In the Senate of the United States,

May 10 (legislative day, May 1), 1995.

Resolved, That the bill from the House of Representatives (H.R. 956) entitled ''An Act to establish legal standards and procedures for product liability litigation, and for other purposes'', do pass with the following

AMENDMENT:

Strike out all after the enacting clause and insert:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Product Liability Fairness Act of 1995''.

TITLE I—PRODUCT LIABILITY

SEC. 101. DEFINITIONS.

For purposes of this Act, the following definitions shall apply:

(1) ACTUAL MALICE.—The term ''actual malice'' means specific intent to cause serious physical injury, illness, disease, or damage to property, or death.

(2) CLAIMANT.—The term ''claimant'' means any person who brings a product liability action and any person on whose behalf such an action is brought. If an action is brought through or on behalf of—

(A) an estate, the term includes the decedent; or

(B) a minor or incompetent, the term includes the legal guardian of the minor or incompetent.

(3) CLAIMANT'S BENEFITS.—The term ''claimant's benefits'' means the amount paid to an employee as workers' compensation benefits.

(4) CLEAR AND CONVINCING EVIDENCE.—

(A) IN GENERAL.—Subject to subparagraph (A), the term ''clear and convincing evidence'' is that measure of degree of proof that will produce in the mind of the trier of fact a firm belief or conviction as to the truth of the allegations sought to be established.

(B) DEGREE OF PROOF.—The degree of proof required to satisfy the standard of clear and convincing evidence shall be—

(i) greater than the degree of proof required to meet the standard of preponderance of the evidence; and

(ii) less than the degree of proof required to meet the standard of proof beyond a reasonable doubt.

(5) COMMERCIAL LOSS.—The term ''commercial loss'' means any loss or damage to a product itself, loss relating to a dispute over its value, or consequential economic loss the recovery of which is governed by the Uniform Commercial Code or analogous State commercial law, not including harm.

(6) DURABLE GOOD.—The term ''durable good'' means any product, or any component of any such product, which has a normal life expectancy of 3 or more years or is of a character subject to allowance for depreciation under the Internal Revenue Code of 1986, and which is—

(A) used in a trade or business;

(B) held for the production of income; or

(C) sold or donated to a governmental or private entity for the production of goods, training, demonstration, or any other similar purpose.

(7) ECONOMIC LOSS.—The term ''economic loss'' means any pecuniary loss resulting from harm (including any medical expense loss, work loss, replacement services loss, loss due to death, burial costs, and

loss of business or employment opportunities), to the extent that recovery for the loss is permitted under applicable State law.

(8) HARM.—The term ''harm'' means any physical injury, illness, disease, or death, or damage to property, caused by a product. The term does not include commercial loss or loss or damage to a product itself.

(9) INSURER.—The term ''insurer'' means the employer of a claimant, if the employer is self-insured, or the workers' compensation insurer of an employer.

(10) MANUFACTURER.—The term ''manufacturer'' means—

(A) any person who is engaged in a business to produce, create, make, or construct any product (or component part of a product), and who designs or formulates the product (or component part of the product), or has engaged another person to design or formulate the product (or component part of the product);

(B) a product seller, but only with respect to those aspects of a product (or component part of a product) which are created or affected when, before placing the product in the stream of com-

merce, the product seller produces, creates, makes, constructs, designs, or formulates, or has engaged another person to design or formulate, an aspect of a product (or component part of a product) made by another person; or

(C) any product seller that is not described in subparagraph (B) that holds itself out as a manufacturer to the user of the product.

(11) NONECONOMIC LOSS.—The term ''noneconomic loss''—

(A) means subjective, nonmonetary loss resulting from harm, including pain, suffering, inconvenience, mental suffering, emotional distress, loss of society and companionship, loss of consortium, injury to reputation, and humiliation; and

(B) does not include economic loss.

(12) PERSON.—The term ''person'' means any individual, corporation, company, association, firm, partnership, society, joint stock company, or any other entity (including any governmental entity).

(13) PRODUCT.—

(A) IN GENERAL.—The term ''product'' means any object, substance, mixture, or raw

material in a gaseous, liquid, or solid state that—

(i) is capable of delivery itself or as an assembled whole, in a mixed or combined state, or as a component part or ingredient;

(ii) is produced for introduction into trade or commerce;

(iii) has intrinsic economic value; and

(iv) is intended for sale or lease to persons for commercial or personal use.

(B) EXCLUSION.—The term ''product'' does not include—

(i) tissue, organs, blood, and blood products used for therapeutic or medical purposes, except to the extent that such tissue, organs, blood, and blood products (or the provision thereof) are subject, under applicable State law, to a standard of liability other than negligence; and

(ii) electricity, water delivered by a utility, natural gas, or steam.

(14) PRODUCT LIABILITY ACTION.—The term ''product liability action'' means a civil action brought on any theory for harm caused by a product.

(15) PRODUCT SELLER.—

(A) IN GENERAL.—The term ''product seller'' means a person who—

(i) in the course of a business conducted for that purpose, sells, distributes, rents, leases, prepares, blends, packages, labels, or otherwise is involved in placing a product in the stream of commerce; or

(ii) installs, repairs, refurbishes, reconditions, or maintains the harm-causing aspect of the product.

(B) EXCLUSION.—The term ''product seller'' does not include—

(i) a seller or lessor of real property;

(ii) 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

(iii) any person who—

(I) acts in only a financial capacity with respect to the sale of a product; or

(II) leases a product under a lease arrangement in which the lessor does not initially select the leased product

and does not during the lease term ordinarily control the daily operations and maintenance of the product.

(16) STATE.—The term ''State'' means each of the several States of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands, and any other territory or possession of the United States, or any political subdivision thereof.

(17) TIME OF DELIVERY.—The term ''time of delivery'' means the time when a product is delivered to the first purchaser or lessee of the product that was not involved in manufacturing or selling the product, or using the product as a component part of another product to be sold.

SEC. 102. APPLICABILITY; PREEMPTION.

