measure taken by a manufacturer after the occurrence of a claimant's harm which, if taken previously, would have made the harm less likely to occur is not admissible to prove liability.

(B) Evidence described in Subsection (A) may be admitted only if necessary:

- (1) to prove ownership, control, or feasibility of precautionary measures, if these issues are controverted; or
- (2) for impeachment.

Section 19. {Expert opinion} 11. {Concert of action.}

~~In any product liability action, expert technical, scientific, or medical opinion shall not be admitted unless:~~

- ~~(A) The expert is professionally qualified in the relevant discipline; and~~
- ~~(B) Such opinion is corroborated by other objective evidence which is consistent with generally accepted technical, medical, or scientific principles.~~

Section 20. {Concert of action.}

In any product liability action, a manufacturer or product seller shall not be liable to the claimant on any theory of express or implied agreement among sellers, parallel behavior, or independent adherence to ~~industrywide~~ industry-wide standards unless the claimant proves, by a preponderance of the evidence, that the seller engaged in ~~"concert of action."~~ "Concert of action" means the conscious and deliberate agreement to, acknowledgment of, and collaborative participation in wrongful conduct by two or more persons who do not have the relationship of master and servant, principal and agent, parent and subsidiary, affiliates, or employer and employee.

Section 21. {Severability clause} 12. {Product Identification Requirement}

Proof that the product seller designed, formulated, produced, constructed, created, assembled, or rebuilt the type of product in question is not proof that the product seller formulated, produced, constructed, created, assembled, or rebuilt the actual defective product in the product liability action. A product seller may not be held liable in a product liability action based on market share, enterprise, or industry-wide liability.

Section 13. {Incorporation of Other ALEC Model Acts.}

[(A) The REGULATORY COMPLIANCE CONGRUITY WITH LIABILITY ACT offers three options for addressing the impact of a product's compliance with government standards or agency approval of its design or warnings on liability.

(B) The TEN-YEAR STATUTE OF REPOSE ACT provides that an injury occurring ten years after a product is sold is presumed to not result from a defect in the product, with certain exceptions.

(C) The ASSUMPTION OF RISK ACT provides that a product seller (or other defendant) is not liable where the claimant knew of and appreciated the risk, and voluntarily encountered it.

(D) The RELIABILITY IN EXPERT TESTIMONY STANDARDS ACT adopts standards and procedures for admissibility of expert testimony that apply in federal courts and most state courts.

(E) The TRANSPARENCY IN LAWSUITS PROTECTION ACT provides that a court shall not create a new private right of action on the basis of a statute that provides regulatory requirements, such as product safety standards, unless the state legislature specifically provides a right to sue.

(F) The ASBESTOS AND SILICA CLAIMS PRIORITIES ACT ensures that those who are truly sick from exposure to asbestos or silica receive prompt, fair and efficient adjudication of their claims by requiring claimants to meet certain medical criteria for showing a physical impairment before proceeding with their claims.

(G) The ASBESTOS CLAIMS TRANSPARENCY ACT assures that courts and litigants have available to them information as to payments an asbestos claimant has or may receive from asbestos-related bankruptcy trusts.]

Section 14. {Severability clause.}

Section ~~22~~.15. {Repealer clause.}

Section ~~23~~.16. {Effective date.}

Amendments to Product Liability Act

Section-by-Section Analysis

Section 1. {Title.}

Section 1 retains the existing title of the model act, the Product Liability Act.

Section 2. {Definitions.}

Sets forth definitions applicable to the model act. These definitions have not changed from the 1995 Act, except for the addition of definitions for “express warranty” and “material fact,” and a clarification that “claimant” includes class actions.

Section 3. {Effect on other laws.}

Section 3, as with the 1995 Act, states that the Model PLA is intended to serve as the exclusive basis for claims arising out of harms caused by products. Courts in several states, including Arkansas, Colorado, Connecticut, Louisiana, New Jersey, Texas and Washington, that have adopted product liability statutes follow this sound approach. *See, e.g., Persichini v. Brad Ragan, Inc.*, 735 P.2d 168 (Colo. 1987) (the PLA applies to claims pled under negligence); *Winslow v. Lewis-Shepard Inc.*, 562 A.2d 517 (Conn. 1989) (the PLA provides the exclusive remedy for claims failing within its scope); *Washington St. Physicians Ins. Exch. & Ass’n v. Fisons Corp.*, 858 P.2d 1054 (Wash. 1993) (the PLA “created a single cause of action for product-related harms, and supplants previously existing common law remedies.”).