(a) APPLICABILITY.—

(1) ACTIONS COVERED.—Subject to paragraph (2), this title applies to any product liability action commenced on or after the date of enactment of this Act, without regard to whether the harm that is the subject of the action or the conduct that caused the harm occurred before such date of enactment.

(2) ACTIONS EXCLUDED.—

(A) ACTIONS FOR DAMAGE TO PRODUCT OR COMMERCIAL LOSS.—A civil action brought for loss or damage to a product itself or for commercial loss, shall not be subject to the provisions of this title governing product liability actions, but shall be subject to any applicable commercial or contract law.

(B) ACTIONS FOR NEGLIGENT ENTRUSTMENT.—A civil action for negligent entrustment shall not be subject to the provisions of this title governing product liability actions, but shall be subject to any applicable State law.

(b) SCOPE OF PREEMPTION.—

(1) IN GENERAL.—This Act supersedes a State law only to the extent that State law applies to an issue covered under this title.

(2) ISSUES NOT COVERED UNDER THIS ACT.—Any issue that is not covered under this title, including any standard of liability applicable to a manufacturer, shall not be subject to this title, but shall be subject to applicable Federal or State law.

(c) STATUTORY CONSTRUCTION.—Nothing in this title may be construed to—

(1) waive or affect any defense of sovereign immunity asserted by any State under any law;

(2) supersede or alter any Federal law;

(3) waive or affect any defense of sovereign immunity asserted by the United States;

(4) affect the applicability of any provision of chapter 97 of title 28, United States Code;

(5) preempt State choice-of-law rules with respect to claims brought by a foreign nation or a citizen of a foreign nation;

(6) affect the right of any court to transfer venue or to apply the law of a foreign nation or to dismiss a claim of a foreign nation or of a citizen of a foreign nation on the ground of inconvenient forum; or

(7) supersede or modify any statutory or common law, including any law providing for an action to abate a nuisance, that authorizes a person to institute an action for civil damages or civil penalties, cleanup costs, injunctions, restitution, cost recovery, punitive damages, or any other form of relief for remediation of the environment (as defined in section 101(8) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, 42 U.S.C. 9601(8)) or the threat of such remediation.

(d) CONSTRUCTION.—To promote uniformity of law in the various jurisdictions, this title shall be construed and applied after consideration of its legislative history.

(e) EFFECT OF COURT OF APPEALS DECISIONS.—Notwithstanding any other provision of law, any decision of a circuit court of appeals interpreting a provision of this title (except to the extent that the decision is overruled or otherwise modified by the Supreme Court) shall be considered a controlling precedent with respect to any subsequent decision made concerning the interpretation of such provision by any Federal or State court within the geographical boundaries of the area under the jurisdiction of the circuit court of appeals.

SEC. 103. ALTERNATIVE DISPUTE RESOLUTION PROCEDURES.

(a) SERVICE OF OFFER.—A claimant or a defendant in a product liability action that is subject to this title may, not later than 60 days after the service of the initial complaint of the claimant or the applicable deadline for a responsive pleading (whichever is later), serve upon an adverse party an offer to proceed pursuant to any voluntary, nonbinding alternative dispute resolution procedure established or recognized under the law of the State in which the product liability action is brought or under the rules of the court in which such action is maintained.

(b) WRITTEN NOTICE OF ACCEPTANCE OR REJECTION.—Except as provided in subsection (c), not later than 10 days after the service of an offer to proceed under sub-

section (a), an offeree shall file a written notice of acceptance or rejection of the offer.

(c) EXTENSION.—The court may, upon motion by an offeree made prior to the expiration of the 10-day period specified in subsection (b), extend the period for filing a written notice under such subsection for a period of not more than 60 days after the date of expiration of the period specified in subsection (b). Discovery may be permitted during such period.

SEC. 104. LIABILITY RULES APPLICABLE TO PRODUCT SELLERS.

(a) GENERAL RULE.—

(1) IN GENERAL.—In any product liability action that is subject to this title filed by a claimant for harm caused by a product, a product seller other than a manufacturer shall be liable to a claimant, only if the claimant establishes—

(A) that—

(i) the product that allegedly caused the harm that is the subject of the complaint was sold, rented, or leased by the product seller;

(ii) the product seller failed to exercise reasonable care with respect to the product; and

(iii) the failure to exercise reasonable care was a proximate cause of harm to the claimant; or

(B) that—

(i) the product seller made an express warranty applicable to the product that allegedly caused the harm that is the subject of the complaint, independent of any express warranty made by a manufacturer as to the same product;

(ii) the product failed to conform to the warranty; and

(iii) the failure of the product to conform to the warranty caused harm to the claimant; or

(C) that—

(i) the product seller engaged in intentional wrongdoing, as determined under applicable State law; and

(ii) such intentional wrongdoing was a proximate cause of the harm that is the subject of the complaint.

(2) REASONABLE OPPORTUNITY FOR INSPECTION.—For purposes of paragraph (1)(A)(ii), a product seller shall not be considered to have failed to ex-

ercise reasonable care with respect to a product based upon an alleged failure to inspect a product if the product seller had no reasonable opportunity to inspect the product that allegedly caused harm to the claimant.

(b) SPECIAL RULE.—

(1) IN GENERAL.—A product seller shall be deemed to be liable as a manufacturer of a product for harm caused by the product if—

(A) the manufacturer is not subject to service of process under the laws of any State in which the action may be brought; or

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

(2) STATUTE OF LIMITATIONS.—For purposes of this subsection only, the statute of limitations applicable to claims asserting liability of a product seller as a manufacturer shall be tolled from the date of the filing of a complaint against the manufacturer to the date that judgment is entered against the manufacturer.

(c) RENTED OR LEASED PRODUCTS.—

(1) Notwithstanding any other provision of law, any person engaged in the business of renting or leas-

ing a product (other than a person excluded from the definition of product seller under section 101 (14)(B)) shall be subject to liability in a product liability action under subsection (a), but any person engaged in the business of renting or leasing a product shall not be liable to a claimant for the tortious act of another solely by reason of ownership of such product.

(2) For purposes of paragraph (1), and for determining the applicability of this title to any person subject to paragraph (1), the term ''product liability action'' means a civil action brought on any theory for harm caused by a product or product use.

SEC. 105. DEFENSES INVOLVING INTOXICATING ALCOHOL OR DRUGS.

(a) GENERAL RULE.—Notwithstanding any other provision of law, a defendant in a product liability action that is subject to this title shall have a complete defense in the action if the defendant proves that—

(1) the claimant was under the influence of intoxicating alcohol or any drug that may not lawfully be sold over-the-counter without a prescription, and was not prescribed by a physician for use by the claimant; and

(2) the claimant, as a result of the influence of the alcohol or drug, was more than 50 percent respon-

sible for the accident or event which resulted in the harm to the claimant.

(b) CONSTRUCTION.—For purposes of this section, the determination of whether a person was intoxicated or was under the influence of intoxicating alcohol or any drug shall be made pursuant to applicable State law.

SEC. 106. REDUCTION FOR MISUSE OR ALTERATION OF PRODUCT.

(a) GENERAL RULE.—

(1) IN GENERAL.—Except as provided in subsection (c), in a product liability action that is subject to this title, the damages for which a defendant is otherwise liable under applicable State law shall be reduced by the percentage of responsibility for the harm to the claimant attributable to misuse or alteration of a product by any person if the defendant establishes that such percentage of the harm was proximately caused by a use or alteration of a product—

(A) in violation of, or contrary to, the express warnings or instructions of the defendant if the warnings or instructions are determined to be adequate pursuant to applicable State law; or

(B) involving a risk of harm which was known or should have been known by the ordinary person who uses or consumes the product

with the knowledge common to the class of persons who used or would be reasonably anticipated to use the product.

(2) USE INTENDED BY A MANUFACTURER IS NOT MISUSE OR ALTERATION.—For the purposes of this title, a use of a product that is intended by the manufacturer of the product does not constitute a misuse or alteration of the product.

(b) STATE LAW.—Notwithstanding section 3(b), subsection (a) of this section shall supersede State law concerning misuse or alteration of a product only to the extent that State law is inconsistent with such subsection.

(c) WORKPLACE INJURY.—Notwithstanding subsection (a), the amount of damages for which a defendant is otherwise liable under State law shall not be reduced by the application of this section with respect to the conduct of any employer or coemployee of the plaintiff who is, under applicable State law concerning workplace injuries, immune from being subject to an action by the claimant.

SEC. 107. UNIFORM STANDARDS FOR AWARD OF PUNITIVE DAMAGES.

(a) GENERAL RULE.—Punitive damages may, to the extent permitted by applicable State law, be awarded against a defendant in a product liability action that is subject to this title if the claimant establishes by clear and

convincing evidence that the harm that is the subject of the action was the result of conduct that was carried out by the defendant with a conscious, flagrant indifference to the safety of others.

(b) LIMITATION ON AMOUNT.—

(1) IN GENERAL.—Except as provided in paragraphs (2) and (3), the amount of punitive damages that may be awarded to a claimant in a product liability action that is subject to this title shall not exceed the greater of—

(A) 2 times the sum of—

(i) the amount awarded to the claimant for economic loss; and

(ii) the amount awarded to the claimant for noneconomic loss; or

(B) $250,000.

(2) SPECIAL RULE.—The amount of punitive damages that may be awarded in a product liability action that is subject to this title against an individual whose net worth does not exceed $500,000 or against an owner of an unincorporated business, or any partnership, corporation, association, unit of local government, or organization which has fewer than 25 full-time employees, shall not exceed the lesser of—

(A) 2 times the sum of—

(i) the amount awarded to the claimant for economic loss; and

(ii) the amount awarded to the claimant for noneconomic loss; or

(B) $250,000.

(3) EXCEPTION.—

(A) DETERMINATION BY COURT.—Notwithstanding subparagraph (C), in a product liability action that is subject to this title, if the court makes a determination, after considering each of the factors in subparagraph (B), that the application of paragraph (1) would result in an award of punitive damages that is insufficient to punish the egregious conduct of the defendant against whom the punitive damages are to be awarded or to deter such conduct in the future, the court shall determine the additional amount of punitive damages in excess of the amount determined in accordance with paragraph (1) to be awarded to the claimant (referred to in this paragraph as the ''additur'') in a separate proceeding in accordance with this paragraph.

(B) FACTORS FOR CONSIDERATION.—In any proceeding under subparagraph (A), the court shall consider—

(i) the extent to which the defendant acted with actual malice;

(ii) the likelihood that serious harm would arise from the misconduct of the defendant;

(iii) the degree of the awareness of the defendant of that likelihood;

(iv) the profitability of the misconduct to the defendant;

(v) the duration of the misconduct and any concurrent or subsequent concealment of the conduct by the defendant;

(vi) the attitude and conduct of the defendant upon the discovery of the misconduct and whether the misconduct has terminated;

(vii) the financial condition of the defendant; and

(viii) the cumulative deterrent effect of other losses, damages, and punishment suffered by the defendant as a result of the misconduct, reducing the amount of puni-

tive damages on the basis of the economic impact and severity of all measures to which the defendant has been or may be subjected, including—

(I) compensatory and punitive damage awards to similarly situated claimants;

(II) the adverse economic effect of stigma or loss of reputation;

(III) civil fines and criminal and administrative penalties; and

(IV) stop sale, cease and desist, and other remedial or enforcement orders.

(C) REQUIREMENTS FOR AWARDING ADDITURS.—If the court awards an additur under this paragraph, the court shall state its reasons for setting the amount of the additur in findings of fact and conclusions of law. If the additur is—

(i) accepted by the defendant, it shall be entered by the court as a final judgment;

(ii) accepted by the defendant under protest, the order may be reviewed on appeal; or

(iii) not accepted by the defense, the court shall set aside the punitive damages award and order a new trial on the issue of punitive damages only, and judgment shall enter upon the verdict of liability and damages after the issue of punitive damages is decided.