In these and other states, there have been several attempts since 1995 to circumvent product liability law and subject product manufacturers to tort law generally. These efforts involve novel tort theories or novel applications of traditional tort theories to go after the deep pocket manufacturer, often regardless of fault. Consider these three prominent examples:

- In high-profile industry litigation over lead paint, firearms and other products, some have tried to subject product manufacturers to public nuisance liability for harms caused by individuals who misused the products, for example by allowing lead paint to fall into a state of disrepair or through criminal gun violence. *See* Victor E. Schwartz & Phil Goldberg, *The Law of Public Nuisance: Maintaining Rational Boundaries on a Rational Tort*, 45 Washburn L.J. 541 (2006). In these cases, it is not alleged that the products were defective, which is the linchpin for liability under products liability law. This effort has largely failed. *See Rhode Island v. Lead Indus. Ass’n Inc.*, 951 A.2d 428, 435, 440 (R.I. 2008); *In re: Lead Paint Litigation*, 924 A.2d 484 (N.J. 2007).
- In pharmaceutical litigation, individuals are seeking to subject manufacturers of brand-name drugs to liability for their harms, even though they fully acknowledge that they only took only generic versions of those drugs, which were manufactured by someone else. This litigation violates the bedrock product liability law principle that one can only sue the company that made the actual product that allegedly caused the harm – not its competitors. While courts in nearly twenty states have rejected these theories, a couple of courts have permitted them. *See, e.g., Conte v. Wyeth*, 85 Cal.Rptr.3d 299 (Cal Ct. App. 2008).

- Product liability claims are routinely cast as consumer protection claims to avoid the need to show an actual physical injury and causation. One recent class action brought on behalf of uninjured cell phone users claimed that radiation from their use placed them at risk of developing cancer, but that the manufacturers represented such products as safe. *See Farina v. Nokia*, 625 F. 3d 97 (3d Cir. 2010) (dismissing claim on basis of federal preemption), *cert. denied*, 2011 WL 4536521 (Oct. 3, 2011). Likewise, plaintiffs' lawyers often attack the safety of prescription drugs under state consumer protection statutes by alleging that they were not as safe or beneficial, or had greater risk, than the manufacturer represented. *See* James P. Muehlberger & Cary Silverman, *Lawsuits Without Injury: The Rise of Consumer Protection Claims*, HarrisMartin Columns: Drugs & Supplements, Oct. 2006, at 4. Such methods attempt to eliminate the need to show the product had an inadequate warning or harmed a patient, as required by product liability law.

To assure courts will interpret paragraph (A)(5) as precluding efforts to circumvent the PLA, revisions have been made to paragraph (A) clarifying this point. For example, it makes clear that the Product Liability Act “establishes the *exclusive* theories of liability for any civil action for harm caused by a product.” The precise language in (A)(5) follows provisions in PLAs enacted in the states listed above where courts have validated that the PLA provides the exclusive remedy for harms caused by products. Also, paragraph (A)(6) expressly adds public nuisance theory to the exclusivity provision of the model act. Such a provision was added to the Ohio PLA after firearm and lead paint litigation was allowed to proceed in that state. *See* 2006 Ohio Am. Sub. S.B. 117 (codified as amended at Ohio Rev. Code Ann. § 2307.71(13)(c)).