(4) APPLICATION BY COURT.—This subsection shall be applied by the court and the application of this subsection shall not be disclosed to the jury.

(5) REMITTITURS.—Nothing in this subsection shall modify or reduce the ability of courts to order remittiturs.

(c) BIFURCATION AT REQUEST OF ANY PARTY.—

(1) IN GENERAL.—At the request of any party, the trier of fact in a product liability action that is subject to this title shall consider in a separate proceeding whether punitive damages are to be awarded for the harm that is the subject of the action and the amount of the award.

(2) INADMISSIBILITY OF EVIDENCE RELATIVE ONLY TO A CLAIM OF PUNITIVE DAMAGES IN A PROCEEDING CONCERNING COMPENSATORY DAMAGES.—If any party requests a separate proceeding under paragraph (1), in any proceeding to determine whether the

claimant may be awarded compensatory damages, any evidence that is relevant only to the claim of punitive damages, as determined by applicable State law, shall be inadmissible.

SEC. 108. LIABILITY FOR CERTAIN CLAIMS RELATING TO DEATH.

In any civil action in which the alleged harm to the claimant is death and, as of the effective date of this Act, the applicable State law provides, or has been construed to provide, for damages only punitive in nature, a defendant may be liable for any such damages without regard to section 107, but only during such time as the State law so provides. This section shall cease to be effective September 1, 1996.

SEC. 109. UNIFORM TIME LIMITATIONS ON LIABILITY.

(a) STATUTE OF LIMITATIONS.—

(1) IN GENERAL.—Except as provided in paragraph (2) and subsection (b), a product liability action that is subject to this title may be filed not later than 2 years after the date on which the claimant discovered or, in the exercise of reasonable care, should have discovered, the harm that is the subject of the action and the cause of the harm.

(2) EXCEPTIONS.—

(A) PERSON WITH A LEGAL DISABILITY.—A person with a legal disability (as determined under applicable law) may file a product liability action that is subject to this title not later than 2 years after the date on which the person ceases to have the legal disability.

(B) EFFECT OF STAY OR INJUNCTION.—If the commencement of a civil action that is subject to this title is stayed or enjoined, the running of the statute of limitations under this section shall be suspended until the end of the period that the stay or injunction is in effect.

(b) STATUTE OF REPOSE.—

(1) IN GENERAL.—Subject to paragraphs (2) and (3), no product liability action that is subject to this title concerning a product that is a durable good alleged to have caused harm (other than toxic harm) may be filed after the 20-year period beginning at the time of delivery of the product.

(2) STATE LAW.—Notwithstanding paragraph (1), if pursuant to an applicable State law, an action described in such paragraph is required to be filed during a period that is shorter than the 20-year period specified in such paragraph, the State law shall apply with respect to such period.

(3) EXCEPTIONS.—

(A) A motor vehicle, vessel, aircraft, or train that is used primarily to transport passengers for hire shall not be subject to this subsection.

(B) Paragraph (1) does not bar a product liability action against a defendant who made an express warranty in writing as to the safety of the specific product involved which was longer than 20 years, but it will apply at the expiration of that warranty.

(C) Paragraph (1) does not affect the limitations period established by the General Aviation Revitalization Act of 1994 (49 U.S.C. 40101 note).

(c) TRANSITIONAL PROVISION RELATING TO EXTENSION OF PERIOD FOR BRINGING CERTAIN ACTIONS.—If any provision of subsection (a) or (b) shortens the period during which a product liability action that could be otherwise brought pursuant to another provision of law, the claimant may, notwithstanding subsections (a) and (b), bring the product liability action pursuant to this title not later than 1 year after the date of enactment of this Act.

SEC. 110. SEVERAL LIABILITY FOR NONECONOMIC LOSS.

(a) GENERAL RULE.—In a product liability action that is subject to this title, the liability of each defendant for noneconomic loss shall be several only and shall not be joint.

(b) AMOUNT OF LIABILITY.—

(1) IN GENERAL.—Each defendant shall be liable only for the amount of noneconomic loss allocated to the defendant in direct proportion to the percentage of responsibility of the defendant (determined in accordance with paragraph (2)) for the harm to the claimant with respect to which the defendant is liable. The court shall render a separate judgment against each defendant in an amount determined pursuant to the preceding sentence.

(2) PERCENTAGE OF RESPONSIBILITY.—For purposes of determining the amount of noneconomic loss allocated to a defendant under this section, the trier of fact shall determine the percentage of responsibility of each person responsible for the claimant's harm, whether or not such person is a party to the action.

SEC. 111. WORKERS' COMPENSATION SUBROGATION STANDARDS.

(a) GENERAL RULE.—

(1) RIGHT OF SUBROGATION.—

(A) IN GENERAL.—An insurer shall have a right of subrogation against a manufacturer or product seller to recover any claimant's benefits relating to harm that is the subject of a product liability action that is subject to this title.

(B) WRITTEN NOTIFICATION.—To assert a right of subrogation under subparagraph (A), the insurer shall provide written notice to the court in which the product liability action is brought.

(C) INSURER NOT REQUIRED TO BE A PARTY.—An insurer shall not be required to be a necessary and proper party in a product liability action covered under subparagraph (A).

(2) SETTLEMENTS AND OTHER LEGAL PROCEEDINGS.—

(A) IN GENERAL.—In any proceeding relating to harm or settlement with the manufacturer or product seller by a claimant who files a product liability action that is subject to this title, an insurer may participate to assert a right of subrogation for claimant's benefits with respect to any payment made by the manufacturer or product seller by reason of such harm, without regard to whether the payment is made—

(i) as part of a settlement;

(ii) in satisfaction of judgment;

(iii) as consideration for a covenant not to sue; or

(iv) in another manner.

(B) WRITTEN NOTIFICATION.—Except as provided in subparagraph (C), an employee shall not make any settlement with or accept any payment from the manufacturer or product seller without written notification to the employer.

(C) EXEMPTION.—Subparagraph (B) shall not apply in any case in which the insurer has been compensated for the full amount of the claimant's benefits.

(3) HARM RESULTING FROM ACTION OF EMPLOYER OR COEMPLOYEE.—

(A) IN GENERAL.—If, with respect to a product liability action that is subject to this title, the manufacturer or product seller attempts to persuade the trier of fact that the harm to the claimant was caused by the fault of the employer of the claimant or any coemployee of the claimant, the issue of that fault shall be submitted to the trier of fact, but only after the manufacturer or product seller has provided timely written notice to the employer.

(B) RIGHTS OF EMPLOYER.—

(i) IN GENERAL.—Notwithstanding any other provision of law, with respect to an issue of fault submitted to a trier of fact pursuant to subparagraph (A), an employer shall, in the same manner as any party in the action (even if the employer is not a named party in the action), have the right to—

(I) appear;

(II) be represented;

(III) introduce evidence;

(IV) cross-examine adverse witnesses; and

(V) present arguments to the trier of fact.

(ii) LAST ISSUE.—The issue of harm resulting from an action of an employer or coemployee shall be the last issue that is presented to the trier of fact.

(C) REDUCTION OF DAMAGES.—If the trier of fact finds by clear and convincing evidence that the harm to the claimant that is the subject of the product liability action was caused by the

fault of the employer or a coemployee of the claimant—

(i) the court shall reduce by the amount of the claimant's benefits—

(I) the damages awarded against the manufacturer or product seller; and

(II) any corresponding insurer's subrogation lien; and

(ii) the manufacturer or product seller shall have no further right by way of contribution or otherwise against the employer.

(D) CERTAIN RIGHTS OF SUBROGATION NOT AFFECTED.—Notwithstanding a finding by the trier of fact described in subparagraph (C), the insurer shall not lose any right of subrogation related to any—

(i) intentional tort committed against the claimant by a coemployee; or

(ii) act committed by a coemployee outside the scope of normal work practices.

(b) ATTORNEY'S FEES.—If, in a product liability action that is subject to this section, the court finds that harm to a claimant was not caused by the fault of the employer or a coemployee of the claimant, the manufacturer or product seller shall reimburse the insurer for reasonable attor-

ney's fees and court costs incurred by the insurer in the action, as determined by the court.

SEC. 112. FEDERAL CAUSE OF ACTION PRECLUDED.

The district courts of the United States shall not have jurisdiction under section 1331 or 1337 of title 28, United States Code, over any product liability action covered under this title.

TITLE II—BIOMATERIALS ACCESS ASSURANCE

SEC. 201. SHORT TITLE.

This title may be cited as the ''Biomaterials Access Assurance Act of 1995''.

SEC. 202. FINDINGS.

Congress finds that—

(1) each year millions of citizens of the United States depend on the availability of lifesaving or life-enhancing medical devices, many of which are permanently implantable within the human body;

(2) a continued supply of raw materials and component parts is necessary for the invention, development, improvement, and maintenance of the supply of the devices;

(3) most of the medical devices are made with raw materials and component parts that—

(A) are not designed or manufactured specifically for use in medical devices; and

(B) come in contact with internal human tissue;

(4) the raw materials and component parts also are used in a variety of nonmedical products;

(5) because small quantities of the raw materials and component parts are used for medical devices, sales of raw materials and component parts for medical devices constitute an extremely small portion of the overall market for the raw materials and medical devices;

(6) under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), manufacturers of medical devices are required to demonstrate that the medical devices are safe and effective, including demonstrating that the products are properly designed and have adequate warnings or instructions;

(7) notwithstanding the fact that raw materials and component parts suppliers do not design, produce, or test a final medical device, the suppliers have been the subject of actions alleging inadequate—

(A) design and testing of medical devices manufactured with materials or parts supplied by the suppliers; or

(B) warnings related to the use of such medical devices;

(8) even though suppliers of raw materials and component parts have very rarely been held liable in such actions, such suppliers have ceased supplying certain raw materials and component parts for use in medical devices because the costs associated with litigation in order to ensure a favorable judgment for the suppliers far exceeds the total potential sales revenues from sales by such suppliers to the medical device industry;

(9) unless alternate sources of supply can be found, the unavailability of raw materials and component parts for medical devices will lead to unavailability of lifesaving and life-enhancing medical devices;

(10) because other suppliers of the raw materials and component parts in foreign nations are refusing to sell raw materials or component parts for use in manufacturing certain medical devices in the United States, the prospects for development of new sources of supply for the full range of threatened raw materials and component parts for medical devices are remote;

(11) it is unlikely that the small market for such raw materials and component parts in the United

States could support the large investment needed to develop new suppliers of such raw materials and component parts;

(12) attempts to develop such new suppliers would raise the cost of medical devices;

(13) courts that have considered the duties of the suppliers of the raw materials and component parts have generally found that the suppliers do not have a duty—

(A) to evaluate the safety and efficacy of the use of a raw material or component part in a medical device; and

(B) to warn consumers concerning the safety and effectiveness of a medical device;

(14) attempts to impose the duties referred to in subparagraphs (A) and (B) of paragraph (13) on suppliers of the raw materials and component parts would cause more harm than good by driving the suppliers to cease supplying manufacturers of medical devices; and

(15) in order to safeguard the availability of a wide variety of lifesaving and life-enhancing medical devices, immediate action is needed—

(A) to clarify the permissible bases of liability for suppliers of raw materials and component parts for medical devices; and

(B) to provide expeditious procedures to dispose of unwarranted suits against the suppliers in such manner as to minimize litigation costs.

SEC. 203. DEFINITIONS.

As used in this title:

(1) BIOMATERIALS SUPPLIER.—

(A) IN GENERAL.—The term ''biomaterials supplier'' means an entity that directly or indirectly supplies a component part or raw material for use in the manufacture of an implant.

(B) PERSONS INCLUDED.—Such term includes any person who—

(i) has submitted master files to the Secretary for purposes of premarket approval of a medical device; or

(ii) licenses a biomaterials supplier to produce component parts or raw materials.