Section 4. {Product liability standards.}

Section 4 provides the core of the Product Liability Act. Paragraph (A) follows the general structure of the 1995 Act with minor revisions to reflect the terminology used Section 2 of the Restatement Third, such as “manufacturing” defect, rather than “construction” defect. In addition, Paragraph (A)(2) follows language added to the Ohio PLA emphasizing that only the manufacturer of the *actual* product that caused the plaintiff's injury is subject to a product liability lawsuit. Thus, in no case is the manufacturer of one product liable for an injury caused by a product made by a competitor. This principle may seem to be commonsense, but as discussed above, courts have entertained claims imposing liability on a manufacturer without requiring any showing that the manufacturer made the actual product causing the plaintiff's harm. Such claims are contrary to the basic foundation of product liability law, which imposes liability on the actual manufacturer because it is the one who had control of the product, had the ability to improve its safety, and profited from its sale.

Section 4 incorporates several other sections from the 1995 Act in order to provide a unified standard for product liability. Specifically,

- The old Section 8 (“Construction Defects”) is incorporated into Paragraph (A)(1)(a);
- The old Section 9 (“Express Warranty”) is in Paragraph (D);
- The old Section 10 (“Knowledge of the Danger”) is in Paragraph (B)(1);
- The old Section 11 (“Feasible Alternative Design”) is in Paragraph (B)(2); and
- The old Section 14 (“Warnings”) is in Paragraph (C).

As mentioned above, wording as been slightly modified to reflect principles in the Restatement Third and state PLAs that have been enacted since 1995. *See, e.g.*, Miss. Code § 11-1-63.

Section 5. {Misuse and modification.}

Section 5 of the Product Liability Act replaces Section 7 of the 1995 Act. The 1995 Act provided an absolute defense in cases where the plaintiff misused a product, or the plaintiff or a third party altered or modified a product post-sale. The revised Model PLA limits the defense to misuse, alterations, or modifications that were not *reasonably foreseeable* to the product seller. A product seller has no duty to protect against an unforeseeable misuse, alteration, or modification. The change follows the laws of many states and the principles of the Restatement Third, that reasonably foreseeable misuses, alterations, and modifications may be relevant to the determination of defect, causation, or comparative responsibility. *See* Restatement Third § 2 cmt. p; *see also* Colo. Rev. Stat. § 13-21-402.5; Mich. Rev. Stat. § 600.2947(1), (2).

For example, if a misuse is foreseeable, a seller could have adopted a reasonable alternative design or provided additional instructions or warnings. In such cases, it may not be appropriate to fully eliminate a plaintiffs' recovery. The plaintiff's recovery can be reduced, though, by his or her degree of fault in misusing, altering, or modifying the product.

Section 6. {Learned intermediary doctrine}

Section 6 codifies the "learned intermediary doctrine," which was not addressed in the 1995 Act. The learned intermediary doctrine provides that manufacturers or suppliers of prescription drugs fulfill their duty to warn consumers of the dangerous propensities of their products by conveying accurate warning information to prescribing physicians. It is the physician's duty to evaluate the medication's benefits and risks for the individual patient. The rule, in effect, directs a manufacturer's legal duty to warn toward physicians, rather than individual consumers.

Almost all jurisdictions follow some formulation of the learned intermediary doctrine with regard to claims involving prescription drugs. *See In re Norplant Contraceptive Prods. Liab. Litig.*, 215 F. Supp.2d 795, 806-09 (E.D. Tex. 2002) (concluding that forty-eight states, the District of Columbia and Puerto Rico have either applied or recognized the learned intermediary doctrine, and providing chart reflecting the same). Courts have cited several reasons for supporting this doctrine. First, training and experience place physicians in a better position than the manufacturer to convey complex medical information and terminology to patients. Second, the physician has a relationship with the individual patient, making it possible to evaluate the patient's treatment needs and provide an assessment of the potential benefits and likely risks specific to the patient's medical and family history. Third, it is more effective and efficient for manufacturers to provide a common set of warnings to an intermediary with more definable knowledge and skill characteristics than to a broad spectrum of consumers. It is difficult, if not impossible, to convey comprehensive drug warnings to consumers due to the highly technical nature of the information and variations in the needs of individual patients.

This provision in the Model PLA draws from states that have codified the doctrine as well as Section 6(d) of the Restatement Third. *See, e.g.*, Miss. Code Ann. § 11-1-63(c); N.J. 2A:58C-4; N.C. Gen. Stat. § 99B-5(c); Ohio Rev. Code Ann. § 2307.76.

Section 7. {Warnings to third parties.}

Section 7 incorporates Section 15 of the 1995 Act without modification. It codifies the bulk supplier doctrine and the sophisticated user defenses.

Bulk suppliers are those who sell their products in bulk, generally to other businesses. These suppliers may not know how the product will be used and may not be able to attach a label or instructions to the raw material or component. The bulk supplier doctrine, therefore, states that a bulk supplier's or raw material manufacturer's duty to warn consumers, or other end users, of the risks of its product is discharged by warning the product's immediate purchaser. It is the immediate purchaser's responsibility to include appropriate warnings when selling those materials or products to others.

The sophisticated user doctrine recognizes that users with superior knowledge of a product are or should already be well-aware of the product's risks. As with the bulk supplier doctrine, the law here anticipates that sophisticated users are businesses, not average individuals. Both provisions recognize that there are special challenges in conveying warnings regarding certain products in the workplace. In these instances, the obligation to warn falls on the party in the best position – because they are the most knowledgeable or informed – to provide such warnings.

Section 8. {Liability of product sellers.}

Section 8 modifies and simplifies Section 16 of the 1995 Act in accordance with product seller statutes enacted in several states. Absent legislation, traditional product liability law allows imposition of liability on wholesalers, distributors, and retailers for harm caused by a defective product, even if it was not aware of and could not have discovered the defect. An innocent seller can be named in a lawsuit simply because of its presence in the chain of distribution. This is often done for strategic litigation purposes, particularly when the “innocent seller” is a local mom-and-pop business, such as a corner pharmacy or grocery store. They are swept up as part of the “sue-everyone” mentality and their presence in the litigation can permit the plaintiff to pick certain favorable jurisdictions to have his or her claims heard. More than half of state legislatures have adopted innocent seller protection to address this problem.

Section 8 of the Model PLA draws from these laws to provide that a product seller, other than the manufacturer, is not subject to suit in a product liability action unless the seller designed or modified the product, or provided an express warranty. A product seller may also be subject to a product liability lawsuit if the plaintiff is unable to proceed with a claim against the manufacturer, such as when the manufacturer is unknown, not subject to service of process, or the manufacturer is insolvent or otherwise judgment proof. The language in this provision is based on the Alabama and Tennessee laws. *See* S.B. 184 (Ala. 2011); H.B. 2008 (Tenn. 2011). Finally, paragraph (B) retains a section of the 1995 Act that clarifies that although product sellers other than the manufacturer are not subject to strict liability absent application of one of the enumerated exceptions, they continue to have a duty of reasonable care in their sale of the product.

Section 9. {Alcohol and drug defense.}

Section 9 incorporates Section 17 of the 1995 Act without modification. It codifies the commonsense principle that an individual injured while drunk or under the influence of an illicit drug should not be able to shift responsibility for his or her injury on a product manufacturer where the influence of alcohol or drugs played the greatest role in causing the injury.

Section 10. {Subsequent remedial measures.}

Section 10 incorporates Section 18 of the 1995 Act without modification. It codifies a well-accepted principle of evidentiary law that is intertwined with product liability law – evidence that a manufacturer took steps to improve the safety of a product after an injury is inadmissible to prove that the earlier product was defective. This rule furthers product safety by encouraging manufacturers to learn from accidents and promptly modify their products to avoid future harm, rather than place them at significant risk of liability for doing so.

Section 11. {Concert of action.}

Section 11 incorporates Section 20 of the 1995 Act without modification. This section reacts to the inappropriate use of “concert of action” claims as a means of circumventing product liability requirements. Traditional application of “concert of action” theory involves conduct by a small number of individuals whose actions resulted in a tort against a single plaintiff, usually over a short span of time. The defendants are held jointly liable for the plaintiff’s injuries.

Most jurisdictions that have considered this theory have rejected its application to product liability cases, which involve numerous manufacturers that compete against each other. Often, the assertion is that the manufacturers shared involvement in regulatory or legislative activities, or collectively worked towards voluntary industry safety standards through industry associations. The Model PLA recognizes that “concert of action” claims must show conscious and deliberate agreement to, acknowledgment of, and collaborative participation in wrongful conduct by two or more persons. These other activities are legitimate, helpful endeavors that should be encouraged.