(2) CLAIMANT.—

(A) IN GENERAL.—The term ''claimant'' means any person who brings a civil action, or on whose behalf a civil action is brought, arising from harm allegedly caused directly or indirectly

by an implant, including a person other than the individual into whose body, or in contact with whose blood or tissue, the implant is placed, who claims to have suffered harm as a result of the implant.

(B) ACTION BROUGHT ON BEHALF OF AN ESTATE.—With respect to an action brought on behalf or through the estate of an individual into whose body, or in contact with whose blood or tissue the implant is placed, such term includes the decedent that is the subject of the action.

(C) ACTION BROUGHT ON BEHALF OF A MINOR.—With respect to an action brought on behalf or through a minor, such term includes the parent or guardian of the minor.

(D) EXCLUSIONS.—Such term does not include—

(i) a provider of professional services, in any case in which—

(I) the sale or use of an implant is incidental to the transaction; and

(II) the essence of the transaction is the furnishing of judgment, skill, or services; or

(ii) a manufacturer, seller, or biomaterials supplier.

(3) COMPONENT PART.—

(A) IN GENERAL.—The term ''component part'' means a manufactured piece of an implant.

(B) CERTAIN COMPONENTS.—Such term includes a manufactured piece of an implant that—

(i) has significant nonimplant applications; and

(ii) alone, has no implant value or purpose, but when combined with other component parts and materials, constitutes an implant.

(4) HARM.—

(A) IN GENERAL.—The term ''harm'' means—

(i) any injury to or damage suffered by an individual;

(ii) any illness, disease, or death of that individual resulting from that injury or damage; and

(iii) any loss to that individual or any other individual resulting from that injury or damage.

(B) EXCLUSION.—The term does not include any commercial loss or loss of or damage to an implant.

(5) IMPLANT.—The term ''implant'' means—

(A) a medical device that is intended by the manufacturer of the device—

(i) to be placed into a surgically or naturally formed or existing cavity of the body for a period of at least 30 days; or

(ii) to remain in contact with bodily fluids or internal human tissue through a surgically produced opening for a period of less than 30 days; and

(B) suture materials used in implant procedures.

(6) MANUFACTURER.—The term ''manufacturer'' means any person who, with respect to an implant—

(A) is engaged in the manufacture, preparation, propagation, compounding, or processing (as defined in section 510(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(a)(1)) of the implant; and

(B) is required—

(i) to register with the Secretary pursuant to section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) and the regulations issued under such section; and

(ii) to include the implant on a list of devices filed with the Secretary pursuant to section 510(j) of such Act (21 U.S.C. 360(j)) and the regulations issued under such section.

(7) MEDICAL DEVICE.—The term ''medical device'' means a device, as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)).

(8) RAW MATERIAL.—The term ''raw material'' means a substance or product that—

(A) has a generic use; and

(B) may be used in an application other than an implant.

(9) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

(10) SELLER.—

(A) IN GENERAL.—The term ''seller'' means a person who, in the course of a business con-

ducted for that purpose, sells, distributes, leases, packages, labels, or otherwise places an implant in the stream of commerce.

(B) EXCLUSIONS.—The term does not include—

(i) a seller or lessor of real property;

(ii) a provider of professional services, in any case in which the sale or use of an implant is incidental to the transaction and the essence of the transaction is the furnishing of judgment, skill, or services; or

(iii) any person who acts in only a financial capacity with respect to the sale of an implant.

SEC. 204. GENERAL REQUIREMENTS; APPLICABILITY; PREEMPTION.

(a) GENERAL REQUIREMENTS.—

(1) IN GENERAL.—In any civil action covered by this title, a biomaterials supplier may raise any defense set forth in section 205.

(2) PROCEDURES.—Notwithstanding any other provision of law, the Federal or State court in which a civil action covered by this title is pending shall, in connection with a motion for dismissal or judg-

ment based on a defense described in paragraph (1), use the procedures set forth in section 206.

(b) APPLICABILITY.—

(1) IN GENERAL.—Except as provided in paragraph (2), notwithstanding any other provision of law, this title applies to any civil action brought by a claimant, whether in a Federal or State court, against a manufacturer, seller, or biomaterials supplier, on the basis of any legal theory, for harm allegedly caused by an implant.

(2) EXCLUSION.—A civil action brought by a purchaser of a medical device for use in providing professional services against a manufacturer, seller, or biomaterials supplier for loss or damage to an implant or for commercial loss to the purchaser—

(A) shall not be considered an action that is subject to this title; and

(B) shall be governed by applicable commercial or contract law.

(c) SCOPE OF PREEMPTION.—

(1) IN GENERAL.—This title supersedes any State law regarding recovery for harm caused by an implant and any rule of procedure applicable to a civil action to recover damages for such harm only to

the extent that this title establishes a rule of law applicable to the recovery of such damages.

(2) APPLICABILITY OF OTHER LAWS.—Any issue that arises under this title and that is not governed by a rule of law applicable to the recovery of damages described in paragraph (1) shall be governed by applicable Federal or State law.

(d) STATUTORY CONSTRUCTION.—Nothing in this title may be construed—

(1) to affect any defense available to a defendant under any other provisions of Federal or State law in an action alleging harm caused by an implant; or

(2) to create a cause of action or Federal court jurisdiction pursuant to section 1331 or 1337 of title 28, United States Code, that otherwise would not exist under applicable Federal or State law.

SEC. 205. LIABILITY OF BIOMATERIALS SUPPLIERS.

(a) IN GENERAL.—

(1) EXCLUSION FROM LIABILITY.—Except as provided in paragraph (2), a biomaterials supplier shall not be liable for harm to a claimant caused by an implant.

(2) LIABILITY.—A biomaterials supplier that—

(A) is a manufacturer may be liable for harm to a claimant described in subsection (b);

(B) is a seller may be liable for harm to a claimant described in subsection (c); and

(C) furnishes raw materials or component parts that fail to meet applicable contractual requirements or specifications may be liable for a harm to a claimant described in subsection (d).

(b) LIABILITY AS MANUFACTURER.—

(1) IN GENERAL.—A biomaterials supplier may, to the extent required and permitted by any other applicable law, be liable for harm to a claimant caused by an implant if the biomaterials supplier is the manufacturer of the implant.

(2) GROUNDS FOR LIABILITY.—The biomaterials supplier may be considered the manufacturer of the implant that allegedly caused harm to a claimant only if the biomaterials supplier—

(A)(i) has registered with the Secretary pursuant to section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) and the regulations issued under such section; and

(ii) included the implant on a list of devices filed with the Secretary pursuant to section 510(j) of such Act (21 U.S.C. 360(j)) and the regulations issued under such section;

(B) is the subject of a declaration issued by the Secretary pursuant to paragraph (3) that states that the supplier, with respect to the implant that allegedly caused harm to the claimant, was required to—

(i) register with the Secretary under section 510 of such Act (21 U.S.C. 360), and the regulations issued under such section, but failed to do so; or

(ii) include the implant on a list of devices filed with the Secretary pursuant to section 510(j) of such Act (21 U.S.C. 360(j)) and the regulations issued under such section, but failed to do so; or

(C) is related by common ownership or control to a person meeting all the requirements described in subparagraph (A) or (B), if the court deciding a motion to dismiss in accordance with section 206(c)(3)(B)(i) finds, on the basis of affidavits submitted in accordance with section 206, that it is necessary to impose liability on the biomaterials supplier as a manufacturer because the related manufacturer meeting the requirements of subparagraph (A) or (B) lacks sufficient financial resources to satisfy any judgment

that the court feels it is likely to enter should the claimant prevail.

(3) ADMINISTRATIVE PROCEDURES.—

(A) IN GENERAL.—The Secretary may issue a declaration described in paragraph (2)(B) on the motion of the Secretary or on petition by any person, after providing—

(i) notice to the affected persons; and

(ii) an opportunity for an informal hearing.

(B) DOCKETING AND FINAL DECISION.—Immediately upon receipt of a petition filed pursuant to this paragraph, the Secretary shall docket the petition. Not later than 180 days after the petition is filed, the Secretary shall issue a final decision on the petition.

(C) APPLICABILITY OF STATUTE OF LIMITATIONS.—Any applicable statute of limitations shall toll during the period during which a claimant has filed a petition with the Secretary under this paragraph.

(c) LIABILITY AS SELLER.—A biomaterials supplier may, to the extent required and permitted by any other applicable law, be liable as a seller for harm to a claimant caused by an implant if—

(1) the biomaterials supplier—

(A) held title to the implant that allegedly caused harm to the claimant as a result of purchasing the implant after—

(i) the manufacture of the implant; and

(ii) the entrance of the implant in the stream of commerce; and

(B) subsequently resold the implant; or

(2) the biomaterials supplier is related by common ownership or control to a person meeting all the requirements described in paragraph (1), if a court deciding a motion to dismiss in accordance with section 206(c)(3)(B)(i) finds, on the basis of affidavits submitted in accordance with section 206, that it is necessary to impose liability on the biomaterials supplier as a seller because the related manufacturer meeting the requirements of paragraph (1) lacks sufficient financial resources to satisfy any judgment that the court feels it is likely to enter should the claimant prevail.

(d) LIABILITY FOR VIOLATING CONTRACTUAL REQUIREMENTS OR SPECIFICATIONS.—A biomaterials supplier may, to the extent required and permitted by any other applicable law, be liable for harm to a claimant

caused by an implant, if the claimant in an action shows, by a preponderance of the evidence, that—

(1) the raw materials or component parts delivered by the biomaterials supplier either—

(A) did not constitute the product described in the contract between the biomaterials supplier and the person who contracted for delivery of the product; or

(B) failed to meet any specifications that were—

(i) provided to the biomaterials supplier and not expressly repudiated by the biomaterials supplier prior to acceptance of delivery of the raw materials or component parts;

(ii)(I) published by the biomaterials supplier;

(II) provided to the manufacturer by the biomaterials supplier; or

(III) contained in a master file that was submitted by the biomaterials supplier to the Secretary and that is currently maintained by the biomaterials supplier for purposes of premarket approval of medical devices; or

(iii)(I) included in the submissions for purposes of premarket approval or review by the Secretary under section 510, 513, 515, or 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360, 360c, 360e, or 360j); and

(II) have received clearance from the Secretary,

if such specifications were provided by the manufacturer to the biomaterials supplier and were not expressly repudiated by the biomaterials supplier prior to the acceptance by the manufacturer of delivery of the raw materials or component parts; and

(2) such conduct was an actual and proximate cause of the harm to the claimant.

SEC. 206. PROCEDURES FOR DISMISSAL OF CIVIL ACTIONS AGAINST BIOMATERIALS SUPPLIERS.

(a) MOTION TO DISMISS.—In any action that is subject to this title, a biomaterials supplier who is a defendant in such action may, at any time during which a motion to dismiss may be filed under an applicable law, move to dismiss the action on the grounds that—

(1) the defendant is a biomaterials supplier; and

(2)(A) the defendant should not, for the purposes of—

(i) section 205(b), be considered to be a manufacturer of the implant that is subject to such section; or

(ii) section 205(c), be considered to be a seller of the implant that allegedly caused harm to the claimant; or

(B)(i) the claimant has failed to establish, pursuant to section 205(d), that the supplier furnished raw materials or component parts in violation of contractual requirements or specifications; or

(ii) the claimant has failed to comply with the procedural requirements of subsection (b).

(b) MANUFACTURER OF IMPLANT SHALL BE NAMED A PARTY.—The claimant shall be required to name the manufacturer of the implant as a party to the action, unless—

(1) the manufacturer is subject to service of process solely in a jurisdiction in which the biomaterials supplier is not domiciled or subject to a service of process; or

(2) an action against the manufacturer is barred by applicable law.