Section 12. {Specific Product Identification}

Section 12 is a new provision addressing instances in which plaintiffs have sought to impose liability based on a market share, enterprise, or other industry wide liability. For example, in the case accredited as the origin of market share liability, the California Supreme Court shifted the burden to the manufacturers of a widely distributed prescription drug to prove that they did not manufacture the drug that caused the plaintiff’s harm. *See Sindell v. Abbott Laboratories, Inc.*, 607 P.2d 924 (Cal. 1980). Otherwise, each defendant would be liable for a share of the plaintiff’s injury equal to its share of the market for the product. The theory was adopted by fewer than a half-dozen courts in diethylstilbesterol (DES) cases. Most courts have rejected market-share liability in a variety of contexts, including cases involving asbestos, handguns, vaccines, breast implants, blood products, and lead paint.

Enterprise liability is another burden-shifting theory with some similarities to market-share theory. Enterprise liability stems from a New York federal court case, where only a handful of companies made a product, blasting caps, and it was not possible to determine the identity of the product that harmed the plaintiffs. *Hall ex rel. Hall v. E.I. du Pont de Nemours & Co., Inc.*, 345 F. Supp. 353, 378 (E.D.N.Y. 1972). Because there was a strong likelihood that the blasting caps were produced by one of six major manufacturers, the court declined to dismiss the complaints

and indicated that it might be appropriate to shift the burden of causation to the defendants. Courts almost universally have rejected the theory or found it inapplicable under the facts of a particular case.

The language of this section of the Model PLA is based on legislation adopted by the Ohio General Assembly in 2006. *See* Ohio Code § 2307.73(C).

Section 13. {Incorporation of Other ALEC Model Acts.}

Since 1995, ALEC has adopted several model acts important to products liability claims, including some that cover topics included in the 1995 Act. These other model acts provide an important source for model legislation affecting products liability actions. The Model PLA includes by reference the following ALEC model bills:

- The **Regulatory Compliance Congruity With Liability Act** (adopted 2007) offers options for addressing the impact of regulatory compliance and product approvals on liability. This model act replaces the government standards defense included in Section 5 of the 1995 Act and regulatory approval defense for adequate warning or instruction, which was in Section 14(A)(2) of the 1995 Act.
- The **Assumption of Risk Act** (adopted 1995) continues to provide language for legislators interested in including such a provision in product liability legislation. This model act replaces Section 13 of the 1995 Act.
- The **Reliability in Expert Testimony Standards Act** (adopted 2000, revised 2005) provides current ALEC policy on expert testimony standards. This model act replaces Section 19 of the 1995 PLA. The 1995 Act was outdated in that it preceded recognition of the importance of the U.S. Supreme Court's ruling in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) and its progeny. In those cases, the Supreme Court deputized judges to serve as "gatekeepers" for the reliability of expert testimony and required expert testimony to follow scientific methods.
- The **Ten-Year Statute of Repose Act** (adopted 2002) provides that an injury occurring ten years after a product is sold is presumed to not result from a defect in the product, with certain exceptions. Approximately twenty states have similar laws.
- The **Asbestos and Silica Claims Priorities Act** (adopted 2003, revised 2006) ensures that those who are truly sick from exposure to asbestos or silica receive prompt, fair and efficient adjudication of their claims by requiring claimants to meet certain medical criteria for showing a physical impairment before proceeding with their claims. At least six states have adopted such medical criteria requirements through legislation. Several courts have taken similar steps through judicial action.
- The **Asbestos Claims Transparency Act** (adopted 2007) assures that courts and litigants have available to them information as to payments an asbestos claimant has or may receive from asbestos-related bankruptcy trusts.

- The **Transparency in Lawsuits Protection Act** (adopted 2007) provides that a court shall not create a new private right of action on the basis of a statute that provides regulatory requirements, such as product safety standards, unless the state legislature specifically provides a right to sue. Georgia was the first state to adopt legislation based on this model act in 2010.



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