(c) PROCEEDING ON MOTION TO DISMISS.—The following rules shall apply to any proceeding on a motion to dismiss filed under this section:

(1) AFFIDAVITS RELATING TO LISTING AND DECLARATIONS.—

(A) IN GENERAL.—The defendant in the action may submit an affidavit demonstrating that defendant has not included the implant on a list, if any, filed with the Secretary pursuant to section 510(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(j)).

(B) RESPONSE TO MOTION TO DISMISS.—In response to the motion to dismiss, the claimant may submit an affidavit demonstrating that—

(i) the Secretary has, with respect to the defendant and the implant that allegedly caused harm to the claimant, issued a declaration pursuant to section 205(b)(2)(B); or

(ii) the defendant who filed the motion to dismiss is a seller of the implant who is liable under section 205(c).

(2) EFFECT OF MOTION TO DISMISS ON DISCOVERY.—

(A) IN GENERAL.—If a defendant files a motion to dismiss under paragraph (1) or (2) of subsection (a), no discovery shall be permitted in connection to the action that is the subject of the motion, other than discovery necessary to determine a motion to dismiss for lack of jurisdiction, until such time as the court rules on the motion to dismiss in accordance with the affidavits submitted by the parties in accordance with this section.

(B) DISCOVERY.—If a defendant files a motion to dismiss under subsection (a)(2) on the grounds that the biomaterials supplier did not furnish raw materials or component parts in violation of contractual requirements or specifications, the court may permit discovery, as ordered by the court. The discovery conducted pursuant to this subparagraph shall be limited to issues that are directly relevant to—

(i) the pending motion to dismiss; or

(ii) the jurisdiction of the court.

(3) AFFIDAVITS RELATING STATUS OF DEFENDANT.—

(A) IN GENERAL.—Except as provided in clauses (i) and (ii) of subparagraph (B), the

court shall consider a defendant to be a biomaterials supplier who is not subject to an action for harm to a claimant caused by an implant, other than an action relating to liability for a violation of contractual requirements or specifications described in subsection (d).

(B) RESPONSES TO MOTION TO DISMISS.—The court shall grant a motion to dismiss any action that asserts liability of the defendant under subsection (b) or (c) of section 205 on the grounds that the defendant is not a manufacturer subject to such section 205(b) or seller subject to section 205(c), unless the claimant submits a valid affidavit that demonstrates that—

(i) with respect to a motion to dismiss contending the defendant is not a manufacturer, the defendant meets the applicable requirements for liability as a manufacturer under section 205(b); or

(ii) with respect to a motion to dismiss contending that the defendant is not a seller, the defendant meets the applicable requirements for liability as a seller under section 205(c).

(4) BASIS OF RULING ON MOTION TO DISMISS.—

(A) IN GENERAL.—The court shall rule on a motion to dismiss filed under subsection (a) solely on the basis of the pleadings of the parties made pursuant to this section and any affidavits submitted by the parties pursuant to this section.

(B) MOTION FOR SUMMARY JUDGMENT.—Notwithstanding any other provision of law, if the court determines that the pleadings and affidavits made by parties pursuant to this section raise genuine issues as concerning material facts with respect to a motion concerning contractual requirements and specifications, the court may deem the motion to dismiss to be a motion for summary judgment made pursuant to subsection (d).

(d) SUMMARY JUDGMENT.—

(1) IN GENERAL.—

(A) BASIS FOR ENTRY OF JUDGMENT.—A biomaterials supplier shall be entitled to entry of judgment without trial if the court finds there is no genuine issue as concerning any material fact for each applicable element set forth in paragraphs (1) and (2) of section 205(d).

(B) ISSUES OF MATERIAL FACT.—With respect to a finding made under subparagraph (A),

the court shall consider a genuine issue of material fact to exist only if the evidence submitted by claimant would be sufficient to allow a reasonable jury to reach a verdict for the claimant if the jury found the evidence to be credible.

(2) DISCOVERY MADE PRIOR TO A RULING ON A MOTION FOR SUMMARY JUDGMENT.—If, under applicable rules, the court permits discovery prior to a ruling on a motion for summary judgment made pursuant to this subsection, such discovery shall be limited solely to establishing whether a genuine issue of material fact exists.

(3) DISCOVERY WITH RESPECT TO A BIOMATERIALS SUPPLIER.—A biomaterials supplier shall be subject to discovery in connection with a motion seeking dismissal or summary judgment on the basis of the inapplicability of section 205(d) or the failure to establish the applicable elements of section 205(d) solely to the extent permitted by the applicable Federal or State rules for discovery against nonparties.

(e) STAY PENDING PETITION FOR DECLARATION.—If a claimant has filed a petition for a declaration pursuant to section 205(b) with respect to a defendant, and the Secretary has not issued a final decision on the petition, the

court shall stay all proceedings with respect to that defendant until such time as the Secretary has issued a final decision on the petition.

(f) MANUFACTURER CONDUCT OF PROCEEDING.—The manufacturer of an implant that is the subject of an action covered under this title shall be permitted to file and conduct a proceeding on any motion for summary judgment or dismissal filed by a biomaterials supplier who is a defendant under this section if the manufacturer and any other defendant in such action enter into a valid and applicable contractual agreement under which the manufacturer agrees to bear the cost of such proceeding or to conduct such proceeding.

(g) ATTORNEY FEES.—The court shall require the claimant to compensate the biomaterials supplier (or a manufacturer appearing in lieu of a supplier pursuant to subsection (f)) for attorney fees and costs, if—

(1) the claimant named or joined the biomaterials supplier; and

(2) the court found the claim against the biomaterials supplier to be without merit and frivolous.

SEC. 207. APPLICABILITY.

This title shall apply to all civil actions covered under this title that are commenced on or after the date of enact-

ment of this Act, including any such action with respect to which the harm asserted in the action or the conduct that caused the harm occurred before the date of enactment of this Act.

Attest:

Secretary.

HR 956 EAS——2

HR 956 EAS——3

HR 956 EAS——4

HR 956 EAS——5

104TH CONGRESS
1ST SESSION

H. R. 956

AMENDMENT